IN THE COURT OF COMMON PLEAS
ROSS COUNTY, OHIO

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STATE OF OHIO *ex rel.* MIKE DeWINE, Ohio Attorney General Plaintiff, v. PURDUE PHARMA L.P., *et al.*, Defendants.	Case No. CV-17 CI 000261 JUDGE SCOTT W. NUSBAUM **ORAL ARGUMENT REQUESTED**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS COMPLAINT FOR FAILURE TO STATE A CLAIM AND TO STRIKE

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I. INTRODUCTION

Through this lawsuit, Plaintiff, the State of Ohio (the "State"), attempts to hold the bulk of a pharmaceutical industry—multiple distinct manufacturers of different prescription opioid medications—liable for Ohio's current opioid "healthcare crisis." Compl. ¶ 2. The State claims that because Defendants[1] allegedly misrepresented the safety and risks of opioids in certain marketing and promotional materials, many of which are over a decade old, Defendants are somehow responsible for the litany of opioid-related social and public-health issues facing Ohio citizens, including issues involving illicit opioids manufactured by companies other than Defendants and involving heroin and illegal street drugs manufactured and distributed by drug dealers and cartels.

This is not the first time that an Ohioan governmental entity has unsuccessfully attempted to blame an entire industry for serious social and public-health issues facing Ohio citizens. Similar efforts to hold lead-paint manufacturers liable for environmental and public-health harms and to hold sub-prime mortgage lenders liable for increased foreclosures and decreased property values have failed for many of the same reasons the State's claims fail here. *See City of Toledo v. Sherwin-Williams Co.* ("*Sherwin-Williams*"), Lucas C.P. No. CI 200606040, 2007 WL 4965044 (Dec. 12, 2007); *Cleveland v. JP Morgan Chase Bank, N.A.* ("*JP Morgan*"), 8th Dist. Cuyahoga No. 98656, 2013-Ohio-1035. Among other defects, in those cases, the plaintiffs failed to plead

[1] The Defendants are Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. ("Purdue"), Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc. ("Teva"), Cephalon Inc. ("Cephalon"), Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. ("Janssen"), Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. ("Endo"), Allergan Finance LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan/Actavis"), Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. ("Watson/Actavis"). Named defendant Allergan plc (which is not an opioid manufacturer) does not join in this motion because it is not subject to personal jurisdiction in this Court, but has filed a separate motion to dismiss. Unless otherwise noted, in this Memorandum emphasis in quotations is added and internal citations and quotation marks are omitted.

facts showing a causal nexus between any defendant's conduct and the attenuated alleged harm. There, as here, the plaintiffs also improperly attempted to use public-nuisance claims to regulate conduct that was expressly authorized by state and federal statutes.

Striking the proper balance between the availability of pain management tools and the risks of addiction is no simple task, and it is one to which the Food and Drug Administration ("FDA") has given and continues to give much thought. "Defendants' own FDA-approved drug labels caution that opioids 'expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death.'" Compl. ¶ 92. But, as the State acknowledges, more than one million Ohio citizens "suffer from chronic pain, which takes an enormous toll on their health, lives and families."[2] *Id.* at ¶ 14. Defendants or their affiliates are all manufacturers of opioid analgesics—FDA-approved prescription drugs for pain management that serve a critical public-health role.

Despite the FDA's approval of many opioid medications for the treatment of chronic pain, the State alleges in this lawsuit that Defendants engaged in a decades-long fraud to "persuade doctors and patients that opioids can and should be used for chronic pain." *Id.* at ¶ 4. Based on this theory, the State seeks reimbursement for alleged "excessive opioid prescriptions" that the State allegedly paid through the Bureau of Workers' Compensation and the Department of Medicaid and for other opioid-related public-health costs, including those for addiction treatment. *Id.* at ¶ 15-16. The State also requests that Defendants be ordered to remedy a litany of other alleged social harms the State attributes to Defendants, including a rising "heroin epidemic," increased incidents of robberies and workplace theft, declines in employee productivity, and increased emergency medical and law enforcement costs, as well as other social issues. *See, e.g.,*

[2] The Complaint defines "chronic pain" as "non-cancer pain lasting three months or longer." Compl. ¶ 3 fn. 1.

id. at ¶ 2, 9-13, 146, 163, 171. The Complaint is facially deficient and subject to dismissal on multiple grounds.

First, the State predicates all its claims on allegations of fraud. Under Ohio Civil Rule 9(B), the State must plead the basis for the alleged fraud with particularity. The State has not done so for any of its claims. Nowhere does the Complaint plead the requisite "who, what, where, when, or how" of any wrongfully prescribed or reimbursed opioids. And the Complaint predominantly relies upon improper group pleading by asserting allegations about the conduct of all "Defendants"—competing companies manufacturing a wide range of different opioid products—as if they were a single actor.

Second, the State contradicts its own central allegation that Defendants deceptively promoted opioids as appropriate for long-term use in treating chronic non-cancer pain. The State concedes that the FDA permitted the use of Defendants' extended-release opioids for the treatment of chronic pain, *id.* at ¶ 151; indeed, the State concedes that opioids may be appropriate for such use in at least some "circumstances," *id.* at ¶ 5. Likewise, the State's admission that Defendants' drug labels disclose the serious health and addiction-related risks of opioids—risks that Ohio physicians are obligated by law to consider when making each prescribing decision—contradicts any claim that Defendants concealed those risks. *Id.* at ¶ 92.

Similarly, the State's claims are preempted by federal law because they are all founded on the theory that Defendants' promotion of opioids as safe and effective for the treatment of chronic non-cancer pain was misleading. This theory is inconsistent with the FDA's longstanding approval of extended-release opioids for such use; this approval indicates that opioid medications are a safe and accepted treatment for chronic non-cancer pain. *Id.* at ¶ 151. The State's theory is also inconsistent with the extensive and widely-disseminated FDA-approved risk infor-

mation that accompanies Defendants' medications. *Id.* at ¶ 92. At its core, the Complaint seeks to substitute the Ohio Attorney General's judgment about how to weigh the risks and benefits of chronic opioid therapy for the FDA's judgment. Under principles of federal preemption, the Court can and should reject the State's effort to hold Defendants liable for promoting opioids for uses approved by the FDA.

Third, the State fails to adequately plead causation, an essential element of all its claims. The State's claims are premised on the theory that Defendants deceived the State into reimbursing opioid prescriptions, but the Complaint alleges no facts showing how the State was deceived or showing that any State representative was exposed to, let alone relied on, Defendants' supposed misrepresentations. Similarly, although the State claims that Defendants' supposed misrepresentations misled Ohio physicians, it fails to identify a physician who received Defendants' supposed misrepresentations or relied on them in prescribing opioids. It also ignores the many intervening events that break any causal connection between any alleged misrepresentation and the State's alleged harm, including each physician's exercise of his or her professional judgment as applied to each patient and the intervening (sometimes criminal) acts that contribute to the cited social ills.

Fourth, each count suffers from claim-specific deficiencies, as discussed below. These glaring deficiencies, alone or together, require dismissal of the Complaint under Ohio Civil Rule 12(B)(6).[3] In addition, the State's claim for civil penalties under the OCSPA should be stricken under Ohio Civil Rule 12(F).

[3] Defendants separately move to stay the Complaint under the primary jurisdiction doctrine. *See* Defs.' Joint Mot. to Stay This Action Under the Primary Jurisdiction Doctrine and the Court's Inherent Authority to Stay Proceedings ("Prim. Jur. Mot."). Each Defendant has also submitted supplemental memoranda addressing issues specific to them, including additional grounds for dismissal of all claims as to them under Rule 12.

II. THE COURT SHOULD DISMISS THE ACTION UNDER RULE 12(B)(6) FOR FAILURE TO STATE A CLAIM.

The Court should dismiss the Complaint under Ohio Civil Rule 12(B)(6) for failure to plead factual allegations that, if true, state a claim upon which relief can be granted.

A. The Complaint Does Not Plead the Alleged Fraud with Particularity.

Because all of the State's claims are based upon allegations that Defendants fraudulently misrepresented the risks and benefits of opioids, *see, e.g.*, Compl. ¶ 164(c), 172(c), 183-191, 199-200, 205-214, 221, 226, 230, they all must satisfy the particularity requirements of Rule 9(B). *See* Civ.R.9(B) (imposing particularly requirement on "all averments of fraud"); *Dottore v. Vorys, Sater, Seymour & Pease, L.L.P.*, 8th Dist. Cuyahoga No. 98861, 2014-Ohio-25, ¶ 108-110 (applying Rule 9(B) to statutory mail-fraud claim); *Bird v. Delacruz,* 411 F. Supp. 2d 891, 895 (S.D.Ohio 2005) (dismissing statutory and common-law fraud claims, including OCPA claim, for lack of particularity); *NorthPoint Properties, Inc. v. Petticord*, 179 Ohio App.3d 342, 2008-Ohio-5996, 901 N.E.2d 869, ¶ 24-25 (same); *Byrd v. Faber*, 57 Ohio St.3d 56, 61, 565 N.E.2d 584 (1991); *cf. In re Ford Fusion & C-Max Fuel Economy Litigation*, S.D.N.Y. No. 13-MD-2450 KMK, 2015 WL 7018369, *18 (Nov. 12, 2015) (dismissing OCSPA claim for failure to plead fraud with particularity).

To satisfy Rule 9(B), a complaint must allege with particularity the "circumstances constituting fraud," including "the time, place, and content of the false representation; the fact misrepresented; the identification of the individual giving the false representation; and the nature of what was obtained or given as a consequence of the fraud." *Pointe at Gateway Condominium Owner's Assn. v. Schmelzer*, 8th Dist. Cuyahoga Nos. 98761, 99130, 2013-Ohio-3615, ¶ 58 (dismissing fraudulent concealment claim where the complaint "contained conclusory statements" but "did not allege any specific instances of concealment or false representations"); *see*

also Bear v. Bear, 9th Dist. Summit No. 26810, 2014-Ohio-2919, ¶ 23. In other words, a complaint must plead facts setting forth "the who, what, where, or how of their fraud claim." *Ford v. Brooks* ("*Brooks*"), 10th Dist. Franklin No. 11AP-664, 2012-Ohio-943, ¶ 28. This includes specifics about "to whom [alleged misrepresentations and/or omissions] were made." *Id.* at ¶ 30.

Here, however, the State alleges almost nothing about Defendants' alleged fraud, let alone with the requisite particularity. Only a small number of the purported misrepresentations are alleged to have reached Ohio at all.[4] Moreover, the State does not connect any of its broad and conclusory allegations about Defendants' opioid marketing to any Ohio patient, prescription, physician, claim, or reimbursement decision. The State fails to plead the relevant particulars of even one transaction that led an Ohio physician to prescribe, and the State to reimburse, a medically inappropriate opioid prescription that injured a patient:

- The Complaint fails to identify ***who*** made or ***who*** received any alleged false statements in Ohio. It does not allege the facts of any interaction between a Defendant and either the State itself or any Ohio physician who purportedly prescribed any of the opioids at issue, including which of the Defendants allegedly had contact with that physician.

- The Complaint fails to identify ***what*** supposedly false statements each Defendant allegedly made to the State or to Ohio physicians who wrote opioid prescriptions for which the State paid, or ***why*** any such statement was allegedly false.

- The Complaint fails to identify ***what*** opioids the State reimbursed that were allegedly improper because they were medically inappropriate.

- The Complaint fails to identify ***where*** in Ohio any allegedly false statement was made.

[4] *See* Compl. ¶ 53, 63, 89, 94, 102, 110, 119, 226 fn. 60, 62-64 (publications containing alleged misrepresentations are "available online"), ¶ 36 (Defendants spread misstatements by "marketing their branded opioids directly to doctors and patients in Ohio"), ¶ 84 ("The 2009 Guidelines * * * were disseminated in Ohio * * * [and] are still available online[.]"), ¶ 68 (APF's "multimedia campaign" "reach[ed] Ohioans"), ¶ 226 (Defendants "made material misstatements or omissions to Ohio physicians, consumers, the State and the general public"), ¶ 231 (Defendants ensured that messaging was consistent "nationwide and throughout the State of Ohio").

- The Complaint fails to identify ***when*** any specific Ohio physician, consumer, or government employee received any false statement or ***when*** the State reimbursed prescriptions on the basis of any Defendant's alleged fraud.

- The Complaint fails to allege ***how*** any alleged fraudulent act by any Defendant affected any of the prescriptions for which the State paid or which the State otherwise contends are at issue in this case. In fact, the State does not allege the specifics about any prescriptions it paid for, such as ***why*** the unidentified physicians prescribed the opioids in question, ***what*** conditions the opioids were prescribed to treat, or whether the prescriptions were medically necessary.

- The Complaint fails to identify ***how*** any patient was injured; it does not identify any prescription that was ineffective or harmful to the patient who received it.[5]

These deficiencies are fatal: absent particularized allegations, there is nothing to connect any State-reimbursed prescription (or any other Ohio prescription) to *anything* false or misleading that any Defendant allegedly said or did. *See, e.g.*, *Brooks* at ¶ 29-30; *West v. West*, 10th Dist. Franklin No. 96APE11-1587, 1997 WL 559477, *4 (Sept. 2, 1997); *City of Chicago v. Purdue Pharma L.P.*, N.D.Ill. No. 14 C 4361, 2015 WL 2208423, *14 (May 8, 2015) (dismissing fraud-based claims similar to those here for failure to allege identities of physicians who prescribed opioids paid for by plaintiff in reliance on manufacturers' alleged misrepresentations).

B. The Complaint Engages in Improper Group Pleading.

To satisfy Ohio's pleading standards, a complaint against multiple defendants must allege

[5] Courts routinely dismiss complaints similar to the State's for failing to allege that a particular prescription was ineffective or harmful. *See, e.g., Williams v. Purdue Pharma Co.*, 297 F.Supp.2d 171, 176 (D.D.C.2003) (absent allegations that medication "failed to provide [patients] effective pain relief or that they suffered any adverse consequences from their use of [the medication]," the plaintiffs had "received the benefit [of their] bargain and ha[d] no basis to recover purchase costs"); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, D.N.J. Nos. 06-3044, 07-2224, 07-2608, 07-2860, 2008 WL 5413105, *8 (Dec. 23, 2008) (dismissing fraud-based claims because plaintiffs failed to "allege that any beneficiaries, insureds, or employees * * * received [an] inadequate [or] inferior [drug]" or "suffered personal injuries as a result of Defendants' alleged misrepresentations"). Even for opioids prescribed off-label, *i.e.*, for conditions other than those for which the medications have been expressly approved, the State's reimbursement costs are not recoverable unless the prescription was ineffective or injured the patient. *See, e.g., In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, D.N.J. No. 2:06-cv-5774, 2010 WL 2346624, *7-*8 (June 9, 2010); *Cent. Regional Emps. Benefit Fund v. Cephalon, Inc.*, D.N.J. No. 09-3418, 2010 WL 1257790, *3 (Mar. 29, 2010).

the requisite facts and particulars about the conduct of ***each*** defendant. Where, as here, a complaint is replete with group pleading—sweeping allegations made generally as to "Defendants"—it fails to state a claim and must be dismissed. In *Dottore v. Vorys, Sater, Seymour & Pease, L.L.P.*, for example, the Court of Appeals affirmed dismissal of mail-fraud claims where plaintiffs grouped all law-firm defendants together and "failed to identify which [plaintiff] was the target of the fraud and by which lawyer." 2014-Ohio-25, at ¶ 108-10. The Court of Appeals held that because plaintiffs' claims "lack[ed] * * * particularity, the allegations were not sufficient" and dismissal was required. *Id.* So, too, here.

Defendants are seventeen distinct companies, each of which is affiliated with one of five distinct corporate families. *See* Compl. ¶ 21-32. They manufacture and sell many different, often competing, opioid products—with different approved indications, product labels, and promotional materials and strategies. *See id.* at ¶ 21-32. Defendants' drugs are not interchangeable. Yet the vast majority of the Complaint's allegations lump together all this group of competitors as "Defendants," without differentiating among them, their products, or their promotional practices. *See, e.g., id.* at ¶ 41-46, 80, 85, 114, 124-133, 145, 150, 152, 162-165, 230-231, 235-239, 242-248. On this basis alone, the Complaint fails to state a claim.

The State cannot circumvent the rule against group pleading through its conclusory allegations that Defendants engaged in a shared "marketing scheme" or "opioid marketing enterprise." *See id.* at ¶ 4-7, 35, 43-44, 46, 87-123, 219-248. As explained above, the State does not plead the necessary details to state a claim against ***any*** Defendant individually. Nor does the State plead facts connecting all Defendants to any particular reimbursement or prescribing decision.

The Complaint merely offers the legal conclusion that the Defendants "formed an associ-

ation-in-fact enterprise" between Defendants, Front Groups, and KOLs to "ensure the prescription of opioids for chronic pain." *Id.* at ¶ 219-220. The State pleads no facts showing that any Defendants jointly agreed to do anything—let alone the specific details of any purported arrangement, such as when it occurred, between whom, how it was implemented, or why it supposedly was improper. At most, the State relies upon allegations of "parallel conduct" in the pharmaceutical industry "that could just as well be independent action," rather than a conspiratorial agreement or enterprise. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556-557 (2007). Because the Complaint fails to plead any facts that could demonstrate any type of coordinated "scheme" to defraud among the Defendants (or anyone else), much less the details required by Ohio Civil Rule 9(B), all claims fail. *See Morrow v. Reminger & Reminger Co., L.P.A.*, 183 Ohio App.3d 40, 2009-Ohio-2665, 915 N.E.2d 696, ¶ 7 (10th Dist.) (unsupported legal conclusions need not be accepted as true).

C. The State's Claims Are Foreclosed by Its Acknowledgement That the FDA Approved Opioids for the Treatment of Chronic Pain and That the FDA-Approved Labels Disclosed the Risks of Addiction.

The State's claims rest upon the sweeping theory that Defendants intentionally misrepresented the safety and efficacy of opioid medicines for chronic pain, which allegedly caused physicians to write medically inappropriate prescriptions and the State to reimburse those prescriptions and incur costs. *See, e.g.*, Compl. ¶ 4-11, 16. But all the State's claims fail because the Complaint acknowledges facts that contradict the cornerstone of the State's fraud theory.

First, the State acknowledges that the FDA has approved the long-term use of Defendants' extended-release opioids for treating chronic non-cancer pain. *See, e.g.*, *id.* at ¶ 151. In fact, the Complaint makes clear that opioids may be appropriate for such use in some "circumstances." *Id.* at ¶ 5. Yet, nowhere does the State explain how it can be fraudulent to market drugs for their lawfully approved indications. The reason for this omission is simple: as a matter of law, it

cannot. Statements that "generally comport with [a drug's] approved label" are "not misleading as a matter of law." *Prohias v. Pfizer, Inc.*, 490 F.Supp.2d 1228, 1235 (S.D.Fla.2007); *see also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F.Supp.2d 296, 299, 301 (S.D.N.Y.1998) (dismissing false advertising claims because challenged statements were "similar enough to the [FDA-]approved statements * * * that they are neither false nor misleading" "as a matter of law").

Moreover, to the extent that the State alleges that any Defendants promoted opioids for unapproved or "off-label" conditions, Compl. ¶ 151, such allegations still fail as a matter of law to show fraud. "[C]ourts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use." *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir.2012); *see also Buckman Co. v. Plaintiffs' Legal Commt.*, 531 U.S. 341, 351 (2001), fn. 5 (off-label prescribing "'often is essential to giving patients optimal medical care'"); *Use of Approved Drugs for Unlabeled Indications*, FDA Drug Bulletin, Vol. 12, No. 1, at 5 (Apr. 1982) ("[A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling."). As a result, off-label promotion is not inherently false or misleading. *In re Actimmune Marketing Litigation*, 614 F.Supp 2d.1037, 1051 (N.D.Cal 2009), fn. 6 ("[O]ff-label marketing of an approved drug is itself not inherently fraudulent.").

Second, the State acknowledges that Defendants' FDA-approved drug labels—the primary means by which both the FDA and manufacturers communicate drug risks to prescribing physicians[6]—disclose the very risks of opioid treatment that Defendants supposedly concealed, including "addiction, abuse and misuse, * * * overdose, and death." Compl. ¶ 92. Patients can ob-

[6] FDA, Guidance for Industry: Assessment of Abuse Potential of Drugs 19 (Jan. 2010) ("Information on the abuse potential of a drug is generally conveyed to healthcare professionals and patients through appropriate labeling. * * * Labeling is the cornerstone of risk minimization efforts for most of the drugs approved by FDA."); 21 C.F.R. 201.56 (prescription drug labeling must set forth "a summary of the essential scientific information needed for the safe and effective use of the drug," including indications, contraindications, and warnings).

tain opioid medications only from authorized healthcare professionals, 21 C.F.R. 1306.03(a)(1), 1306.11, and Ohio law imposes on such professionals a "duty to know * * * the qualities and characteristics of the drugs or products to be prescribed for [a] patient's use," *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St.3d 147, 149, 569 N.E.2d 875 (1991). Those professionals also have a duty to consider a controlled "drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug." Ohio Adm.Code 4731-11-02(B); *see also* R.C. 4731.052(E) (providing similar duties specific to prescriptions for chronic pain).

As a matter of Ohio law, therefore, Ohio prescribers had a duty to be aware of the labeled risks of opioids before they wrote *any* opioid prescriptions. Given this legal duty and the extensive FDA-approved information about opioids provided and otherwise available to prescribers, any alleged misstatements by Defendants cannot have been misleading. *See* FTC Policy Statement at 2 & fn. 7 ("The entire advertisement, transaction or course of dealing will be considered"; claims must be examined in the context of the "entire document" and the "nature of the transaction"); R.C. 1345.02(C) (requiring Ohio courts to give "great weight" to FTC "orders, trade regulation rules and guides"); *cf. Veracity Group, Inc. v. Cooper-Atkins Corp.*, S.D.Ohio No. 1:11-cv-526, 2012 WL 203415, *4 (Jan. 24, 2012) (analyzing claim under R.C. 1345 and holding that "[w]hether a statement is opinion or fact depends on the totality of the circumstances," including "the general context of the statement" and "the broader context in which the statement appears").[7] Put simply, Ohio law and Defendants' disclosure of addiction concerns and

[7] *See also In re AIG Advisor Grp. Secs. Litig.*, 309 F.App'x 495, 498 (2d Cir.2009) (affirming dismissal where defendant's website detailed the allegedly undisclosed facts); *Standard Life & Acc. Ins. Co. v. Dewberry & Davis, LLC*, 210 F.App'x 330, 334-35 (4th Cir.2006) (affirming dismissal of claim brought by reinsurer of a corporate health plan where allegedly withheld med-

other risks in their FDA-approved product labeling (which the Complaint acknowledges) foreclose any claim that Defendants concealed or minimized these risks. The Complaint's internal contradictions are fatal.

D. The State's Claims, Which Challenge Promotion Consistent with FDA-Approved Indications, Are Preempted by Federal Law

Because the Complaint challenges the propriety of marketing opioids for the treatment of long-term chronic pain, an FDA-approved use, the State's claims are preempted under the Supremacy Clause of the U.S. Constitution. The Supreme Court of Ohio and other courts have long recognized that claims may be dismissed on preemption grounds, including at the pleading stage. *E.g. PNH, Inc. v. Alfa Laval Flow, Inc.*, 130 Ohio St.3d 278, 2011-Ohio-4398, 958 N.E.2d 120; *City of Cleveland v. Public Util. Commn.*, 54 Ohio St.2d 209, 414 N.E.2d 718 (1980) (per curiam); *Robbins v. New Cingular Wireless PCS, LLC*, 854 F.3d 315 (6th Cir.2017). Here, the Complaint makes clear that the State's claims conflict with and are preempted by FDA determinations.

As noted above, the State recognizes that the FDA has *approved* almost all of the Defendants' opioid drugs for long-term treatment of chronic pain. Compl. ¶ 151. Of course, FDA approval does not mean that a drug has no risk. All prescription drugs carry risks. The State concedes, as it must, that the FDA-approved labeling for Defendants' opioids "caution[s] that opioids 'expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death,' that the drugs contain 'a substance with a high potential for abuse,' and that addiction 'can occur in patients appropriately prescribed' opioids." *Id.* at ¶ 92 (quoting from this labeling).

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ical information of a dependent was disclosed in the contract); *City of Monroe Emps. Retirement Sys. v. Bridgestone Corp.*, 399 F.3d 651, 676 (6th Cir.2005) ("It makes logical sense that a claim based on the alleged withholding from the public of information that contradicts information publicly stated is defeated by a demonstration that the allegedly withheld information was in fact disclosed to the public").

Nor does FDA approval mean the drug will work well for every patient, even for approved indications. But it does mean that the FDA has found that there is "substantial evidence that the drug will have the effect it purports or is represented to have" and that the drug is sufficiently safe for use, in accordance with its approved labeling for treatment of the conditions there specified. 21 U.S.C. 355(d) (FDA drug approval regulations).

Because FDA approval signifies that the agency has found a drug to be sufficiently safe and effective for its approved indications, any claim seeking to hold Defendants liable for promoting opioids as safe and effective for their FDA-approved indications necessarily conflicts with FDA determinations and is preempted. *See Prohias*, 490 F.Supp.2d at 1234 (claims were preempted because they "conflict[ed] with the FDA's jurisdiction over drug labeling, and specifically its approval of [certain indications]"); *Rheinfrank v. Abbott Laboratories, Inc.*, 680 Fed.App'x 369, 385-386 (6th Cir.2017). Stated simply, FDA approval legally entitles Defendants to promote their extended-release opioids for long-term treatment of chronic non-cancer pain.

Similarly, the State cannot use state-law claims to force a prescription drug manufacturer to make statements about safety or efficacy that are inconsistent with FDA requirements. Courts routinely dismiss complaints that attempt to do so. *See, e.g.*, *Rheinfrank* at 385-86; *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir.2017); *In re Celexa and Lexapro Marketing & Sales Practices Litigation*, 779 F.3d 34, 42-43 (1st Cir.2015); *Utts v. Bristol-Myers Squibb Co.*, S.D.N.Y. No. 16-cv-5668, __ F.Supp.3d __, 2017 WL 1906875, *20 (May 8, 2017); *In re Incretin-Based Therapies Prods. Liab. Litigation*, 142 F.Supp.3d 1108, 1123-1124 (S.D. Cal. 2015), *appeal filed* (9th Cir.). For all these reasons, the State's claims are preempted.

E. The Complaint Fails to Adequately Plead Causation.

The Complaint also must be dismissed because it does not adequately allege causation, an essential element of all the State's claims. *See* R.C. 2307.73(A)(2)-(3) (Ohio Products Liability

Act); *Muruschak v. Schafer*, 11th Dist. Lake No. 2015-L-071, 2015-Ohio-5340, ¶ 18 (fraud); *Crown Property Dev., Inc. v. Omega Oil Co.*, 113 Ohio App.3d 647, 658, 681 N.E.2d 1343 (12th Dist.1996) (public nuisance); *Jacobson v. Kaforey*, 149 Ohio St.3d 398, 2016-Ohio-8434, 75 N.E. 3d 203, ¶ 10 (R.C. 2307.60); *Celebrezze v. Hughes*, 18 Ohio St.3d 71, 75, 479 N.E.2d 886 (1985) (Consumer Sales Practices Act).

The State alleges that Defendants' purported misrepresentations in marketing materials altered: (1) physicians' prescribing decisions; and (2) the State's reimbursement decisions, causing it to expend funds it otherwise would not have expended. Compl. ¶ 153-158. Yet, the State fails to allege any connection between any Defendant's marketing and promotion and any relevant prescription or reimbursement decisions in Ohio. It also fails to plead proximate causation.

1. The State Fails to Allege That Defendants' Purported Misrepresentations Were the Actual Cause of Any Opioid Prescriptions.

The State alleges that Defendants "deceived doctors and patients about the risks and benefits of long-term opioid use," thereby inducing them to prescribe and use opioid medications to treat chronic pain when it was not medically appropriate. *See, e.g.,* Compl. ¶ 14, 108, 130. But the Complaint does not identify even a single Ohio physician who improperly prescribed an opioid for chronic pain—let alone one who did so as a result of any Defendant's conduct. Nor does the Complaint identify a single Ohio patient who requested or used an opioid prescription for chronic pain because of Defendants' supposed marketing and promotion.

Indeed, the Complaint does not even allege that *any* specific Ohio physician or *any* specific Ohio patient *ever* heard, read, or otherwise received any purported misrepresentations made by a Defendant, much less that any physician or patient did so at any time prior to deciding to prescribe or use any Defendant's medications. The State also fails to allege facts showing that

any specific prescriber or patient relied on any Defendant's supposed misrepresentations in deciding to prescribe or use opioid medications.

This failure to connect any Defendant's purported conduct to any allegedly improper prescription defeats all the State's claims. *See, e.g., Smith v. Hartz Mountain Corp.*, N.D.Ohio No. 3:12-CV-00662, 2012 WL 5451726, *4 (Nov. 7, 2012) (dismissing claims where plaintiffs failed to allege "specific advertising or marketing materials" on which they relied); *Gator Dev. Corp. v. VHH, Ltd.*, 1st Dist. Hamilton No. C-080193, 2009-Ohio-1802, ¶ 19, 22 (affirming dismissal where complaint "did not allege any detrimental reliance on a positive misrepresentation").

Ohio courts have dismissed other attempts to use public-nuisance and related litigation to regulate entire industries on similar grounds. In *Sherwin-Williams Co.*, 2007 WL 4965044, for example, the court dismissed the City of Toledo's claim that lead-paint manufacturers had negligently created "an environmental hazard and unreasonably interfere[d] with the health, safety, peace, comfort, and convenience of the city's residents." Like the State here, the City relied upon improper group pleading that indiscriminately attacked the entire industry. *Id.* The court found the complaint facially deficient because "plaintiff must establish a causal connection between the defendant's actions and the plaintiff's injuries * * * . Failing to allege that certain defendants have caused certain injuries does not adequately allege proximate cause." *Id.*; *see also JP Morgan*, 2013-Ohio-1035.

Further, courts routinely dismiss complaints that fail to allege reliance on the purported misrepresentations. For example, in *Smith v. Hartz Mountain*, the plaintiffs alleged that a flea-powder manufacturer failed to warn about its product's risks. 2012 WL 5451726, at *2. The court dismissed the plaintiffs' claims under the Ohio Consumer Sales Practices Act and the Ohio Products Liability Act, finding that besides "conclusory" allegations, "[p]laintiffs d[id] not allege

they relied on [the defendant's] advertising in purchasing the product, or even that they were aware of advertising for the [powder] before they purchased it." *Id.* at *2-*4.

A similar pleading failure recently led another court to dismiss fraud claims in an analogous lawsuit brought by the City of Chicago against many of the same opioid manufacturers that the State sues here. *See City of Chicago v. Purdue*, 2015 WL 2208423, at *14. In that case, the court found plaintiff's fraud claims facially deficient because "the City d[id] not allege * * * the identities of doctors who, as a result of one or more of defendants' alleged misrepresentations, prescribed opioids for chronic pain to a City-insured patient or worker's compensation recipient whose claim for that prescription the City paid, or any other details about such claims." *Id.*

Consistent with this ruling, other courts across the country have regularly dismissed claims premised on allegedly false or misleading pharmaceutical marketing that "lack[] specific allegations regarding whether [a particular] physician received or relied upon any information from [the] defendant" in making a prescribing decision. *Baron v. Pfizer, Inc.*, Albany Cty. (NY) Sup. Ct. No. 6429-04, 2006 WL 1623052, *4-*5 (May 2, 2006), *aff'd* 42 A.D.3d 627, 840 N.Y.S.2d 445 (3d Dep't 2007); *see also In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litigation*, N.D.Cal. No. 11-cv-00310, 2012 WL 3154957, *8-*9 (Aug. 2, 2012); *United States ex rel. Polansky v. Pfizer, Inc.*, E.D.N.Y. No. 04-cv-0704, 2009 WL 1456582, *9-*10 (May 22, 2009). The same pleading failure requires dismissal here.

2. The State Fails to Allege That Any Defendant's Purported Misrepresentations Were the Actual Cause of Any Reimbursement Decisions.

The State also alleges that Defendants' alleged misconduct caused it to reimburse prescriptions it otherwise would not have reimbursed. Compl. ¶ 153. But the State fails to adequately plead a causal link between such alleged misconduct and the State's reimbursement decisions.

The State does not allege that *any* State employee or agent ever read, heard, or otherwise received even a single purported misrepresentation made by any Defendant at any time. Nor does the State allege any specific instance in which the State reasonably relied upon any purported misrepresentation in deciding to reimburse an opioid prescription. And the State nowhere alleges whether, when, or how any Defendant's supposed misrepresentations influenced any State agent's reimbursement decision. In fact, the State fails to identify even a single specific opioid prescription that it reimbursed that it claims was medically unnecessary. The State's failure to plead any particulars connecting any Defendant's conduct to even one opioid prescription that the State improperly reimbursed requires dismissal of all claims.

Moreover, the Complaint affirmatively demonstrates that Defendants' supposed misrepresentations did *not* materially influence the State's reimbursement decisions, because the State concedes that it "continues to pay * * * claims" for Defendants' opioid medications. *Id.* at ¶ 200. As a matter of law, this concession precludes any finding that Defendants' alleged misrepresentations were material to or otherwise influenced the State's reimbursement decisions. Payors "who continue to pay or reimburse for [a drug], while claiming they were harmed by allegedly false advertising, are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it. They were injured by their own conduct." *Teamsters Local 237 Welfare Fund v. AstraZeneca Pharmaceuticals LP*, 136 A.3d 688, 696 (Del.2015); *see also Davis v. Montenery*, 173 Ohio App.3d 740, 2007-Ohio-6221, 880 N.E.2d 488, ¶ 73-75.

3. The State's Alleged Injuries Are Too Remote and Depend on Multiple Intervening Events.

Under Ohio law, the requirement of proximate causation restricts legal responsibility to "those causes which are so closely connected with the result and of such significance that the law is justified in imposing liability." *Hester v. Dwivedi*, 89 Ohio St.3d 575, 581, 733 N.E.2d 1161

(2000). Liability thus extends only to those acts "which immediately precede[] and produce[] the effect," not to acts that are a "remote, mediate, or predisposing cause." *Hunt v. Marksman Prod. Div. of S/R Industries, Inc.*, 101 Ohio App.3d 760, 763, 656 N.E.2d 726 (9th Dist.1995). The proximate-cause requirement aims to prevent the imposition of "infinite liability for all wrongful acts," which would "set society on edge and fill the courts with endless litigation." *Hester* at 581.

Here, any connection between Defendants' alleged misconduct and the State's alleged injuries, including the social harms associated with Ohio's multifaceted opioid crisis, depends on multiple independent, intervening events and contingencies. These include (1) the prescribing physician's exercise of independent medical judgment in diagnosing and treating individual patients who present with their own medical conditions, needs, and treatment preferences; (2) each patient's decision whether and how to use a prescribed medication; (3) each patient's response to the medication; and (4) the State's decision to reimburse an opioid prescription.

The prescribing doctor plays a particularly important role given the closely regulated prescription medications at issue. As a learned intermediary, the physician "stands between the manufacturer and the patient" and has a "duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." *Tracy*, 58 Ohio St.3d at 149, 569 N.E.2d 875. Those "qualities and characteristics" include risks of addiction, abuse, and overdose that are prominently disclosed in all opioid medications' FDA-approved labels, Compl. ¶ 92. As a result, the physician—who "exercise[s] his [own] informed judgment in the patient's best interest"—is best positioned "to balance the needs of patients against the risks and benefits of a particular drug" and "to supervise its use." *Tracy* at 149, 150.

The physician thus breaks any chain of causation between the pharmaceutical manufacturer, who does not "control [the physician's] judgment, duties and responsibilities," and the pa-

tient. *Id.* at 150-51; *see also Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St.3d 380, 385, 763 N.E.2d 160 (2002). Given the physician's critical role, courts routinely dismiss complaints in which the plaintiffs' allegations—like the State's allegations here—would impermissibly require courts to perform an unworkable "inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit." *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*, 585 F.Supp.2d 1339, 1344 (M.D.Fla.2008); *see also United Food & Commercial Workers Cent. Pa. & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F.App'x 255, 257 (9th Cir.2010); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litigation*, S.D.Ill. Nos. 3:09-md-02100, 3:09-cv-20071, 2010 WL 3119499, *7-*9 (Aug. 5, 2010).

Causation is even further attenuated here because the State seeks to hold Defendants liable not just for the reimbursement of allegedly improper (but unidentified) opioid prescriptions, but also for the costs of addressing a sprawling public-health "epidemic" that includes, *inter alia*, teenage drug abuse, foster-care services for children of opioid-addicted parents, costs for the treatment of infants whose mothers abused opioids while pregnant, increased availability of other drugs such as heroin and illicit fentanyl, and criminal acts associated with an illicit drug market, such as pharmacy robberies and employee workplace theft. Compl. ¶ 163(b)-(c), (k), 171(b)-(c), (i), (j) 228.

Ohio courts have repeatedly ruled similar allegations of sweeping societal harm too attenuated to establish proximate causation. For example, in *JP Morgan*, the City of Cleveland sued multiple nationwide financial institutions seeking to hold them liable for the City's subprime mortgage crisis. 2013-Ohio-1035 at ¶ 2-3. Relying upon a multi-link causal chain akin to the one alleged here, the City claimed that Defendants "caused a foreclosure crisis in Cleveland"

that "increased costs for fire and safety services as a result of a glut of vacant and foreclosed homes; [and] * * * led to greatly diminished housing prices, which resulted in huge losses in property taxes; and other costs caused by a foreclosure crisis in Cleveland." *Id.* at ¶ 3. The Court of Appeals, citing the "several intervening factors necessary for the harm suffered by the City to materialize," concluded that "the City's complaint allege[d] an injury too remote to assert a justiciable claim." *Id.* at ¶ 13. For example, "[f]irst, mortgage originators and brokers offered high-risk mortgage products to individuals with questionable credit histories. * * * Next, potential home buyers were required to apply for, receive, and then fail to repay these home loans." *Id.* at ¶ 14. The Court of Appeals thus found that the mortgage originators—like the intervening actors here—bore "more responsibility than [the defendants] purchasing these loans and constituted an intervening break in the causal chain." *Id.*; *see also City of Cincinnati v. Deutsche Bank Natl. Trust Co.* ("*Deutsche Bank*"), 863 F.3d 474, 480 (6th Cir.2017); *City of Cleveland v. Ameriquest Mortg. Secs., Inc.* ("*Ameriquest*"), 621 F.Supp.2d 513, 528 (N.D.Ohio 2009), *aff'd*, 615 F.3d 496 (6th Cir.2010).

Further, the State's unprecedented liability theory against the Defendants here depends on intervening third-party criminal acts, which necessarily preclude proximate causation. *See Robinson v. Vehicle Acceptance Corp.*, 8th Dist. Cuyahoga No. 105006, 2017-Ohio-6886, ¶ 19; *Levy v. Stokes*, 8th Dist. Cuyahoga Nos. 38070, 38071, 1978 WL 218304, *8 (Dec. 14, 1978). Because the State fails to and cannot allege the necessary proximate cause, all claims should be dismissed.

F. The Ohio Products Liability Act Abrogates Counts II, III, and V.

The Ohio Products Liability Act ("OPLA"), R.C. 2307.71 *et seq.*, "abrogate[s] all common law product liability claims or causes of action." R.C. 2307.71(B). And "it is the substance of the claim, not the manner in which it is pleaded, that determines" whether OPLA abrogates it.

Miles v. Raymond Corp., 612 F.Supp.2d 913, 921 (N.D.Ohio 2009). OPLA abrogates Counts II, III, and IV of the Complaint.

1. The OPLA Abrogates Count II.

Count II asserts a claim for common-law public nuisance. Ohio law is clear, however, that "public nuisance actions * * * were intended to be abrogated by the OPLA." *Sherwin-Williams*, 2007 WL 4965044. OPLA explicitly abrogates "any public nuisance claim or cause of action at common law in which it is alleged that the * * * promotion, advertising, [or] labeling * * * of a product unreasonably interferes with a right common to the general public." R.C. 2307.71(A)(13). That is precisely what Count II alleges. *See* Compl. ¶ 170-71.

The State cannot circumvent this controlling law by stating that it "does not seek compensatory damages for death, physical injury to person, emotional distress, or physical damage to property" under Count II. *Id.* at ¶ 169. The Ohio legislature expressly stated that the OPLA was intended to "abrogate ***all*** common law product liability causes of action including common law public nuisance causes of action, * * * [and] claims against a manufacturer * * * for a public nuisance allegedly caused by a manufacturer's * * * product." (Emphasis added.) *Sherwin-Williams* (quoting footnote to R.C. 2307.71).

Many courts have rejected similar attempts to plead around OPLA abrogation. In *Meta v. Target Corp.*, for example, the court held that a plaintiff "may not carve out a common law product liability claim for economic loss only where * * * the facts underpinning his common law claims constitute the same conduct that * * * giv[es] rise to [the] products liability claim." 74 F.Supp.3d 858, 864 (N.D.Ohio 2015) (internal quotation marks omitted); *see also Mitchell v. Proctor & Gamble*, S.D.Ohio No. 2:09-CV-426, 2010 WL 728222, *4 (Mar. 1, 2010) (similar).[8]

[8] Cases holding to the contrary pre-date the 2006 amendments to the OPLA and the clear language that it is intended to abrogate *all* common-law product-liability claims. *Compare LaPuma*

Here, the State's OPLA public-nuisance claim (Count I) and common-law public nuisance claim (Count II) stem from the same alleged misconduct; in fact, over two pages of allegations are repeated verbatim in both counts. *Compare* Compl. ¶ 162-165 (Count I) *with* Compl. ¶ 170-174 (Count II). Count II is thus a product-liability claim at heart, and it is abrogated by the OPLA regardless of the type of damages the State seeks.

2. The OPLA Abrogates Count III.

Count III asserts a cause of action under the Ohio Consumer Sales Practices Act ("OCSPA"), R.C. 1345.02 *et seq.* Although the claim is statutory, not common-law, OPLA still abrogates it because "the OCSPA claims are primarily rooted in product liability claims." *Mitchell* at *4; *Hendricks v. Pharmacia Corp.*, S.D.Ohio No. 2:12-CV-00613, 2014 WL 2515478, *5 (June 4, 2014), *report and recommendation adopted*, 2014 WL 4961550 (Oct. 2, 2014).

Here, the State alleges that Defendants failed to warn of the risks of opioids in their marketing and promotional materials. *See* Compl. ¶ 183-88. The OCSPA claim thus arises from both the "marketing of th[e] product" and a "lack of warning or instructio[n] associated with that product." R.C. 2307.71(A)(13)(a), (b). Count III is therefore abrogated. *See Hendricks* at *5 (OCSPA claim arising from "'misleading statements' about the risks" of pharmaceuticals is abrogated); *Bouchard v. Am. Home Prods. Corp.*, N.D.Ohio No. 3:98 CV 7541, 2002 WL 32597992, *11 (May 24, 2002) (OCSPA claim alleging "injury which arises from marketing, [or] a lack of warning" is abrogated); *see also Schnell v. Am. Home Prods. Corp.*, N.D.Ohio No. 3:00 CV 7228, 2000 WL 35777837, *2 (July 11, 2000) (OCSPA claim arising from "an express

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v. Collinwood Concrete, 75 Ohio St.3d 64, 661 N.E.2d 714 (1996) (holding common-law claim alleging only economic damages was not abrogated by OPLA) *and Abele v. Bayliner Marine Corp.*, 11 F.Supp.2d 955 (N.D.Ohio 1997) (same) *with Miles* at 921 (rejecting plaintiff's "unilateral decision to assert [product-liability] claims outside of the [OPLA]") *and Mitchell* at *4 (rejecting attempt to avoid OPLA by claiming only economic losses).

representation of a material fact concerning the character, quality, or safety of a product" is abrogated); *Blake v. Interneuron Pharmaceuticals*, S.D.Ohio No. C-1-98-672, 1998 WL 35307753, *1 (Dec. 9, 1998) (OCSPA claim alleging "false and/or misleading advertising, representations and statements" about pharmaceuticals is abrogated).

3. The OPLA Abrogates Count V.

Count V alleges common law fraud. OPLA abrogates "fraud claims arising from a duty to warn." *Hogue v. Pfizer, Inc.*, S.D.Ohio No. 2:10-cv-805, 893 F.Supp.2d 914, 918 (Sept. 27, 2012); *Stratford v. SmithKline Beecham Corp.*, S.D.Ohio No. 2:07-CV-639, 2008 WL 2491965, *8 (June 17, 2008) (same). The State's fraud cause of action alleges that Defendants failed to warn physicians about the risks of using opioids to treat non-cancer pain. Compl. ¶ 204-210. Count V is therefore abrogated. *See Krumpelbeck v. Breg, Inc.*, 491 Fed.App'x 713, 721 (6th Cir.2012) (fraud claims based on allegedly false "representations regarding the safety and quality of" Defendant's medical devices were abrogated by OPLA); *Hogue* at 917 (fraud claims alleging that "Defendants failed to warn doctors and patients of the degree of risk associated with" their pharmaceuticals were abrogated by OPLA); *Stratford* at *8 (allegation that Defendant "engaged in fraud by both failing to disclose material facts and actively misrepresenting information about Paxil's safety" was abrogated by OPLA).

G. Each Claim Is Deficient on Multiple Additional Grounds.

1. The Statutory Public-Nuisance and Common-Law Public-Nuisance Claims (Counts I and II) Must Be Dismissed.

Through its sweeping public-nuisance claims, the State seeks to hold Defendants responsible for a variety of social problems associated with Ohio's opioid epidemic. Compl. ¶ 163, 164,

171, 172. Both of the State's public-nuisance claims fail for multiple reasons.[9]

a. Counts I and II Fail Because a Public-Nuisance Theory Cannot Be Premised on the Promotion of Approved Indications.

The State's public-nuisance claims are barred to the extent the State seeks to hold Defendants liable for promoting opioids in accordance with the products' FDA-approved indications. "[A] showing that the challenged conduct is subject to regulation and was performed in conformance therewith insulates such conduct from suit as a public nuisance. * * * This is so regardless of whether, despite compliance with the regulations, such conduct could otherwise be described as negligent." *Ameriquest*, 621 F.Supp.2d at 528 (internal citation and footnote omitted); *see also, e.g.*, *Toledo Disposal Co. v. State*, 89 Ohio St. 230, 236, 106 N.E. 6, 8 (1914) ("[A]n act which has been authorized by law cannot be a public nuisance.").[10]

The opioid medications at issue here are some of the most closely regulated pharmaceutical products. As discussed in Section II.C above, federal law authorized Defendants to promote extended-release opioids for their approved indications, which include the treatment of chronic pain. In addition, Ohio law expressly permits physicians to prescribe Defendants' opioid products when necessary, including for chronic pain. *See* R.C. 4731.052 (regulating use of controlled substances, including opioids, for chronic pain); *see also* R.C. 3719.06(A)(1)(a) (permitting health professionals to prescribe controlled substances); Ohio Adm.Code 4123-6-21.7 (regulat-

[9] In addition to the reasons discussed below, the State's OPLA claim (Count I) fails because the Complaint does not identify the specific OPLA provision at issue. *Stratford*, 2008 WL 2491965, at *5; *see also Delahunt v. Cytodyne Techs.*, 241 F.Supp.2d 827, 843 (S.D.Ohio 2003).

[10] The State may cite *City of Cincinnati v. Beretta U.S.A. Corp.* in opposition to this ground for dismissal, but that case is distinguishable because it stemmed from distribution and marketing practices that were not regulated by federal law. *Beretta*, 95 Ohio St.3d 416, 2002-Ohio-2480, 768 N.E.2d 1136, at ¶ 14. Here, as discussed in Section II.C above, the practices alleged in the Complaint are regulated by both state and federal law. Further, *Beretta*'s rulings on product liability and public nuisance were superseded by statutory amendment to the OPLA. *Sherwin-Williams*, 2007 WL 4965044.

ing and allowing reimbursement for use of opioids in the subacute or chronic phases of pain treatment for a work-related injury or occupational disease). The State cannot premise public-nuisance claims on conduct that both federal and state law authorized and regulated, *i.e.,* marketing FDA-approved opioid medications, for their approved indications, to physicians legally authorized to prescribe them.

b. Count I Fails Because It Seeks to Recover Economic Damages Not Covered by the OPLA.

"Under the [OPLA], a claimant (including a governmental entity) cannot recover economic damages alone." *City of Cincinnati v. Beretta U.S.A. Corp.*, 95 Ohio St.3d 416, 2002-Ohio-2480, 768 N.E.2d 1136, ¶ 30; *see also* R.C. 2307.72(C). Instead, the OPLA provides for recovery of damages for "harm," defined as "death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question," where "harm is not 'economic loss.'" *Mitchell*, 2010 WL 728222, at *3 (quoting R.C. 2307.71(B), (G), (M)). Here, the State fails to identify any specific "harm" caused by the Defendants that is not simply an alleged economic loss to the State. Indeed, the State expressly seeks economic damages for the cost of providing opioid addiction treatment and treatment services. Compl. ¶ 161. This is quintessential "pecuniary loss" not covered by the OPLA. R.C. 2307.71(A)(2) ("economic loss" means "direct, incidental, or consequential pecuniary loss").

c. The Economic-Loss Rule Bars the State's Common-Law Public-Nuisance Claim (Count II).

The State's common-law public-nuisance claim is similarly barred by the economic-loss rule, which prevents recovery in tort of damages for purely economic losses. *Corporex Dev. & Constr. Mgt., Inc. v. Shook, Inc.*, 106 Ohio St.3d 412, 2005-Ohio-5409, 835 N.E.2d 701, ¶ 6. "[T]he well-established general rule is that a plaintiff who has suffered only economic loss due to another's negligence has not been injured in a manner which is legally cognizable or compen-

sable." *Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 42 Ohio St.3d 40, 44, 537 N.E.2d 624 (1989).

Here, the State expressly ***admits*** that it seeks only economic damages in connection with its common-law public-nuisance claim. Compl. ¶ 169. The claim is thus barred by the economic-loss rule. *See RWP, Inc. v. Fabrizi Trucking & Paving Co., Inc.*, 8th Dist. Cuyahoga No. 87382, 2006-Ohio-5014, ¶ 25-26 (noting that "'public nuisance' is a theory of recovery in tort" and that the economic-loss rule prevents recovery in tort for damages based on purely economic loss); *JP Morgan*, 2013-Ohio-1035, at ¶ 27 (public-nuisance claim barred by economic-loss rule); *Ashtabula River Corp. Group II v. Conrail, Inc.*, 549 F.Supp.2d 981, 987 (N.D.Ohio 2008) (same); *Ameriquest*, 621 F.Supp.2d at 522, 526 (same).

d. Counts I and II Fail Because the Complaint Fails to Plead Defendants Proximately Caused Any Alleged Public Nuisance.

Though all of the State's claims fail for lack of proximate causation, as discussed in Section II.E.3 above, its public-nuisance claims are even more deficient in this respect. The causal chain between Defendants' alleged misrepresentations and the prescriptions challenged by the State is already too tenuous to support a claim, but the additional links between those prescriptions and the social ills on which its public-nuisance claims are based compound this lack of proximate causation.

A public-nuisance claim requires proximate causation in the form of a "direct relationship" between a Defendant's conduct and the alleged nuisance. *Ameriquest* at 533, 536; *see also Deutsche Bank*, 863 F.3d at 477; R.C. 2307.73(A)(2); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F.Supp.2d 787, 792 (S.D.Ohio 2009).[11] Here, therefore, the State must plead a "direct rela-

[11] While some courts recognize market-share or enterprise liability as an alternative to proximate causation, Ohio courts have rejected that doctrine. *See Sutowski v. Eli Lilly & Co.*, 82 Ohio St.3d 347, 355, 696 N.E.2d 187 (1998) ("In Ohio, market-share liability is not an available theory of

tionship" between Defendants' alleged misrepresentations and the social ills the State alleges that Defendants caused, such as increased healthcare costs, loss of value of "productive and healthy employees," costs borne by the families of addicts, the creation of illegal drug markets, and increased demands on emergency responders and law-enforcement officials. Compl. ¶ 163, 171.

But the Complaint alleges no facts linking Defendants' alleged misconduct to these remote social ills and makes no effort to plead a theory of causation under which Defendants can be held liable for them. *See Ameriquest*, 621 F.Supp.2d at 536 (dismissing complaint where alleged harm "affected [residents] in the first instance, not the [c]ity"); *JP Morgan*, 2013-Ohio-1035, at ¶ 13 (holding that "the [c]ity's complaint alleges an injury too remote to assert a justiciable claim" given "several intervening factors necessary for the harm suffered by the [c]ity to materialize"). The social ills alleged in the Complaint are the result of independent, intervening third-party criminal acts from which Defendants are many times removed. *See Ameriquest* at 533-34, 536 (holding that proximate cause is absent if injury is contingent upon actions of absent parties).[12] Proximate causation is therefore absent.

e. Counts I and II Fail Because the Complaint Fails to Plead an Unreasonable Interference with a Public Right.

A public nuisance consists of (1) an "unreasonable interference" with (2) a "public right." *JP Morgan* at ¶ 9. The Complaint here alleges neither of these two elements.[13]

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recovery in a products liability action."); *Tirey v. Firestone Tire & Rubber Co.*, 33 Ohio Misc.2d 50, 51, 513 N.E.2d 825 (C.P.1986). The OPLA also expressly bars the doctrine's application. *See* R.C. 2307.73(A)(3) (requiring that the "manufacturer * * * produced * * * *the actual product that was the cause of harm* for which the claimant seeks to recover compensatory damages" (emphasis added)).

[12] *See also, e.g.*, *Price v. Purdue Pharma Co.*, 920 So.2d 479, 485-86 (Miss.2006); *Kaminer v. Eckerd Corp. of Fla., Inc.*, 966 So.2d 452, 454-55 (Fla.App.2007); *Foister v. Purdue Pharma, L.P.*, 295 F.Supp.2d 693, 704-705 (E.D.Ky.2003).

[13] In addition, to the extent the State tries to pursue an "absolute" public-nuisance theory, this requires "either intentional conduct or an abnormally dangerous condition that cannot be main-

First, the State fails to allege how Defendants' conduct interferes with any "public right." A public right is a "right[] common to all members of the public." *Brown v. Scioto Cty. Bd. of Commrs.*, 87 Ohio App.3d 704, 712, 622 N.E.2d 1153, 1158 (4th Dist.1993). "Examples of such rights, from Ohio and elsewhere, include: a right of public passage (e.g., obstruction of highways); a right to use public space (e.g., pollution of fisheries); a right to navigable waterways (e.g., obstruction of public streams); * * * [and] a right to public peace (e.g., excessive noise)." *Deutsche Bank*, 863 F.3d at 477. At most, the State alleges here that medically unnecessary opioid prescriptions may injure patients who receive them and cause related economic costs to the State. *See, e.g.*, Compl. ¶ 153-154, 156-157. Any alleged harms from such prescriptions are derived from alleged injuries to individuals who use (or misuse) Defendants' opioid products, not "rights common to all." *Brown* at 1158. Furthermore, there is no "public right to be free from the threat that some individuals may use an otherwise legal product * * * in a manner that may create a risk of harm." *City of Chicago v. Beretta U.S.A. Corp.*, 213 Ill.2d 351, 374-375, 821 N.E.2d 1099, 1116 (2004).

Second, the State does not allege facts supporting the conclusion that Defendants' conduct constituted an "unreasonable interference." *See JP Morgan*, 2013-Ohio-1035, at ¶ 9. To determine whether an interference is unreasonable, courts should consider, *inter alia*, whether the conduct is "contrary to a statute, ordinance, or regulation." *Id.* Here, the State challenges the marketing of opioid pain medications for chronic pain, but as discussed in Section II.C above,

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tained without injury to property, no matter what care is taken." *State ex rel. R.T.G., Inc. v. State*, 98 Ohio St.3d 1, 13, 780 N.E.2d 998 (2002). The State has pleaded neither prong. *First*, the State does not allege promotion of a product with the intent to create such opioid-related social ills. It alleges that "Defendants knew or should have known that their promotion of opioid use would create a public nuisance," Compl. ¶ 164, but "[k]nowledge does not equal intention" for the purpose of pleading an absolute public nuisance. *Deutsche Bank*, 863 F.3d at 478. *Second*, the State nowhere alleges that Defendants' conduct created an inherently dangerous condition that cannot be maintained without injury, no matter what care is taken.

the FDA has approved the use of extended release opioids for precisely that purpose. Likewise, as discussed in the same section, Ohio law authorizes the use of opioids for chronic pain, and even off-label prescribing often forms the appropriate standard of care. Put simply, both the FDA and the State of Ohio have recognized that opioids, when prescribed and used appropriately, do *not* unreasonably interfere with the public interest. Thus, the State's broad-brush nuisance claims must be dismissed.

2. The Ohio Consumer Sales Practices Act Claim (Count III) Must Be Dismissed On Numerous Grounds.

The State fails to allege an actionable claim under the Ohio Consumer Sales Practices Act ("OCSPA"). The OCSPA prohibits "unfair or deceptive act[s and] practice[s] in connection with * * * consumer transaction[s]." R.C. 1345.02. The claim must be dismissed because the State fails to plead facts showing the existence of (1) a consumer transaction, (2) an unfair act, or (3) deceptive conduct.[14] It is also barred by the OCSPA's safe-harbor provision and—to the extent the State seeks to recover damages before June 30, 2015—by the statute of limitations.

a. The State Does Not Allege a "Consumer Transaction."

The OCSPA defines a consumer transaction as any "sale * * * or other transfer of an item of goods * * * to an individual." R.C. 1345.01(A). Here, the State fails to plead facts about a single transaction involving any Ohio consumer. As discussed in Section II.E.1, it does not identify a single opioid prescription that was written because any Defendant's allegedly false or misleading statement, a single Ohio resident who paid for any improper prescription, or a single Ohio

[14] The Complaint references Section 1345.03 in the heading of its "Third Cause Of Action." But it fails to identify any act or practice that is allegedly "unconscionable" (and any claim based on alleged unconscionability would fail for the same reasons that the State's "unfair" and "deceptive" theories of OCSPA liability fail).

patient who was prescribed an opioid when it was not medically appropriate.[15] The Complaint thus fails to allege a consumer transaction, an essential element of the OCSPA.

In addition, the OCSPA does not apply to transactions by the State because the State is not a natural person. *Culbreath v. Golding Ents., L.L.C.*, 114 Ohio St.3d 357, 2007-Ohio-4278, 872 N.E.2d 284, ¶ 2, 27 (holding that "individual" under the OCSPA means "natural person"); *see also City of Findlay v. Hotels.com, L.P.*, 441 F.Supp.2d 855, 862 (N.D.Ohio 2006) ("Because the City is not a natural person, it may not assert an [OCSPA] claim."); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litigation*, 495 F.Supp.2d 1027, 1032 (N.D.Cal.2007) (dismissing OCSPA claim by third-party payor on the ground that the payor was not a natural person); *S. Ill. Laborers' & Emps. Health & Welfare Fund v. Pfizer Inc.*, S.D.N.Y. No. 08-cv-5175, 2009 WL 3151807, *9 (Sept. 30, 2009) (same).

b. The State Fails to Plead That Defendants Engaged in "Unfair" Conduct.

The State also fails to adequately allege that Defendants engaged in "unfair" practices in violation of the OCSPA. The "OCSPA does not contain a list of acts that are unfair[,]" but rather "directs the Court to look to the FTC Act for guidance." *United States v. Dish Network LLC*, C.D.Ill. No. 09-3073, ___ F.Supp.3d ___, 2017 WL 2427297, *127 (June 5, 2017) (applying Ohio law and citing R.C. 1345.02(C)).[16] Under the FTC Act, an act is not unfair unless it "is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers

[15] In addition, the OCSPA exempts from its purview any "consumer transaction" between individuals and any third-party health insurer. *See* R.C. 1345.01(A), 5725.01(C). The State thus cannot bring a claim based upon any such transaction.

[16] In interpreting the OCSPA, courts are to "give due consideration and great weight to federal trade commission orders, trade regulation rules and guides, and the federal courts' interpretations of subsection 45 (a)(1)" of the FTCA. R.C. 1345.02(C).

themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. 45(n); *see also Dish Network* at *127.

Here, the State does not—and cannot—allege that any purported injury to an Ohio consumer is *not outweighed by countervailing benefits* to consumers. The Complaint ignores that any opioid prescription is the result of a physician's determination that the medication's benefits exceed its risks for a particular patient, and that Ohio law recognizes that opioids are appropriate for the treatment of chronic pain. R.C. 4731.052. The Complaint also ignores that the FDA's approval of opioids for the treatment of chronic pain represents a determination that they are effective and safe for that use. 21 U.S.C. 355(d). The fact that some patients suffered the risks disclosed in the labels for those medications cannot render the statements unfair.

The Complaint also makes clear that any claimed injury could have been reasonably avoided—meaning that no unfair practice existed. The State concedes that "warnings on Defendants' own FDA-approved drug labels caution that opioids 'expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death,' that the drugs contain 'a substance with a high potential for abuse,' and that addiction 'can occur in patients appropriately prescribed' opioids." Compl. ¶ 92. Every patient who legally obtains an opioid receives the label, and—as discussed in Section II.C—every physician is presumed to know its contents and communicate necessary information to his or her patients. Any patient or physician could thus avoid potential injury by adhering to the label's cautionary statements or by not prescribing or taking opioids altogether. *Cf. Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1168-1169 (9th Cir.2012) (dismissing claim on grounds that injury was avoidable where terms and conditions of credit-card application disclosed fee plaintiff alleged to have been hidden).

c. The State Fails to Plead That Any Defendant Engaged in "Deceptive" Conduct.

The State also fails to adequately allege that any Defendant engaged in "deceptive" conduct in violation of the OCSPA. To be "deceptive," the representation, omission, or practice in question must be both "material" and "likely to mislead." FTC Policy Statement on Deception at 1 (Oct. 14, 1983); *see also Davis v. HSBC*, 691 F.3d at 1168. They also must be likely to deceive physicians, because physicians are the relevant "targeted group" as a matter of law. *See Tracy*, 58 Ohio St.3d at 149, 569 N.E.2d 875 (duty to warn about prescription drugs runs to physician, not patient); FTC Policy Statement on Deception at 2-3 (a "prescription drug advertisement to doctors[] would be judged in light of the knowledge and sophistication of that group").

As discussed in Section II.C, the determination of whether an allegedly deceptive representation, omission or practice is likely to mislead must be viewed not in isolation but in the context of the totality of information available to the person allegedly misled. And that totality of information shows that there was no deception as a matter of law. *Id.*

d. Count III Is Barred by the OCSPA's Safe-Harbor Provision.

OCSPA liability cannot be premised on any "act or practice required or specifically permitted by or under federal law, or by or under other sections of the Revised Code[.]" R.C. 1345.12; *cf. Bergmoser v. Smart Document Solutions, LLC*, 268 F.App'x 392, 395 (6th Cir.2008) (affirming dismissal of OCSPA claim based on "transactions * * * expressly authorized by the Medical Records Statute"); *Pilgrim v. Universal Health Card, LLC*, N.D.Ohio No. 5:09-cv-879, 2010 U.S. Dist. LEXIS 9260, *9-*10 (Feb. 3, 2010) (dismissing OCSPA claim based on advertising approved pursuant to statute).

Courts interpreting similar safe-harbor statutes or doctrines have regularly held that representations consistent with FDA-approved drug labeling cannot be the basis for consumer-

protection claims. For example, in *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, D.Mass. No. 13-11343, 2014 WL 866571 (Mar. 5, 2014), the court applied the safe-harbor rule to dismiss claims under California's consumer-protection laws. Noting that the FDA had approved the labeling and sale of the drug for the indication in question, the Court explained:

> Where, as here, Congress has entrusted the FDA to determine 1) whether there is a substantial evidence of efficacy for a particular indication and 2) whether a proposed label is false or misleading in any way, and the FDA approves a label for a certain indication, the safe harbor provision applies to bar a claim that the label was false or misleading.

2014 WL 866571, at *4; *see also Prohias*, 490 F.Supp.2d at 1235; *Cytyc*, 12 F.Supp.2d at 299, 301; *Apotex Inc. v. Acorda Therapeutics, Inc.*, S.D.N.Y. No. 11-cv-8803, 2014 WL 5462547, *8 (Oct. 23, 2014) (statement "consistent with the FDA label" not misleading); *Newman v. McNeil Consumer Healthcare*, N.D.Ill. No. 10 C 1541, 2013 WL 7217197, *5 (Mar. 29, 2013) (same).[17] As the State concedes, the FDA has approved Defendants' extended-release opioids for long-term treatment of chronic pain. Compl. ¶ 151. And Ohio law likewise authorizes the use of opioids for chronic pain. R.C. 4731.052(E).

Defendants are therefore entitled to advertise and promote extended-release opioids for treatment of long-term non-cancer pain, and the State's OCSPA misrepresentation claims based on such advertising and promotion fail.

[17] Indeed, the FTC expressly defers to the FDA with regard to the "truth or falsity" of representations about prescription drugs. *See* Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (1971). And FTC orders consistently recognize that representations consistent with the label are not actionable. *See, e.g., In re Basic Research, LLC*, 2006 FTC LEXIS 34, *10-*11 (FTC June 19, 2006) (excluding from consent order "any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the [FDA]"); *In re Maxf James*, 127 F.T.C. 324, 1999 FTC LEXIS 26, *19 (FTC Mar. 15, 1999) (same); *In re Metagenics, Inc.*, 1996 FTC LEXIS 742, *33-*34 (FTC Dec. 23, 1996) (same).

a. Count III Is Time-Barred as to Any Alleged Damages Before June 30, 2015.

Alternatively, Count III is barred as to any alleged damages before June 30, 2015 by the applicable two-year statute of limitations. While the State is exempt from certain statutes of limitations, the OCSPA is clear that "[n]o action may be brought ***by the attorney general under this section*** to recover for a transaction more than two years after the occurrence of a violation." R.C. 1345.07 (emphasis added); *see also State ex rel. Celebrezze v. Grogan Chrysler-Plymouth, Inc.*, 73 Ohio App.3d 792, 797, 598 N.E.2d 796, *cause dismissed*, 62 Ohio St.3d 1458, 580 N.E.2d 440 (1991). Thus, even if the State has managed to state a claim under the OCSPA (and it has not), that claim should be dismissed as to any alleged damages before June 30, 2015 (two years prior to the date the State filed suit).

3. The State's Request for Civil Penalties Under the OCSPA Must Be Stricken.

The individualized-proof rule defeats the State's civil-penalty claim under the OCSPA. Although Ohio courts have not yet had occasion to apply the rule to the OCSPA, other courts have applied it to dismiss similar claims brought under analogous consumer protection statutes, and the reasoning of those decisions applies equally here.

In *In re Zyprexa Products Liability Litigation*, for instance, the court rejected Mississippi's "request[] [that] a penalty * * * be assessed for each of almost a million estimated Zyprexa prescriptions in Mississippi" on the ground that a proper assessment of the claimed penalties "would require individualized consideration of the circumstances of each prescription alleged to be in violation of the statute." 671 F.Supp.2d 397, 456, 458-59 (E.D.N.Y.2009). The *Zyprexa* court refused to undertake such an assessment because: (1) the State failed to "offer[] the kind of individualized information relating to each prescription that is needed to enable the requisite inquiry by the court in imposing discretionary penalties"; and (2) the imposition of civil penalties

on a per-violation basis would require an inquiry that "is impractical and beyond the resources of any court." *Id.* at 459. As in *Zyprexa*, the State here has pleaded no individualized information relating to any opioid prescription—and here, the impracticality of the required inquiry is vastly compounded because Defendants are multiple companies that sell different types of opioid medications. The Court should thus strike the State's claim for discretionary civil penalties.

4. The State Has Not Adequately Pleaded a Cause of Action Under the Ohio Medicaid Fraud Statute (Count IV).

a. The State Has Not Pleaded Medicaid Fraud with Particularity.

Under Ohio law, Medicaid fraud consists of "knowingly mak[ing] or caus[ing] to be made a false or misleading statement or representation for use in obtaining reimbursement from the [M]edicaid program." R.C. 2913.40(B). It is therefore subject to Rule 9(B), and thus the Complaint "must contain allegations of fact which tend to show each and every element" of that claim. *Mar Jul, L.L.C. v. Hurst*, 4th Dist. Washington No. 12CA6, 2013-Ohio-479, ¶ 41. The Complaint lacks particularized allegations of fact as to two critical elements.

First, the Complaint contains no particularized allegations that any Defendant's marketing and promotional materials were made "*for use in obtaining reimbursement* from the medicaid program." (Emphasis added.) R.C. 2913.40(B). All the State offers is a conclusory allegation that Defendants disseminated marketing and promotional materials "for the purpose of getting the Department of Medicaid to pay for opioids for long-term treatment of chronic pain." Compl. ¶ 197. The Complaint fails to identify any specific statement or omission that any Defendant made to an Ohio Medicaid official, let alone any statement that influenced any Medicaid reimbursement decision. There is simply no link between any of Defendants' alleged misrepresentations and any Medicaid claim that was submitted to and paid for by the State.

Further, manufacturer marketing campaigns with only tenuous and indirect links to Medicaid reimbursement cannot constitute Medicaid fraud as a matter of law. Ohio's Medicaid fraud statute is "aimed at the ***provider or recipient*** of medical goods or services who engages in or knowingly facilitates fraud" (emphasis added), L.R. Katz et al., Baldwin's Ohio Prac. Crim. L. 101:2 (3d ed. Dec. 2016 update). It is not aimed at manufacturers—like the pharmaceutical manufacturers here—who merely market or distribute medications and who have no direct contact with Medicaid or involvement with the submission of Medicaid claims. For this reason, convictions under R.C. 2913.40 are almost exclusively against other healthcare providers and pharmacists.[18]

Second, the State fails to plead with particularity an actionable "false or misleading statement or representation" within the meaning of the Ohio Medicaid Fraud Statute. R.C. 2913.40(B). Under the statute, a "statement or representation" must "identify * * * goods or * * * service[s] for which [Medicaid] reimbursement may be made" or be "be used to determine a rate of reimbursement under the [M]edicaid program." R.C. 2913.40(A)(1). The Complaint contains no allegation that Defendants made any statements "to identify an item of goods or a service for * * * reimbursement"—much less statements that were "used to determine a rate of reimbursement." Rather, the State's allegations focus exclusively on Defendants' allegedly deceptive marketing and promotional materials. Compl. ¶ 87-123, 196-197. But a pharmaceutical manufacturer's marketing efforts are clearly not "used to identify an item of goods" *for Medicaid*

[18] *See, e.g., State v. Urban*, 10th Dist. Franklin No. 01AP-239, 2002-Ohio-1438 (physician's clinic fraudulently billed patients); *State v. Barron*, 10th Dist. Franklin No. 99AP-59, 2000 WL 739427 (June 8, 2000) (clinic director instituted double-billing scheme); *State v. Worsencroft*, 100 Ohio App.3d 255, 653 N.E.2d 746 (10th Dist.1995) (pharmacist sought reimbursement for name-brand drugs while substituting generics); *State v. Herrmann*, 4th Dist. Scioto No. 93 CA 2185, 1994 WL 534880 (Sept. 28, 1994) (physician forged prescriptions).

reimbursement. Nor are they used to "determine a rate of reimbursement." The State nowhere alleges otherwise.

a. The State May Not Maintain a Civil Action to Enforce Ohio's Criminal Medicaid Fraud Statute.

Ohio's Medicaid fraud statute is exclusively criminal, with no *qui tam* or civil-enforcement mechanism. *See* R.C. 2913.40(E). The State nevertheless purports to bring a civil cause of action by invoking a separate catch-all statute, R.C. 2307.60(A)(1), which provides: "Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law." *See* Compl. ¶ 195. The State, however, is not a party entitled to invoke this statute.

For decades, Ohio appellate courts held that R.C. 2307.60 did not create any cause of action at all, but rather was "only a codification of the common law in Ohio that a civil action is not merged in a criminal prosecution which arose from the same act or acts," and thus a "separate cause of action must be available before this section is invoked." *Applegate v. Weadock*, 3d Dist. Auglaize No. 2-95-24, 1995 WL 705214, *3 (Nov. 30, 1995). Last year, the Supreme Court of Ohio held otherwise, ruling that the statute does create "a civil cause of action for damages resulting from any criminal act." *Jacobson*, 149 Ohio St.3d 398, 2016-Ohio-8434, 75 N.E.3d 203, at ¶ 12. But the *Jacobson* court cautioned: "We make no ruling today beyond answering th[at] * * * question." *Id.* at ¶ 11. "Any ensuing issues regarding how the statute operates or what a plaintiff must do to prove a claim under R.C. 2307.60(A)(1) are beyond the scope of this appeal." *Id.* The "ensuing issue" here is whether the statute operates to confer such claims on the *State*. It does not.

Neither *Jacobson* nor any other case has ruled that the sovereign *State*, as opposed to a private party, may bring a civil action for damages under R.C. 2307.60 where one is not other-

wise available. *Cf. Vermont Agency of Natl. Resources v. U.S. ex rel. Stevens*, 529 U.S. 765, 780 (2000) (noting the "longstanding interpretive presumption that 'person' does not include [a] sovereign [State]"). It does not appear that the State has ever attempted to bring a civil cause of action for Medicaid fraud under R.C. 2307.60. In fact, it does not appear that the State has ever attempted to bring *any* civil action at all under R.C. 2307.60. That is not surprising; R.C. 2307.60 presupposes an underlying criminal act, and prosecuting criminal acts is *precisely* how the State obtains redress for injuries to public property, including to the public fisc. *See* W. Blackstone, 4 *Commentaries on the Laws of England* 5 (1769) ("[C]rime and misdemesnors [*sic*] are breach and violation of the public rights and duties, due to the whole community, considered as community."). So unlike private plaintiffs, who would be left with no recourse but for R.C. 2307.60, the State can vindicate the public interest by bringing a criminal prosecution. The Court should thus decline the State's unprecedented attempt to extend of R.C. 2307.60 to claims brought on behalf of the State itself.

The Complaint here is also an improper attempt to use the criminal Medicaid fraud statute as if it were a civil False Claims Act statute. But the two are not the same. Many states have laws that echo the federal False Claims Act. *E.g.*, 740 Ill.Comp.Stat. 175/1 *et seq.* Ohio—by contrast—does not, and its legislature has long rejected calls to enact one. *See, e.g.*, H.B. 317, 130th Gen. Ass'y (Oct. 24, 2013) (died in committee); S.B. 143, 129th Gen. Ass'y (April 7, 2011) (same); H.B. 355, 127th Gen. Ass'y (Oct. 18, 2007) (same). Although the legislature has authorized the Attorney General to institute civil actions against Medicaid *providers* under a separate statute, *see* R.C. 5164.35(E), it has not authorized the Attorney General to institute civil actions against non-provider perpetrators of Medicaid fraud under R.C. 2913.40. This Court should not

endorse a reading of the decades-old R.C. 2307.60 that allows the executive branch to maintain a False Claims Act-like action here, in direct contravention of the legislature's judgment.

b. Count IV Is Barred by the One-Year Statute of Limitations.

A civil action brought under R.C. 2307.60 has a one-year statute of limitations. *State ex rel. Cty. of Cuyahoga v. Jones Lang LaSalle Great Lakes Corp. Real Estate Partners LLC*, 8th Dist. Cuyahoga No. CA-16-104157, 2017-Ohio-4066, ¶ 123; *see also* R.C. 2305.11(A).[19] Although the statute of limitations is an affirmative defense, it is a permissible ground for dismissal "when the bar of the statute of limitations is obvious from the face of the complaint." *Steiner v. Steiner*, 85 Ohio App.3d 513, 519, 620 N.E.2d 152, 156 (4th Dist.1993); *accord Mills v. Whitehouse Trucking Co.*, 40 Ohio St.2d 55, 60, 320 N.E.2d 668, 671 (1974). Here, the Complaint on its face fails to identify with particularity any allegedly false statements postdating May 31, 2016. *See Mar Jul*, 2013-Ohio-479, at ¶ 41 (fraud allegations must "include the time, place and content of the false representation"); *cf.* Compl. ¶ 153, 201. Count IV is thus time-barred.

5. The Common-Law Fraud Claim (Count V) Must Be Dismissed.

a. The State's Fraud Claim Fails Because It Is Not Predicated on Alleged Misrepresentations and Omissions Made to and Relied Upon by the State.

A plaintiff "fails to state a valid cause of action for fraud when he alleges that a third party relied on misrepresentations made by a defendant and that [the plaintiff] suffered injury from that third party's reliance." *Wiles v. Miller*, 2013-Ohio-3625, 3 N.E.3d 226, ¶ 33 (10th Dist.); *see also Howick v. Lakewood Village Ltd. Partnership*, 3rd Dist. Mercer No. 10-06-25, 2007-Ohio-4370, ¶ 61; *Moses v. Sterling Commerce America, Inc.*, 10th Dist. Franklin No. 02AP-161, 2002-

[19] The State may argue that it is exempt from this statute of limitations. *See State v. Sullivan*, 38 Ohio St.3d 137, 527 N.E.2d 798 (1988). But such an exemption would in effect allow the State to enforce the criminal laws *forever*—all the more reason to believe the legislature never intended to permit the sovereign State to bring a civil action under R.C. 2307.60 in the first place.

Ohio-4327, ¶ 21; *Hammond v. Citibank, N.A.*, S.D.Ohio No. 2:10-cv-1071, 2011 WL 4484416, *9 (Sept. 27, 2011).

This is exactly what the State alleges here. It claims that Ohio physicians and patients—rather than the State—received and relied upon Defendants' alleged misrepresentations. *See, e.g.*, Compl. ¶ 130 ("Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use"), ¶ 131 ("Defendants' deceptive marketing scheme caused and continues to cause doctors in Ohio to prescribe opioids for chronic pain conditions.").

In fact, the Complaint fails to specify even one purported misrepresentation allegedly directed at the State—much less at the State officials responsible for determining what prescription medications the State should pay for or reimburse. *Id.* at ¶ 206-210. To the contrary, the State claims that Defendants disseminated allegedly misleading statements to physicians and staff at Ohio hospitals, *id.* at ¶ 206, made allegedly deceptive statements to Ohio prescribers, *id.* at ¶ 207, and caused alleged misstatements regarding opioids' risks and benefits to be published in third-party prescriber educational materials, *id.* The State's fraud claim is thus predicated entirely on purported misrepresentations allegedly made to third parties, and it therefore fails as a matter of law.

b. The Alleged Misrepresentations Were Not Materially Misleading as a Matter of Law.

A misrepresentation can support a fraud claim only if it is material—that is, only if "it is likely, under the circumstances, to affect the conduct of a reasonable person with reference to the transaction." *Saxe v. Dlusky*, 10th Dist. Franklin No. 09AP-673, 2010-Ohio-5323, ¶ 48. Here, without providing any specifics, the State alleges that Ohio physicians relied on Defendants' alleged misrepresentations in marketing materials when prescribing opioid medications. Alleged marketing misrepresentations would therefore be material "under the circumstances" only if they

were sufficiently significant to influence a physician's prescribing decision for a particular patient with a unique presentation, medical needs, and potential contraindications.

The Complaint does not meet this burden. As described above, physicians have a "duty to know * * * the qualities and characteristics of the drugs" they prescribe, *Tracy*, 58 Ohio St.3d at 149, and a duty to consider a controlled "drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug," Ohio Adm.Code 4731-11-02(B). As discussed in more detail in Section II.C, the State here concedes that the risks of opioids are disclosed in the products' FDA-approved labeling, including the risks of "addiction, abuse and misuse, * * * overdose, and death." Compl. ¶ 92.

Given the duties imposed by Ohio law and the State's own allegations, the State cannot plausibly contend that reasonable physicians prescribing opioids would rely on promotional materials (particularly unbranded materials about pain medicines generally) in disregard of their obligations under Ohio law to know and consider the extensive and specific risk information in the FDA-approved labeling for the particular opioid medicines they were prescribing. The State's fraud claim should thus be dismissed.

6. The State Has Not Adequately Pleaded a Cause of Action Under the Ohio Corrupt Practices Act (Count VI).

The Ohio Corrupt Practices Act (OCPA) provides that "[n]o person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity." R.C. 2923.32(A)(1). "The OCPA is modeled on the federal RICO Act, and its body of federal law is instructive." *JP Morgan*, 2013-Ohio-1035, at ¶ 30 (citation omitted). "To state a civil claim under the OCPA, 'a plaintiff must establish: (1) that conduct of the defendant involves the commission of two or more specifically pro-

hibited state or federal criminal offenses; (2) that the prohibited criminal conduct of the defendant constitutes a pattern; and (3) that the defendant has participated in the affairs of an enterprise or has acquired and maintained an interest in or control of an enterprise.'" *Morrow*, 183 Ohio App.3d 40, 2009-Ohio-2665, 915 N.E.2d 696, at ¶ 27.

A complaint alleging an OCPA violation must plead each and every element "with particularity" to survive a motion to dismiss. *Id.* Courts thus apply "stricter standards for cases in which RICO and/or OCPA claims are alleged." *Dixon v. Huntington Natl. Bank*, 2014-Ohio-4079, ¶ 13 (8th Dist.). The Complaint fails to meet this high burden.

a. The State Has Failed to Plead with Particularity Any Details of the Predicate Acts of Mail and Wire Fraud.

"A RICO offense is dependent upon a defendant committing two or more predicate offenses," *State v. Miranda*, 138 Ohio St.3d 184, 2014-Ohio-451, 5 N.E.3d 603, ¶ 13, which include mail fraud and wire fraud. *See* R.C. 2923.31(I) (incorporating federal RICO definition of "racketeering activity"); 18 U.S.C. 1961(1)(B) (defining racketeering activity to include federal mail fraud and wire fraud).

The predicate acts alleged in the Complaint are "multiple instances of mail fraud, and multiple instances of wire fraud," Compl. ¶ 226, but none of these predicate acts is adequately pleaded. First, federal mail and wire fraud require an intent to defraud. *See Dottore*, 2014-Ohio-25, at ¶ 102; *United States v. Turner*, 465 F.3d 667, 680 (6th Cir.2006); *Bender v. Southland Corp.*, 749 F.2d 1205, 1216 (6th Cir.1984) (dismissing RICO claim for failure to plead intent to defraud on the predicate act of mail fraud). Yet nowhere does the State allege that Defendants had such intent.

In addition, the State does not allege with particularity the requisite details of the alleged mail and wire fraud. For example, the State fails to allege, *inter alia*, which of the Defendants'

alleged misrepresentations involved the interstate mail or wires, or when any misrepresentation via mail or wire occurred.[20] When, as here, a complaint fails to identify "a particular communication, the date of the communication, the location of the sender or receiver of any communication, nor the contents of any communication," an OCPA claim is facially deficient and must be dismissed. *Aaron v. Durrani*, S.D.Ohio No. 1:13-CV-202, 2014 WL 996471, *6 (Mar. 13, 2014).

b. The State Fails to Plead a Pattern of Corrupt Activity.

The OCPA count also fails because the Complaint lacks the required allegations that Defendants' criminal conduct constituted the necessary "pattern of corrupt activity." The OCPA "requires that the alleged 'pattern' [of] corrupt activity include at least one predicate act that is something other than mail fraud [or] wire fraud." *Mercy Health Partners of Southwest Ohio v. Miller*, Hamilton Cty. C.P. No. A0301165, 2005 WL 2592674, *4 (Sept. 30, 2005).

The Complaint fails to satisfy this threshold requirement because the State does not allege any predicate acts other than mail or wire fraud. *See* Compl. ¶ 226 (alleging "pattern of racketeering activity" comprising only "multiple instances of mail fraud, and multiple instances of wire fraud"); *accord id.* at ¶ 235. The OCPA count must therefore be dismissed. *See Mercy Health* at *4 (dismissing OCPA count for failure to plead predicate acts other than mail or wire fraud).

c. The State Fails to Plead with Particularity the Existence of an Enterprise.

The State also fails to plead with particularity the existence of an enterprise. An OCPA "enterprise" includes "any organization, association, or group of persons associated in fact although not a legal entity." R.C. 2923.31(C). Such an "association-in-fact enterprise must have at

[20] Despite the State's conclusory allegation that the "precise dates" of the relevant conduct "cannot be alleged without access to Defendants' * * * books and records," Compl. ¶ 241, the State gives no explanation why it is unable to plead with particularity the details of Defendants' "[w]ritten and oral communications directed to State agencies," *id.* at ¶ 242(h).

least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Boyle v. United States*, 556 U.S. 938, 946 (2009); *see also State v. Beverly*, 143 Ohio St.3d 258, 2015-Ohio-219, 37 N.E.3d 116, ¶ 9-11 (relying on *Boyle*). Here, the State's failure to plead the first two of these structural features is fatal.

First, the State fails to plead a "purpose," which in this context means a "*common* purpose," *i.e.*, conduct for the benefit of the larger group and not just the individual defendant. (Emphasis added.) *Boyle* at 948; *see also Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993); *State v. Sparks*, 2014-Ohio-1130, 10 N.E.3d 755, ¶ 20 (12th Dist.). The only particularized allegation regarding Defendants' purpose is that they wished to "ensure their *own* profits remained high." (Emphasis added.) Compl. ¶ 236. Nowhere does the State allege that Defendants, many of whom are direct competitors, "joined together to make money *for the same enterprise*," as required to adequately plead an OCPA claim. (Emphasis sic.) *State v. Baker*, 12th Dist. Warren No. CA2012-12-127, 2013-Ohio-2398, ¶ 22. In fact, nowhere does the State even allege a common purpose; rather, it alleges only that Defendants each "had *similar* purposes." Compl. ¶ 236 (emphasis added); *see also* Compl. ¶ 238 ("similar pattern and purpose," "similar intended purposes"). Pursuing "similar" purposes in parallel, however, is *not* the same as jointly pursuing a *common* purpose on behalf of an enterprise. *See In re Ins. Brokerage Antitrust Litigation*, 618 F.3d 300, 374 (3d Cir.2010). "Were the rule otherwise, competitors who independently engaged in similar types of transactions with the same firm could be considered associates in a common enterprise. Such a result would contravene [the] definition of 'enterprise.'" *Id.* at 375. That is precisely the case here: Defendants in fact *are* competitors simply "engag[ing] in similar types of

transactions." That parallel behavior is insufficient to allege a common purpose necessary to establish a criminal enterprise.

Second, the State fails to allege the necessary "relationships among those associated with the enterprise." *Boyle* at 946. Specifically, an OCPA plaintiff must allege "a degree of hierarchical organization or structure that distinguishes a RICO enterprise from a simple conspiracy." *Morrow*, 183 Ohio App.3d 40, 2009-Ohio-2665, 915 N.E.2d 696, at ¶ 38. The State has done nothing of the sort here; the "pleadings are entirely silent as to the internal workings of the organization of the alleged enterprise, explaining neither how it was run nor by whom." *Greenberg v. Blake*, E.D.N.Y. No. 09 Civ. 4347 (BMC), 2010 WL 2400064, *6 (June 10, 2010) (dismissing complaint for failure to adequately plead details about the enterprise's "hierarchy, operations, and activities"). There are no factual allegations showing any communications between any of the Defendants, any agreement by the Defendants to operate some type of criminal enterprise, or any of details about the operation of the supposed enterprise. Instead, all the State offers is an assertion, unsupported by particularized factual allegations, that Defendants "are systematically linked through contractual relationships, financial ties, and continuing coordination of activities." Compl. ¶ 222. Even if this allegation were not conclusory, it would still be insufficient to plead a criminal enterprise. *See Hager v. ABX Air, Inc.*, S.D.Ohio No. 2:07-CV-317, 2008 WL 819293, *15 (March 25, 2008) (alleged enterprise based on "a series of contracts" failed to state a claim).

III. CONCLUSION

For all of the foregoing reasons, the Court should dismiss the Complaint under Civil Rule 12(B)(6) or, alternatively, strike its claim for civil penalties under Civil Rule 12(F).

Dated: September 8, 2017

Respectfully submitted,

By: _____

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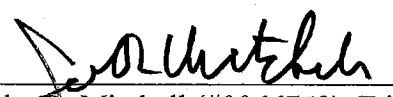

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