UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT[1]

Through this lawsuit, Summit County, Ohio and 23 political subdivisions within the County (together, "Plaintiffs") seek to hold the Manufacturer Defendants[2] liable for the entire spectrum of public costs arising from widespread misuse and abuse of opioids in Ohio, including the trafficking and use of illegal drugs such as heroin and illicit fentanyl. According to Plaintiffs, the Manufacturer Defendants are responsible for these costs because they marketed prescription opioid medications for the treatment of chronic pain—a treatment the Food and Drug Administration ("FDA") has expressly approved for extended-release/long-acting opioid ("ER/LA") medications. Absent that marketing, Plaintiffs claim, this public health crisis would never have happened. Plaintiffs assert that the Manufacturer Defendants should be liable despite

[1] Per Special Master Cohen's instruction, this motion is against Plaintiffs' Second Amended Complaint ("2AC"), dated May 18, 2018. *See In re Nat'l Prescription Opiate Litig.*, Dkt. No. 477.

[2] "Manufacturer Defendants" refers to Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. ("Purdue"); Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan/Actavis"); Watson Laboratories, Inc., Actavis Pharma, Inc.; Actavis LLC; Teva Pharmaceuticals, USA, Inc.; and Cephalon, Inc. ("Teva"); Johnson & Johnson ("J&J") and Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Janssen"); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. ("Endo"); Insys Therapeutics, Inc. ("Insys"); and Mallinckrodt LLC ("Mallinckrodt"). Defendant Noramco, Inc., a company referenced in the 2AC as a former affiliate of Janssen (*see* 2AC ¶ 80), joins in this Motion to the extent applicable. Noramco does not (and did not at all material times relevant hereto) manufacture, package, brand, market, distribute, or sell the finished drug products at issue in this litigation, and it reserves all rights and defenses specific to it. Although the arguments raised herein apply equally to Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc, these Manufacturer Defendants do not join this motion because they are an Israeli corporation, Irish holding company, and Irish company, respectively, that have not been served and over which no personal jurisdiction exists. Further, the 2AC added Defendant SpecGX LLC, an affiliate of Mallinckrodt, as a party on May 18, 2018. *See* 2AC at 2 n.2. SpecGX LLC has not been served, but nonetheless adopts in full the arguments made in this Motion. Two new Defendants, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (which is actually now known as Endo Generics Holding), defined collectively by Plaintiffs in the 2AC as "Endo," were only recently named in an amendment to the complaint and have not yet been served. *Id*. The 2AC should, however, be dismissed as to them for the reasons raised in this brief. Unless otherwise noted, this Memorandum adds all emphasis in quotations and omits citations and internal quotation marks.

the myriad social and economic reasons for prescription and illicit opioid abuse and the many intervening links separating each company's marketing from Plaintiffs' expenditures on public services, including:

- Extensive FDA and Drug Enforcement Administration ("DEA") regulations and actions;
- Individual doctor prescribing decisions;
- Misuse and abuse of opioid medications by people who were never prescribed them by their doctors; and
- Criminal conduct, including drug trafficking and diversion.

Properly prescribed, opioid pain medications serve a critical public health objective by helping to provide relief to patients suffering from pain. FDA has recognized that "[c]hronic pain is a serious and growing health problem: it affects millions of Americans; contributes greatly to national rates of morbidity, mortality, and disability; and is rising in prevalence."[3] Ex. A, Letter from FDA to PROP (Sept. 10, 2013) ("FDA Response") at 3 & nn. 4-6. As FDA has found, "[w]hen prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority." *Id.* at 3. It has also long been known that opioids have "grave risks," including "addiction, overdose, even death." *Id.*; 2AC ¶ 131. Accordingly, the FDA-approved "labeling for these products contains prominent warnings about these risks. Moreover, the boxed warning states that all patients should be routinely monitor[ed] . . . for signs of misuse, abuse, and addiction." FDA Response at 3.

Despite FDA's longstanding approval of opioid therapy for treatment of chronic pain, and the well-known risks of opioid therapy, Plaintiffs accuse the Manufacturer Defendants of engaging in a fraudulent marketing scheme to promote their opioid medications for their FDA-approved uses and to conceal their risks. Plaintiffs also seek to hold the Manufacturer

[3] All exhibits cited herein are attached to the Declaration of Charles C. Lifland.

Defendants responsible for the criminal acts of third parties who diverted these medications on the theory that the Manufacturer Defendants violated their purported duties to monitor, report, and stop shipments of "suspicious" prescription opioid orders. Based on these theories of liability, and despite the many intervening acts, events, and decisions by multiple independent actors (including doctors, pharmacists, distributors, patients, and payors), the 2AC brings sweeping federal RICO and state law claims against the Manufacturer Defendants.

Each of these claims is fundamentally flawed and should be dismissed as a matter of law for multiple reasons. The Sixth Circuit, Ohio courts, and other courts across the country have repeatedly dismissed similar efforts to assert RICO, nuisance, fraud, and other state law claims against manufacturers of lawful products that are based upon multi-factorial public health and economic crises. Here too, the claims fail to satisfy threshold requirements, including:

- ***No standing***. Plaintiffs are political subdivisions in Ohio, including a county, various cities, townships, and villages, and a fire district, that seek to regulate a public health crisis of statewide concern. But only the State of Ohio has the authority to bring claims to do so. And the State of Ohio, through the Attorney General, has already exercised that authority here.[4]

- ***No but-for causation***. Plaintiffs allege that the Manufacturer Defendants deceived prescribers, but the 2AC fails to identify any prescriber who was even exposed to—let alone relied on—a supposed misrepresentation before writing a prescription for any opioid medication. Nor does the 2AC plausibly allege that, but for the Manufacturer Defendants' purported failure to report suspicious orders of opioid medications, Plaintiffs would have averted the costs of the opioid crisis that they seek to recover.[5]

- ***No proximate causation***. Plaintiffs' claims against the Manufacturer Defendants ignore the many independent actions, including criminal conduct, that break any alleged causal connection between the Manufacturer Defendants' marketing and the societal harms for which Plaintiffs seek to

[4] *See, e.g.*, O.R.C. § 109.02; *Reading v. Pub. Util. Comm'n*, 846 N.E.2d 840, 846 (Ohio 2006); *Am. Fin. Servs. Ass'n v. Cleveland*, 858 N.E.2d 776, 781 (Ohio 2006).

[5] *See, e.g.*, *City of Chi. v. Purdue Pharma, L.P.*, 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *6-8 (N.D. Cal. Aug. 2, 2012).

recover. Plaintiffs do not and cannot meet the requirement that they plead "some direct relation between the injury asserted and the injurious conduct alleged." *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1306 (2017). Instead, Plaintiffs allege only an "attenuated theor[y] of damage." *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480 (6th Cir. 2017). Courts have repeatedly dismissed such claims as too remote as a matter of law.[6]

- ***No cognizable injury***. The 2AC does not state a cognizable injury under RICO and for common law public nuisance. The alleged injuries—increased public expenditures and reduced tax revenue—are wholly derivative of alleged personal injuries among Ohioans who have misused, abused, or become addicted to prescription opioids or ***illegal*** drugs. They do not meet the "direct-injury" or "business or property" requirements for RICO standing.[7] Nor do they affect a "public right," as required for a public nuisance claim.[8]

- ***No actionable fraudulent marketing***. Federal preemption principles foreclose Plaintiffs' attack on promotion for FDA-approved indications and for alleged off-label promotion. In addition, the 2AC establishes that the Manufacturer Defendants extensively disclosed the risks of prescription opioids that Plaintiffs claim were "concealed," and it fails to plead any fraud with particularity or any basis to hold the Manufacturer Defendants liable for statements made by third parties.[9]

- ***No actionable "diversion" conduct***. Pharmaceutical manufacturers' duty to monitor and report "suspicious" orders is owed to ***DEA***, not Plaintiffs, and the right to enforce any such obligation lies exclusively with the federal government. Plaintiffs cannot circumvent the absence of any private cause of action in the Controlled Substances Act ("CSA") or its implementing

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[6] *See, e.g.*, *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 502 (6th Cir. 2010); *In re Yasmin & Yaz Marketing, Sales Practices & Prods. Liab. Litig.*, 2010 WL 3119499, at *7-9 (S.D. Ill. Aug. 5, 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344-46 (M.D. Fla. 2008).

[7] *See, e.g.*, *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 566 (6th Cir. 2013); *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976 (9th Cir. 2008); *Cty. of Oakland v. City of Detroit*, 866 F.2d 839, 847 (6th Cir. 1989).

[8] *See, e.g.*, *Brown v. Scioto Cty. Bd. of Comm'rs*, 622 N.E.2d 1153, 1159 (Ohio Ct. App. 1993); *Chi. v. Beretta U.S.A. Corp.*, 821 N.E. 2d 1099, 1116 (Ill. 2004).

[9] *See, e.g.*, *United Food & Commercial Workers Cent. Pa. & Reg. Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 553 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3rd Cir. 2015); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014).

> regulations.[10] In addition, manufacturers have no legal duty to monitor, report, or prevent ***downstream*** diversion of prescription opioids or to stop selling their FDA-approved products based on Plaintiffs' concerns about diversion. Any such "stop-shipment" requirement under state law would be preempted because it would conflict with FDA's exclusive authority to determine which drugs should (and should not) be on the market.[11]

There is no question that the opioid crisis involves issues that merit immediate attention and creative problem solving. Plaintiffs do not and cannot, however, allege a viable legal theory to recover their alleged governmental costs, lost tax revenue, or any other alleged damages from the Manufacturer Defendants. The 2AC should be dismissed in its entirety.[12]

LEGAL STANDARD

All of Plaintiffs' claims are based on their contention that the Manufacturer Defendants fraudulently marketed prescription opioids and "engaged in a scheme of deception" by "refusing to identify suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted." 2AC ¶ 932; *id.* ¶¶ 155, 174, 349, 440, 446, 1094. Therefore, to survive a motion to dismiss, each claim must meet both the *Iqbal*/*Twombly* plausibility standards, *Ashcroft v. Iqbal*, 556 U.S. 662, 677-79 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and the particularity standard of Rule 9(b), *see Frank v. Dana*, 547 F.3d 564, 570 (6th Cir. 2008). In assessing whether Plaintiffs have met these standards, "legal conclusions" and "conclusory statements" must be disregarded. *Iqbal*, 556 U.S. at 678. In addition, the 2AC must detail the "who, what, when, where, and how" of the alleged

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[10] *See, e.g., Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011); *Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010); *Safe Sts. Alliance v. Alternative Holistic Healing, LLC*, 2016 WL 223815, at *3 (D. Colo. Jan. 19, 2016), *aff'd*, 859 F.3d 865 (10th Cir. 2017).

[11] *See*, *e.g.*, *Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *1-2 (D. Mass. Apr. 15, 2014); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014).

[12] Pursuant to § 2.g. of CMO One, the Manufacturer Defendants raise only certain key "issues common to all manufacturers" that warrant dismissal of the 2AC. The Manufacturer Defendants expressly reserve the right to raise additional grounds for dismissal at the appropriate time.

fraud. *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 256 (6th Cir. 2012). This includes "the time, place, and content of the alleged misrepresentations," the "fraudulent scheme," "fraudulent intent" and "injury resulting from the fraud." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006).

ARGUMENT

I. PLAINTIFFS LACK STANDING TO BRING CLAIMS THAT INVADE THE STATE'S EXCLUSIVE POWER TO ADDRESS MATTERS OF STATEWIDE CONCERN

All of Plaintiffs' claims in this lawsuit should be dismissed for lack of standing because only the Ohio Attorney General has the power to bring them. Plaintiffs—composed only of political subdivisions in Ohio, 2AC ¶¶ 28-52—have no such power for two reasons: (1) political subdivisions may not infringe on the State's exclusive power to address matters of "statewide concern"; and (2) Ohio law designates the Attorney General as the "chief legal officer" to pursue the types of claims at issue here, and the State has exercised its controlling authority to do so in an earlier-filed lawsuit pending in Ohio state court.

A. Plaintiffs Lack Standing Under the "Statewide Concern" Doctrine

It is a "fundamental principle" of Ohio law that, under the "statewide concern" doctrine, a "municipality may not, in the regulation of local matters, infringe on matters of ***general and state-wide concern***." *Reading v. Pub. Util. Comm'n*, 846 N.E.2d 840, 846 (Ohio 2006). "[W]here matters of statewide concern are at issue, the state ***retains the power*** . . . to address those matters." *Am. Fin. Servs. Ass'n v. Cleveland*, 858 N.E.2d 776, 781 (Ohio 2006). Thus, any power granted to local governments, "even in the regulation of . . . local matters[,] . . . may not infringe on matters of general and statewide concern." *Cleveland Elec. Illuminating Co. v. City of Painesville*, 239 N.E.2d 75, 78 (Ohio 1968). Examples of such matters include railroad safety, predatory lending, and, most relevant here, public health. *See State v. Underwood*, 27 N.E.2d

773, 775 (Ohio 1940); *id.* at 776 ("[T]he state did not surrender its sovereign power to protect the public health.").[13]

The statewide concern doctrine precludes local ordinances that improperly seek to regulate matters of statewide concern, and its underlying principles apply equally to litigation brought by political subdivisions. Plaintiffs acknowledge that the opioid crisis is a matter of general concern with effects extending well beyond Summit County. 2AC ¶¶ 16-18. The Attorney General cited the reach of the crisis in bringing his own lawsuit. *See* Ex. B ("Ohio AG Compl."). Through that suit, the Attorney General seeks to vindicate the interests of Ohio and its citizens. *Id.* ¶ 20. Ohio's lawsuit makes clear that addressing any alleged "fraudulent marketing" scheme, including remedying the alleged effects of this supposed scheme in Ohio, is a matter of statewide—not local—concern. *Id.* ¶ 9. So just as Plaintiffs would be prohibited from passing an ordinance regulating pharmaceutical opioid marketing generally, they cannot bring a lawsuit that seeks to accomplish the same end through injunctive and monetary relief.

Plaintiffs cite no constitutional provision granting them authority to bring a lawsuit vindicating statewide interests. And the two statutory provisions Plaintiffs cite for authority to bring claims "on behalf of the State"—O.R.C. §§ 3767.03 and 4729.35—show exactly why they lack standing. On their face, these statutes are limited to nuisance claims, not the other claims that Plaintiffs assert. Had the General Assembly intended to permit the filing of other claims by political subdivisions, it would have ***expressly*** authorized such claims. It did not.

Further, these statutes nowhere permit ***duplicative*** nuisance actions based upon the same conduct—which would result in impermissible claim splitting and risk inconsistent rulings and duplicative recoveries for the same alleged harms, among other problems. Because the Attorney

[13] *See also Reading*, 846 N.E.2d at 846 (2006) (railroad safety); *Am. Fin.*, 858 N.E.2d at 781 (predatory lending).

General has already brought a nuisance action against prescription opioid manufacturers based upon the same conduct alleged here, Plaintiffs' action should be dismissed.

B. Plaintiffs Lack Standing Given Ohio Law's Mandate That the Ohio Attorney General Is the State's Chief Legal Officer

The Attorney General is a constitutional officer, Ohio Const. Article III, Section 1, who serves as "***the chief law officer*** for the state and ***all its departments***," O.R.C. § 109.02, and retains its common law powers to control all litigation that implicates matters of statewide concern, *see State v. Plumb*, 156 N.E. 457, 458 (Ohio 1927); *State v. Crabbe*, 143 N.E. 189, 190 (Ohio 1924).

By contrast, under Ohio's constitutional division of powers, local governments are subservient to the State. Although they have the capacity to sue, counties "are created only for the purpose of aiding the state in its general plan and policy of government . . . [and] [t]hey have always been counted as subordinate to the state in the exercise of governmental power." *State v. Price*, 128 N.E. 173, 175 (Ohio 1920). Likewise, municipal corporations "function as agents or instrumentalities of the state government and therefore constitute political subdivisions." *Wolf v. City of Columbus*, 129 N.E.2d 309, 311 (Ohio Ct. App. 1954).

In exercising its discretion to determine the best interests of Ohio, its citizens, and all political subdivisions, the Attorney General has already brought an enforcement action against the same core group of Manufacturer Defendants, based upon the same conduct alleged here—that is, the alleged improper marketing and sale of opioids. Ohio AG Compl. ¶¶ 1-159. In that action, the Attorney General has affirmatively asserted that there is "***no other Plaintiff . . . better situated*** to seek a remedy for the economic harms" purportedly caused by the Manufacturer Defendants. *Id.* ¶ 247. Further, the Attorney General seeks to "recover all measures of damages allowable under" statute and the common law, *id.* at 100—a request that encompasses the relief

sought here. As municipalities with limited powers, Plaintiffs lack standing to usurp the authority of the Attorney General, who has chosen to exercise that authority as the chief law officer of the State by bringing a lawsuit against opioid manufacturers.

II. PLAINTIFFS' RICO MARKETING ENTERPRISE CLAIM FAILS (COUNT 1)

To state a claim under the federal Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, Plaintiffs must plead facts sufficient to show that they suffered a cognizable and direct injury, and therefore have standing to bring their claims. *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 614 (6th Cir. 2004). Plaintiffs must also allege facts showing that their alleged injuries were actually and proximately caused by "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 404-05 (6th Cir. 2012). Plaintiffs do not adequately plead ***any*** of these requirements.

A. Plaintiffs Lack RICO Standing Because They Do Not Allege a Cognizable Injury

RICO imposes two standing limitations, neither of which Plaintiffs meet: first, the plaintiff must suffer an injury to ***"his business or property"***; second, the injury must be ***"direct"***—injuries "derivative [of] or passed-on [from]" third parties are insufficient. *Trollinger*, 370 F.3d at 612, 614. Plaintiffs allege two categories of injuries resulting from the Manufacturer Defendants' marketing: (1) public expenditures made in response to opioid abuse, misuse, and addiction; and (2) lost tax revenue resulting from that abuse, misuse, and addiction. 2AC ¶¶ 902(a)-(k), 934(a)-(k).[14] Such derivative injuries do not satisfy either RICO standing requirement.

[14] Although the 2AC vaguely alleges a third category of injuries related to "[l]osses caused by diminished property values," 2AC ¶¶ 902(m)-(n), 934(l)-(m), it nowhere alleges loss to properties that ***Plaintiffs*** own. Plaintiffs' failure to establish any interest in these properties defeats RICO standing as to these alleged injuries. *See Trollinger*, 370 F.3d at 614.

1. Derivative Injuries Do Not Meet RICO's Direct-Injury Requirement

It is well-settled that Plaintiffs lack standing to use RICO to recover for derivative injuries sustained by third parties; instead, the "immediate victims" of an alleged RICO violation are the ones that have standing to "vindicate the laws by pursuing their own claims." *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006). In *Anza*, for example, the Supreme Court held that a business lacked standing under RICO to sue its competitor for tax fraud (which allowed the competitor to offer lower prices), as "[t]he direct victim of this conduct was the State of New York, not" the plaintiff. *Id.* at 458. Here, too: because each of Plaintiffs' alleged injuries is derivative of personal injuries allegedly suffered by third-party opioid users, Plaintiffs lack RICO standing.

For example, Plaintiffs seek to recover their public expenditures for "providing healthcare and medical care" for opioid addiction. 2AC ¶ 902(b). These alleged injuries are derivative of harms to individual opioid users who received such care. *See Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013). Similarly, Plaintiffs' request for lost tax revenue due to "decreased efficiency and size of the working population" in their communities, 2AC ¶ 902(k), is derivative of the "pecuniary losses flowing from [] personal injuries" to third-party opioid users, such as lost wages. *Jackson*, 731 F.3d at 565. When the conclusory allegations are stripped away, *e.g.*, 2AC ¶ 904, Plaintiffs' failure to allege direct, pecuniary injury to ***their*** business or property defeats the RICO Marketing Enterprise claim. *Jackson*, 731 F.3d at 565 ("[B]oth personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under § 1964(c).").

2. Public Expenditures Are Not an Injury to "Business or Property"

Plaintiffs' public expenditures do not qualify as an injury to "business or property" under § 1964(c). Although a government entity may recover costs incurred when acting in its capacity

as a commercial actor in the market place, *see Cty. of Oakland v. City of Detroit*, 866 F.2d 839, 847 (6th Cir. 1989), it "cannot rely on [public] expenditures" made in its "sovereign and/or quasi-sovereign capacities" to establish RICO standing, *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976, 979 (9th Cir. 2008). Thus, government costs for "health care services," "criminal justice services," and other public services do not constitute "damages to . . . property for purposes of civil RICO standing." *Id.* at 979.

Here, all of Plaintiffs' alleged expenditures were made in Plaintiffs' sovereign capacities. *See* 2AC ¶ 902(a) (alleging a "decrease in funding available for Plaintiffs' ***public services***" because "[funding] was diverted to other ***public services*** designed to address the opioid epidemic"). Because RICO provides no basis to recover such costs, Plaintiffs' RICO Marketing Enterprise claim should be dismissed.

B. Plaintiffs Fail to Plead Causation and Other Elements Under RICO

1. Plaintiffs Do Not Allege That Any Purported Misrepresentation Actually Caused a Harmful Prescription to be Written

Plaintiffs must show that the Manufacturer Defendants' conduct was a "***but for*** cause of [their] injury." *Holmes*, 503 U.S. at 268. Plaintiffs seek to hold the Manufacturer Defendants liable for a litany of social problems associated with Ohio's opioid crisis, including "increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff and Plaintiff's Community." 2AC ¶ 1007. Despite the breadth of this theory, however, Plaintiffs rely upon nothing but conclusory statements and plead virtually no ***facts*** to establish the requisite causal link to support it. *See Twombly*, 550 U.S. at 555-56.

Indeed, Plaintiffs do not allege a single fact to establish even the first step in the causal

chain—namely, that specific Ohio prescribers were exposed to the Manufacturer Defendants' alleged deceptive marketing. The 2AC fails to identify even one such prescriber, let alone one who then wrote an allegedly harmful, ineffective, or medically unnecessary opioid prescription ***as a result*** of the alleged deceptive marketing. As numerous courts across the country have recognized in dismissing similar complaints against pharmaceutical manufacturers, these basic pleading deficiencies are fatal to Plaintiffs' unlawful marketing claims under RICO and other laws. *See City of Chi. v. Purdue Pharma, L.P.*, 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015) (dismissing fraud-based claims because "the City d[id] not allege . . . the identities of doctors who, as a result of [the] alleged misrepresentations, prescribed opioids" that caused the resulting harm); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *6-8 (N.D. Cal. Aug. 2, 2012) (dismissing RICO claims because Plaintiffs failed to allege "***specific***" facts that individual physicians actually relied on these misrepresentations in writing the challenged prescriptions").[15] This case is no different.

2. Plaintiffs' Proposed Causal Chain Is Too Attenuated and Remote to Establish Proximate Causation

RICO's proximate cause element requires plaintiffs to show "some direct relation between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Investor Prot. Corp.*, 502 U.S. 258, 268 (1992). This analysis draws on "judicial tools used to limit a person's responsibility" and is based on concerns about what "justice demands" and what is "administratively possible and convenient." *Id.*; *accord City of Miami*, 137 S. Ct. at 1306. Three

[15] *See also Dist. 1199P Health & Welfare Plan v. Janssen, LP*, 784 F. Supp. 2d 508, 522-23 (D.N.J. 2011); *In re Schering-Plough Corp. Intron/Temodar Cons. Class Action*, 2010 WL 2346624, at *7-8 (D.N.J. June 9, 2010); *Cent. Reg'l Emps. Benefit Fund v. Cephalon, Inc.*, 2010 WL 1257790, at *3 (D.N.J. Mar. 29, 2010); *In re Actimmune Mktg. Litig.*, 2010 WL 3463491, at *10-11 (N.D. Cal. Sept. 1, 2010); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1287 (S.D. Fla. 2009); *United States ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at *9-10 (E.D.N.Y. May 22, 2009).

factors must be considered:

(1) whether it would be difficult to "ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors";

(2) whether permitting liability would "force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries"; and

(3) whether there is no need to stretch the bounds of liability for purposes of deterrence, because "directly injured victims can generally be counted on to vindicate the law."

Holmes, 502 U.S. at 269. Under these factors, "a plaintiff who complained of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts was generally said to stand at too remote a distance to recover." *Id.* at 268-69.

As discussed *supra* § II(A), Plaintiffs' alleged RICO injuries consist of public expenditures and lost tax revenue. But Plaintiffs' alleged injuries are a remote, indirect byproduct of numerous independent events and decisions, including alleged personal injuries suffered by individual opioid users and by other actors' criminal conduct, as well as non-opioid causes. Plaintiffs' alleged chain of causation would require, at a minimum, the following series of events for each alleged statement, prescription, and injury:

(1) A Manufacturer Defendant made a misrepresentation regarding prescription opioid medications;

(2) A prescriber in Summit County was exposed to that misrepresentation;

(3) Instead of exercising her own independent medical judgment, *see infra* § II(B)(4)(a), that prescriber prescribed that Manufacturer Defendant's prescription opioid to a Summit County resident because of the allegedly false statement and without knowledge or an understanding of the risks of the medication;

(4) The prescription was medically unnecessary for the patient;

(5) The pharmacist dispensed the medically unnecessary opioid prescription, without informing the patient about the risks;

(6) The patient or someone who illicitly obtained the opioid from the patient misused, abused, and/or became addicted to opioids and/or began using illicit opioids due to the allegedly fraudulently-induced prescription, as opposed to other factors (e.g., the individual's mental health or history of addiction) or other medically appropriate prescriptions;

(7) In some cases, the patient independently chose to move from prescription opioids to illegal non-prescription drugs and/or the medically inappropriate prescription was illegally diverted by someone else for illicit use; and

(8) A Plaintiff incurred costs or lost tax revenue as a result of that patient's misuse, abuse, or addiction that would not have occurred but for the Manufacturer Defendant's allegedly false statement.

Federal courts around the country have rejected similar multi-layered and speculative causal theories in cases by governments and health benefit providers as far too attenuated and remote to establish RICO proximate causation. *See*, *e.g.*, *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849-51 (6th Cir. 2003) (affirming dismissal of RICO claim against tobacco companies for lack of proximate cause and collecting cases uniformly rejecting claims against tobacco companies for increased healthcare expenses); *accord Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1074-76 (D.C. Cir. 2001); *Laborers Local 17 v. Philip Morris, Inc.*, 191 F.3d 229, 239 (2d Cir. 1999); *City & Cty. of S.F. v. Philip Morris, Inc.*, 957 F. Supp. 1130, 1137-38 (N.D. Cal. 1997).

The remoteness of Plaintiffs' proposed causal chain is compounded by two factors—each of which independently breaks that chain: (1) prescribing physicians' exercise of independent medical judgment as "learned intermediaries" when prescribing pharmaceutical products; and (2) intervening third-party criminal acts that directly caused the claimed societal harms. As to Ohio's learned intermediary doctrine, *see infra* § II(B)(4)(a), the prescribing physician breaks any causal link between the pharmaceutical manufacturer and patient, and numerous courts have dismissed RICO complaints based upon false marketing precisely because the plaintiff's allegations, like

the ones 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 Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008).[16] Similarly, proximate causation is lacking because Plaintiffs' alleged injuries depend on intervening third-party criminal acts such as street-level drug dealing and heroin usage. *See Robinson v. Vehicle Acceptance Corp.*, 2017 WL 3084579, at *3 (Ohio Ct. App. July 20, 2017); *Levy v. Stokes*, 1978 WL 218304, at *8 (Ohio Ct. App. Dec. 14, 1978).

In fact, courts have dismissed personal injury cases alleging a pharmaceutical manufacturer's marketing of its prescription opioid medication caused the plaintiff's addiction-related injuries because those ***individual*** claims were too attenuated. *See, e.g.*, *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 520-22 (11th Cir. 2017); *Timmons v. Purdue Pharma Co.*, 2006 WL 263602, at *4 (M.D. Fla. Feb. 2, 2006); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 704-05 (E.D. Ky. 2003); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003); *Price v. Purdue Pharma Co.*, 920 So. 2d 479, 485-86 (Miss. 2006). Here, the Manufacturer Defendants' alleged conduct is all the more attenuated from the macro-level societal injuries Plaintiffs allege—in essence, the aggregation of many unidentified and undifferentiated personal injuries.

The Sixth Circuit repeatedly has rejected similar attempts to impose sweeping liability against corporate defendants for complex, interdependent societal harms. For example, in *City of Cleveland v. Ameriquest Mortgage Securities, Inc.*, the City of Cleveland sued multiple financial institutions, seeking to impose widespread liability for the City's subprime mortgage crisis. 615

[16] *See United Food & Commercial Workers Cent. Pa. & Reg'l 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. Litig.*, 2010 WL 3119499, at *7-9 (S.D. Ill. Aug. 5, 2010).

F.3d 496, 499-500 (6th Cir. 2010). Relying upon a multi-link causal chain like the one alleged here, the City claimed that the defendants caused "a foreclosure crisis in Cleveland that devastated its neighborhoods and economy," which led to the City suffering reduced tax revenue and increased public expenditures for "fire and police protection," among other things. *Id.*

The Sixth Circuit affirmed dismissal on proximate cause grounds. *Id.* at 507. Citing the numerous intervening factors that led to the City's claimed injuries, the Sixth Circuit concluded that "the connection between the alleged harm and the alleged misconduct [was] too indirect to warrant recovery." *Id.* at 506. For example, even assuming that the defendant financial institutions improperly financed a market for subprime loans, "[1] [the] [c]ompanies that [initially] sold mortgages to home buyers . . . ultimately made the decisions regarding where they would seek financing, which types of loans they would market and sell, and, once the mortgagee, whether to keep the mortgage or sell it to another buyer, . . . [2] home buyers [voluntarily] chose to enter into a subprime mortgage and to default on their loans. And, [3] once the mortgagor defaulted, the mortgagee or his assigns [voluntarily] chose to begin the foreclosure process." *Id.* at 504-05. Like here, "[t]hese voluntary choices were made for a variety of reasons unrelated to the Defendants," and thus could not sustain a finding of proximate causation under Ohio law. *Id.*

These holdings are consistent with the three-factor test set forth in *Holmes*—which compels dismissal in this case, too. First, Plaintiffs' allegations, even if true, provide no basis to permit the Court to determine (1) which of Plaintiffs' injuries allegedly associated with the entire opioid crisis are attributable to each specific Manufacturer Defendants' alleged misconduct, and (2) how to apportion liability among each Manufacturer Defendant and other intervening actors, such as physicians, distributors, pharmacists, patients, and insurance companies, for Plaintiffs'

claimed injuries.[17] Second, as discussed *supra* § II(A)(1), individual opioid consumers are more direct victims of any alleged harm who can bring suit for any injuries they allegedly experienced as a result of their use of any Manufacturer Defendants' prescription opioid medications. *See Or. Laborers*, 185 F.3d at 965-66; *Laborers Local*, 191 F.3d at 240-41. "The general tendency in these cases, in regard to damages at least, is not to go beyond the first step." *City of Miami*, 137 S. Ct. at 1306. Lastly, the Court would face the impossible and complicated tasks of apportioning damages between various classes of potential plaintiffs to avoid duplicative recoveries, including opioid users and the various public and private entities who purportedly bore the costs associated with widespread opioid abuse, misuse, and addiction. *See Or. Laborers*, 185 F.3d at 965-66; *Laborers Local*, 191 F.3d at 240-41.

Under the *Holmes* factors, proximate causation principles have required dismissal of claims brought by governments, other benefits providers, and their constituencies seeking damages under RICO from product manufacturers for alleged harms to product users. *See Perry*, 324 F.3d at 849-51; *San Francisco*, 957 F. Supp. at 1137-38 (dismissing RICO claim against tobacco manufacturers for increased healthcare costs). Those principles should do so here as well.

3. Plaintiffs Do Not Plead the Existence of an "Opioid Marketing Enterprise"

To establish an "association-in-fact" enterprise, Plaintiffs must show that the Manufacturer Defendants "associated together for a common purpose of engaging in a course of

[17] The 2AC's repeated references to aggregate statistical evidence (e.g., 2AC ¶¶ 4-5, 12, 16, 458-97, 673-74, 682, 689, 709, 714-745), only underscores Plaintiffs' inability to plead the requisite direct causal link. Indeed, courts routinely reject similar efforts to rely on aggregate evidence or similar market theories of causation. *E.g.*, *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 441-42 (3d Cir. 2000); *Or. Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 964-65 (9th Cir. 1999).

conduct." *Boyle v. United States*, 556 U.S. 938, 946 (2009). This requires Plaintiffs to plead "at least three structural features": (1) a shared "purpose," (2) "relationships among those associated with the enterprise," and (3) "longevity sufficient to permit these associates to pursue the enterprise's purpose." *Id.* Plaintiffs do not adequately plead any of these elements.

First, Plaintiffs have not adequately alleged that the members of the purported Opioid Marketing Enterprise shared a "common purpose." *Id.* at 948.[18] Although Plaintiffs allege that the Manufacturer Defendants had the purpose of "increas[ing] their profits and sales," 2AC ¶ 814, this is not a ***common*** purpose: Plaintiffs nowhere allege, for example, that the enterprise's members shared or pooled their profits from the sale of prescription opioids. Indeed, the Manufacturer Defendants directly compete with one another (and others) in the market for opioid prescriptions. Allegations of parallel, profit-seeking activity among competitors are insufficient to establish the "common purpose" necessary for a racketeering enterprise. *See Boyle*, 556 U.S. at 947 n.4 (engaging in "a pattern of crimes" "independently and without coordination" insufficient to establish an enterprise); *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 375 (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."); *Abbott Labs. v. Adelphia Supply USA*, 2017 WL 57802, at *5 (E.D.N.Y. Jan. 4, 2017) ("When there is parallel conduct of the same nature in the same timeframe by different actors in different locations, it is all too facile for plaintiffs to claim a RICO violation.").

Second, Plaintiffs do not plead "relationships among those associated" with the alleged Opioid Marketing Enterprise. *Boyle*, 556 U.S. at 946. For example, although Plaintiffs allege that

[18] The alleged "Opioid Marketing Enterprise" consists of Purdue, Cephalon, Janssen, and Endo, as well as non-party "Front Groups" (e.g., the American Pain Foundation), and key opioid leaders ("KOLs") (i.e., Drs. Portenoy, Webster, Fine, and Fishman). 2AC ¶¶ 815, 880.

the Manufacturer Defendants attempted to impose a "hierarchical decision-making structure" on the enterprise by maintaining uniform messaging in their marketing of their different individual prescription opioids during different periods of time, 2AC ¶ 830, these allegations merely describe each Manufacturer Defendant engaging in its ordinary course of business—that is, independent parallel conduct. Neither that allegation nor any others establish a "framework or superstructure for making and carrying out decisions" for any collective RICO enterprise for fraudulent marketing. *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 793 (6th Cir. 2012). Also absent are allegations that the Opioid Marketing Enterprise had "established duties" for its members. *Id.* And despite Plaintiffs' conclusory allegations, 2AC ¶¶ 886, 894, they do not plead facts showing that the Opioid Marketing Enterprise had an existence "separate and distinct from the pattern of racketeering activity," *Ouwinga*, 694 F.3d at 793.

The ***only*** allegation of the existence of an association-in-fact enterprise is the fact that the Manufacturer Defendants marketed prescription opioids. To be sure, "evidence used to prove the pattern of racketeering activity and the evidence establishing an enterprise may in particular cases coalesce," *Boyle*, 556 U.S. at 947, but where, as here, that evidence consists of nothing more than parallel conduct by business competitors, it is insufficient as a matter of law to show an agreement or structure, *id.* at 947 n.4; *Twombly*, 550 U.S. at 553-54.

4. Plaintiffs Do Not Plead Any Actionable Racketeering Activity

Plaintiffs also fail to plead any actionable "racketeering activity." Under RICO, "racketeering activity" includes "any act 'indictable' under numerous specific federal criminal provisions." *Sedima S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 481-82 (1985) (quoting 18 U.S.C. § 1961(1)(B)). Plaintiffs allege two predicate acts of racketeering activity on their RICO Marketing Enterprise claim: mail and wire fraud under 18 U.S.C. §§ 1341 and 1343. 2AC ¶¶ 888-90, 944. To plead these predicate acts, Plaintiffs must allege a "[s]cheme to defraud" that

includes "false, deceptive, or fraudulent pretenses, representations, or promises." *Heinrich*, 668 F.3d at 404. Plaintiffs fail to do so, much less with the particularity required by Rule 9(b).

a. Plaintiffs' Own Allegations and the Legal Obligations of Prescribers To Be Aware of the Risks of the Opioids They Prescribe Negate Plaintiffs' Theory of Fraud

The central premise underlying Plaintiffs' unlawful marketing claims is that the Manufacturer Defendants concealed and minimized the well-known risks of prescription opioid addiction and abuse, which caused Ohio prescribers to write harmful and ineffective opioid prescriptions. *See* 2AC ¶¶ 174-76. Plaintiffs' fraud theory fails as a matter of law because the Manufacturer Defendants' FDA-approved product labels and other FDA-approved materials disclosed all relevant risks related to prescription opioids. *See Pizza Hut, Inc. v. Papa Johns Int'l, Inc.*, 227 F.3d 489, 495 n.5 (5th Cir. 2000) (an allegedly misleading "statement must be viewed in the light of the overall context"); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund* v. *Cephalon, Inc.* ("*Carpenters*"), 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (dismissing RICO claims for fraudulent marketing because prescribers are presumed to know a drug label's contents, which disclosed risks to "potential prescribing physicians").[19]

Plaintiffs concede that opioids' potential for "abuse and addiction" "[has] been recognized for millennia." 2AC ¶ 131. Indeed, the prescription opioids at issue here are among the most highly regulated drugs on the market, and patients can obtain them only through a

[19] *See also Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 553 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3rd Cir. 2015) (dismissing fraud-based claims against manufacturer for alleged false marketing because doctors are "sophisticated consumers who themselves have an affirmative duty to be familiar" with the labels of the medicines they prescribe); *Veracity Grp., Inc. v. Cooper-Atkins Corp.*, 2012 WL 203415, at *4 (S.D. Ohio Jan. 24, 2012) ("Whether 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."); *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991) ("Where a prescription drug has been prescribed . . . by the patient's physician, the manufacturer has been held to discharge its duty to warn if the manufacturer adequately warns the physician.").

prescription written by a licensed healthcare professional authorized to prescribe controlled substances. 21 C.F.R. §§ 1306.03(a)(1), 1306.11. In Ohio, prescribers have a duty to know the risks associated with drugs they prescribe. For example, Ohio's learned intermediary doctrine requires prescribers to know "the qualities and characteristics of the drugs or products to be prescribed for [a] patient's use," *Tracy*, 569 N.E.2d at 878, and Ohio regulations require that, when determining whether to prescribe a controlled drug, prescribers must consider its "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." O.A.C. § 4731-11-02(B); *see* O.R.C. § 4731.052(E).

In accordance with these state law requirements, FDA recognizes that a medication's FDA-approved labeling is the primary channel for communicating risk information to prescribers (and, through them, to patients). *See Aventis Pharm., Inc. v. Barr Labs., Inc.*, 411 F. Supp. 2d 490, 516-17 (D.N.J. 2006) (noting "FDA's expectation that physicians will use the cited safety information on the label . . . in choosing what medication to prescribe"); *see also* 21 C.F.R. § 201.56. In turn, physicians are presumed to transmit the labeling's warnings to their patients. *See Tracy*, 569 N.E.2d at 878-79.

Here, the Manufacturer Defendants' FDA-approved labeling has extensive, detailed information about the contraindications and risks associated with prescription opioids, including addiction, abuse and misuse, overdose, and death. Plaintiffs do not challenge the adequacy of the labeling for any prescription opioid. *See* 2AC ¶ 349 (alleging that statements were "contrary to the Manufacturer Defendants' products' labels"). For example, a Nucynta ER "black box" warning effective during the limitations period stated:

> **Addiction, Abuse, and Misuse**
> **NUCYNTA ER exposes patients and other users to the risks of opioid**

> **addition, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing NUCYNTA ER, and monitor all patients regularly for the development of these behaviors or conditions . . . .**
>
> **<u>Life-threatening Respiratory Depression</u>**
> **Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA ER. Monitor for respiratory depression, especially during initation of NUCYNTA ER or following a dose increase. Instruct patients to swallow NUCYNTA ER tablets whole; crushing, chewing, or dissolving NUCYNTA ER tablets can cause rapid release and absorption of a potentially fatal dose of tapentadol . . . .**

Ex. C ("Nucynta ER Label") at 4.[20]

The labeling details these risks and emphasizes the need for prescribers to monitor and counsel patients on proper opioid use. *E.g.*, Nucynta ER Label at 2. It also provides risk information directly to patients in Patient Medication Guides. *E.g.*, *id.* at 33-34. In addition, Plaintiffs allege that FDA has mandated risk evaluation and mitigation strategies ("REMS") for opioid medications that both "educate[d] prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" and imposed significant duties on prescribers both before and after writing opioid prescriptions. 2AC ¶ 473; *see* Ex. K ("FDA Press Release").[21]

Given the duty of prescribers to be aware of the risks associated with drugs they prescribe, as well as the Manufacturer Defendants' widespread dissemination of risk

[20] *See also, e.g.*, Ex. D at 5 & Exs. E-J at 4 (similar warnings for certain other of Manufacturer Defendants' drugs).

[21] As Plaintiffs acknowledge, before writing a prescription for a transmucosal immediate-release fentanyl opioid (like Actiq, Fentora, and Subsys), physicians must comply with the stringent requirements of a unique FDA-approved REMS tailored to that class of medications. 2AC ¶ 462. Among other things, the prescriber must pass a knowledge assessment, review FDA-approved medication guides and other educational materials with the patient, and sign an agreement (with the patient) confirming that the prescriber understands and has counseled the patient about the medicine's approved uses and risks. At each follow-up visit, the prescriber must assess the patient for appropriateness of the prescription and for signs of misuse and abuse. The TIRF REMS program precludes Plaintiffs' fraud and causation theory as to these medicines. *See Transmucosal Immediate-release Fentanyl Risk Evaluation and Mitigation Strategy (REMS)*, Ex. L ("TIRF REMS"), available at http://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_SS_2015-12-21_REMS_FULL.pdf.

information, Plaintiffs cannot plausibly allege that the Manufacturer Defendants fraudulently concealed or minimized such risks, thereby defrauding prescribers into writing medically inappropriate opioid prescriptions. Pursuant to the principles set forth in *Tracy*, *Pizza Hut*, *Carpenters*, and *Travelers*, Plaintiffs' claims should be dismissed.

b. Plaintiffs Fail to Plead Any Mail or Wire Fraud with the Requisite Particularity

Plaintiffs' RICO Marketing Enterprise claim is based entirely on allegations that the Manufacturer Defendants fraudulently marketed opioids in Summit County. *See, e.g.*, 2AC ¶ 879. But, despite over 1100 paragraphs of general and conclusory allegations, Plaintiffs have not pleaded any such fraudulent marketing anywhere ***in Summit County*** as to ***any*** Manufacturer Defendant with the particularity required by Rule 9(b). Indeed, Plaintiffs fail to identify even one transaction that led a prescriber to prescribe an ineffective or harmful opioid as a result of the alleged fraud. For instance, the 2AC fails to explain:

- ***who*** made or ***who*** received any alleged false statements in Summit County, including any particular prescriber who purportedly prescribed any medically inappropriate opioid;
- ***what*** specific false statements each (or any) Manufacturer Defendant made to Plaintiffs or to any prescriber in Summit County;
- ***where*** or ***when*** any specific false statement was made; and
- ***how*** any specific false statement by any Manufacturer Defendant affected any prescription by a prescriber in Summit County, including why the unidentified prescriber(s) prescribed the opioids in question, what conditions the opioids were prescribed to treat, or whether the patient received a benefit from that prescription.

Instead, Plaintiffs simply assert a series of conclusory allegations of fraud unconnected to any prescription, prescriber, or injury in Summit County. For this reason alone, Plaintiffs' RICO Marketing Enterprise claim should be dismissed. *See, e.g.*, *Marek v. Navient Corp.*, 2017 WL

2881606, at *6 (N.D. Ohio July 6, 2017); *Bender v. Southland Corp.*, 749 F.2d 1205, 1216 (6th Cir. 1984); *Amgen,* 400 F. App'x at 257; *Carpenters*, 2014 WL 2115498, at *7.[22]

The 2AC's allegations about the Manufacturer Defendants' "nine categories of misrepresentations" do not cure these deficiencies. 2AC ¶ 177. At best, those conclusory allegations refer only to general marketing activities, such as sponsoring third-party organizations, CMEs, publications, and studies. *See id.* ¶¶ 206, 235-39, 241-43, 247, 253-54, 264, 272, 275, 277, 279, 287-93. These allegations do ***not*** plead the details required under Rule 9(b). For example, only a few of the purported misrepresentations are alleged even to have been made in Summit County, *see id.* ¶¶ 675-76, 678-80, and again, none is connected to any patient, prescription, or injury suffered by any particular Plaintiff.

The same is true for Plaintiffs' allegations purporting to summarize interviews with Summit County prescribers allegedly detailed by sales representatives. The 2AC never identifies any such doctor or sales representative, nor does it allege what specific representations were made, when they were made, or whether any such representation in fact caused the prescriber to prescribe a medically unnecessary opioid. *Id.* ¶¶ 672-73. Plaintiffs themselves acknowledge that physicians, obligated under Ohio law to know the respective risks and benefits of medicines they prescribe, *see supra* § II(B)(4)(a), were told by the Manufacturer Defendants' sales representatives to prescribe opioids only to "appropriate" patients. 2AC ¶ 676. This is not actionable fraud. *See, e.g.*, *Carpenters,* 2014 WL 2115498, at *6; *see also supra* §§ II(B)(2), (B)(4)(a).

[22] *See also Dist. 1199P Health & Welfare Plan*, 784 F. Supp. 2d at 527-28; *Cent. Reg'l Empls. Benefit Fund*, 2010 WL 1257790, at *4; *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *10 (D.N.J. July 10, 2009); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 2009 WL 1703285, at *6-8 (C.D. Cal. June 17, 2009); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1049-52 (N.D. Cal. 2009); *Se. Laborers Health & Welfare Fund*, 655 F. Supp. 2d at 1277-78.

Worse yet, although the 2AC recognizes that the Manufacturer Defendants comprise twenty-two distinct companies spanning seven distinct corporate families, *see, e.g.*, 2AC ¶ 106, the 2AC repeatedly lumps them together and makes allegations about them as a whole—without differentiating among those disparate companies, their products, promotional techniques, or individual roles in the alleged fraud.[23] And much of the 2AC improperly combines the Manufacturer Defendants ***and*** the Distributor Defendants—an entirely distinct category of Defendants—and, thus, asserts allegations against this mixed group without any differentiation.[24] Plaintiffs' "group pleading" strategy violates basic pleading requirements. *See Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992); *Windsor-Laurelwood Ctr. Behavioral Med. v. Waller Lansden Dortch & Davis*, 2013 WL 12303992, at *5 (N.D. Ohio July 24, 2013).

In short, despite its prolixity, the 2AC fails to plead the details surrounding any specific alleged misrepresentation or omission made by any Manufacturer Defendant that led to a specific harmful prescription in Summit County. This basic failure requires dismissal of Plaintiffs' RICO Marketing Enterprise claim. *See, e.g.*, *Marek*, 2017 WL 2881606, at *6; *Bender*, 749 F.2d at

[23] *See* 2AC ¶¶ 10-12, 15, 63, 106, 141-42, 146, 151, 164, 170, 174-81, 186, 232-33, 240-41, 252, 255-57, 267-68, 281, 285-86, 294, 308, 348-54, 356, 360, 363-64, 367, 374, 376, 382, 391-92, 394-403, 406, 408-09, 414, 417, 424, 429-30, 432-33, 440-50, 452-55, 462, 465, 467, 470, 487, 488, 491, 493, 498-99, 513-14, 516, 527-30, 535, 540, 542, 548, 554-56, 575, 578, 602, 671, 673-74, 676, 678, 702, 708, 714, 771-72, 774, 778, 781-82, 815-16, 829-31, 835, 839, 859, 863, 884, 886, 989, 1013-15, 1019, 1021, 1046, 1053-54, 1073-77, 1079-81, 1083, 1088, 1116, 1126, 1132.

[24] *See* 2AC ¶¶ 13-14, 17-18, 20-22, 24, 26-27, 59-62, 128-29, 171-73, 183, 188, 233, 242, 252, 308, 352, 356, 361, 363, 365, 370-71, 378, 412, 432, 491, 494, 498-505, 512, 517-18, 520, 522-23, 525-26, 530-31, 534-35, 537, 541, 543-53, 557-66, 568, 570-71, 573-74, 576, 579-80, 585-93, 606, 610, 628, 672, 674, 686, 688, 701, 705, 709-10, 713-14, 760-70, 773, 775-81, 793, 796, 813, 849-50, 852-54, 857, 863, 870-71, 873, 896, 903, 922, 925, 927-29, 935, 966, 970, 982-92, 998, 1000-05, 1007, 1010-12, 1016-28, 1030, 1035-36, 1038, 1040-45, 1047-50, 1052-66, 1068, 1070-71, 1075, 1077, 1079-80, 1082, 1084-85, 1087-89, 1092-99, 1101-04, 1106, 1109, 1111, 1113-19, 1121, 1123-25, 1127-34.

1216; *Hoover*, 958 F.2d at 745; *Windsor-Laurelwood*, 2013 WL 12303992, at *5.

c. Plaintiffs Cannot Rely on Third-Party Statements Not Attributable to the Manufacturer Defendants to State a Claim Against the Manufacturer Defendants

The bulk of the alleged misrepresentations cited in the 2AC were made not by the Manufacturer Defendants, but by third-party physicians, medical organizations, and patient advocacy groups. *See, e.g.*, 2AC ¶¶ 350-441, 444-51, 462-64. But under basic principles of agency law, a defendant cannot be liable for statements made by a third party when, as here, the complaint fails to establish that the third party acted as the defendant's agent with respect to the challenged statements. *See McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008). In Ohio, the "central factor" in determining whether an agency relationship exists is the "right of control" vested in the principal. *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416-17 (S.D. Ohio. 1986). Plaintiffs have not pleaded the existence of an agency relationship here.[25]

Although the 2AC applies suggestive labels like "Front Groups," and alleges in conclusory fashion that the Manufacturer Defendants "exerted influence and effective control" over third parties, 2AC ¶ 352, it alleges no ***facts*** explaining how any Manufacturer Defendant controlled the content of third-party statements, or how any Manufacturer Defendant's purported control led to the specific statements that Plaintiffs challenge. Instead, the 2AC relies on vague and conclusory allegations that the Manufacturer Defendants "took an active role in guiding, reviewing, and approving many of the misleading statements issued by" third-parties, *id.* ¶ 356, and that the Manufacturer Defendants funded research, educational programs, or advocacy organizations, *id.* ¶¶ 206, 212-13, 354, 363, 370-71, 384, 396-97, 433. Allegations of

[25] To the extent Plaintiffs seek to hold the Manufacturer Defendants liable for third-party statements under a RICO enterprise or conspiracy theory of liability, these claims fail for the additional reasons stated *supra* § II(B)(3) and *infra* §§ III(B)(3), XIII.

sponsorship alone, however, are insufficient to establish an agency relationship. *See Gen. Bldg. Contractors Ass'n v. Pennsylvania*, 458 U.S. 375, 395 (1982); *City of Chi.*, 2015 WL 2208423, at *11.[26]

Plaintiffs' mere speculation about the potential effect of the Manufacturer Defendants' sponsorship of third parties, *see* 2AC ¶¶ 352, 441, is patently inadequate to state a claim. *See Twombly*, 550 U.S. at 555. Plaintiffs' failure to allege facts sufficient to establish control over and responsibility for attributing third-party statements to the Manufacturer Defendants compels dismissal of all unlawful marketing claims premised on such statements. *See id.*; *City of Chi.*, 2015 WL 2208423, at *11; *McWilliams*, 581 F. Supp. 2d at 893.

III. PLAINTIFFS' RICO SUPPLY CHAIN ENTERPRISE CLAIM FAILS (COUNT 2)

Plaintiffs' RICO Supply Chain Enterprise claim is equally deficient.

A. Plaintiffs Lack Statutory Standing and Cannot Use RICO to Circumvent the Absence of a Private Cause of Action Under the CSA

Plaintiffs' Supply Chain Enterprise claim fails to allege a cognizable injury and establish RICO standing for the same reasons as their RICO Marketing Enterprise claim. *See supra* at § II(A).

Plaintiffs also lack standing for the RICO Supply Chain Enterprise claim for another reason. At bottom, Plaintiffs' claim is an attempt to hold the Manufacturer Defendants liable for failing to satisfy purported obligations to monitor, report, and halt suspicious orders under the Controlled Substances Act ("CSA"), 21 U.S.C. § 823, and its implementing regulations. 2AC ¶¶ 956-58. However, the Manufacturer Defendants owe no purported duty to ***Plaintiffs*** to monitor, report, or stop shipment of suspicious orders. Instead, the relevant DEA regulation provides only that "[t]he registrant shall ***inform the Field Division Office of the [DEA]*** . . . of suspicious

[26] *See also Batzel v. Smith*, 333 F.3d 1018, 1036 (9th Cir. 2003); *Protostorm, LLC v. Antonelli, Terry, Stout & Kraus, LLP*, 834 F. Supp. 2d 141, 162 (E.D.N.Y. 2011).

orders when discovered by the registrant." 21 C.F.R. § 1301.74(b). And it is solely "the ***Administrator*** [who] shall use the security requirements set forth [under federal law]" "[i]n order to determine whether a registrant has provided effective controls against diversion." *Id.* § 1301.71(a). In accordance with these regulations, the right to determine violations and enforce any such duty rests exclusively with the federal government, not Plaintiffs. *See Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010). Indeed, "federal courts uniformly have held that there are no private rights of action under the CSA." *Safe Sts. Alliance v. Alternative Holistic Healing, LLC*, 2016 WL 223815, at *3 (D. Colo. Jan. 19, 2016), *aff'd*, 859 F.3d 865 (10th Cir. 2017); *Durr*, 602 F.3d at 789 ("no private right of action exists under" the CSA). Plaintiffs cannot use RICO or any state law to circumvent the absence of any private cause of action in the CSA. Therefore, Plaintiffs' claims should be dismissed to the extent they are an impermissible "end-run" around the federal government's exclusive authority to bring enforcement actions under the CSA. *See Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011); *Safe Sts. Alliance*, 2016 WL 223815, at *3.[27]

B. Plaintiffs Fail to Plead Causation and Other Elements Under RICO

1. Plaintiffs Fail to Allege That the Manufacturer Defendants' Purported Failures to Report Were the But-For Cause of the Alleged Harms

Like their Marketing Enterprise claim, Plaintiffs' RICO Supply Chain Enterprise claim fails to adequately plead but-for causation. *See supra* § II(B)(1). Plaintiffs allege that but for the Manufacturer Defendants' purported failure to monitor and report suspicious orders of prescription opioids to DEA Field Division Offices, Plaintiffs would not have suffered any

[27] *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1289-90 (C.D. Cal. 2008) (dismissing fraud-based claims that merely sought "to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder" because "what the FDCA does not create directly, RICO cannot create indirectly").

injuries associated with prescription opioid misuse, abuse, and addiction. 2AC ¶¶ 931, 935.

Instead, Plaintiffs provide only vague and conclusory allegations that the Manufacturer Defendants' failure to report suspicious orders to DEA increased the supply of prescription opioids in Summit County by some unspecified amount. *See, e.g.*, *id.* ¶¶ 502, 594. Plaintiffs, however, provide no allegations suggesting that, had the Manufacturer Defendants reported "suspicious" orders to DEA, then (1) those reports would have led to an enforcement action, and (2) any enforcement action would in fact have averted prescription opioid diversion and related societal harms in Summit County. Nor have Plaintiffs alleged any facts suggesting that, had the Manufacturer Defendants reported suspicious orders to DEA, then (1) DEA would have relied on those reports and set lower national production quotas, and (2) lowering national production quotas would have averted prescription opioid diversion and related societal harms in Summit County. Plaintiffs' RICO Supply Chain Enterprise claim is thus "too speculative to satisfy but-for causation." *Bourke v. Vill. of Downers Grove*, 2009 WL 1531809, at *5 (N.D. Ill. May 29, 2009).

2. The Causal Chain Connecting the Manufacturer Defendants' Alleged Failures to Report and Plaintiffs' Alleged Injuries is Too Indirect to Establish Proximate Causation

Plaintiffs' alleged connection between the Manufacturer Defendants' purported failure to report and prevent suspected diversion and Plaintiffs' claimed injuries is too indirect to establish proximate cause. Plaintiffs' proposed chain of causation requires, at minimum:

(1) the Manufacturer Defendants failed to comply with their alleged duties to monitor, report, and stop shipment of "suspicious orders" of prescription opioids;

(2) the distributors, which are intermediate links in the chain of distribution and have separate monitoring and reporting obligations, failed to comply with their alleged duties in monitoring, reporting, and stopping shipments of those same "suspicious orders";

(3) those "suspicious orders" were subsequently distributed;

(4) retailers filled prescription opioids from those "suspicious orders";

(5) patients and/or residents in Summit County misused, abused, and/or diverted those prescription opioids for illicit use and/or began using illicit opioids due to use of an opioid medication filled through the "suspicious order";

(6) patients and/or residents were physically harmed as a result of those prescription opioids and/or that diversion; and

(7) Plaintiffs incurred costs or lost tax revenue as a result of that harm to patients or residents that would not have occurred but for the Manufacturer Defendants' alleged failure to report "suspicious orders."

As with Plaintiffs' RICO Marketing Enterprise claim, this causal chain is too attenuated, remote, and speculative to establish proximate causation. *See supra* § II(B)(2) (citing cases).

3. Plaintiffs Fail to Plead the Existence of an "Opioid Supply Chain Enterprise"

Plaintiffs also fail to allege with particularity the existence of the so-called "Opioid Supply Chain Enterprise."[28] For example, Plaintiffs allege that the enterprise had the "common purpose" of "vastly increasing [its members'] ***respective*** profits and revenues," 2AC ¶ 849, by maintaining informal business relationships through the joint participation in trade associations and organizations, *see, e.g.*, *id.* ¶¶ 855, 909, and by engaging in parallel manufacturing activities. But as discussed *supra* § II(B)(3), allegations that business competitors engaged in parallel conduct to increase their respective profits are insufficient to establish a racketeering enterprise.

Indeed, Plaintiffs barely attempt to allege ***any*** framework or structure to support this supposed enterprise. 2AC ¶¶ 849-77. The 2AC alleges that the Manufacturer Defendants formed unspecified business relationships through their participation in trade organizations like the Healthcare Distribution Alliance ("HDA"). *Id.* ¶ 853. But Plaintiffs do not explain how such relationships constitute the necessary "framework or superstructure for making and carrying out

[28] The alleged "Opioid Supply Chain Enterprise" consists of Purdue, Cephalon, Endo, Mallinckrodt, Actavis, and wholesale distributors McKesson, Cardinal, and AmerisourceBergen. 2AC ¶ 878.

[enterprise-related] decisions." *Ouwinga*, 694 F.3d at 793. As a matter of law, they do not. *See Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017); *Consol. Metal Prods., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 293-94 (5th Cir. 1988). Plaintiffs' attempt to establish the existence of an "Opioid Supply Chain Enterprise" thus fails. *See id.*; *Greenberg v. Blake*, 2010 WL 2400064, at *6 (E.D.N.Y. June 10, 2010).

4. Plaintiffs Fail to Plead Any Actionable Racketeering Activity

Plaintiffs' RICO Supply Chain Enterprise claim against the Manufacturer Defendants is predicated entirely on the contention that pharmaceutical manufacturers have federal and state law duties to maintain effective controls to prevent the unlawful diversion of prescription opioids. *See* 2AC ¶¶ 501-510. Specifically, Plaintiffs assert that, under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74(b), as incorporated into Ohio law,[29] the Manufacturer Defendants had a duty to establish and maintain effective anti-diversion programs that (1) detected suspicious orders, and (2) stopped shipment of orders deemed suspicious and permitted shipment of orders flagged as potentially suspicious if the order likely will not be subject to diversion. *Id.* ¶¶ 9, 498, 501-10. This theory fails at multiple levels.

a. Alleged Failure to Comply with DEA Monitoring and Reporting Requirements Cannot Serve As a Predicate Act

Under a plain reading of the RICO statute, the Manufacturer Defendants' alleged failure to comply with CSA or DEA regulations concerning suspicious order reports cannot serve as a RICO predicate act. *See* 18 U.S.C. § 1961(1). Although certain conduct involving the manufacture and distribution of controlled substances may constitute a predicate act if it is "punishable by imprisonment for ***more than one year***," *id.*, failure to monitor and report

[29] To the extent Plaintiffs' Opioid Supply Chain Enterprise claims also allege violation of O.R.C. § 4729.01(F) and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28, *see* 2AC ¶¶ 984, 1058, none of these provisions applies to the Manufacturer Defendants, for the reasons stated *infra* § VIII.

suspicious orders amounts to (at most) a violation of 21 U.S.C. § 842(a)(5), which is punishable by imprisonment of ***not more*** than one year, *id*. § 842(c).

Moreover, Plaintiffs' allegations regarding the Manufacturer Defendants' purported failure to report and halt suspicious orders fail on their own terms. *First*, the Manufacturer Defendants have no duty to monitor, prevent, or report the ***downstream*** diversion of prescription opioids at the pharmacy or physician level, where diversion occurs. DEA regulations require only that the Manufacturer Defendants, as DEA registrants, "design and operate a system to disclose to the registrant suspicious ***orders*** of controlled substances," and "inform [DEA] of suspicious ***orders*** when discovered by the registrant." 21 C.F.R. § 1301.74(b). Under the regulation's plain text, the Manufacturer Defendants' duty extends only to monitoring and reporting suspicious orders placed with them by their direct customers (e.g., pharmaceutical distributors).

Second, the Manufacturer Defendants have no duty to stop shipment of "suspicious orders." As noted above, DEA regulations require only that the Manufacturer Defendants "design and operate a system" for the ***"disclos[ure]"*** of suspicious orders and to "***inform*** [DEA]" of those orders. *Id.* Nothing in the CSA or DEA regulations imposes Plaintiffs' proposed "stop-shipment" requirement for suspicious opioid orders.[30]

[30] To the extent Plaintiffs allege that the Manufacturer Defendants had common law duties to report and decline to ship "suspicious orders" independent of federal or state statute or regulation, 2AC ¶ 505, no such duties exist under Ohio common law. "Generally, there is no duty [under Ohio law] to prevent a third person from causing harm to another absent a special relation between the parties." *Desir v. Mallett*, 2015 WL 3492499, at *6 (Ohio Ct. App. June 2, 2015). Plaintiffs have not alleged any special relationship here. Plaintiffs' bare contention that the Manufacturer Defendants "were negligent" because "an illegal, secondary prescription opioid market [] resulted in a foreseeable and unreasonable risk of harm to Plaintiffs," 2AC ¶ 1049, is similarly insufficient to create a duty. *See Simpson v. Big Bear Stores Co.*, 652 N.E.2d 702, 705 (Ohio 1995) ("Foreseeability alone is insufficient to create liability.").

b. Plaintiffs Fail to Plead Any Mail or Wire Fraud with the Requisite Particularity

In a transparent attempt to manufacture an actionable RICO claim, Plaintiffs instead purport to base their RICO Supply Chain Enterprise claim on three predicate fraud activities: (1) federal mail fraud, (2) federal wire fraud, and (3) furnishing false or fraudulent information in documents filed with DEA, in violation of the CSA, 21 U.S.C. § 843(a)(4). 2AC ¶¶ 911-16. Those allegations fail to plead actionable racketeering activity, much less with the particularity required by Rule 9(b).[31] As with Plaintiffs' RICO Marketing Enterprise claim, the RICO Supply Chain Enterprise allegations similarly fail to satisfy Rule 9(b). Plaintiffs fail to identify even ***one*** false or misleading statement or omission regarding the Manufacturer Defendants' alleged violations of their purported federal and state diversion monitoring obligations—let alone plead with particularity facts involving any alleged "suspicious" prescription opioid orders placed in, or otherwise affecting, Summit County residents. 2AC ¶¶ 501-606. In addition, the 2AC nowhere identifies any of the other requisite details to state a claim based on such orders, including:

- ***what*** allegedly false or misleading statements or omissions the Manufacturer Defendants made, ***when*** they were submitted, and ***why*** they were false;
- regarding ***what*** "suspicious orders" of prescription opioids should not have been shipped into the Summit County;
- ***how*** the Manufacturer Defendants knew such orders would be diverted by downstream users for illicit uses; and
- ***what*** purported harm(s) resulted in Summit County from these alleged failures to report and/or false or misleading reports.[32]

[31] RICO's list of predicate acts does not include alleged violations of § 843(a)(4), which relates solely to the fraudulent furnishing or omission of information in documents "made, kept, or filed" under the CSA. 21 U.S.C. § 843(a)(4). Rather, predicate acts involving controlled substances are limited to "the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance." 18 U.S.C. § 1961(1)(D).

[32] *See* 2AC ¶¶ 838, 840-41, 846, 854-56, 859-61, 866, 871, 874, 877, 879, 885, 890-91, 900-02, 911, 916, 921-22, 928, 933, 944, 946, 955, 960, 962-67.

Plaintiffs' failure to plead these details in connection with any specific instance of alleged mail or wire fraud by any Manufacturer Defendant in Summit County requires dismissal of their RICO Supply Chain Enterprise claim. *See Aaron v. Durrani*, 2014 WL 996471, at *6 (S.D. Ohio Mar. 13, 2014).

IV. PLAINTIFFS' STATE LAW CLAIMS (COUNTS 3-11) ARE PREEMPTED

Plaintiffs' state law claims in this lawsuit should be dismissed as preempted because they conflict with FDA's decisions about the approval and labeling for the Manufacturer Defendants' medications.[33]

A. Plaintiffs' Claims Challenging Promotion Consistent with FDA-Approved Labeling and for Off-Label Uses Are Preempted and Barred

Implied preemption arises when it is "impossible" for a defendant to comply with both state and federal law, or when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). The Supreme Court has made clear that claims seeking to impose a duty to alter FDA-approved labeling or otherwise market FDA-approved prescription medications in a way that conflicts with federal law are subject to implied preemption under the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq. Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-89 (2013). This is true regardless of whether the claims challenge the FDA-approved labeling, or instead challenge marketing materials that are consistent with FDA-approved labeling. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013).

Here, the core assertion on Plaintiffs' unlawful marketing claims is that the Manufacturer

[33] The same analysis applies to defeat Plaintiffs' RICO Marketing Enterprise claim. Indeed, although preemption involves "the question [of] whether state law is pre-empted by a federal statute," preemption principles are "instructive" in cases "concern[ing] the alleged preclusion of a cause of action under one federal statute" (here, RICO) "by the provisions of another federal statute" (here, the FDCA). *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014).

Defendants falsely represented opioids as safe and effective for the long-term treatment of chronic non-cancer pain. *See, e.g.*, 2AC ¶¶ 10-11, 175, 180, 274, 281-84, 349. But FDA has ***approved*** many opioid medications for long-term use in treating chronic pain, including most of the ER/LA opioid medications at issue here. *See, e.g.*, Ex. D ("OxyContin Label") at 2. And FDA approval necessarily means that FDA found "substantial evidence that the drug will have the effect it purports or is represented to have" and that these medications are safe and effective for treating chronic pain. 21 U.S.C. § 355(d); *see also* FDA Response at 3.

Courts have repeatedly held that state law claims are preempted where, as here, they would require a prescription drug manufacturer to make statements about safety or efficacy that differ from what FDA required after it evaluated the information at issue. *See, e.g.*, *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 386 (6th Cir. 2017); *In re Celexa and Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42-43 (1st Cir. 2015); *Utts v. Bristol-Meyers Squibb Co.*, 251 F. Supp. 3d 644, 663-73 (S.D.N.Y. 2017). Here too, Plaintiffs' claims challenging the Manufacturer Defendants' marketing of medications as unsafe and ineffective for their approved uses are preempted.

In addition, to the extent Plaintiffs seek to recover from the Manufacturer Defendants for alleged promotion of their medications' "off-label" uses (i.e., uses beyond those approved by FDA), these claims are also preempted. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 347 (2001). The FDCA provides FDA with exclusive authority and a "variety of enforcement options" to address alleged off-label promotion; this flexibility is a "critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing objectives)," with respect to off-label promotion, *id.* at 349, particularly given that federal law recognizes the potential health benefits of allowing physicians to prescribe drugs

and devices for off-label uses when, in their medical judgment, that is the best treatment for a particular patient. *Id*. at 350-51 & n.5; *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) ("[C]ourts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use.").

Thus, because "[t]he restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA," and "[t]he FDCA does not provide a private right of action" to enforce its provisions, state law claims based on alleged off-label promotion are preempted. *Perdue v. Wyeth Pharms., Inc.*, 209 F. Supp. 3d 847, 851-52 (E.D.N.C. 2016); *see also McDaniel v. Upsher-Smith Pharms., Inc.*, 229 F. Supp. 3d 707, 713 (W.D. Tenn. 2017); *Caltagirone v. Cephalon, Inc.*, 2018 WL 2126405, at *3 (Pa. Super. Ct. May 9, 2018).

B. Plaintiffs' Claims Seeking to Hold Defendants Liable for Not Stopping Sales of Prescription Opioids Are Preempted by Federal Law

Under the doctrine of obstacle preemption, a state law is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000). Plaintiffs' diversion monitoring theory would present such an obstacle by hindering Congress's objectives under the FDCA.

In enacting the FDCA, a "core objective[]" of Congress was to "ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting 21 U.S.C. § 393(b)(2)). To that end, Congress vested FDA with the sole authority to determine whether a drug should be introduced into—and kept on—the market. And it set criteria for FDA to make those determinations. For instance, before approving a new drug, FDA must first determine whether 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 and effective for its approved indications. 21 U.S.C. § 355(d); *see* 21 C.F.R. § 314.50; *Bartlett*, 570 U.S. at 476. If, after approval, FDA determines that the drug is ***not*** safe or effective, it "shall, after due notice and opportunity for hearing to the applicant, withdraw approval of the drug." *Brown*, 529 U.S. at 134.

Time and again, courts have held that this regulatory scheme preempts any state law claim seeking to prohibit drug manufacturers from selling their FDA-approved products as permitted by FDA. *See*, *e.g.*, *Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *1-2 (D. Mass. Apr. 15, 2014); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (requiring a drug manufacturer "to stop production of a drug" "would directly conflict with" FDA's "sole authority . . . to determine whether a drug may be marketed."), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014).[34]

Zogenix is instructive. There, the court enjoined Massachusetts from enforcing a state regulation banning doctors and pharmacists from prescribing and dispensing Zohydro ER, an ER/LA opioid not at issue here, until the state "determined that adequate measures to safeguard against diversion, overdose, and misuse had been implemented." 2014 WL 1454696, at *1. The court held that Massachusetts's ban was preempted because it "obstruct[ed] the FDA's Congressionally-given charge" to "approve for sale to the public a range of safe and effective prescription drugs," and if Massachusetts "were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health." *Id.* at *2. The court distinguished *Wyeth*,

[34] *See also, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015); *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012); *cf. Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) (decision whether a drug may be sold over the counter or by prescription "is for the FDA to make").

which permits (as not preempted) certain state tort suits challenging the adequacy of drug labeling, on the ground that "*Wyeth* ***assumed the availability*** of the drug at issue." *Id.* In other words, while state law claims seeking stronger labeling disclosures may "complement[]" FDA's efforts to ensure safe pharmaceutical products, *Wyeth*, 555 U.S. at 578-79, an attempt to ***restrict*** or ***ban*** the availability of such products impermissibly obstructs FDA's role. *See also Bartlett*, 570 U.S. at 488.

Here, Plaintiffs contend that the Manufacturer Defendants had a duty not to sell their prescription opioids due to concerns with opioid diversion. 2AC ¶ 932. They seek both to hold the Manufacturer Defendants liable for not doing so, *id.* ¶ 938, and the issuance of "[a]n order enjoining any further violations" of this purported duty, *id*. As in *Zogenix*, allowing these claims to proceed "would undermine the FDA's" decision to make (and keep) the Manufacturer Defendants' prescription opioids available to the public (*see supra* §§ II(B)(4)(a), IV(A)). 2014 WL 1454696, at *2. Plaintiffs' effort to impose such restrictions via this lawsuit is preempted. *See id.* at *1-2; *Gross*, 825 F. Supp. 2d at 659.

V. PLAINTIFFS' OCPA CLAIMS FAIL (COUNTS 3-4)

Because the OCPA is "patterned" on RICO, the "analysis of [RICO] applies equally" to OCPA claims. *Aaron*, 2014 WL 996471, at *8. Accordingly, Plaintiffs' Marketing Enterprise and Supply Chain Enterprise claims under the OCPA should be dismissed for substantially the same reasons described above, specifically:

- Plaintiffs fail to plead actual and proximate causation, *see supra* §§ II(B)(1)-(2), III(B)(1)-(2), *City of Cleveland*, 615 F.3d 496 at 503 ("The Ohio Supreme Court has adopted [the *Holmes*] proximate cause analysis.");
- Plaintiffs fail to plead the existence of either an "Opioid Marketing Enterprise" or "Opioid Supply Chain Enterprise," *see supra* §§ II(B)(3), III(B)(3);
- Plaintiffs fail to plead any actionable racketeering activity, including with the particularity required under Rule 9(b), *see supra* §§ II(B)(4), III(B)(4), O.R.C. §

2923.31(I)(1) ("corrupt activity" includes "racketeering activity" under § 1961(1)); and

- The claim is preempted, *see supra* § IV.

Plaintiffs' OCPA claims fail for an additional reason: Plaintiffs do not allege a "pattern" of racketeering activity. To establish a "pattern" of racketeering activity under the OCPA, a plaintiff must allege "at least one incident other than" a violation of the federal mail or wire fraud statutes. O.R.C. § 2923.34(A). Here, however, Plaintiffs' OCPA Marketing Enterprise claim alleges only incidents of mail and wire fraud as predicate acts. 2AC ¶¶ 944, 955, 961.

In an attempt to side-step the OCPA's requirements, Plaintiffs allege, in conclusory fashion, that the purported OCPA Marketing Enterprise and OCPA Supply Chain Enterprise both committed "telecommunications fraud" in violation of O.R.C. § 2913.05. *Id.* Ohio's telecommunications fraud statute, however, is substantively identical to the federal mail and wire fraud statutes. *Compare* O.R.C. § 2913.05(A) *with* 18 U.S.C. § 1341 *and* 18 U.S.C. § 1343. And as Plaintiffs concede, the acts that constitute the Manufacturer Defendants' alleged telecommunications fraud are the same acts that constitute their alleged federal mail and wire fraud. *See* 2AC ¶ 944 (alleging the Manufacturer Defendants' purported mail and wire fraud "***also*** constitute a pattern of telecommunications fraud"). Accordingly, any "incident" that constitutes a "violation" one of Ohio's telecommunications fraud statutes is also an "incident" that constitutes a "violation" of the federal mail and wire fraud statutes. O.R.C. § 2923.34(A). Because the Manufacturer Defendants' alleged telecommunications fraud does not stem from a separate "incident," it cannot establish a pattern of racketeering activity under the OCPA. *See id.*

And although Plaintiffs attempt to allege an additional predicate act for violation of 21 U.S.C. § 843 on their OCPA Supply Chain Enterprise claim, 2AC ¶¶ 955, 961, the OCPA does not recognize a violation of that statute as a predicate act, either directly or by incorporation. *See*

O.R.C. §§ 2923.31(I)(2)(a)-(g) (listing predicate state crimes), 2923.31(I)(1) (incorporating a subset of RICO predicate acts, none of which is § 843; *see also supra* n.31)). Thus, alleged violations of 21 U.S.C. § 843 also cannot serve to establish the requisite pattern of racketeering activity under the OCPA. *Mercy Health Partners of Sw. Ohio v. Miller*, 2005 WL 2592674, at *4 (Ohio Ct. Com. Pl. Sept. 30, 2005).

VI. THE COMMON LAW AND STATUTORY PUBLIC NUISANCE CLAIMS (COUNTS 5-6) ARE ABROGATED BY THE OHIO PRODUCT LIABILITY ACT

Plaintiffs' common law and statutory public nuisance claims are conventional products liability claims under the Ohio Product Liability Act ("OPLA"), O.R.C. § 2307.71 *et seq.*, and, as such, should be dismissed as abrogated by the OPLA as detailed in the Distributor Defendants' memorandum in support of their motion to dismiss (Dkt. No. 491-1). The Manufacturer Defendants thus adopt by reference § II.A. of that memorandum. Moreover, even if Plaintiffs' nuisance claims are not abrogated, they nevertheless fail for other, independent reasons as described *infra* §§ VII-VIII.

VII. THE COMMON LAW PUBLIC NUISANCE CLAIM FAILS (COUNT 6)

Count 6 is a sweeping common law absolute public nuisance claim that alleges that the Manufacturer Defendants' marketing and sale of their medications caused the full spectrum of public health, criminal, and social problems associated with the abuse and diversion of prescription opioid medications and sales and use of illicit drugs in these municipalities. 2AC ¶ 1002. Ohio courts have dismissed other attempts to use public nuisance law to regulate entire industries and to impose liability for social ills that are many times removed from the conduct alleged. Plaintiffs' claim too should be dismissed for two independent reasons: (1) it is barred by the economic loss rule; and (2) in any event, it is not adequately pleaded.[35]

[35] Plaintiffs' common law public nuisance claim also fails on preemption grounds. *See supra* §

A. The Claim Is Barred by the Economic Loss Rule

In Ohio, the economic loss rule "prevents recovery in tort of damages for purely economic loss" due to the defendants' negligence. *Kamnikar v. Fiorita*, 2017 WL 2817467, at *5 (Ohio Ct. App. June 29, 2017). "[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 compensable." *Corporex Dev. & Constr. Mgmt., Inc. v. Shook, Inc.*, 835 N.E. 2d 701, 704 (Ohio 2005); *see also RWP, Inc. v. Fabrizi Trucking & Paving Co.*, 2006 WL 2777159, at *3 (Ohio Ct. App. Sept. 28, 2006). Here, Plaintiffs' common law nuisance claim seeks to recover only Plaintiffs' economic loss, including the costs of addiction treatment and social, healthcare, and law enforcement services. *See, e.g.*, 2AC ¶¶ 20, 734, 744, 1006, 1062. Plaintiffs' common law nuisance claim is therefore barred by the economic loss rule.

B. Plaintiffs Do Not Plead Actual and Proximate Causation

In Ohio, actual and proximate cause are essential elements for common law public nuisance. *Deutsche Bank*, 863 F.3d at 480; *City of Cleveland*, 615 F.3d at 502-03. Plaintiffs, however, fail to plead actual cause on both the unlawful marketing and diversion control theories for the reasons discussed *supra* (§§ II(B)(1), III(B)(1)). Any connection between the Manufacturer Defendants' alleged misconduct and the alleged opioid crisis is too attenuated and remote to establish proximate causation as a matter of law, as Plaintiffs' alleged injuries all depend on multiple independent, intervening events and decisions by unrelated third parties. Indeed, allowing public nuisance claims in circumstances like these would "open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these [manufacturer] defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities." *People v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 96

IV.

(N.Y. App. Div. 2003); *see also Hester v. Dwivedi*, 733 N.E.2d 1161, 1165 (Ohio 2000); *Hunt v. Marksman Prod. Div. of S/R Indus., Inc.*, 656 N.E.2d 726, 728 (Ohio Ct. App. 1995); *Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 663 (8th Cir. 2009).

In *Ashley*, for example, Arkansas counties brought claims against pharmaceutical companies for public nuisance and deceptive trade practices, seeking "compensation to recoup the costs expended by the counties in dealing with the societal effects of the methamphetamine epidemic in Arkansas, with liability premised on the use of the Defendants' products in the methamphetamine manufacturing process." 552 F.3d at 663. In affirming dismissal, the Eighth Circuit determined that "[p]roximate cause seems an appropriate avenue for limiting liability in this context . . . particularly where an effect may be a proliferation of lawsuits not merely against these defendants but against other types of commercial enterprises—manufacturers, say, of liquor, anti-depressants, SUVs, or violent video games—in order to address a myriad of societal problems regardless of the distance between the 'causes' of the 'problems' and their alleged consequences." *Id.* at 671-72. The same analysis applies and supports dismissal of Plaintiffs' nuisance claim here.

C. Plaintiffs Fail to Plead the Remaining Elements for a Public Nuisance Under Ohio Law

Ohio law defines a public nuisance as "an unreasonable interference with a right common to the general public." *City of Cincinnati v. Beretta*, 768 N.E.2d 1136, 1142 (Ohio 2002). Further, to establish an ***absolute*** public nuisance as Plaintiffs allege here, a plaintiff must show that the defendant's conduct was intentional.[36] *Brown v. Scioto Cty. Bd. of Comm'rs*, 622 N.E.2d

[36] The other basis for an absolute nuisance in Ohio—inherently dangerous activities that cannot be maintained even with due care—is not alleged here. *Deutsche Bank*, 863 F.3d at 478. Nor could it be alleged, given FDA's conclusion, when approving each of the medications at issue, that physicians should be permitted to prescribe them to patients, notwithstanding their known risks.

1153, 1159 (Ohio Ct. App. 1993). Plaintiffs have failed to allege an intentional, unreasonable interference with a public right.

No public right. In Ohio, a public right is "collective in nature," Restatement (Second) of Torts § 821B cmt. g., and is held "common to all members of the public," *Brown*, 622 N.E.2d at 1158. "Conduct does not become a public nuisance merely because it interferes with a large number of people." *Id.* Examples of such "public rights" include "a right of public passage (e.g., obstruction of highways); a right to use public space (e.g., pollution of fisheries); [and] a right to navigable waterways (e.g., obstruction of public streams)." *Deutsche Bank*, 863 F.3d at 477. There is no public right, however, "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." *Chi. v. Beretta U.S.A. Corp.*, 821 N.E. 2d 1099, 1116 (Ill. 2004).[37]

Here, Plaintiffs' alleged harms are derived solely from alleged injuries to individuals who misused, abused, or were addicted to prescription opioids. *See supra* § II(A), II(B)(2), III(A), III(B)(2). Accordingly, any rights with which the Manufacturer Defendants allegedly interfered—including any right not to be injured through harmful or ineffective prescription medications—are strictly individual, *see State v. Lead Indus. Ass'n, Inc.*, 951 A.2d 428, 454 (R.I. 2008) ("[T]here is no common law public right to . . . a certain standard of medical care[.]"), and not held "common to all," *Brown*, 622 N.E.2d at 1158. The fact that a large number of people may suffer from opioid addiction does not transform this collection of individual issues into a

[37] Although the Ohio Supreme Court in *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002), held that widespread possession of guns by criminals could interfere with a common right "to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property," (*City of Cincinnati v. Beretta*, 2002 WL 34429690 (Ohio Ct. Com. Pl. Aug. 14, 2002), Compl. ("*Beretta* Compl.") ¶ 110)), the apprehension of danger to person and property among any and all members of the community present in *Beretta* is not alleged here.

public right. Restatement (Second) of Torts § 821B cmt. g.

No unreasonable interference. Second, Plaintiffs cannot establish that the Manufacturer Defendants unreasonably interfered with any supposed public right. "Ohio courts have long imposed the following concrete limitation on public nuisance claims: What the law sanctions cannot be held to be a public nuisance." *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 621 F. Supp. 2d 513, 526 (N.D. Ohio 2009). This limitation creates a "safe harbor" from nuisance liability where "the challenged conduct is subject to regulation and was performed in conformance therewith." *Id.* at 528.

Here, the manufacture, promotion, sale, and use of prescription opioid medications are extensively regulated by federal and state statutes and agencies. Like FDA, the General Assembly has authorized the use of opioids for the long-term treatment of chronic non-cancer pain. *See* O.R.C. §§ 3719.06(A)(1)(a), 4731.052; O.A.C. § 4123-6-21.7; *supra* § II(B)(4)(a), IV. And both federal law and Ohio law regulate the manufacture, sale, and use of prescription opioid medications, creating a "closed system" of distribution under which licensed manufacturers may sell only to licensed wholesalers, licensed wholesalers only to licensed pharmacies, and licensed pharmacies only to individuals with legitimate prescriptions—who are then prohibited from distributing their medications to any other person. 21 U.S.C. §§ 823(a)-(b), (e), 829, 844, 844a; 28 C.F.R. § 0.100; O.R.C. § 2925.11. Plaintiffs have not pleaded facts establishing that the Manufacturer Defendants have failed to comply with those requirements with respect to any prescription written in Summit County. *See supra* §§ II(B), III(B), IV. The public nuisance claim against the Manufacturer Defendants—whether for marketing or selling opioids—fails as a

matter of law. *See Ameriquest*, 621 F. Supp. 2d at 526-31.[38]

No allegation of necessary intent. Plaintiffs also fail to adequately plead the intent required to state a claim for absolute public nuisance. An allegation that a party "knew or should have known" that its conduct would create a public nuisance "does not equal intention." *Deutsche Bank*, 863 F.3d at 478. Yet Plaintiffs allege only that the Manufacturer Defendants "knew or should have known" their conduct would "produce[] an ongoing nuisance." 2AC ¶ 1003. The claim requires dismissal for this reason alone.

VIII. THE STATUTORY PUBLIC NUISANCE CLAIM FAILS (COUNT 5)

Plaintiffs' statutory public nuisance claim fails for lack of causation and on preemption grounds. *See supra* §§ II(B)(1)-(2), III(B)(1)-(2), IV. But it should be dismissed for other reasons, too. Ohio statutes and regulations "define certain conduct as being a public nuisance. These statutes amount to a legislative declaration that the proscribed conduct is an unreasonable interference with a public right." *Brown*, 622 N.E.2d at 1158; *see also* O.R.C. § 3767.01(C)(1) (defining "nuisance" as "[t]hat which is defined and declared by statutes to be a nuisance"). To establish their claim for statutory public nuisance, Plaintiffs must therefore allege facts sufficient to show that the Manufacturer Defendants violated such a statute. *See id.* Plaintiffs fail to do so.[39]

More fundamentally, most of the predicate statutes and regulations that Plaintiffs cite do

[38] In *Beretta*, the Ohio Supreme Court withheld application of the safe harbor for gun manufacturers after finding that "the law does not regulate the distribution practices alleged in the complaint" such as "straw purchasing" (i.e., an authorized purchaser buying a gun for an unauthorized purchaser) or "kitchen table" dealers (i.e., dealers who do not operate through a retail establishment). 768 N.E.2d at 1143; *see Beretta* Compl. ¶ 79. The comprehensive regulation of prescription opioids through the entire supply chain, including their manufacture, promotion, distribution, sale, and use, distinguishes this case from *Beretta*.

[39] The Court also should strike Plaintiffs' request for damages pursuant to this count because the predicate statutes allow a property owner only to abate or enjoin a public nuisance. *See* O.R.C. §§ 3767.03, 4729.35. Damages are not authorized.

not even regulate the conduct of pharmaceutical manufacturers. One statute, O.R.C. § 4729.01(F), merely defines the term "[d]angerous drug." 2AC ¶ 984. And three statutes on their face apply only to "wholesale distributors." O.R.C. § 4729.01(O); *see* O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28 (entitled "Verification of License ***as a Distributor of Dangerous Drugs*** or Exempt Status of a Prescriber," "Minimum Requirements for ***Wholesalers***," and "Licensure as a Virtual ***Wholesale Distributor***," respectively); 2AC ¶ 984. Plaintiffs do not and cannot allege that the Manufacturer Defendants qualify as "wholesale distributors" for purposes of these statutes. To the contrary, Plaintiffs limit their allegations regarding "wholesale distributors" to the Distributor Defendants. *See* 2AC ¶¶ 107, 515, 522-23, 527-28, 538, 684-85, 712, 1058.[40]

Plaintiffs' remaining predicate statutes and regulations—21 U.S.C. § 823, 21 C.F.R. § 1301.74, and O.R.C. § 2925.02(A))—also cannot sustain a claim for statutory nuisance. *See id.* ¶¶ 984, 986. Plaintiffs fail to plead a violation of the first two (federal) laws for the reasons detailed *supra* §§ III(A), III(B)(4), VII(C). Plaintiffs similarly fail to plausibly allege violation of § 2925.02(A). Plaintiffs invoke subsections 2925.02(A)(1) and (3), which, respectively, prohibit the administering, inducing, or causing another to use a controlled substance "[b]y force, threat, or deception," *id.* § 2925.02(A)(1), and the administering, inducing, or causing another to use such a substance "by any means," with the additional causal requirement that the actions "cause serious harm" or "cause the other person to become drug dependent," *id.* § 2925.02(A)(3). 2AC ¶¶ 986-87. But any claim under these provisions is preempted to the extent it seeks to hold the Manufacturer Defendants liable for failing to stop the sale of prescription opioids that have been approved for sale by FDA and are regulated by DEA. *See supra* § IV. And, to the extent not preempted, any such claim is barred under § 2925.02(B)'s safe harbor provisions, as the

[40] Moreover, the statutes define pharmaceutical "manufacturers" separate from "wholesale distributors." *Compare* O.R.C. § 4729.01(O), *with* O.R.C. § 4729.01(P).

Manufacturer Defendants have complied with all relevant federal and state controlled substances requirements. *See* O.R.C. § 2925.02(B) (safe harbor provision). Nor have Plaintiffs alleged any facts to show that any Manufacturer Defendant somehow deceived a particular resident in Summit County into using opioids, much less into becoming opioid dependent. Because Plaintiffs cannot establish violation of any predicate federal or Ohio statute or regulation, the Court should dismiss Plaintiffs' statutory nuisance claim.

IX. THE NEGLIGENCE CLAIM FAILS (COUNT 7)

Plaintiffs' negligence claim is premised on allegations of fraudulent marketing and purported failures to maintain effective controls against opioid diversion. *See* 2AC ¶¶ 1045-46. This claim fails for many of the reasons discussed above, including:

- The claim is barred by the economic loss rule, *supra* § VII(A), *Corporex*, 835 N.E.2d at 704;
- Plaintiffs do not and cannot plead actual and proximate causation, *supra* §§ II(B)(1)-(2), III(B)(1)-(2), *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975);
- The claim is prempted, *supra* § IV; and
- Plaintiffs fail to plead any actionable conduct, including with the particularity required by Rule 9(b), *supra* §§ II(B), III(B), *D'Amico v. Delliquadri*, 683 N.E.2d 814, 816-17 (Ohio Ct. App. 1996); *Operations Mgmt. Int'l v. Clermont Cty., Ohio*, 2006 WL 3306317, at *5 (S.D. Ohio Nov. 13, 2006).

To the extent Plaintiffs purport to bring a negligence *per se* claim, *see* 2AC ¶ 1060, this claim fails for additional reasons. First, Plaintiffs have failed to allege a violation of any predicate statute or regulation, as required to state a negligence *per se* claim. *See supra* §§ II(B)(4), III(B)(4), VII(C), VIII. Second, Ohio does not permit a negligence *per se* claim when "the underlying statute does not allow for a private right of action," *Rogozinsky v. Danek Med., Inc.*, 1999 WL 33537323, at *2 (N.D. Ohio July 8, 1999), or for "the violation of administrative rules and regulations," *Kemp v. Medtronic, Inc.*, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001).

Plaintiffs' negligence *per se* claim thus fails to the extent it is based on an alleged violation of the CSA, DEA regulations, or Ohio's statutes or administrative regulations—none of which provides a private right of action, *supra* § III(A).[41]

X. THE FRAUD CLAIM FAILS (COUNT 8)

Plaintiffs' fraud claim is similarly premised on the 2AC's allegations regarding unlawful marketing and purported failures to maintain effective controls against opioid diversion. *See* 2AC ¶ 1074. Thus, this claim too fails for many of the reasons discussed above, including:

- Plaintiffs do not and cannot plead actual and proximate causation, *supra* §§ II(B)(1)-(2), III(B)(1)-(2), *see Picklesimer v. Balt. & O. R. Co.*, 84 N.E. 2d 214, 217 (Ohio 1949);
- The claim is preempted, *supra* § IV; and
- Plaintiffs fail to plead any actionable conduct, including with the particularity required by Rule 9(b), *supra* §§ II(B), III(B), *Casey v. Reidy*, 906 N.E.2d 1139, 1141 (Ohio Ct. App. 2009); *Operations Mgmt. Int'l*, 2006 WL 3306317, at 4.

The claim fails for the additional reason that Plaintiffs must, but do not, plead "justifiable reliance upon the [allegedly fraudulent] representation or concealment." *Lucarell v. Nationwide Mutual Ins. Co.*, 2018-Ohio-15, ¶ 61, --- N.E.3d --- (Ohio Jan. 4, 2018). "A fraud claim cannot be predicated on . . . [alleged] misrepresentations made to ***third parties***." *Id.* at ¶¶ 68-69. In Ohio, therefore, "[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 he suffered injury from that third-party's reliance." *Mike McGarry & Sons, Inc. v. Constr. Resources One, LLC*, 2018-Ohio-528, ¶ 78, --- N.E.3d --- (Ohio Ct. App. Feb. 9, 2018).

Here, Plaintiffs' fraud claim is based ***solely*** on alleged misrepresentations made to third parties, not Plaintiffs. *See* 2AC ¶¶ 179, 256, 350, 399, 429-30, 440, 443-44, 452, 465, 493.

[41] O.R.C. § 4729.35 provides a cause of action only for nuisance. *See* O.R.C. § 4729.35; *State v. Shadyside Party Ctr.*, 13 N.E.3d 684, 689 n.1 (Ohio Ct. App. 2014).

Although the 2AC makes conclusory allegations about reliance (that must be disregarded), *id.* ¶ 1081, it fails to identify even one false statement or omission that was directed towards Plaintiffs or even received by Plaintiffs—let alone one they relied on. Indeed, the 2AC repeatedly alleges that the Manufacturer Defendants supposedly made misrepresentations and omissions "to induce reliance" by third-party prescribers and patients, *id.* ¶ 1074, or directed at "state and federal regulators," *id.* ¶ 856, and "with the intent that [unspecified] ***others*** rely on their omissions," *id.* ¶ 1075.[42] Thus, this claim fails under Ohio's requirement of first-party reliance for common law fraud. *Lucarell*, 2018-Ohio-15, at ¶ 66.

XI. THE "INJURY THROUGH CRIMINAL ACTS" CLAIM FAILS (COUNT 9)

Count 9 seeks relief under O.R.C. § 2307.60(A)(1), which provides a cause of action for damages for "[a]nyone injured in person or property by a ***criminal act***." *Jacobson v. Kaforey*, 75 N.E.3d 203, 205 (Ohio 2016); *see* 2AC ¶¶ 1090-1107. To maintain a § 2307.60 claim, a plaintiff ***must***—absent one exception not applicable here[43]—show, as a threshold matter, a conviction for the alleged predicate criminal act, as the vast majority of courts to address the issue have held. *See Jane v. Patterson*, 2017 WL 1345242, at *4 (N.D. Ohio Apr. 12, 2017); *A.A. v. Otsego Local Sch. Bd. of Educ.*, 2016 WL 7387261, at *9 (N.D. Ohio Dec. 21, 2016); *see also Ortiz v.*

[42] *See also* 2AC ¶¶ 179 ("Each Marketing Defendants' conduct . . . aimed to . . . mislead doctors, patients, and payors."), 350 ("The Marketing Defendants' false marketing campaign not only targeted the medical community . . . but also patients."), 911 ("The RICO Supply Chain Defendants carried out . . . a scheme to defraud federal and state regulators, and the American public . . . .").

[43] The exception pertains to claims "to recover damages from any person who willfully damages ***the owner's property*** or who commits a ***theft offense, as defined in [§ 2913.01], involving the owner's property***," O.R.C. § 2307.61(A), and permits the trier of fact to determine liability "***whether or not*** any person has pleaded guilty to or has been convicted of any criminal offense," *id.* § 2307.61(G)(1); *see Corbett v. Beneficial Ohio, Inc.*, 847 F. Supp. 2d 1019, 1029 (S.D. Ohio 2012) ("The theft offenses set forth in [§ 2913.01] clearly relate only to the theft of ***personal*** property, *e.g.*, burglary, robbery, breaking and entering, safecracking, forgery, passing bad checks, misuse of credit cards.").

Kazimer, 2015 WL 1400539, at *12 (N.D. Ohio Mar. 26, 2015), *aff'd*, 811 F.3d 848 (6th Cir. 2016); *Tri-State Comp. Exch., Inc. v. Burt*, 2003 WL 21414688, at *6 (Ohio Ct. App. June 20, 2003).[44]

Notwithstanding this case law and clear statutory text, Plaintiffs have failed to allege the requisite criminal conviction against any Manufacturer Defendant.[45] Plaintiffs identify three general categories of criminal predicate acts underlying their § 2307.60 claim: (1) violation of O.R.C. § 2925.02(A); (2) criminal wire fraud, mail fraud, telecommunications fraud, and unlawful dealing in controlled substances; and (3) criminal RICO and OCPA violations. Setting aside Plaintiffs' failure to plead a substantive violation of any of these predicate statutes (*see supra* §§ II(B)(4), III(B)(4), VII(C), VIII), Plaintiffs do not (and cannot) allege that any Manufacturer Defendant has been convicted of any such crime. *See* 2AC ¶¶ 1093-94, 1096, 1098. This defeats Count 9.

XII. THE UNJUST ENRICHMENT CLAIM FAILS (COUNT 10)

Plaintiffs' unjust enrichment claim is derivative of their other claims and thus falls with them. *See Boladian v. UMG Recordings, Inc.*, 123 F. App'x 165, 169, 171 (6th Cir. 2005). The unjust enrichment claim also fails on its own terms. To plead such a claim, Plaintiffs must allege that ***they*** conferred a benefit on the Manufacturer Defendants. *Andersons, Inc. v. Consol, Inc.*,

[44] To the extent courts have held otherwise, they have done so with little to no analysis or based on a misreading of relevant precedent. For example, in *Chemical Bank v. Kausmeyer*, the court held that, under *Cuyahoga Heights Local School District v. Palazzo*, 2016 WL 4037309 (Ohio Ct. App. July 28, 2016), "§ 2307.60(A)(1) clearly authorizes a civil action for damages for anyone injured by a criminal act, regardless of whether any person has pleaded guilty to or been convicted of a criminal offense." 2016 WL 7178662, at *7 (N.D. Ohio Dec. 9, 2016). But *Palazzo* considered only whether a conviction is required under § 2307.**61(G)(1)**, the provision specifically exempting claims for property damage or thefts of personal property only.

[45] Plaintiffs' "injury through criminal acts" claim also fails: (1) under the economic loss rule, *see supra* § VII(A), *Corporex*, 835 N.E.2d at 704; (2) for lack of causation, *see supra* §§ II(B)(1)-(2), III(B)(1)-(2), *Jacobson*, 75 N.E.3d at 206 (Ohio 2016) (damages must be "resulting from" the criminal act); and (3) on preemption grounds, *see supra* § IV.

348 F.3d 496, 501 (6th Cir. 2003). Here, Plaintiffs fail to plead this element because they did not enter into a direct "economic transaction" with the Manufacturer Defendants and, thus, conferred no benefit on them. *Randleman v. Fid. Nat'l Title Ins. Co.*, 465 F. Supp. 2d 812, 824 (N.D. Ohio 2006). Instead, Plaintiffs simply allege that their public expenditures somehow "helped sustain Defendants' businesses." 2AC ¶ 1113. Plaintiffs fail to plead facts to support this speculative and attenuated theory. *See Randleman*, 465 F. Supp. 2d at 824.[46]

XIII. THE CIVIL CONSPIRACY CLAIM FAILS (COUNT 11)

Like the unjust enrichment claim, Plaintiffs' follow-on claim for civil conspiracy also should be dismissed for failure to allege any actionable underlying tort. *See Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 354 (6th Cir. 2000); *Doane v. Givaudan Flavors Corp.*, 919 N.E.2d 290, 298 (Ohio Ct. App. 2009).[47]

The conspiracy claim is also inadequately pleaded. In Ohio, "civil conspiracy requires an agreement between two or more persons and a concerted action to accomplish a criminal or unlawful purpose or to accomplish a lawful purpose by criminal or unlawful means." *Kerr v. Hurd*, 694 F. Supp. 2d 817, 832 (S.D. Ohio 2010). These elements "must be pled with some degree of specificity; vague or conclusory allegations unsupported by material facts are insufficient to state [conspiracy claims]." *McElrath v. City of Cleveland*, 2017 WL 3189477, at *5 (N.D. Ohio July 26, 2017). Instead, Plaintiffs must "plead when, where, why, or how the conspiracy occurred or how the alleged conspiracy resulted in damages." *Coley v. Lucas Cty.*, 2014 WL 272667, at *9 (N.D. Ohio Jan. 23, 2014). Plaintiffs fall short of meeting these

[46] *See also Young v. Carrier Corp.*, 2014 WL 6617650, at *7 (N.D. Ohio Nov. 21, 2014); *Savett v. Whirlpool Corp.*, 2012 WL 3780451, at *7 (N.D. Ohio Aug. 31, 2012); *In re Whirlpool Corp.*, 684 F. Supp. 2d 942, 951-53 (N.D. Ohio 2009).

[47] In any event, Plaintiffs' negligence claim cannot serve as a predicate for civil conspiracy, which requires "some type of underlying ***intentional*** tort." *Hunt v. City of Toledo Law Dep't*, 881 F. Supp. 2d 854, 879-80 (N.D. Ohio 2012).

requirements.

Critically, Plaintiffs have failed to plead the existence of a conspiratorial agreement between ***any*** of the more than 25 separate and distinct Defendants. For example, the 2AC nowhere alleges any direct communications among the individual Manufacturer and Distributor Defendants from which to infer an unlawful agreement. Instead, it relies upon vague and conclusory allegations that the Manufacturer Defendants "agreed among themselves" to both establish a fraudulent "marketing network" and, together with the Distributor Defendants, "increas[e] the supply of opioids." 2AC ¶¶ 746, 760, 1128, 1130. These allegations are plainly deficient, as "a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 557; *see also Dixon v. Ginley*, 2013 WL 2425132, at *9 (N.D. Ohio June 3, 2013).

Equally deficient are Plaintiffs' allegations that some of the Manufacturer Defendants sponsored some of the same medical professionals, organizations, and publications. 2AC ¶¶ 352-451, 532-34, 754-58. These allegations at best show "parallel conduct that could just as well be independent action," not an unlawful conspiracy. *Twombly*, 550 U.S. at 556-57. That is particularly true here, given that the Manufacturer Defendants are competitors, and courts should, "without suspecting illegal collusion, expect competing firms to keep close track of each other's . . . market behavior and often . . . imitate that behavior." *In re Text Messaging Antitrust Litig.*, 782 F.3d 867, 879 (7th Cir. 2015); *see In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 322 (the fact that "market behavior is interdependent and characterized by conscious parallelism" is insufficient to allege an agreement).

Similarly, although Plaintiffs allege that the Manufacturer and Distributor Defendants participated in two industry-wide trade associations (the "Pain Care Forum" and the "HDA"),

2AC ¶¶ 532, 763, courts routinely hold that mere participation in a trade association is insufficient to show an illicit agreement. *See, e.g.*, *Almanza*, 851 F.3d at 1072; *Consol. Metal Prods.*, 846 F.2d at 293-94. Plaintiffs' allegations regarding the structure and operation of the HDA and Pain Care Forum are entirely consistent with lawful industry conduct: indeed, Plaintiffs concede that the HDA put forth strict "Industry Compliance Guidelines" designed to encourage distributors to report suspicious orders. 2AC ¶¶ 522, 853.[48] Because Plaintiffs allege only parallel conduct between business competitors, and not the existence of any agreement to do something improper, Plaintiffs' civil conspiracy claim should be dismissed.

XIV. ALL CLAIMS SHOULD BE DISMISSED, IN PART, AS TIME-BARRED

A. The Applicable Statutes of Limitations Bar Plaintiffs' Claims

Plaintiffs' claims rely largely on alleged acts or omissions that occurred as far back as the mid-1990s. *See, e.g.*, 2AC ¶¶ 190, 258, 303. But each claim is subject to a statute of limitations, and the ***longest*** applicable limitations period is five years. *See* O.R.C. § 2923.34(J) (five-year period for OCPA claim); *Bradley v. Miller*, 96 F. Supp. 3d. 753, 768 n.12 (S.D. Ohio 2015).[49]

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[48] The 2AC also references "agreements whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds." 2AC ¶ 530. The 2AC, however, does not allege that such agreements are unlawful (they are not). Nor does it come close to pleading the necessary specifics about how the agreements were purportedly used "as a tool to violate" the law.

[49] The "injury through criminal acts" claim is subject to a one-year limitations period. *See State ex rel. Cty. of Cuyahoga v. Jones Lang Lasalle Great Lakes Co.*, 2017 WL 4177024, at *24 (Ohio Ct. App. Sept. 21, 2017). The remaining claims are subject to a four-year limitations period. *See Agency Holding Corp. v. Malley-Duff & Assocs.*, 483 U.S. 143, 156 (1987) (RICO); O.R.C. § 2305.09(C) (fraud); *id.* § 2305.09(D) (statutory public nuisance, common law absolute nuisance, negligence); *see also Elmer v. S.H. Bell Co.*, 127 F. Supp. 3d 812, 823 (N.D. Ohio 2015) (applying O.R.C. § 2305.09(D) to negligence claim); *Ashtabula River Corp. v. Conrail*, 549 F. Supp. 2d 981, 984 (N.D. Ohio 2008) (same as to statutory and common law public nuisance claims). Although unjust enrichment claims can have up to a six-year statute of limitations, a six-year period is inapplicable to the unjust enrichment claim here for two reasons: (1) the claim is derivative; and (2) the claim should be subject to § 2305.09(C), as it is grounded in fraud. *Hambleton v. R.G. Barry Corp.*, 465 N.E.2d 1298, 1301 (Ohio 1984).

For each of these claims, Plaintiffs' "cause of action accrue[d], and [the] statute of limitations beg[an] to run, when the [alleged] wrongful act [was] committed." *Lutz v. Chesapeake Appalachia, LLC*, 717 F.3d 459, 473 (6th Cir. 2013). Accordingly, the Court should dismiss Plaintiffs' claims to the extent they rely on alleged conduct committed before January 22, 2013: (1) five years before Plaintiffs brought suit—by the entities named in the original complaint; and (2) before April 25, 2013 and May 18, 2013 by the entities named for the first time in the 1AC and 2AC, respectively. *See Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 112 (2002) ("[D]iscrete acts that fall within the statutory time period do not make timely acts that fall outside the time period."); *Asher v. Unarco Material Handling, Inc.*, 596 F.3d 313, 318 (6th Cir. 2010) ("[A]n amendment which adds a new party creates a new cause of action and there is no relation back to the original filing for purposes of limitations."). By way of example, claims premised on allegations that the Manufacturer Defendants' alleged misconduct began roughly 20 years ago, *see* 2AC ¶¶ 4, 7, 175, 187-201, 271, 315, 327, 788-89, 829, including publications, advertisements, and third-party materials that were allegedly created and published before January 2013, *e.g.*, *id.* ¶¶ 211, 215-16, 224, 232-33, 246-50, 254-55, 260, 269, 272, 275, 285-86, 288, 298, 302, 313, 369, 381, 390-92, 404, are barred by the statute of limitations. Plaintiffs cannot recover for any alleged injuries caused by such conduct, nor can they rely on more recent conduct as a "bootstrap to recover for injuries" caused by that time-barred conduct. *Meros v. Dimon*, 2017 WL 6508723, at *7 (S.D. Ohio Dec. 20, 2017).

B. No Exception to the Limitations Periods Applies

The 2AC attempts to avoid dismissal of Plaintiffs' claims as time-barred by citing four exceptions to the limitations period: the discovery rule and the fraudulent concealment, equitable tolling, and continuing violation doctrines. *See* 2AC ¶¶ 767-77. None applies.

1. The Discovery Rule, Fraudulent Concealment Doctrine, and Equitable Tolling Doctrine Do Not Apply

The discovery rule, fraudulent concealment doctrine, and equitable tolling doctrine must be "specially tailored" to the particular context, *Flagstar Bank, FSB v. Airline Union's Mortg. Co.*, 947 N.E.2d 672, 676 (Ohio 2011), and applied only in "compelling cases," *Sharp v. Ohio Civil Rights Comm'n*, 2005 WL 589889, at *2 (Ohio Ct. App. Mar. 10, 2005). At a minimum, to invoke any of these tolling doctrines, each Plaintiff must allege facts showing that it "failed to discover the facts giving rise to the claim despite the exercise of due diligence." *Id.*; *see also Flowers v. Walker*, 589 N.E.2d 1284, 1287-88 (Ohio 1992) (under discovery rule, plaintiff "need not have discovered all the relevant facts necessary to file a claim"; rather, the plaintiff must just be on "notice to investigate the [relevant] facts and circumstances" to pursue claim). In addition, the fraudulent concealment and equitable estoppel doctrines require affirmative conduct—apart from the underlying fraud—to "conceal evidence of the alleged wrongdoing." *Sharp*, 2005 WL 589889, at *2; *see also Cheatom v. Quicken Loans*, 587 F. App'x 276, 280 (6th Cir. 2014) (equitable estoppel); *Thornton v. State Farm Mut. Auto Ins. Co.*, 2006 WL 3359448, at *6 (N.D. Ohio Nov. 17, 2006) (fraudulent concealment).

Here, Plaintiffs fail to plead facts sufficient to support application of any of these exceptions. To the contrary, the 2AC confirms that Plaintiffs knew, or reasonably should have known, of the alleged fraud long before January 22, 2013. Indeed, many of the matters Plaintiffs rely upon in their 2AC were publicly available before 2013. For example:

- FDA's public regulatory actions related to opioids began as early as 2001, which Plaintiffs now claim show actionable misconduct on the part of the Manufacturer Defendants. *See, e.g.*, 2AC ¶¶ 198-201, 271, 315, 327, 788-89;
- Articles related to opioids and opioid addiction that were published as early as 2001. *See, e.g.*, *id.* ¶¶ 267, 271, 284, 286; and
- The Manufacturer Defendants' efforts to market opioids, which were public

by their very nature. *See, e.g.*, *id.* ¶¶ 169, 183-88.

In addition to having access to this pre-2013 publicly available information, Plaintiffs also necessarily knew of their costs associated with opioids more than five years ago. Nor have Plaintiffs alleged (and, indeed, cannot allege) that any Manufacturer Defendants took affirmative steps to prevent Plaintiffs from bringing their claims, particularly given that the allegedly fraudulent statements were publicly available. As a result, the discovery rule, fraudulent concealment doctrine, and equitable estoppel doctrine do not apply. *See Egerer v. Woodland Realty, Inc.*, 556 F.3d 415, 424-25 (6th Cir. 2009); *Cheatom*, 587 F. App'x at 280; *Lutz*, 717 F.3d at 470.

2. The Continuing Violation Doctrine Does Not Apply

Like other tolling doctrines, the continuing violation doctrine is narrow—courts are "extremely reluctant" to apply it outside the context of Title VII. *Nat'l Parks Conserv. Ass'n v. Tenn. Valley Auth.*, 480 F.3d 410, 416 (6th Cir. 2007). For it to apply, a plaintiff must show: "(1) the defendants engage in continuing wrongful conduct; (2) injury to the plaintiff accrues continuously; ***and*** (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided." *Hensley v. City of Columbus*, 557 F.3d 693, 697 (6th Cir. 2009).

The first element is not met, as there are no facts to show that the Manufacturer Defendants have engaged in continuing conduct capable of triggering the continuing violation doctrine. To show such conduct, Plaintiffs cannot simply allege that the alleged improper acts are "sufficiently related." *Sharpe v. Cureton*, 319 F.3d 259, 268 (6th Cir. 2003). Rather, Plaintiffs must show that the acts "cannot be said to occur on any particular day, but [rather] occur over a series of days or years." *Id.* at 267. By contrast, if a defendant engages in "discrete acts" that, standing alone, are "potentially actionable," there is no continuing violation. *Bowerman v. Int'l*

Union, 646 F.3d 360, 366-67 (6th Cir. 2011).[50] Here, Plaintiffs allege (and at the time were aware of) discrete acts that were themselves potentially actionable: that is, different defendants engaging in different conduct at different periods of time causing different alleged harms. *Id.*

The remaining two elements also are not met. First, injury has not accrued continuously; even assuming that Plaintiffs can show causation (and they cannot), the Manufacturer Defendants' alleged earlier conduct caused only some injuries, but their later alleged conduct would have caused different, stand-alone injuries. Different prescribers, for example, may have relied on different alleged representations in writing different prescriptions that led to different alleged harms; and different "suspicious" opioid orders may have caused different alleged harms, too. Second, ceasing conduct would not have prevented further alleged harm—indeed, according to Plaintiffs, the Manufacturer Defendants' earlier conduct has caused "ongoing" harm to Plaintiffs. 2AC ¶ 19; *see id.* ¶¶ 988, 1004-05. The continuing violation doctrine therefore does not apply.

CONCLUSION

For the foregoing reasons, the 2AC should be dismissed with prejudice.

Dated: May 25, 2018

Respectfully submitted,

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[50] Also, Plaintiffs may not simply allege that pre-limitations period acts caused post-limitations period harm. *Trzebuckowski v. City of Cleveland*, 319 F.3d 853, 858 (6th Cir. 2003) (noting the "difference between a continuing violation and a continuing effect of a prior violation"); *see Pittman v. Spectrum Health Sys.*, 612 F. App'x 810, 814 (6th Cir. 2015) (collecting cases).

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the "litigation track" pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, and L.R. 7.1(f).

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CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2018, a copy of the foregoing **Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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