

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPI-  
ATE 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

**REPLY IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION  
TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT**

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## INTRODUCTION

This case is one of multiple lawsuits seeking to saddle a handful of pharmaceutical manufacturers with the costs of all social ills associated with opioid abuse throughout the State of Ohio.<sup>1</sup> Ignoring the multitude of factors that have contributed to the current public health crisis, Plaintiffs urge the Court to award both forward-looking equitable relief to attempt to ameliorate the problem and retrospective damages for all public expenditures supposedly stemming from the abuse of both lawful prescription opioid medications and criminally prohibited street drugs. As the Manufacturer Defendants demonstrated in their Motion, Plaintiffs' lawsuit suffers from multiple defects as a matter of law.

Plaintiffs' claims fail for many reasons, but the most fundamental—one that applies equally across all claims—is that Plaintiffs cannot allege a causal chain that satisfies the requirements of either but-for or proximate causation. As to but-for causation, Plaintiffs must plead and prove that “but for” the Manufacturer Defendants' alleged wrongful conduct, the broad-ranged social ills associated with the opioid crisis and their attendant costs would not have occurred. But Plaintiffs have not provided the necessary link between the Manufacturer Defendants' alleged misrepresentations and the public expenditures for which Plaintiffs seek recovery. Indeed, the 2AC does not identify even a *single* doctor who was exposed to (let alone relied on) any alleged misrepresentation by a Manufacturer Defendant before prescribing a harmful or medically unnecessary opioid medication to a Summit County resident, or any alleged damage Plaintiffs suffered as a result of any such (unidentified) wrongful prescription.

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<sup>1</sup> Unless otherwise noted, all capitalized terms and acronyms are defined in Defendants' Memorandum in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint (Dkt. #499-1) (“Motion” or “JM”), emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted. “Opposition” or “Opp.” refers to Plaintiffs' Omnibus Memorandum in Opposition (Dkt. #654).

Of course, even if Plaintiffs could establish but-for causation, they have not pleaded and cannot establish proximate causation. Foreseeability of ultimate harm alone is not enough: the kinds of broad social ills for which Plaintiffs seek recompense—such as police work relating to drug abuse, adjudicating drug-related offenses, incarcerating drug offenders, treating drug addicts, placing children in foster care, and lower property and income taxes in Ohio, *see, e.g.*, 2AC ¶¶ 20, 902, 934, 948, 972—are simply too remote to satisfy the proximate cause requirement. Further, the attenuated causal chain between the Manufacturer Defendants’ supposed wrongful conduct and Plaintiffs’ alleged damages is broken, at a minimum, by both (i) physicians’ exercise of independent medical judgment in prescribing lawful opioid medications to patients and (ii) the intervening criminal conduct of third parties.

Plaintiffs’ claims also run headlong into FDA’s exclusive regulation of prescription drugs and their marketing, improperly seeking to hold the Manufacturer Defendants liable for doing exactly what the federal government has authorized. Plaintiffs turn 180 degrees from their 2AC and now concede that FDA has approved most of the opioid medications at issue as “safe and effective for the long-term treatment of chronic non-cancer pain.” Opp. 116. Plaintiffs also acknowledge, as they must, that the products’ FDA-approved labeling fully and prominently discloses the risks of abuse at issue. *Id.* Plaintiffs concede that the Manufacturer Defendants cannot be held liable for promoting their drugs for FDA-approved uses or for offering FDA-approved drugs for sale. At bottom, however, that is the basis for their claims. No matter how Plaintiffs spin their claims, they cannot escape that only FDA has authority to decide which prescription drugs should be available, and only DEA has authority to decide whether scheduled drugs may be distributed.

Although all Plaintiffs’ claims for relief fail, the RICO claims stand out in the sheer number of dispositive flaws. The 2AC does not adequately allege a single element of a civil RICO claim.

A governmental entity’s public expenditures are not an injury to “business or property” within the meaning of the statute. The 2AC does not establish any conceivable RICO “enterprise.” Nor have Plaintiffs adequately pleaded any plausible “predicate act” or injury “by reason of” the Manufacturer Defendants’ alleged conduct. Rhetoric equating lawful businesses’ marketing of FDA-approved prescription medications to criminal “racketeering” does not make a RICO claim.

With no basis to seek past damages, what’s left of Plaintiffs’ 2AC—principally a forward-looking claim for abatement under public nuisance—is equally flawed. While Plaintiffs rely on the Ohio Supreme Court’s *Beretta* decision, the prevailing view of courts across the country, including those applying Ohio law, is that public nuisance law cannot be used to try to solve multifaceted societal problems. That is precisely what Plaintiffs aim to do, and their nuisance claims should be dismissed.

Beyond these and other flaws foreclosing Plaintiffs’ claims, the rules of standing and primary authority preclude political subdivisions like Plaintiffs from bringing such claims in these circumstances. It is unfair, unwieldy, and impractical to allow myriad state subdivisions to bring multiple me-too lawsuits, particularly when, as here, the state’s own attorney general is already pursuing parallel claims for the state as a whole. Basic standing principles bar this multiplicative litigation. And under settled Ohio law, a political subdivision cannot usurp the power of the state’s attorney general to prosecute legal claims of statewide concern on the state’s behalf.

Hence, the 2AC should be dismissed in its entirety.

### **ARGUMENT**

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

##### **A. Plaintiffs Lack Standing Under the “Statewide Concern” Doctrine**

Plaintiffs do not dispute that, under Ohio law, 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). And they concede that the opioid crisis alleged here presents matters of “statewide or even nationwide concern.” Opp. 110. This suffices to dismiss Plaintiffs’ claims. JM 6-8. Plaintiffs’ responses lack merit.

*First*, Plaintiffs contend that, as political subdivisions, they share “police power” with the State in adopting local health and safety regulations impacting matters of statewide concern. Opp. 109-10 & n.78. But all the cases Plaintiffs cite for that proposition involve purely local, not statewide, issues. *See, e.g., Marich v. Bob Bennett Constr. Co.*, 880 N.E.2d 906, 912 (Ohio 2008) (local traffic ordinance); *In re Thornburg*, 9 N.E.2d 516, 518-19 (Ohio Ct. App. 1936) (same); *Kovar v. City of Cleveland*, 102 N.E.2d 472, 475 (Ohio Ct. App. 1951) (local dog muzzling ordinance). Nor do Plaintiffs provide any authority for them to bring a *lawsuit*—as opposed to enacting an ordinance—on statewide matters under their purported police power. To the contrary, Plaintiffs concede they “have not asserted their claims *parens patriae* and do not seek to do so.” Opp. 109 n.75.

*Second*, Plaintiffs cite Ohio statutes permitting certain types of municipal prosecutors to bring public nuisance claims “in the name of the state.” Opp. 112 (citing O.R.C. §§ 3767.03, 4729.35). Critically, however, those statutes only permit municipalities (through their public prosecutors) to bring claims “in the name of the state;” but that is what the Ohio Attorney General is doing. JM 7. Contrary to Plaintiffs’ suggestion, these two lawsuits “conflict”: if both proceed, they would impermissibly split the claims at issue and risk inconsistent rulings and duplicative recoveries. *Id.* In any event, those statutes, of course, have no relevance to Plaintiffs’ non-nuisance claims.

*Third*, Plaintiffs argue they can recover “their own,” purely local costs “to address and/or

abate the opioid crisis.” Opp. 112. The Ohio Supreme Court has rejected similar attempts to circumvent the statewide concern doctrine based on the argument that local matters are also at issue. For good reason: because any matter of statewide concern necessarily also affects local concerns, permitting local concerns to prevail in such circumstances would eviscerate the statewide concern doctrine. Thus, “*even if there is a matter of local concern involved*, if the regulation of the subject matter affects the general public of the state as a whole more than it does the local inhabitants *the matter passes from what was a matter for local government to a matter of general state interest.*” *City of Kettering v. State Employment Relations Bd.*, 496 N.E.2d 983, 987 (Ohio 1986). That principle applies here and defeats Plaintiffs’ claims.

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

Plaintiffs concede that the Ohio Attorney General is Ohio’s chief law enforcement officer, has already filed a lawsuit based upon the same alleged conduct, Opp. 113, and seeks to “recover all measures of damages allowable under” statute and the common law, AG Compl. ¶ 248(C)—a request that encompasses the relief sought here. These concessions are dispositive. Plaintiffs cite no authority allowing them to circumvent the Attorney General’s constitutional authority by bringing a duplicative action based on matters of statewide concern.<sup>2</sup> Unable to challenge the Attorney General’s exclusive authority, Plaintiffs instead dispute his assertion that there is “no other Plaintiff . . . better situated to seek a remedy for the economic harms” purportedly caused by the Manufacturer Defendants. *Id.* ¶ 247; *see* Opp. 114. But the Attorney General has the power to control *all litigation* implicating matters of statewide concern, JM 8, and he has exercised that authority

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<sup>2</sup> Plaintiffs also cannot usurp the Attorney General’s common law powers to “[c]hampion[] the proprietary and pecuniary interests of the government itself, and contest[] infringements of the rights of the general public via the doctrine of *parens patriae*.” 16 Ohio Jur. 3d Const. Law § 269.

here. As entities “subordinate to the state in the exercise of governmental power,” *State v. Price*, 128 N.E. 173, 175 (Ohio 1920),<sup>3</sup> Plaintiffs cannot usurp the Attorney General’s authority by asserting the same allegations, against the same manufacturers, in an entirely separate action.

## **II. THE ABSENCE OF BUT-FOR AND PROXIMATE CAUSATION IS FATAL TO ALL OF PLAINTIFFS’ CLAIMS**

All Plaintiffs’ claims against the Manufacturer Defendants—not just the RICO claims but all other claims as well—turn on the premise that the Manufacturer Defendants engaged in conduct that actually and proximately caused the opioid crisis. To prevail, Plaintiffs must plead (and then prove) *both* that but for the Manufacturer Defendants’ supposedly wrongful conduct, the opioid crisis would not have happened, *and* that the resulting harms to Plaintiffs are not so attenuated or remote that recovery is barred as a matter of law. Plaintiffs have not done so, nor could they.

### **A. Plaintiffs’ Theory of Wrongful Marketing Fails for Lack of Causation**

#### **1. Plaintiffs Have Not Identified Any Purported Misrepresentation That Actually Caused a Prescriber to Write a Harmful Prescription**

Plaintiffs concede that the 2AC fails to identify any prescribers who were exposed to, let alone misled by, the Manufacturer Defendants’ alleged deceptive marketing. Opp. 29. Plaintiffs argue that there is “no authority” requiring them to do so, *id.*, but the cases cited in the Motion refute that argument. *See* JM 12 & n.15 (collecting cases). Those cases show that Plaintiffs cannot adequately plead but-for causation for their claims without identifying Summit County prescribers who wrote harmful, ineffective, or medically unnecessary opioid prescriptions *as a result* of the

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<sup>3</sup> Although Plaintiffs suggest that the Ohio Constitution abrogated this principle by extending home rule power to municipalities in 1933, Opp. 113, Ohio courts have continued to recognize that political subdivisions are mere “instrumentalities” or “agents” of the State. *See, e.g., Cook-Johnson Realty Co. v. Bertolini*, 299 N.E.2d 80, 83-84 (Ohio 1968); 19 Ohio Jur. 3d Counties § 31.

alleged fraud. *Id.*<sup>4</sup> Rule 9(b)'s pleading requirements aside,<sup>5</sup> the 2AC's failure to identify even *one* such prescriber defeats Count 1 under *Iqbal* and *Twombly*'s basic plausibility standard. *See, e.g., In re Actimmune Mktg. Litig.*, 2010 WL 3463491, at \*10 (N.D. Cal. Sept. 1, 2010) ("Even with the benefit of the lower pleading standard under Rule 8(a), plaintiffs have failed to adequately allege causation" when the plaintiffs failed to "allege that their doctors believed that Actimmune was an effective treatment . . . as a result of defendants' off-label promotion of Actimmune.").

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

Plaintiffs' injuries are too attenuated and remote to satisfy the proximate causation standard as a matter of law. JM 12-17. Plaintiffs respond to this defect with two arguments: (1) their alleged damages were "directly caused" by the Manufacturer Defendants, and (2) even if not direct, the alleged damages satisfy the three *Holmes* factors. Opp. 38-45. Both arguments fail.

As to the directness of their alleged injuries, Plaintiffs ignore the uniform authority holding that third-party payors' injuries from alleged fraud by manufacturers cannot, as a matter of law, be proximately caused by the manufacturers' misrepresentations. JM 14. Rather than distinguish those cases,<sup>6</sup> Plaintiffs instead argue that, under *Wallace v. Midwest Financial & Mortgage Services, Inc.*, 714 F.3d 414 (6th Cir. 2013), they need only establish "a link" between their alleged harms and the alleged fraud. Opp. 39-40. Plaintiffs misread *Wallace*, as the quoted language states only that the link *in that case* was sufficient to establish proximate cause—the court nowhere held

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<sup>4</sup> Without even these first steps, Plaintiffs also necessarily fail to identify any harmful, ineffective, or medically unnecessary opioid prescription written as a result of alleged fraud that then allegedly caused Plaintiffs' alleged damages or created the alleged public nuisance.

<sup>5</sup> To the extent Plaintiffs argue that they need not identify prescribers because Rule 9(b) should be relaxed here, that argument fails for the reasons stated *infra* § IV.B.2.b.

<sup>6</sup> Plaintiffs' lone attempt to distinguish *Perry v. Am. Tobacco Co.*, 324 F.3d 845 (6th Cir. 2003), fails for the reasons stated in the text and *infra* § IV.A.1.

that any “link,” no matter how attenuated, is sufficient. 714 F.3d at 420.<sup>7</sup>

Nor have Plaintiffs dispelled the policy concerns at issue when, as here, a RICO claim would require the court to “ascertain the damages caused by some remote action.” *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006) (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 269 (1992)). As to the first *Holmes* factor (difficulty of attributing damages to particular defendants), Plaintiffs ignore the extensive authorities holding that a prescribing physicians’ exercise of independent medical judgment when prescribing medications requires dismissal of fraud-based RICO claims against pharmaceutical manufacturers because those claims would require an unworkable inquiry into the doctor-patient relationship. JM 15 & n.16.<sup>8</sup> Similarly, as to the second *Holmes* factor (duplicative recovery), although Plaintiffs assert that there is “no risk” of overlapping damages, they nowhere explain how recovery by individual opioid consumers for addiction-related injuries would not be duplicative of Plaintiffs’ recovery for addiction-related services. Opp. 45. Lastly, as to the third *Holmes* factor (deterrence), Plaintiffs ignore the fact that individual con-

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<sup>7</sup> *Wallace* is factually distinguishable. There, a homeowner sued his mortgage broker for allegedly using inflated appraisals. 714 F.3d at 420. But unlike this case—which alleges an attenuated, multi-part causal chain—the fraudulent appraisals in *Wallace* were the homeowners’ “first priorities” that “clear[ly]” “played a significant role” in their alleged harm. *Id.* The claims here are more like those of the city seeking to recover public expenditures in *City of Cleveland v. Ameriquest Mortgage Securities, Inc.*, where the alleged harm was held to be too remote because it was caused by “a set of actions (neglect of property, starting fires, looting and dealing drugs)” “completely distinct from the asserted misconduct (financing subprime loans).” 615 F.3d 496, 507 (6th Cir. 2010). Plaintiffs attempt to distinguish *City of Cleveland* on the ground that the banking defendants in that case offered lawful financial services, *see* Opp. 14, but the Manufacturer Defendants’ prescription opioid medications are equally lawful. *See* JM 19-20, 34-38, 42-47.

<sup>8</sup> Plaintiffs contend that the alleged simple correlation between opioid promotion and an increase in opioid misuse and abuse can establish the requisite connection. Opp. 44 n.29. But multiple courts have rejected similar statistical modeling approaches as insufficient to adequately plead proximate causation, including under the *Holmes* factors. *See* JM 16-17 & n.17 (citing *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)).

sumers can bring lawsuits for injuries they allegedly suffered because of the Manufacturer Defendants' alleged misconduct. *Id.* 44. Nor do Plaintiffs account for the existing enforcement action brought by the State, based upon the exact same conduct.

Plaintiffs fare no better in arguing that the Manufacturer Defendants “contemplated and caused the intervening acts.” *Id.* 41. Plaintiffs cite *In re Neurontin Mktg. and Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013), for the proposition that the Manufacturer Defendants caused prescribers—despite prescribers’ duty to exercise independent medical judgment with their patients—to write improper prescriptions, *Opp.* 41, but *Neurontin* has been widely disapproved, as it “implies disagreement with . . . four circuits . . . that improper representations made to physicians do not support a RICO claim by [individuals] several levels removed in the causal sequence.” *Sidney Hillman Health Center of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017). In addition, the *Neurontin* plaintiff’s injury was considered to be direct because the alleged misstatements and omissions purportedly reached plaintiff (and its pharmacy benefit managers), causing it to forgo cheaper alternative medications for the off-label indications. 712 F.3d at 32-33, 40. Unlike here, the *Neurontin* plaintiff’s injury did not involve the costs of addressing various social ills many steps removed from the alleged misconduct. Tellingly, ignoring the *Holmes* factors, Plaintiffs neither identify nor allege any basis for isolating the impact of allegedly fraudulent marketing from the impact of lawful marketing on such downstream injuries in this already attenuated causal chain, much less how this possibly could be done in the context of numerous distinct third parties and defendants who compete against one another.

Plaintiffs also argue that the Manufacturer Defendants themselves caused intervening third-party criminal conduct (e.g., street-level drug dealing and heroin usage). *Opp.* 42. But courts recognize that such conduct is the result of “independent decisions.” *City of Cleveland*, 615 F.3d

at 505. Those “independent decisions” break Plaintiffs’ proposed causal chain. *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).

Given the attenuated causal chain and the multiple intervening forces that break that chain, Plaintiffs are left to rely only on conclusory allegations that their alleged harms were the foreseeable result of the allegedly wrongful marketing conduct. But “foreseeability alone is not sufficient to establish proximate cause.” *Bank of Am. v. City of Miami*, 137 S. Ct. 1296, 1305 (2017). Plaintiffs thus cannot establish proximate cause for their injuries as a matter of law.<sup>9</sup>

### **B. Plaintiffs’ Supply Chain Theory Fails for Lack of Causation**

Plaintiffs’ supply chain theory fares no better than their marketing theory does.

First, Plaintiffs argue that the 2AC pleads but-for causation for Count 2 by alleging that the Manufacturer Defendants “concealed and suppressed and/or ignored” unspecified “warnings” about unspecified “suspicious orders,” which “le[d] to the diversion” of prescription opioids into unspecified communities. Opp. 41. But apart from failing to specify any order that any Manufacturer Defendant could or should have identified and reported, Plaintiffs also fail to allege how any such report, had one been made, would have led to any action by DEA that would have averted prescription opioid diversion and, in turn, prescription opioid misuse, abuse, and addiction *in Summit County*. JM 28-29.

Second, Plaintiffs’ failure to dispute that the causal chain on their supply chain theory includes intervening conduct by third parties, including distributors, retailers, patients, and criminals, Opp. 41, similarly dooms their attempt to establish proximate causation on that claim. JM 29-30;

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<sup>9</sup> Plaintiffs suggest that the Court cannot decide issues of proximate causation at the pleading stage, Opp. 38, but the Sixth Circuit has expressly rejected this argument. *City of Cleveland*, 615 F.3d at 503 (citing *Anza*, 547 U.S. at 459).

*supra* § II.A.2. In fact, the 2AC itself contains numerous allegations demonstrating the **absence** of proximate causation (many of which the Opposition itself references). These include, most notably, allegations of multiple independent and intervening acts that break Plaintiffs’ proposed causal chain, including criminal diversion and illegal use of street drugs. Opp. 7 (quoting 2AC ¶ 20); *see also White v. Vrable*, 1999 WL 771053, at \*6 (Ohio Ct. App. Sept. 30, 1999).

### III. PLAINTIFFS’ STATE LAW CLAIMS (COUNTS 3-11) ARE PREEMPTED

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

In their Opposition, Plaintiffs contend that:

- (1) they “do not challenge” any Manufacturer Defendants’ “FDA-approved labeling,” Opp. 116;
- (2) they “do not contend that the Manufacturer Defendants should have changed their labels,” *id.* 118;
- (3) “None of [the alleged] misrepresentations includes the claim that opioids cannot be safe and effective for the long-term treatment of chronic non-cancer pain,” *id.* 116;
- (4) “Plaintiffs’ claims do not rest on any allegation of fraud on the FDA,” *id.* 119; and
- (5) “FDA has exclusive authority to enforce the [FDCA’s] prohibitions on off-label marketing,” and “Plaintiffs do not seek to enforce that FDCA prohibition.” *Id.*

By abandoning any claims based on these five theories,<sup>10</sup> Plaintiffs acknowledge that such claims are preempted by federal law—including any claim alleging that the Manufacturer Defendants falsely promoted opioids as safe and effective for the long-term treatment of chronic non-cancer pain. Indeed, Plaintiffs do not contest that federal law preempts claims based on promotion consistent with FDA-approved product labeling. *See* JM 34-36 (citing cases).

Plaintiffs nevertheless maintain that federal law does not preempt claims premised on the

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<sup>10</sup> These first two concessions further undermine Plaintiffs’ statement, elsewhere in the Opposition, that “the Manufacturer Defendants did not adequately warn doctors.” Opp. 47; *see supra* § II.A.2; *infra* §§ IV.B.2.a, IX.



nine categories of purported misrepresentations alleged at 2AC ¶ 177. Opp. 116 & n.85. But each of these categories includes alleged misrepresentations that relate either to the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain (e.g., 2AC ¶ 177 (a)-(c), (f)-(i)), or to the dosage and FDA-approved use of the medications (e.g., *id.* (d)-(e)). These alleged misrepresentation claims cannot escape preemption. *See* JM 34-36.

Plaintiffs also argue that alleged “off-label” marketing exposes certain Manufacturer Defendants to state-law liability for fraud, misrepresentation, or nuisance. Opp. 119. But it is well-settled that “the promotion of off-label drug use is *not in and of itself false or misleading*,” *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012), and, for this reason, courts routinely dismiss similar false marketing claims based upon allegations of off-label promotion. *See, e.g., Ind./Ky./Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498, at \*5, 9 (E.D. Pa. May 21, 2014) (“*Carpenters*”); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 552 (E.D. Pa. 2014), *aff’d*, 620 F. App’x 82 (3d Cir. 2015). Moreover, this argument walks directly into preemption; it confirms that Plaintiffs’ allegations of off-label promotion merely seek to usurp FDA’s authority to enforce its regulatory rules. As such, federal law therefore preempts Plaintiffs’ state-law claims premised on alleged “off-label” marketing of opioids. *See* JM 35-36.

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

Plaintiffs also concede that their claims are preempted by federal law to the extent they seek to hold the Manufacturer Defendants liable for “offering [their] FDA-approved drugs for sale.” Opp. 120-21; *see id.* 122 & n.88. Faced with this bar, Plaintiffs assert that they “do not allege that the [Manufacturer Defendants] should have stopped selling their products—*only* that they should have monitored the quantity of opioids being sold and taken steps to avoid diversion and misuse.” *Id.* 120-21. The Opposition itself belies this assertion by recognizing that Plaintiffs also

“allege that Defendants had a duty . . . to **stop shipment** of suspicious orders.” *Id.* (citing 2AC ¶ 512). This purported “stop shipment” requirement, which would require the Manufacturer Defendants to “cease[] filling orders for opioids,” 2AC ¶ 688, is also preempted. Indeed, such a requirement would present the same impermissible conflict as the “stop selling” requirement Plaintiffs disavow: both would intrude on FDA’s exclusive authority to determine which prescription drugs should (and should not) be on the market. *Cf. Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at \*1-2 (D. Mass. Apr. 15, 2014) (state regulation banning doctors and pharmacists from prescribing and dispensing a prescription opioid was preempted); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (requiring a drug manufacturer “to stop production of a drug” “directly conflict[s] with” FDA’s “sole authority” to decide “whether a drug may be marketed.”); *see also* JM 36-38.

Plaintiffs’ proposed “stop shipment” requirement would also conflict with DEA’s authority to determine whether a prescription opioid may lawfully be distributed. 21 U.S.C. § 824(a)-(b). No matter how Plaintiffs dress up their claims based on these allegations,<sup>11</sup> they are preempted.

Plaintiffs’ discussion of *Wyeth* and **impossibility** preemption are inapposite. Opp. 115 & n.84. As Plaintiffs concede, *Wyeth* addresses preemption of claims based on labeling, *id.*, not on the “availability of [drugs]” for the public. JM 38 (quoting *Zogenix*, 2014 WL 1454696, at \*1-2). By contrast, Plaintiffs’ claims seek to hold the Manufacturer Defendants liable for not stopping shipment (or sales) of their products to the public and are preempted under principles of **obstacle** preemption. *Id.* 36. Thus, regardless of whether it would have been “impossible” for the Manufacturer Defendants to stop shipment (or sales) of opioids, FDA’s and DEA’s authority to make (and keep) prescription opioids on the market suffices to preempt claims based on this conduct. *Id.*

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<sup>11</sup> That Plaintiffs’ diversion-monitoring claims also challenge other conduct (e.g., monitoring, reporting) is beside the point. Claims based on such conduct fail for other reasons. *See supra* § II.B; *infra* §§ V-XIII.

#### IV. THE RICO MARKETING ENTERPRISE CLAIM (COUNT 1) FAILS FOR ADDITIONAL REASONS

##### A. The Opposition Confirms That Plaintiffs Lack RICO Standing

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

To maintain a RICO claim, the plaintiff must be an “immediate victim[]” of the alleged misconduct. *Anza*, 547 U.S. at 460. Plaintiffs who suffer injuries “passed on by another party that had a more direct relationship with the defendant” lack RICO standing. *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 615 (6th Cir. 2004); see JM 9. Here, Plaintiffs concede they seek recovery only for “police and fire services, lost taxes, revenue and funding.” Opp. 37. These are quintessentially *indirect* injuries passed on by opioid consumers who allegedly suffered direct injuries from the claimed RICO violations. See 2AC ¶¶ 902, 934.

Joining eight other circuits, the Sixth Circuit has expressly rejected “cost-recovery claims” for “health-related expenses” where, as here, the “claims are inherently contingent on injury to third-part[ies].” *Perry*, 324 F.3d at 849. Indeed, Plaintiffs’ alleged damages are even more remote than the “pecuniary losses proximately resulting from a personal injury” deemed insufficient in *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013)—damages which were at least related to the plaintiffs’ *own* injuries. Because Plaintiffs’ alleged injuries “rest[] on the independent actions of third and even fourth parties,” and there are “multiple steps” separating “the alleged fraud from the asserted injury,” Plaintiffs lack standing to support a RICO claim as a matter of law. *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 15 (2010).

###### 2. Public Expenditures Are Not Injuries to “Business or Property”

Plaintiffs’ alleged public expenditures also do not constitute injuries to “business or property” sufficient for RICO standing. JM 10-11. Rather than address this fatal deficiency, Plaintiffs argue, irrelevantly, that government entities have RICO standing to sue for lost tax revenue. Opp.

37-38. That argument fails at many levels. First, Plaintiffs’ primary case, *Welborn v. Bank of New York Mellon Corp.*, holds that a government’s RICO standing is limited to “injuries suffered in its capacity *as a consumer* of goods and services.” 557 F. App’x 383, 387 (5th Cir. 2014). Plaintiffs allege no such losses. JM 11. Second, Plaintiffs’ own cases show that to the extent courts have permitted governments to recover damages related to tax revenue, recovery is limited to “tax losses from *unpaid taxes*”—not public expenditures paid out of general tax revenues as Plaintiffs allege here. *See City of N.Y. v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 444-45 (2d Cir. 2008); *see also Ill. Dep’t of Revenue v. Phillips*, 771 F.2d 312, 317 (7th Cir. 1985).<sup>12</sup> At bottom, where, as here, “a governmental body acts in its sovereign or quasi-sovereign capacity, seeking to . . . promote the public well-being, it cannot claim to have been injured in its property for RICO purposes.” *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976 (9th Cir. 2008).

**B. Plaintiffs Fail to Plead Other Elements Required Under RICO**

**1. Plaintiffs Do Not Plead the Existence of an “Opioid Marketing Enterprise”**

Plaintiffs cannot establish the existence of an Opioid Marketing Enterprise for two reasons. First, Plaintiffs now concede that each Manufacturer Defendant was pursuing only its *own* profits and revenues—not those of any alleged *enterprise*. Opp. 50. That concession forecloses any attempt to show that the alleged members of the purported Opioid Marketing Enterprise had a “common purpose.” *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 794 (6th Cir. 2012); *see Boyle v. United States*, 556 U.S. 938, 946 (2009). Indeed, it is black-letter law that RICO defendants must have “conducted or participated in the conduct of the ‘*enterprise’s* affairs,’ not just their

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<sup>12</sup> Notably, the Supreme Court reversed the Second Circuit in *Smokes-Spirits*, *see Hemi Grp.*, 559 U.S. at 15-16 (holding that lost revenue from unpaid taxes does not satisfy RICO’s causation requirements), and the Sixth Circuit has rejected the holding in *Phillips*, *see State of Mich., Dep’t of Treasury, Revenue Div. v. Fawaz*, 848 F.2d 194, 1988 WL 44736, at \*1 (6th Cir. 1988).

*own* affairs.” *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993) (emphases in original). “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.” *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 375 (3d Cir. 2010).

Second, Plaintiffs have not pleaded a “framework or superstructure for making and carrying out decisions.” *Ouwinga*, 694 F.3d at 793. Plaintiffs speculate that the Manufacturer Defendants had “interpersonal relationships” because they were members of trade associations such as PCF and HDA. Opp. 52-53. But “membership in a trade organization . . . does not make Defendants part of an enterprise,” nor does it “render plausible the existence of a conspiratorial agreement.” *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017).

## **2. Plaintiffs Do Not Plead Any Actionable Racketeering Activity**

### **a. Plaintiffs’ Theory of Fraud Is Not Actionable**

Plaintiffs do not dispute that the central premise of their unlawful marketing theory is that the Manufacturer Defendants concealed opioids’ risks of addiction and abuse. *See* JM 20-23. Nor do they dispute the critical facts that establish the implausibility of this theory, namely: that Ohio prescribers have a duty to know the risks of the drugs they prescribe; that an alleged misrepresentation must be viewed in context; and that the context here includes the Manufacturer Defendants’ dissemination of all relevant risk information about their prescription opioids in FDA-approved labels and REMS. *See id.* Rather, Plaintiffs respond by mischaracterizing the Manufacturer Defendants’ argument as asserting that FDA labels “absolve defendants from telling the truth.” Opp. 47. The Manufacturer Defendants make no such argument; instead, they have shown that their FDA-approved labels and REMS were made available to the “learned intermediary” healthcare providers, which establishes as a matter of law that the Manufacturer Defendants did not conceal or minimize opioids’ risks. JM 22-23. To the extent Plaintiffs respond to that argument, each of

their responses fail.

First, Plaintiffs contend that the learned intermediary doctrine does not apply to RICO claims. Opp. 46 n.30. This is wrong. Courts considering civil RICO claims for alleged improper advertising have routinely applied learned intermediary principles when rejecting the plaintiffs' claims. *See, e.g.*, JM 15 (citing, among others, *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008)).<sup>13</sup> A plaintiff must thus allege that the defendants made misrepresentations “reasonably calculated to deceive persons of ordinary prudence and comprehension.” *Advocacy Org. v. Auto Club Ins. Ass’n*, 176 F.3d 315, 322 (6th Cir. 1999); *Ford v. Pa. Higher Educ. Assistance Agency*, 2018 WL 1377858, at \*5 (N.D. Ohio Mar. 19, 2018). Given the Manufacturer Defendants’ extensive risk disclosures, Plaintiffs cannot establish that the Manufacturer Defendants’ alleged concealment of those risks was “calculated to deceive” physicians of “ordinary prudence and comprehension.”<sup>14</sup>

Second, Plaintiffs attempt—for the first time—to challenge the adequacy of the Manufacturer Defendants’ labels. Plaintiffs’ Opposition asserts that the “December 2016 warning labels” submitted as exhibits to the Motion “were preceded by FDA announcements regarding safety label changes and post market study requirements,” which purportedly show that prior labels “did not adequately warn doctors.” Opp. 47. But as the Opposition later admits, the 2AC expressly disclaims any “challenge [to] [Defendants’] FDA-approved labeling.” *Id.* 116; *see* 2AC ¶ 349 (alleging misrepresentations were “contrary to” labels); *see also supra* § III.A. Plaintiffs’ attempt to

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<sup>13</sup> Plaintiffs’ reliance here on *Neurontin* is misplaced for the reasons stated *supra* § II.A.2.

<sup>14</sup> Plaintiffs attempt to distinguish *Carpenters* and *Travelers* by arguing that the plaintiffs there failed to plead fraud because their allegations of unlawful marketing were vague and incomplete. Opp. 48-50. But the allegations of improper marketing were significantly more detailed than those alleged here. Moreover, the court in each case held that, *pleading deficiencies aside*, the plaintiff still could not allege actionable fraud because prescribers are presumed to have knowledge of risks disclosed in drug labeling. *Carpenters*, 2014 WL 2115498, at \*6; *Travelers*, 32 F. Supp. 3d at 553.

modify the 2AC's allegations should be rejected. *See Thomason v. Nachtrieb*, 888 F.2d 1202, 1205 (7th Cir. 1989) (a "complaint may not be amended by the briefs in opposition to a motion to dismiss").

Similarly, while Plaintiffs assert that the 2016 labels "misrepresent label warnings during the relevant time period," Opp. 47, they nowhere allege what prior warnings these labels "misrepresent" or how any relevant warning changed materially over time.<sup>15</sup> Nor could they, as the Manufacturer Defendants' labels have *always* contained extensive disclosures of the risks at issue, including addiction, abuse, and misuse. Judicially-noticeable materials confirm this.<sup>16</sup> Because Plaintiffs do not allege that prescribers lacked access to these disclosures, they cannot maintain their core fraud theory. *See* JM 20-23.

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

Plaintiffs concede that, to satisfy Rule 9(b), they must plead the Manufacturer Defendants' alleged RICO scheme with particularity. Opp. 35. The Opposition fails to point to any allegations in the 2AC that satisfy this requirement. Instead, Plaintiffs contend that the Court should excuse their pleading deficiencies because Rule 9(b) is relaxed in "complex" fraud cases involving publicly available information. *Id.* 27.

That is not the standard. Plaintiffs are not excused in this case from alleging with particularity the factual basis for their contention that the Manufacturer Defendants defrauded prescribers

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<sup>15</sup> For the same reasons, Plaintiffs are wrong that the December 2016 labels "have absolutely no relevance" to "prior" conduct. Opp. 47.

<sup>16</sup> Given Plaintiffs' concession that they do not challenge any label, Opp. 116; 2AC ¶ 349, it is unnecessary and would be impractical to require the Manufacturer Defendants to submit every version of the labeling used for each opioid. Should the Court wish to review earlier labels, they are publicly available at FDA's Online Label Repository, <https://labels.fda.gov>, and FDA's Drug Database, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>, and the Court can judicially notice their contents. *See* Manufacturer Defs.' Request for Judicial Notice (Dkt. #499-2).



in Summit County into writing harmful, ineffective, or medically unnecessary opioid prescriptions. See JM 12 & n.15 (collecting cases); see also *Pirelli Armstrong Tire Corp. Retiree Med. Bens. Tr. v. Walgreen Co.*, 631 F.3d 436, 446 (7th Cir. 2011). Plaintiffs’ recitation of the Manufacturer Defendants’ alleged marketing practices and the nine categories of alleged misrepresentations does not satisfy their obligation. These allegations omit the critical details, failing to identify even one Summit County prescriber whom a Manufacturer Defendant purportedly misled. Opp. 29. The “complex[ity]” of the alleged fraud does not “relax” Rule 9(b); to the contrary, it makes it more critical that Plaintiffs plead the details. See *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 564 (6th Cir. 2003) (“[A] plaintiff should not be able to avoid the specificity requirements of Rule 9(b) by relying upon the complexity of the edifice which he created.”).<sup>17</sup>

Lastly, Plaintiffs turn a blind eye to the 2AC’s flagrant violation of the “prohibition on group pleading.” Opp. 34; see JM 25. Plaintiffs argue with no support that group pleading is barred only in securities fraud cases. Opp. 34. In fact, courts routinely apply the rule against group pleading outside the securities context. See *Aaron v. Durrani*, 2013 WL 5177144, at \*3 (S.D. Ohio Sept. 12, 2013); *Windsor-Laurelwood Ctr. Behavioral Med. v. Waller Lansden Dortch & Davis*, 2013 WL 12303992, at \*5 (N.D. Ohio July 24, 2013); *Kurek v. Ohio Dep’t of Dev. Disabilities*, 2017 WL 1555930, at \*6 (N.D. Ohio Jan. 20, 2017). The group pleading rule requires dismissal here.

**c. Plaintiffs Cannot Attribute Any Third-Party Statements to the**

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<sup>17</sup> Plaintiffs’ reliance on *SFS Check, LLC v. First Bank of Delaware* only undermines their position, as the court there *dismissed* a fraud claim for failure to “specify the time, place, and content of the alleged misrepresentation” and “describe the injury resulting from the fraud.” 774 F.3d 351, 358 (6th Cir. 2014). So too with *Carpenters*, as the court there *dismissed* a RICO claim alleging fraudulent pharmaceutical marketing for failure to plead “the who, what, when, where and how . . . required under Rule 9(b),” including how prescribers—who “are presumed to have knowledge of a drug label’s content”—were misled by the alleged fraud. 2014 WL 2115498, at \*6. The failures here are even worse: Plaintiffs fail to allege even one instance in which any Manufacturer Defendant’s allegedly misleading statements or omissions led a Summit County prescriber to write an ineffective or harmful opioid. JM 24-26. This defeats Count 1. *Id.*



### Manufacturer Defendants

Plaintiffs' Opposition confirms that the Manufacturer Defendants cannot be liable for any third-party statement at issue. As Plaintiffs concede, such statements cannot be attributed to the Manufacturer Defendants absent factual "allegations about a relationship between the parties" that provide a "basis upon which control could be inferred." Opp. 54. According to Plaintiffs, such allegations would include, for example, that the "Manufacturer Defendants gave [third parties] *detailed, step-by-step directions* . . . in carrying out their business operations and were given *virtually no discretion* in performing these operations." *Id.* (quoting *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 417 (S.D. Ohio 1986)).

Plaintiffs nowhere identify any *factual* allegations showing such control. Instead, they double-down on their conclusory allegations that the Manufacturer Defendants "fund[ed], direct[ed], edit[ed], [and] approv[ed]" unspecified third-party activities. Opp. 55. These allegations neither "detail[]" nor "fully explain" any "editorial control." *Id.* They do not explain what "editorial control, if any, is entailed" in the Manufacturer Defendants' unspecified funding, directing, editing, or approving of third-party "materials or events." *City of Chi. v. Purdue Pharma L.P.*, 2015 WL 2208423, at \*11 (N.D. Ill. May 8, 2015). Nor do they link any purported control to any third-party statements at issue. At most, Plaintiffs speculate that control may have existed. For example:

- When discussing grant proposals, Plaintiffs allege only that the Manufacturer Defendants "*suggested*" certain activities. 2AC ¶ 394; *see also id.* ¶ 361.
- When discussing individual physicians, Plaintiffs allege only that the Manufacturer Defendants "kept close tabs on the content of [their] materials" and worked with parties "*likely* to remain on-message." *Id.* ¶ 401.
- When discussing CME programs, Plaintiffs allege only that, by funding purported "Front Groups," the Manufacturer Defendants "*could expect* instructors to deliver messages favorable to them." *Id.* ¶ 441.

None of these allegations shows the requisite “*right of control*” held by [the Manufacturer Defendants] over [any third parties] specifically in the areas of operation relevant to Plaintiffs’ claims.” *Taylor*, 627 F. Supp. at 418. Plaintiffs’ allegations about third-party statements therefore are insufficient to state an unlawful marketing claim against the Manufacturer Defendants. JM 26-27.

**V. THE RICO SUPPLY CHAIN ENTERPRISE CLAIM (COUNT 2) FAILS FOR ADDITIONAL REASONS**

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

Plaintiffs concede that their RICO Supply Chain Enterprise claim is based entirely on the theory that certain Manufacturer Defendants failed to satisfy their purported obligations to monitor, report, and halt suspicious orders under the CSA. Opp. 30; *see* JM 27-33 & n.28. Plaintiffs do not dispute that these purported obligations are owed *only* to DEA, or that the right to enforce the CSA rests exclusively with *the federal government*. *See* JM 27. The federal government’s exclusive enforcement authority on these issues would be meaningless if Plaintiffs could use RICO as an end-run around the CSA. *See id.*; *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1289-90 (C.D. Cal. 2008) (“[W]hat the FDCA does not create directly, RICO cannot create indirectly.”). Plaintiffs cite nothing allowing them to wield RICO in this novel and improper fashion, and the Court should reject their attempt to do so here.

**B. Plaintiffs Fail to Plead Other Elements Required Under RICO**

**1. Plaintiffs Fail to Allege the Existence of an “Opioid Supply Chain Enterprise”**

Plaintiffs’ allegations that the Manufacturer Defendants engaged in parallel conduct and had the mere “*opportunity* to form agreements” by joining industry trade groups, Opp. 56, are insufficient to establish a RICO enterprise, *see supra* § IV.B.1. Plaintiffs cannot cure that deficiency with conclusory allegations that the Manufacturer Defendants tracked their competitors’

prescription opioid sales “yet failed to report them.” Opp. 56-57. As explained *infra* § V.B.2.a, the CSA requires DEA registrants only to monitor and report suspicious orders placed with them for their *own* products—not their competitors’ products. Failure to comply with non-existent obligations cannot establish an unlawful enterprise or conspiracy—and Plaintiffs cite nothing showing otherwise. *Id.*

## 2. Plaintiffs Fail to Plead Any Actionable Racketeering Activity

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

Plaintiffs abandon any claim that the Manufacturer Defendants’ purported monitoring and reporting violations themselves constitute RICO predicates. *See, e.g.*, 2AC ¶¶ 898, 901; Opp. 59. Instead, Plaintiffs argue that the Manufacturer Defendants committed RICO predicate acts by violating 21 U.S.C. § 843(a)(4)(A), a recordkeeping provision that prohibits registrants from knowingly or intentionally furnishing fraudulent information in, or omitting material information from, records filed with DEA. Opp. 59-60. But violation of Section 843(a)(4)(A) is not included in RICO’s list of predicate crimes. *See* 18 U.S.C. § 1961(1). Plaintiffs contend that *any* “felony violation of the CSA is a racketeering activity under section 1961(1)(D).” Opp. 62. If that were the case, however, Section 1961(1)(D) would say so. Instead, Section 1961(1)(D) enumerates *particular types* of felony controlled substance offenses that constitute RICO predicate acts; namely, “the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance.” Plaintiffs’ argument that Section 1961(1)(D) (which applies to felony *drug dealing*) includes recordkeeping violations under Section 843(a)(4)(A) has no support in either the text of the statute or in case law.

Section 843(a)(4)(A) has no application here for additional reasons. The failure to monitor and report suspicious orders implicates, at most, Section 842(a)(5), JM 31-32, which Plaintiffs

concede is not a RICO predicate. Opp. 59-60. In addition, Plaintiffs do not meaningfully respond to the Manufacturer Defendants' argument that under the CSA, DEA registrants have no duties to (1) monitor and report *downstream* suspicious orders or (2) halt suspicious orders at all. JM 32. The relevant DEA regulations require only that DEA registrants monitor and report suspicious orders from *their customers* (i.e., here, wholesale distributors). *See id.*; *see also* Opp. 60 ("The word 'downstream' does not appear in either CSA § 823 or § 1301.74 of the C.F.R.").<sup>18</sup> Similarly, Plaintiffs' proposed "stop shipment" requirement has no basis in any controlled substances statute or regulation. JM 32. Nor does any case impose that requirement on pharmaceutical manufacturers.<sup>19</sup> Plaintiffs' only support for such a requirement comes from a sub-regulatory letter from DEA to its registrants. *See* Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007), *as filed in Cardinal Health, Inc. v. Holder*, No. 12-0185 (D.D.C. Feb. 10, 2012), Dkt. #14-8; *see also* 2AC ¶¶ 523-35 (citing DEA letter). But that letter carries no legal force, is not entitled to *Chevron* deference, and thus cannot sustain the sweeping obligations that Plaintiffs attempt to impose on the Manufacturer Defendants. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001).

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

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<sup>18</sup> Plaintiffs' observation that Mallinckrodt's July 2017 settlement with DEA resolved allegations that Mallinckrodt did not properly monitor and report suspicious orders makes no difference, Opp. 60, as the settlement included no admission that Mallinckrodt owed a duty to monitor and report downstream orders. *See* Admin. Memo. of Agreement § I.4 (July 7, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (last visited July 13, 2018). And, of course, nothing in that settlement can be imputed to other Defendants.

<sup>19</sup> Plaintiffs cite *Masters Pharm., Inc. v. DEA*, but that case involves only distributors. 861 F.3d 206, 212-13 (D.C. Cir. 2017). Further, to the extent *Masters Pharm.* held that non-binding internal DEA policy statements impose a "stop shipment" requirement on DEA registrants, it did so with no analysis. *Id.* The court's reliance on these policy statements fails for the reasons stated above.

Count 2 also fails for lack of particularity. As the Motion explains, Plaintiffs have not alleged any specific misrepresentations or omissions in connection with the Manufacturer Defendants' alleged failure to comply with the monitoring and reporting obligations under the CSA and its implementing regulations. JM 33. Rather than respond to this argument,<sup>20</sup> Plaintiffs assert that “[t]he mail and wire fraud statutes [] do not require a misrepresentation or omission; a scheme or artifice to defraud will suffice.” Opp. 30. But a “scheme to defraud” necessarily consists of “intentional fraud,” and “[t]o allege intentional fraud, there must be proof of misrepresentation[] or omission[.]” *Advocacy Org.*, 176 F.3d at 322. Because the 2AC fails to identify any such misrepresentation or omission with the particularity required under Rule 9(b), Plaintiffs' RICO Supply Chain Enterprise claim should be dismissed. JM 33-34.

#### VI. THE OCPA CLAIMS (COUNTS 3-4) FAIL FOR ADDITIONAL REASONS

Plaintiffs' failure to state a RICO claim dooms their OCPA claims. *See* JM 38; *Aaron v. Durrani*, 2014 WL 996471, at \*8 (S.D. Ohio Mar. 12, 2014) (“[RICO analysis] applies equally” to the OCPA).<sup>21</sup> The Opposition also confirms that Plaintiffs cannot establish OCPA's requisite “pattern” of corrupt activity. As Plaintiffs acknowledge, Opp. 68, “[a] plaintiff seeking to recover under the [OCPA] must allege a pattern of corrupt activity that includes at least one predicate act that is not *a form of* securities fraud, mail or wire fraud.” *W. & S. Life Ins. Co. v. JPMorgan Chase*

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<sup>20</sup> The Opposition refers only to generalized allegations of “false and misleading statements.” *See, e.g.*, Opp. 30 (citing 2AC ¶ 856). None of these allegations specifically identifies any fraudulent representation or omission made in connection with any particular suspicious order.

<sup>21</sup> Contrary to Plaintiffs' suggestion, Opp. 64-65, the Manufacturer Defendants did not move to dismiss the OCPA claim for lack of standing, *see* JM 38-39. And Plaintiffs' argument that OCPA does not require a “direct injury,” Opp. 66, is immaterial. The Ohio Supreme Court has “adopted the *Holmes* Court's proximate cause analysis” as state law. *City of Cleveland*, 615 F.3d at 503. Regardless of whether OCPA imposes a “direct injury” requirement for standing, proximate causation sufficient to satisfy *Holmes* is an essential element of the claim. *See Trollinger*, 370 F.3d at 613.

*Bank, N.A.*, 54 F. Supp. 3d 888, 915 (S.D. Ohio 2014). To the same end, the OCPA expressly requires that the alleged incidents giving rise to the “[p]attern of corrupt activity . . . are not so closely related to each other and connected in time and place that they constitute a single event.” O.R.C. § 2923.31(E).

Here, Plaintiffs allege no predicate act that is not “a form of” mail or wire fraud: Ohio’s telecommunications fraud statute is substantively identical to the federal mail and wire fraud statutes.<sup>22</sup> Indeed, the cases they cite all involve alleged predicate acts that, unlike here, were *not* forms of mail or wire fraud. *See Canterbury v. Columbia Gas of Ohio*, 2001 WL 1681132, at \*10-13 (S.D. Ohio Sept. 25, 2001) (extortion and theft); *Bradley v. Miller*, 2013 WL 1326868, at \*7 (S.D. Ohio Mar. 28, 2013) (money laundering). Moreover, the acts underlying the alleged telecommunications fraud are the same acts underlying the alleged mail and wire fraud. JM 39. That is fatal to Plaintiffs’ OCPA claim. *See Cap City Dental Lab, LLC v. Ladd*, 2016 WL 4573993, at \*10 (S.D. Ohio Sept. 1, 2016) (“[U]nderlying offenses . . . cannot support a pattern of corrupt activity” when they “are predicated upon the same set of operative facts, are raised against the same set of defendants, and involve the same property.”); *Rahimi v. St. Elizabeth Med. Ctr.*, 1997 WL 33426269, at \*2 n.1 (S.D. Ohio July 16, 1997). Plaintiffs’ OCPA claim should be dismissed. *See* JM 38-40.

## **VII. THE COMMON LAW AND STATUTORY PUBLIC NUISANCE CLAIMS (COUNTS 5-6) FAIL FOR ADDITIONAL REASONS**

### **A. Both Claims Are Abrogated by the Ohio Product Liability Act**

For the reasons stated in the opening briefs and the Distributor Defendants’ Reply (Dkt. #744) (which is here adopted by reference), OPLA abrogates Plaintiffs’ common law and statutory

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<sup>22</sup> 21 U.S.C. § 843(a)(4)(A) does not qualify as a predicate act under the OCPA. *See supra* § V.B.2.a.

nuisance claims. Counts 5 and 6 should be dismissed accordingly.

**B. The Common Law Claim Is Barred by the Economic Loss Rule**

Plaintiffs concede that Ohio’s economic loss rule prevents tort plaintiffs from recovering economic losses absent injury to their persons or property. Opp. 21-22. Attempting to avoid this bar, Plaintiffs argue that their absolute public nuisance claim is an “equitable claim to abate a nuisance.” *Id.* 21. This new “equitable” claim is much narrower and different than the tort-based nuisance claim asserted in the 2AC. *See, e.g.*, 2AC ¶ 1037 (“Plaintiffs assert this Cause of Action as a common law tort claim . . .”). In the 2AC, Plaintiffs pleaded a broad public-nuisance claim and requested “all *legal* and equitable relief as allowed by law,” including “compensatory and *punitive* damages.” *Id.* ¶ 1038. Plaintiffs now have abandoned any claim for damages and seek only prospective relief to “abate” the nuisance. Opp. 8 n.6 (“To the extent the SAC can be read to also assert a nuisance claim for damages as private litigants, Plaintiffs have chosen not to press and withdraw that claim.”); *see also id.* 21 (“There are numerous differences between an action for tort damages and an action for an injunction or abatement . . . [A]n award of damages is retroactive, applying to past conduct, while an injunction applies only to the future.”). Even Plaintiffs’ reconfigured equitable public nuisance claim does not avoid the bar of the economic loss rule.

As an initial matter, it is well-settled that, in Ohio, “public nuisance is a theory of recovery *in tort*.” *RWP, Inc. v. Fabrizi Trucking & Paving Co.*, 2006 WL 2777159, at \*4 (Ohio Ct. App. Sept. 28, 2006); *Parker v. City of Upper Arlington*, 2006 WL 832523, at \*2 (Ohio Ct. App. Mar. 31, 2006) (same); *see* JM 41. Plaintiffs do not cite a single Ohio case holding that an absolute public nuisance claim is equitable in nature.

Likewise, nothing supports Plaintiffs’ argument that the economic loss doctrine does not apply to absolute public nuisance claims because they are intentional torts. Opp. 22. No Ohio court has made this distinction in a public nuisance case. *See City of Cincinnati v. Deutsche Bank Nat’l*

*Tr. Co.*, 863 F.3d 474, 478 (6th Cir. 2017). Plaintiffs’ reliance on *Eysoldt v. ProScan Imaging*, Opp. 22, is misplaced—that case involved a claim for conversion, not public nuisance. 957 N.E.2d 780, 784 (Ohio Ct. App. 2011). By contrast, in *RWP*, the Ohio Court of Appeals held that the economic loss rule barred absolute nuisance claims, as “a claim of absolute nuisance . . . requires that the plaintiff sustain injury to property.” 2006 WL 2777159, at \*3-4. This Court should follow *RWP* and hold that the economic loss rule bars Count 6.

Even if the Court were to allow this absolute public nuisance claim at this stage, the Manufacturer Defendants respectfully suggest the Court should, at a minimum, limit the damages request to prospective abatement of the alleged nuisance.

### C. Plaintiffs Fail to Plead the Necessary Elements for the Common Law Claim

***No Public Right.*** Plaintiffs incorrectly assert that their claims do not rely on the individual rights of Summit County residents to be “safe from defective products.” Opp. 10. Under the Restatement (Second) of Torts (“Restatement”),<sup>23</sup> to qualify as a “public right” for purposes of a

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<sup>23</sup> Plaintiffs’ citation to dismissal orders from other opioid litigation matters is unavailing. *See* Opp. 9-10. The Restatement governs Ohio common law nuisance claims. *See Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at \*3 (Ohio Ct. App. March 21, 2013). By contrast, the court in *State v. AmerisourceBergen Drug Corp.*, No. 12-C-141 (W.V. Cir. Ct. Dec. 12, 2014), expressly declined to follow the Restatement in interpreting West Virginia law. The court in *In re Opioid Litig.*, Index No. 400000/2017 (N.Y. Sup. Ct. June 18, 2018), did apply the Restatement in interpreting New York law, but did so, the Manufacturer Defendants respectfully submit, incorrectly. Under the Restatement § 821B cmt. g, contrary to the court’s holding, the mere allegation that a large number of people suffer from opioid addiction does not transform their individual rights into a public right. The court thus erred in holding that plaintiffs had alleged the existence of a public right by pleading that the opioid crisis had “affected a considerable number of persons.” *In re Opioid Litig.*, Index No. 400000/2017 (N.Y. Sup. Ct. June 18, 2018) (Slip op. at 28). Moreover, the court conflated the elements of “public right” and “unreasonable interference.” Under the Restatement, conduct does not qualify as a public nuisance absent interference with a “**public right**,” even if that conduct constitutes a “significant interference” to the “public health.” Restatement § 821B(1)-B(2)(a). Thus, for example, conduct that exposes individuals who use a public right-of-way to a contagious illness qualifies as an unreasonable interference with the public right to use that right-of-way; by contrast, making false statements that may harm an individual’s health,



public nuisance claim, the right must be “collective in nature and *not* like the individual right that everyone has not to be . . . defrauded or negligently injured.” Restatement § 821B cmt. g. Here, however, the purported rights with which the Manufacturer Defendants allegedly interfered—the right not to be defrauded or injured in connection with the provision of prescription opioid treatment—are individual, not collective. *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.”). As such, Plaintiffs have not adequately alleged the existence of a “public right.”

***No Unreasonable Interference.*** Plaintiffs concede that “protection against public nuisance liability is awarded to those who operate subject to the limitations imposed by a comprehensive regulatory scheme.” Opp. 11. But Plaintiffs allege no facts establishing that the Manufacturer Defendants failed to comply with any federal or state law governing the manufacture, sale, or marketing of prescription opioids. *See* JM 44. Recognizing their pleading deficiencies, Plaintiffs argue that the Court nevertheless should permit the public nuisance claim to proceed under *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002). Opp. 12. That case is inapposite, as the alleged conduct there involved specific distribution and marketing practices that were not subject to federal or state law firearms regulation. *See id.* at 1143 (“[T]he law does not **regulate** the distribution practices alleged in the complaint.”). Here, the Manufacturer Defendants’ manufacturing and marketing activities are subject to extensive and comprehensive federal and state regulation. JM 44-45.

***No Allegation of Necessary Intent.*** Plaintiffs do not allege facts showing that the Manu-

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as alleged here, is an interference only with an “individual right.” *Id.* § 821B cmt. g. The Manufacturer Defendants intend to take an interlocutory appeal of the New York ruling.

facturer Defendants “intended to bring about the conditions” of the opioid crisis—widespread opioid abuse, misuse, and addiction. *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017).<sup>24</sup> Instead, Plaintiffs allege only that the Manufacturer Defendants’ marketing activity was “designed to dramatically increase the demand for and sale of opioids,” 2AC ¶ 9, and that the Manufacturer Defendants “should have known” that their alleged failure to maintain effective anti-diversion controls would have “serious consequences,” *id.* ¶ 520. But intending to increase the lawful sale of lawful products does not amount to intending to create a public health crisis, and knowledge is insufficient to establish intent for absolute public nuisance claims. JM 44. Plaintiffs’ failure to adequately plead such intent also defeats Count 4. *Id.*<sup>25</sup>

#### **D. Plaintiffs Fail to Plead a Predicate Violation for the Statutory Claim**

The Manufacturer Defendants’ Motion explained why the 2AC fails to plead a violation of any predicate statute or regulation for Plaintiffs’ statutory nuisance claim. JM 45-47. Plaintiffs offer no response.<sup>26</sup> Instead, they simply assert in conclusory fashion that the 2AC pleads “violat[ions] [of] federal and state laws constituting a nuisance.” Opp. 17. This non-response is wholly

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<sup>24</sup> To the extent Plaintiffs argue they need not allege intent to establish an absolute public nuisance, this argument fails. Opp. 15. The Sixth Circuit has held that Ohio law recognizes only “two forms” of absolute public nuisance: the “[1] the intentional creation of a public nuisance or [2] an abnormally dangerous condition.” *City of Cincinnati*, 863 F.3d at 477. Plaintiffs thus cannot establish an absolute public nuisance merely by alleging that the Manufacturer Defendants engaged in “unlawful conduct.” Opp. 15. Even if they could, Plaintiffs have not adequately pleaded that the Manufacturer Defendants violated any law. JM 19-20, 34-38, 42-47; *see supra* §§ IV.B.2, V.B.2, VI; *infra* §§ VII.D, VIII-IX.

<sup>25</sup> Plaintiffs are wrong in their assertion that public nuisance claims raise factual issues that cannot be resolved at the pleading stage. Opp. 13. Courts can, and routinely do, dismiss such claims on the pleadings, including for failure to plead proximate cause. *See, e.g., District of Columbia v. Beretta U.S.A. Corp.*, 872 A.2d 633, 646-51 (D.C. App. 2005); *Camden Cty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp.*, 273 F.3d 536, 541 (3d Cir. 2001); *City of Cleveland*, 621 F. Supp. 2d at 532; *City of Chi. v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1136-38 (Ill. 2004).

<sup>26</sup> Plaintiffs’ response to Count V’s other defects—i.e., lack of causation and preemption—fails for the reasons discussed *supra* §§ II-III. Moreover, Plaintiffs have withdrawn their request for

inadequate to rebut the Manufacturer Defendants' arguments or show how Count 5 otherwise pleads a requisite statutory or regulatory violation.

Nor can Plaintiffs save Count 5 by arguing that its deficiencies turn on "factual dispute[s]." *Id.* 18. The deficiencies turn on straightforward interpretations of statutes and regulations, including some that on their face apply only to wholesale distributors; another that merely defines "dangerous drug"; and a final one that exempts from liability "manufacturers . . . whose conduct is in accordance with" certain Ohio laws.<sup>27</sup> JM 46-47. Plaintiffs' failure to identify a germane (and actionable) statutory or regulatory violation defeats Count V. *See Roberts v. Hamer*, 655 F.3d 578, 582 (6th Cir. 2011) ("A matter requiring statutory interpretation is a question of law.")<sup>28</sup>

### VIII. THE NEGLIGENCE CLAIM (COUNT 7) FAILS FOR ADDITIONAL REASONS

Plaintiffs have not adequately pleaded the existence of a duty or causation. JM 47. Nor can they circumvent the economic loss rule or federal preemption. *Id.* For each of these reasons, the Court should dismiss Plaintiffs' negligence claim.

In an attempt to re-characterize their failed negligence claim, Plaintiffs argue that they do not seek to enforce "statutory duties," but instead rely on Ohio and federal statutes only as evidence

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nuisance damages, *see* Opp. 8 n.6, providing another basis to strike that request. *See* JM 45, n.39.

<sup>27</sup> Plaintiffs argue that the Court cannot decide whether the safe harbor defense under O.R.C. § 2925.02(B) applies because it is "an affirmative defense" not resolvable at the pleading stage. Opp. 18 n.14. But the Court may consider the defense because Plaintiffs have "explicitly addressed it in the pleadings," and "the undisputed facts conclusively establish [it] as a matter of law." *Estate of Barney v. PNC Bank*, 714 F.3d 920, 926 (6th Cir. 2013); *see* 2AC ¶ 987; JM 46-47.

<sup>28</sup> In their Opposition, Plaintiffs cite additional purported statutory and regulatory violations that the 2AC does not invoke. *Compare* Opp. 17 (citing 21 U.S.C. § 821; O.R.C. §§ 3719, 4729; and 21 C.F.R. §§ 1303.11, 1306.04), *with* 2AC ¶¶ 984-86. The Court should ignore all of them. *See Thomason*, 888 F.2d at 1205. Moreover, none of these additional authorities can sustain Count V, as none imposes any duties or obligations on the Manufacturer Defendants: 21 U.S.C. § 821 and 21 C.F.R. § 1303.11 govern the scope of the federal government's regulatory authority; 21 C.F.R. § 1306.04 applies only to prescribers; and O.R.C. §§ 3719.01, 4729 merely define certain terms.

of the Manufacturer Defendants’ common-law duties under a negligence *per se* theory. Opp. 74-77. But Ohio does not allow a negligence *per se* claim unless the underlying statute provides a private right of action. *Rogozinsky v. Danek Med., Inc.*, 1999 WL 33537323, at \*2 (N.D. Ohio July 8, 1999); *see also Chambers v. St. Mary’s Sch.*, 697 N.E.2d 198, 202-03 (Ohio 1998). Plaintiffs purport to base their negligence *per se* claim on alleged violations of the CSA and “similar Ohio statutes,” Opp. 75, but none of the cited statutes provides a private right of action, *see supra* §§ V.A, VII.D; JM 27-28, 45-47. Plaintiffs therefore cannot rely on a negligence *per se* theory. 2AC ¶¶ 1060-61.

#### **IX. THE FRAUD CLAIM (COUNT 8) FAILS FOR ADDITIONAL REASONS**

Under Ohio Supreme Court precedent, “a fraud claim cannot be predicated on . . . misrepresentations made to third parties.” *Lucarell v. Nationwide Mutual Ins. Co.*, 97 N.E.3d 458, 469 (Ohio 2018). Plaintiffs’ failure to plead first-party reliance dooms their fraud claim. JM 48-49. *Lucarell* forecloses Plaintiffs’ argument that they may maintain a common law fraud claim when a defendant allegedly made a misrepresentation to an intermediary with the intent that the misrepresentation be conveyed to the plaintiff. Opp. 91.<sup>29</sup> Even if Plaintiffs’ characterization of the standard were correct (and it is not), the 2AC still would not meet it here. The crux of Plaintiffs’ fraud theory is that the Manufacturer Defendants made representations and omissions to physicians, who in turn prescribed opioid medications to patients. *E.g.*, 2AC ¶ 1074. The 2AC does not allege that the Manufacturer Defendants made any misrepresentations or omissions with intent that they be

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<sup>29</sup> Plaintiffs’ reliance on *Nernberg v. Pearce*, 35 F.3d 247 (6th Cir. 1994), and *Lewis v. Horace Mann Ins. Co.*, 410 F. Supp. 2d 640 (N.D. Ohio 2005), fails, as both cases pre-date *Lucarell*. *See* Opp. 91-92. And neither treatise Plaintiffs cite discusses any post-*Lucarell* case that dictates a different result. *See id.* (citing 50 Ohio Jur. 3d Fraud and Deceit § 79 and Restatement § 533).

conveyed to *Plaintiffs*. The 2AC asserts in general terms that the Manufacturer Defendants’ alleged misrepresentations and omissions caused Plaintiffs harm, *id.* ¶ 1083, but it nowhere alleges that the Manufacturer Defendants targeted the alleged fraud at Plaintiffs or that Plaintiffs made expenditures for any allegedly improper opioid prescriptions that resulted, *see* Opp. 3 n.2.

**X. THE “INJURY THROUGH CRIMINAL ACTS” CLAIM (COUNT 9) FAILS FOR ADDITIONAL REASONS**

Plaintiffs cannot plead violation of O.R.C. § 2307.60 because they cannot allege that any Manufacturer Defendant has been convicted of the alleged criminal acts underlying their claim.<sup>30</sup> Plaintiffs argue that the Ohio Supreme Court, in *Jacobson v. Kaforey*, 75 N.E.3d 203 (Ohio 2016), abolished the criminal conviction requirement. Opp. 92-93.<sup>31</sup> But *Jacobson* did not even address that requirement. Rather, the *Jacobson* court held only that § 2307.60 authorizes a cause of action “for damages resulting from any criminal act,” 75 N.E.3d at 207, and expressly limited its holding: “*Any* ensuing issues regarding how the statute operates or what a plaintiff must do to prove a claim under R.C. 2307.60(A)(1) are beyond the scope of this appeal,” *id.* at 206.

*Jacobson* thus left intact existing Ohio precedent requiring a conviction under § 2307.60. *See* JM 49-50. Indeed, the only cases Plaintiffs cite purportedly holding otherwise mistakenly re-

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<sup>30</sup> The alleged criminal acts are: (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. 2AC ¶¶ 1092-98. Plaintiffs’ allegations that certain Manufacturer Defendants pleaded guilty to unrelated criminal charges or entered into civil settlements are insufficient, Opp. 95, as Plaintiffs fail to allege that any plea involved the specific criminal acts alleged here, and civil settlements by definition are not criminal convictions.

<sup>31</sup> Plaintiffs’ additional argument that the Manufacturer Defendants do not “dispute that Plaintiffs’ allegations support a finding of violations of R.C. § 2925.02(A),” Opp. 94-95, is contradicted by the Motion: as the Manufacturer Defendants have argued, Plaintiffs have not alleged any violation of Ohio or federal law, including O.R.C. § 2925.02(A). *See, e.g.*, JM 46.

lied on a *different section* of the Ohio Revised Code—§ **2307.61(G)(1)**—which provides an exception, not applicable here, to the general requirement that plaintiffs must plead a conviction.<sup>32</sup> That § 2307.61(G)(1) explicitly specifies that no criminal conviction is required under that provision reinforces the case law holding that § 2307.60 *does* require one—if the Ohio legislature did not want to require a conviction under § 2307.60, “it certainly knew how” to say so, and it did not. *Felton v. Felton*, 679 N.E.2d 672, 678 (Ohio 1997). Plaintiffs have not pleaded any facts to satisfy the conviction requirement, and Count 9 should be dismissed accordingly.

#### **XI. THE UNJUST ENRICHMENT CLAIM (COUNT 10) FAILS FOR ADDITIONAL REASONS**

Plaintiffs mischaracterize the Manufacturer Defendants’ argument for dismissing the unjust enrichment claim. The Manufacturer Defendants do not argue that Plaintiffs cannot raise claims in the alternative. *See* Opp. 95-96. Rather, the claim must be dismissed because it is premised on the same defective allegations as Plaintiffs’ other claims. *See* JM 50; 2AC ¶¶ 1109, 1118-19. Plaintiffs do not respond to that argument.

Nor do Plaintiffs rebut the second ground for dismissing their unjust enrichment claim: under Ohio law, only direct purchasers may bring such claims. *See* JM 51; *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005). The cases Plaintiffs cite for their “negative externality” theory, *see* Opp. 96-99, are inapposite: all either preceded the Ohio Supreme Court’s decision in *Johnson*, were not decided under Ohio law, did not involve unjust enrichment claims, or, unlike

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<sup>32</sup> The two cases that Plaintiffs cite are *Gonzalez v. Spofford*, 2005 WL 1541016 (Ohio Ct. App. June 30, 2005) and *Chem. Bank v. Kaumeyer*, 2016 WL 7178662 (N.D. Ohio Dec. 9, 2016). Opp. 94. But as the Ohio Court of Appeals has explained, *Gonzalez*’s reliance on Ohio Revised Code § 2307.**60** “*appears to be a clerical error*—the proposition is found in R.C. 2307.**61**.” *Cuyahoga Heights Local Sch. Dist. v. Palazzo*, 69 N.E.3d 162, 166 n.1 (Ohio Ct. App. 2016). *Kaumeyer* is similarly erroneous, as it relied on *Palazzo*, which was referencing § 2307.**61(G)(1)**. *See* 2016 WL 7178662, at \*7; *Palazzo*, 69 N.E.3d at 166. Plaintiffs’ remaining cases do not address whether a conviction is required under § 2307.60.

here, involved a direct relationship between the parties.<sup>33</sup> Further, despite Plaintiffs' contention otherwise, federal courts regularly apply *Johnson* outside the antitrust context to dismiss unjust enrichment claims where, as here, there is no direct economic relationship between the parties.<sup>34</sup> This Court should do the same.<sup>35</sup>

## **XII. THE CIVIL CONSPIRACY CLAIM (COUNT 11) FAILS FOR ADDITIONAL REASONS**

The Opposition confirms that Plaintiffs cannot establish a claim for civil conspiracy.<sup>36</sup> Recognizing their failure to plead an express agreement, Plaintiffs contend that they have instead alleged that the Manufacturer Defendants acted pursuant to “a common understanding or design.” Opp. 100. But Plaintiffs' attempt to re-characterize their civil conspiracy claim fails for the same reasons stated in the Motion: the 2AC fails to plead with the requisite specificity *any* common understanding between the 35 distinct Defendants (many of whom are competitors). JM 51-53.

For example, on Plaintiffs' marketing-based claims, the Opposition merely cites to various

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<sup>33</sup> See, e.g., *Moore v. Texaco, Inc.*, 244 F.3d 1229, 1233 (10th Cir. 2001) (applying Oklahoma law); *McCloud v. Testa*, 97 F.3d 1536, 1551 n. 21 (6th Cir. 1996) (no unjust enrichment claim; pre-*Johnson*); *Little Hocking Water Ass'n v. E.I. du Pont de Nemours & Co.*, 91 F. Supp. 3d 940, 986 (S.D. Ohio 2015) (defendant alleged to have dumped waste directly onto plaintiff's property); *White v. Smith & Wesson*, 97 F. Supp. 2d 816 (N.D. Ohio 2000) (pre-*Johnson*); *Hummel v. Hummel*, 14 N.E.2d 923, 927 (Ohio 1938) (contracting parties; pre-*Johnson*).

<sup>34</sup> See, e.g., *Young v. Carrier Corp.*, 2014 WL 6617650, at \*7 (N.D. Ohio Nov. 21, 2014) (products liability); *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Lit.*, 684 F. Supp. 2d 942, 951-53 (N.D. Ohio 2009) (same); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d 1090, 1116 (C.D. Cal. 2012) (consumer protection); *Randleman v. Fid. Nat'l Title Ins. Co.*, 465 F. Supp. 2d 812, 824 (N.D. Ohio 2006) (same).

<sup>35</sup> Even if Plaintiffs could pursue a “negative externality” theory, they have failed to adequately plead it: for example, the 2AC makes only conclusory allegations that Plaintiffs have “pa[id] for Defendants' externalities,” 2AC ¶¶ 1113-14, and nowhere explains how Plaintiffs' alleged increased expenditures were “part of the [Manufacturer] Defendants' businesses,” Opp. 98.

<sup>36</sup> Plaintiffs do not dispute that their derivative civil conspiracy fails to the extent there are no actionable underlying torts. JM 51. Nor do Plaintiffs dispute that their negligence claim cannot serve as a predicate for civil conspiracy. *Id.* 51 n.47.



paragraphs in the 2AC and asserts, in general terms, that these allegations are sufficient to establish a conspiratorial agreement. Opp. 101. But these paragraphs plead only parallel conduct,<sup>37</sup> which is insufficient to establish a common understanding or design. JM 52. So too with their diversion-based claims: Plaintiffs cite paragraphs that are either wholly irrelevant to the Manufacturer Defendants, Opp. 103 (citing 2AC ¶¶ 607-26), or make only a conclusory allegation of conspiracy or parallel activity, *id.* (citing 2AC ¶¶ 906-38, 950-73, 1122-36). The Opposition identifies no allegations establishing any communications or meetings between any Manufacturer Defendants that evince a “common understanding or design”—much less an actual agreement—to engage in deceptive marketing or to violate any suspicious order monitoring and reporting obligations.<sup>38</sup>

The Court also cannot infer the existence of a conspiracy merely because the Manufacturer Defendants participated in two industry-wide trade associations (PCF and HDA). *Id.* 104. “[M]ere participation in trade organizations does not render plausible the existence of a conspiratorial agreement.” *Almanza*, 851 F.3d at 1072. Otherwise, every trade association would be a *de facto* conspiracy. In any event, this theory rests entirely on two conclusory allegations, 2AC ¶¶ 547, 549, and the Opposition pleads no unlawful conduct by these associations; indeed, Plaintiffs concede

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<sup>37</sup> By way of example, Plaintiffs argue that an industry-wide agreement to engage in false marketing can be inferred from the Manufacturer Defendants’ “marketing conduct” itself. Opp. 101-02. But Plaintiffs concede that the Manufacturer Defendants sell different opioids and engaged in different marketing activities at different times, using different methods, through different media. 2AC ¶¶ 67, 72, 76, 83, 91, 95, 104, 357-464. As in other competitive industries, parallel funding of third party organizations like trade associations establishes only independent profit-seeking behavior, not an illicit agreement. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 564 (2007) (“[Plaintiffs’ conspiracy] claim [is based] on descriptions of parallel conduct and not on any independent allegation of actual agreement.”).

<sup>38</sup> Plaintiffs’ failure to adduce any such allegations of conspiracy, whether direct or circumstantial, distinguishes this case from *Weberg v. Franks*, 229 F.3d 514, 526-28 (6th Cir. 2000).



that the HDA published materials to encourage distributors to report suspicious orders—the opposite of any illicit conspiracy. *Id.* ¶¶ 512, 824e.<sup>39</sup>

### **XIII. ALL CLAIMS SHOULD BE DISMISSED, IN PART, AS TIME-BARRED**

Contrary to Plaintiffs’ contention, *see* Opp. 123, the Court may dismiss Plaintiffs’ claims, in part,<sup>40</sup> as time-barred because the 2AC “explicitly address[es]” the limitations defense and “the undisputed facts conclusively establish [it] as a matter of law.” *Estate of Barney*, 714 F.3d at 926. Specifically, the 2AC devotes an entire section to discussing the purported timeliness of Plaintiffs’ claims. *See* 2AC ¶¶ 767-77. And as the Motion explains, Plaintiffs’ claims—which rely largely on conduct dating back to the mid-1990s—are time-barred as a matter of law to the extent they rely on alleged conduct committed outside the applicable limitations periods. JM 53-54 & n.49.<sup>41</sup> Plaintiffs’ Opposition attempts to escape this result based on the fraudulent concealment, equitable tolling, and continuing violation doctrines.<sup>42</sup> None applies.

First, the 2AC establishes that Plaintiffs were on notice of their claims before 2013. *See*

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<sup>39</sup> Plaintiffs incorrectly rely on *In re Polyurethane Foam Antitrust Litig.*, 152 F. Supp. 3d 968 (N.D. Ohio 2015), to argue that trade membership alone could support an inference of conspiracy. But the alleged co-conspirators in that case engaged in regular joint communications in connection with the operation of joint ventures and on sales calls with shared customers. *Id.* at 992. No such allegation is made here.

<sup>40</sup> Courts routinely consider on a Rule 12(b)(6) motion whether claims are time-barred in part, rather than in whole. *See, e.g., Meros v. Dimon*, 2017 WL 6508723, at \*7 (S.D. Ohio Dec. 20, 2017). Plaintiffs cite no support for their claim that such dismissal is improper. Opp. 122 & n.90.

<sup>41</sup> This includes Plaintiffs’ nuisance claims, which, contrary to Plaintiffs’ argument, are not exempt from statutes of limitations. Opp. 123-24. Unlike the State of Ohio, political subdivisions like Plaintiffs are not exempt from such limitations. *See Ohio Dep’t of Transp. v. Sullivan*, 527 N.E.2d 798, 799-800 (Ohio 1988). Further, the rule pronounced in *Little Miami R.R. Co. v. Comm’rs of Green Cty.*, 31 Ohio St. 338, 349 (1877), was later cabined to adverse possession cases, *Houck v. Bd. of Park Comm’rs*, 876 N.E.2d 1210, 1213 (Ohio 2007), and then abrogated by O.R.C. § 2305.09(D), which sets a four-year limitations period for nuisance claims. *See Law v. Lake Metroparks*, 2006 WL 3833863, at \*3 n.2 (Ohio Ct. App. Dec. 29, 2006); *Ashtabula River Corp. v. Conrail, Inc.*, 549 F. Supp. 2d 981, 984 (N.D. Ohio 2008).

<sup>42</sup> Plaintiffs’ Opposition abandons any argument relating to the discovery rule.

2AC ¶¶ 169, 183-88, 198-201, 267, 271, 284, 286, 315, 327, 788-89. And Plaintiffs have not alleged what action of the Manufacturer Defendants—apart from the alleged underlying fraud itself—kept Plaintiffs from filing suit sooner. *See id.* ¶¶ 767-77; *Bishop v. Lucent Techs., Inc.*, 520 F.3d 516, 520-21 (6th Cir. 2008). Instead, Plaintiffs stand on their bare allegation that they were unaware of the facts underlying their cause of action. Opp. 124-26; 2AC ¶¶ 772-73. These allegations, however, are insufficient to trigger application of either the fraudulent concealment or equitable tolling doctrines. *See Bishop*, 520 F.3d at 520-21 (“[P]laintiffs may not simply rely on the bare assertion that they were unaware of the facts underlying their cause of action.”).

Second, the continuing violation doctrine also does not apply here. The doctrine applies narrowly to claims of a “cumulative violation” caused by a “continuing course of misconduct.” *Sta-Rite Indus., LLC v. Franklin Elec. Co.*, 519 F. App’x 370, 381 (6th Cir. 2013).<sup>43</sup> Conceding that the 2AC alleges only “discrete acts” by the Manufacturer Defendants, Plaintiffs argue that these acts are merely “representative examples” of continuing conduct. Opp. 127 & n.93. But Plaintiffs cite no authority holding that pleading discrete acts as “examples” of continuous conduct satisfies the continuing violation doctrine.<sup>44</sup> Plaintiffs also cannot show that the Manufacturer Defendants’ alleged conduct has caused Plaintiffs’ alleged injuries to accrue continuously. Plaintiffs vaguely point to the various costs associated with the opioid epidemic. Opp. 127-28. But even assuming they could show causation, Plaintiffs cannot avoid the fact that different prescribers

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<sup>43</sup> Plaintiffs cite no Sixth Circuit case that supports their contention that the continuing violation doctrine applies broadly outside the Title VII context. *See* Opp. 126 n.92. There is none. *See* JM 56. Instead, Plaintiffs cite only a law review article, which in turn cites only an overruled Ohio case. *See* Kyle Graham, *The Continuing Violations Doctrine*, 43 Gonz. L. Rev. 271, 301 (2008).

<sup>44</sup> Moreover, the few “examples” the Opposition cites—the Manufacturer Defendants’ supposed “invisible control over prescribing guidelines”—do not involve continuing *conduct* but rather purported continuing *effects*, specifically, that these guidelines “remain in circulation.” Opp. 127, n.93. Continuing effects of alleged misconduct, however, are insufficient to trigger the continuing violation doctrine. *See Pittman v. Spectrum Health Sys.*, 612 F. App’x 810, 814 (6th Cir. 2015).

would have relied on different alleged representations, and different “suspicious” orders would have caused discrete harms. *See Bowerman v. Int’l Union*, 646 F.3d 360, 367 (6th Cir 2011). Finally, Plaintiffs’ Opposition confirms that the Manufacturer Defendants would not have prevented further alleged harm by ceasing the alleged misconduct. Indeed, Plaintiffs assert that opioid abuse, misuse, and addiction still “continues to spread.” Opp. 127-28. The continuing violation doctrine simply does not apply.

### **CONCLUSION**

For the foregoing reasons, the Court should dismiss the 2AC with prejudice.

Dated: July 13, 2018

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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 reply brief adheres to the page limitations set forth in CMO Four at 3.

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 13, 2018, a copy of the foregoing **Reply 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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