

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss

SUPERIOR COURT

COMMONWEALTH OF MASSACHUSETTS,)

v.)

PURDUE PHARMA L.P., PURDUE PHARMA INC.,)

RICHARD SACKLER, THERESA SACKLER, KATHE)

SACKLER, JONATHAN SACKLER, MORTIMER D.A.)

SACKLER, BEVERLY SACKLER, DAVID SACKLER,)

ILENE SACKLER LEFCOURT, PETER BOER, PAULO)

COSTA, CECIL PICKETT, RALPH SNYDERMAN,)

JUDY LEWENT, CRAIG LANDAU, JOHN STEWART,)

MARK TIMNEY, and RUSSELL J. GASDIA.)

CIVIL ACTION NO.
1884-CV-01808 (BLS2)

**PURDUE'S REPLY MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO DISMISS**

LEAVE TO FILE EXCESS PAGES GRANTED APRIL 23, 2019

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Purdue Pharma L.P. and Purdue Pharma Inc. (collectively, “Purdue”) respectfully submit this reply memorandum of law in support of their motion to dismiss the Commonwealth of Massachusetts’s (“the Commonwealth”) Amended Complaint pursuant to Mass. R. Civ. P. 12(b)(6).¹

PRELIMINARY STATEMENT

The Commonwealth’s Opposition fails to cure the significant deficiencies that plague its Amended Complaint. Unable to bolster its far-flung legal theories, the Commonwealth continues to spin a sensationalist and distorted narrative that ignores the underlying facts of this case. A similarly overreaching attempt to pin all of a state’s opioid damages on Purdue was recently dismissed in full by a court in North Dakota² and Purdue requests that this Court do the same in the present case.

From the outset, the Commonwealth summarizes its allegations against Purdue as follows: “[t]he Commonwealth alleges that Purdue misled prescribers, pharmacists, patients and the public about the serious dangers of Purdue’s opioid drugs, which include addiction, overdose and death.” Opp. 1. The Commonwealth’s theory ignores that the FDA-approved label for OxyContin has always warned of the risk of addiction and since 2001 has included a black box warning that “OxyContin exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death.” Br. Ex. B, at 1. The Commonwealth does not contest that Purdue listed these risks on the medication labeling, and does not explain exactly how Purdue “misled prescribers, pharmacists, patients and the public” about the very risks it highlighted in the labeling for its medications. Stripped of hyperbole, the Commonwealth’s thesis seems to be that Purdue should be held absolutely

¹ Unless otherwise noted, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted.

² Purdue attaches the recent decision in *State of North Dakota v. Purdue Pharma*, Case No. 08-2018-CV-01300, Order Granting Defendants’ Motion to Dismiss (N.D. District Court May 10, 2019), dismissing nearly identical claims brought against Purdue by the State of North Dakota, as Ex. A.

liable for any harm arising from the company's efforts to promote its FDA-approved medications for their FDA-approved purposes in Massachusetts.

The Opposition also fails to address FDA findings and the Commonwealth's own actions, both of which further contradict the allegations made in the Amended Complaint. For example, the Commonwealth alleges that Purdue "deceptively . . . suggested that prescribers could screen out potential addicts," Opp. 2; that reformulated OxyContin was ineffective to reduce opioid abuse, Opp. 3; and that Purdue's opioids were inherently unsafe. These allegations fly in the face of the expert scientific judgment of the FDA, which explicitly counsels that "[s]creening tools should be used to evaluate the known risk factors for opioid use disorder or abuse"³; granted reformulated OxyContin abuse-deterrent labeling, Br. 15; and repeatedly approved Purdue's opioids as safe and effective, Br. 19. Moreover, the Commonwealth's own actions in the real world prove the speciousness of the claims in the Amended Complaint. *See, e.g.*, Br. Ex. O (showing that the Commonwealth includes Purdue's opioids on its Covered Drug List); Br. 14 (explaining that the Commonwealth required its own employee health benefits program to cover reformulated OxyContin, deeming it safer than preexisting alternatives). The Commonwealth does not even attempt to explain *its own findings* that "[n]o single substance or health care practice is solely responsible for the current opioid crisis. Rather, it's a complex issue with a number of contributing factors." Br. 2.

The Commonwealth fails to correct—and indeed perpetuates—these and other inaccuracies through its Opposition. Although the Commonwealth doubled down on the inflammatory rhetoric, it still has not pleaded viable claims.

³ See "FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain," *available at* <https://www.fda.gov/media/105199/download>.

ARGUMENT

I. STATEMENTS THAT COMPORT WITH FDA-APPROVED MATERIALS ARE NOT MISLEADING OR ACTIONABLE AS A MATTER OF LAW.

In an attempt to avoid asserting claims that conflict with federal law, the Commonwealth insists it “does not attack the Food and Drug Administration (“FDA”) label or approved indications of Purdue’s drugs, nor does it call for restrictions on their use.” Opp. 1. The Commonwealth does not—and cannot—contest that the FDA expressly denied a request to limit opioid doses or duration of use, because the proposed changes were “not supportable.” Br. 7-8, 23-24. Statements that conform to determinations made by the FDA in the exercise of its regulatory authority cannot be false or misleading *as a matter of law*, and therefore cannot form the basis of the Commonwealth’s claim under 93A. Br. 19-21. Yet the Commonwealth nonetheless argues it was somehow illegal for Purdue to market its medications *in accordance with* the FDA’s regulatory approvals. Indeed, the Commonwealth’s theory goes so far as to criticize marketing of OxyContin, Butrans, and Hysingla that Purdue submitted to the FDA for review. In doing so, the Commonwealth impermissibly seeks to substitute its judgment for that of the FDA. *Id.*

The Commonwealth devotes more than five pages of its briefing to the argument that federal law does not preempt the state-law claims in this case. The Commonwealth has responded to an argument Purdue did not make at this stage of the proceedings. In response to the Commonwealth’s argument that other courts have rejected preemption arguments in similar cases, however, Purdue directs this Court to a recent decision that dismissed nearly identical claims brought against Purdue by the State of North Dakota. *See North Dakota v. Purdue*, Ex. A. The *North Dakota* court found federal law preempted all of the state’s claims because they “conflict[] with the FDA’s jurisdiction over drug labeling, and specifically its [approved] indications” of Purdue’s medications. *Id.* at 15.

The Commonwealth fails to substantively engage with Purdue’s actual argument. In a single sentence, the Commonwealth dismisses Purdue’s cited precedents as “based on federal preemption” or otherwise “consider[ing] claims not at all relevant here.” Opp. 8-9. The Commonwealth is incorrect. While some of the cases raised by Purdue do consider the scope of federal preemption under the FDCA, they also consider permitted practices exemptions like the one at issue here. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 2014 WL 866571 (D. Mass. Mar. 5, 2014) (addressing whether California’s safe harbor rule barred misrepresentation claims brought against a prescription medication manufacturer); *see also Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1232-1233 (S.D. Fla. 2007) (addressing whether either the Massachusetts or Florida’s safe harbor rule barred plaintiffs’ consumer fraud act claims related to prescription medication). Likewise, contrary to the Commonwealth’s assertion, the remaining cases cited by Purdue address arguments relevant to the present case. *See, e.g., In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 39 (1st Cir. 2015) (discussing at length the FDA approval process for prescription drugs, which includes a finding by the FDA that the “proposed label is not false or misleading in any particular”); *Cytoc Corp. v. Neuromedial Sys., Inc.*, 12 F. Supp. 2d. 296, 301 (S.D.N.Y. 1998) (allegedly misleading marketing representations that “comport substantively with statements approved as accurate by the FDA” cannot be false or misleading “as a matter of law”). The Commonwealth’s fallback position—that it is not challenging the FDA’s judgment because it does not directly challenge Purdue’s FDA-approved drug labels, but rather Purdue’s marketing, Opp. 10—is similarly unconvincing and has been rejected by a number of courts. *See, e.g., Prohias*, 490 F. Supp. 2d at 1234; *see also North Dakota v. Purdue*, Ex. A at 24 (rejecting the State’s “attempts to characterize its claims as focusing only on Purdue’s marketing conduct, and not on the actual sale of opioids”).

Finally, the Commonwealth also misconstrues and fails to answer Purdue's argument that the Commonwealth should be estopped from bringing its claims under the terms of the 2007 Consent Judgment. Purdue's argument is not that the Commonwealth is estopped due to the extended time it has taken to redress alleged violations of the Consent Judgment, as the Opposition suggests. *See* Opp. 16. Rather, the Consent Judgment precludes the Commonwealth's claims because they are predicated upon marketing that was approved by the FDA. In short, the Commonwealth's position is fundamentally inconsistent: in the 2007 Consent Judgment, the Commonwealth mandated that Purdue make statements consistent with FDA findings, while in the present case, the Commonwealth is arguing that Purdue should be held legally liable for making statements that comported with FDA findings. As part of the Consent Judgment and corresponding Corporate Integrity Agreement, the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG") reviewed Purdue's marketing materials for five years. In 2013, the OIG found that Purdue had successfully satisfied its obligations under the terms of this Agreement and the Agreement was ended. Accordingly, the Commonwealth is judicially estopped from asserting these claims. *See Otis v. Arbell Mut. Ins. Co.*, 443 Mass. 634, 639-640 (2005).

II. THE CHAPTER 93A CLAIM MUST BE DISMISSED BECAUSE THE ALLEGED CONDUCT IS WITHIN THE PERMITTED PRACTICES EXEMPTION.

The Commonwealth argues that dismissal under the permitted practices exemption is "premature" because it "is an affirmative defense that must be asserted in the pleadings and proved at trial." Opp. 11-12. This is incorrect, and depends on selective quotation of *Fleming v. National Union Fire Insurance Company*, 445 Mass. 381, 388 (2005). In that case, the Court concluded, "[i]f it is evident from the allegations of the complaint alone that the defendant is entitled to [an affirmative defense under the permitted practices exemption], the matter may be decided by means of a motion to dismiss." *Id.* at 389-90. Likewise, other Massachusetts courts have previously

dismissed cases under the permitted practices exemption of 93A. *See, e.g., Riccio v. Ford Motor Credit Co.*, 238 F.R.D. 44, 48 (D. Mass. 2006).

Next, the Commonwealth argues that Purdue does not show that the related regulatory scheme “affirmatively permits the practice alleged to be unfair or deceptive.” Opp. 12. In support of this assertion, the Commonwealth relies on two cases—*Aspinall v. Philip Morris*, 453 Mass. 431 (2009) and *O’Hara v. Diageo-Guinness, USA, Inc.*, 2019 WL 1437910 (D. Mass. Mar. 30, 2019)—both of which are inapposite. In *Aspinall*, the Court found that the permitted practices exemption was inapplicable where the Federal Trade Commission had not taken an official position about the use of the terms “light” and “lower tar and nicotine” to describe cigarettes. *Aspinall*, 453 Mass. at 435-437. The opposite is true here. The FDA expressly considered the appropriateness of long-term and high-dose opioid use and determined that the available science did not support limits on dosages or duration of use. *See* Br. 7-8. In contrast to the FTC’s regulatory inaction in *Aspinall*, here the applicable federal regulatory agency—the FDA—affirmatively allowed the practices at issue. Therefore, the permitted practices exemption bars the 93A claim because Purdue cannot be liable for advertising in accordance with the FDA’s actions.

The Commonwealth’s reliance on *O’Hara v. Diageo-Guinness* is similarly unhelpful. That case focused on the permitted practices exemption as applied to the labeling of beer. In the initial *O’Hara* decision, 306 F. Supp. 3d 441 (D. Mass. 2018), the federal district court determined that labels on beer cartons were not deceptive because they were materially identical to bottle labeling approved by the Alcohol Tobacco Tax and Trade Bureau (“TTB”). The Commonwealth now points to a subsequent opinion in the case. 2019 WL 1437910 (D. Mass. Mar. 30, 2019). Based on newly-discovered evidence that the beer cartons included claims that were not on the bottles—and therefore not approved by the TTB—the permitted practices exemption did not bar the claims as a matter of

law. Here, by contrast, the FDA affirmatively permitted the practices that the Commonwealth claims are deceptive (i.e. long-term and high-dose opioid use). A recent ruling from a North Dakota court dismissed nearly identical claims brought by that state's Attorney General, because "the marketing practices of Purdue that the State claims are improper—including claims relating to OxyContin's appropriateness for long-term treatment of chronic pain, maximum dosing, and the use of screening tools, were consistent with the FDA-approved product labeling. *North Dakota v. Purdue*, Ex. A at 9, 11-13 (internal citations omitted). The North Dakota court also concluded that the FDA specifically approved statements about "OxyContin and 12-hour relief," "Higher doses," "Pseudoaddiction," "Manageability of addiction risk," "Withdrawal", and "Abuse-deterrent formulations." *Id.*

Finally, the Commonwealth unsuccessfully attempts to distinguish some—but not all—of the cases Purdue cited to show that the permitted practices exemption bars the 93A claim. Notably, the Commonwealth fails to respond to Purdue's extensive discussion of *Reckis v. Johnson & Johnson*, 471 Mass. 272 (2015), Br. 24-25. Instead, the Commonwealth simply attempts to distinguish the court's decision in *Animal Legal. Def. Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Mass. 1986) by asserting, without support, that the challenged advertising—related to veal treated with antibiotics, as approved by the FDA—somehow provides "no basis to exempt Purdue's deceptive marketing from Chapter 93A." Opp. at 13, n.6. The Commonwealth's attempt to distinguish *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2016), is similarly unsupported. *Id.* Rather, as in *Prohias*, this Court should dismiss the Commonwealth's 93A claims because the FDA has permitted the statements in Purdue's marketing.

III. THE COURT SHOULD DISMISS THE COMPLAINT BECAUSE THE COMMONWEALTH DOES NOT ADEQUATELY PLEAD CAUSATION.

The Opposition asserts a number of arguments related to causation, none of which remedy the Commonwealth's failure to adequately plead causation. First, the Commonwealth claims it would be premature to dismiss the Amended Complaint for lack of causation. This is incorrect, as multiple Massachusetts courts have granted motions to dismiss claims that do not adequately plead causation. *See, e.g., Fletcher Fixed Income Alpha Fund, Ltd. v. Grant Thornton LLP*, 89 Mass. App. Ct. 718, 726, 54 N.E.3d 570 (2016) (affirming dismissal for lack of proximate cause, and concluding, "lack of proximate cause is appropriate for determination under rule 12(b)(6), where the complaint itself demonstrates that causation, as alleged, was not proximate"); *Kent v. Com.*, 437 Mass. 312, 322, 771 N.E.2d 770, 778 (2002) (court dismissed negligence claims for lack of proximate cause on motion to dismiss); *see also Leavitt v. Brockton Hosp., Inc.*, 454 Mass. 37, 907 N.E.2d 213 (2009); *HMA Adm'rs, LLC v. Mintz, Levin, Cohn, Ferris, Glovsky & Popeo P.C.*, 87 Mass. App. Ct. 1131, 32 N.E.3d 369 (2015).

The Commonwealth provides no legal support for its position. It does not even attempt to address the insurmountable causation problems in this case; Purdue produces fewer than 2% of the prescription opioids sold in the U.S. and, moreover, the vast majority of opioid deaths cited by the Commonwealth involved illicit opioids, rather than prescription opioids. Br. 28-29. When faced with similar allegations by a state, the *North Dakota* court dismissed the claims, finding that "[h]olding Purdue solely responsible for the entire opioid epidemic in North Dakota is difficult to comprehend, especially given Purdue's small share of the overall market for lawful opioids. It is also difficult to comprehend given the large market for unlawful opioids The causal chain the State attempts to allege is simply too attenuated." *North Dakota v. Purdue*, Ex. A at ¶ 58-59.

The Commonwealth attempts to excuse its failure to plead but-for causation by arguing that the learned intermediary doctrine “does not bar claims that a drug manufacturer deceived physicians.” Opp. 22. In support of this proposition, the Commonwealth relies only on *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306 (2016), and in doing so misstates the holding. The Court’s decision to require manufacturers of oral contraceptives to directly warn consumers was “a narrow exception to the learned intermediary rule,” required by “several factors that set birth control pills apart from other prescription drugs” *Id.* at 309, and has no applicability here.

More fundamentally, the Commonwealth misunderstands the importance of the “learned intermediary” in this case. The point is that healthcare professionals, as learned intermediaries, are required to exercise their independent judgment, based on their training, experience, and consideration of the best treatment plan for the individual patient. These individualized and independent medical decisions cut off any connection between Purdue’s alleged conduct and the harm claimed by the Commonwealth. *See North Dakota*, Ex. A at ¶ 55 (“The State’s claims – no matter how styled – have to account for the independent actor (i.e. doctors) who stands between Purdue’s alleged conduct and the alleged harm. In the face of information available to physicians, the State has not pleaded facts showing that Purdue’s alleged misrepresentations – as opposed to the undisputed multiple layers of individualized decision-making by doctors and patients or other possible intervening causes – led to any relevant prescribing or reimbursement decision.”).

Although the Commonwealth bases its entire case on the claim that Purdue deceived physicians, the Commonwealth fails to identify specific doctors who wrote specific unnecessary prescriptions as a result of Purdue’s alleged misrepresentations. In the Opposition, the Commonwealth attempts to remedy this failure by pointing to non-specific allegations regarding unnamed “top 100 targets.” Opp. 23. This misses the mark, as the Commonwealth still fails to

identify which, if any, of the prescriptions provided by these unnamed doctors were written unnecessarily and as a result of alleged deceptions. *See North Dakota*, Ex. A at ¶ 50 (“the State essentially alleges that there is an opioid problem . . . that has caused the State and its citizens great financial burden, and that the problem was the fault of Purdue and its marketing, but then completely fails to allege how Purdue’s allegedly deceptive marketing actually caused the alleged great financial burden.”). The Commonwealth’s reliance on *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 915 F.3d 1, 12 (1st Cir. 2019) is likewise unhelpful; in that case, the court found that the plaintiff’s causation evidence was sufficient to avoid dismissal *because* the plaintiff presented evidence of specific prescribers relying on specific misrepresentations. *Id.* In contrast, the Commonwealth fails to allege a single improper prescription that was written as a result of Purdue’s alleged misrepresentations.

The Commonwealth’s final argument strains the causation requirement far beyond its breaking point. The Commonwealth insists it is not required to show that any doctors actually relied on Purdue’s alleged misrepresentations. Opp. 25. Rather than respond substantively to Purdue’s reliance argument, the Commonwealth claims—without any legal support—that Purdue cited distinguishable RICO cases. The Commonwealth tries to minimize the importance of the leading RICO causation case, *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992), with the suggestion that the decision addressed only damage apportionment among various parties. This misses the point of *Holmes*, and even the issue of damage apportionment would be a major problem in this case. The Commonwealth seeks to recoup all of its opioid-related damages—whether caused by licit or illicit substances regardless of whether they were obtained legally or illegally—from a single company that manufactured only a small fraction of the legal opioids sold in the Massachusetts. *See, e.g., North Dakota v. Purdue*, Ex. A at 22 (“Purdue has absolutely no

control over how doctors prescribe the drug and how patients choose to use the drug. Purdue also has no control over how other manufacturers of opioids promote the drugs . . . [T]he State has failed to allege facts which, if true, show that Purdue, alone, caused the opioid crisis for which the State seeks compensation.”).

IV. THE PUBLIC NUISANCE CLAIM FAILS.

The Opposition cannot avoid that the Commonwealth’s public nuisance claim is merely a poorly disguised products liability claim. To begin with, the Commonwealth still fails to identify the “public right” with which Purdue allegedly interfered. As the Commonwealth concedes, for a nuisance to be public, it must “interfere[] with the exercise of a public right by directly encroaching on public property or by causing a common injury.” Opp. 17 (citing *Sullivan v. Chief Justice for Admin. & Mgmt. of Trial Court*, 448 Mass. 15, 34 (2006)). Indeed, as the Commonwealth’s reliance on *Sullivan* makes clear, a court must first inquire into whether there is a public right at stake, before determining whether there was interference with that right. *Sullivan*, 448 Mass. at 36.⁴ Yet the Commonwealth focuses its analysis solely on “interference.” Massachusetts precedent does not support the Commonwealth’s theory that there is a public right to avoid harm resulting from legal products that are lawfully placed into the stream of commerce. None of the cases cited by the Commonwealth support its overly broad view of public nuisance. See, e.g., *Sullivan*, 448 Mass. at 36 (dealing with asbestos exposure in a public building); *Leary v. City of Boston*, 20 Mass. App. Ct. 605, 609-10 (1985) (“long-standing public right such as travel on public highway or on navigable

⁴ The Commonwealth also points to unrelated dicta from *Sullivan* to assert that it is entitled to bring a public nuisance claim to address harms suffered by Massachusetts residents. While this may be true on some occasions, the Commonwealth fails to address Purdue’s argument that in doing so the Commonwealth is not excused from the ordinary rules of standing and causation, which require the State to show that the alleged nuisance was the proximate cause of the alleged harm. *Alholm v. Town of Wareham*, 371 Mass. 621, 626 (1976); Br. 32, n.13.

stream.”); *Evans v. Lorillard Tobacco Co.*, 2007 WL 796175 (Mass. Super. Ct. Feb. 7, 2007) (discussing public right created by statute).

Indeed, the Commonwealth can point to only one case in Massachusetts history—*City of Boston v. Smith & Wesson Corp.*—where the Superior Court declined to dismiss a public nuisance claim against the manufacturer of a consumer product (a gun manufacturer). 2000 WL 1473568, at *4 (Mass. Super. July 13, 2000). That decision is of very limited precedential value: it settled before going to trial and no higher court had an opportunity to examine the case. Furthermore, the court in *City of Boston* acknowledged that the plaintiff in that case had asserted an “extreme theory of liability” and that the court’s decision was rooted in “uncertainty about the state of the law.” 2000 WL 1473568, at *4 (Mass. Super. July 13, 2000); cf. *City of Philadelphia v. Beretta U.S.A., Corp.*, 126 F. Supp. 2d 882, 910 (E.D. Pa. 2000), aff’d, 277 F.3d 415 (3d Cir. 2002) (“the lack of precedent implies the lack of a legal theory affording a plaintiff a right to relief, and is the very reason to dismiss this theory here.”).

The one court that has subsequently examined *City of Boston* was a Massachusetts federal district court, which declined to extend the ruling and instead dismissed the plaintiff’s public nuisance claim. See *Town of Westport v. Monsanto Co.*, 2015 WL 1321466 at *2-3 (D. Mass. Mar. 24, 2015). Likewise, in *Jupin v. Kask*, which was also decided after the *City of Boston* decision, the court upheld the dismissal of a public nuisance claim against the owner of a gun, reasoning that, “[u]nloaded firearms do not, in and of themselves, discharge. Thus, they do not inherently interfere with or threaten the public safety and are not appropriately considered a public nuisance.” 447 Mass. 141, 159 (2006).

Despite the Commonwealth’s attempt to paint recent decisions in nearby states as outliers, the decisions in *Town of Westport* and *Jupin* make clear that *City of Boston* is the true outlier. As a

Delaware court recently held when dismissing a nearly identical public nuisance case against Purdue, “[t]here is a clear national trend to limit public nuisance to land use.” *State of Delaware ex rel. Jennings v. Purdue Pharma L.P.*, 2019 WL 446382 at *12 (Del. Super. Ct. Feb. 4, 2019). In *North Dakota*, the court similarly declined to “extend[] the public nuisance statutes to cases involving the sale of goods,” and held that “[t]he State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the ‘overprescribing and sale’ of opioids manufactured by Purdue.” Ex. A at 27. Accordingly, the Commonwealth’s attempt to stretch public nuisance law far beyond its historical bounds must be rejected.

V. THE COMMONWEALTH SEEKS RELIEF TO WHICH IT IS NOT ENTITLED.

The Commonwealth does not contest that public nuisance claims in Massachusetts are equitable in nature and therefore, should its public nuisance claim be allowed to proceed, the only available remedy is abatement. Br. 34. However, the Commonwealth also seeks disgorgement and restitution for the alleged violation of Chapter 93A claim. Opp. 26. This argument is completely inconsistent with the Commonwealth’s contention that it need not prove “resulting economic injury” to maintain a Chapter 93A claim because the Commonwealth seeks “penalties, costs, and injunctive relief.” Opp. 21 (citing *Commonwealth v. Equifax*, 2018 WL 3013918 (Mass. Super. Ct. April 3, 2018)). Because the Commonwealth also seeks disgorgement or restitution, it had to plead a causal link between Purdue’s conduct and the alleged harm. It has failed to do so. Notably, Purdue established that the Commonwealth would be unable to make this showing because a defendant’s legal responsibility for damages must be determined one person at a time, rather than *en masse*. Br. 34. The Commonwealth has not addressed this point.

VI. THE STATUTES OF LIMITATIONS BAR THE CLAIMS IN PART.

The State does not contest that a large portion of its Amended Complaint targets conduct outside the limitations period. Instead, the Commonwealth first attempts to sidestep the statute of limitations argument by citing some allegations of misconduct during the relevant period. Opp. 28. But the issue is not whether the Amended Complaint contains *some* allegations within the relevant period. Rather, the problem is that it is difficult to reasonably discern what portion of the alleged conduct occurred during the actionable time period and what did not, because of the breadth of the Commonwealth's claims and the intertwined manner in which it has pleaded them. It will be practically impossible to confine the Commonwealth's theory of liability and damages solely to conduct that allegedly occurred within the relevant period.

The Commonwealth attempts to excuse its failure to properly plead its claims by arguing that it is protected by the discovery rule. Opp. 30. In doing so, the Commonwealth misstates the relevant law in Massachusetts, which holds that "the statute of limitations starts to run when an event or events have occurred that were reasonably likely to put plaintiff on notice that someone may have caused [the] injury." *Bowen v. Eli Lilly & Co.*, 408 Mass. 204 (1990). A reasonable plaintiff would have been put on notice of the allegations raised in the Amended Complaint by the various news articles dating back to 2009 detailing Purdue's supposed misconduct, which the Commonwealth itself cites. Br. 36.

For these reasons, Purdue requests that the Court dismiss the Commonwealth's claims as time-barred. While the Commonwealth asserts that such a determination is not appropriate on a motion to dismiss, Massachusetts precedent says otherwise. *See, e.g., Taylor v. Moskow*, 92 Mass. App. Ct. 1114 (2017) (affirming dismissal of complaint as barred by that statute of limitations because "the documentary evidence showed that [plaintiff] was on notice of [plaintiff's] claims more than three years before she filed suit."); *Hanley v. Citizens Bank of Mass.*, 803 N.E.2d 1289 (Mass. App. Ct. 2004) (affirming dismissal of complaint on motion to dismiss on statute of limitations

grounds). Alternatively, Purdue requests that the Court require the Commonwealth to identify the specific paragraphs in its Amended Complaint that allege misconduct during the relevant time period, and the Court should limit the Commonwealth's claims to those supported by the identified paragraphs. *See, e.g., Alston v. Town of Brookline*, 321 F.R.D. 41, 44 (D. Mass. 2017) (striking from complaint allegations that were "far-removed in time from the allegations here.").

CONCLUSION

For the foregoing reasons, Purdue respectfully requests that the Court dismiss the Commonwealth's claims in their entirety.

Dated: May 22, 2019

Respectfully submitted,

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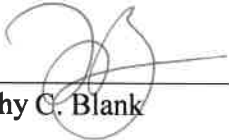
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EXHIBIT A

STATE OF NORTH DAKOTA

IN DISTRICT COURT

COUNTY OF BURLEIGH

SOUTH CENTRAL JUDICIAL DISTRICT

State of North Dakota Ex Rel. Wayne
Stenehjem, Attorney General,

Plaintiff,

v.

Purdue Pharma L.P.; Purdue Pharma, Inc.,
The Purdue Frederick Company, Inc., and
Does 1 through 100, inclusive,

Defendants.

Case No. 08-2018-CV-01300

**ORDER GRANTING DEFENDANTS'
MOTION TO DISMISS**

INTRODUCTION

[¶1] This matter is before the Court on the Defendants', Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (collectively "Purdue"), Motion to Dismiss for failure to state a claim. The State has sued Purdue in this matter seeking to essentially hold it liable for the impact of opioid overuse and addiction in North Dakota. The State asserts claims for alleged violations of the North Dakota Unlawful Sales or Advertising Practices statute, N.D.C.C. § 51-15-01 *et seq.* (Consumer Fraud law) (Counts 1 & 2) and the nuisance statute, N.D.C.C. § 42-01-01 *et seq.* (Count 3).

[¶2] In its Motion, Purdue argues the present case should be dismissed on the pleadings for various reasons, including the following:

1. The State's claims fail as a matter of law because it seeks to impose liability for Purdue's lawful promotion of FDA-approved medications for an FDA-approved use, i.e. the claims are preempted by federal law.
2. The State does not plead the essential elements of causation.
3. The State's statutory public nuisance claim fails because North Dakota

courts have not extended that statute to cases involving the sale of goods, and, even it did apply, the State does not allege that Purdue unlawfully interfered with a public right in North Dakota.

[¶3] The Plaintiff, the State of North Dakota ex rel. Wayne Stenehjem, Attorney General (“the State”), resists the Motion arguing they have sufficiently pled their claims and Purdue’s arguments mischaracterize the claims.

[¶4] A hearing was held on the Motion on February 26, 2019. Parrell Grossman and Elin Alm appeared on behalf of the State. Will Sachse appeared and argued on behalf of Purdue. Robert Stock also appeared on behalf of Purdue.

[¶5] The Court has extensively reviewed the parties’ briefing on the present Motion, on more than one occasion, and has reviewed the oral arguments presented by both parties. The Court has also extensively reviewed the State’s Complaint in this matter, paying careful attention to the allegations detailed therein, following oral argument.

FACTS

[¶6] The facts underlying this Action are detailed at length in the Complaint [DE 2], and in the parties’ respective briefing on the present Motion to Dismiss [DE 13 & DE 34]. The Court will not restate the facts as outlined by the parties, but incorporates those facts by reference into this Order.

[¶7] The State of North Dakota filed this action against drug manufacturer, Purdue Pharma, alleging the opioid epidemic and a public health crisis in North Dakota were caused, in large part, by a fraudulent and deceptive marketing campaign intended by Purdue to increase sales of its opioid products. The State alleges it has paid and will continue to pay expenses for the medical care and law enforcement response of North Dakota’s population due to overuse, addiction, injury, overdose, and death. The State

seeks damages, injunctive relief, and civil penalties.

[¶8] The State's Complaint asserts three causes of action: (1) violations of North Dakota's Consumer Fraud Law – Deceptive Practices (N.D.C.C. 51-15-01 et seq.); (2) violation of North Dakota's Consumer Fraud Law – Unconscionable Practices (N.D.C.C. 51-15-01 et seq.); and (3) statutory public nuisance.

[¶9] Purdue now seeks to dismiss the State's claims as a matter of law.

LEGAL STANDARD

[¶10] A motion to dismiss a complaint under N.D.R.Civ.P. 12(b)(6) test the legal sufficiency of the statement of the claim presented in the complaint. *Ziegelmann v. Daimler Chrysler Corp.*, 2002 ND 134, ¶ 5, 649 N.W.2d 556. "Because determinations on the merits are generally preferred to dismissal on the pleadings, Rule 12(b)(vi) motions are viewed with disfavor." *Id.* A complaint "should not be dismissed unless it is disclosed with certainty the impossibility of proving a claim upon which relief can be granted." *Id.* A court's scrutiny of the pleadings should be deferential to the plaintiff. *Id.*

[¶11] The Court notes at the outset that Purdue filed the present Motion as a Motion to Dismiss under Rule 12(b)(6). However, both parties have cited to multiple documents and sources outside of the pleadings and each relies heavily on these sources in their briefing. "When a motion to dismiss for failure to state a claim upon which relief can be granted is presented before the court and 'matters outside the pleadings are presented to and not excluded by the court, the motion should be treated as one for summary judgment and disposed of as provided in Rule 56.'" *Podrygula v. Bray*, 2014 ND 226, ¶7, 856 N.W.2d 791 (quoting *Livingood v. Meece*, 477 N.W.2d 183, 187 (N.D. 1991)).

[¶12] The Court does not intend to ignore or exclude the materials cited by the parties and incorporated in their briefing, which are technically outside the pleadings. Based on the parties framing of the issues, both in their briefing and at the hearing on the present Motion, and based upon Purdue's reliance on matters technically outside the pleadings, the Court will treat Purdue's Motion as a motion for summary judgment.

[¶13] Rule 56(c) of the North Dakota Rules of Civil Procedure directs a trial court to enter summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

[¶14] The standard for summary judgment is well established:

Summary judgment is a procedural device for the prompt resolution of a controversy on the merits without a trial if there are no genuine issues of material fact or inferences that can reasonably be drawn from undisputed facts, or if the only issues to be resolved are questions of law. A party moving for summary judgment has the burden of showing there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. . . . [W]e must view the evidence in the light most favorable to the party opposing the motion, and that party will be given the benefit of all favorable inferences which can reasonably be drawn from the record.

Golden v. SM Energy Co., 2013 ND 17, ¶ 7, 826 N.W.2d 610, 615 (quoting *Hamilton v. Woll*, 2012 ND 238, ¶ 9, 823 N.W.2d 754.

[¶15] "Although the party seeking summary judgment bears the initial burden of showing there is no genuine issue of material fact, the party opposing the motion may not simply rely upon the pleadings, but must present competent admissible evidence which raises an issue of material fact." *Black v. Abex Corp.*, 1999 ND 236, ¶ 23, 603 N.W.2d 182. "Summary judgment is appropriate against a party who fails to establish

the existence of a factual dispute on an essential element of her claim and on which she will bear the burden of proof at trial.” *Id.*

ANALYSIS

A. Federal Preemption

[¶16] Purdue first argues the State’s claims are improper because they seek to impose liability for lawful promotion of FDA-approved medications for an FDA-approved use. Specifically, Purdue argues that the FDA has approved opioid medications for long-term treatment of chronic non-cancer pain, and Purdue’s promotion is consistent with the FDA-approved indications and labeling decisions. Because their promotion/marketing is consistent with FDA-approved labeling decisions and because the FDA has previously declined to alter the labeling and/or warnings, Purdue argues the State’s claims are preempted.

[¶17] The Supremacy Clause of the United States Constitution makes federal law the supreme law of the land, and state law that conflicts with federal law is without effect. *Home of Economy v. Burlington N. Santa Fe R.R.*, 2005 ND 74, ¶ 5, 694 N.W.2d 840. Whether claims are preempted is a question of law that may be resolved at the pleading stage. *See NoDak Bancorporation v. Clarkson*, 471 N.W.2d 140, 142 (N.D. 1991). The North Dakota Supreme Court has described when federal law preempts state law under the Supremacy Clause:

First, Congress can define explicitly the extent to which its enactments pre-empt state law. Pre-emption fundamentally is a question of congressional intent, and when Congress has made its intent known through explicit statutory language, the courts’ task is an easy one.

Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be

inferred from a “scheme of federal regulation ... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,” or where an Act of Congress “touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.” Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: “Where ... the field which Congress is said to have pre-empted” includes areas that have “been traditionally occupied by the States,” congressional intent to supersede state laws must be “clear and manifest.”

Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

Home of Economy v. Burlington N. Santa Fe R.R., 2005 ND 74, at ¶ 5.

[¶18] “The United States Supreme Court’s framework for analyzing preemption claims starts with the assumption that Congress does not intend to displace state law.”

Id. at ¶ 6. “The assumption that Congress did not intend to displace state law is not triggered when a state regulated in an area where there has been history of significant federal presence.” *Id.* (citing *United States v. Locke*, 529 U.S. 89 (2000)).

[¶19] Although there are three established types of federal preemption as detailed above, the parties in this case agree that “conflict preemption” is the only potential basis for preemption in this case. Conflict preemption exists where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law. *Lefavre v. KV Pharmaceutical Co.*, 636 F.3d 935, 939 (8th Cir. 2011). There are two types of conflict preemption, impossibility preemption and obstruction preemption. *Id.* “Impossibility preemption arises when compliance with both federal and state regulations is a physical impossibility. *Id.* (internal quotations omitted). “Obstruction

preemption exists when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.*

[¶20] “[T]he FDCA’s treatment of prescription drugs includes neither an express preemption clause (as in the vaccine context, 42 U.S.C. § 300aa-22(b)(1)), nor an express non-preemption clause (as in the over-the-counter drug context, 21 U.S.C. §§ 379r(e), 379s(d)).” *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 493 (2013). “In the absence of that sort of ‘explicit’ expression of congressional intent, we are left to divine Congress’ will from the duties the statute imposes.” *Id.*

[¶21] In determining whether the State’s claims against Purdue in this case are preempted in this case, the Court must review Congress’ purpose and intent in enacting the Federal Food, Drug, and Cosmetic Act (FDCA). This was succinctly summarized by the 10th Circuit in *Cereveny v. Aventis, Inc.*, 855 F.3d 1091, 1096 (10th Cir. 2017):

The Federal Food, Drug, and Cosmetic Act has long required a manufacturer to obtain approval from the FDA before the manufacturer can introduce a new drug in the market. 21 U.S.C. § 355(a). For brand-name drugs, a manufacturer must submit an application. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 133 S.Ct. 2466, 2470–71, 186 L.Ed.2d 607 (2013). The application must include the proposed label, “full reports of investigations which have been made to show whether such drug is [safe and effective],” comprehensive information of the drug’s composition and the “manufacture, processing, and packing of such drug,” relevant nonclinical studies, and “any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source.” 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(c)(2)(i), (d)(1), (2), (5)(iv).

If the FDA approves the application, the manufacturer generally is restricted from changing the label without advance permission from the FDA. 21 U.S.C. §§ 331(a), (c), 352; 21 C.F.R. § 314.70(a), (b). But an exception exists, allowing a manufacturer under certain circumstances to change the label before obtaining FDA approval. 21 C.F.R. § 314.70(c).4 But even when this exception applies, the FDA will ultimately approve the label change only if it is based on reasonable evidence of an

association between the drug and a serious hazard. 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii).

Cereveny v. Aventis, Inc., 855 F.3d 1091, 1096 (10th Cir. 2017).

[¶22] Purdue argues the FDCA “preempts state-law claims that seek to impose a duty to alter FDA-approved labeling or to market FDA-approved prescription medications in a way that conflicts with federal law.” [DE 13 (Purdue’s Brief in Support of Motion to Dismiss) at ¶ 20. Specifically, Purdue argues the State’s claims are preempted because they require Purdue to include, either in the label for opioids or in its marketing of the opioids, a more extensive warning of the risks and benefits of Opioids than what has been approved by the FDA. Purdue contends federal law preempts such state law claims where they would require a pharmaceutical manufacturer to make statements about safety or efficacy that are inconsistent with what the FDA has required after it evaluated the available data.

[¶23] Similar issues were addressed by the United States Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2009). At issue in *Levine* was the label warning and accompanying use instructions for Phenargen, an antihistamine approved by the FDA for the intravenous treatment of nausea. *Id.* at 559. The plaintiff argued the manufacturer violated its common law duty to warn of the risks associated with the injection of Phenargen, including the manner in which it is injected. *Id.* at 559-60. The manufacturer argued the claim was preempted because the FDA had previously approved the warning and use instructions for the drug’s label. *Id.* at 560.

[¶24] The United States Supreme Court held that the state failure to warn claim was not preempted by FDA regulations. *Id.* at 581. The Court rejected the manufacturer’s argument that, once a label is approved by the FDA, the manufacturer is not obligated

to seek revision of its contents. *Id.* at 570-71. The Court outlined that FDA regulations permit a drug manufacturer, without first obtaining FDA approval, to strengthen a warning contained in a label already approved by the FDA, if the manufacturer has evidence to support an altered warning. *Id.*

[¶25] The *Levine* Court established a “clear evidence” standard of proof required to support a claim of conflict preemption based on FDA labeling regulations. *Id.* at 571-72. *Levine* did not hold that impossibility preemption based on FDA labeling regulations is precluded in all cases. Rather, *Levine* established that the FDA labeling regulations do not preempt state law claims unless the manufacturer presents “clear evidence that the FDA would not have approved a change” to the drug’s label or warning, thereby making it “impossible” for the manufacturer to comply with “both federal and state requirements.” *Levine*, 555 U.S. at 571.

[¶26] The *Levine* Court did not define “clear evidence,” and it did not establish the level of proof required to constitute such evidence. The Court simply held that in the circumstances of that case, there was no evidence that the manufacturer tried to alter the label to include additional warnings, and, therefore, the state law claims were not preempted by FDA regulations.

[¶27] In this case, the Court concludes the marketing practices of Purdue that the State claims are improper – including claims relating to OxyContin’s appropriateness for long-term treatment of chronic pain [DE 2 (Complaint) at ¶¶107-08], maximum dosing [Complaint at ¶¶ 95, 115-16], and the use of screening tools [Complaint at ¶¶ 85-89], were consistent with the FDA-approved product labeling. *See generally* [DE 14-16 (Exhibits 1-3 to Purdue’s Brief)].

[¶28] The State claims it is not pursuing an inadequate labeling theory, but simultaneously argues Purdue could have, and should have, strengthened its labeling and warnings to include additional risk information without prior FDA approval. [DE 34 (State's Opposition Brief) at 26-27]. The Complaint, however, contains no allegations of newly acquired information that could provide a basis for Purdue to change its labeling without prior FDA approval. Instead, consistent with the Supreme Court's decision in *Levine*, there is "clear evidence" that the FDA would not have approved changes to Purdue's labels to comport with the State's claims.

[¶29] In 2013, the FDA addressed the same issues raised by the State, and concluded that no modification to the product labeling was necessary. [DE 14-16 (Exhibits 1-3)]. In response to a 2012 citizen's petition from PROP, the FDA studied the available scientific evidence and concluded that it supports the use of ER/LA opioids to treat chronic non-cancer pain. [DE 17 (Exhibit 4)]. Therefore, the FDA has communicated its disagreement with the State's specific contention that Purdue "falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence," and therefore that it was improper to promote OxyContin for chronic pain. PROP and other commentators raised these same concerns as a reason to limit the indication for opioid medications, but the FDA rejected the request. [DE 17 (Exhibit 4) at 5]. Nor did the FDA direct Purdue to stop marketing the medications for long-term use. *Id.* at 14 ("FDA has determined that limiting the duration of use for opioid therapy to 90 days is not supportable.").

[¶30] As to certain risks that were already included in the labeling for Purdue's opioid medications, the FDA required Purdue to conduct additional studies and further assess those risks along with the benefits of use before any changes or additional warnings would be included. *Id.* at 11. The FDA is awaiting any new evidence to determine whether the medications' labeling should be revised to provide any different or additional information about those risks and benefits to physicians.

[¶31] The following allegations made by the State in its Complaint similarly conflict with statements the FDA has specifically approved:

[¶32] **Oxy Contin and 12-hour relief:** The State alleges "Purdue misleadingly promoted OxyContin as . . . providing 12 continuous hours of pain relief with one dose." [DE 2 (Complaint) at ¶ 115]. The FDA specifically addressed and rejected this claim. In a January 2004 citizen's petition, the Connecticut Attorney General requested labeling changes for OxyContin, asserting that OxyContin is not a true 12-hour drug and that using it on a more frequent dosing schedule increases its risk for diversion and abuse. In September 2008, the FDA denied the petition, and concluded the evidence failed to support that using OxyContin more frequently than every 12 hours created greater risk. *See* [DE 18 (FDA's September 2008 letter to Richard Blumenthal, Attorney General, State of Connecticut) at 14-17; cited by Complaint at ¶ 117). Since then, the FDA continues to approve OxyContin as a 12-hour medication. [DE 14 (Exhibit 1)].

[¶33] **Higher Doses:** The State alleges Purdue misrepresented the safety of increasing opioid doses. [DE 2 (Complaint) at ¶¶ 94-100]. This allegation is contrary to the FDA's labeling decision in response to the PROP Petition, which denied a request to limit the

dose of opioids. The FDA concluded “the available information does not demonstrate that the relationship [between opioid dose and risk of certain adverse events] is necessary a causal one.” [DE 17 (Exhibit 4)].

[¶34] **Pseudoaddiction:** The State claims Purdue falsely promoted the concept of “psuedoaddiction” – drug seeking behavior that *mimics* addiction, occurring in patients who receive adequate pain relief – to diminish addiction concerns by implying this concept is substantiated by scientific evidence. [DE 2 (Complaint) at ¶¶ 77-84]. However, the FDA has approved labeling for Purdue’s medications that embody this concept, both before and after the FDA’s evidentiary review in response to the PROP petition. The FDA-approved labeling for extended-release opioid medications discusses “[d]rug-seeking behavior” in “persons with substance use disorders[,]” but also recognizes that “preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.” See FDA REMS, FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics at 3.

[¶35] **Manageability of Addiction Risk:** The State alleges Purdue misrepresented that addiction risk screening tools allow prescribers to identify and safely prescribe opioids to patients predisposed to addiction. [DE 2 (Complaint) at ¶¶ 85-89]. However, again, the State ignores that the FDA-approved REMS for Purdue’s medications directs doctors to use screening tools and questionnaires to help mitigate opioid abuse. [DE 14 (Exhibit 1 - Oxy Contin Labeling)]. The FDA’s response to the PROP Petition also clarified this distinction between physical dependence and addiction. [DE 17 (Exhibit 4) at 16 n.64 (the DSM-V “combines the substance abuse and substance dependence categories into a single disorder measured on a continuum, to try to avoid an

inappropriate linking of ‘addiction’ with ‘physical dependence,’ which are distinct issues.”)].

[¶36] **Withdrawal:** The State alleges Purdue falsely claimed that “opioid withdrawal is not a problem.” [DE 2 (Complaint) at ¶ 90]. The State contends symptoms associated with withdrawal can “decrease the likelihood that . . . patients will be able to taper or stop taking opioids.” *Id.* However, the FDA approved Purdue’s labeling, which informs doctors that physically dependent patients can be withdrawn safely by gradually tapering the dosage, and that addiction is “separate and distinct from physical dependence.” [DE 14 (Exhibit 1 - Oxy Contin Labeling)].

[¶37] **Abuse-Deterrent Formulations:** The State alleges Purdue deceptively claimed that abuse-deterrent formulations of its opioid medications could “deter abuse,” and “create false impressions that” abuse-deterrent formulations could “curb addiction and abuse.” [DE 2 (Complaint) at ¶ 101]. The FDA-approved Oxy Contin labeling states that “OXYCONTIN is formulated with inactive ingredients intended to make the tablet more difficult to manipulate for misuse and abuse.” [DE 14 (Exhibit 1 – OxyContin Labeling)]. Therefore, statements that abuse-deterrent formulations are designed to reduce the incidence of misuse, abuse, and diversion, [Compl. At ¶¶101-106], are consistent with the FDA-approved labeling and FDA policies. The State’s allegations are also inconsistent with the FDA’s 2013 “extensive review of the data regarding reformulated OxyConin” and the FDA’s conclusion that reformulated Oxy Contin is “expected” to “make abuse via injection difficult,” “reduce abuse via the intranasal route,” and “deter certain types of misuse in therapeutic contexts.” 78 Fed. Reg. 23273-01, 2013 WL 1650735 (Apr. 18, 2013).

[¶38] In other words, when presented with many of the same concerns the State alleges against Purdue in its Complaint regarding the enhanced risks of using opioids in high doses and for long durations, and with inadequate or misleading warnings, the FDA chose neither to impose those limits on opioid use nor to add warnings about those risks. The Court concludes this is “clear evidence” under *Levine* that the FDA would not have approved the changes to Purdue’s labeling that the State contends were required to satisfy North Dakota law.

[¶39] “[T]he Court in *Levine* did not say that for evidence to be clear it must result from a formal procedure of approval or disapproval.” *Rheinfrank v. Abbott Laboratories, Inc.*, 680 Fed. Appx. 369, 386 (6th Cir. 2017). The *Levine* Court concluded the claims were not preempted in that case because there was “no evidence in [the] record.” *Wyeth*, 555 U.S. at 572. However, the Court noted that the claims in *Levine* “would have been preempted upon clear evidence that the FDA would have rejected the desired label change.” *Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1098 10th Cir. 2017). “*Levine* did not characterize the proof standard as requiring a manufacturer in every case to prove that it would have been impossible to alter the drug’s label.” *Dobbs v. Wyeth Pharmaceuticals*, 797 F. Supp.2d 1264, 1279 (W.D. Okla. 2011). “[T]his court does not interpret *Levine* as imposing upon the drug manufacturer a duty to continually ‘press’ an enhanced warning which has been rejected by the FDA.” *Id.*

[¶40] In this case, the Court concludes Purdue has met its burden under *Levine*’s clear evidence standard. “[A] court cannot order a drug company to place on a label a warning if there is clear evidence that the FDA would not approve it.” *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010). Given that the FDA

does not yet believe the state of the data supports additional warnings or altered labeling when presented with the issues asserted by the State in this case, it would have been impossible for Purdue to comply with what the State alleges was required under North Dakota law while still respecting the FDA's unwillingness to change the labeling and warnings, both on its labels for opioids and in its advertising.

[¶41] Accordingly, federal law preempts the State's state-law claims, which are based on the marketing of Purdue's medications for their FDA-approved uses, including for treatment of chronic, non-cancer pain. Those claims necessarily "conflict[]" with the FDA's jurisdiction over drug labeling, and specifically its approval of" those indications. *Prohios v. Pfizer, Inc.*, 490 F.Supp.2d 1228, 1234 (S.D. Fla. 2007). Because Purdue has met its burden under *Wyeth v. Levine*, the court concludes the state law claims asserted by the State are preempted in this matter by federal law.

B. Consumer Fraud Law Claims

[¶42] In addition to the preemption arguments detailed above, Purdue also argues the State's Consumer Fraud Law claims (First and Second Causes of Action) should be dismissed because the State has failed to plead the essential element of causation. The State argues it is not required to allege causation to prevail under the Consumer Fraud Law.

[¶43] The Unlawful Sales or Advertising Practices Act prohibits deceptive or fraudulent conduct in the sale or advertising of merchandise:

The act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice. The act, use, or employment by any person of any act or

practice, in connection with the sale or advertisement of any merchandise, which is unconscionable or which causes or is likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition, is declared to be an unlawful practice.

N.D.C.C. § 51-15-02.

[¶44] Purdue relies on *Ackre v. Chapman & Chapman, P.C.*, 2010 ND 167, 788 N.W.2d 344, for the argument that causation is an element the State must plead and prove to support its cause of action under the Consumer Fraud Law. *Ackre* involved a lawsuit brought under the private right of action in N.D.C.C. § 51-15-09. Because of this, the State argues “[w]hen the Court stated that the Plaintiff was required ‘to show the putatively illegal action caused some threatened or actual injury to his or her legal rights and interests,’ the Court was referring to what is required for a private plaintiff to have standing to bring a private right of action under N.D.C.C. § 51-15-09.” [DE 34 (State’s Response Brief) at ¶ 66]. Specifically, the State asserts “Consumer Fraud Actions brought by the Attorney General are civil law enforcement actions, not civil tort actions, and causation, and requirements applied to tort actions are, therefore, inapplicable to consumer fraud claims.” [DE 34 (State’s Response Brief) at ¶ 65].

[¶45] These arguments blatantly ignore the State’s own Complaint and the types of damages it is seeking in this lawsuit.

[¶46] The State specifically alleges that “Purdue’s conduct has resulted in a financial burden on the State of North Dakota.” [DE 2 (Complaint) at ¶ 15]. It goes on to allege that the State and its Departments have “spent millions of dollars on opioid prescriptions for chronic pain and addiction treatment – costs directly attributable to the opioids Purdue unleashed on the State.” *Id.* “Purdue’s deceptive marketing of opioids

and the resulting opioid epidemic also has caused the State to incur additional cost for law enforcement, North Dakota Workforce Safety and Insurance, Department of Corrections, North Dakota Department of Human Services, and North Dakota Behavioral Health and other agencies.” *Id.* at ¶ 16. “The State seeks injunctive relief, disgorgement and restitution for amounts the State’s Medicaid program and other State agencies have paid for excessive opioid prescriptions.” *Id.* at ¶ 17. The State also clearly asserts it is seeking “restitution for North Dakota consumers who, like the State, paid for excessive prescriptions of opioids for chronic pain.” *Id.*

[¶47] The State’s Complaint clearly includes requests for money damages for purported violations of the Consumer Fraud Law. For additional examples, the Complaint requests the Court to “restore any loss suffered by persons as a result of the deceptive acts or practices of Defendants as provided in N.D.C.C. § 51-15-07.” [DE 2 (Complaint) at ¶ 186(d) (emphasis added)]. The State also alleges “Purdue is responsible for the claims submitted and the amount the State’s Medicaid program and other State agencies spent on its opioids.” *Id.* at ¶ 182. The Prayer for Relief also requests “[t]hat Purdue be ordered to pay restitution to the State, [and] State agencies, including the Department of Human Services.” [DE 2 (Complaint – Prayer for Relief (E))].

[¶48] The plain language of § 51-15-07 requires proof that the money to be restored was acquired “by means of” the allegedly deceptive act. Whether styled as a claim for money damages or for restitution pursuant to § 51-15-07, the requirement is the same: The State must plead and prove causation, i.e. the loss of money occurred “by means of” the alleged deception. *Compare* N.D.C.C. § 51-15-09 (allowing claim “against any

person who has acquired any moneys or property by means of any practice declared to be unlawful un this chapter”) (emphasis added) *with* N.D.C.C. § 51-15-07 (allowing restitution of money “that may have been acquired by means of any practice in this chapter . . . declared to be unlawful”) (emphasis added).

[¶49] When the State makes a claim under the Consumer Fraud Law for out-of-pocket losses, it is no different than a private plaintiff’s claim to recover actual damages suffered “by means of” the deception. *See* N.D.C.C. § 51-15-09. There is simply no basis in North Dakota law to conclude the “by means of” language in the private consumer section of the Consumer Fraud Act (51-15-09) has a different meaning than the “by means of” language in § 51-15-07.

[¶50] The State’s Complaint fails to identify which losses occurred “by means of” – i.e., because of – any specific alleged deception or misrepresentation on the part of Purdue. The State does not allege that every opioid prescription in North Dakota was unlawful. In fact, the State expressly acknowledges that it does not seek an outright ban on the sale of opioids. [DE 34 (State’s Response Brief) at 25]. The State acknowledges that “not every sale” of opioids “contributed” to the public health problem. *Id.* at 49. To put it succinctly, the State essentially alleges that there is an opioid problem in North Dakota that has caused the State and its citizens great “financial burden”, and that the problem was the fault of Purdue and its marketing, but then completely fails to allege how Purdue’s allegedly deceptive marketing actually caused the alleged great “financial burden.”

[¶51] The State does not identify any North Dakota doctor who ever received any specific purported misrepresentation made by Purdue, or who wrote a medically

unnecessary prescription because of those alleged statements. The State also does not allege any false statement caused the State to reimburse prescriptions it otherwise would not have reimbursed. Under the State's theory, it can recover for reimbursements under the Consumer Fraud Act even if the State fails to show any such reimbursements were caused by a deception, and even when the State continued to pay for reimbursements with knowledge of the alleged deception.

[¶52] Rather than plead the requisite specifics, the Complaint offers only conclusory allegations that Purdue had "a marketing campaign" since the 1990s, which was "designed to convince prescribers and the public that its opioids are effective for treating chronic pain" and allegedly resulted in the routine prescription of opioids for long-term use. [DE 2 (Complaint) at ¶ 4]. These allegations are unconnected to any particular North Dakota doctor or prescription. Additionally, the State fails to plead how the alleged misstatements, most of which are alleged to have occurred over a decade ago, could have caused specific prescribing decisions to this day.

[¶53] A generalized "fraud-on-the-market" theory does not suffice to establish causation. In cases that assert claims for fraudulent or deceptive pharmaceutical marketing, "a fraud-on-the-market theory cannot plead the necessary element of causation because the relationship between the defendants' alleged misrepresentations and the purported loss suffered by the patients is so attenuated . . . that it would effectively be nonexistent." *In re Actimmune Mktg. Litig.*, 614 F.Sup.2d 1037, 1054 (N.D. Cal. 2009), *aff'd*, 464 F.App'x 651 (9th Cir. 2011).

[¶54] The State acknowledges that patients may not lawfully obtain Purdue's opioid medications without a valid prescription. [DE 2 (Complaint) at ¶ 11]. The State also

recognizes that doctors themselves have many resources available about Purdue's products, including FDA-approved labeling that discloses the risks Purdue allegedly concealed. *Id.* at ¶¶ 69-70, 72-73, 75-76, 83-84, 88, 93, 97-100, 104, 111-12, 117.

[¶55] Even assuming, for purposes of argument only, that Purdue had failed to disclose these risks, such a failure would not be the "proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) (internal quotations and citations omitted) (concluding North Dakota would adopt the "learned intermediary" doctrine). The State's theory in this case depends on an extremely attenuated, multi-step, and remote causal chain. The State's claims – no matter how styled – have to account for the independent actor (i.e. doctors) who stands between Purdue's alleged conduct and the alleged harm. *Id.* In the face of information available to physicians, the State has not pleaded facts showing that Purdue's alleged misrepresentations – as opposed to the undisputed multiple layers of individualized decision-making by doctors and patients or other possible intervening causes – led to any relevant prescribing or reimbursement decision.

[¶56] A defendant is not liable for alleged injuries that either result from a superseding, intervening cause, or "if the cause is remote" from the injury. *Moum v. Maercklein*, 201 N.W.2d 399, 403 (N.D. 1972); *see also Price v. Purdue Pharma Co.*, 920 So.2d 479, 485-86 (Miss. 2006) (observing lack of proximate cause for claims of opioid addiction brought against Purdue, because injuries were the result of illegally obtained and improper use of opioids). "A superseding cause is an act of a third person or other force which by its intervention prevents the actor from being liable for harm to

another which his antecedent negligence is a substantial factor in bringing about.” *Leistra v. Bucyrus-Erie Co.*, 443 F.2d 157, 163 n.3 (8th Cir. 1971) (internal quotations omitted).

[¶57] *Ashley County, Ark. v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009), which was decided under analogous facts, is instructive. In *Ashely County*, Arkansas counties brought claims against pharmaceutical companies for, *inter alia*, public nuisance and deceptive trade practices, seeking “compensation to recoup the costs expended by the counties in dealing with the societal effects of the methamphetamine epidemic in Arkansas, with liability premised on the use of the Defendants’ products in the methamphetamine manufacturing process. *Id.* at 663. The Eighth Circuit affirmed the dismissal of the complaint for failure to state a claim, and determined that “[p]roximate cause seems an appropriate avenue for limiting liability in this context . . . particularly ‘where an effect may be a proliferation of lawsuits not merely against these defendants but against other types of commercial enterprises – manufacturers, say, of liquor, anti-depressants, SUVs, or violent video games – in order to address a myriad of societal problems regardless of the distance between the ‘causes’ of the ‘problems’ and their alleged consequences.’” *Id.* at 671-72 (quoting *Dist. of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 651 (D.C. 2005)).

[¶58] Similarly, in this case, the connection between the alleged misconduct and the prescription depends on multiple, independent, intervening events and actors. These intervening events and actors include: the doctor’s independent medical judgment, the patient’s decision whether and how to use the medication, the patient’s response to the medication, and the State’s own decision to reimburse the prescriptions. Additionally,

it is nearly impossible to trace any of the harms the State alleges back to solely Purdue's own medications, as opposed to other manufacture's opioids and other unlawful opioids. Holding Purdue solely responsible for the entire opioid epidemic in North Dakota is difficult to comprehend, especially given Purdue's small share of the overall market for lawful opioids. It is also difficult to comprehend given the large market for unlawful opioids.

[¶59] The State's claims that Purdue can, should, or should have in the past, "changed the message" regarding opioids to include stronger warnings and labeling is not taken well by the Court. Even if Purdue can and does "change the message," Purdue has absolutely no control over how doctors prescribe the drug and how patients choose to use the drug. Purdue also has no control over how other manufacturers of opioids promote the drugs. Doctors can be loose with their prescribing practices, and patients do not always follow their doctor's orders. The Court does not mean to suggest this is the sole cause of the opioid crisis in North Dakota. But the State has failed to allege facts which, if true, show that Purdue, alone, caused the opioid crisis for which the State seeks compensation. The causal chain the State attempts to allege is simply too attenuated.

[¶60] The State seems to acknowledge its attenuated theory of causation in its Complaint by identifying a number of behaviors that contribute to the opioid crisis, such as "doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment." [DE 2 (Complaint) at ¶ 151]. The State also clearly acknowledges the "high statistic of people that first get addicted after obtaining opioids free from a friend or relative." *Id.* at ¶ 145. These are not Purdue's

acts or misrepresentations, yet the State seeks to hold Purdue solely liable. The State's effort to hold one company to account for this entire, complex public health issue oversimplifies the problem.

[¶61] The Court concludes the State's causal theory is too attenuated and requires dismissal of the State's Consumer Fraud Law Claims as a matter of law. If the State can proceed on the causation it has alleged in this lawsuit against Purdue, it begs the question of how far the causal chain can go. There are a seemingly limitless number of actors who could have "tried harder" under the State's theory and claims. Purdue is no higher up in the causal chain under the facts alleged by the State than any other actor who could be held liable. The State has not pleaded facts that Purdue's alleged misrepresentations caused North Dakota doctors to write medically unnecessary prescriptions or that Purdue's alleged misrepresentation caused the State to reimburse prescriptions.

[¶62] Because the State has failed to adequately plead causation, its Consumer Fraud Law claims fail as a matter of law and must be dismissed.

C. Public Nuisance

[¶63] Purdue additionally argues the State's Third Cause of Action for public nuisance must be dismissed because no North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. Because the State's nuisance claim in this case revolves around the effects of a product (opioids) sold and used in North Dakota, Purdue argues the State's public nuisance claim fails.

[¶64] The State's claim for public nuisance is brought under N.D.C.C. § 42-01-01 *et seq.* (nuisance) and 42-02-01 *et seq.* (abatement of common nuisance). A nuisance is defined by N.D.C.C. § 42-01-01, which provides:

A nuisance consists in unlawfully doing an act or omitting to perform a duty, which act or omission:

1. Annoys, injures, or endangers the comfort, repose, health, or safety of others;
2. Offends decency;
3. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake, navigable river, bay, stream, canal, basin, public park, square, street, or highway; or
4. In any way renders other persons insecure in life or in the use of property.

N.D.C.C. § 42-01-01.

[¶65] "A public nuisance is one which at the same time affects an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." N.D.C.C. § 42-01-06. The N.D.C.C. § 42-01-01 definition of nuisance applies to public nuisance claims. *Kappenman v. Klipfel*, 2009 ND 89, ¶ 36, 765 N.W.2d 716.

[¶66] In response to Purdue's argument on this issue, the State attempts to characterize its claims as focusing only on Purdue's marketing conduct, and not on the actual sale of opioids. The State alleges "[t]he Complaint does not identify Purdue's sale of the opioids as the public nuisance; instead, the nuisance is Purdue's misrepresentations and deceptive promotion of their risks and benefits." [DE 34 (State's Response Brief) at ¶ 73]. This argument, again, ignores the clear allegations in the State's Complaint.

[¶67] The State specifically alleges a public nuisance in this case in that “Purdue’s conduct unreasonably interfered with the public health, welfare, and safety of North Dakota residents by expanding the opioid market and opioid use through an aggressive and successful marketing scheme that relied on intentional deception and misrepresentation regarding the benefits, safety and efficacy of prescription opioids.” [DE 34 (State’s Response Brief) at ¶ 72; and DE 2 (Complaint) at ¶¶ 4, 7, & 9]. The State further alleges that Purdue’s conduct “caused and maintained the overprescribing and sale of opioid for long-term treatment of chronic pain at such volumes and degrees as to create an epidemic.” [DE 2 (Complaint) at ¶ 201].

[¶68] The State cannot escape the true nature of the nuisance claim it has pleaded. The “overprescribing and sale” of opioids manufactured by Purdue are directly at the heart of the State’s nuisance claim, regardless of how it otherwise now tries to characterize its claim.

[¶69] Purdue is correct, as the State concedes, that North Dakota courts have not extended the nuisance statute to cases involving the sale of goods. [DE 34 (State’s Response Brief) at ¶ 74; DE 13 (Purdue’s Brief in Support of Motion) at ¶ 45]. Such a situation was addressed by the Eighth Circuit Court of Appeals in *Tioga Pub. Sch. Dist. No. 15 of Williams Cty. State of N. Dakota v. United States Gypsum Co.*, 984 F.2d 915, 920 (8th Cir. 1993). Although *Tioga* was a federal case, in the absence of binding North Dakota Supreme Court decisions interpreting North Dakota law, federal court decisions are given deference. *N. Dakota Fair Hous. Council, Inc. v. Peterson*, 2001 ND 81, ¶¶ 20-24, 625 N.W.2d 551, 559 (N.D. 2001).

[¶70] In *Tioga*, the 8th Circuit concluded that the North Dakota Supreme Court would not extend the nuisance doctrine to cases involving the sale of goods. *Tioga*, 984 F.2d at 920. The Court reasoned:

Tioga has not presented us with any North Dakota cases extending the application of the nuisance statute to situations where one party has sold to the other a product that later is alleged to constitute a nuisance, nor has our research disclosed any such cases. North Dakota cases applying the state's nuisance statute all appear to arise in the classic context of a landowner or other person in control of property conducting an activity on his land in such a manner as to interfere with the property rights of a neighbor

Id. (emphasis added).

[¶71] The State urges this Court to distinguish *Tioga* “because it does not arise from a direct injury to a private individual from the use of the product purchased, and it’s not a product liability or warranty type claim.” [DE 34 (State’s Response Brief) at ¶ 74]. However, the statutory definition of nuisance applies equally to public and private nuisances. Additionally, as the Eighth Circuit warned in *Tioga*:

[T]o interpret the nuisance statute in the manner espoused by *Tioga* would in effect totally rewrite North Dakota tort law. Under *Tioga*’s theory, any injury suffered in North Dakota would give rise to a cause of action under section 43–02–01 regardless of the defendant’s degree of culpability or of the availability of other traditional tort law theories of recovery. Nuisance thus would become a monster that would devour in one gulp the entire law of tort, a development we cannot imagine the North Dakota legislature intended when it enacted the nuisance statute.

Tioga, 984 F.2d at 921.

[¶72] This Court agrees with the reasoning of the Eighth Circuit in *Tioga*. The State is clearly seeking to extend the application of the nuisance statute to a situation where one party has sold to another a product that later is alleged to constitute a nuisance. *Id.* at 920 (emphasis added). The reality is that Purdue has no control over its product after it

is sold to distributors, then to pharmacies, and then prescribed to consumers, i.e. after it enters the market. Purdue cannot control how doctors prescribe its products and it certainly cannot control how individual patients use and respond to its products, regardless of any warning or instruction Purdue may give.

[¶73] No North Dakota court has extended the public nuisance statutes to cases involving the sale of goods. The Eighth Circuit Court of Appeals, while applying North Dakota law, expressly declined to do so, and this Court declines to do so in this case. The State does not have a cause of action for nuisance against Purdue since its nuisance claim arises from the “overprescribing and sale” of opioids manufactured by Purdue. Therefore, the State’s claim for public nuisance must be, and is, dismissed.

CONCLUSION

[¶74] Based upon the foregoing, the Court concludes that the State has not adequately pleaded its causes of action against Purdue. Therefore, for all the reasons stated above, Purdue’s Motion to Dismiss is, in all respects, hereby **GRANTED**.

[¶75] Counsel for Purdue is tasked with the responsibility of drafting a judgment consistent with this memorandum.

IT IS SO ORDERED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated this 10th day of May, 2019.

BY THE COURT:



James S. Hill, District Judge
South Central Judicial District

cc: