UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 1:18-op-45090 MDL NO. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

PLAINTIFFS COUNTY OF SUMMIT, OHIO, AND CITY OF AKRON, OHIO'S OMNIBUS MEMORANDUM IN OPPOSITION TO (1) DEFENDANTS AMERISOURCEBERGEN DRUG CORP., CARDINAL HEALTH, INC., AND McKESSON CORP.'S MOTION TO DISMISS (Doc. 491); (2) MOTION TO DISMISS COMPLAINT BY DEFENDANTS WALMART INC., CVS HEALTH CORP., RITE AID CORP., AND WALGREENS BOOTS ALLIANCE, INC. (Doc. 497); AND (3) MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT (Doc. 499)

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INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT

There is no question as to the nature of the harm Summit County and the City of Akron (together, "Plaintiffs"), seek to remedy in this case—a widespread and unprecedented public health epidemic, which compelled the County Executive to declare a State of Emergency in 2017. Indeed, Defendants concede the Plaintiffs face a "public health crisis." *See* Memorandum in Support of Distributors' Motion to Dismiss Second Amended Complaint, ECF No. 491-1 at 1 (hereinafter "Dist. Mem."); Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint, ECF No. 499-1 at 5 ("Mfr. Mem.") (acknowledging "opioid crisis"). What created and fueled this epidemic, the likes of which has not been seen in modern times, is the intentional conduct of Fortune 500 companies.

Manufacturer Defendants employed a sophisticated campaign to convince the medical community and the public that opioids were safe—essentially, that high doses of pharmaceutical-grade heroin could treat run-of-the-mill, chronic pain, without significant risk of addiction. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Manufacturer Defendants, through their multi-pronged campaign—which included sales representatives, and respected pain specialists and organizations serving as paid mouthpieces for Defendants—callously manipulated what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately. Without Manufacturer Defendants' conduct, which caused prescribing of opioids—previously a confined, niche market—to skyrocket, the opioid epidemic would not have occurred, and would not have become the crisis it is today.

Once Manufacturer Defendants created the mass market for prescription opioids, Distributor Defendants¹ flooded it. Distributor Defendants had financial incentives to continue to supply opioids to pill mills (doctors, clinics, or pharmacies that prescribe or dispense opioids inappropriately or for non-medical reasons). And they put those incentives ahead of the health of Plaintiffs' communities and their statutory and common law duties, supplying opioids in quantities that they knew or should have known exceeded any legitimate market need, and failing to carry out their affirmative obligations to guard against diversion of these powerful narcotics. Distributor Defendants were not alone in this misconduct. Manufacturer and Distributor Defendants alike deliberately disregarded their legal obligations to maintain effective controls against diversion, to report suspicious orders and prescribers, and to cease supplying them. Instead, they fostered black markets for diverted prescription opioids and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. Meanwhile, the RICO Defendants worked together to shore up markets for their drugs by fraudulently increasing quotas that would otherwise limit the supply of prescription opioids. Defendants' conduct, including opioid diversion, fostered economic diversion: profits from increased sales flowed to Defendants, while the costs of increased addiction were diverted onto Plaintiffs.

The public health epidemic Plaintiffs face, with its profound, ongoing harms, is precisely what public nuisance law is designed to address, and to remedy through abatement, injunction, and other equitable relief. *See City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002).

¹ Consistent with the Corrected Second Amended Complaint, ECF No. 514 ("SAC"), § II.B., the term "Distributor Defendants" herein normally includes the national chain pharmacy defendants, except when referring directly to the motions at issue. When referring to the motions, "Distributor Defendants" means the motion filed by AmerisourceBergen Drug Corp., *et al.*, while "Pharmacy Defendants" refers to the motion filed by Walmart Inc., *et al.* The term "Defendants" used herein shall refer to all Defendants, unless otherwise more narrowly defined in the context of the specific argument section.

Further, caring for the public health, safety, and welfare of their citizens is particularly the province of local governments such as Plaintiffs, who are not only within their rights and duties, but well-positioned to address the crisis at the ground level. Plaintiffs have acted proactively to increase funding for existing services being strained by the epidemic, in many cases to the point of breaking, and to create new programs to address the crisis. Plaintiffs' other claims seek to recover for the costs of these services and the extraordinary burden Defendants have imposed on public resources.²

Contrary to this Court's instruction in Case Management Order 1, ECF No. 232 ("CMO 1") that, in this initial round of motions to dismiss, Defendants should "raise only those issues they believe are most critical and most relevant to the settlement process," CMO 1 ¶ 2.g. (5), Defendants have chosen to take a blunderbuss approach, attacking every count in the SAC, on virtually every ground they could imagine, often with little or no legal analysis or authority. Many of their arguments also rest on disputes about the accuracy of the facts alleged in the SAC, and thus are not appropriately raised in a motion to dismiss. The motions filed by Manufacturer, Distributor, and Chain Pharmacy Defendants, while organized quite differently, overlap in many of their arguments.

In order to help the Court follow this lengthy, omnibus response,³ Plaintiffs briefly summarize the structure of the arguments herein. This memorandum is organized into two main sections. The first part proceeds claim by claim, beginning with Plaintiffs' equitable nuisance claims and then proceeding through Plaintiffs' claims for retrospective relief. Plaintiffs respond in this part to all of the claim-specific arguments made by any of the Defendant groups, identifying where the arguments were raised and by which Defendants. Then, in part two, Plaintiffs respond to

² As noted in the SAC, Plaintiffs in this action do not assert any claim for spending on prescription opioids by their health plans, workers' compensation program, or other programs. SAC at 319, n. 224. Other bellwether cases, however, have not determined if they will be pursuing such claims.

³ Magistrate Judge Ruiz approved Plaintiffs' request to file a single consolidated response, in this and the other cases subject to motions practice. To conform to the page limits established by the Court, Plaintiffs in all cases will collectively limit their responses to a total of no more than 400 pages. Case Management Order No. Four, ECF No. 485, at 3.

Defendants' arguments that cut across multiple claims, including arguments related to standing, preemption, and the statute of limitations.

In cases across the country outside this MDL, courts have rejected many of the arguments raised by Defendants here. ⁴ Just this week, in the consolidated New York state opioid litigation, the court denied defendants' motions to dismiss virtually in their entirety. ⁵ See In re New York State Opioid Litigation, No. 40000/2017, slip op. (N.Y. Sup. Ct. June 18, 2018) (attached as Exhibit A). Defendants' scattershot effort to find fault with each and every cause of action here should fare no better.

LEGAL STANDARD

On a motion to dismiss, a court "must construe the complaint in the light most favorable to the plaintiff and accept all allegations as true." *Doe v. Miami Univ.*, 882 F.3d 579, 588 (6th Cir. 2018) (quoting *Keys v. Humana, Inc.*, 684 F.3d 605, 608 (6th Cir. 2012)). A court should deny a Rule 12(b)(6) motion to dismiss as long as a complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "This standard 'does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct]." *Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 383 (6th Cir. 2016) (quoting *Twombly*, 550 U.S. at 556).

⁴ See, e.g., State ex rel. Morrisey v. AmerisourceBergen Drug Corp., No. 12-C-141 (W.V. Cir. Ct. Dec. 12, 2014) (attached as Exhibit B); City of Chicago v. Purdue Pharma L.P., No. 14 CV 4361, 2015 WL 2208423 (N.D. Ill. May 8, 2015); City of Everett v. Purdue Pharma L.P., No. C17-209RSM, 2017 WL 4236062 (W.D. Wash. Sept. 25, 2017); People v. Purdue Pharma, L.P., No. 30-2014-00725287 (Cal. Super. Ct. Feb. 13, 2018); State v. Purdue Pharma L.P., No. 2017 CP 04872 (S.C. Ct. Com. Pl. Apr. 12, 2018); State v. Purdue Pharma. L.P., No. 17-2-25505-0, (Wash. Super. Ct. May 14, 2018) (attached as Exhibit C); State ex rel. Hawley v. Purdue Pharma, L.P., No. 1722-CC10626 (Mo. Cir. Ct. Apr. 25, 2018) (attached as Exhibit D). To the best of Plaintiffs' knowledge, no case has been dismissed in its entirety.

⁵ The court granted only Allergan plc's motion to be dismissed on jurisdictional grounds.

With respect to the RICO, OCPA, and fraud counts, Federal Rule of Civil Procedure 9(b) requires a plaintiff alleging fraud to "state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). But "Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." Williams v. Duke Energy Int'l, Inc., 681 F.3d 788, 803 (6th Cir. 2012) (citation omitted)). Thus, "[s]o long as a [plaintiff] pleads sufficient detail—in terms of time, place, and content, the nature of a defendant's fraudulent scheme, and the injury resulting from the fraud—to allow the defendant to prepare a responsive pleading, the requirements of Rule 9(b) will generally be met." United States ex rel. SNAPP, Inc. v. Ford Motor Co., 532 F.3d 496, 504 (6th Cir. 2008).
Furthermore, where a complaint alleges "a complex and far-reaching fraudulent scheme," pleading every instance of fraud "would be extremely ungainly, if not impossible." United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 509-10 (6th Cir. 2007) (addressing issue under False Claims Act) (internal quotation omitted).

For all other claims, the notice-pleading standard under Federal Rule of Civil Procedure 8(a)(2), which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" governs. *See* Fed. R. Civ. P. 8(a)(2).

Defendants seek to alter this established standard by attempting to recast the well-pled nuisance, negligence, Injury Through Criminal Acts, unjust enrichment, and civil conspiracy claims into causes of action that "sound in fraud." A claim "sounds in fraud," however, only if the plaintiff "allege[s] a unified course of fraudulent conduct and rel[ies] entirely on that course of conduct as the basis of a claim." *In re Daon Sys., Inc.*, 411 F.3d 1006, 1027 (9th Cir. 2005) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2003)). By contrast, "[i]n a case where fraud is not an essential element of a claim, only allegations of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b)." *Id.* (quoting *Vess*, 317 F.3d at 1105). "Allegations of non-

fraudulent conduct need satisfy only the ordinary notice pleading standards of Rule 8(a)." *Id.*; *see also, Lone Star Ladies Inv. Club v. Schlotzsky's Inc.*, 238 F.3d 363, 368 (5th Cir. 2001) ("Where averments of fraud are made in a claim in which fraud is not an element, an inadequate averment of fraud does not mean that no claim has been stated.")

ARGUMENT

I. Plaintiffs Summit County and the City of Akron Have Stated Valid Causes of Action

A. <u>Plaintiffs Have Properly Pled Equitable Claims for Abatement of a Public Nuisance</u>

Plaintiffs assert two separate equitable claims for abatement of the public nuisance that Defendants have created: an absolute public nuisance claim at common law, as well as a statutory public nuisance claim. Both have been validly pled.

1. Absolute Public Nuisance

Defendants erroneously argue that the Plaintiffs have failed to state a claim for absolute public nuisance. Dist. Mem. at 26-30; Mfr. Mem. at 40-45; Memorandum of Law in Support of Motion to Dismiss Complaint by Defendants Walmart, Inc., CVS Health Corp., Rite Aid Corp., and Walgreens Boots Alliance, Inc., ECF No. 497-1 ("Pharm. Mem.") at 19-20. These arguments are contrary to the law of Ohio and the motion to dismiss on these grounds must be denied.

a. The SAC properly alleges an interference with a public right

The SAC sets forth in great detail the existence of—and effects of—the opioid epidemic in Summit County and Akron. Specifically, the SAC details what the Centers for Disease Control has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis." SAC ¶ 18. The condition that constitutes the public nuisance—whether termed the "increased volume of opioid prescribing", SAC ¶ 18, or the "explosion in opioid use," SAC ¶ 19, or the "massive amount of opioids that flooded into Summit County," SAC ¶ 714—has had widespread public health consequences, including:

Severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiffs and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

Id. at ¶ 20; see also id. at ¶ 21 ("The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis."). In short,

Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiffs' communities, flooded Plaintiffs' communities with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and the residents of Plaintiffs' communities.

Id. at ¶ 1002.

Despite this extensive and detailed description of what federal, state and local agencies have all determined is a public health emergency, Defendants argue that there is no actionable common law public nuisance. Such an argument completely ignores the clear and unequivocal language of the SAC and flies in the face of black letter public nuisance law.

Representative public nuisance actions brought by governmental plaintiffs are equitable claims. For more than a century, courts have recognized the applicability of public nuisance claims when the conduct of a defendant interferes with the public health and safety of the community. The United States Supreme Court summarized this history over a century ago in *Mugler v. Kansas*:

"In regard to public nuisances," Mr. Justice Story says, "the jurisdiction of courts of equity seems to be of a very ancient date, and has been distinctly traced back to the reign of Queen Elizabeth.... In case of public nuisances, properly so called, an indictment lies to abate them, and to punish the offenders. But an information, also, lies in equity to redress the grievance by way of injunction." The ground of this jurisdiction... is the ability of courts of equity to give a more speedy, effectual, and permanent remedy than can be had at law. They cannot only prevent nuisances that

are threatened, and before irreparable mischief ensues, but arrest or abate those in progress, and, by perpetual injunction, protect the public against them in the future; whereas courts of law can only reach existing nuisances, leaving future acts to be the subject of new prosecutions or proceedings. This is a salutary jurisdiction, especially where a nuisance affects the health, morals, or safety of the community. Though not frequently exercised, the power undoubtedly exists in courts of equity thus to protect the public against injury.

123 U.S. 623, 672-673 (1887) (emphasis added) (citations omitted); see also Restatement (Second) of Torts § 821C(2)(b).

The general jurisdiction of a court of equity to restrain nuisances is not limited to cases of interference with property rights. *Beretta*, 768 N.E.2d 1136, 1142 ("Contrary to appellees' position, there need not be injury to real property in order for there to be a public nuisance."); *State ex rel. Chalfin v. Glick*, 175 N.E.2d 68, 73 (Ohio 1961) (court of equity has jurisdiction to restrain conduct "dangerous to public health, morals, safety or welfare, and injunctions have issued to protect the public from irreparable injury"). *See also* Restatement (Second) of Torts § 821B(2)(b), Cmt. h ("Unlike a private nuisance, a public nuisance does not necessarily involve interference with use and enjoyment of land.").⁷

⁶ Public nuisance actions can also be brought for damages by private actors who "have suffered harm of a kind different from that suffered by other members of the public exercising the right common to the general public that was the subject of interference." Id. at § 821C(1); Brown v. Cty. Comm'rs, 622 N.E.2d 1153, 1160 (Ohio Ct. App. 1993) ("A public nuisance as such does not afford a basis for recovery of damages in tort unless there is particular harm to the plaintiff that is of a different kind than that suffered by the public in general."). Summit County and Akron herein assert only an equitable public nuisance claim brought in their representative capacity to abate a public health crisis. See Cty. of Santa Clara v. Atl. Richfield Co., 137 Cal. App. 4th 292, 309-310, 40 Cal. Rptr. 3d 313, 328-329 (Cal. Ct. App. 2006). To the extent that the SAC can be read to also assert a nuisance claim for damages as private litigants, Plaintiffs have chosen not to press and withdraw such a claim. (Other MDL plaintiffs may, of course, make a different choice.)

⁷ While the term "nuisance" is often loosely used to encompass both public nuisance and private nuisance actions, the two claims are distinct. As explained in *Brown*, 622 N.E.2d at 1158:

Nuisance describes two separate fields of tort liability that through the accident of historical development are called by the same name. One of these two fields of liability bears the name of public nuisance and covers the invasion of public rights, *i.e.*, rights common to all members of the public. . . .

The other field of liability is called private nuisance. This tort covers the invasion of the private interest in the use and enjoyment of land. As such, plaintiff's action must always be footnote continued on next page

Ohio law follows this ancient understanding of public nuisance. In *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142, the Ohio Supreme Court declared that:

The definition of 'public nuisance' . . . is couched in broad language. According to the Restatement, a 'public nuisance' is 'an unreasonable interference with a right common to the general public.' 'Unreasonable interference' includes those acts that significantly interfere with public health, safety, peace, comfort, or convenience, conduct that is contrary to a statute, ordinance, or regulation, or conduct that is of a continuing nature or one which has produced a permanent or long-lasting effect upon the public right, an effect of which the actor is aware or should be aware.⁸

In *Beretta*, the court rejected the gun industry's arguments that their conduct, which the city alleged "ensure[d] the widespread accessibility of the firearms to prohibited users . . . [and thereby] fostered the criminal misuse of firearms," cannot form the basis of an actionable public nuisance claim, ruling that "the city should be permitted to bring suit against the manufacturer of a product under a public-nuisance theory, when, as here, the product has allegedly resulted in widespread harm and widespread costs to the city as a whole and to its citizens individually." *Id.* at 1142 (internal quotation omitted).

Defendants ignore this clear language and precedent when they claim that the opioid epidemic cannot constitute a public nuisance because it does not interfere with a "public right." See

footnote continued from previous page

founded upon her interest in the land. However, numerous Ohio decisions do not appear to follow the Restatement limitation on restricting injury to property rights.

- (1) A public nuisance is an unreasonable interference with a right common to the general public.
- (2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
- (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
- (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
- (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

⁸ The *Beretta* decision followed, and adopted, the definition of public nuisance in § 821B of the Restatement (Second) of Torts:

Dist. Mem. at 26; Mfr. Mem. at 43. Public nuisance law specifically contemplates that "acts that significantly interfere with the public health" are public nuisances—something that the Defendants do not even acknowledge. See Beretta, 768 N.E.2d at 1142. The New York Supreme Court expressly rejected Defendants' "public right" argument: "it suffices to note the defendants' failure to establish why public health is not a right common to the general public, nor why such continuing, deceptive conduct as alleged would not amount to interference; it can scarcely be disputed, moreover, that the conduct at the heart of this litigation, alleged to have created or contributed to a crisis of epidemic proportions, has affected a considerable number of persons." In re Opioid Litigation, supra, slip op. at 28 (internal citation omitted); see also State of West Virginia, ex rel. Morrisey v. AmerisourceBergen Drug Corp., No. 12-C-141 (W.V. Cir. Ct. Dec. 12, 2014), at 19 (finding that the State's allegations that Defendants interfered with West Virginians' common right "to be free from unwarranted injuries, addictions, diseases and sicknesses and have caused ongoing damage, hurt or inconvenience to WV residents exposed to the risk of addiction to prescription drugs, who have become addicted, and/or have suffered other adverse consequences from the use of the addictive prescription drugs distributed by Defendants, and countless others who will suffer the same fate in the future as Defendants' conduct is continuing" sufficiently alleged a right "common to the general public" and public nuisance). Plaintiffs have extensively outlined the acts by the Defendants that interfered with the public health in Akron and Summit County and their effects on the County and City and their residents. See, e.g., SAC, ¶ 714-745.

Instead of discussing the opioid epidemic's effect on the public health, Defendants instead attempt to recast Plaintiffs' claims as an amalgamation of private, personal injury claims suffered by Akron and Summit County residents. This argument fails on two fronts. *First*, this case does not hinge on whether individual residents in Akron and Summit County have a right to be personally and individually "safe" from defective products. Dist. Mem. at 28. While it is true that thousands of

people in Akron and Summit County have been personally touched by the opioid crisis, the Plaintiffs' public nuisance claim does not seek recovery based on, or for, the personal injuries of individual residents. Instead, as in *Beretta*, Plaintiffs allege that the Defendants engaged in conduct that creates "widespread harm and widespread costs to the city [and county] as a whole and to [their] citizens individually." *Beretta*, 768 N.E.2d at 1142.

Second, even if the only measure of this nuisance were the number of people affected, that alone can establish that a public nuisance exists. As explained in the comments to Restatement § 821B, a public nuisance can be something that "affect[s] the heath of so many persons as to involve the interests of the public at large." Id., Cmt. g. "It is not . . . necessary that the entire community be affected by a public nuisance, so long as the nuisance will interfere with those who come in contact with it in the exercise of a public right or it otherwise affects the interests of the community at large." Id. The opioid epidemic fits squarely within this definition.

b. Defendants' conduct was not sanctioned by law

Defendants' next argument—that they are immune from liability for the public nuisance because they engage in "extensively regulated activities"—is equally untenable under the law and facts of this case. Here, the acts that contributed to the creation of the widespread public health crisis in Akron and Summit County were not sanctioned by law and thus are not protected under Brown v. County Commissioners, 622 N.E.2d 1153, 1158 (Ohio Ct. App. 1993). As Brown points out, protection against public nuisance liability is awarded to those who operate "subject to the limitations imposed" by a "comprehensive . . . regulatory scheme." Id at 1160 (emphasis added). Both common sense and Brown dictate that the immunity that Defendants seek is reserved for those who actually operate within the bounds of those regulations. Id. As explained by the Court in City of Cleveland v. Ameriquest Mortgage Securities, Inc., 621 F. Supp. 2d 513, 528 (N.D. Ohio 2009), "showing that the challenged conduct is subject to regulation and was performed in conformance therewith insulates such

conduct from suit as a public nuisance." (emphasis added)(citation omitted). *See also Bd. of Brimfield Twp. Trs. v. Bush*, No. 2005-P-0022, 2007 WL 2759495, *15-16 (Ohio Ct. App. Sept. 21, 2007) (recognizing that immunity from a public nuisance suit only arises when the actions of the defendants are conducted in accordance with regulatory scheme or generally accepted practices).

Most illuminating on this issue is the Ohio Supreme Court's decision in *Beretta*. There the gun manufacturers and distributors argued that they could not be held liable for the public nuisance alleged because "the distribution of firearms is highly regulated and covers 'legislatively authorized conduct." *Beretta*, 768 N.E.2d at 1143. The court expressly rejected this argument; while a "comprehensive regulatory scheme involving the manufacturing, sales, and distribution of firearms" existed, the law "does not regulate the distribution practices alleged in the complaint." *Id*.

Here, as in *Beretta*, the law does not authorize the defendants to engage in the conduct that is alleged to have created the nuisance. The Complaint repeatedly alleges that the Defendants engaged in "unlawful" conduct, including violations of Federal law and Ohio statutes and regulations. *See, e.g.*, SAC ¶ 1010, 1011, 1015, 1016. Specifically, the following conduct of the Defendants was not authorized by (and actually violates) the regulatory scheme: distributing opioids in a way that "facilitated and encouraged their flow into [an] illegal secondary market"; distributing opioids without maintaining effective controls against their diversion; choosing not to monitor, investigate, report, or stop suspicious orders. *Id.* at ¶ 1011, 1012. Manufacturer Defendants additionally engaged in the following conduct that was likewise not authorized by any regulatory scheme: pursuing a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing sales to skyrocket; and misleading doctors and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids. *Id.* at ¶ 1013, 1014, 1015, 1016 1019, 1021.

c. Plaintiffs have adequately pled causation

Manufacturer Defendants next argue that their conduct cannot be a legal cause of the public health crisis that exists in Akron and Summit County. Mfr. Mem. at 41-42 ("the alleged opioid crisis is too attenuated and remote to establish proximate causation as a matter of law. . . ."). Notably, the Defendants cite to no actual facts in the Complaint (or elsewhere) to support this assertion, instead relying on conclusory generalizations to support their argument. For this reason alone, the argument must be rejected.

Second, under Ohio law, questions of proximate cause are typically left to the trier of fact, except in the rare case where no facts alleged justify "any reasonable inference" of causation. *See Brondes Ford, Inc. v. Habitec Sec.*, 38 NE 3d 1056, 1086 (Ohio Ct. App. 2015). Here, Plaintiffs have, at a minimum, raised a reasonable inference that the Defendants' conduct is a cause of the public nuisance alleged. *See also City of New York v. Beretta U.S.A. Corp.*, 315 F. Supp. 2d 256, 281 (E.D.N.Y. 2004) ("Satisfaction of the causation requirement for liability in public nuisance actions requires proof that a defendant, alone or with others, created, contributed to, or maintained the alleged interference with the public right. Whether specific acts or omissions meet this standard involves a fact-intensive inquiry, making it difficult to resolve the issue on a motion to dismiss on the pleadings.")(citation omitted); *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 104, 227 Cal. Rptr. 3d 499, 545-546 (2017) ("Defendants argue that they should be absolved of responsibility for the current hazard because their wrongful conduct was 'too remote' and 'attenuated' from the current hazard. This was a question of fact for the trial court. . . . [T]he trial court could have reasonably concluded that defendants' promotions, which were a substantial factor in creating the current hazard, were not too remote to be considered a legal cause of the current . . . nuisance.").

Third, in public nuisance claims, "where the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases." *NAACP v. AcuSport, Inc.*, 271 F. Supp. 2d 435, 497 (E.D.N.Y. 2003). More specifically,

The tortious actions or omissions of a defendant or defendants need not be the immediate cause of injury to the public. If a defendant's conduct 'remains the dominant and relevant fact without which the public nuisance would not have resulted where and under the circumstances it did,' it may be held liable for setting in motion or being a force in the sequence of events resulting in injury to the public. Intervening actions, even multiple or criminal actions taken by third parties, do not break the chain of causation if a defendant could reasonably have expected their nature and effect.

City of New York v. Beretta U.S.A. Corp., 315 F. Supp. 2d at 282 (internal citations omitted).

The very same remoteness arguments were raised, and denied, in *Beretta*. The Ohio Supreme Court rejected defendants' argument that "the causal connection between the alleged wrongdoing and the alleged harm is too tenuous and remote and . . . the claims asserted are indirect and wholly derivative of the claims of others," finding that the complaint alleged that "as a direct result of the misconduct of appellees, appellant has suffered 'actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services." 768 N.E.2d 1136 at 1147.9

Here, as in *Beretta*, the Plaintiffs have alleged a direct link between Manufacturer Defendants' conduct and the public nuisance. SAC ¶¶ 171-173.

⁹ See also White v. Smith & Wesson, 97 F. Supp. 2d 816, 825 (N.D. Ohio 2000) (Plaintiffs' claims, including public nuisance claims, "are the "fairly traceable" result of Defendants' actions of allegedly designing and manufacturing unreasonably dangerous products."); Beretta, 315 F. Supp. 2d at 284 ("It cannot be concluded, as a matter of law, that defendants' marketing and distribution practices are too remote from the injury to the public caused by the illegal possession and use of firearms. Given the City's assertion that defendants are a direct link in the causal chain resulting in the harm suffered by the public as a result of illegal gun use and that they are realistically in a position to prevent such harm, it is arguably appropriate to hold them accountable for their alleged tortious conduct.").

d. Plaintiffs have adequately pled intentional conduct

Manufacturer Defendants also incorrectly claim that the Plaintiffs have not pled the requisite "intent" to succeed in their public nuisance claim. Under Ohio law, for an absolute public nuisance, the wrongful act must be "either intentional or unlawful." *Beretta*, 768 N.E. 2d 1136 n.4. *accord*Nottke v. Norfolk S. Ry. Co., 264 F. Supp. 3d 859, 862 (N.D. Ohio 2017) (citing Gevelaar v. Millennium Inorganic Chems., No. 2012-A-0013, 2013 WL 501745 (Ohio Ct. App. Feb. 8, 2013)) ("[A]n absolute nuisance "consists of [1.] an intentional act resulting in harm; [or] [2.] an act involving...unlawful conduct causing unintentional harm"). Furthermore, Defendants misapprehend the type of "intent" contemplated by Ohio law. Id. (quoting Angerman v. Burick, No. 02-CA-0028, 2003 WL 1524505 (Ohio Ct. App. Mar. 26, 2003) ("Intentional, in this context, means not that a wrong or the existence of a nuisance was intended but that the creator of it intended to bring about the conditions which are in fact found to be a nuisance."). Here, the SAC is replete with allegations of intentional and unlawful conduct by Manufacturer Defendants that gave rise to the nuisance. SAC ¶¶ 1013-16, 1019, 1021.

2. Statutory Public Nuisance

Plaintiffs separately bring a claim, through their chief legal officers, for statutory public nuisance, pursuant to R.C. §§ 3767.03, 4729.35 (Summit), and 715.44 (Akron), to abate and enjoin the public nuisance Defendants have created. Defendants challenge Plaintiffs' authority to bring this claim and the scope of relief available. Dist. Mem. at 31-32; Pharm. Mem. at 17-18. Defendants also assert, somewhat amazingly, that Plaintiffs have not adequately pled their claim because they have not plausibly alleged that Defendants violated federal and state drug laws. Mfr. Mem. at 45-47; Pharm. Mem. at 18-19. Neither argument has merit.

¹⁰ There is also a third category of absolute public nuisance, not at issue in this case: "a non-culpable act resulting in accidental harm, for which, because of the hazards involved, absolute liability attaches notwithstanding the absence of fault." *Id.*

First, without any support in the statutory language or otherwise, Defendants argue that R.C. § 4729.35 extinguishes Akron's statutory right to advance a nuisance claim, ¹¹ and the rights of either Plaintiffs to recover certain categories of relief (though Defendants disagree as to what those purported limitations are). ¹² R.C. § 4729.35, however, is not the exclusive authority for statutory nuisance claims.

Section 4729.35 declares that violations of federal and Ohio laws or Ohio Board of Pharmacy rules controlling the distribution of drugs of abuse "constitute a public nuisance," and authorizes, *inter alia*, county prosecuting attorneys to "maintain an action in the name of the state to enjoin" these violations. Separately, R.C. § 3767.03 affirms that "[w]henever a nuisance exists . . . [the] city director of law, or . . . the prosecuting attorney of the county in which the nuisance exists; . . . *may bring an action* in equity . . . to abate the nuisance and to perpetually enjoin the person maintaining the nuisance from further maintaining it." *Id.* (emphasis added). Further, R.C. § 715.44 allows municipal corporations to "(A) Abate *any* nuisance and prosecute . . . *any person* who creates, continues, contributes to, or suffers such nuisance to exist; [and] (C) Prevent injury and annoyance from any nuisance" Nothing in the plain language of these statutes suggests that § 4729.35 is the exclusive statute applicable to drug-related nuisances.

Defendants cite no legislative history or Ohio case law in support of their position. To the contrary, in *State ex rel. DeWine v. Fred's Party Center, Inc.*, 13 N.E.3d 699, 705 (Ohio Ct. App. 2014), a nuisance abatement action based on drug trafficking was brought under both R.C. §§ 3719.10 and 4729.35, thus at least implicitly recognizing that § 4729.35 is not the sole means by which drug-related nuisance actions can be brought.

¹¹ Defendants concede that Akron and Summit County have the authority to bring a claim under R.C. § 4729.35.

¹² Contrast Dist. Mem. at 31-32 (arguing that abatement relief is barred by § 4729.35) with Mfr. Mem. at 45 n.39 (arguing that "abate[ment]" is allowed, but that "damages" are not).

Defendants' theory is contrary to Ohio rules of statutory construction which provide that an "entire statute is intended to be effective," R.C. § 1.47(B), and that general and special provisions "shall be construed, if possible, so that effect is given to both." R.C. § 1.51. For a special provision to negate a general one, there must be an "irreconcilable" conflict. No such conflict exists here.

Because it is clear that Plaintiffs may bring their statutory public nuisance claim under R.C. §§ 3767.03 and 715.44, Defendants' argument against abatement relief also falls. Both statutes expressly provide for an abatement remedy.

As for the argument that Plaintiffs have not plausibly pled this cause of action, the SAC includes specific, detailed allegations of Defendants' misconduct that violated federal and state laws constituting a nuisance under Ohio law, both through Manufacturer Defendants' fraudulent marketing of opioids and all Defendants' failure to stop, suspend, or report suspicious orders. *See, e.g.,* SAC, Factual Allegations Pts. I.D., I.E., and II; *see also* ¶¶ 504, 584, 612, 684, 686, 863, 915, 917, 961, 965 & n.222, 966 & n.223, 983, 984, 987, 1009-10, 1058, 1060, 1095, 1097 ((discussing violations of *inter alia* 21 U.S.C. §§ 801 *et seq.*; 21 U.S.C. §§ 821, 823, 826; 21 C.F.R. § 1301.74; 21 C.F.R. § 1303.11; 21 C.F.R. § 1306.04; Ohio Rev. Code § 3719.; Ohio Rev. Code § 4929; Ohio Admin. Code §§ 4729-9-16). The SAC also more than plausibly alleges that Defendants engaged in this conduct in Ohio, thereby creating a nuisance in Akron and Summit County. *Id.*, Pt. I.G.

¹³ See United Tel. Co. of Ohio v. Limbach, 643 N.E.2d 1129, 1131 (Ohio 1994) ("All provisions of the Revised Code bearing upon the same subject matter should be construed harmoniously . . . unless they are irreconcilable and in hopeless conflict.") (citation omitted). RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639 (2012), the case on which Defendants rely, likewise acknowledged "the cardinal rule that, if possible, effect shall be given to every clause and part of a statute." Id. at 645. And the Sixth Circuit has consistently distinguished RadLAX on that basis. See, e.g., In re Connolly North America, LLC, 802 F.3d 810, 818 (6th Cir. 2015).

Defendants dispute that they have violated any of the statutes and regulations Plaintiffs cite, but their argument raises a factual dispute that cannot be resolved as a matter of law.¹⁴

3. OPLA Does Not Abrogate Plaintiffs' Equitable Public Nuisance Claims

Defendants next argue that both Plaintiffs' statutory and absolute public nuisance claims were abrogated by the Ohio General Assembly's 2007 amendment to the Ohio Products Liability Act (OPLA) which, Defendants contend, "effectively overruled *Beretta*." Dist. Mem. at 23; *see generally id.* at 22-26; Mfr. Mem. at 40; Pharm. Mem. at 8. That is an implausible construction of the 2007 amendment—given that the legislature never even mentioned *Beretta* and affirmatively declared that the amendment was "not intended to be substantive," 2006 Ohio Laws File 198 (Am. Sub. S.B. 117)—and should not be credited by this Court, especially because a narrower, and more plausible, construction of the amendment is available.

In 2007, the General Assembly amended the definition of "product liability claim" under OPLA to add the highlighted text below:

"Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 71 to 80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

- (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
- (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
- (c) Any failure of that product to conform to any relevant representation or warranty.

¹⁴ Moreover, to the extent that Defendants assert, contrary to the allegations of the SAC, *see* ¶ 987, that they are entitled to the protections of the safe harbor provision of R.C. § 2925.02(B) to escape liability under R.C. § 2925.02(A), that would be an affirmative defense which cannot be raised by 12(b)(6) motion, when it cannot be conclusively established on the face of the complaint. *Cf. United States v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004) ("Dismissal under Rule 12(b)(6) was irregular, for the statute of limitations is an affirmative defense.").

"Product liability claim" also includes any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public.

R.C. § 71(A)(13).

In passing the amendment, the General Assembly stated:

"The General Assembly declares its intent that the amendments made by this act to sections 71 and 73 of the Revised Code are not intended to be substantive but are intended to clarify the General Assembly's original intent in enacting the Ohio Product Liability Act, sections 71 to 80 of the Revised Code, as initially expressed in Section 3 of Am. Sub. S.B. 80 of the 125th General Assembly, to abrogate all common law product liability causes of action including common law public nuisance causes of action, regardless of how the claim is described, styled, captioned, characterized, or designated, including claims against a manufacturer or supplier for a public nuisance allegedly caused by a manufacturer's or supplier's product."

2006 Ohio Laws File 198 (Am. Sub. S.B. 117) (emphasis added).

On its face, this amendment to OPLA cannot apply to, and abrogate, Plaintiffs' statutory public nuisance claims brought pursuant to R.C. §§ 3767.03, 4729.35, and 715.44. The amendment defines a "product liability claim" to include only a public nuisance "claim or cause of action at common law." Claims based on statutory authority are not common law claims and Defendants' argument must be rejected.

But the amendment should also be understood as inapplicable to equitable nuisance claims brought by governmental entities in their representative capacities, as Summit and Akron do here.

This is so for at least three reasons.

First, the phrase "claim or cause of action at common law" is frequently understood not just to exclude statutory claims, but also to refer to legal causes of action, as opposed to those arising in equity. Both the Ohio and U.S. Supreme Courts have used the term "common law action" in precisely this way, in holding that "an abatement action [is] 'not a common law action, but a summary proceeding more in the nature of a suit in equity" *State ex rel. Miller v. Anthony*, 647 N.E.2d 1368, 1371 (Ohio 1995) (quoting *Cameron v. United States*, 148 U.S. 301, 304 (1893)); *see also*

BLACK'S LAW DICTIONARY (5th ed. 1979) p. 251 (defining "common[]law action" as an "[a]ction governed by common law, rather than statutory, *equitable*, or civil law" (emphasis added)). For this reason, the 2007 amendment should properly be understood as applying only to legal public nuisance claims.

This reading is further supported by the first paragraph of OPLA's definition of "product liability claim" which limits such claims to those "that seek[] to recover compensatory damages." R.C. § 71(A)(13). The General Assembly gave no indication that that same limitation would not also apply to product liability claims brought as public nuisance claims. The new paragraph is therefore best understood as incorporating the limitations in the earlier paragraph.¹⁵

Finally, this reading of the 2007 amendment is compelled by the primary principle of statutory interpretation: "when construing a statute, [a] court's 'paramount concern' is the statute's legislative intent." *State ex rel. Cincinnati Post v. City of Cincinnati*, 668 N.E.2d 903, 906 (Ohio 1996). The General Assembly clearly declared that it did not intend the amendment "to be substantive," but only "to clarify the General Assembly's original intent" in enacting OPLA. 2006 Ohio Laws File 198 (Am. Sub. S.B. 117). *Beretta* had already determined that municipalities could bring equitable claims to abate public nuisances without running afoul of the limitations in OPLA. It would be inconsistent with the legislature's expressed intent to read the 2007 amendment, as Defendants seek, as overturning that ruling *sub silentio*. 16

¹⁵ Defendants will no doubt point to the inclusion of the word "also" in the new definitional paragraph: "Product liability claim' also includes any public nuisance claim" But that word was necessary because of a separate limitation in the first paragraph of the definition, limiting a product liability claim to "a claim or cause of action that is asserted in a civil action pursuant to sections 71 to 80." The 2007 amendment thus makes clear that the definition "also" applies to claims for compensatory damages asserted as public nuisance claims.

¹⁶ By contrast, when the General Assembly amended OPLA in 2005 to make clear that the Act was intended to "abrogate all common law product liability claims," R.C. § 71(B), overturning the decision in *Carrel v. Allied Products. Corp.*, 677 N.E.2d 795 (Ohio 1997), the legislature expressly repudiate the *Carrel* ruling. *See infra* p. 91, n. 61.

This interpretation of the 2007 amendment does not render the amendment a nullity. As discussed earlier, *supra* p.8, n. 6, public nuisance actions can also be brought for damages by private actors who "have suffered harm of a kind different from that suffered by other members of the public exercising the right common to the general public that was the subject of interference." Rest. (2d) of Torts, § 821C(1). When such a "public nuisance claim or cause of action at common law" meets the definitional requirements for a "product liability claim" in R.C. § 71(A)(13), it must be brought under OPLA.

4. The Economic Loss Doctrine Does Not Bar Plaintiffs' Public Nuisance Claims

Finally, Defendants argue that the economic loss doctrine bars Plaintiffs' public nuisance claims. Mfr. Mem. at 41; Dist. Mem. at 43-44. That argument can be quickly dismissed.¹⁷

The economic loss doctrine is a principle of tort law that, under certain circumstances, prevents tort plaintiffs from recovering compensatory damages for purely economic losses that do not arise from tangible physical injury to persons or property. See Corporex Dev. & Const. Mgmt., Inc. v. Shook, 835 N.E.2d 701, 704 (Ohio 2005). It simply has no application to an equitable claim to abate a nuisance. See Restatement (Second) of Torts § 821B, Cmt. i ("There are numerous differences between an action for tort damages and an action for an injunction or abatement, and precedents for the two are by no means interchangeable. . . . [A]n award of damages is retroactive, applying to past conduct, while an injunction applies only to the future. In addition, for damages to be awarded significant harm must have been actually incurred, while for an injunction harm need only be

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Defendants base their argument almost entirely on a single Court of Common Pleas decision, *City of Toledo v. Sherwin-Williams Co.*, No. CI 200606040, 2007 WL 4965044 (Ohio Ct. Com. Pl. Dec. 12, 2007), that was not appealed, has never been cited by any court, and that does not consider any of the statutory interpretation arguments advanced above.

¹⁷ Plaintiffs address the implications of the economic loss doctrine for some of their other claims at greater length below. *See infra* pp. 87-89.

threatened and need not actually have been sustained at all."). Because Plaintiffs seek only equitable relief from the nuisance, the economic loss rule does not apply.¹⁸

Even if Plaintiffs' absolute public nuisance claim were somehow construed to be a tort claim for damages, the economic loss doctrine would still not apply, because "the economic-loss doctrine does not apply to intentional torts." *Eysoldt v. ProScan Imaging,* 957 N.E.2d 780, 785 (Ohio Ct. App. 2011). Plaintiffs expressly allege in that claim that "Defendants' nuisance-creating conduct was intentional and unreasonable." SAC ¶ 1001.

The only Ohio cases that have applied the economic loss doctrine to public nuisance claims have involved common law tort claims seeking compensatory damages for qualified public nuisance (i.e., nuisance based on negligence). See, e.g., RWP, Inc. v. Fabrizi Trucking & Paving Co., No. 87382, 2006 WL 2777159, at *4 (Ohio Ct. App. Sept. 28, 2006) (private plaintiff sought "recovery in tort" for economic losses caused by public nuisance); City of Cleveland v. J.P. Morgan Chase Bank, N.A., No. 98656, 2013 WL 1183332, at *7-8 (Ohio Ct. App. Mar. 21, 2013) (city's qualified public nuisance claim sought to recover damages for purely economic losses in tort); City of Cincinnati v. Deutsche Bank Nat'l Tr. Co., 863 F.3d 474, 477 (6th Cir. 2017) (city "disavowed any claims for injunctive and declaratory relief," leaving only "damages claim for common law public nuisance"). By contrast, the

¹⁸ A court, sitting in equity on a public nuisance claim, may include equitable relief that includes the payment of money from Defendants to Plaintiffs under equitable theories. This does not convert the claim into a legal claim for damages. Courts have "long recognized the distinction between an action at law for damages—which are intended to provide a victim with monetary compensation for an injury to his person, property, or reputation—and an equitable action for specific relief-which may include an order . . . for 'the recovery of specific property or monies' The fact that a judicial remedy may require one party to pay money to another is not sufficient reason to characterize the relief as 'money damages'." *Veda, Inc. v. U.S. Dep't of the Air Force*, 111 F.3d 37, 40 (6th Cir. 1997); *see also Santos v. Ohio Bureau of Workers' Comp.*, 801 N.E.2d 441, 446 (Ohio 2004) (recognizing that a court sitting in equity can allow payment of attorney fees and costs by a defendant). Even in circumstances where a legal claim for damages is statutorily prohibited, the allowance of equitable claims allows the recovery of money, including restitution if appropriate. *Porter v. Warner Holding Co.*, 328 U.S. 395, 402 (1946). In such a case, the plaintiff does not seek compensatory damages; rather the plaintiff simply seeks to restore the status quo ante. *See id.*

economic loss doctrine has no application to the exclusively equitable absolute public nuisance claims Plaintiffs bring here.

- B. Plaintiffs Have Properly Pled Their Claims Under Federal RICO and OCPA.¹⁹
 - 1. This is a Classic RICO Case, Asserted Plausibly and With Rule 9(b)

 Particularity
 - a. RICO is the appropriate civil remedy under the circumstances of this case

Without a doubt, the federal RICO Act is strong medicine, developed by Congress and consistently interpreted by the Supreme Court to "protect[] the public from those who would unlawfully use an 'enterprise' (whether legitimate or illegitimate)" to commit unlawful activity. *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 164 (2001) (citation omitted); *see also Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 498-99 (1985) (RICO was an "aggressive initiative to . . . develop new methods . . . that can be "used against respected businesses allegedly engaged in a pattern of specifically identified criminal conduct"); *United States v. Turkette*, 452 U.S. 576, 586 (1981) (Congress acted boldly because "existing law, state and federal, was not adequate to address the problem, which was of national dimensions. . . . ").

In passing it, Congress was aware of the need to "protect the public from those who would run 'organization[s] in a manner detrimental to the public interest[,]" *Cedric Kushner*, 533 U.S. at 165 (citing S. Rep. No. 91–617, at 82), subverting the public goals of a stable economic system, free competition, fair commerce, domestic security, and the general welfare of the nation and its citizens, *Beck v. Prupis*, 529 U.S. 494, 496 (2000) (quoting Title IX of the Organized Crime Control Act of 1970, Pub. L. 91–452, 84 Stat. 922, 923), and specifically targeting the economic engine of the dangerous "illicit prescription drug industry," *Turkette*, 452 U.S. at 589-90. Its civil remedy provisions

¹⁹ For purposes of this section only, references to Manufacturer Defendants and Distributor Defendants refer to the Manufacturer and Distributor Defendants named as defendants in the RICO and OCPA claims in the SAC, Claims for Relief 1-4.

are an integral part of the enforcement regime. *See Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 473 (2006) (Thomas, J., concurring in part and dissenting in part) (RICO provides civil remedies to protect and vindicate the public interest in an honest and competitive marketplace); *Sedima*, 473 U.S. at 495 (discussing broad remedial purposes of civil RICO).

RICO has been employed to hold corporations accountable when they participate in vast illegal enterprises that inflict unprecedented—and disastrous—consequences on society. In *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), Judge Gladys Kessler issued a 1,683-page bench trial ruling finding that the tobacco companies, conspiring with each other and using various front groups and pseudo-scientific research entities, were liable under RICO. The Court found that the industry profited from

selling a highly addictive product which causes diseases that lead to a staggering number of deaths per year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national health care system. Defendants have known many of these facts for at least 50 years or more. Despite that knowledge, they have consistently, repeatedly, and with enormous skill and sophistication, denied these facts to the public, to the Government, and to the public health community. . . . In short, Defendants have marketed and sold their lethal product with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted.

Id. at 28. The tobacco defendants used an "intricate, interlocking, and overlapping web of national and international organizations, committees, affiliations, conferences, research laboratories, funding mechanisms, and repositories for smoking and health information" to achieve the tobacco enterprise's goals of countering unfavorable scientific evidence, avoiding civil liability, and ensuring "the future economic viability of the industry." *Id.* at 34-35. The tobacco defendants worked together, competing only for market share, "coordinat[ing] significant aspects of their public relations, scientific, legal, and marketing activity in furtherance of the shared objective—to use mail

and wire transmissions to maximize industry profits by preserving and expanding the market for cigarettes through a scheme to deceive the public." *Id.* at 869, 904. ²⁰

RICO has been employed to hold pharmaceutical manufacturers liable for using a web of entities to market a dangerous prescription drug for off-label use, deceiving doctors into prescribing it widely and causing insurers to pay for off-label prescriptions. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21 (1st Cir. 2013). In *Neurontin*, the First Circuit upheld a RICO award of \$140 million, finding that the defendants' fraudulent marketing enterprise caused excessive prescriptions, damaging the insurer plaintiff. *Id.* at 33-50.

Plaintiffs' well-pleaded RICO claims are similarly appropriate in this unprecedented litigation. The widespread scope and pervasiveness of Defendants' RICO enterprises cannot be overstated. The Opioid Marketing Enterprise—which relied on front groups and key opinion leaders to spread pseudo-science that fostered opioid addiction—rivals the tobacco defendants' enterprise consisting of "formal and informal entities, many with overlapping participants and purposes" in "the largest piece of civil litigation ever brought." *Philip Morris*, 449 F. Supp. 2d at 34, 170. Plaintiffs' claim that Defendants created a fraudulent enterprise to get thousands of unwitting physicians to foster widespread dependence on prescription pharmaceuticals is even stronger than the *Neurontin* plaintiff's RICO claims, which were proved by statistical evidence at trial and upheld by the First Circuit on appeal. Having created widespread dependence, the Defendants formed the Opioid Supply Chain Enterprise whose members systematically concealed, and refused to report,

²⁰ Despite multiple appeals to higher courts and Congress, the tobacco defendants were required to implement Judge Kessler's remedy publishing "corrective statements" on their respective websites and in the media. *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d at 938-41 (D.D.C. 2006), *aff d in part and vacated in part*, 566 F.3d 1095, 1105 (D.C. Cir. 2009) (*per curiam*), *cert. denied*, 561 U.S. 1025 (2010); *United States v. Philip Morris USA*, *Inc.*, No. 99-cv-02496-PLF, Dkt. 6260 (May 1, 2018 Third Superseding Consent Order Implementing The Corrective Statements Remedy for Websites and Onserts). The text of the corrective statements can be found at https://goo.gl/MKpy4r (Campaign for Tobacco-Free Kids website).

suspicious orders of prescription opioids so that the flood gates of unlawful opioids would remain wide open, and annual quotas would increase. Plaintiffs' claims are consistent with the purpose and spirit of RICO, and specifically the economic losses civil RICO compensates, punishes and deters. In this equally important case, the RICO claims should proceed.

b. Plaintiffs plead their claims plausibly and with particularity

Fundamentally, Defendants' motions to dismiss rest on an unreasonably restrictive reading of RICO that contradicts decades of Supreme Court authority and instruction:

RICO is to be read broadly. This is the lesson not only of Congress' self-consciously expansive language and overall approach, but also of its express admonition that RICO is to "be liberally construed to effectuate its remedial purposes," Pub.L. 91–452, § 904(a), 84 Stat. 947. The statute's "remedial purposes" are nowhere more evident than in the provision of a private action for those injured by racketeering activity.

Sedima, 473 U.S. at 497-98 (1985) (quoting *Turkette*, 452 U.S. at 586-587 and Pub. L. 91-452, § 904(a), 84 Stat. 947).

Congress chose "self-consciously expansive language" for RICO, broadly defined the predicate racketeering acts, and mandated a liberal construction. *Jackson v. Sedgwick Claims Mgmt.*Servs., Inc., 731 F.3d 556, 563 (6th Cir. 2013). "The fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth." Id.

The Supreme Court has consistently applied Civil RICO to new scenarios and a broad array of enterprises, recognizing that "respected" businesses can nonetheless combine and act to violate RICO. In Sedima, the Court stated that "Congress wanted to reach both 'legitimate' and 'illegitimate' enterprises," because "[t]he former enjoy neither an inherent incapacity for criminal activity nor immunity from its consequences." Id.

This principle reaches its zenith with respect to RICO's private right of action, which is intentionally broad and provides flexible concepts of causation. *See, e.g., Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 652, 654 (2008).

The Manufacturer and Distributor Defendants are businesses engaged in sophisticated, complex, and decades-long fraudulent schemes for economic gain designed to create a captive market of addicted individuals in order to unlawfully profit from opioids sales, and then open the distribution flood gates and knowingly profit from the diversion of suspicious orders. They knowingly externalized foreseeable and inevitable economic losses from this conduct. Defendants created and profited from a mess they knew and intended that Plaintiffs and other public entities would be left to clean up.

Rule 9(b)'s notice and reputational functions are fulfilled by Plaintiffs' detailed RICO pleading. SFS Check, LLC v. First Bank of Del., 774 F.3d 351, 358 (6th Cir. 2014) (Rule 9(b): (1) alert[s] defendants to the particulars of the allegations against them so they can intelligently respond; (2) prevent[s] "fishing expeditions"; . . . [and] (3) protect[s] defendants' reputations against fraud allegations"). A RICO fraudulent scheme need not depend on or include any mail or wire communications that contain false or misleading information. Instead, mail or wire communications must simply be "a step in the plot" or otherwise further a fraudulent scheme. Schmuck v. United States, 489 U.S. 705, 710-11 (1989). Where a plaintiff delineates the specific circumstances constituting the overall fraudulent scheme, "neither the reputational interests nor the notice function served by Rule 9(b) would be advanced in any material way by insisting that a complaint contain a list of letters or telephone calls [or emails]." Angermeir v. Cohen, 14 F. Supp. 3d 134, 145-146 (S.D.N.Y. 2014).

In Williams v. Duke Energy Intern., Inc., the Sixth Circuit recognized the

"principle of basic fairness that a plaintiff should have an opportunity to flesh out [its] claim through evidence unturned in discovery." *Williams*, 681 F.3d 788, 803 (6th Cir. 2012) (internal citations omitted). As long as the circumstances of the fraud are "pled with enough specificity to put defendants on notice as to the nature of the claim," the action can continue. *See id.* This is particularly the case "where the facts underlying the claims are within the defendant's control." *See id.*

Rule 9(b) must be read in harmony with Rule 8's "policy of simplicity in pleading" and courts should not be "too exacting" or "demand clairvoyance from pleaders" in determining whether Rule 9(b) is

satisfied. Ford v. Penn. Higher Educ. Assist. Agency, 2018 WL 1377858, *5 (N.D. Ohio Mar. 19, 2018). "If the defendant has fair notice of the charges against [it], [Rule 9(b)] is satisfied." Id.; Williams, 681 F.3d at 803. Here, Plaintiffs' allegations exceed Rule 9(b)'s requirements.

i. Opioid marketing claims

Plaintiffs allege that Manufacturer Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of mail and wire fraud that included communications that were a "step in the plot," and actual misrepresentations and omissions regarding the dangers of prescription opioid use. The SAC lists nine categories of specific misrepresentations attributed to each of Manufacturer Defendants and/or the Front Groups and Key Opinion Leaders ("KOLs"). This bill of particulars includes 54 pages of detailed and specific examples of Manufacturer Defendants' patently false claims, including pictures and quotes taken directly from source material, regarding prescription opioids in general and their specific products (SAC at 45-100), the ways in which those misrepresentations were disseminated through Front Groups (id. at 97-113), KOLs (id. at 100-115), continuing medical education ("CME") programs (id. at 124-27), "branded" advertising to promote their products directly to doctors and consumers (id. at 129-30), "unbranded" advertising to promote their products directly to doctors and consumers without FDA review (id. at 130-31) and funding, editing, and distributing publications that supported their misrepresentations (including the nine falsehoods alleged earlier in the Complaint) (id. at 131-32). The SAC describes how these misrepresentations were disseminated, including through speakers' bureaus and programs (id. at 136-37), and detailing to doctors. (Id. at 136).

There is no risk of damaging these Defendants' reputations, or of fishing for claims that do not exist: Defendants named in the Opioid Marketing Claims have already been subject to enforcement actions, pleaded guilty to misbranding, or settled claims against them for misrepresentations regarding opioid use in general, and for specific misrepresentations about their

drugs. (SAC at 46-47, 71-72 n.49, 234-38, 53-54.); see also Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc., 2014 WL 2115498, *3 (E.D. Pa. May 21, 2014) (recognizing DOJ and state legal actions against Cephalon for its marketing of Actiq) ("Carpenters").

Here, the Manufacturer Defendants proffered particularity requirements like "who made or who received any allegedly false statements," and "when or where any specific false statement was made," but the controlling cases demand only particularity, not a recitation of minute details. The Manufacturer Defendants' remaining arguments similarly fail as a matter of law. First, they provide no authority requiring Plaintiffs to connect misrepresentations directly to a prescription, prescriber, or injury in Akron and Summit County in order to plead mail or wire fraud.²¹ Second, the Manufacturer Defendants' portrayal of the "nine categories of misrepresentations" as "conclusory" is belied by the detailed, objectively verifiable allegations discussed above. Finally, the Manufacturer Defendants' argument regarding the location of the misrepresentations fails as well: the case law governing particularity in complex, far-reaching fraud cases, read in light of Plaintiffs' factual allegations, contradicts the Manufacturer Defendants' position. For example, Plaintiffs identify the primary Manufacturer Defendants who made marketing visits to prescribers in Akron and Summit County, the number of visits made between 2013 and 2016, as well as the amounts of money that they expended on payments to prescribers. (SAC ¶¶ 671-83). Plaintiffs' alleged failure to identify specific prescribers or sales representatives in this massive, years-long fraudulent scheme is irrelevant where the Complaint alleges publicly available information that is also obviously within the Manufacturer Defendants' knowledge regarding their own marketing practices, detailing visits and payments to doctors.

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²¹ In re Actimmunte Mktg. Litig., cited by Defendants, does not address this topic except to analyze causation, which is discussed below. See 514 F. Supp. 2d 1037, 1049 (N.D. Cal. 2009) (noting that the complaint contained a substantial number of allegations "that do not depend on mere off-label uses" and that a number of them "specifically allege statements made and their falsity," but stating that "[t]he allegations relating to the causal chain of injury as a result of these marketing efforts, however, is scanty").

ii. Opioid supply chain claims

Plaintiffs' mail and wire fraud allegations regarding the Opioid Supply Chain Enterprise likewise satisfy Rule 9(b). Defendants attempt to cast Plaintiffs' Opioid Supply Chain claim as exclusively alleging affirmative misrepresentations, but that is incorrect: Plaintiffs allege a fundamentally omission-based claim that also included misrepresentations made in furtherance of the overall omissions. Specifically, Defendants had a duty under the Controlled Substances Act ("CSA") and its implementing regulations to identify and report suspicious orders of prescription opioids, yet failed to do so, in order to increase and maintain high quotas for the manufacture and distribution of their drugs, thereby unlawfully expanding the market. (SAC ¶¶ 849-59.) The mail and wire fraud statutes, moreover, do not require a misrepresentation or omission; a scheme or artifice to defraud will suffice. Even so, Plaintiffs pleaded misrepresentations and omissions with sufficient particularity to notify Defendants of the claims against them.

Plaintiffs detail the specific circumstances constituting the overall fraudulent scheme, including instances where the Defendants omitted material information, the overall methods they used, and instances in which some Manufacturers and all of the Distributors made misrepresentations.²³ In addition to the list of false and misleading statements (SAC ¶¶ 849-54, 856, 859-61, 867-70, 875, 920-22, 928), Plaintiffs allege specific examples of the Defendants' material

²² Misrepresentation is merely one means by which either crime may be committed. Section 1341 refers to "... any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretense, representations or promises. 18 U.S.C. § 1341 (emphasis added); 18 U.S.C. § 1343. The essence of mail and wire fraud is taking money or property belonging to another and using those instrumentalities in furtherance of the scheme. A misrepresentation is not required. *Carpenter v. United States.*, 484 U.S. 19, 26-28 (1987); *McNally v. Gray*, 483 U.S. 350, 359 (1987) (mail fraud reaches "false promises and misrepresentations as to the future *as well as other frauds* involving money or property") (emphasis added); *Bridge, supra*, (describing a classic fraud-by-concealment scheme, with no communications to the victims).

²³ A "RICO claim does not require proof of affirmative misrepresentations because the omission of material facts suffice to prove the predicate acts of mail or wire fraud." *In re Duramax Diesel Litig.*, 298 F. Supp. 3d 1037, 1045 (E.D. Mich. 2018); *see also In re Whirlpool Corp.*, 684 F. Supp. 2d at 961. Plaintiffs must only allege their "theory of fraudulent omissions with enough specificity to provide Defendants with fair notice of the claims." *Duramax, supra*, (citing *United States v. Walgreen Co.*, 846 F.3d 879, 880-81 (6th Cir. 2017)).

omissions, including their awareness of specific orders, awareness of competing Manufacturer and Distributor Defendants' orders, and their failure to report them, including that the Defendants had a duty to make a full and complete disclosure regarding their compliance with the CSA, and failed to do so while allowing hundreds of millions of pills to be diverted into Akron and Summit County. (See SAC ¶¶ 454,502-05, 506, 519-25, 537-38, 555-99, 769-70, 752, 775, 849-72.) For example, Mallinckrodt was prosecuted for failing to report suspicious orders, including the orders that "Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics." (SAC ¶¶ 520-21, 583.) The Complaint details similar enforcement actions against each of the Distributor Defendants, all of which confirm that the Distributor Defendants were aware of and refused to report suspicious orders. (SAC ¶¶ 579-93.) Plaintiffs also allege that all of the Distributor Defendants, and some of the Manufacturer Defendants, made additional affirmative misrepresentations that furthered the common purpose of the Opioid Supply Chain Enterprise. (SAC ¶¶ 579-93, 594-606, 684-708, 772, 775, 856, 858-59.) These allegations are sufficient to satisfy Rule 9(b) as to a scheme to defraud fraud by omission. "Rule 9(b) does not require fraud-byomission claims to specify the time, place, and specific content of an omission as precisely as would a . . . false representation claim." In re Whirlpool Corp., 684 F. Supp. 2d 942, 961 (N.D. Ohio 2009). These allegations provide the Distributor Defendants with sufficient "who, what, when, and how" to distinguish the holdings in Heinrich and Durrani that involved failure to allege the dates on which allegedly fraudulent misrepresentations were emailed directly to the plaintiff, and vague allegations of fraud without any specification.²⁴

²⁴ Heinrich v. Waiting Angels Adoption Servs., Inc., 668 F.3d 393, 405 (6th Cir. 2012) (holding that failure to allege the dates of emails that were sent between 2005 and 2006, specifically addressed to the plaintiffs by a single defendant, did not provide sufficient particularity); Aaron v. Durrani, Nos. 13-cv-202, 13-cv-214, 2014 WL 996471, *6 (S.D. Ohio Mar. 13, 2014) (dismissing RICO claims because "[a]ll that Plaintiffs allege[d was] that 'All named Defendants in this complaint knew" that wires and mails would be used to 'to further the scheme' footnote continued on next page

Plaintiffs' allegations are no surprise: national news organizations have documented multiple Manufacturer and Distributor Defendants' failures to fulfill their duty to identify and report suspicious orders despite actual knowledge of diversion through organized crime rings; some have entered into memoranda of understanding with the DEA and, in at least one instance, admitted failure to fulfill their obligations. (SAC ¶¶ 554-606.) Plaintiffs' RICO allegations satisfy the particularity standard for fraud allegations based on a complex and far-reaching fraudulent scheme, where pleading every instance of fraud would be extremely ungainly, if not impossible." *Bledsoe*, 501 F.3dat 509-10. Defendants' arguments to the contrary lack merit.

First, Plaintiffs allege the total number of pills that were diverted into Akron and Summit County and Ohio (SAC ¶¶ 697-94), and the fact of a known diversion route between Florida and Ohio called the "Blue Highway" that affected counties like Summit in Ohio. (SAC ¶¶ 660-66.) The law does not require Plaintiffs to allege the specific dates on which each of the Manufacturer Defendants knew of each suspicious order, or exactly which orders were suspicious. *Williams*, 681 F.3d at 803; *accord*, *Michaels*, 848 F.2d at 680.²⁵ Similarly, because Plaintiffs' allegations rest on information within Distributor Defendants' knowledge—for example, where or when they made statements about their compliance with the CSA, failed to report suspicious orders, or submitted quota applications based on incomplete suspicious order reports)—that information need not be alleged with particularity. "At this stage of the case, where a major part of the surviving evidence that would affirm or negate the individual culpability of each defendant is in the hands of those

footnote continued from previous page

and that Defendants used the mails and wires for their billing. These vague allegations fail to meet the basic elements of pleading mail and wire fraud").

²⁵ Moreover, the Manufacturer Defendants' four bullet points purporting to highlight facts that are missing from Plaintiffs' Complaint ignores that Manufacturer Defendants are alleged to have known about suspicious orders, omitted that information when they failed to report those orders as required by the CSA and, in some instances, made affirmative misrepresentations about their compliance with the duty to identify and report suspicious orders. (SAC ¶¶ 403, 506, 510-11, 543-78, 569, 641-47, 669-70, 675-76, 820-25, 827, 830-32, 838-41, 846, 890-92, 898.)

defendants themselves, it is appropriate to allow the plaintiffs claim to proceed"). *JAC Holding Enter., Inc. v. Atrium Cap. Partners*, *LLC*, 995 F. Supp. 2d 710, 727-28 (E.D. Mich. 2014).

Second, Distributor Defendants' authority that purportedly requires Plaintiffs to specify the fraudulent statements, identify the speaker, state where and when each statement was made, and why each was fraudulent are *all* distinguishable on their face. (Dist. Mem. at 16-17 and n.13). These cases involve a small number of fraudulent acts occurring in a short amount of time (*American Biocare; Heinrich; Prater*), or barebones allegations without an allegation that anything false occurred (*Arnold; Aaron; Hot-Shot Motorworks*). Here, unlike the cases they cite, Distributor Defendants' fraudulent statements and omissions do not fit neatly into a small time period; rather, they involve years-long failures to report hundreds, if not thousands (or more) suspicious orders, as well as misrepresentations about their compliance with the duty to identify and report suspicious orders. This complex and broad-ranging fraudulent scheme is exactly the kind of situation in which plaintiffs are excused from pleading each and every detail about a fraudulent scheme. *United States*. *ex. rel. Bledsoe*, 501 F.3d at 509-10.

Finally, Distributor Defendants cannot plausibly argue that Plaintiffs fail to allege a mail and wire fraud scheme that was used to deprive someone of money or property. "[T]he scheme to defraud element required under s[ection] 1341 [and 1343] is not defined according to a technical standard." *United States v. Van Dyke*, 605 F.2d 220, 225 (6th Cir. 1979). The standard is "a reflection of moral uprightness, of fundamental honesty, fair play and right dealing in the general and business life of members of society." *Id.* Plaintiffs specifically allege a fraudulent scheme, including that the entire purpose of the Opioid Supply Chain Enterprise was to deprive people of money or property by inflating and/or artificially maintaining high quotas, by refusing to identify, report, and reject suspicious orders despite their knowledge that they had a duty to do so and despite representations that they were complying with these obligations. (*See* SAC ¶¶ 499, 508-09, 519-20, 522-25, 526-30,

579-606, 849-54, 859-60, 866-67, 870.) This scheme evidences fundamental dishonesty, unfairness, improper dealings, and an absence of moral uprightness, as well as fraudulent misrepresentations and omissions. *Van Dyke*, 605 F.2d at 225; *Jamieson*, 427 F.3d at 402.

iii. Group pleading

Both Manufacturer and Distributor Defendants argue that Plaintiffs failed to satisfy Rule 9(b) because Plaintiffs improperly "group plead." The prohibition on group pleading arises in the securities context, under a factually distinguishable scenario in which a plaintiff attempts to hold corporate officers liable for the statements of their corporations. The cases cited by Distributor Defendants, Hoover v. Langston Equip. Assocs., Inc., Winsor-Laurelwood Ctr. Behavioral Med. v. Waller Lansden Dortch & Davis, and D.E. J, involve relatively small numbers of defendants who are charged with making a relatively small number of misrepresentations, and situations in which the allegations did not support the inference of responsibility for the representation of another. 26

Defendants' group pleading argument fails because Plaintiffs specifically identify the representations of each Manufacturer Defendant named in the Opioid Marketing claim and puts them on notice of the claims against them. Plaintiffs specifically allege the similarity of their misrepresentations regarding prescription opioids in general, and the misrepresentations that each Manufacturer Defendant made, the way they were disseminated, and the control and direction that each of the Manufacturer Defendants exercised over the KOLs and Front Groups. (Mfr. Mem. at 46-126.

²⁶ Jiaxi Hu v. Chan, No. 1:15-CV-709, 2016 WL 4269065, *6 (S.D. Ohio Aug. 16, 2016) (plaintiff failed to satisfy Rule 9(b) regarding fraud and securities violations where he plaintiff argued that group pleading was not prohibited because the defendants were all related by blood or marriage with little or no distinction between the individual defendants and the entities they controlled); Arnold v. Alphatec Spine, Inc., No. G064 2002, 2014 WL 289638, *4 (N.Y. Work. Comp. Bd. 2014) ("the reference to 'Defendants' collectively fail[ed] to specify the conduct attributable to each party and [was], therefore, insufficient to meet Rule 8's notice requirement" because the court determined that the "FAC does not provide any facts to support the allegation that all Defendants colluded in the alleged fraudulent conduct").

Similarly, Plaintiffs did not improperly group plead allegations against the Manufacturer or Distributor Defendants arising out of the Opioid Supply Chain claims. Rather, Plaintiffs pleaded specific examples of the ways in which the Manufacturer Defendants were aware of and omitted information regarding suspicious orders. (SAC ¶¶ 414, 516, 520-21, 555-70, 581, 660-66, 688-89, 694-95, 849-54, 856, 859-61, 867-70, 875, 920-22, 928.) And Plaintiffs pleaded specific examples of Manufacturer Defendants who made misrepresentations regarding their duty to identify and report. (SAC ¶¶ 155-58, 181-84.) Plaintiffs likewise allege the specific misrepresentations and omissions made by each of the Distributor Defendants. (SAC ¶¶ 175-184.) These allegations satisfy the "who, what, when, where and why" for a group of Defendants whose specific wrongful conduct has been amply documented in other litigation, including with the DEA. *Id*.

2. Plaintiffs' Injuries Establish RICO Standing and Proximate Cause

"RICO's civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause. Standing poses a threshold question involving constitutional, prudential and . . . statutory limitations on who may sue, regardless of the merits of that person's claims." *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 611 (6th Cir. 2004).

a. Plaintiffs suffered injuries to their business or property

Contrary to Defendants' assertions, Plaintiffs plead categories of damages that are direct, not derivative. Plaintiffs allege that they were directly injured in their business or property by the opioid epidemic that was created by the Manufacturer Defendants' fraudulent marketing of prescription opioids, and the Manufacturer and Distributor Defendants' failure to identify and report suspicious orders as required by the CSA that fostered and sustained the opioids epidemic—*i.e.*, the exact harm that the CSA was designed to prevent. (SAC ¶¶ 900-03, 929-37, 946-49)); see Traveler's Prop. Cas. Co. of Am. v. Actavis, Inc., 225 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017); see also 970 U.S.C.C.A.N. 4566 ("a closed system should significantly reduce the widespread diversion of these drugs out of legitimate

channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotics and dangerous drug control"); *United States v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic").

Plaintiffs' damages arise directly, foreseeably, and traceably from Defendants' misrepresentations and omissions, and conduct around the pills that the Manufacturer Defendants marketed and sold to an unsuspecting public and from the illicit pills that the Manufacturer and Distributor Defendants allowed to divert into illegitimate channels when they failed to identify, report, and reject suspicious orders. (SAC ¶¶ 902, 934, 943, 972, subparagraphs a, h-i, k-m).²⁷

The Manufacturer Defendants' citations to *Anza, Jackson*, and *Trollinger* are unpersuasive and inapplicable here. The *Anza* plaintiff did not have standing because the conduct alleged (defrauding the state tax authority) directly harmed the state of New York, while competitive harm to the plaintiff (the defendant's ability to offer lower prices) was only an indirect side effect of the defendant's failure to pay taxes. *Anza*, 547 U.S. at 458. Here, by contrast, the actions causing Plaintiffs' harm *are* the alleged RICO violations, including the Manufacturer Defendants' intentional fraudulent misrepresentations and omissions regarding the prescription opioids that caused the opioid epidemic, and they directly injured Plaintiffs' business and property causing economic losses. (SAC ¶¶ 900-02); *see also Traveler's*, 225 Cal. Rptr. 3d at 19. Similarly, *Jackson* only applies to Plaintiffs' claims to the extent that they are for "personal injuries and pecuniary losses proximately resulting

²⁷ Although Plaintiffs are not seeking recovery for pill purchases of the type upheld in *Neurontin*, other bellwether Plaintiffs do assert such claims and may have claims related to misrepresentations and omissions giving rise to the Opioid Supply Chain claims. (*See Cty. of Cuyahoga v. Purdue Pharma, L.P., et al.*, No. 1:17-op-45004-DAP. Master Docket No. 1:17-md-02804-DAP, ECF No. 521, ¶ 764-67; *Broward Cty. v. Purdue Pharma, L.P., et al.*, No. 1:18-op-45332-DAP. Master Docket No. 1:17-md-02804-DAP, ECF No. 525, ¶ 807-09); *see Medicaid Mut. of Ohio v. Purdue Pharma, L.P., et al.*, No. 1:18-op-45307-DAP, Master Docket No. 1:17-md-02804-DAP, ECF No. 344, ¶ 1554.

from a personal injury." Jackson, 731 F.3d at 565. Here, unlike Jackson, Plaintiffs' damages claims are not for personal injuries, but police and fire services, lost taxes, revenue and funding. The Manufacturer Defendants' attempt to argue that Plaintiffs' alleged failure to establish an interest in any property that suffered a diminished value ignores Plaintiffs' allegations and distorts Trollinger. The harms that the Manufacturer and Distributor Defendants caused, which also impact the Plaintiffs' revenue-generating function, are direct injuries to their "business and property," which has been decisively and functionally construed as any form of economic loss: "anything of material value owned or possessed." Reiter v. Sonotone Corp., 442 U.S. 330, 338 (1979). "Money, of course, is a form of property." Id.

Defendants' argument that Plaintiffs failed to allege an injury to business or property because Plaintiffs failed to plead anything more than governmental expenditures also fails.

Defendants' argument ignores more recent circuit court holdings, stretches the logic of *Canyon County v. Syngenta Seeds* ("Canyon Cty") too far, and ignores Plaintiffs' damages. The Fifth Circuit held, in *Wellborn v. Bank of N.Y. Mellon Corp.*, 557 F. App'x 383 (5th Cir. 2014), that a government entity could not sue under RICO because the injury at issue did not affect an interest that was "created to serve a revenue-generating function for the states." *Id.* (emphasis added). A governmental entity may, therefore, sue for injuries to its revenue-generating functions, *i.e.*, taxes, even if those injuries are not competitive or commercial injuries. Multiple circuits have recognized this point. See City of New York v. Smokes-Sprites.com, Inc., 541 F.3d 425, 445 (2d Cir. 2008) (reversing Town of West Hartford, and holding that "lost taxes can constitute injury to 'business or property' for purposes of RICO . . . notwithstanding that [the City's] injury did not arise from its participation in a commercial transaction"), rev'd on other grounds, Hemi Group, LLC v. City of N.Y., 559 U.S. 1 (2010); Ill. Dep't of Revenue v. Phillips, 771 F.2d 312, 314-16 (7th Cir. 1986).

The Manufacturer Defendants also argue that public expenditures made by Plaintiffs in their sovereign capacity cannot establish RICO standing. But those cases are inapposite. In *Canyon Cty.*, the plaintiff alleged no concrete financial loss proximately caused by the alleged scheme and was not suing to abate a public nuisance (a recognized exception to the application of the municipal recovery rule which plaintiff conceded applied). In *Cty. of Oakland*, meanwhile, the Sixth Circuit upheld Oakland's RICO claim against Detroit's challenge even where Oakland had arguably passed on its damages to consumers and was purportedly without an injury. The Court noted the importance of a "case by case" standing analysis "in deciding whether the law affords a remedy in specific circumstances," and recognized not only that recovery "would, presumably, rebound to the benefit of the county's residents" but also that the defendants had an alleged improper motive. *Cty. of Oakland v. City of Detroit*, 866 F.2d 839, 848-51 (6th Cir. 1989). Here, Plaintiffs' damages include direct injuries to Plaintiffs' revenue generating function resulting in unreplaced lost revenue and reduced tax income. (SAC ¶¶ 902, 934, 948, 972.)²⁸

b. <u>Plaintiffs' injuries were directly caused by the defendants'</u> fraudulent scheme

Defendants contend that Plaintiffs fail to plead proximate causation because they do not allege a direct link between Defendants' fraudulent conduct and Plaintiffs' injuries. *See* Mfr. Mem. at 12-17; Dist. Mem. at 11-16. But they fail to cite recent, relevant Sixth Circuit precedent, miscast well-pleaded RICO allegations, and improperly employ an inflexible causation test at a premature stage of the litigation, contrary to prevailing precedent.

²⁸ The Distributor Defendants' reliance on the non-binding decisions in *Haw. Health & Welfare Tr. Fund v. Philip Morris* ("*Haw. Health*") and *Gucwa v. Lawley* are similarly inapplicable. In *Haw. Health* the plaintiff sought to recover for the increased cost of medical care and the court dismissed that claim, finding that it was too remote and founded, in all material respects, on personal injury to smokers. *Haw. Health*, 52 F. Supp. 2d 1196, 1200 (D. Hawaii 1999). And, in *Gucwa*, the court merely followed the logic of *Jackson* to dismiss RICO claims for lost workers' compensation. *Gucwa*, No. 17-1823, 2018 WL 1791994, *2-3 (S.D. Ohio Apr. 16, 2018). Neither case warrants dismissal because Plaintiffs plead direct injuries to their revenue generative function that are not derivative of personal injuries.

Defendants challenge proximate cause, which is the name for "the judicial tools used to limit a person's responsibility for the consequences of that person's own acts," and requires that there be "some direct relation between the injury asserted and the injurious conduct alleged." Bridge, 553 U.S. at 654 (Proximate cause is "a flexible concept that does not lend itself to 'a black-letter rule that will dictate the result in every case,"); accord Brown v. Cassens Transp. Co., 546 F.3d 347, 357 (6th Cir. 2008). The direct injury requirement ensures that: (1) damages can be properly and efficiently apportioned, (2) no party recovers excessively, and (3) the directly injured are able to vindicate the law by bringing suit to enforce it. Holmes v. Securities Investor Protection Corp., 503 U.S. 258, 269-70 (1992). Here, Plaintiffs' damages were directly caused by the Defendants' actions. Even if the Court questions the directness of Plaintiffs' injuries, the Holmes analysis weighs in favor of finding sufficient proximate cause at this early stage because Plaintiffs' damages may be properly and efficiently apportioned among the Defendants, Plaintiffs' RICO damages cannot not be sought or recovered by any other party, and Plaintiffs' recovery is necessary to vindicate the purposes underlying RICO and deter future violations. See Bank of Am. v. City of Miami, 137 S.Ct. 1296, 1306 (2017) (relying on Holmes to remand a case involving a lengthy causal chain rather than holding that direct causation was absent).

The "direct injury" requirement simply requires a "link between the scheme and the type of injury [plaintiff] suffered." Wallace v. Midwest Fin. & Mortg. Servs., Inc., 714 F.3d 414, 420 (6th Cir. 2013). "What matters . . . is not whether there is a direct relationship between the plaintiff and defendant, but whether there is a 'sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury" In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prod. Liab. Litig., No. MDL 2672 CRB (JSC), 2017 WL 4890594, at *9 (N.D. Cal. Oct. 30, 2017) (quoting Bridge, 553 U.S. at 657 (2008)).

The Sixth Circuit recently clarified the direct injury requirement in a case where it allowed the claim of plaintiff who contended a mortgage broker and mortgage lender falsely appraised his home, inflating its value by more than \$100,000 "as part of a larger scheme to secure high-interest loans." *Wallace*, 714 F.3d at 420. Based on the "illusion" of substantial home equity, the plaintiff decided he could afford to renovate his basement; a mortgage broker convinced him to enter into a large option adjustable rate mortgage (ARM), "the unfavorable terms of which were never made clear to [the plaintiff]." *Id.* When the accruing interest eventually outpaced his ability to pay, the plaintiff found himself unable to sell the home for enough money to repay the mortgage. *Id.* He thus claimed to have been injured in the amount of the fees, interest costs, and other expenses tied to the option ARM. *Id.*

The Sixth Circuit criticized the district court's "unnecessarily rigid understanding of the case," finding both that it was "clear enough" that "the inflated appraisal itself played a significant role" in the plaintiff's negotiations with his mortgage broker, and that it was "certainly possible that the illusion of equity made the difference" in the plaintiff's decision to obtain the ARM. *Id.* at 420-21. This allowed it "to trace a straight line between the alleged fraud and the asserted injury," *id.* at 420, notwithstanding the many steps in the chain of causation between the inflated appraisal and the plaintiff's injuries. "While the illusion alone did not compel [the plaintiff] to borrow as he did here, it certainly increased the likelihood that he would. Put another way, the inflated appraisal appears to be 'a substantial factor in the sequence of responsible causation' according to [the plaintiff's] version of the facts." *Id.* at 421. "That is sufficient at this stage in the litigation." *Id.* at 421-22; *see also Trollinger*, 370 F.3d at 618-19 (declining to dismiss RICO claim on proximate cause grounds at pleading stage).

Plaintiffs more than meet these causation standards: they directly link Defendants' fraudulent scheme with the injuries suffered by Akron and Summit County, alleging in ample detail that Defendants created two association in fact enterprises, an Opioid Marketing Enterprise and an

Opioid Supply Chain Enterprise. Employing certain Front Groups and KOLs, the Manufacturer Defendants concealed the true risks and dangers of opioids from the medical community and the public, including the Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. SAC at ¶ 816. This conduct was specifically intended to, and did, promote the widespread use of dangerous, addictive opioids, causing an epidemic of addiction that injured the Plaintiffs "in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic." *Id.* at ¶¶ 900-04 (detailing specific costs directly and foreseeably caused by the Manufacturer Defendants' fraudulent activity).

Likewise, the RICO Supply Chain Defendants concealed and suppressed and/or ignored warnings from "third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market." *Id.* at ¶ 920. This consequence—the creation of a widespread opioid epidemic—was foreseeable, and it in turn directly and foreseeably caused the Plaintiffs to suffer substantial losses of money and property as a result of the RICO Supply Chain Defendants' fraudulent scheme. *Id.* at ¶¶ 932-37. *See Travelers*, 225 Cal. Rptr. at 9.

Defendants' contentions regarding intervening causes lack merit where, as here, the original tortfeasor's intentional acts contemplated and caused the intervening acts, the original tortfeasor remains liable for the consequences of its actions—even if the intervening actors negligently or intentionally cause injury. See, e.g., In re Neurontin, 712 F.3d at 39 ("Pfizer now argues that because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes. But Pfizer's scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer's fraudulent marketing."); Restatement

(Second) of Torts § 447. Plaintiffs allege that Defendants *knowingly and intentionally caused* the very actions they hide behind as "intervening causes" involving "illegal conduct" (Dist. Mem. at 13; Mfr. Mem. at 13-14); doctors overprescribing opioids, pharmacies over-dispensing opioids, patients becoming addicted to opioids, all of which caused the Plaintiffs to suffer pecuniary loss. The Plaintiffs' "alleged injury . . . is the direct result of [Defendants'] fraud. It was a foreseeable and natural consequence of [Defendants'] scheme." *Bridge*, 553 U.S. at 656–58 (holding that a RICO plaintiff need not even show reliance in order to satisfy the direct injury requirement). Far from "multilayered and speculative," increased costs to the Plaintiffs are direct and foreseeable harms caused by the criminal enterprises alleged in the SAC.

Defendants attempt to analogize the comprehensive RICO schemes detailed in the Complaint to readily distinguishable cases. In *Hemi Grp. LLC v. City of New York*, 559 U.S. 1 (2010), a cigarette company failed to file sales reports with the State of New York. Some of the customers who were legally obligated to pay a cigarette tax to the City of New York failed to do so, but lacking these reports from Hemi, the State could not pass on the information to the City, and the City in turn could not determine which customers had failed to pay the tax. *Id.* at 9. The City thus could not pursue those customers for payment, so the City claimed injury in the amount of uncollected back taxes. *Id.* The Supreme Court held that this stretched the RICO direct causation connection too far: "the only fraudulent *conduct* alleged here is a violation of the Jenkins Act"—the state cigarette tax reporting requirement—which it held was too far removed from the injury alleged. *Id.* at 11 (declining to "extend RICO liability to situations where the defendant's fraud on the third party (the State) has made it easier for a fourth party (the taxpayer) to cause harm to the plaintiff (the City)").

Here, the Plaintiffs allege two longstanding RICO schemes whose express purpose was to enrich Defendants by generating massively increased demand for and ensuring a commensurate supply of dangerous, addictive opioids—deliberately inducing doctors to write prescriptions and

patients to take them, all while intentionally turning a blind eye to diversion—and the Plaintiffs have been injured by being forced to bear the direct and foreseeable costs of these actions. The Distributor Defendants' contention that the Plaintiffs seek to hold them liable for "fail[ing] to report certain information" to certain governmental entities ("the DEA and/or BOP"), Dist. Mem. at 12, is belied by Plaintiffs' allegations: the RICO Supply Chain Defendants, among other acts, actively misrepresented their actions to the public, sought to undermine DEA enforcement action through lobbying and other activities, made false and misleading statements to federal *and* state regulators, failed to report and filled suspicious orders by themselves and their co-conspirators, made payments to the Manufacturer Defendants in furtherance of the scheme, and took other actions not knowable to the Plaintiffs at this time. See SAC ¶¶ 852-71. Only by ignoring the well-pleaded allegations in the SAC could one say that these organized criminal activities amounted to no more than a simple state law reporting violation.

In *Holmes*, market manipulation caused share prices to drop, leading to: certain broker-dealer bankruptcies; customers whose funds had been invested (in other securities) to experience losses because the broker-dealers could not keep promises to their customers; Securities Investor Protection Corp. (SIPC) paying claims and, in turn, suing market manipulators, setting off this chain of events. 503 U.S. at 262-64. To state the facts of the case is to distinguish it: there is no attenuated chain of causation here, where the express object of the comprehensive RICO schemes was to manipulate doctors, pharmacies, regulators, and members of the public to foster consumption and addiction which directly and foreseeably caused the County to spend \$66 million on, increased costs for drug treatment for adults and infants, foster care, communicable disease prevention, law enforcement and incarceration, and lose significant funding and tax revenue. That there are two categories of direct victims: those who suffer personally and those who suffer economically, is no bar to standing *or* causation. Plaintiffs' claim presents no problem involving the apportionment of

damages or multiple recovery because there is a direct causal link between the Defendants' actions and Plaintiffs' injury.²⁹ Additionally, without Plaintiffs' suit, few, if any, victims of the RICO conspiracy will be able to "vindicate the law as private attorneys general." *Holmes*, 503 U.S. at 269-270. The policy interests underlying the direct injury requirement thus favor allowing the Plaintiffs' claim to proceed. Therefore, the first and third inquiries in *Holmes* weigh in favor of finding proximate cause.

The Plaintiffs' costs are also directly linked to skyrocketing opioid use and addiction: the express purpose of Defendants' criminal RICO activities. This link distinguishes this case from City of Cleveland v. Ameriquest Mortgage Securities, 615 F.3d 496 (6th Cir. 2010). There, the Sixth Circuit found that the negative consequences created by defendants' legal activities in financing the subprime mortgage market failed to directly cause a panoply of effects, ranging from neglect of property to starting fires, looting, and dealing drugs that were "completely distinct from the asserted misconduct (financing subprime loans)." The "eyesores, fires, drug deals, and looting" were caused, respectively, by homeowners, negligent or malicious individuals, shoddy construction, independent criminal decisions, and the actions of other companies that financed subprime loans and properties. 615 F.3d at 505. Here, in contrast, the illegal RICO misconduct the Plaintiffs have identified matches the harm it suffered: by engaging in a fraudulent scheme to promote the widespread use of addictive opioids, and (as to the RICO Supply Chain Defendants) fostering large-scale diversion, Defendants created the addiction problem the Plaintiffs must spend money to combat.

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²⁹ Apportionment and approximation of damages may also be addressed through statistical analysis to establish the necessary causal link to satisfy the question of apportionment. *See Cty. of Cook v. Wells Fargo*, No. 14 C 9548, 2018 WL 1469003, at *8 (N.D. Ill. Mar. 26, 2018) (acknowledging that statistical analysis of aggregative data might establish "the likelihood that a loan modification denied would lead to foreclosure," and sufficiently link Wells Fargo's conduct to at least part of the county's harm); *see also City of Miami*, 137 S.Ct. at 1302 (noting that "[t]he complaint describes statistical analyses that trace the City's financial losses to the Banks' discriminatory practices"). *Anza* and *Canyon County*, relied on by the Defendants did not address a situation where there is an alleged provable and quantifiable causal link between the defendant's conduct and plaintiff's injury despite multiple links in the causal chain.

Nor can the Plaintiffs' harms be characterized as "exclusively derivative" of its residents' injuries. The costs the Plaintiffs have incurred as a result of Defendants' fraudulent enterprises are not derived from the physical injury to any particular persons, but constitute direct injuries to their revenue generating functions and, in addition, the collective harm imposed on the community. Defendants' conduct was designed to and did create an increased demand for and overabundant supply of their products on a national scale, which generated an opioid crisis in these communities and across the country. It is that crisis which has caused the Plaintiffs to incur direct costs. The Plaintiffs' injuries here are not personal injuries incurred by individuals suffering as a result of overprescription, overuse, and addiction. The harm is the pecuniary injury the Plaintiffs themselves have incurred specifically to address the Opioid Crisis, and its lost revenue and funds. The Plaintiffs seek to recover their own funds, not "stand in the shoes of nonpurchasing customers" or a business competitor, see Pik-Coal Co. v. Big Rivers Elec. Corp., 200 F.3d 884, 889 (6th Cir. 2000), or recover monies for health insurance plan members required to pay increased health insurance premiums as a result of other smokers, Perry v. Am. Tobacco Co., 324 F.3d 845, 849 (6th Cir. 2003). If Plaintiffs cannot recover for these injuries, no other, more direct plaintiff will vindicate Plaintiffs' important rights. Therefore, the second inquiry under *Holmes* is satisfied because there is no risk of overlapping or duplicative damages. Cf. Ill. Brick Co. v. Illinois, 431 U.S. 720 (1977). In short, Plaintiffs alleged injuries in a detailed, 343-page complaint that were directly caused by and the intended result of the Defendants' conduct. Their claims should be allowed to proceed. See Trollinger, 370 F.3d at 619 (6th Cir. 2004).

c. The Manufacturer Defendants' drug labels and the learned intermediary doctrine do not disturb the causal link between the Manufacturer Defendants' conduct and Plaintiffs' injuries

The Manufacturer Defendants reframe Plaintiffs' allegations to fit their narrow view of the case, stating that Plaintiffs allege that the Manufacturer Defendants concealed and minimized the

well-known risks of prescription opioid use. (Mfr. Mem. at 20.) Then, the Manufacturer Defendants cobble together an argument to disavow liability for their misrepresentations and omissions because: their product labels contained the FDA-required warning information, doctors have a duty to be familiar with these labels, and the Manufacturer Defendants' misrepresentations and omissions regarding their products and prescription opioids are not misleading when viewed within this context. The Manufacturer Defendants provide this Court with a plethora of inapplicable cases. However, the Manufacturer Defendants' arguments—which are highly fact-inflected— are contested, and hence inappropriate on motions to dismiss, nor do they defeat causation or undermine the merit of Plaintiffs' mail and wire fraud claims.

First, the Manufacturer Defendants' argument is based on warning labels that were not approved by the FDA until December 2016. The "black box' warning effective during the limitations period" that the Manufacturer Defendants provide to the Court for Nucynta ER is actually "a true and correct copy of the prescription drug label for NUCYNTA® ER approved by the FDA *as revised December 2016.*" (Mfr. Mem. at 21-22; 499-3, ¶ 4.) Manufacturer Defendants claim that they have provided the Court with "similar warnings for certain other of Manufacturer Defendants' drugs" in Exhibits D and E-J; but all of those "warnings" were "approved by the FDA *as revised December 2016.*" (Decl. of Charles C. Lifland in Support of Mfr. Mem., ECF No 499-3, at ¶¶ 5-11.)³¹ In contrast to misrepresentations and omissions beginning in the 1990s, warning labels

³⁰ In addition to their attempt to shoe-horn this argument into a discussion of the merits of Plaintiffs' mail and wire fraud allegations, the Manufacturer Defendants vaguely refer to it the learned intermediary doctrine. (Mfr. Mem. at 14-15, n. 16.) Because the learned intermediary doctrine is an issue of causation, it is provided to the Court within Plaintiffs' discussion of standing and causation, but applies equally to the Manufacturer Defendants' attempt to assert this argument in relation to the merits of Plaintiffs' mail and wire fraud allegations. Moreover, other courts have rejected the "learned intermediary" defense in the RICO context. See Neurontin, supra.

³¹ The Manufacturer Defendants' cite Risk Evaluation and Mitigation Strategy ("REMS") and FDA warnings regarding transmucosal immediate-release fentanyl ("TIRF") opioids in defense of their argument that the FDA has mandated the use of REMS to educate prescribers, pharmacists, and patients on the potential for footnote continued on next page

approved by the FDA in December 2016 have absolutely no relevance. The December 2016 warning labels cannot undermine any liability that the Manufacturer Defendants have for conduct that occurred prior to December 2016, and cannot interrupt any causal link between that conduct and Plaintiffs' injuries. Moreover, labeling statutes and regulations do not absolve defendants from telling the truth or immunize them or preempt state claims arising from a violation of what the Supreme Court calls "the duty not to deceive." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 529 (1992).

Second, the December 2016 warning labels and Plaintiffs' Complaint demonstrate that the Manufacturer Defendants did not adequately warn doctors. The Manufacturer Defendants' latestage warning labels were preceded by FDA announcements regarding safety label changes and post market study requirements for long-acting opioid analysesics in September 2013. (SAC at 49 n.24.) The Manufacturer Defendants' warning labels "did not adequately address the risks associated with [their] product[s] and [needed] to be corrected." SAC ¶¶ 181-82 n.24, 197-202, 298, 324-44, 349. Warning labels provided by the Manufacturer Defendants to the Court misrepresent label warnings during the relevant time period and demonstrate that the Manufacturer Defendants did not adequately advise doctors.

Third, the Manufacturer Defendants' argument rests on the presumption that they cannot be held liable for marketing their drugs untruthfully because the warning labels approved by the FDA in December 2016 contained the information that the FDA required. But the multiple revisions to the Manufacturer Defendants' warning labels, and the absence of any authority supporting the

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misuse, abuse, addiction, and overdose. Here, again, the REMS and FDA warnings were not issued until 2011 years after the Manufacturer Defendants began making misrepresentations regarding TIRFs while they were on the market.

Manufacturer Defendants' position, compels the opposite conclusion. In any event, this argument has been raised and rejected in similar litigation.³²

The Manufacturer Defendants cite two cases where Cephalon avoided liability for off-label marketing claims for the proposition that "prescribers are presumed to know a drug label's contents, which disclosed risks to 'potential prescribing physicians." Carpenters, No. 13-7167, 2014 WL 2115498, *6 (E.D. Pa. May 21, 2014); Travelers, 32 F. Supp. 3d 538, 553 (E.D. Pa. 2014). (Mfr. Mem. at 20). Both are factually inapplicable to Plaintiffs' claims. In Carpenters, the court noted that "[t]he Fund pleads Cephalon's marketing plan for Fentora in broad brushstrokes" but only "references three communications concerning Fentora that Cephalon allegedly directed at the market for the drug." Id. at 3-4. The plaintiff only referenced "a small handful of specific communications made by Cephalon to the market for Fentora." Id. While the court recognized the plaintiff's "reference to direct-to-patient online advertisements that were misleading and the subject of the FDA warning letter, the content, timing, and circumstances of [those] advertisements are not to be found in the complaint." Id. Furthermore, the "Fund [gave] only the broadest contents of the communications that it [did] name." Id. The holding of Travelers, is based on similarly inapplicable allegations and principles of law. Travelers., 32 F. Supp. 3d at 552-53, ("the Amended Complaint itself refers to a very few specific communications by the defendants regarding off-label use of Actiq and Fentora").33

³² City of Chicago v. Purdue Pharma L.P., 2015 WL 2208423, *4 (N.D. Ill. May 8, 2015) ("Courts are equipped to adjudicate" whether opioids "are marketed truthfully; specifically, whether defendants misrepresented the risks, benefits and superiority of opioids to treat long-term chronic pain").

³³ Manufacturer Defendants cite two Lanham Act cases, *Pizza Hut*, 227 F.3d 489, 495 n.5 (5th Cir. 2000), and *Veracity Grp.*, No. 1:11-cv-526, 2012 WL 203415, at *4 (S.D. Ohio Jan. 24, 2012), for the unremarkable proposition that false advertising claims under that act need to be viewed in context. *Aventis Pharms., Inc. v. Barr Labs, Inc.*, 411 F. Supp. 2d 490, 516-17 (D.N.J. 2006), is cited because it includes the words "FDA's expectation that physicians will use the cited safety information on the label . . . in choosing what medication to prescribe." But *Aventis* involved patent infringement, not whether any misrepresentations were made about the safety or efficacy of any drug. *Aventis* is irrelevant to the facts of this case. *Tracy v. Merrell Dow Pharm., Inc., footnote continued on next page*

These non-binding cases are neither persuasive nor comparable to Plaintiffs' allegations. The vague and incomplete pleading of purely off-label marketing claims in Carpenters and Travelers, forbid comparison to Plaintiffs' Complaint. In contrast, Plaintiffs allege a multi-drug, false marketing scheme through a RICO enterprise in order to profit from increased demand for opioids created by affirmatively and categorically misrepresenting the dangers of prescription opioid use, and that misrepresentations about Defendants' products that directly contradicted the warning labels they were required to place on their products. Off-label marketing is merely one aspect of Plaintiffs' claims that prevents analysis through the narrow lens of the Pennsylvania decisions. Unlike the plaintiffs in either case, Plaintiffs provide the Manufacturer Defendants with fifty-four pages of allegations, that contained detailed and specific examples of patently false claims that the Manufacturer Defendants made, including pictures and quotations taken directly from source material, regarding the category of prescription opioids in general (SAC at 46-100), the ways in which those misrepresentations were disseminated through Front Groups (id. SAC at 100-15), Key Opinion Leaders ("KOLs") (id. at 115-26), through continuing medical education ("CME") programs (id. at 126-29), "branded" advertising to promote their products directly to doctors and consumers (id. at 129-30), "unbranded" advertising to promote their products directly to doctors and consumers without FDA review (id. at 130-31), funding, editing, and distributing publications that supported their misrepresentations (including the nine falsehoods alleged earlier in the Complaint) (id. at 131-33), used speakers' bureaus and programs to spread their deceptive messages (id. at 136-37), and engaged in direct detailing to doctors where the Manufacturer Defendants' sales agents made the misrepresentations they had been trained by their employers to make (id. at 133-36).

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is similarly inapplicable to Plaintiffs' RICO and OCPA claims because it involved questions regarding the learned intermediary instruction in a case asserting medical malpractice and product liability claims. *Tracy*, 569 N.E.2d 875, 878-79 (Ohio 1991).

Even if the Court considers the "context" argument, the appropriate context includes the branded and unbranded materials the Manufacturers created, controlled, and disseminated as part of the totality of information available. Defendants engaged in a widespread marketing campaign involving both branded and unbranded materials, which was intended to, and did, drastically increase the number of prescriptions written and dispensed, and which misled physicians, patients, and Plaintiffs, leading a significant number of Plaintiffs' residents into drug addiction. Here, "context" does not prevent Plaintiffs from asserting mail and wire fraud, or from establishing the causal relationship necessary to establish RICO liability.

Finally, the learned intermediary doctrine does not interrupt the causal chain between the Manufacturer Defendants' misrepresentations and omissions and Plaintiffs' injuries for the reasons discussed below in connection with Plaintiffs' negligence claims. *See infra* § I.C.2.B.

3. Plaintiffs Plead Strong Cognizable RICO Marketing Claims

a. Formation and existence of the Opioid Marketing Enterprise

The Manufacturer Defendants acknowledge that Plaintiffs do, in fact, allege a common purpose for the Opioid Marketing Enterprise—"to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for long-term chronic pain." (SAC ¶ 814; Mfr. Mem. at 18.) But they argue that Plaintiffs do not allege a common purpose because the enterprise's members did not share or pool. (Mfr. Mem. at 18). But there *is no* profit-sharing requirement to allege a common purpose, and the Manufacturer Defendants provide this Court with no authority for it.

Defendants' alternative argument, that Plaintiffs did not allege anything more than parallel, profit-seeking activity among competitors is also meritless. The Manufacturer Defendants' cases observe, unremarkably, that parallel conduct "without more" does not establish a common purpose.

See In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 375 (3d Cir. 2010) ("nothing more than parallel conduct by separate actors is insufficient: there has to be something that ties together the various defendants . . . into a single entity"); Abbott Labs. v. Adelphia Supply USA, 15-CV-5826 (CBA) (LB), 2017 WL 57802, *6 (E.D.N.Y. Jan 4, 2017) ("parallel conduct of a number of spokes, even through a central hub, is not a RICO enterprise without more—that is, without a rim that connects the spokes"). "A statement of parallel conduct . . . needs some setting suggesting the agreement necessary to make out a § 1 claim." Atlantic v. Twombly, 550 U.S. 544, 557 (2007).

Plaintiffs allege precisely this *Twombly* "setting" to show both common purpose and agreement. The Manufacturer Defendants participated in two closely-knit organizations—the PCF and the HDA—that enabled them to coordinate their actions and develop personal relationships, and were used to form agreements regarding their members' overall approach to marketing prescription opioids. SAC ¶¶ 531-46. Defendants worked together to grow and sustain the market for opioids.

Plaintiffs further allege conduct that is not necessarily or merely parallel; while the Manufacturer Defendants were ostensibly competitors, they cooperated in a non-competitive way. The Manufacturer Defendants not only engaged in similar conduct (*i.e.*, financing KOLs and Front Groups), but they cooperated in financing the same KOLs and Front Groups, and jointly cooperated in publishing pro-opioid articles, guidelines, websites, and CMEs. The cooperatively published statements contained the same false messages that each of the individual Manufacturer Defendants were making about their specific opioid products despite the fact that each of the Manufacturer Defendants had the opportunity to use their control and direction over KOLs and Front Groups to disseminate competitive statements about their competitors' products. SAC ¶¶ 46-148. Here, the fact that they engaged in cooperative conduct, while members in the PCF and HDA, places the conduct within the necessary *Twombly* setting. Plaintiffs' allegations also satisfy the Sixth

Circuit's approach to association in fact enterprises, explained in *Ouwinga v. Benistar 419 Plan Services*, *Inc.*: "common sense suggests that the existence of an association-in-fact is oftentimes more readily proven by what it does, rather than by abstract analysis of its structure. A pattern of racketeering activity may be sufficient in a particular case to permit *a jury* to infer the existence of an association in fact enterprise." *Ouwinga v. Benistar 419 Plan Services, Inc.*, 694 F.3d 783, 792 (6th Cir. 2012) (emphasis added).

The Manufacturer Defendants misleadingly argue that an enterprise must possess "some sort of framework or superstructure" and "established duties." Mfr. Mem. at 19. But, their circumscribed quotation from *Ouvinga* are succeeded by the statement that "this organizational structure need not be hierarchical, can make decisions on an ad hoc basis, and does not require the members to have fixed roles. Put another way, a plaintiff must show 'simply a continuing unit that functions with a common purpose." *Ouvinga*, 597 F.3d at 794 (quoting *Boyle v. United States*, 553 U.S. 938, 949 (2009) (emphasizing the "breadth of the 'enterprise' concept")). The Manufacturer Defendants' attempt to extract a requirement from *Ouvinga* regarding the separation of an enterprise from its racketeering activity ignores *Ouvinga*'s statement that function outweighs structure when common sense directs that racketeering activity allows the inference of an association in fact enterprise. *Ouvinga*, 694 F.3d at 792.

There is no question that Plaintiffs' allegations demonstrate relationships between the Manufacturer Defendants. Their membership in the PCF and HDA provided them with interpersonal relationships that were a selling feature of the HDA when it sought new members. SAC ¶¶ 531-50. These interpersonal relationships existed through the PCF and HDA, separate and apart from any decision to use them to conduct and participate in a pattern of racketeering activity. As alleged in the Complaint, the PCF and HDA engaged in a number of activities that had nothing to do with the fraudulent marketing of prescription opioids. *Id.* at 522, 528, 531-33, 535-37, 540-41,

545. Therefore, the pattern of racketeering activity, although it is further evidence of the association-in-fact as permitted by *Ouvinga*, existed separately from the Opioid Marketing Enterprise. *Ouvinga*, 694 F.3d at 792.

Moreover, Plaintiffs allege that the Manufacturer Defendants "functioned as a continuing unit with a common purpose." The Manufacturer Defendants engaged in anti-competitive conduct when they had the opportunity to compete. And they made nearly identical representations about the efficacy of opioids in general; directly, through the same Front Groups and KOLs, and even collaborated on their dissemination by jointly financing the creation and publication of multiple documents that furthered the common purpose of the Opioid Marketing Enterprise. SAC ¶¶ 46-148.

Finally, the Manufacturer Defendants baldly state that Plaintiffs did not plead any element of the Opioid Marketing Enterprise, but do not argue longevity. Nevertheless, Plaintiffs alleged that the Opioid Marketing Enterprise was formed as early as the 1990s and that the members of the Opioid Marketing Enterprise worked cooperatively together in a sprawling decades-long fraud within that enterprise through the current day. SAC ¶¶ 3, 46-148, 216, 251-55, 270-79. The longevity of the Opioid Marketing Enterprise is not plausibly in dispute.

b. Plaintiffs allege sufficient factual information to establish the Manufacturer Defendants' control over the Front Groups and KOLs

The Manufacturer Defendants argue that Plaintiffs failed to establish that they had sufficient control over the Front Groups or KOLs to hold them liable for the misrepresentations that were disseminated, on their behalf and at their direction, by the KOLs and Front Groups. Mfr. Mem. at 26.³⁴ However, the Manufacturer Defendants' cases are inapplicable here, and ignore Plaintiffs'

³⁴ The Manufacturer Defendants' argument in footnote 25 that Plaintiffs is unable to hold them liable for statements made by the KOLs and Front Groups under a RICO enterprise or conspiracy theory fail.
footnote continued on next page

factual allegations. For example, in *McWilliams v. S.E., Inc.*, the plaintiff first alleged "in his response to [the defendant's] motion to dismiss, . . . that [the defendant] 'breached its duty when it failed to adequately train and/or supervise its employees;" "the complaint [did] not allege any such relationship." *McWilliams*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008). The case only stands for the proposition that a plaintiff must include allegations about a relationship between the parties in its complaint, as Plaintiffs did here. *Id.*

In *Taylor v. Checkrite*, *Ltd.*, 627 F. Supp. 2d 415, 416-17 (S.D. Ohio. 1986), the franchise contract between the franchisee and the franchisor did, in fact, give the Defendant a right of control over the franchisee. *Id.* at 417. *Taylor* stands for the proposition that a court may determine that a right of control exists where the Manufacturer Defendants gave their KOLs and Front Groups "detailed, step-by-step directions . . . in carrying out [their] business operations" and were given "virtually no discretion in performing these operations." *Id.* The Manufacturer Defendants' remaining cases do not compel an alternative conclusion because they are either not binding authority, failed to allege any basis upon which control could be inferred, or dismiss allegations in *City of Chicago* that were superseded by more detailed allegations.³⁵

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Plaintiffs allege sufficient facts to establish the KOLs and Front Groups as part of the Opioid Marketing Enterprise and furthered the common purpose thereof.

³⁵ Gen. Bldg. Contractors Ass'n v. Pa., 458 U.S. 375, 395 (1982) (funding activities did not create a servant or agent without some right to control the entity and "there [was] no record basis for believing that to be the case"); Batzel v. Smith, 333 F.3d 1018, 1036 (9th Cir. 2003) (the "agreement executed by Mosler and Cremers requires, in essence, that Cremers include Mosler's trademark in future editions of the Network. It [did] not give Mosler any right to control what is published by Cremers"); City of Chicago. v. Purdue Pharma L.P., 2015 WL 2208423, *11 (N.D. Ill. May 8, 2015) (dismissing the First Amended Complaint because the "City [did] not . . . explain what editorial control, if any, is entailed in 'sponsoring' or 'facilitating' materials or events"); Protostorm, LLC v. Antonelli, Terry, Stout & Kraus, LLP, 834 F. Supp. 2d 141, 162 (E.D.N.Y. 2011) ("nothing in the record indicates that D&S gave Worthington consent to act on its behalf or that Worthington's work on the patent application was subject to D&S's control . . . [because] . . . Worthington was retained to act as Plaintiffs' agent[,]" not the defendant's).

Unlike the Manufacturer Defendants' cases, Plaintiffs allege that the Manufacturer Defendants maintained control over the Front Groups and KOLs and had the right to direct their activities, including "funding, directing, editing, approving," etc. SAC ¶¶ 352, 354-57, 360-63, 365-70, 372, 378-80, 383-85, 380-90, 391-98, 401-03, 817-20, 830-31, 835-37. The agreements between the Manufacturer Defendants and their KOLs and Front Groups, unlike *Batzel*, allowed them to exercise control over what was published, spoken or disseminated. *Id.* The allegations in Plaintiffs' Complaint, unlike the now superseded *City of Chicago* decision, are much more detailed and fully explain the editorial control the Manufacturer Defendants had over the KOLs and Front Groups. (*See*, generally, *id.*) Finally, unlike the *Protostorm* relationships, the KOLs and Front Groups were not retained on behalf of any other entity in this case but the Manufacturer Defendants. ³⁶

4. Plaintiffs Pleads Strong Cognizable RICO Supply Chain Claims

Unlike the Distributor Defendants, who concede the existence of the Opioid Supply Chain Enterprise, the Manufacturer Defendants argue that Plaintiffs failed to plead a common purpose or relationships among the Opioid Supply Chain Enterprise members. The argument is based on nearly identical law and facts, and similarly lacks merit.

First, the Manufacturer Defendants incorporate and re-assert the argument that Plaintiffs' failure to allege profit-sharing belies a common purpose. Their argument, unsupported by case law, still lacks merit when applied to the Opioid Supply Chain. The SAC pleads the requisite common purpose, including "unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of

³⁶ The KOLs and Front Groups are not named as defendants, so Plaintiffs need not establish their liability. Nevertheless, Plaintiffs pleaded that they understood and shared a common purpose with the Manufacturer Defendants. SAC ¶ 814. The Manufacturer Defendants' claim, in footnote 25, that they cannot be held liable for liable for third-party statements under a RICO enterprise or conspiracy theory fails for the reasons set forth in II.B.3, III.B.3. and XIII of their motion to dismiss. But such arguments fail for the reasons set forth in this section.

prescription opioids to manufacture and distribute." (SAC ¶ 854.) And Plaintiffs allege the setting in which the common purpose was formed. The PCF and the HDA provided the opportunity to coordinate actions, develop personal relationships, and form agreements regarding and approach to issues like marketing prescription opioids. SAC ¶¶ 531-50. The Manufacturer Defendants had the opportunity to form agreements, and the PCF and the HDA were, in fact, used to form agreements regarding the members' overall approach to the identify and reporting suspicious orders, and the quotas that governed the manufacture and sale of prescription opioids. These allegations demonstrate the setting necessary to suggest an agreement. *Twombly*, 550 U.S. at 557.

Furthermore, Plaintiffs allege conduct that is not parallel given the competition in which the Manufacturer and Distributor Defendants should have engaged. The Manufacturer Defendants not only engaged in similar conduct (i.e., failing to identify and report suspicious orders and requesting ever increasing manufacturing quotas), they also engaged in similarly anti-competitive conduct. Through their relationships with the Distributor Defendants and their acquisition of sophisticated marketing data, the Manufacturer Defendants tracked their sales, their competitors' sales, and were aware of their suspicious orders of controlled substances, yet failed to report them as required by the CSA and state law. SAC ¶¶ 555-78, 583, 601-06, 850-54. Instead, the Manufacturer Defendants engaged in cooperative, anti-competitive conduct that falls within Twombly and Ouwinga, as explained in the preceding section. Plaintiffs pleaded a setting suggesting an agreement, and the ongoing pattern of racketeering activity in which all of the Manufacturer and Distributor Defendants cooperatively engaged further evidences an association-in-fact enterprise with a common purpose. The Manufacturer Defendants' Supply Chain arguments similarly fail when compared with the full statement of the law from Ouvinga and Boyle because Plaintiffs allege sufficient factual information regarding their membership and participation in the PCF and the HDA, and the purpose for which those entities were used. Defendants' non-binding cases are also unpersuasive; they stand for the

proposition that participation in a trade organization is not enough when the defendants merely remained silent about their own wrongdoing. *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017). *Almanza* actually supports Plaintiffs' allegations: Defendants here not only remained silent about their own wrongdoing, they also remained silent about their competitors' wrongdoing. Under the logic of *Almanza*, Plaintiffs have alleged more than mere participation in a trade organization or remaining silent in self-interest: Plaintiffs allege that the Manufacturer and Distributor Defendants remained silent out of common interest, mutually benefitting all members of the Opioid Supply Chain Enterprise by enabling them to increase the overall market while preserving each co-conspirator's market share.³⁷

a. The Distributor Defendants controlled and participated in the opioid supply chain enterprise

While the Manufacturer Defendants conceded their control of and participation in the Opioid Supply Chain Enterprise, Distributor Defendants argue that routine business relationships are insufficient to establish a RICO claim.³⁸ Dist. Mem. at 21. Therefore, the Court must determine whether the Distributor Defendants "had 'some part in directing the enterprise's affairs." *United States v. Fowler*, 535 F.3d 408, 419 (6th Cir. 2008) (emphasis in original).

As noted in *Reves v. Ernst & Young*, section 1962(c) allows an injured plaintiff to impose RICO liability on any "person" who "conduct[s] or participate[s], *directly or indirectly*, in the conduct of such enterprises' affairs." 18 U.S.C. § 1962(c) (emphasis added). The word "conduct" requires an

³⁷ Plaintiffs' allegations also satisfies the suggestion in *Consol. Metal Prods., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 293-94 (5th Cir. 1988) that plaintiff present evidence that tends to exclude the possibility of conduct consistent with permissible competition and the possibility that the alleged conspirators acted independently because the conduct at issue was anti-competitive and, membership in the PCF and HDA, precludes the possibility independent actions.

³⁸ The Distributor Defendants raise this argument exclusively in support of their argument that they did not conduct or participate in the Opioid Supply Chain Enterprise. Therefore, they, waived argument about formation of the enterprise. Nevertheless, Plaintiffs pleaded sufficient facts to establish the setting in which the Manufacturer and Distributors Defendants' allegedly parallel conduct and routine business relationships furthered a common purpose.

element of direction," but the word "participate" is a "term of breadth." Reves, 507 U.S. at 178. "To participate in the conduct of affairs' must be broader than 'to conduct." *Id.* at 179. "Of course, the word 'participate' makes clear that RICO liability is not limited to those with primary responsibility for the enterprise's affairs, just as the phrase 'directly or indirectly' makes clear that RICO liability is not limited to those with a formal position in the enterprise, but *some* part in directing the enterprise's affairs is required." *Id.* To have some part in directing the enterprise's affairs, a defendant only needs to "mak[e] decisions on behalf of the enterprise or . . . knowingly carry[] them out." *Fowler*, 535 F.3d at 418. "[A]n enterprise can be operated by 'lower rung participants in the enterprise." *Id.* at 419.

Here, Plaintiffs allege facts showing that each of the Distributor Defendants participated in making decisions about the formation and conduct of the Opioid Supply Chain Enterprise. *See* SAC ¶¶ 526-53, 579-606. And the Distributor Defendants participated by carrying out the decisions of the Opioid Supply Chain Enterprise, including: refusing to report and reject suspicious orders of controlled substances (including their competitors' suspicious orders); publicly misrepresenting their compliance with the duty to identify and report suspicious orders; and applying for ever increasing quotas governing prescription opioids. (*See* SAC ¶¶ 499, 519-25, 526-53, 579-606, 849-53, 855, 856-57, 859.) Unquestionably, the Distributor Defendants were aware of the Opioid Supply Chain Enterprise's common purpose, made decisions that conducted the enterprise, and participated in the conduct of the enterprise by implementing them.

Second, the Distributor Defendants' argument regarding routine business relationships and parallel conduct are no more applicable to the facts of this case than when asserted by the Manufacturer Defendants. The Distributor Defendants' cases do not support the conclusion that they did not participate in the Opioid Supply Chain Enterprise. Those cases recognize that allegations of parallel conduct or routine business relationships "without more" are insufficient to

establish RICO liability. See Robins v. Global Fitness Holdings, LLC, 838 F. Supp. 2d 631, 652 (N.D. Ohio. 2012). Although the Distributor Defendants obliquely use cases discussing parallel conduct or routine business relationships, they ignore Plaintiffs' allegations that the Distributor Defendants, at a minimum, refrained from competitive activities like reporting their competitors' suspicious orders and, incredibly, struck the exact same balance of identifying and reporting suspicious orders, including the decision to completely ignore their obligations. See SAC ¶¶ 849-53. These practices are anything but routine business relationships. Also ignored are the allegations that "suggest[] the agreement necessary" to demonstrate that the Distributor Defendants formed an association in fact enterprise and, at a minimum, participated in the conduct of that enterprise. See SAC ¶¶ 518-606, 849-53. These allegations demonstrate that the Distributor Defendants closely interacted in organizations that encouraged personal relationships, and used those organizations to form agreements about subjects like the duty to identify and report suspicious orders. SAC ¶¶ 544-46.

b. A felony violation of § 843(a)(4)(A) of CSA is an actionable racketeering activity pursuant to RICO § 1961(1)(D)

The Manufacturer Defendants distort the allegations of Plaintiffs' Complaint while ignoring the clear purpose of the CSA, to argue that they have no duty to report "downstream diversion," or stop delivery of suspicious orders. Each of these arguments fails.

First, the Manufacturer Defendants re-plead Plaintiffs' Opioid Supply Chain RICO claim by arguing that a violation of CSA § 842(a)(5) cannot serve as a racketeering activity under RICO § 1961(1)(A) because it is not a felony punishable by imprisonment for more than one year. However, Plaintiffs plead that the Defendants violated § 1961(1)(D) by engaging in the "felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a

³⁹ Bonadio v. PHH Mortg. Corp., No. 12 CV 3421, 2014 WL 522784, at *3 (S.D.N.Y. Jan. 31, 2014) and Nordberg v. Trilegiant Corp., 445 F. Supp. 2d 1082, 1092 (N.D. Cal. 2006) are also inapplicable to the facts of this case: there were no allegations that placed the alleged business relationships within the context of an agreement.

controlled substance . . . punishable under any law of the United States," including a violation of § 843(a)(4)(A), which makes it unlawful to "furnish false or fraudulent information in, *or omit any material information from*, any application, report, record, or other document required to be made, kept, or filed." Unlike section 842(a)(5) cited by the Manufacturer Defendants, a violation of section 843(a)(4)(A) is a felony punishable by a term of imprisonment of not more than 4 years. Therefore, violation of section 843(a)(4)(A) satisfies the racketeering activity definition in section 1961(1)(D) because it is a felony that involves the manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance. The Manufacturer Defendants provided no authority to the contrary.

The Manufacturer Defendants argue that they do not have a duty to report "downstream diversion" (Mfr. Mem. at 32), by reading words into the text of the CSA and its regulations that do not exist. The Manufacturer Defendants were required to register in order to manufacture prescription opioids. 21 U.S.C. § 823(a). The DEA's interpretation of the CSA, codified at 21 C.F.R. § 1301.74, requires Registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Although the Manufacturer Defendants argue that the duties to prevent diversion, and to identify and report and halt suspicious orders does not require "downstream" reporting, that argument finds no support in the statute or case law. The word "downstream" does not appear in either CSA § 823 or § 1301.74 of the C.F.R.

The Manufacturer Defendants' argument also strains credulity when considered in light of the DEA enforcement action against Mallinckrodt and Mallinckrodt's admission that, as a registrant, it had a duty to "maintain effective controls against Diversion, including . . . that it review and monitor these sales and report suspicious orders to the DEA." SAC ¶¶ 520-21, 583. The DEA found that Mallinckrodt violated its duty, as a registrant, to identify and report suspicious orders against Mallinckrodt when it "supplied distributors, and then the distributors then supplied various

U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying the DEA of these suspicious orders." *Id.* at 583. Plaintiffs thus allege facts demonstrating that Manufacturer Defendants had a downstream reporting requirement when they were aware of suspicious orders.⁴⁰

The Manufacturer Defendants further argue that they had no duty to stop shipment of suspicious orders. Official statements by the DEA contradict Manufacturer Defendants' interpretation. See SAC ¶¶ 523-25; see also, Masters Pharm., Inc. v. D.E.A., 861 F.3d 206, 212-13 (D.C. Cir. 2017) (the "Shipping Requirement" requires registrants to make "one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence.") This interpretation of the CSA, entitled to deference by the Court, must stand in the face of Manufacturer Defendants' completely unsupported argument. The DEA's interpretation is entitled to deference and "given considerable weight" because it reflects the DEA's construction of the CSA it was entrusted to administer, including the "registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. 821; Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843-44 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"); All. for Cmty. Media v. F.C.C., 529 F.3d 763, 776 (6th Cir. 2008); Pension Ben. Guar. Corp. v. Bendix Comm. Veh. Sys's, LLC, No. 1:11 CV 1961, 2012 WL 629928, at *6 (N.D. Ohio Feb. 24, 2012). And the existence of a duty to halt suspicious orders does not undermine Plaintiffs' 1961(1)(D) racketeering claims because failure to halt a suspicious order is not an element of a violation of section 843(a)(4)(A) which occurs merely by furnishing false or

⁴⁰ The Manufacturer Defendants' argument also lacks credibility in the context of Manufacturer Defendants' direct awareness of pill mills that were illegally diverting massive amounts of their prescription opioids and failed to report these issues to the DEA. SAC ¶ 569; *City of Everett v. Purdue Pharma L.P.*, No. C17-209RSM, 2017 WL 4236062, *2, *4-7 (W.D. Wash. Sept. 25, 2017).

omitting material information. Therefore, Plaintiffs plausibly allege violation of section 843(a)(4)(A) as racketeering activity pursuant to section 1961(1)(D).

The Manufacturer and Distributor Defendants further argue that Plaintiffs cannot plead a violation of CSA section 843(a)(4)(A) as a racketeering activity because CSA section 843(a)(4)(A) is a "record keeping felony." There is no case to support their position, which is contradicted by the history of the CSA and multiple cases interpreting its provisions. *RJR Nabisco, Inc. v. European Community*, 136 S.Ct. 2090, 2096 (2016) ("RICO . . . defines 'racketeering activity' to encompass dozens of state and federal offenses . . . [including] . . . drug-related activity that is 'punishable' under federal law") (citing 18 U.S.C. § 1961(1)(D)). There is no doubt that a felony violation of the CSA is a racketeering activity under section 1961(1)(D). Defendants were required to obtain a registration in order to manufacture, i.e. manufacture, buy, sell or otherwise deal in, prescription opioids. *See* 21 U.S.C. § 822(2) ("Every person who dispenses, or who proposes to dispense, any controlled substances, shall obtain from the Attorney General a registration"). The Defendants' registration was subject to their maintenance of effective controls against diversion and a system to identify and report suspicious orders. 21 U.S.C. § 823(b)(1); 21 C.F.R. 1301.74(b); SAC ¶ 513-15.

Although the Defendants argue that a violation of section 843(a)(4)(A) is not a racketeering activity because it does not amount to felony manufacturing, buying, selling, receiving, concealing or otherwise dealing in controlled substances, or because "record keeping" is somehow a different category of felonies, the history of the CSA and promulgating regulations demand a different conclusion. That conclusion is further supported by the legislative history and case law interpreting the CSA and its record keeping/reporting requirement, and the facts of this case. *See* 970

⁴¹ The Manufacturer Defendants argue section 843(a)(4)(A) solely relates to the fraudulent furnishing of information or omission of information from "documents 'made, kept or filed' under the CSA." (Mfr. Mem. at 33, n. 31.) Manufacturer Defendants essentially argue, like Distributor Defendants, that section 843(a)(4)(A) created a "record keeping" felony.

U.S.C.C.A.N. 4566 ("a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market"); *United States v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels" and "was aware that *registrants*, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, *were responsible for a large part of the illegal drug traffic*") (emphasis added); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 207, 212-13 (D.D.C. 2017) ("The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA 'investigators in the field' can aggregate reports from every point along the legally regulated supply chain *and use the information to ferret out 'potential illegal activity*") (citing *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)); *Neil Labs. Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 85 (D.D.C. 2002) ("The CSA purports to 'control the flow of controlled substances *through registration of and record keeping* by all those within the legitimate distribution chain").

By refusing to identify and report suspicious orders, the Manufacturer and Distributor Defendants knowingly facilitated diversion, *i.e.* the illegal sale, that the registration and reporting requirements in the CSA were intended to prevent. With this backdrop, the language of section 1961(1)(D), including the terms "concealment" "or otherwise dealing in controlled substances" are, at a minimum, sufficiently broad enough to allow the Court to determine that a felony violation of section 843(a)(4)(A)—wherein the Manufacturer and Distributor Defendants omitted their knowledge of suspicious orders that were being directed into illicit channels—qualifies as the "felonious *manufacture*, importation, *receiving, concealment*, buying, selling, or *otherwise dealing in a controlled substance*" pursuant to section 1961(1)(D) (emphasis added). Plaintiffs' claim is further supported by Plaintiffs' allegations that demonstrate, at a minimum, that Purdue was aware of a pill mill run by "an organized drug ring" in Los Angeles that was "packed with a line out the door, with people who

looked like gang members," and a particularly egregious pill mill in Pennsylvania, but failed to report them, and that Endo's sales representatives received bonuses for detailing prescribers who were subsequently arrested for illegal prescribing. SAC ¶¶ 569-78.

Finally, the Distributor Defendants' authority for the proposition that Plaintiffs may not bring a RICO cause of action because the underlying felony is a violation of the CSA is inapplicable to the facts of this case. In *In re Epogen*, the plaintiff alleged RICO liability for off-label marketing solely relying on mail and wire fraud as racketeering activities. *In re Epogen*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008) The court held that the plaintiff could not use RICO to privately enforce the Food, Drug, and Cosmetic Act ("FDCA") where no cause of action existed. But the *In re Epogen* plaintiff did not assert felony predicate acts, claims under the CSA, or the existence of a felony violation of the FDCA. Therefore, *In re Epogen* is irrelevant to Plaintiffs' 1961(1)(D) allegations.

5. Plaintiffs Plead Strong Cognizable OCPA Claims

Defendants' attempt to dismiss Plaintiffs' OCPA claims by arguing that Plaintiffs' OCPA claims are subject to dismissal for the same reasons as its RICO claims. (Dist. Mem. at 8; Mfr. Mem. at 38.) The OCPA, while based on RICO, is even broader and more flexible in important respects, discussed below. However, Defendants' assertion by incorporation of their arguments regarding the existence of an enterprise, the Distributor Defendants' participation therein, standing, causation or particularity, all fail for the reasons discussed above.

a. The OCPA does not require an injury to business or property

The Manufacturer and Distributor Defendants argue that Plaintiffs have no standing to assert their OCPA claims without a direct injury to business or property. (Dist. Mem. at 11; 499-1 at 38.) Ohio Rev. Code, § 2923.34 states, in relevant part, that "[a]ny person who is injured or threatened with injury by a violation of section 2923.32 may institute a civil proceeding." Ohio, therefore, omitted the RICO requirement that Plaintiffs plead an injury to "business or property."

Section 2923.34(E) further explains that under Plaintiffs' injury may be "direct[] or indirect[]." The OCPA thus "provides that persons indirectly injured by violations of the act have standing".

Bourke v. Carnahan, 840 N.E.2d 1101, 1106 (Ohio Ct. App. 2005). Iron Workers Local Union No. 17 Ins.

Fund v. Philip Morris, Inc., 23 F. Supp. 2d 771 (N.D. Ohio 1998) ("the Ohio General Assembly has determined that persons indirectly injured should have standing to bring an action under the Ohio Pattern of Corrupt Activity Act").

Although Defendants ignore the distinction, the OCPA allows Plaintiffs to seek all of the damages alleged in the Complaint, including governmental expenditures, injuries that are derivative of personal injuries, and/or indirect injuries. *Burgese v. Starwood Hotels & Resorts Worldwide, Inc.*, 101 F. Supp. 3d 414, 420-21 (D.N.J. 2015) (stating that "[u]nlike the federal RICO statute, the Florida RICO Act by its plain language does not restrict injuries to "business or property" injuries"). Because "[t]he plain language of the Florida statute does not exclude pecuniary losses resulting from personal injury," the *Townsend* and *Burgese* courts allowed the plaintiff to recover a broader category of damages.

The OCPA's omission of the direct injury requirement broadens the categories of damages available to the Plaintiffs under the OCPA: Plaintiffs may recover every aspect of their damage allegations under the OCPA, including any damages that the Court may deem indirect or derivative of personal injuries under the RICO Act. To the extent that Distributor Defendants argue that *City of Cleveland v. J.P. Morgan Chase Bank, N.A.*, establishes that Plaintiffs must still plead a direct injury under *Holmes*, they are mistaken: *City of Cleveland*, and the authority on which it relies, did not apply the *Holmes* analysis to the OCPA. (Dist. Mem. at 11); *City of Cleveland v. J.P. Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *5 (Ohio Ct. App. Mar. 21, 2013).

b. The OCPA claim does not require direct injury to establish causation

The text of the OCPA also does not require direct causation. As discussed in *Holmes*, the "by reason of" language in the RICO act was modeled after the Sherman Act and has been interpreted to include both a but-for and a proximate cause requirement. *Holmes*, 503 U.S. at 267-68. Although Defendants advocate for a similar application to OCPA, the statute refutes it. Unlike RICO, which requires an "injur[y] . . . *by reason of* a violation of 1962," the OCPA omits the "by reason of" requirement. Instead, the OCPA states that a plaintiff who is "*directly or indirectly injured* by conduct in violation of section 2923.32, shall have a cause of action" and removes the direct causation requirement. This interpretation of the statute's plain language is demonstrated by Ohio's Civil Jury Instructions on OCPA. *See* 1 CV Ohio Jury Instructions 445.03 ("OJI 445.03"). The Comment to OJI 445.03 reads as follows:

R.C. 2923.23(A)(1). Damages may include, but are not limited to, competitive injury and injury distinct from that inflicted by the corrupt activity. *R.C. 2923.34.* Note that injury may be directly or indirectly caused. If there is evidence that the injury was "indirectly" caused, the word indirectly must be added to the definition of proximate cause. OJI-CV 405.01 § 2.

Id. Here, the jury instruction makes clear that the causal chain may be indirect. Plaintiffs' OCPA claims cannot be dismissed and all of Plaintiffs' damages—whether directly or indirectly caused by the Defendants' conduct—are available as a matter of law.⁴²

c. <u>Mail Fraud, Wire Fraud and Telecommunications Fraud are pleaded with particularity</u>

The Manufacturer Defendants argue that Plaintiffs failed to plead any actionable racketeering activity because mail fraud, wire fraud, and telecommunications fraud are not pleaded

⁴² The Ohio legislature included "by reason of" language when and where it intended to, including OCPA § 2923.32(B)(3): "In addition to any other penalty or disposition authorized or required by law, the court shall order any person who is convicted of or pleads guilty to a violation of this Section or who is adjudicated by reason of a violation of this section to criminally forfeit to the state under Chapter 2981." Ohio Rev. Code § 2923.32(B)(3).

with particularity under the OCPA. Defendants provide no authority to demand a level of particularity different than RICO, which Plaintiffs amply satisfy. Defendants attempt to analogize their mail and wire fraud argument to Plaintiffs' telecommunications fraud claim is similarly unavailing.

As acknowledged in Cap City Dental Lab, LLC v. Ladd, No. 2:15-CV-2407, 2016 WL 4573993 (S.D. Ohio Sept. 1, 2016), Ohio's telecommunications fraud statute states that no person, having devised a scheme to defraud, shall knowingly disseminate, transmit, or cause to be disseminated or transmitted by means of a wire, radio, satellite, telecommunication, telecommunications device, or telecommunications service any writing, data, sign, signal, picture, sound, or image service with the purpose of executing or otherwise furthering a scheme to defraud. Id. at *9; Ohio Rev. Code § 2913.05(A). Plaintiffs have pleaded that the Defendants formed schemes to defraud and utilized, at a minimum, the wire, radio, satellite, telecommunications, telecommunications devices, or telecommunications services, to further their fraudulent scheme. Plaintiffs allege that the Manufacturer Defendants made misrepresentations regarding the risks and benefits of opioid use that were untrue, contradicted their warning labels, and disseminated those messages directly and through KOLs and Front Groups. Plaintiffs allege that the Defendants formed a scheme to refuse to report (i.e. omit material information) suspicious orders in order to increase or maintain artificially high quotas from which they could continue to sell ever increasing amounts of opioids and profit therefrom. Plaintiffs also allege that the Distributor Defendants made false statements about their compliance with the CSA obligations to identify and report suspicious orders, and provided specific examples of Manufacturer Defendants who made similar misrepresentations regarding their compliance. These affirmative misrepresentations, in addition to the omissions alleged throughout the Complaint, satisfy any false statement requirement of mail, wire, or telecommunications fraud.

d. The Complaint pleads a pattern of corrupt activity under R.C. § 2923.34(A)

Defendants argue that the OCPA requires Plaintiffs to plead a pattern of corrupt activity that includes at least one instance of corrupt activity that is either not identical to (Mfr. Mem. at 39) or could not be pleaded as mail or wire fraud (Dist. Mem. at 20). However, the OCPA does not identify a corrupt activity that is not "substantively identical," or "could not be pled as mail or wire fraud;" it only requires plaintiff to plead one corrupt activity that is not a specifically enumerated corrupt act. All Plaintiffs satisfy the OCPA by pleading telecommunications fraud, and felony dealing in controlled substances pursuant to RICO section 1961(1)(D). The Distributor Defendants' cases do not compel an alternative conclusion: W. & S. Life Ins. clarifies that "[a] plaintiff... 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., 54 F. Supp. 3d at 915. Neither the statute nor W. & S. Life Ins. require Plaintiffs to allege a corrupt act that cannot be pleaded as mail or wire fraud.

Recent decisions also refute Defendants' analysis. For example, in *Canterbury v. Columbia Gas of Ohio*, No. C2-99-1212, 2001 WL 1681132, *10 (S.D. Ohio Sep. 25, 2001) the plaintiffs alleged corrupt activities that included "mail, wire telecommunications fraud as well as extortion and theft." Although each of these crimes could arguably be pleaded as either mail or wire fraud under the logic of *Rahimi*, the *Canterbury* court took no issue with the similarity. And in *Bradley v. Miller*, 2013 WL

⁴³ Here, the principle of statutory construction "expressio unius est exclusio alterius" finds particular application. The Ohio legislature included some state law corrupt acts within the portion of section 2923.34 at issue, but did not include telecommunications fraud. Therefore, the Court should determine that the exclusion of telecommunications fraud was intentional and purposeful act. *Hale v. Johnson*, 845 F.3d 224, 227-28 (6th Cir. 2016).

⁴⁴ The only case that approaches the Distributor Defendants' argument has not been followed by any other court for the cited principle. *Rahimi v. St. Elizabeth Medical Center*, No. C3-96-126, 1997 WL 33426269, *2 n.1 (S.D. Ohio Jul. 16, 1997). There, the plaintiff alleged *only* mail fraud, and attempted to cure that deficiency by alleging theft. The court stated, without any supporting authority, that plaintiff must allege facts that constitute another criminal offense, not merely allege another criminal offense arising from the same conduct. But Plaintiffs does so here.

13268688, *7 (S.D. Ohio Mar. 28, 2013), superseded by *Bradley v. Miller*, 96 F. Supp. 3d 753 (S.D. Ohio 2015), the plaintiff's claims proceeded despite alleging mail and wire fraud, and money laundering and tampering with records as corrupt acts. These cases demonstrate that the similarity of the facts underlying the crime is not a bar to recovery under the OCPA. The correct inquiry is whether the Plaintiffs alleged at least one corrupt activity that is not mail or wire fraud. Plaintiffs have satisfied that requirement. Regardless, Plaintiffs sufficiently allege a felony violation of the CSA as another corrupt activity under the OCPA that satisfies the pattern requirement. *See* Ohio Rev. Code § 2923.31(I)(1).

Finally, a felony violation of Section 843(a)(4)(A) satisfies the OCPA corrupt activity definition. The Manufacturer Defendants' argument is undermined by the statute's text, which specifically identifies RICO section 1961(1)(D) as a corrupt activity. Ohio Rev. Code § 2923.31(I)(1) ("Corrupt activity means. . . (1) Conduct defined as 'racketeering activity under the 'Organized Crime Control Act of 1970' . . . 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended"). OCPA section 2923.34(A) clearly identifies racketeering activity as defined in RICO section 1961(1)(D) as a corrupt activity.

C. <u>Plaintiffs Have Properly Pled Their Negligence Claims Against All Defendants</u>

Plaintiffs assert claims for negligence against all Defendants. The elements of a negligence claim in Ohio are (1) a duty requiring the defendant to conform to a certain standard of conduct; (2) breach of that duty; (3) a causal connection between the breach and injury, and (4) damages.

*Cromer v. Child. Hosp. Med. Ctr. of Akron, 29 N.E.3d 921, 928 (Ohio 2015). At least some Defendants challenge Plaintiffs' pleading of every element; they also contend that OPLA abrogates Plaintiffs' claims. Each of their arguments should be rejected.

1. Plaintiffs Properly Plead the Existence of a Duty

Defendants make two arguments that Plaintiffs do not properly plead a duty of care. First, they contend that the common law imposes no such duty; second, they argue that, to the extent that Plaintiffs rely on statutory duties, the statutes in question provide no private right of action. Neither argument has merit: Defendants owe a common law duty of care and, to the extent that Plaintiffs reference statutes that Defendants have violated, Plaintiffs are not seeking thereby to enforce the statutes, but merely to define the standard of care applicable to their pre-existing duty.

a. <u>Defendants owe a common law duty of reasonable care</u>

Under Ohio law, every person is required to use reasonable care to avoid injuring another person or his/her property. *See* Ohio Jury Instructions ("OJI") CV 401.01; *see also* Restatement of the Law 3d, Torts, Section 7 (2010); *Phila. Fire & Marine Ins. Co. v. Hirschfield Printing Co.*, 53 N.E.2d 827 (Ohio Ct. App. 1943). Reasonable care "is the care that a reasonably careful person would use under the same or similar circumstances." 1 OJI-CV 401.04; *see also* Restatement (Second) of Torts § 281 (1965).

"[A] duty may be established by common law, legislative enactment, or by the particular facts and circumstances of the case." *Horvath v. Ish*, 979 N.E.2d 1246, 1255 (Ohio 2012) (citing *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198 (Ohio 1998)). The duty of care the common law requires is commensurate with the risk of harm the conduct creates. *Berdyck v. Shinde*, 613 N.E.2d 1014, 1020–21 (Ohio 1993) ("In negligence cases the duty is always the same: to conform to the legal standard of reasonable conduct in the light of apparent risk."). Moreover, the question of whether defendants owed a duty of reasonable care to the Plaintiffs here is a question for the trier of fact. *See, e.g., City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1145 (Ohio 2002) ("It is often for a jury to decide whether a plaintiff falls within the range of a defendant's duty of care and whether that duty was fulfilled.").

That is because Ohio has long recognized that "[t]he existence of a duty depends on the foreseeability of the injury." *Menifee v. Ohio Welding Prods., Inc.*, 472 N.E.2d 707, 710 (Ohio 1984); accord Wallace v. Ohio Dept. of Com., 773 N.E.2d 1018, 1026 (Ohio 2002). "[T]he test for foreseeability is whether a reasonably prudent person would have anticipated that an injury was likely to result from the performance or nonperformance of an act." *Id.* (citations omitted); see also Bohme, Inc. v. Sprint Int'l Comm. Corp., 686 N.E.2d 300, 303 (Ohio Ct. App. 1996) ("Injury is foreseeable if a defendant knew or should have known that its act was likely to result in harm to someone.") The Ohio Supreme Court has recently explained:

As a society, we expect people to exercise reasonable precautions against the risks that a reasonably prudent person would anticipate. Conversely, we do not expect people to guard against risks that the reasonable person would not foresee. The foreseeability of the risk of harm is not affected by the magnitude, severity, or exact probability of a particular harm, but instead by the question of whether some risk of harm would be foreseeable to the reasonably prudent person. Accordingly, the existence and scope of a person's legal duty is determined by the reasonably foreseeable, general risk of harm that is involved.

Cromer, 29 N.E.3d at 928-29 (internal citations omitted) (emphasis in original). Thus, "in order to owe a duty of care, it is not necessary that the defendant foresee the injury in the precise form in which it occurred. Rather, it is sufficient if defendant's action or inaction was likely to result in an injury to someone." *Bohme*, 686 N.E.2d at 303 (internal quotations and citations omitted).

In *Cincinnati v. Beretta U.S.A. Corp.*, the Ohio Supreme Court considered whether the City of Cincinnati could sue gun manufacturers and distributors for negligence in the manufacturing, marketing, and distribution of firearms. The Court found the harms at issue sufficiently foreseeable to impose a duty of care, citing with approval the rationale of a similar case in Boston:

Taking Plaintiffs' allegations as true, Defendants have engaged in affirmative acts (i.e., creating an illegal, secondary firearms market) by failing to exercise adequate control over the distribution of their firearms. . . . The method by which Defendants created this market, it is alleged, is by designing or selling firearms without regard to the likelihood the firearms would be placed in the hands of juveniles, felons or others not permitted to use firearms. . . . Taken as true, these facts suffice to allege

that Defendants' conduct unreasonably exposed Plaintiffs to a risk of harm. Worded differently, the Plaintiffs were, from Defendants' perspective, foreseeable plaintiffs.

Beretta, 768 N.E.2d at 1144, quoting City of Boston v. Smith & Wesson Corp., No. 199902590, 2000 WL 1473568 (Mass. Super. Ct. July 13, 2000).

Beretta is squarely on point and controlling. Here, as in Beretta, Defendants failed to exercise adequate control over the marketing and distribution of their wares, in this case, opioids. Here, as in Beretta, Defendants' products—opioids classified as Schedule II drugs by the DEA—were known to be potentially highly dangerous. It was entirely foreseeable that, if not marketed, distributed, and sold with requisite care, they could cause serious harm. See SAC ¶ 1043 (Defendants' conduct in marketing, distributing, and selling dangerously addictive drugs required a high degree of care and placed them in a position of great responsibility). Here, as in Beretta, Defendants disregarded that danger, in this case the likelihood that opioids would both cause individuals to become addicted and be diverted to feed an illegal secondary market for drugs. Just as the Ohio Supreme Court held that the Beretta defendants owed a duty of care to the City of Cincinnati, here, too, the Defendants owed a duty of care to the Plaintiffs.

The potential that opioids could cause widespread harms to communities was so foreseeable that federal and state laws were enacted in an effort to prevent these harms—including addiction, abuse, and diversion—from occurring. Indeed, the DEA repeatedly reminded the Defendants of their obligations and the need to prevent abuses and diversion and advised them that their responsibility was critical as "the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people" and that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.". See SAC ¶¶ 523-525 (emphasis added).

Defendants were all keenly aware of the oversupply of prescription opioids and of the likelihood of diversion. *See, e.g.,* SAC ¶¶ 571-74 ("[M]anufacturers were keenly aware of the doctors

who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales."); ¶ 607 ("National retail pharmacy chains . . . were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries."); ¶ 763 ("[Marketing and Supply Chain] Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities."); ¶ 859 ("Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market."). The harms for which Plaintiffs now seek redress were thus not merely foreseeable, but actually foreseen.⁴⁵

Defendants also argue that they owe no duty of reasonable care to the Plaintiffs because they have no special relationship with them that would give rise to a duty to protect against harm caused by third parties. But no special relationship is required where, as here, Plaintiffs' claims are based on Defendants' own negligent conduct, not the conduct of third parties. That was the specific holding of the Ohio Supreme Court in *Beretta*, 768 N.E.2d at 1144. Responding to the same argument, the Court observed:

[T]he issue is whether appellees are themselves negligent by manufacturing, marketing, and distributing firearms in a way that creates an illegal firearms market that results in foreseeable injury. Consequently, the "special relationship" rule is not determinative of the issue presented here.

Beretta, 768 N.E.2d at 1144 (emphasis added).

Here, Plaintiffs do not allege that Defendants failed to protect them from harm caused by others. Rather, they allege that Defendants *themselves* engaged in conduct the foreseeable result of which was to cause harm to Plaintiffs. *See, inter alia*, SAC ¶¶ 350-428 (by spreading deceptive

⁴⁵ Pharmacy Defendants argue that Plaintiffs' injuries are too remote from Defendants' conduct for a duty of care to exist. Pharm. Mem. at 14. But the closeness of the connection between Defendants' conduct and Plaintiffs' injuries pertains not to whether Defendants have a duty of care, but rather to whether Defendants' conduct was the proximate cause of those injuries, an argument we address below, at § II.C.2.

messaging about the safety and addictiveness of opioids through front groups and "key opinion leaders"); ¶¶ 429-442 (by funding continuing medical education programs to encourage and pay doctors for increasing their prescriptions of opioids); ¶¶ 516, 568-569, 673 (providing incentives to sales representatives with pill mills in their territories and ignoring red flags of diversion during regular visits to pharmacies and doctors); ¶¶ 579-593 (failing to report suspicious orders or otherwise act to prevent diversion); ¶¶ 1046-1071. Under *Beretta*, these allegations are sufficient to establish Defendants' duty of care. ⁴⁶ While Defendants contend that the Plaintiffs' injuries derive from the conduct of, and injury to, others who, for example, abused opioids, Defendants ignore Plaintiffs' well-pleaded allegations that the harms resulted from the over-prescribing and over-use of opioid, and not only their abuse, and that Defendants' own conduct both caused and made foreseeable these precise risks. *Infra* § II.C.2.

b. Plaintiffs do not seek to enforce statutory duties

All of the Defendants argue that Plaintiffs' claims should be dismissed because there is no private right of action to enforce the statutes and regulations referred to in the Complaint. But Plaintiffs do not seek to enforce Defendants' statutory and regulatory duties. Rather, as explained above, Defendants' duty is grounded in traditional Ohio common law principles.

⁴⁶ By contrast, the cases Defendants cite all involve purported duties to protect against harm caused by third parties. The question in *Simpson v. Big Bear Stores Co.*, 652 N.E.2d 702, 705 (Ohio 1995), was whether a supermarket had a duty to warn patrons of criminal dangers on property they did not own or control. In *Shivers v. Univ. of Cincinnati*, No. 06AP–209, 2006 WL 3008478 (Ohio Ct. App. Oct. 24, 2006), the court found that a university could not be held liable for the rape of a student that occurred off campus because it was not foreseeable. *Id.*, at *2. In *Heimberger v. Zeal Hotel Group*, *Ltd.*, 42 N.E.3d 323 (Ohio Ct. App. 2015), the court held that a hotel did not owe a duty to warn its business invitees and the theft of a guest's purse from the lobby was not foreseeable. *Id.* at 330. Plaintiffs do not allege that Defendants failed to protect them from third parties, but rather that Defendants' own conduct caused them harm.

It is true that the SAC references the federal Controlled Substances Act ("CSA") and similar Ohio statutes governing the manufacture, marketing, and distribution of opioids.⁴⁷ But Plaintiffs reference such statutes and regulations as informing the standard of care, *see, e.g.,* SAC ¶ 1042, and to show the foreseeability of the harms that flowed from Defendants' breach of their duties, *see, e.g., id* ¶ 1058. Defendants' liability arises from their failure to use reasonable care under the circumstances, not their failure to abide by federal or state statutes. Moreover, and contrary to Defendants' suggestion, the existence of a parallel statutory duty does not in any way undermine an existing common law claim; it would be illogical for a party to gain immunity for otherwise actionable negligence because the legislature has also recognized, and chosen to regulate, the same dangers the common law requires him to protect against.⁴⁸

Instead, the statutes provide a standard of care for the underlying common law duty by establishing how a reasonable manufacturer or distributor of dangerous drugs would and should behave under the circumstances. *See Eisenhuth v. Moneyhon*, 119 N.E.2d 440 (Ohio 1954) (holding legislative enactments, including administrative rules, and judicial decisions may establish a standard by which defendant's duty is measured); *Kooyman v. Staffco Constr. Inc.*, 937 N.E.2d 576 (Ohio Ct. App. 2010) (violation of an administrative rule may establish standard); *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198 (Ohio 1998) (violation of an administrative rule is admissible as evidence of negligence); *Stephens v. A-Able Rents Co.*, 654 N.E.2d 1315 (Ohio Ct. App. 1995) (regulations are admissible as bearing on violations of duty); *see also* Restatement (Second) of Torts § 285 Cmt. c

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⁴⁷ Plaintiffs do not allege violations of statutes or regulations applicable specifically to retailers who sell opioids. To the extent that Pharmacy Defendants also act as distributors, however, they may be subject to requirements under the CSA and Ohio law applicable to distributors.

⁴⁸ Significantly, Defendants may be liable in negligence even if they *did* meet their statutory guidelines. Pharmaceutical personal injury cases present a helpful analogy. Persons injured by a drug manufacturer's failure to provide adequate warnings may sue even if the manufacturer met its FDA labeling obligations, because state common law may set higher standards of care than the one set by the FDA. *See Wyeth v. Levine*, 555 U.S. 555 (2009).

(1977) ("Even where a legislative enactment contains no express provision that its violation shall result in tort liability, and no implication to that effect, the court may, and in certain types of cases customarily will, adopt the requirements of the enactment as the standard of conduct necessary to avoid liability for negligence.")

The cases cited by Defendants are distinguishable because they do not involve parallel state common law duties, but rather claims that arise directly and solely from statutes for which there is no private right of action. *See, e.g., Grey v. Walgreen Co.*, 967 N.E.2d 1249 (Ohio Ct. App. 2011) (complaint asserted only a private right of action for breach of workers compensation statute; no common law duty to charge a lower price existed independent of the statute); *Cuyler v. United States*, 362 F.3d 949, 955 (7th Cir. 2004) (abuse-notification statute created no duty to aid a person in peril or to be a "good Samaritan" where common law specifically refused to impose such a duty). These cases do not involve claims for *negligence*, but rather claims in which, absent a common law standard or claim, plaintiffs specifically attempted to sue for statutory breaches.⁴⁹

⁴⁹ See, e.g., Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015) (claim to enforce Medicaid rate provision with no negligence claim); Jesner v. Arab Bank, PLC, 138 S. Ct. 1386 (2018) (terrorist attack suit with no negligence claim); Smith v. Hickenlooper, 164 F. Supp. 3d 1286 (D. Colo. 2016) (suit to enjoin marijuana sales in Colorado with no negligence claim); Myers v. United States, 17 F.3d 890 (6th Cir. 1994) (suit alleging failure to inspect dangerous conditions in mines involving only statutory negligence claim); Coffman v. Bank of Am., NA, No. 2:09-cv-00587, 2010 WL 3069905 (S.D. W.Va. Aug. 4, 2010) (unconscionable inducement and fraud and conspiracy suit against Bank of America with no negligence claim); Cort v. Ash, 422 U.S. 66 (1975) (improper campaign expenditures case with no discussion of negligence); Nielsen v. Ford Motor Co., 681 N.E.2d 470 (Ohio Ct. App. 1996) (declaratory suit regarding monitoring of machinery with no discussion of negligence); Miami Valley Hosp. v. Combs, 695 N.E.2d 308 (Ohio Ct. App. 1997) (suit for unpaid medical expenses with no discussion of negligence); Gilford v. Ohio State Bd. of Pharmacy, No. 8979, 1985 WL 7634 (Ohio Ct. App. 1985) (suit regarding denial of pharmaceutical license with no discussion of negligence); State v. Frye, No. 1-17-30, 2018 WL 1256532 (Ohio Ct. App. Mar. 12, 2018) (felony criminal case with no discussion of negligence); Tekavec v. Van Waters & Rogers, Inc., 12 F. Supp. 2d 672, 683 (N.D. Ohio 1998) (court found supplier had no knowledge of latent defect of manufacturer); McKesson Corp. v. Hembree, No. 17cv-323, 2018 WL 340042 (N.D. Okla. Jan. 1, 2018) (suit for preliminary injunction enjoining defendants from taking any action in parallel tribal court action with no discussion of negligence); Welch v. Atmore Cmty. Hosp., 704 F. App'x 813 (11th Cir. 2017) (pro se wrongful death action with no discussion of negligence); Shmatko v. footnote continued on next page

Defendants also misunderstand the effect of Plaintiffs' assertion of negligence *per se.* That claim in no way suggests that Plaintiffs are seeking to enforce statutory or regulatory obligations. A statutory standard of care may be evidence that a defendant has breached an underlying common law duty, or it may establish that breach conclusively as a matter of law. The latter situation describes negligence *per se.* But a claim for negligence *per se* is still a claim based on a common law duty; the breach of the statute would not give rise to liability on its own if the common law duty did not exist. Thus, as the Supreme Court of Ohio explained a half century ago, the distinction between negligence and negligence *per se.* "is the means and method of ascertainment" of the standard of care and the breach. *Ornella v. Robertson*, 237 N.E.2d 140, 143 (Ohio 1968). Negligence "must be found by the jury from the facts, the conditions, and circumstances disclosed by the evidence," while with negligence *per se*, "the only fact for determination by the jury [is] the commission or omission of the specific act inhibited or required." *Id.*

In Ohio, the effect of a statutory breach on a common law negligence claim depends on the specificity of the statute. If a statute contains "a general, abstract description of a duty," a violation of the statute can be considered as evidence of negligence, but does not alone conclusively demonstrate breach. *Mann v. Northgate Inv'rs, L.L.C.*, 5 N.E.3d 594, 601 (Ohio 2014). On the other hand, if the statutory requirements are "fixed and absolute, the same under all circumstances," and

footnote continued from previous page

Ariz. CVS Stores LLC, No. 14-cv-01076, 2014 WL 3809092 (D. Ariz. Aug. 1, 2014) (medical malpractice action with no discussion of negligence); United States v. Real Prop. & Improvements Located at 1840 Embarcadero, 932 F. Supp. 2d 1064, 1072 (N.D. Cal. 2013) (landlord-tenant dispute with no discussion of negligence); McCallister v. Purdue Pharma L.P., 164 F. Supp. 2d 783, 793 (S.D. W. Va. 2001) (suit against Purdue Pharmaceuticals for encouraging widespread use of Oxycontin; court found state law claims not preempted, with no discussion of negligence); In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig., No. 2:13-md-2433, 2015 WL 4092866 (S.D. Ohio July 6, 2015) (raising only statutory claims).

Webster v. Pacesetter, Inc., 259 F. Supp. 2d 27 (D.D.C. 2003) is inapplicable for a different reason. There, the court held that the plaintiff could not use violations of FDA regulations as a basis for a failure-to-warn claim because such claims are expressly preempted by the Medical Device Amendments of 1976, a statute inapplicable here. Absent preemption, infra § II.B, there is no bar to Plaintiffs' negligence claims.

imposed upon all similar actors, the statutory requirements are "stated with sufficient specificity to impose negligence per se." *Id.* at 602. The statutes cited by Plaintiffs meet these criteria.

But this Court need not determine, at this juncture, whether Defendants' breaches of their statutory duties, as alleged in the SAC, conclusively establish their negligence, or merely provide evidence of it. In neither circumstance does Plaintiffs' negligence claim arise directly under the statutes or regulations and the use of these enactments as a measure of the standard of care in no way justifies dismissal of these claims.⁵⁰

2. The Complaint Sufficiently Pleads that Plaintiffs' Injuries Were Proximately Caused by the Defendants' Conduct

Ohio law defines proximate cause in the context of a negligence action as "an act or failure to act that in natural and continuous sequence directly produced the [injury/damages asserted] and without which the injury would not have occurred." Ohio Jury Instructions ("OJI") 405.01. "A defendant's conduct need not be the *only* cause; rather, it is sufficient that the defendant's conduct was a *substantial factor* in producing the harm." OJI 405.01(3) (Multiple Contributing Causes) (emphasis added). Under Ohio law, questions of proximate cause and whether a defendant's negligence was a substantial factor in causing the injury are questions for the trier of fact. *Queen City*

The cases cited by Pharmacy Defendants with respect to negligence per se actually reinforce this point. In Mussivand v. David, 544 N.E.2d 265 (Ohio 1989), the court considered the question whether breach of a particular statute constituted negligence per se. It found that because the statute only required persons to "take reasonable measures" it was not sufficiently specific to provide a conclusive standard of care. The court held, however, that plaintiff's negligence claim should not be dismissed because plaintiff owed a common law duty to the defendant. In Western Reserve Care Sys. v. Masters, No. 97 CA 95, 1999 WL 783951 (Ohio Ct. App. Sep. 28, 1999), the court specifically recognized that "the lack of a private cause of action for a certain statutory violation does not preclude a plaintiff from bringing a separate claim that is based upon the same conduct, but is recognized at common[]law." Moreover, as another judge of this Court has recognized, the decision in Western Reserve Care appears to confuse a private right of action with negligence per se. See Thornton v. State Farm Mut. Auto Ins. Co., No. 1:06-CV-00018, 2006 WL 3359448, at *14 & n.8 (N.D. Ohio Nov. 17, 2006). And in In re Tenn. Valley Auth. Ash Spill Litig., No. 3:09-cv-009, 2012 WL 3647704 (E.D. Tenn. Aug. 23, 2012), the court dismissed claims for negligence per se under Tennessee law, but permitted the plaintiff to proceed on a claim for negligence arising from a common law duty.

Terminals v. Gen. Am. Transp. Corp., 653 N.E.2d 661, 669 (Ohio 1995); Trollinger v. Tyson Foods, Inc., 370 F.3d 602 (6th Cir. 2004) (analysis may be too speculative at the pleadings stage).

Defendants argue that proximate cause fails for three reasons. First, they argue that Plaintiffs' injuries are insufficiently direct. Second, they argue that the criminal acts of third parties break the causal chain. Third, they argue that the role of physicians in prescribing opioids breaks the causal chain. None of these arguments has merit.

a. Plaintiffs' injuries are sufficiently direct

In *Beretta*, the Ohio Supreme Court applied the analysis for proximate cause (or remoteness) adopted by the United States Supreme Court in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992). *See Beretta*, 768 N.E.2d at 1148. The *Beretta* Court noted that "there must be some direct relation between the injury asserted and the injurious conduct alleged." *Id. citing Holmes*, 503 U.S. at 268. The *Holmes* Court had identified three reasons why directness of relationship is relevant to causation:

(1) indirectness adds to the difficulty in determining which of the plaintiff's damages can be attributed to the defendant's misconduct, (2) recognizing the claims of the indirectly injured would complicate the apportionment of damages among plaintiffs to avoid multiple recoveries, and (3) these complications are unwarranted given the availability of other parties who are directly injured and who can remedy the harm without these associated problems.

Beretta, 768 N.E.2d at 1148. The *Beretta* court applied these three factors to the claims before it, and concluded that proximate cause, or directness of injury, was sufficiently alleged.

The claims in *Beretta* were strikingly similar to those alleged here. The City of Cincinnati alleged that defendants' negligent marketing and distribution of firearms resulted in creation of an illegal secondary market. The City further alleged that, as a direct result of the defendants' misconduct, plaintiff "suffered actual injury and damages including, but not limited to significant expenses for police, emergency, health, prosecution, corrections and other services." *Beretta*, 768 N.E.2d at 1148.

The *Beretta* court first noted that the complaint sufficiently alleged pecuniary harm in the form of increased municipal expenditures as a direct result of defendants' bad acts. *Id.* Applying the *Holmes* factors, the Court found that the municipal costs alleged could be easily computed. *Id.* With respect to the second factor, the court noted "there is little risk of double recovery, since [the City] is seeking recovery for injuries to itself only." *Id.* Finally, the court considered whether "the general interest in deterring injurious conduct' will be better served by requiring that suit be brought by more directly injured victims." *Id.* The court noted that while [the City] was indirectly attempting to protect its citizens from the alleged misconduct by the gun manufacturers and trade associations, [the City] was seeking recovery for its own harm." Consequently, the Court held that the City's claims were not too remote to serve as a basis for recovery.

The same conclusion is warranted here. In this case, Plaintiffs have alleged that Defendants engaged in two types of unlawful conduct, both of which were substantial factors in causing the opioid crisis: (1) the Manufacturer Defendants dramatically increased the demand for opioids (and the number of opioids prescriptions) by disseminating false and misleading information about the risks and benefits of these drugs (including, in particular, the risk of addiction); and (2) both they and the Distributor Defendants failed to control the supply of dangerous Schedule II drugs. The harms Plaintiffs alleged are the municipal costs they were forced to incur as a result of Defendants' actions that caused the opioid crisis.

Indeed, Plaintiffs' injuries are even more direct in this case than they were in *Beretta*. Here, the Manufacturer Defendants had direct and complete control over the relevant information they disseminated to the public about their drugs at all times. The Supply Chain Defendants too had control over their own gatekeeping function. Further, whereas the defendants in *Beretta* were

engaged in the legal sale of firearms, Defendants here were conducting their business in violation of multiple laws.⁵¹

Defendants cite *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496 (6th Cir. 2010), in support of their argument that proximate cause is lacking, but that decision supports the opposite conclusion. In *Ameriquest*, the City of Cleveland asserted that defendants' financing, purchasing and pooling of subprime mortgages led to a foreclosure crisis in Cleveland that devastated its neighborhoods and economy. 615 F.3d at 498-99. The court held that the City's claims against the defendant banks were too remote, because the defendant banks did not originate the rash of mortgages that created the foreclosure crisis. The *Ameriquest* court specifically distinguished *Beretta:*

[I]n Beretta, the plaintiffs accused the defendants of creating and supplying an illegal firearms market in Cincinnati through their marketing, distribution, and selling of firearms. . . . By contrast, the complaint concedes that, for the most part, the Defendants did not directly make subprime loans to the homeowners of Cleveland. The Defendants are instead accused of financing a legal market for these loans. Thus, for Beretta to be analogous to the instant case, the Ohio Supreme Court would have had to allow a suit against the banks that provided financing to the gun manufacturers that allegedly created the illegal secondary market.

Ameriquest, 615 F.3d at 505.

Here, Defendants themselves inflated the demand for opioids through their fraudulent marketing and supplied both the lawful and the unlawful market for opioids by failing to prevent diversion; they stand in the shoes of the firearms defendants in *Beretta* who manufactured and sold the guns and created an illegal secondary market for them, not the bankers who only financed their

⁵¹ Defendants argue that *Beretta*'s proximate cause analysis is no longer good law, citing to a single 2007 Court of Common Pleas case. Pharm. Mem. at 16 n. 4 (citing City of Toledo v. Sherwin-Williams Co., 2007 WL 4965055, at n.2 (Ohio Ct. Comm. Pl. Dec. 12, 2007)). However, both Ohio courts and the Sixth Circuit continue to cite *Beretta* as good law. See, e.g., Cleveland Housing Renewal Project v. Deutsche Bank Trust Co., 621 F.3d 554, 565 (6th Cir. 2010) (citing the *Beretta* proximate cause analysis); City of Cleveland v. Ameriquest Mort. Sec., Inc., 615 F.3d 496, 505 (6th Cir. 2010).

sale. Under *Beretta*, the Defendants' conduct is a sufficiently direct cause of Plaintiffs' injuries to establish proximate causation.

b. The acts of third parties do not break the causal chain

Defendants argue that the acts of third parties break the causal chain between their misconduct and the Plaintiffs' injuries. Defendants point both to physicians who wrote prescriptions for opioids and third-parties who engaged in criminal diversion of opioids, as purported superseding causes. But the acts of both groups were entirely foreseeable and their conduct was *not* independent of Defendants, but specifically triggered by them. In neither instance was the causal chain broken.

Under Ohio law, the negligent or intentional act of any other person is not a defense to the negligence of the defendant, unless the other person's negligence or intentional act was an independent and superseding cause. OJI 405.01(3)(B). Moreover, the causal connection is only "broken when another's negligent or intentional act, which could not have been reasonably foreseen and is fully independent of the defendants' negligence, intervenes and completely removes the effect of the defendant's negligence and becomes itself a proximate cause of the injury/damages." OJI 405.05. As the Ohio Supreme Court has explained, "[t]he test used to determine foreseeability of the intervening cause to the original negligent actor is "whether the original and successive acts may be joined together as a whole, linking each of the actors as to the liability, or whether there is a new and independent act." Queen City Terminals, Inc. v. Gen. Am. Transp. Corp., 653 N.E.2d 661, 671 (emphasis added). "[T]he term 'independent' means the 'absence of any connection or relationship of cause and effect between the original and subsequent act of negligence." Id. Thus, Defendants would be relieved of liability for their negligent conduct only if the actions of physicians and criminal actors could not have been reasonably foreseen and were fully independent of Defendants' negligence. "2

⁵² Pharmacy Defendants cite Cascone v. Herb Kay Co., 451 N.E.2d 815 (Ohio 1983) for the proposition that "any chain of causation is severed by the intervening conduct of other actors[.]" Pharm. Mem. at 14. The footnote continued on next page

Here, the conduct of doctors in prescribing opioids was not in any sense independent of the wrongs of the Manufacturer Defendants. On the contrary, Plaintiffs specifically allege that the Manufacturer Defendants misled prescribing doctors by misrepresenting the risks and benefits of opioids. *See, e.g.* SAC ¶ 179 ("Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids"); ¶ 374 (guidelines drafted by Front Groups influenced doctors); ¶ 399 (through use of KOLs, Manufacturer Defendants controlled information to doctors); ¶¶ 429-441 (Manufacturer Defendants used CME programs to mislead doctors); ¶ 442 (branded advertising directed at doctors); *see also* SAC ¶¶ 605, 675, 714, 770-72, 946, 1007 and 1013. Physicians' decisions to prescribe opioids were thus not independent of Defendants' wrongdoing; those decisions were the intended, actual, and entirely foreseeable *result* of the Manufacturer Defendants' fraudulent conduct.

Nor does a doctor's role as a "learned intermediary" break the causal chain. The learned intermediary doctrine is an exception to a manufacturer's duty to warn the ultimate consumer by providing an adequate warning to a "learned intermediary," such as a prescribing doctor. *Dunlap v. Medtronic, Inc.*, 47 F. Supp. 2d 888, 898 (N.D. Ohio 1999); see Vaccariello v. Smith & Nephew Richards, Inc., 763 N.E.2d 160, 164 (Ohio 2002) ("The learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the warning reaches the ultimate user through the learned intermediary.") It is a doctrine of products liability law, see Seley v. G.D. Searle & Co., 423 N.E.2d 831 (Ohio 1981), and has

footnote continued from previous page

court nowhere makes such a pronouncement. To the contrary, Cascone held that "the status of [the repair company's] acts as a concurrent or superseding intervening cause, [was] a dispute of material facts which could not properly be determined by the trial court upon summary judgment." Cascone, 451 N.E.2d at 820. The Ohio Supreme Court in Queen City Terminals quoted Cascone in describing the test for foreseeability and independence of intervening conduct. See Queen City Terminals, 653 N.E.2d. at 671.

not been applied outside that context. Moreover, the doctrine only applies where the manufacturer provides an *adequate* warning to the doctor. *See* Ohio Rev. Code 75 and 76. Here, Plaintiffs have alleged that the warnings in opioid labeling were overcome by the Manufacturer Defendants' aggressive and deceptive marketing of their drugs, *see*, *e.g.*, SAC ¶¶ 605, 675, 714, 770-72, 946, 1007 and 1013; this fraudulent overpromotion, which overstated the benefits and understated the risks of opioids, negated the adequacy and effectiveness of any label warnings. *Cf. Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973) (warnings may be rendered inadequate by overpromotion). Because physicians were foreseeably misled by Defendants' misrepresentations, the learned intermediary doctrine does not break the chain of causation.

Nor do the actions of individuals participating in the illegal secondary market break the causal chain. There, too, the illegal conduct of those engaged in drug abuse and diversion is not independent of the Defendants' conduct, but the natural result of it. "When the willful, malicious or criminal act of a third person intervenes between the defendant's conduct and a plaintiff's injuries, the defendant's negligence is the proximate cause of the plaintiff's injuries if the defendant could have reasonably foreseen the intervening act of the third person." Feichtner v. Ohio Dep't of Transp., 683 N.E.2d 112, 120 (1995). Thus, the analysis is precisely the same with respect to the illegal secondary drug market as for prescribing physicians: the issue is the extent to which the criminal conduct was a foreseeable consequence of the Defendants' behavior or was, instead, entirely independent of it. In this case, as described above, see § I-C-2, it is clear that the illegal drug activity was an entirely foreseeable consequence of the Defendants' failure to control the opioid supply chain. Widespread addiction was also an entirely foreseeable consequence of the Manufacturer Defendants' misrepresentations that opioids are rarely addictive when taken for chronic pain. See

⁵³ Volter v. C. Schmidt Co., Inc., 598 N.E.2d 35 (Ohio Ct. App. 1991), relied on by Defendants, is not to the contrary. Rather, the court in *Volter* applied precisely the same test – whether the intervening acts were foreseeable—to determine whether the causal chain was broken.

SAC ¶¶ 177-78; 180-232; *see also id.* at ¶¶ 130-45. Criminal conduct, including abuse and diversion, is, in turn, an entirely foreseeable consequence of addiction. *See, e.g.,* SAC ¶ 132.

Once again, *Beretta* forecloses Defendants' argument. In *Beretta*, nearly all of the harm the City of Cincinnati alleged involved criminal use of firearms. Yet, because the defendants were alleged to have helped create the illegal secondary market for guns, the Ohio Supreme Court held that the plaintiff had sufficiently alleged proximate cause. 768 N.E.2d at 1144-46. If criminal conduct did not break the causal chain in *Beretta*, it does not do so here.⁵⁴

3. The Economic Loss Doctrine Does Not Bar Plaintiffs' Negligence Claims

Defendants argue that the economic loss doctrine requires dismissal of Plaintiffs' negligence claim. Mfr. Mem. at 47; Dist. Mem. at 43-44. Their argument reflects a profound misunderstanding of the scope of that doctrine.

The economic loss doctrine concerns commercial relationships and polices the boundary between claims sounding in contract and in tort. The doctrine "stems from the recognition of a balance between tort law, designed to redress losses suffered by breach of a duty imposed by law to protect societal interests, and contract law, which holds that 'parties to a commercial transaction should remain free to govern their own affairs." Corporex Dev. & Constr. Mgt., Inc. v. Shook, Inc., 835 N.E.2d 701, 704 (Ohio 2005) (quoting Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co., 537 N.E.2d 624, 628). The economic loss doctrine therefore provides that "a party cannot recover purely economic damages in a tort action against another party based upon the breach of contractually created duties. Digiknow, Inc. v. PKXL Cards, Inc., No. 96034, 2011 WL 2899600, at *1 (Ohio Ct. App. July 21, 2011)(citing Corporex) (emphasis added); see also Chemtrol, 537 N.E.2d at 631 ("[W]hen the promisee's

⁵⁴ Ignoring the Ohio Supreme Court's decision in *Beretta*, Defendants turn to gun cases from other jurisdictions. Dist. Mem. at 49 (citing *City of Philadephia v. Beretta U.S.A. Corp.*, 277 F.3d 415 (3rd Cir. 2002)); Pharm. Mem. at 15 (citing *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004)). *Beretta*, however, remains the governing law in Ohio.

injury consists merely of the loss of his bargain, no tort claim arises because the duty of the promisor to fulfill the term of the bargain arises only from the contract.") (quoting *Battista v. Lebanon Trotting Assn.*, 538 F.2d 111, 117 (6th Cir. 1976)). For this reason, the vast majority of cases in which the doctrine arises involve disputes between parties in a commercial relationship.

The economic loss doctrine has only limited application outside this context. As the Ohio Supreme Court said in *Corporex*: "When a duty in tort exists, a party may recover in tort." 835

N.E.2d at 705. *Accord Chemtrol*, 537 N.E.2d at 630 ("the key factor is the extent, and more important, the source, of the duty owed"). More specifically, courts hold that "the economic loss rule does not apply—and the plaintiff who suffered only economic damages can proceed in tort—if the defendant breached a duty that did not arise solely from a contract." *Campbell v. Krupp*, 961 N.E.2d 205, 211

(Ohio Ct. App. 2011); *see also Clemens v. Nelson Fin. Group, Inc.*, No. 14AP–537, 2015 WL 1432604 at *8 (Ohio Ct. App. Mar. 31, 2015). ("Although the economic-loss rule sweeps widely, it does not preclude all tort claims for economic damages. A plaintiff may pursue such a tort claim if it is 'based exclusively upon [a] discrete, preexisting duty in tort and not upon any terms of a contract or rights accompanying privity.") (quoting *Corporex*, 835 N.E.2d. at 705); *Ineos USA LLC v. Furmanite Am., Inc.,* No. 1–14–06, 2014 WL 5803042, at *6 (Ohio Ct. App. Nov. 10, 2014) ("where a tort claim alleges that a duty was breached independent of the contract, the economic loss rule does not apply"). ⁵⁵

The Ohio Supreme Court decision in *Beretta* clearly establishes that under Ohio law Defendants owed a preexisting duty—independent of any contract—to Plaintiffs. In *Beretta*,

⁵⁵ Cf. Cleveland v. J.P. Morgan Chase Bank, N.A., No. 98656, 2013 WL 1183332, *8 (Ohio Ct. App. Mar. 21, 2013) ("The doctrine does not present a strong case for application to the City's suit where the duty alleged to have been breached is not related to a contractual relationship and the City has alleged particularized damages associated with decreased tax revenue and increased costs of safety services.") The J.P. Morgan Chase court nevertheless felt bound by, and applied, a prior ruling in the same court that the economic loss rule applies to qualified public nuisance claims. Id.

Cincinnati sued in negligence, *inter alia*, for the consequential economic damages the city incurred as a result of the illegal firearms market, "including reimbursement for expenses such as increased police, emergency, health, and corrections costs." 768 N.E. 2d at 1140. The court stated: "The continuing nature of the misconduct may justify the recoupment of such governmental costs. Therefore, if appellant can prove all the elements of the alleged torts, it should be able to recover the damages flowing from appellees' misconduct." *Beretta*, at ¶ 45.

The holdings in *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474 (6th Cir. 2017), *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 621 F. Supp. 2d 513 (N.D. Ohio 2009), and *Ashtabula River Corp. Grp. II v. Conrail, Inc.*, 549 F. Supp. 2d 981, 987 (N.D. Ohio 2008), cited by Defendants, Dist. Mem. at 43-44, are all expressly limited to qualified public nuisance cases. Claims for qualified public nuisance and negligence are distinct causes of action under Ohio law. Indeed, Judge Lioi, who also authored the *Ameriquest* decision, recently held that *in the context of negligence*, the economic loss rule "does not bar recovery . . . if the duty breached is independent from a contract." *Cf. JBlanco Enters. Soprema Roofing and Waterproofing, Inc. Barlovento, LLC v. Great Am. Ins. Group*, No. 1:13-cv-2831, 2016 WL 6600423, at *1 (N.D. Ohio Nov. 8, 2016) ("Ohio law prevents the recovery of purely economic losses in a negligence action . . . where recovery of such damages is not based upon a tort duty independent of contractually created duties").

Thus, in *Beretta* Cincinnati properly stated a claim for negligence to recover its municipal expenditures resulting from illegal firearms. 768 N.E. 2d at 1144. If the economic loss doctrine had applied, Cincinnati's negligence claim would have had to be dismissed. Because the court held that a

duty to the city existed, it necessarily found that the economic loss rule did not apply. Similarly, the economic loss doctrine does not bar Plaintiffs' claims here.⁵⁶

4. OPLA Does Not Abrogate Plaintiffs' Negligence Claim

Defendants argue that Plaintiffs' common law claims, including their negligence claims, are abrogated by OPLA. Not so, because Plaintiffs do not seek damages for "harm" as that term is defined in the statute. OPLA's definitional section divides compensatory damages into two distinct categories: "Harm" and "Economic loss." Only claims for "harm" count as "product liability claims" under OPLA. See R.C. § 71(A)(13). And, pursuant to R.C. § 72, only "product liability claims" (i.e., claims for "harm") are subject to OPLA; claims solely for "economic loss" are expressly exempted from the statute and remain available at common law. 59

The Ohio Supreme Court has repeatedly recognized this distinction, holding that "Ohio's product liability statutes, by their plain language, neither cover nor abolish claims for purely economic loss caused by defective products." *LaPuma v. Collinwood Concrete*, 661 N.E.2d 714, 716 (Ohio 1996); *see also Cincinnati v. Beretta*, N.E.2d. at 1146 ("to be considered a 'product liability claim' under R.C. § 71(M), the complaint must allege damages other than economic ones. . . ."); *Volovetz v.*

⁵⁶ The Manufacturer Defendants assert that Plaintiffs' negligence claims should be dismissed for failure to allege any actionable conduct and failure to allege conduct with the requisite particularity. *See* Man. Mem. at 47 (simply cross-referencing their similar arguments with respect to Plaintiffs' RICO claims). Plaintiffs incorporate their responses to those arguments, set forth above at § I-B.

⁵⁷ R.C. § 71(A)(2): "Economic loss' means direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product. Harm is not 'economic loss." R.C. § 71(A)(7): "Harm' means death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question. Economic loss is not 'harm."

⁵⁸ OPLA's definition of a product liability action is in accord with the common understanding of that term. See BLACK'S LAW DICTIONARY (10th ed. 2014) (emphasis added) (defining a "products-liability action" as "[a] lawsuit brought against a manufacturer, seller, or lessor of a product—regardless of the substantive legal theory or theories on which the lawsuit is brought—for personal injury, death, or property damage caused by the manufacture, construction, design, formulation, installation, preparation, or assembly of a product").

⁵⁹ "Any recovery of compensatory damages based on a *product liability claim* is subject to [OPLA]." R.C. § 72(A) (emphasis added). "Any recovery of compensatory damages for *economic loss* based on a claim that is asserted in a civil action, *other than a product liability claim*, is not subject to [OPLA], *but may occur under the common law of this state or other applicable sections of the Revised Code.*" R.C. § 72(C) (emphasis added).

Tremco Barrier Sols., Inc., 74 N.E.3d 743, 753 n.4 (Ohio Ct. App. 2016) ("[A] claim for purely economic loss is not included in the statutory definition of 'product liability claim,' and, consequently, a plaintiff with such a claim may pursue a common[] law remedy."). 60

That Plaintiffs' claims concern Defendants' products in some fashion does not mean that the claims are "product liability claims" within the meaning of OPLA. Rather, as the Ohio Supreme Court held in *LaPuma*, "R.C. 72 makes it clear that although a cause of action may concern a product, it is not a product liability claim within the purview of Ohio's product liability statutes unless it alleges damages other than economic ones." *LaPuma*, 661 N.E.2d at 716.⁶¹

Defendants argue that it is the essential nature of the allegations, not the label, that determines if a claim is one for product liability; they further assert that Plaintiffs' claims are, at their core, product liability claims. *See* Dist. Mem. at 34-35. But Plaintiffs do not seek to recover for physical injuries caused by products; they seek to recover for economic harms inflicted on their communities by Defendants' conduct in marketing and distributing their products. Defendants' argument that Plaintiffs' claims are product liability claims is foreclosed both by the express statutory language of OPLA, discussed above, and by the repeated interpretations of that act by the

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⁶⁰ The *Volovetz* court recognized that "physical damage to property other than the product in question" is not "economic loss," *Volovetz*, 74 N.E.3d at 753 n.4, but this statement is of no help to the Defendants. Plaintiffs do not seek to recover for "*physical* damage to property," but rather seek abatement and money damages to compensate them for past costs incurred in addressing the opioid epidemic. These damages – including costs of substance abuse treatment, EMT services, and the like – are classic economic loss with no connection to physical harm to property.

⁶¹ Both LaPuma and Beretta predate the 2005 amendment to OPLA (although Volovetz, was decided well after). Defendants have not argued, but may attempt to do so on reply, that the 2005 amendment alters the analysis in those cases. However, the 2005 amendment did not (and did not purport to) alter the definition of "product liability action" as set forth in the statute and as construed by the Ohio Supreme Court. Rather, the amendment simply altered the effect of the statute on claims for "harm" that do fall within its definitions. In Carrel v. Allied Prods. Corp. 677 N.E.2d 795 (Ohio 1997), the Ohio Supreme Court had held that claims that fall within the purview of OPLA could be brought under the common law and under OPLA concurrently. The 2005 amendment expressly overruled Carrel, and required that claims that fall within the scope of OPLA be brought only under the statute. This amendment had no effect on the holdings in LaPuma and Beretta—that claims for purely economic loss do not fall within the scope of the statute in the first place and remain available at common law. Volovetz confirms that this rule remains vital after the 2005 amendment.

Ohio Supreme Court. See Beretta, 768 N.E.2d at 1146-47. See also below at § C-3 (discussing Beretta case).⁶²

D. <u>Plaintiffs Have Properly Pled Their Claim for Fraud Against the Manufacturer</u> Defendants

The Complaint details the Manufacturer Defendants' falsehoods (¶¶ 174-349), how they were disseminated generally (¶¶ 350-494), and, notably, their dissemination in Ohio and Akron and Summit County (¶¶ 672-713). It alleges that the Manufacturer Defendants "intended and had reason to expect" that "Plaintiffs, Plaintiffs' agents," "and persons on whom Plaintiffs and their agents relied would be deceived by" the Manufacturer Defendants' misrepresentations, that they "intended and knew that such reliance would cause Plaintiffs to suffer loss," and that Plaintiffs, through their agents and persons on whom Plaintiffs and their agents relied, in fact relied on the misrepresentations. ¶¶ 1079-1082. Thus, the Complaint states a claim for fraud.

Despite Plaintiffs' thorough and specific allegations, the Manufacturer Defendants assert that the fraud claim fails. Primarily, they assert that it fails for reasons addressed elsewhere in the parties' briefs: because it is preempted and because Plaintiffs' have pled neither causation nor

⁶² The authorities cited by Defendants are not to the contrary. As noted above, Volovetz expressly recognizes that claims for economic loss do not fall within the scope of OPLA. 74 N.E.3d at 753 n.4. By contrast, as this Court is well aware, Decker v. GE Healthcare, Inc. (In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.), Nos. 1:08-GD-50000, 1:12-GD-50004, 2013 WL 587655, at *13 (N.D. Ohio Feb. 13, 2013), aff'd, 770 F.3d 378 (6th Cir. 2014), was a classic product liability case, in which the plaintiff alleged serious physical injuries resulting from the use of defendants' product. The remaining cases cited by Defendants are also all prototypical product liability suits involving physical injuries or death. See Greenway v. Kimberly-Clark Corp., No. 1:15CV1720, 2016 WL 3460229, at *3 (N.D. Ohio June 24, 2016) (shoulder cartilage damage and chondrolysis as a result of the use of defendant's product); Evans v. Hanger Prosthetics & Orthotics, Inc., 735 F. Supp. 2d 785, 788 (N.D. Ohio 2010) (physical injuries resulting from fall caused by defects in prosthetic leg); Mitchell v. Proctor & Gamble, No. 2:09-CV-426, 2010 WL 728222, at *4 (S.D. Ohio Mar. 1, 2010) (food-borne illnesses suffered by plaintiff as a result of using defendant's product); Miles v. Raymond Corp., 612 F. Supp. 2d 913, 916 (N.D. Ohio 2009) (plaintiff's decedent was crushed to death while operating allegedly defective forklift); Stratford v. SmithKline Beecham Corp., No. 2:07-CV-639, 2008 WL 2491965, at *1 (S.D. Ohio June 17, 2008) (death of infant following mother's use, during pregnancy, of defendant's product; court characterized plaintiff's claims as seeking "damages from a manufacturer for death, physical injury and emotional distress"). They in no way support the argument that Plaintiffs' economic loss negligence claims are "product liability actions" within the scope of OPLA.

actionable conduct. Mfr. Mem. at 48. For the reasons addressed in §§ II.B, I.A.1.c, and I.A.1.d herein, these assertions are unfounded.

The Manufacturer Defendants also incorrectly contend that the fraud claim cannot proceed because Plaintiffs did not plead justifiable reliance. *Id.* As a factual proposition, this is simply untrue. Paragraph 1081 of the SAC expressly alleges that "Plaintiffs . . . did in fact rightfully, reasonably, and justifiably rely on Manufacturer Defendants' representations and/or concealments" And paragraph 1082 explains that Plaintiffs' reliance on Defendants' misrepresentations caused them to "misapprehend[d] that the opioid crisis was simply a result of conduct by persons other than Defendants," thereby "prevent[ing] Plaintiffs from a more timely and effective response to the opioid crisis." Whether Plaintiffs will ultimately be able to prove such reliance is a question of fact, inappropriate for resolution on a motion to dismiss. *See Greenberg v. Life Ins. Co. of Va.*, 177 F.3d 507, 516-17 (6th Cir. 1999) (noting that reliance is a factual issue and reversing dismissal of fraud claim for lack of justifiable reliance as a matter of law).

Manufacturer Defendants appear to suggest, through selective quotations drawn from a pair of recent Ohio decisions, that "[a] fraud claim cannot be predicated on . . . [alleged] misrepresentations made to **third parties**." Mfr. Mem. at 48 (quoting *Lucarell v. Nationwide Mutual Ins. Co.*, 97 N.E.3d 458, 469 (Ohio 2018) (emphasis added in Mem.); also citing *Mike McGarry & Sons, Inc. v. Constr. Res. One, LLC,* No. S–17–005, 2018 WL 798533, *13 (Ohio Ct. App. Feb. 9, 2018)). That is not an accurate statement of Ohio law.

Ohio law has long recognized "that where a party makes false representations to another with the intent or knowledge that they be exhibited or repeated to a third party for the purpose of deceiving him or her, the third party can maintain an action in tort against the party making the false statements for the damages resulting from the fraud." 50 Ohio Jur. 3d, Fraud and Deceit § 79

(2018). The Sixth Circuit agrees. Nernberg v. Pearce, 35 F.3d 247, 251 (6th Cir. 1994) (construing Michigan law); see Lewis v. Horace Mann Ins. Co., 410 F. Supp. 2d 640, 664 (N.D. Ohio 2005) (applying Nernberg to Ohio law). That is precisely what Plaintiffs have alleged. SAC ¶ 1079-1082.

The cases Defendants cite do not disagree that a fraud claim can be based on a plaintiff's justifiable reliance on a defendant's misrepresentations to a third party. In those cases, however, unlike here, there was no evidence of any such reliance by the plaintiffs. *See Lucarell*, 97 N.E.3d at 461, 469 (defendant's sales manager fraudulently altered plaintiff employee's "loan application to mislead the bank into giving her a loan[;]" no evidence misrepresentation in application had been communicated to, let alone relied upon, by plaintiff); *McGarry*, 2018 WL 798533, at *13 (no evidence that costs incurred by counterclaim plaintiff in defending and bonding off allegedly fraudulent mechanic's lien were made in reliance on misrepresentations in lien). Thus, Plaintiffs' fraud claim has been adequately pled and should not be dismissed.

E. Plaintiffs Have Properly Pled Their Statutory Claim for Injury from Criminal Acts (R.C. § 2307.60)

The Manufacturer Defendants and the Pharmacy Defendants contend that R.C. § 2307.60 requires a criminal conviction for Plaintiffs' claims to proceed, Mfr. Mem. at 49-50; Pharm. Mem. at 23. However, the case law on which Defendants rely cannot be squared with a 2016 decision by the Supreme Court of Ohio, *Jacobson v. Kaforey*, 75 N.E.3d 203 (Ohio 2016).⁶⁴ In *Jacobson*, the Supreme

⁶³ The Restatement of the Law (Torts) similarly provides that

The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss to another who acts in justifiable reliance upon it if the misrepresentation, although not made directly to the other, is made to a third person and the maker intends or has reason to expect that its terms will be repeated or its substance communicated to the other, and that it will influence his conduct in the transaction or type of transaction involved.

Restatement (Second) of Torts § 533 (2018).

⁶⁴ Defendants cite one case decided by this Court after Jacobson, Jane v. Patterson, No. 1:16-CV-2195, 2017 WL 1345242 (N.D. Ohio Apr. 12, 2017). Jane, however, does not acknowledge Jacobson, and instead relies for its conclusion entirely on earlier authority. Id. at *4 (citing A.A. v. Otsego Local Schools Bd. of Education, No. 3:15-footnote continued on next page

Court of Ohio resolved a dispute among the lower courts and held that "R.C. 2307.60 independently authorize[s] a civil action for damages caused by criminal acts, unless otherwise prohibited by law[.]" *Id.* at 204. The court found this conclusion to be dictated by the "plain and unambiguous" language of the statute:

Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law, may recover the costs of maintaining the civil action and attorney's fees if authorized by any provision of the Rules of Civil Procedure or another section of the Revised Code or under the common law of this state, and may recover punitive or exemplary damages if authorized by section 2315.21 or another section of the Revised Code.

R.C. § 2307.60(A)(1).

As the Supreme Court of Ohio explained:

R.C. 2307.60(A)(1), by its plain and unambiguous terms, creates a statutory cause of action for damages resulting from any criminal act. The wording chosen by the Ohio General Assembly is explicit: any person "injured * * * by a criminal act has * * * a civil action" unless a civil action "is specifically excepted by law." (Emphasis added.) R.C. 2307.60(A)(1). The title of the legislation originally enacting that language in R.C. 2307.60, which became effective in 1985, demonstrates that the General Assembly specifically sought to create a civil cause of action for damages resulting from any criminal act: "AN ACT * * * to amend, for the purpose of adopting a new section number as indicated in parentheses, section 1.16 (2307.60) * * * of the Revised Code to establish a specific statutory civil action for the recovery of full damages for personal injury or property loss arising from any criminal act * * *." (Boldface and capitalization sic.) Am.Sub.H.B. No. 426, 140 Ohio Laws, Part II, 3783. These legislative statements are crystal clear.

75 N.E. 3d at 206.

Jacobson itself did not involve a prior conviction. Plaintiff brought suit under § 2307.60 against two medical facilities and a court-appointed conservator seeking damages for violations of criminal statutes for unlawful restraint, kidnapping, and child enticement. *Id.* at 204. There is no

suggestion that any of the defendants had ever been charged with, let alone convicted of, any of these crimes. Yet the court permitted Jacobson to proceed with her claims.

Courts applying Jacobson have recognized the viability of causes of action under R.C. 2307.60 in the absence of any prior conviction. See, e.g., Drivetime Car Sales Co. v. Pettigrew, No. 2:17-CV-371, 2018 WL 741138, at *3 (S.D. Ohio Feb. 7, 2018); Evans v. Ohio Dep't of Rehab. & Corr., No. 16AP-767, 2018 WL 1391617, at *5 (Ohio Ct. App. Mar. 20, 2018); Sun Bldg. Ltd. P'ship v. Value Learning & Teaching Acad., NOS. C-160789, C-160793, 2017 WL 5903365, at *6 (Ohio Ct. App. Nov. 29, 2017). These cases are consistent with earlier decisions expressly holding that prior convictions are not required. See, e.g., Gonzalez v. Spofford, No. 85231, 2005 WL 1541016, at *4 (Ohio Ct. App. June 30, 2005) ("R.C. 2307.60 . . . specifically provides that a criminal conviction is not a condition precedent to civil liability"); Chem. Bank v. Kausmeyer, No. 4:15CV1080, 2016 WL 7178662, at *7 (N.D. Ohio Dec. 9, 2016) ("\$ 2307.60 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.").

By contrast, all of the cases Defendants cite derive from, and cite to, the decision in *Ortiz v. Kazimer*, 2015 WL 1400539. *Ortiz*, in turn, rests on a magistrate judge's report and recommendation, which began its analysis with the proposition that "Ohio courts have found that Section 2307.60 itself does not create a cause of action." *Ortiz v. Kazimer*, No. 1:11CV1521, 2013 WL 10372123, at *16 (N.D. Ohio June 5, 2013). That is, of course, the precise proposition rejected by the Ohio Supreme Court in *Jacobson.* 75 N.E.3d at 205-07. In short, the law undergirding *Ortiz* and its progeny has been superseded. In light of *Jacobson*, this Court should reject Defendants' argument that a criminal conviction is a prerequisite to the Plaintiffs' claims under R.C. 2307.60.

On the merits, neither the Manufacturer Defendants nor the Pharmacy Defendants actually dispute that Plaintiffs' allegations support a finding of violations of R.C. § 2925.02(A) through their

actions in inducing or causing others to use opioids. See SAC ¶¶ 1092-1093. Furthermore, Defendants have made no attempt to demonstrate that their conduct has been "in accordance with Chapters 3719., 4715., 4723., 4729., 4730., 4731., and 4741. of the Revised Code," the affirmative showing they must make to except themselves from criminal liability for that conduct under R.C. § 2925.02(B). At most, the Pharmacy Defendants argue that Plaintiffs' statement that the Defendants are not in compliance with the listed provisions of Ohio law constitutes a "generic legal conclusion," notwithstanding the serious and detailed allegations set forth in the SAC regarding their alleged conduct in violation of Ohio law provisions related to controlled substances (R.C. Chapter 3719) and pharmacists: dangerous drugs (R.C. Chapter 4731). See SAC ¶¶ 684-713. Furthermore, Plaintiffs have alleged that numerous Manufacturer Defendants and Pharmacy Defendants have pled guilty to criminal charges, entered agreements to pay penalties to federal agencies, been indicted on felony charges, and engaged in serious violations of controlled substances laws related to their marketing and distribution of opioids. See, e.g., SAC ¶¶ 70 (Purdue), 99 (Insys), 154 (Purdue), 160 (Purdue), 481 (Insys), 486 (Insys), 583 (Mallinckrodt), 629 (CVS), 637-39 (CVS), 651 (Rite Aid), 702f (Mallinckrodt), 786 (Cephalon), 791 (Purdue), 812 (Endo), 1102 (Purdue, Insys, Mallinckrodt). These allegations demonstrate that Plaintiffs have a more than plausible basis for their claim under R.C. 2307.60.65

F. Plaintiffs Have Properly Pled Their Unjust Enrichment Claim

Defendants seek to dismiss Plaintiffs' claim for unjust enrichment as duplicative of other claims, or, in the alternative, because Plaintiffs did not engage in transactions directly with Defendants. Dist. Mem. at 49-52; Mfr. Mem. at 50-51; Pharm. Mem. at 21. The first argument is

⁶⁵ Pharmacy Defendants also argue that this claim is barred by the economic loss doctrine. Pharm. Mem. at 24. As discussed above, however, that doctrine has no application where "the defendant breached a duty that did not arise solely from a contract." *Campbell v. Krupp*, 961 N.E.2d at 211. It also does not apply to intentional torts. *Eysoldt v. Imaging*, 957 N.E.2d at 785. The criminal statutes Plaintiffs allege Defendants violated involve intentional conduct and the duty to comply with the law does not arise from contract.

easily dispatched: the same conduct may give rise to multiple causes of action and "nothing prohibits a plaintiff from pleading multiple claims when there are, in fact, multiple theories of liability that are legally viable and consistent with the facts; where a plaintiff has a contract claim, tort claim, and a claim for statutory violation, all may be pled." *PCA Minerals, LLC v. Merit Energy Co., LLC*, No. 16-2598, 2018 WL 846565, at *6 (6th Cir. Feb. 14, 2018); *see also Hutchings v. Nationstar Mortg., LLC*, No. 1:13 CV 00569, 2013 WL 5670939, at *3 (N.D. Ohio Oct. 16, 2013) ("a plaintiff is not precluded from arguing or pursuing multiple theories in the alternative throughout the course of the litigation").⁶⁶

Defendants also contend that Plaintiffs may not maintain a claim for unjust enrichment in the absence of a direct, transactional relationship between the parties. But that is not the law. "[U]njust enrichment of a person occurs when he has and retains money or benefits which in justice and equity belong to another." *Hummel v. Hummel*, 14 N.E.2d 923, 927 (Ohio 1938). The elements of this claim are: "(1) a benefit conferred by a plaintiff upon a defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by the defendant under circumstances where it would be unjust to do so without payment." *Hambleton v. R.G. Barry Corp.*, 465 N.E.2d 1298, 1302 (Ohio 1984).

Contrary to Defendants' argument, "[u]njust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss." White v. Smith & Wesson, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (applying Ohio law). In White, the court held that, under Ohio law, a plaintiff paying for "the Defendants' externalities—the costs of the harm caused by [their] failure to incorporate safety

⁶⁶ Defendants rely on *McCarty v. Pedraza*, 17 N.E.3d 71, 80-81 (Ohio Ct. App. 2014), but *McCarty* addresses a specific limitation on legal malpractice claims, which, whether they are cast in negligence or breach of contract, may only be brought as malpractice claims. The case has no applicability outside that context. *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005) similarly does not support Defendants' position and indeed does not discuss the question of so-called "duplicative" claims at all.

devices into their handguns and negligent marketing practices"—conferred a benefit on Defendants and stated a claim for unjust enrichment. Id. 67 Other courts agree. See City of L.A. v. Wells Fargo & Co., 22 F. Supp. 3d 1047, 1061 (C.D. Cal. 2014) (citing White, and cases in the footnote below, to hold that plaintiff's claim "that the benefits it conferred on Defendants are the so-called 'externalities'—the costs of harm caused by Defendants' discriminatory lending that the City has had to shoulder" states an unjust enrichment claim). 68 This analysis is also reflected in cases holding that a defendant is unjustly enriched when a third party must bear the cost of remediating the pollution caused by the defendant (a negative externality); Little Hocking Water Ass'n v. E.I. du Pont de Nemours & Co., 91 F. Supp. 3d 940, 986 (S.D. Ohio 2015) (under Ohio law a plaintiff whose property was used as a dumping site may plead unjust enrichment as an alternative theory of damages since "it would be unjust to allow Defendant to benefit from disposal of waste on a plaintiff's property without payment of any kind."). See also Moore v. Texaco, Inc., 244 F.3d 1229, 1233 (10th Cir. 2001) ("The performance of another's statutory duty to remediate pollution can give rise to a claim for unjust enrichment."); Ergon, Inc. v. Amoco Oil Co., 966 F. Supp. 577, 586 (W.D. Tenn. 1997) (plaintiff stated an unjust enrichment claim because "[b]y remediating the contamination which was allegedly caused by Amoco, Ergon arguably confers upon Amoco a benefit of which it is aware."); Evans v. City of Johnstown, 96 Misc. 2d 755, 766-70 (N.Y. Sup. Ct. 1978) (holding that plaintiff could proceed on claim for unjust enrichment against municipalities for money saved by not properly disposing of waste materials); United States v. Healy Tibbitts Const. Co., 607 F. Supp. 540, 542-43 (N.D. Cal. 1985) (in case involving party refusing to clean up oil spill, court noted that the "portrait of [the defendant]

⁶⁷ "Negative externalities occur when the private costs of some activity are less than the total costs to society of that activity," and thus the "private parties engaging in that activity essentially shift some of their costs onto society as a whole." *McCloud v. Testa*, 97 F.3d 1536, 1551 n.21 (6th Cir. 1996).

⁶⁸ City of Boston v. Smith & Wesson Corp., No. 199902590, 2000 WL 1473568, at *18 (Mass. Super. Ct. July 13, 2000) (sustaining unjust-enrichment claim at pleadings stage based on "externalities" that the city covered due to gun manufacturer's actions); City of New York v. Lead Indus. Ass'n, Inc., 190 A.D.2d 173 (N.Y. App. Div. 1993) (allowing restitution claim for "reasonable costs of [lead] abatement" to survive motion to dismiss).

indifferently standing idle while its [harm] is neutralized at public expense – and thereafter spiritedly disavowing any responsibility for recompensing the [county]—offers as compelling an example of unjust enrichment as has lately been brought before the Court.").

In this case, the cost of the Defendants' wrongful conduct in selling and distributing opioids includes increased healthcare services and addiction treatment for opioid users, to name but a few categories. SAC ¶¶ 1083-84, 1089-92. These costs are part of the Defendants' businesses, but they do not bear these costs. Plaintiffs do, and these costs are "not part of the normal and expected costs of a local government's existence." *Id.* at ¶¶ 1083-88, 1091. Moreover, although Defendants argue that Plaintiffs do not allege knowledge of the benefit conferred, the Complaint specifically alleges that by using Plaintiffs to pay for the Defendants' negative externalities – the cost of the harms caused by their wrongful practices – the Defendants were aware that they saved costs and expenses that allowed them to sell and distribute more opioids, and make more money, than if they had internalized the actual cost of their activities. *Id.* at ¶¶ 1084-88.

Defendants rely on *Ohio Edison Co. v. Direct Energy Bus., LLC*, No. 5:17 CV 746, 2017 WL 3174347, at *3 (N.D. Ohio July 26, 2017), for their argument, but misread the court's analysis in that case. In *Ohio Edison*, the court was concerned about the inability to match up benefits and losses in a complicated marketplace with multiple actors buying and selling to each other. In that scenario, one party might gain and another might lose, without one being at the expense of the other. No such concerns exist here, and *Ohio Edison* does not address the problem of externalities imposed on the public by a business that simply does not wish to pay for the costs associated with its profits. This case is, instead, analogous to *White* and to *Little Hocking Water Ass'n.*, which did involve such externalities, rather than to *Ohio Edison. Johnson*, 834 N.E.2d 791, is even further afield. There, the court considered a claim for unjust enrichment from monopolistic pricing. Under antitrust law, however, only the harms of direct purchasers are recognized. The court was, for that reason,

concerned that permitting a claim for unjust enrichment by an indirect purchaser would constitute an end-run around limitations that reflected specific policy choices about the allocations of gains and losses. *Id.* at 799. That the court, in that situation, looked for a direct transaction between a buyer and seller within the market where the gains and losses were alleged to have occurred in no way suggests that such privity is required here.

G. Plaintiffs Have Properly Pled Their Claim for Civil Conspiracy

The Complaint contains numerous and specific factual allegations sufficient to plead that all Defendants had a common understanding and design to commit thousands of unlawful acts related to the marketing and distribution of prescription opioids. In Ohio, a civil conspiracy consists of: "(1) a malicious combination; (2) two or more persons; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy." *Hale v. Enerco Group, Inc.*, No. 1:10 CV 00867-DAP, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (citations omitted). The Distributor and Chain Pharmacy Defendants wrongly assert that the Complaint fails to adequately allege the existence of the first and fourth elements, Dist. Mem. at 52-54, Pharm. Mem. at 21-23. (The Manufacturer Defendants appear to challenge only the first element. Mfr. Mem. at 51-53.)

1. <u>Defendants Improperly Heighten the Pleading Standard</u>

As an initial matter, Defendants improperly assert a higher pleading standard than Ohio law requires. While civil conspiracy "must be pled with some degree of specificity," this does not equate to a Rule 9(b)-like particularity standard for every element of Plaintiffs' civil conspiracy claim. *Auto. Fin. Corp. v. WW Auto*, No. 2:04-CV-261, 2005 WL 1074331, at *5 (S.D. Ohio Apr. 20, 2005). The Manufacturer Defendants rely on *Coley v. Lucas*, No. 3:09 CV 8, 2014 WL 272667, at *9 (N.D. Ohio Jan. 23, 2014), for the proposition that a civil conspiracy claim must "plead when, where, why, or how the conspiracy occurred." Mfr. Mem. at 51. But the plaintiffs in *Coley* relied exclusively on legal conclusions for their state conspiracy claim and pleaded *no* material facts. The *Coley* court's ruling

does not dictate an affirmative list of facts that must be pleaded. Rather, it stands for the unremarkable proposition that a conspiracy claim unsupported by any factual allegations fails.

Similarly, the Distributor Defendants rely on *Spears v. Chrysler*, *LLC*, No. 3:08 CV 331, 2011 WL 540284, at *11 (S.D. Ohio Feb. 8, 2011), for the proposition that vague and conclusory allegations of agreement will not suffice. Dist. Mem. at 52-53. But the plaintiff in *Spears* alleged in a single paragraph, without supporting factual allegations, that the defendants had "reached an agreement to act in concert"—an allegation the court found to be insufficient. *Spears*, 2011 WL 540284, at *11-12. In contrast, as set forth below, Plaintiffs here allege in detail how Defendants conspired to achieve their shared objectives.

Further, the Distributor and Manufacturer Defendants mischaracterize Plaintiffs' conspiracy claim as based solely on "fraud and misrepresentation" and thus subject to Rule 9(b)'s heightened standard. Dist. Mem. at 53; Pharm. Mem. at 22. Although Plaintiffs do allege fraud and misrepresentation in conjunction with the distribution of opioids—allegations Plaintiffs plead with requisite particularity—Plaintiffs also allege numerous underlying unlawful acts that do not sound in fraud. Those acts—public nuisance, negligence, and injury through criminal acts⁶⁹—are not subject to Rule 9(b). *Compare* ¶ 1123 (alleging civil conspiracy in unlawful marketing and distribution) with ¶ 1124 (alleging civil conspiracy to commit fraud).

2. The Complaint Adequately Alleges That Defendants Engaged in Malicious Combinations

A malicious combination requires "only a common understanding or design, even if tacit, to commit an unlawful act." *Nat'l Credit Union Admin. Bd. v. Zovko*, No. 1:13 CV 1430, 2017 WL 4535070, at *8 (N.D. Ohio Jan. 27, 2017) (quoting *Gosden v. Louis*, 687 N.E.2d 481, 496 (Ohio Ct. App. 1996)). Neither an express agreement nor even a meeting between the co-conspirators is

⁶⁹ See ¶ 1123 (stating conspiracy claim based on unlawful distribution); ¶ 1125 (stating conspiracy claim based on unlawful failure to monitor or prevent diversion and suspicious orders).

required. *Brown v. United States*, No. 1:10 CV 752, 2014 WL 4231063, at *13 (N.D. Ohio Aug. 26, 2014). As the Sixth Circuit has explained, "[r]arely in a conspiracy case will there be direct evidence of an express agreement among all of the conspirators to conspire, . . . circumstantial evidence may provide adequate proof of conspiracy." *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000) (alterations in original).⁷⁰ Plaintiffs have sufficiently alleged material facts from which the inference of agreement can be drawn.

a. <u>Plaintiffs sufficiently plead malicious combination with regard to their marketing allegations</u>

The Complaint provides detailed allegations of the Manufacturer Defendants' conspiracy to fraudulently market prescription opioids that are sufficient to show a "common understanding or design, even if tacit, to commit an unlawful act." *Gosden*, 687 N.E. 2d at 496; *see*, e.g., SAC ¶¶ 746-766; 814-973. For example, it alleges that Manufacturer Defendants (the "who") conspired to establish, develop, and fund a network to promote the use of opioids for the management of pain through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids (the "what," set forth in detail in ¶¶ 174-349) with the intent of misleading physicians, patients, health care providers, and health care payers to increase sales, revenue, and profit from their opioid products (the "why," set forth in detail in ¶¶ 487-497). To accomplish this goal, the Manufacturer Defendants collectively used unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Manufacturer Defendants (the "where," set forth in detail in ¶¶ 350-464).⁷¹

⁷⁰ See also Bash v. Textron Fin. Corp., 575 B.R. 814, 818 (N.D. Ohio 2017) ("With respect to the level of agreement that must be established, [the Sixth Circuit] has stated that all that must be shown is that . . . the alleged coconspirator shared in the general conspiratorial objective . . .").

⁷¹ While Plaintiffs do not detail the exact time and place of every communication, publication, representation, statement, electronic transmission, and payment used to perpetuate and maintain Defendants' conspiracy, as noted in the SAC, such occasions numbered in the thousands, have been deliberately hidden by Defendants, footnote continued on next page

Plaintiffs also explain that the Manufacturer Defendants' marketing conduct is not consistent with rational, legal business behavior. *See, e.g.*, SAC ¶¶ 819, 849, 852. These allegations of actions taken against self-interest are a "plus factor" supporting the plausibility of Plaintiffs' conspiracy allegations against them. *In re Polyurethane Foam Antitrust Litig.*, 152 F. Supp. 3d 968, 989 (N.D. Ohio 2015).

None of the cases cited by the Manufacturer Defendants concern allegations as detailed as those pled here. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 564 (2007), concerned "few stray statements speak[ing] directly of agreement" that were legal conclusions. *McElrath v. City of Cleveland*, No. 1:16 CV 2907, 2017 WL 3189477, at *5 (N.D. Ohio July 26, 2017), chided the plaintiff's "loose use of the term 'conspired" as "plainly insufficient." *Dixon v. Ginley*, No. 1:13cv489, 2013 WL 2425132, at *9 (N.D. Ohio June 3, 2013), found that the plaintiff had not presented any factual allegations suggesting actual agreement of conspiracy. The Complaint here does not suffer the same infirmities.

The Manufacturer Defendants assert that one small piece of the Complaint's conspiracy allegations – namely, the Manufacturer Defendants' participation in the same medical organizations and publications – is deficient, Mfr. Mem. at 52-53, but the authority they cite actually undermines their assertion. Specifically, the Manufacturer Defendants rely on *In re Text Messaging Antitrust Litig.*, which upheld *summary judgment* because discovery had not revealed sufficient circumstantial evidence of the conspiracy. 782 F.3d 867, 879 (7th Cir. 2015). But, at the motion to dismiss stage, the same court found the complaint sufficiently alleged an "industry structure, and industry practices, that facilitate collusion." *In re Text Messaging Antitrust Litig.*, 630 F.3d 622, 627 (7th Cir. 2010). Here, Plaintiffs' allegations that the Manufacturer Defendants worked together through industry organizations to commit unlawful acts are sufficient to plead a malicious combination.

footnote continued from previous page

and cannot be accessed without Defendants' books and records. ¶¶ 871, 892; cf. Bank One, Columbus, Ohio N.A. v. Fin. Ventures, LLC, No. C2-01-0049, 2002 WL 484307, at *3 (S.D. Ohio Mar. 26, 2002).

b. <u>Plaintiffs sufficiently plead malicious combination with regard to their distribution allegations</u>

Plaintiffs also plead throughout the Complaint that Defendants shared a common design and general conspiratorial objective to illegally flood the market with prescription opioids, thereby increasing their bottom line. The Complaint contains numerous paragraphs setting forth the malicious distribution combination as to all Defendants (¶¶ 607-626, 760-766, 906-938, 950-973, 1122-1136), including, for example, that:

- Defendants "facilitat[ed] the supply of far more opioids than could have been justified to serve [the] market [for opioids]" and "unlawfully and surreptitiously increas[ed] the volume of opioids" in order to "to bolster their revenue, increase profit, and grow their share of the prescription painkiller market" (¶¶ 498-499);
- Defendants shared the common purpose of increasing quotas governing the manufacture and distribution of opioids (¶¶ 526-553, 765);
- Defendants deliberately failed to report suspicious orders to meet that objective (¶¶ 550-593, 765);
- Defendants used trade associations to, among other things, "control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution" (¶ 549);
- Defendants pretended to cooperate and collaborate with law enforcement and each other to prevent diversion and publically portrayed themselves as being in compliance with their legal duties (¶¶ 594-606);
- Defendants worked together through their participation in organizations such as the Pain Care Forum and the HDA, "to engage in the unlawful sale of prescription opioids" (¶ 543);
- the Manufacturer Defendants provided "financial incentives" to Distribution and Chain Pharmacy Defendants, including discounts, rebates, and other forms of consideration, which created the incentive "to refrain from reporting or declining to fill suspicious orders" (¶ 528) and in exchange for the prescribing information of individual doctors (¶ 610); and
- the Chain Pharmacy Defendants⁷² "failed to use data available to them to identify doctors who were writing suspicious orders" (¶ 622), even while

⁷² The Pharmacy Defendants' assertion that the allegations against them are "bare bones" is hollow; they simply fail to address any of the factual allegations set forth herein. Pharm. Mem. at 22.

maintaining "extensive data on opioids they distributed and dispenses (¶ 610).

Although Defendants assert that Plaintiffs' allegations identify nothing more than "routine commercial activities" or "parallel conduct", that assertion does not address the factual allegations in the Complaint. For example, Plaintiffs allege that through their participation in the PCF and the HDA, Defendants worked together to mislead the public regarding Defendants' commitment to complying with their legal obligations and safeguarding against diversion, and to influence policymakers to enact laws and regulations supporting the use of opioids and curtailing the ability to limit illicit or inappropriate opioid prescription and distribution. ¶¶ 547, 549.

Plaintiffs' allegations regarding Defendants' participation in trade associations are not the only hallmarks of the conspiracy alleged, but rather are part of a raft of conduct that constitute circumstantial evidence of conspiracy. *In re Polyurethane Foam Antitrust Litig.*, 152 F. Supp. 3d at 992; *In re Text Messaging Antitrust Litig.*, 630 F.3d at 628. And Plaintiffs specifically plead how the defendant co-conspirators deliberately concealed their knowledge of each other's wrongdoing. ¶¶ 550-593, 763-64. These actions go "far beyond what could be considered ordinary business conduct." ¶ 849; *see also*, ¶¶ 850-877, 906-938, 950-973.

3. <u>Plaintiffs Adequately Allege Defendants Engaged in Independently Unlawful Acts</u>

Plaintiffs specifically allege that the co-conspirators pursued their mutually beneficial goal via independently unlawful acts. While the allegations are sufficient to show that each defendant engaged in underlying unlawful acts, Ohio law provides that the "unlawful acts of any one member of the conspiracy will satisfy the underlying unlawful act requirement." *Hale*, 2011 WL 49545, at *5 (internal quotation marks and citations omitted).

Plaintiffs allege a number of underlying unlawful acts, each independently sufficient to meet the conspiracy requirement:

- Defendants Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen violated RICO, 18 U.S.C. § 1961 et seq. (¶¶ 878-938) and the Ohio Corrupt Practices Act, R.C. § 2923.31 et seq. (¶¶ 939-973);
- All Defendants are liable for statutory public nuisance (¶¶ 974-996), common law absolute public nuisance (¶¶ 997-1038), negligence (¶¶ 1039-1071), and injury through criminal acts (¶¶ 1090-1107); and
- The Manufacturer Defendants are also liable for common law fraud (¶¶ 1072-1089).

Each of these claims is predicated on purposeful, wrongful acts undertaken "without a reasonable or lawful excuse." *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998). So, each is alone sufficient to constitute an underlying unlawful act. Further, the allegations of unlawful acts here are supported by the numerous allegations of and settlements totaling almost \$1 billion for violating laws and regulations related to the marketing and distribution of prescription opioids.⁷³ Thus, the Complaint meets the Ohio requirement that a civil conspiracy allege an underlying unlawful act.

II. <u>Defendants' Arguments for Dismissal of Multiple Claims Also Lack Merit</u>

A. Plaintiffs Have Standing to Bring Their Claims

Defendants raise a number of arguments under the rubric of "standing." The Pharmacy Defendants argue that Plaintiffs lack article III constitutional standing to pursue their actions. *See* Pharm. Mem. at 4-7. The Manufacturers Defendants argue that Plaintiffs lack standing because the issue is one of "state-wide concern" for which only the Ohio Attorney General may relief. *See* Man.

⁷³ For the Manufacturer Defendants, *see*, *e.g.*, ¶ 70 (Purdue paid \$635 million to resolve criminal and civil charges of misbranding OxyContin); ¶ 99 (Insys founder and CEO arrested and charged with felonies arising from a scheme to bribe practitioners and defraud insurance companies relating to Subsys). For the Distributor Defendants, *see*, *e.g.*, ¶¶ 581-82 (McKesson paid \$150 million for failing to report suspicious orders, including in Ohio); ¶¶ 584-585 (Cardinal paid \$44 million and \$20 million in separate settlements to resolve allegations that it violated the CSA by failing to report suspicious orders); ¶ 585 (AmerisourceBergen paid \$16 million to resolve allegations that it violated the CSA). For the Pharmacy Defendants, *see*, *e.g.*, ¶¶ 628-640 (CVS paid more than \$40 million in fines through July 2017 resulting from DEA/DOJ investigations); ¶¶ 641-649 (Walgreens paid \$80 million, the largest settlement in DEA history, to resolve CSA violations, among other fines and settlements paid to the DEA/DOJ and states); ¶¶ 650-651 (Rite Aid paid \$5 million in fines resulting from a DOJ investigation).

Br. at 6-9. The Distributor Defendants also assert the "state-wide concern" doctrine, but do not call it standing. *See* Dist. Br. at 44-45. Regardless of labels, all of these arguments challenge the capacity of the Plaintiffs to sue and all should be rejected.

1. Plaintiffs Have Article III Standing

The Pharmacy Defendants argue that Plaintiffs lack standing because they have suffered no cognizable injury caused by the Defendants. Standing is established when a plaintiff alleges that it suffered "injury in fact" that is "fairly traceable" to the defendant's conduct and "that is likely to be redressed by a favorable judicial decision." *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1302 (2017); *accord Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 494 (6th Cir. 1999). An injury in fact is one that is concrete and particularized as well as actual or imminent. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). "At the pleading stage, general factual allegations of injury resulting from the defendants conduct may suffice. . . ." *Id.*

Defendants offer two arguments why they believe Plaintiffs lack standing. First, they assert that Plaintiffs have suffered only a "generalized grievance" that "no more directly and tangibly" affects [them] "than it does the public at large." Pharm. Mem. at 5, *citing Lujan*, 504 U.S. at 574-75. Second, they contend that Plaintiffs' injury is not "fairly traceable" to Defendants' conduct. Pharm. Mem. at 6.⁷⁴

Plaintiffs do not, however, assert a "generalized grievance." Plaintiffs have alleged that they have made and will be required to make, direct payments from the public coffers to address the opioid crisis. *See, e.g.,* SAC ¶¶ 51, 727-745, 902-903, 934-935, 946-949, 972-973, 993, 1006, 1062-63, and 1112. Plaintiffs have a cognizable interest in abating the nuisance that afflicts their community, SAC ¶¶ 714-45, and in maintaining the fiscal integrity of their communities by seeking reimbursement for past and future abatement costs they necessarily and foreseeably incurred

⁷⁴ Defendants do not appear to challenge the third element, redressability.

responding to the opioid crisis. The Supreme Court and the Sixth Circuit have held that plaintiffs have standing to recover as long as they allege something more than a harm that affects many in the same way. See, e.g., Valley Forge Christian Coll. v. Ame. United for Separation of Church and State, Inc., 454 U.S. 464, 464 (1982); Coyne, 183 F.3d at 494; see also Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1548 n.7 (2016) ("The fact that an injury may be suffered by a large number of people does not of itself make that injury a nonjusticiable generalized grievance."); United States v. Students Challenging Regulatory Agency Procs. (SCRAP), 412 U.S. 669, 688 (1973) (standing cannot be denied to plaintiffs actually injured simply because many others are also injured; such a rule would mean that the most injurious and widespread . . . actions could be questioned by nobody).

The specific municipal expenses Plaintiffs allege more than satisfy this requirement. Indeed, the allegations here are similar to those found sufficient to support standing in *Bank of America Corp.*, 137 S. Ct. at 1301-1304 (city's allegations that unlawful racially-discriminatory mortgage lending practices impaired racial composition of the city, frustrated city's interests in integration and in promoting fair housing, and disproportionately caused foreclosures and vacancies in minority communities, decreasing property values, reducing property tax revenues and forcing City to spend more on municipal services sufficient to show that city was aggrieved and had standing); *see also Gladstone Realtors v. Vill. of Bellwood*, 441 U.S. 91, 110-11 (1979) (village had standing to challenge discriminatory housing practices because "[a] significant reduction in property values directly injures a municipality by diminishing its tax base, thus threatening its ability to bear the costs of local government and to provide services.").

Defendants rely heavily on *Coyne*, but that case is simply inapplicable. In *Coyne*, two individuals brought a "taxpayer action" purportedly on behalf of the State of Ohio, alleging that the State had been harmed by the expenses of treating tobacco-related illnesses. 183 F.3d at 491.

Although the *Coyne* plaintiffs were both elected officials in Ohio, *they did not sue in that capacity. Id.*

Instead, they sued as individual taxpayers, alleging that they had paid higher taxes to the general revenue fund and the Public Employees Retirement Fund because of State's expenditures for smoking related illnesses. *Id.* at 494. The Sixth Circuit found that plaintiffs lacked standing because they asserted no injury particular to them, distinct from the grievances of any taxpayer. *Id.* at 494-96. Nothing in the *Coyne* decision suggests, however, that the State itself, or a county or municipality, cannot sue for direct economic harms to the public entity. Indeed, comparison with the Supreme Court decision in *Bank of American* makes that clear: the City of Miami had standing to sue for injuries, including increased expenses incurred by the city itself, whereas, presumably, under *Coyne*, individual taxpayers could not bring the suit instead.

Plaintiffs have also shown that their injuries "fairly can be traced" to the actions of the Defendants as required by Article III. This is a low bar. As the Supreme Court and the Sixth Circuit have squarely held, causation sufficient to satisfy Article III need not be proximate, nor need it be direct. Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1391 n.6; Parsons v. U.S. Dep't of Justice, 801 F.3d 701, 713 (6th Cir. 2015); see also SCRAP, 412 U.S. at 688 ("attenuated line of causation to the eventual injury" sufficient to establish standing). As described above, see § I.C.2, Plaintiffs' injuries are proximately caused by the Defendants' conduct. But even if this Court were to find proximate cause lacking with respect to any of Plaintiffs' claims, Plaintiffs would still meet the much lower traceability requirements for standing. It is ludicrous to suggest that a widespread epidemic of addiction is not even "fairly traceable" to the conduct of Defendants alleged to have misrepresented the addictive properties of opioids, minimizing the dangers of these drugs and exaggerating their benefits, or to the Defendants' failure to control the supply chain and prevent abuse and diversion of these dangerously addictive substances. Defendants' arguments that

Plaintiffs' injuries are "indirect" or "derivative" are thus beside the point. Even if it were true – and it is not – the "fairly traceable" standard encompasses such injuries.⁷⁵

2. The "Statewide Concern" Doctrine Does Not Defeat Plaintiffs' Standing

Whether styled as "standing" or otherwise, the "statewide concern" doctrine does not preclude Plaintiffs from pursuing their claims. The "statewide concern" doctrine relates to the scope of authority granted to municipalities through the Home Rule Amendment to the Ohio Constitution. Because the Home Rule Amendment recognizes areas of shared power, however, it does not preclude Plaintiffs from pursuing their claims in this case and does not reserve to the Attorney General the sole authority to seek redress for the opioid epidemic.

a. Plaintiffs are not precluded from pursuing their claims

The Home Rule Amendment grants authority to municipalities (1) over "powers of local self-government"; and (2) "to adopt and enforce" within municipal limits "such local police, sanitary and other similar regulations, as are not in conflict with general laws" of the state of Ohio. Section 3, Article XVIII. The "statewide concern" doctrine "is relevant only in deciding, as a preliminary matter, whether a particular issue is not a matter of merely local concern, but is of statewide concern, and therefore not included within the power of local self-government" *Am. Fin. Servs.*Assn. v. Cleveland, 858 N.E.2d 776, 782 (Ohio 2006) (internal marks omitted).

A municipality is not necessarily precluded from addressing an issue that is one of statewide concern. The second clause of the Home Rule Amendment creates an "area of shared power" with respect to "the adoption of police regulations, with points of friction between enactments of the two levels of government subject to resolution by the 'no conflict' test." *Id.* at 781 (citation omitted).

⁷⁵ Defendants argue that assertion of their claims in a *parens patriae* capacity would not create standing here. Plaintiffs have not asserted their claims *parens patriae* and do not seek to do so.

The police powers possessed by municipalities like Akron—as well as counties like Summit that possess the powers of home rule -include powers to adopt and enforce local health and safety measures. See, e.g., Marich v. Bob Bennett Constr. Co., 880 N.E.2d 906, 911 (Ohio 2008) (police power allows municipalities "to protect the public health, safety, or morals, or the general welfare of the public."). Defendants rely on State v. Underwood, 27 N.E.2d 773, 775 (Ohio 1940), which held that the state possesses the power to regulate public health, including through state-created local health districts. Id. at 775-77. Critically, however, Underwood did not hold that municipalities or counties lacked authority, pursuant to their police powers, to also regulate public health within their borders so long as such regulations do not conflict with the general laws of Ohio. Indeed, the Court recognized that municipalities could "supplement[] the health administration work" of the state-sponsored health districts. Id. at 776. Ohio courts have consistently recognized that municipal and county ordinances designed to protect public health are a proper exercise of police power. Thus, regardless of whether the opioid crisis presents issues of statewide or even nationwide concern,

⁷⁶ See, e.g., County of Summit v. Meyer, No. 21882, 2004 WL 1885872, at *2, n.1 (Ohio Ct. App. Aug. 25, 2004) ("Article X, Section 3 of the Ohio Constitution provides, in pertinent part, that '[a]ny [county] charter may provide for the concurrent or exclusive exercise by the county, in all or in part of its area, of all or of any designated powers vested by the constitution or laws of Ohio in municipalities[.]' Summit County has adopted a charter and has the same authority to enact laws as the Ohio Constitution grants to a municipality."). See also Clarke v. Warren Cty. Bd. of Commrs., No. CA2005-04-048, 2006 WL 689039, at *5 (Ohio Ct. App. March 20, 2006) (applying police power conflict analysis to with respect to county zoning ordinance).

⁷⁷ See also Downing v. Cook, 431 N.E.2d 995, 997 (Ohio 1982) (municipal "legislation will be upheld against constitutional challenge if it comes within the police power, i.e., if it has a real and substantial relation to the public health, safety, morals or general welfare of the public . . . ").

⁷⁸ See, e.g., In re Thornburg, 9 N.E.2d 516, 519 (Ohio App Ct. 1936) (municipal ordinance that "prohibits distribution of drugs, patent medicines, or combinations of drugs ... is a valid exercise of the police power because it relates to the public health."); Kovar v. City of Cleveland, 102 N.E.2d 472, 474 (Ohio Ct. App. 1951) (ordinance regarding collection, housing, and disposal of stray dogs "is one dealing with the public health and safety of the citizens of Cleveland and comes clearly within the proper exercise of the police power"); Schlenker v. Bd. of Health of Auglaize Cty Gen. Health Dist., 167 N.E.2d 920, 922 (Ohio 1960) (regulation of pasteurization of milk "represents a proper exercise of the police power by the Auglaize County board in the interests of public health"); Mr. Fireworks, Inc. v. City of Dayton, 548 N.E.2d 984, 987 (Ohio Ct. App. 1988) (municipal regulation of fireworks permissible if not in conflict with Ohio law); Traditions Tavern v. Columbus, 870 N.E.2d 1197, 1202 (Ohio Ct. App., 2006) ("there is no dispute that the Columbus smoking ban is an exercise of police power"); D.A.B.E., Inc. v. City of Toledo, 292 F. Supp. 2d 968, 973 (N.D. Ohio 2003) (same).

Akron and Summit County possess the constitutional authority to regulate public health and safety issues related to the opioid crisis within their borders, as they seek to do through this action.

Here, there is no conflict between the positions of the Plaintiffs and the State. "In determining whether an ordinance is in 'conflict' with general laws, the test is whether the ordinance permits or licenses that which the statute forbids and prohibits, and vice versa." *Am. Fin. Servs. Assn.*, 858 N.E.2d at 784 ("(citation omitted)). Defendants do not identify any general law of the state of Ohio that authorizes the misconduct targeted by the present lawsuit. Nor do Defendants explain how there could be any conflict where the Plaintiffs are not enacting their own ordinances or regulations but instead are merely suing to enforce their own rights under existing *state* law.

Defendants cite dicta in *City of Cleveland v. J.P. Morgan Chase Bank*, N.A., No. 98656, 2013 WL 1183332, at *6 (Ohio Ct. App. Mar. 21, 2013), which discussed, without deciding, whether a city's nuisance lawsuit constituted "regulation" for the purposes of a specific statute providing that the "state solely shall regulate" mortgage origination. The Court of Appeals noted that suits pursuant to state common law have been preempted by *federal* statutory provisions that bar the imposition of regulatory standards by *state* governments. *Id.* (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008)). However, even if suits pursuant to state common law constitute the imposition of *state law* requirements, it simply does not follow that suits by a municipality to enforce *state* law amount to *local* regulation, much less local regulation in conflict with state law.⁷⁹

Defendants note that the State also filed suit related to the marketing of opioids, but do not identify any conflict between the respective litigation positions of the State and County. The mere fact that the State seeks to address opioid marketing through litigation does not preempt the

⁷⁹ Additionally, the Ohio Supreme Court has refused to engage in preemption analysis unless the county action that purportedly conflicts with state law was a "municipal ordinance or similar municipal provision having the force of law." *State ex rel. Associated Builders & Contrs. of Cent. Ohio v. Franklin Cty. Bd. of Commrs.*, 926 N.E.2d 600, 605-06 (Ohio 2010).

County's exercise of its police powers absent a conflict. See Am. Fin. Servs. Assn, 858 N.E.2d at 782 (even if the State expresses an "intent to preempt a field of legislation," such intent "may be considered to determine whether a matter presents an issue of statewide concern, but does not trump the constitutional authority of municipalities . . . to enact local police regulations," which "emanates from the Constitution and 'cannot be extinguished by a legislative provision."). This is especially true because Plaintiffs seek to recover their own damages, funds they, and not the State, have expended or will have to expend in the future to address and/or abate the opioid crisis.

Defendants note that the State has enacted laws and regulations regarding the distribution of controlled substances, Dist. Mem. 45, but do not cite any conflict between what theses state laws permit and the activity the County challenges in its lawsuit. *See Am. Fin. Servs. Assn.*, 858 N.E.2d at 784 (standard for "conflict" is whether exercise of local police power "permits or licenses that which the [state] statute forbids and prohibits, and vice versa"). Defendants also argue that the state board of pharmacy has "exclusive enforcement authority" over Ohio's statute addressing pharmacists and dangerous drugs, Dist. Mem. 45 (citing R.C. § 4729.25), but entirely ignore that another provision of this statute expressly authorizes suits regarding the unlawful distribution of drugs to be brought by the County in the name of the state. *See* R.C. § 4729.35.

Finally, Defendants offer a red herring in asserting that the Plaintiffs "cite no constitutional provision granting them authority to bring a lawsuit vindicating statewide interests." Mfr. Mem. at 7. But the Plaintiffs seek to vindicate their *own* interests, protecting their own resources and, through their nuisance claims, the public health and safety in their communities. Although the Fifth Claim for Relief for Statutory Public Nuisance is brought "in the name of" the State of Ohio, it is brought pursuant to statutory provisions that expressly authorize the City and County to assert claims "in the name of the state" with respect to violations occurring within their jurisdictions. *See* SAC ¶¶ 946-48 (citing R.C. §§ 3767.03, 4729.35, and 715.44).

b. The Attorney General's status as Ohio's Chief Law Officer does not extinguish the Plaintiffs' capacity to sue

Defendants concede that Akron and Summit County have the capacity to file lawsuits, *see* Mfr. Mem. 8, ⁸⁰ but nonetheless argue that the statute making the Attorney General the chief law officer of Ohio and its departments, R.C. § 109.02, somehow strips them of their authority to file litigation in their own name. No authority supports this argument.

Defendants cite cases that address the authority of the Attorney General to file various suits or appoint counsel to represent departments of the state. State ex rel. Crabbe v. Plumb, 156 N.E. 457, 458 (Ohio 1927); State ex rel. Walton v. Crabbe, 143 N.E. 189, 191 (Ohio 1924). But these cases do not consider the authority of a municipality to file suit, and certainly do not hold that a city or county particularly one with its own home rule authority—is preempted from filing suit merely because the county and its residents were harmed by conduct that also caused harm elsewhere in the state. Defendants also cite State v. Price, 128 N.E. 173 (Ohio 1920), which discussed how counties were created "for the purpose of aiding the state" and were "subordinate to the state in the exercise of governmental power," id. at 175. But this opinion was issued prior to the enactment of R.C. § 301.22, which gave counties the capacity to sue, and prior to the 1933 amendment to the Ohio Constitution that extended the powers of home rule to counties like *Summit. See* footnote 76 above. In any event, *Price* is inapposite. It addressed *criminal* matters, which are prosecuted by county prosecuting attorneys in the name of the state, and merely held that the state attorney general could empanel a special grand jury in a county in which a regular grand jury was already empaneled. 128 N.E. at 175. Price did not address whether a county or its prosecuting attorney was preempted from bringing a *civil* lawsuit in its own name—or in the name of the state, where provided for by statute merely because the state attorney general has also filed suit with respect to similar conduct.

⁸⁰ See also R.C. § 301.22 (county "is capable of suing and being sued").

Finally, Defendants cite no authority that would give preemptive force to the Attorney General's assertion, in the context of pleading an OCPA claim, that no other plaintiff is "better suited to seek a remedy for the economic harms" caused by Defendants. Mfr. Mem. 8 (quoting Ohio AG Compl. ¶ 247. Summit County and Akron seek relief through the exercise of their own police powers for the injuries that they themselves have suffered. There is no irreconcilable conflict between this suit and the Attorney General's action.

B. Plaintiffs' State Law Claims Are Not Preempted

The Manufacturer Defendants make a perfunctory attempt to argue that all of the Plaintiffs' state law claims (counts 3-11) are preempted by federal law.⁸¹ Mfr. Mem. at 34-38. Their arguments rest on a mischaracterization of both Plaintiffs' claims and also the controlling jurisprudence concerning federal preemption of state law claims involving prescription drugs regulated by the FDA. Defendants' preemption argument should, therefore, be summarily rejected. *Cf. In re Opioid Litig.*, Index No. 40000/2017, slip op. at 5-11 (Ex. A) (denying motion to dismiss based on federal preemption); *State v. Purdue Pharma. L.P.*, No. 17-2-25505-0, slip op. at 2 (Ex. C) (same).⁸²

In the seminal case of *Wyeth v. Levine*, 555 U.S. 555 (2009), the U.S. Supreme Court rejected the argument that FDA approval of pharmaceutical labeling preempts state law failure-to-warn claims. In so holding, the Supreme Court expressly declared that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. To the

⁸¹ The Manufacturer Defendants suggest, in a footnote, that their arguments apply as well to Plaintiffs' federal RICO Marketing Enterprise claims. Mfr. Mem. At 34 n. 33. Plaintiffs note, however, that in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236-37 (2014), the case cited by Defendants, the Supreme Court distinguished the issue of preemption (involving potential conflicts between federal and state law) from that of potential conflicts among different federal laws and left open the question of the proper standard for reconciling or harmonizing statutes in the latter scenario. This Court need not wade into this complicated question, however, because, for the same reasons that Plaintiff's state law claims are not preempted, as discussed in the text, there is no conflict between Plaintiff's RICO Marketing Enterprise claim and any other federal statute.

⁸² Defendants do not cite any authority from opioid cases in support of their position, because no court has found that any governmental opioid litigation is preempted.

contrary, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574. The FDA, likewise, "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579.83

It is in the context of *Levine*'s decisive rejection of preemption claims based on FDA regulation of prescription drugs that the manufacturers' preemption arguments must be evaluated—and found wanting. The Manufacturers cannot and do not identify any federal obligation that conflicts with the state law relief Plaintiffs seek, let alone one that would render it "impossible for a private party to comply with both state and federal requirements," as required for preemption. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). ⁸⁴ Instead, the Manufacturers blatantly mischaracterize Plaintiffs' claims, in an attempt to create a conflict where none exists.

1. Plaintiffs' Marketing-Based Claims Are Not Preempted

Manufacturers first argue that Plaintiffs' unlawful marketing claims are preempted by the FDA's approval of "many opioid medications for long-term use in treating chronic pain." Mfr. Mem. at 35. They contend that "the core assertion" of Plaintiffs' marketing claims is that "the Manufacturer Defendants falsely represented opioids as safe and effective for the long-term

⁸³ More generally, the Supreme Court has recognized a strong presumption against federal preemption. Riegel v. Medtronic, Inc., 552 U.S. 312, 334 (2008). The presumption against preemption is heightened where federal law is said to bar state action in fields of traditional state regulation, such as the protection of public health and safety. *Id.*

⁸⁴ As the Supreme Court noted in *Levine*, "[i]mpossibility preemption is a demanding defense." *Levine*, 555 U.S. at 572. The burden of proving the basis for a preemption defense rests with the defendant. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984). Thus, Plaintiffs are not required to show that it was possible for the Manufacturers to comply with federal law; rather, the Manufacturer Defendants must establish that it was *impossible* for them to comply with Ohio law without violating their duties under federal law. *See Levine*, 555 U.S. at 572; *see also Mensing*, 564 U.S. at 618; *cf. Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 294 (6th Cir. 2015) ("plaintiffs injured by brand-name prescription drugs retain state law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law.").

treatment of chronic non-cancer pain," and that that assertion is in conflict with the FDA's determination that these drugs are safe and effective for treating chronic pain." *Id.*

There are two fundamental flaws with this argument. First, the Manufacturer Defendants do not accurately describe Plaintiffs' misrepresentation claims. The SAC identifies nine categories of misrepresentations made by Defendants. *See, e.g.,* SAC ¶ 177.85 None of these misrepresentations includes the claim that opioids cannot be safe and effective for the long-term treatment of chronic non-cancer pain. Thus, the Manufacturer Defendants can point to nothing in Plaintiffs' marketing claims that directly conflicts with any FDA determination about the safety or effectiveness of opioid drugs.

Second, Plaintiffs do not challenge the FDA-approved labeling of any of Defendants' products, but rather their false and misleading promotion of these drugs. There can be no preemptive conflict between those state law claims and federal law, because federal law did not require the Manufacturers to promote their products—let alone to promote them misleadingly, through falsehoods and omissions. See, e.g., SAC ¶¶ 174-471. They were not required, by virtue of FDA regulations to disseminate falsehoods about the likelihood, frequency, and seriousness of addiction, or engage in any of the other deceptive marketing described in the SAC. Cf. In re Opioid Litig., Index No. 40000/2017, slip op. at 9 (Ex. A) (New York court found no preemption because "manufacturer defendants have failed to show that the FDA has approved their means, methods, and/or content of their drug promotion"); State v. Purdue Pharma. L.P., No. 17-2-25505-0, slip op. at 2 (Ex. C) (Washington court "finds that the State has alleged that Purdue engaged in conduct that

⁸⁵ The nine categories of misrepresentations include: "a. The risk of addiction from chronic opioid therapy is low; b. To the extent there is a risk of addiction, it can be easily identified and managed; c. Signs of addictive behavior are 'pseudoaddiction,' requiring more opioids; d. Opioid withdrawal can be avoided by tapering; e. Opioid doses can be increased without limit or greater risks; f. Long-term opioid use improves functioning; g. Alternative forms of pain relief pose greater risks than opioids; h. OxyContin provides twelve hours of pain relief; [and] i. New formulations of certain opioids successfully deter abuse." *Id.*

exceeded the parameters of the FDA labeling"). Moreover, the allegations in Plaintiffs' SAC do not require Manufacturer Defendants to stop selling their products, but only to stop marketing them deceptively.

Because drug manufacturers are under no federal obligation to promote their products, courts have consistently refused to find preemption of fraud-based marketing claims involving FDA-approved drugs even where the manufacturer would be precluded from altering its label (as in the case of generic drugs for which the manufacturer is required to maintain a label identical to the branded equivalent). See Arters v. Sandoz Inc., 921 F. Supp. 2d 813, 819-820 (S.D. Ohio 2013) (state law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous promotion of generic drug were not preempted); see also Priest v. Sandoz, Inc., No. A-15-CV-00822-LY-ML, 2016 WL 11162903, at *7 (W.D. Tex. Dec. 29, 2016), report and recommendation adopted, No. 1:15-CV-822-LY, 2017 WL 8896188 (W.D. Tex. Jan. 31, 2017) (claims based on fraudulent promotion not preempted because "nothing in the FDCA requires defendants to promote their drug for an offlabel use"); In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings, No. 14 C 1748, 2016 WL 861213, at *3 (N.D. Ill. Mar. 7, 2016) (obligation to refrain from falsely promoting drugs does not make it impossible to comply with federal law regarding labelling); Beavers-Gabriel v. Medtronic, Inc., No. CIV. 13-00686 JMS, 2015 WL 143944, at *6 (D. Haw. Jan. 9, 2015) (no impossibility preemption for fraud claims); Elmore v. Gorsky, No. 2:12-CV-00347, 2012 WL 6569760, at *3 (S.D. Tex. Dec. 17, 2012).

The Manufacturer Defendants cite an unreported Sixth Circuit decision, Rheinfrank v. Abbott Labs., Inc., 680 F. App'x 369 (6th Cir. 2017), but Rheinfrank is completely inapplicable here. In Rheinfrank, the plaintiff argued, inter alia, that defendant should have added a warning to its label about developmental delay in children exposed in utero to defendant's drug Depakote. The Sixth Circuit found that claim preempted because the defendant was able to show that it twice proposed,

and FDA twice rejected, precisely the warning plaintiff claimed should have been given. 680 F. App'x at 384-388. On the specific facts of *Rheinfrank*, it was thus impossible for the defendant to change its label in the manner plaintiff claimed state law required, because FDA had specifically prohibited it from doing so. But here, Plaintiffs do not contend that the Manufacturer Defendants should have changed their labels, nor can the Defendants show that FDA actually required them to make the marketing misrepresentations that Plaintiffs challenge.⁸⁶

Defendants also cite, without any discussion, *In re Celexa & Lexapro Mktg & Sales Pracs. Litig.*, 779 F.3d 34 (1st Cir. 2015), and *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017), but both cases are also readily distinguishable. In *Celexa*, plaintiffs argued that FDA ought never to have approved the drug Lexapro. They claimed that the manufacturer should have disclosed to the FDA information showing a lack of efficacy, but all of the information on which they relied for that claim had been submitted to the FDA with the defendant's New Drug Application. 779 F. 3d at 36-43. Here, by contrast, Defendants cannot plausibly contend that FDA approved their false and misleading marketing misrepresentations; in fact, the SAC notes that Defendants' misrepresentations expressly conflicted with their FDA-approved labels. SAC ¶ 349.

Utts is inapposite for different reasons. In that case, the court found the plaintiffs' fraudbased clams to be preempted because they alleged nothing more than a fraud on FDA, a claim that the Supreme Court has found to be preempted. 251 F. Supp. 3d at 679-80, citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). Here, by contrast, Plaintiffs' claims do not rest on

⁸⁶ Even if the Manufacturer Defendants did contend, as a matter of fact, that FDA considered and rejected any changes in conduct at issue, such a claim could not be adjudicated at the pleading stage, without the development of a full factual record, as was available in *Rheinfrank*. See Levine, 555 U.S. at 571 (requiring "clear evidence" based on administrative record that FDA would have rejected the label change); In re Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 285-86 (3rd Cir. 2017) (manufacturer must show by clear and convincing evidence that FDA would have rejected warnings plaintiff claims were necessary); Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010) (requiring evidence more persuasive than was available in Levine); Cerveny v. Aventis, Inc., 855 F.3d 1091, 1099 (10th Cir. 2017).

any allegation of fraud on the FDA, but rather on Defendants' misconduct in marketing and distributing their opioids.

Next, the Manufacturer Defendants argue that claims involving off-label promotion are preempted because FDA has exclusive authority to enforce the prohibitions on off-label marketing found in the Food Drug & Cosmetic Act ("FDCA"). But Plaintiffs do not seek to enforce the FDCA prohibition; rather, Plaintiffs assert state law claims sounding in fraud, misrepresentation, and nuisance. Plaintiffs allege that the Manufacturers' off-label marketing was false and fraudulent because of their numerous misrepresentations about the risks and benefits of their drugs. SAC ¶¶ 177-349. That such marketing may also have been prohibited by the FDCA is incidental to Plaintiffs' claims.

Even where a plaintiff's state law claims are premised on a violation of federal law duties, such claims are preempted *only* to the extent that they "exist solely by virtue of the" federal law in question and do not "rely[] on traditional state tort law." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352-53. (2001); *see also Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 580 (6th Cir. 2013) (claim that manufacturer misrepresented the health benefits of Vitamin C in its OTC cold remedy "relies solely on traditional state tort law predating the FDCA" and is not preempted even though conduct also violated FDCA); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008) (claims premised on traditional state law duties not preempted); *Arters*, 921 F. Supp. 2d at 820 (claims arising from off-label promotion did not seek to enforce FDCA where plaintiff did not allege that defendants violated their duty because the promotion was off-label, but rather because it was fraudulent). *Loreto* is controlling here: a

plaintiff does not lose a traditional state law fraud (or nuisance or negligence) claim merely because the defendant's conduct also falls afoul of federal regulations.⁸⁷

The authorities cited by the Manufacturers are not to the contrary. In *Perdue v. Wyeth*Pharmaceuticals, Inc., 209 F. Supp. 3d 847 (E.D.N.C. 2016), appeal dismissed, No. 16-1947, 2018 WL

994177 (4th Cir. Feb. 8, 2018), plaintiff sought to hold the defendant liable for promoting its drug
for an unapproved indication; she did not allege that defendant's marketing was fraudulent, only that
it was off-label. The court expressly noted that plaintiff's claim would not be preempted if the
conduct she alleged "would give rise to a recovery under state law even in the absence of the
FDCA," but found that was not the case for the claim styled directly as one for off-label promotion.

209 F. Supp. 3d at 851-853. Similarly, in *McDaniel v. Upsher–Smith Pharmaceuticals, Inc.*, 229 F.Supp.3d

707, 711-13 (W.D. Tenn. 2017), the court held that a claim based solely on off-label promotion was
preempted, but claims for fraud were not. Finally, in *Caltagirone v. Cephalon, Inc.*, No. 1303 EDA

2017, 2018 WL 2750560 (Pa. Super. Ct. June 8, 2018), the court found plaintiff's claims preempted
because they "could not exist in the absence of federal laws and regulations." That is not the case
here, where the state law duties Plaintiffs allege the Manufacturers breached exist independently of
the federal regulatory structure.

2. <u>Plaintiffs' Supply-Chain Claims Are Not Preempted</u>

The Manufacturer Defendants contend that Plaintiffs' supply-chain claims stand as an obstacle to the accomplishment of congressional purpose and thus are preempted. Mfr. Mem. at 36-38. This argument is based on a fundamental mischaracterization of Plaintiffs' claims. Plaintiffs do not allege that the Manufacturers should have stopped selling their products—only that they should

⁸⁷ See also Fulgenzi v. PLIVA, Inc., 711 F.3d 578 (6th Cir. 2013) (rejecting argument that plaintiff's Ohio failure-to-warn claim against generic drug manufacturer that had failed to provide warning FDA had approved for brand drug equivalent was preempted as improper private enforcement of FDCA). "Fulgenzi's suit is not even premised on violation of federal law, but rather on an independent state duty. The alleged breach arises from the same act, but the legal basis is different. This is simply not grounds for preemption." *Id.* at 587.

have monitored the quantity of opioids being sold and taken steps to avoid diversion and misuse. Thus, Plaintiffs allege that "Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances," SAC ¶ 502; that they were required to "set up a system to prevent diversion, including excessive volume and other suspicious orders," to report suspicious orders to relevant enforcement authorities, and to stop shipment of suspicious orders, id. ¶ 512; and that "Defendants refused to identify, investigate and report suspicious orders . . . when they became aware of the same despite their actual knowledge of drug diversion rings." Id. ¶ 566. Plaintiffs further allege that "Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags." Id. ¶ 568. Indeed, the SAC alleges that Manufacturers had specific, detailed knowledge of abuse and diversion, see SAC ¶¶ 567-570, and that, after identifying doctors engaged in improper prescribing, the Manufacturers chose "not to report them, but to market to them." Id. ¶ 570.

The Manufacturers attempt to analogize these allegations to the statute found unconstitutional in *Zogenix, Inc. v. Patrick*, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696 (D. Mass. Apr. 15, 2014), or to the claims in *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654 (D. Md. 2011), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014), but the analogy fails. In *Zogenix*, the Commonwealth of Massachusetts sought to ban use of Zohydro ER, an opioid approved by the FDA. 2014 WL 1454696, *1. The court held that Massachusetts could not countermand FDA approval of the drug. Likewise, in *Gross*, the court rejected, as inconsistent with FDA approval of a drug, plaintiff's argument that a generic drug company, which was prohibited by federal law from altering its allegedly inadequate label, could have complied with both federal and state-law duties if it "simply stopped manufacturing" the drug. 825 F. Supp. 2d at 659. Both cases thus involve attempts to preclude drug manufacturers from offering FDA-approved drugs for sale under any

circumstances. *Cf. Bartlett*, 570 U.S. at 488 ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state law obligations is not required to cease acting altogether in order to avoid liability."). 88

Here, by contrast, Plaintiffs do not seek to preclude Manufacturer or Distributor Defendants from selling their product lawfully. Plaintiffs allege only that the Defendants were (and are) obliged to use due care in selling their dangerous products and that they are liable for failing to use such care. Indeed, Plaintiffs point to federal law standards of care specifically applicable to the sale of opioids, with which Plaintiffs' supply-chain claims are fully consistent. See, e.g., SAC ¶¶ 491-495.89 Because Plaintiffs' claims do not require the Defendants to stop selling opioids in order to comply with their obligations to monitor and control the supply chain for these products, their preemption argument should be rejected.

C. Plaintiffs' Claims Are Not Barred By the Statute of Limitations

Finally, Manufacturer Defendants, but no other Defendants, move to dismiss—"in part" all of Plaintiffs' claims as time-barred by the applicable statutes of limitations. Mfr. Mem. at 53-57. That motion should be denied.

⁸⁸ The remainder of the authorities cited by Defendants similarly relate to a "stop selling" argument that Plaintiffs do not make. See Yates, 696 F.3d at 300 (rejecting "never start selling" argument); Moore v. Mylan Inc., 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012) (claim that defendant failed to stop selling drug was preempted); see also Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 867 (7th Cir. 2010) (rejecting potential argument that over-the-counter drug should be available only by prescription, while noting that state law may require warnings on the label of an over-the-counter drug beyond what the FDA has required).

⁸⁹ In this regard, it is worth noting that the federal Controlled Substances Act on its face explicitly saves state law from federal preemption: *see* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.").

⁹⁰ Manufacturer Defendants do not appear to argue that any of Plaintiffs' claims are completely time-barred. They instead seek to "dismiss Plaintiffs' claims to the extent they rely on alleged conduct committed before January 22, 2013," or several other dates. This is not an appropriate basis for a Rule 12(b)(6) motion, but rather more in the nature of a motion to strike allegations or to limit the introduction of evidence, neither of which were contemplated by CMO 1.

First, because the statute of limitations is an affirmative defense, Fed. R. Civ. P. 8(c)(1), it is rarely an appropriate subject for a motion to dismiss. *See United States v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004) ("Dismissal under Rule 12(b)(6) was irregular, for the statute of limitations is an affirmative defense."). A complaint may be dismissed under Rule 12(b)(6) for failing to comply with the statute of limitations only when "the complaint on its face *conclusively* indicates that the action is time-barred." *Savoy v. Univ. of Akron*, No., 11AP-183, 2012 WL 3085515, *1 (Ohio Ct. App. May 3, 2012). Where, as here, Plaintiffs assert various tolling exceptions to Ohio's statutes of limitation, SAC ¶¶ 767-77, the applicability of those exceptions "are questions for summary judgment or for trial, and they should not be resolved on a motion to dismiss." *Lutz v. Chesapeake Appalachia, L.L.C.*, 717 F.3d 459, 476 (6th Cir. 2013); *see also Am. Premier Underwriters, Inc. v. Nat'l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016) ("courts should not dismiss complaints on statute-of-limitations grounds when there are disputed factual questions relating to the accrual date . . . includ[ing, for example,] claims that the defendant fraudulently concealed facts").

Here, of course, it appears that Manufacturer Defendants do not even assert that any of Plaintiffs' claims is completely time-barred. For this reason alone, the motion should be denied.

1. There is No Statute of Limitations for Plaintiffs' Nuisance Claims

Since 1877, it has been clear in Ohio that no statute of limitations runs against an equitable claim to abate a public nuisance. In *The Little Miami* RR *Co. v. Comm'rs of Greene Cty.*, 1877 WL 31 (Ohio Dec. 1, 1877), municipal officials sought to compel the railroad to restore a public highway that had been restricted by the construction of a crossing. The railroad asserted that the county's claim was barred by the statute of limitations. The Supreme Court of Ohio rejected that defense:

No principle is more firmly settled at common law, than that no length of time can legalize a public nuisance. . . . Lord Mansfield . . . said: "The length of time is clearly not a bar, nor anything like a bar. It is a public nuisance which may increase every hour." Every continuance of a nuisance is, in judgment of law, a fresh nuisance.

Id. at 349-50 (internal citations omitted). Thus, as to Plaintiffs' nuisance claims, the Manufacturer Defendants' limitations argument are completely without merit. *Cf. People v. Conagra Grocery Prods. Co.*, 17 Cal. App. 5th 51, 227 Cal. Rptr. 3d 499 (upholding public nuisance verdict against lead paint companies based on marketing for residential use more than fifty years earlier).

2. <u>Plaintiffs Adequately Plead Fraudulent Concealment</u>

As to Plaintiffs' other claims against the Manufacturer Defendants, Plaintiffs have alleged that Defendants are equitably estopped from asserting a statute of limitations defense, because they purposefully concealed their unlawful conduct and fraudulently assured the public, including Plaintiffs, that they were actively working to comply with their obligations under controlled substances laws and to curb the opioid epidemic. SAC ¶¶ 769-777.

As discussed above, Plaintiffs allege the existence of a coordinated and concealed Opioid Marketing Enterprise, which included the exchange of information, payment of rebates and/or chargebacks with Distributor Defendants, SAC ¶ 529, collaboration to ensure that the opioid production and procurement quotas set by the DEA remained high, *id.* ¶ 550, efforts to surreptitiously undermine policies and prescribing recommendations that limited opioid use, *id.* ¶¶ 823-25, and creating and providing a body of misleading medical literature, advertising, training materials, and CMEs and speaker presentations. *Id.* ¶ 829. The scheme alleged by Plaintiffs could not have succeeded without the close collaboration of the Manufacturer Defendants, Distributor Defendants, Front Groups, and KOLs, and this close collaboration was concealed from Plaintiffs and the public. *Id.* ¶ 818.

Second, Plaintiffs sufficiently allege that the Manufacturer Defendants disseminated many of their misrepresentations through the guise of ostensibly objective third parties, KOLs and Front Groups, while hiding the fact that the Manufacturer Defendants were funding them and controlling their messaging. *See* SAC ¶¶ 352-395 (discussing Front Groups); *id.* ¶¶ 396-428 (discussing KOLs).

Manufacturer Defendants' role in directing the Front Groups was hidden from the public and intended to stay that way.⁹¹

Third, when some information about the dangers of opioids began to filter through Defendants' pervasive misrepresentations, Defendants responded by (1) blaming a few "bad actor" physicians and patients, *see, e.g., id.* ¶ 575, and (2) claiming that their new, patent-protected formulations of opioid medication would deter abuse and resist tampering. *Id.* ¶¶ 308-49, 679-81. Not one Manufacturer Defendant has taken action to correct its misrepresentations.

Finally, Manufacturer Defendants (along with Distributor Defendants) also hid their lack of cooperation with law enforcement, while making public assurances that they were committed to working with public authorities to preventing diversion. SAC ¶¶ 601-606. Purdue, for example, asserted a need for secrecy about its supposed anti-diversion programs, stating that "[i]mproperly disclosing the workings of these programs is irresponsible and only aids those seeking to divert and abuse prescription opioids, potentially worsening a national health crisis." *See* Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016), cited at SAC ¶ 602 n.171.

Thus, Plaintiffs have alleged each of the elements of equitable estoppel based on fraudulent concealment. As Plaintiffs allege, Manufacturer Defendants deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims, and Plaintiffs did not discover the nature and magnitude of Defendants' misconduct, nor could they have acquired such knowledge earlier through the exercise of reasonable diligence. SAC ¶¶ 772-73. Manufacturer Defendants do not dispute that Plaintiffs have made these allegations, but contend that they are not "sufficient to support application" of the doctrine. Mfr. Mem. at 55. That argument improperly seeks to shift the burden to Plaintiffs on this motion to dismiss. As even the authorities on which

⁹¹ Indeed, one major front group, the American Pain Foundation, disbanded as soon as its financial ties to the Manufacturer Defendants became public. *Id.* ¶ 364.

Defendants rely recognize, "these are questions . . . [that] should not be resolved on a motion to dismiss." *Lutz*, 717 F.3d at 476; *see also Egerer v. Woodland Realty, Inc.*, 556 F.3d 415 (6th Cir. 2009) (affirming grant of *summary judgment* on statute of limitations grounds).

For purposes of the present motion, Plaintiffs have pleaded more than sufficient facts to support tolling the statute of limitations based on Defendants' fraudulent concealment.

3. The Continuous Violations Doctrine Applies to Plaintiffs' Claims

Plaintiffs' claims are also timely under the continuing violations doctrine. As a general matter, "[s]tatutes of limitations . . . are intended to keep stale claims out of the courts," and "[w]here the challenged violation is a continuing one, the staleness concern disappears." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 380 (1982). The continuing violations doctrine "is rooted in general principles of common law and is independent of any specific action." *Hensley v. City of Columbus*, 557 F.3d 693, 697 (6th Cir. 2009); *see also Guba v. Huron Cty.*, 600 F. App'x 374, 379 (6th Cir. 2015) (describing the doctrine as "a common[]law limited exception to the accrual of a cause of action"). Under the doctrine, "The statute of limitations for a continuing tort generally runs from the date of the last tortious act." *Gross v. United States*, 676 F.2d 295, 300 (8th Cir. 1982).

In the Sixth Circuit, "a 'continuous violation' exists if: (1) the defendants engage in continuing wrongful conduct; (2) injury to the plaintiffs accrues continuously; and (3) had the defendants at any time ceased their wrongful conduct, further injury would have been avoided." Hensley, 557 F.3d at 697 (citing Kuhnle Bros., Inc. v. County of Geauga, 103 F.3d 516, 521 (6th Cir.1997)). The doctrine "does not apply to a series of discrete acts, each of which is independently actionable,"

⁹² Defendants describe the doctrine as a "narrow" one usually limited to Title VII cases, Mfr. Mem. at 56, but the doctrine has historically been applied to a wide variety of torts. See generally Kyle Graham, The Continuing Violations Doctrine, 43 Gonz. L. Rev. 271, 296-321 (2008) (surveying the application of the doctrine to various types of claims, including false imprisonment, the tort of "seduction," intentional infliction of emotional distress, and nuisance and trespass, as well as civil rights violations, antitrust violations, and hostile work environment claims). In particular, the doctrine applies to claims of ongoing nuisance. See Restatement (Second) of Torts § 161 Cmt. b, § 899 Cmt. d (1965); id. § 930 (1979).

but rather, to a "cumulative violation" caused by a "continuing course of misconduct." *Guba*, 600 F. App'x at 380; *see also Sta-Rite Indus.*, *LLC v. Franklin Elec. Co.*, 519 F. App'x 370, 381 (6th Cir. 2013) ("to apply the continuing tort exception, there must be both a continuing course of misconduct and one of the defendant's allegedly tortious acts must fall within the limitations period").

A "cumulative violation" caused by a "continuing course of misconduct" is exactly what Plaintiffs alleged in their complaint. Defendants argue that Plaintiffs alleged "discrete acts that were themselves potentially actionable: that is, different defendants engaging in different conduct at different periods of time causing different alleged harms." Mfr. Mem. at 57. But this mischaracterizes Plaintiffs' allegations. In Defendants' telling, their misconduct did not extend beyond the examples of misleading promotional materials, sales tactics, and manipulated studies that Plaintiffs provided. But the discrete acts alleged in the SAC were representative examples of a complex and far-reaching fraudulent scheme, not isolated acts. Defendants' deceptive campaign was well orchestrated and continuous, and it continues to harm Plaintiffs and countless other communities across the United States.⁹³

Defendants attempt to downplay the grave consequences of their conduct by arguing that "Manufacturer Defendants' alleged earlier conduct caused only some injuries, but their later alleged conduct would have caused different, stand-alone injuries." Mfr. Mem. at 57. As most residents in Akron and Summit County can confirm, however, the harms from the opioid epidemic—the worst man-made epidemic in modern medical history—are ongoing. Addiction continues to spread,

today.

⁹³ For example, Manufacturer Defendants' invisible control over prescribing guidelines continue to cause harm to this day. As Manufacturer Defendants knew, treatment guidelines are especially influential with primary care physicians, to whom Manufacturer Defendants promoted their opioids heavily. SAC ¶¶ 374-75, 431. But Defendants hid their involvement in the Front Groups creating these guidelines and other educational materials, to make them appear disinterested and objective. See, e.g., id. ¶¶ 359, 376. The prescribing guidelines and other medical literature that Defendants published through Front Groups have not been retracted. They remain in circulation—and continue to influence some prescribing decisions—even

including as a result of Defendants' reformulated and supposedly abuse-deterrent opioids, which, contrary to Manufacturer Defendants' representations, are just as addictive as their predecessors and still subject to abuse. Overdoses continue to outpace the capacity of Akron and Summit County's morgue, SAC ¶ 724, and the Medical Examiner's Office continues to face mounting costs from staff burnout, overtime, toxicology testing, and transporting the deceased. *Id.* ¶ 727. Plaintiffs' first responders continue to have to respond to overdose calls, and Plaintiffs must purchase additional supplies of naloxone. *Id.* ¶ 729. The costs to Plaintiffs from simply trying to keep up with the epidemic will continue to grow, without even coming close to the resources needed to fully address the epidemic. SAC ¶ 744.

These events occurring in 2018 are not the result of Defendants' "[p]assive inaction," *Paschal v. Flagstar Bank*, 295 F.3d 565, 573 (6th Cir. 2002), or "continual ill effects from an original violation" decades ago. *Tolbert v. State of Ohio Dep't of Transp.*, 172 F.3d 934, 940 (6th Cir. 1999). Instead, the opioid epidemic that Plaintiffs battle today is the result of Defendants' "continual unlawful acts." *Id.* But if Manufacturer Defendants, who have coordinated their efforts so successfully to promote opioid use, had ceased their unlawful conduct and devoted the same coordination to correcting their misrepresentations, further injuries could have been avoided.

Plaintiffs' have properly alleged facts sufficient to invoke the continuous violations doctrine. For this reason as well, Manufacturer Defendants' motion to dismiss Plaintiffs' claims based on the statute of limitations should be denied.

CONCLUSION

For the foregoing reasons, each of the motions to dismiss should be denied.

Respectfully submitted,

Dated: June 22, 2018 /s/ Linda Singer

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1 (f)

Pursuant to Local Rule 7.1(f), I hereby certify that the foregoing Plaintiffs County Of

Summit, Ohio, and City of Akron, Ohio's Omnibus Memorandum in Opposition to (1)

Defendants AmerisourceBergen Drug Corp., Cardinal Health, Inc., And McKesson Corp.'s

Motion to Dismiss (Doc. 491); (2) Motion to Dismiss Complaint By Defendants Walmart

Inc., CVS Health Corp., Rite Aid Corp., and Walgreens Boots Alliance, Inc. (Doc. 497); And

(3) Manufacturer Defendants' Joint Motion to Dismiss is associated with a Track One case, The

County of Summit, Ohio v. Purdue Pharma L.P., Case No. 18-OP-45090 (N.D. Ohio), and is within the

page limitations permitted by CMO-1 and CMO-4 in this matter.

Dated: June 22, 2018

Linda Singer

Attorney for the Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of June, 2018, I caused a copy of the foregoing Plaintiffs County Of Summit, Ohio, and City of Akron, Ohio's Omnibus Memorandum in Opposition to (1) Defendants AmerisourceBergen Drug Corp., Cardinal Health, Inc., And McKesson Corp.'s Motion to Dismiss (Doc. 491); (2) Motion to Dismiss Complaint By Defendants Walmart Inc., CVS Health Corp., Rite Aid Corp., and Walgreens Boots Alliance, Inc. (Doc. 497); And (3) Manufacturer Defendants' Joint Motion to Dismiss to be served, by filing a true and correct copy with this Court's CM/ECF system, to all counsel of record.

Dated: June 22, 2018

/s/Linda Singer

Linda Singer

Attorney for the Plaintiffs