UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	
	)	**Judge Dan Aaron Polster**
Track One Cases	)	
	)	**OPINION AND ORDER REGARDING DEFENDANTS' SUMMARY JUDGMENT MOTIONS ON CAUSATION**

Before the Court are three related summary judgment motions filed by Defendants: (1) the Pharmacy Defendants' Motion for Summary Judgment on Causation (**Doc. #: 1885**); (2) the Manufacturer Defendants' Motion for Summary Judgment for Plaintiffs' Failure to Offer Proof of Causation (**Doc. #: 1894)**; and (3) the Distributor Defendants' Motion for Summary Judgment on Proximate Causation Grounds (**Doc. #: 1920)**. For the reasons set forth below, the Motions are **DENIED**.

I. Legal Standard.

The Court hereby incorporates the legal standards set forth in the Court's Opinion and Order regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, see Doc. #: 2483.

II. Overview.

Plaintiffs' remaining claims in this case are broadly based on two theories of recovery: (1) public nuisance, and (2) conspiracy. Under the theory of public nuisance, Plaintiffs assert claims based on (a) Ohio statutory law; and (b) Ohio common law, styled "absolute public nuisance." Under the conspiracy theory, Plaintiffs assert claims based on (a) the Racketeer Influenced and Corrupt Organizations Act ("RICO"); (b) the Ohio Corrupt Practices Act; and (c) civil conspiracy under Ohio common law. Plaintiffs assert all claims against all Defendants.

Against the Manufacturers, under each claim, Plaintiffs assert two theories of relief: (1) fraudulent marketing; and (2) failure to maintain effective controls against diversion. Against the Distributors and Pharmacies, under each claim, Plaintiffs assert only the latter theory of relief, *i.e.* failure to maintain effective controls against diversion. With the above-listed motions, Defendants seek summary judgment on all claims, asserting Plaintiffs do not have sufficient evidence of causation. The Court first examines the fraudulent marketing claims against the Manufacturers, followed by the claims against all Defendants for failure to maintain effective controls against diversion.

III. Analysis.

A. Fraudulent Marketing Claims Against Manufacturers.

The Manufacturers assert that, as a matter of law, Plaintiffs cannot show their allegedly fraudulent marketing activities proximately caused the harms that Plaintiffs seek to redress in this lawsuit – that is, harms caused by an increase in and/or oversupply of opioid prescriptions. More specifically, the Manufacturers assert Plaintiffs cannot show: (1) the alleged marketing misconduct caused medically unnecessary and/or excess prescriptions in the *Track One* Counties; or (2) these

excess prescriptions proximately caused harm to Plaintiffs. The Manufacturers also assert that Plaintiffs may not rely on aggregate proof, but must prove causation individually, connected to the specific conduct of each Defendant in the case.

1. Effect of Alleged Marketing Misconduct.

The Manufacturers assert Plaintiffs cannot show their allegedly fraudulent marketing activities resulted in unnecessary and/or increased opioid prescriptions in the *Track One* Counties. *See* Manuf. Brief at 6-8 (Doc. #: 1894-1). Plaintiffs respond with extensive evidence they contend demonstrates, both collectively and individually, that the Manufacturers engaged in a widespread promotion and marketing campaign that trivialized the medical risks of addiction and exaggerated the benefits of long-term opioid use. *See* Pls. Opp. at 2-18 (Doc. #: 2204). Construed in the light most favorable to Plaintiffs, this evidence would allow a reasonable jury to find that each Manufacturer engaged in misleading marketing activities. *See, e.g., id.*; Perri Rpt. at 86-137 (listing marketing messages by defendant); Pls. Ex. 8 (Doc. #: 2404-1) (Mallinckrodt); Pls. Ex. 22 (Doc. #: 2408-2 (Allergan); Pls. Ex. 27 (Doc. #: 2408-7) (Mallinckrodt); Pls. Ex. 41 (Doc. #: 2414-7) (Allergan); Pls. Ex. 112 (Doc. #: 2424-4) (Teva); Pls. Ex. 146 (Doc. #: 2431-4) (Janssen).

In addition, Plaintiffs point to evidence that suggests, over this same time period, the supply of prescription opioids dramatically increased. For instance, the expert opinion of Jonathan Gruber, a health economist, shows that, from 1997 to 2016, shipments of prescription opioids nationwide increased by more than 500 percent.[1] *See* Gruber Rpt. at 16 (Doc. #: 1916-5). Another expert, Meredith Rosenthal, a health economist, opines: "the combined effect of the Defendant

[1] The Court overruled Defendants' motion to exclude Gruber's testimony. *See* Doc. #: 2531.

[M]anufacturers' promotion of prescription opioids since 1995 was a substantial contributing factor to the increase in the use of prescription opioids" in the *Track One* Counties."[2] Rosenthal Rpt. ¶ 8 (Doc. #: 1913-4). Likewise, Matthew Perri, III, an expert in pharmaceutical marketing, states: "Defendants' approach to marketing opioids was purposeful, aggressive, and effective in increasing sales. The marketing outcomes, including Defendants' own internal metrics, support the fact that the Defendants were able to persuade prescribers and other stakeholders to increase the use of opioids for pain." Perri Rpt. at 139 (Doc. #: 1999-18). Construing this evidence in the light most favorable to Plaintiffs, a factfinder could easily conclude the Manufacturers' misleading marketing activities resulted in a substantial increase in the supply of prescription opioids. This conclusion is further buttressed by Defendants' own documents. *See, e.g.,* Pls. Ex. 91 (Doc. #: 2421-3) (Teva's marketing plan, noting consultant meetings and medical education programs proved incredibly effective in driving prescription growth).

On this record, the Court finds Plaintiffs have shown evidence sufficient to support their claim that the Manufacturers' allegedly fraudulent marketing activities caused an increase in the supply of prescription opioids in the *Track One* Counties.

2. Causation of Harm to Plaintiffs.

The Manufacturers assert Plaintiffs cannot show this increase in prescription opioids proximately caused harm to Plaintiffs. In response, Plaintiffs point to Gruber's expert report that

[2] The Court overruled Defendants' motion to exclude Rosenthal's testimony. *See* Doc. #: 2495. Defendants' arguments that Rosenthal's opinions do not sufficiently link their allegedly deceptive practices to Plaintiffs' alleged losses go to the weight of this evidence. *See* Manuf. Brief at 7-8 (Doc. #: 1894-1); Order Denying Mtn. to Excl. Rosenthal at 13-14 (Doc. #: 2495).

finds a direct causal relationship between Defendants' shipments of prescription opioids and the misuse and mortality from prescription opioids. *See* Gruber Rpt. at 8-10, 61 (Doc. #: 2000-6). Additionally, Plaintiffs' expert in health and public economics, David Cutler, performed a detailed analysis showing how the shipments of prescription opioids caused harm to the *Track One* Counties.[3] *See* Cutler Rpt. at 5-6, 13-80 (Doc. #: 1901-4). And Katherine Keyes, an epidemiologist, reviewed dozens of studies and concluded that increases in prescription opioids are causally related to increases in various opioid-related harms.[4] *See* Keyes Rpt. at 18-29 (Doc. #: 1868-4). Based on this evidence, a jury could reasonably conclude that the increases in prescription opioids proximately caused harm to Plaintiffs. *See, e.g.,* Order Adopting in Part R&R on Mtns. to Dismiss at 7-10 (allegations of deceptive marketing that worked to increase the supply of prescription opioids to the black market, and forced Plaintiffs to expend additional resources in response to associated harms, are sufficient to support a finding of proximate causation).

The Manufacturers contend Plaintiffs cannot show causation based on aggregate proof. *See* Manuf. Brief at 16-22 (Doc. #: 1894-1). As discussed above, Plaintiffs have presented evidence to support a finding that each Manufacturer engaged in deceptive marketing practices that resulted in an increased supply of prescription opioids and caused harm to Plaintiffs. Moreover, construing this evidence in the light most favorable to Plaintiffs, the record supports an inference that the conduct of each Manufacturer was a substantial factor in producing the harm. *See Pang v. Minch*, 53 Ohio St. 3d 186, 559 N.E.2d 1313, 1324 (Ohio 1990) (where plaintiff

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[3] The Court overruled Defendants' motion to exclude Cutler's testimony. *See* Doc. #: 2542. Defendants' challenges to Cutler's methodology go to the weight of this evidence. *See* Manuf. Brief at 9-11 (Doc. #: 1894-1); Order Denying Mtn. to Excl. Cutler at 5-7 (Doc. #: 2495).

[4] The Court overruled Defendants' motion to exclude Keyes' testimony. *See* Doc. #: 2549.

suffers a single injury as a result of the tortious acts of multiple defendants, the burden of proof is on the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm; thereafter, the burden of persuasion shifts to the defendants to demonstrate that the harm produced by their separate tortious acts is capable of apportionment).[5] Because Plaintiffs have presented evidence that shows they have suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct, Plaintiffs have made a sufficient showing to withstand summary judgment on this issue. *See, e.g., BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011) ("Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation.").[6]

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[5] In *Pang,* the Ohio Supreme Court noted the rationale behind this ruling:

> The reason for the exceptional rule placing the burden of proof as to apportionment upon the defendant or defendants is the injustice of allowing a proved wrongdoer who has in fact caused harm to the plaintiff to escape liability merely because the harm which he has inflicted has combined with similar harm inflicted by other wrongdoers, and the nature of the harm itself has made it necessary that evidence be produced before it can be apportioned. In such a case the defendant may justly be required to assume the burden of producing that evidence, or if he is not able to do so, of bearing the full responsibility. As between the proved tortfeasor who has clearly caused some harm, and the entirely innocent plaintiff, any hardship due to lack of evidence as to the extent of the harm caused should fall upon the former.

559 N.E.2d at 1324 (quoting Comment d to 2 Restatement of the Law 2d, Torts 442, Section 433B(2)). The same rationale applies here, *i.e.* Defendants should not be allowed to avoid responsibility for the alleged misconduct merely because it is difficult or impossible to trace individual harms to the conduct of individual Defendants.

[6] The Court agrees with Plaintiffs that Defendants' arguments regarding market-share liability do not apply here. *See* Pls. Opp. at 37-38 (Doc. #: 2204). Plaintiffs do not allege that only one of the Defendants caused the alleged harm. *See, e.g., Sutowski v. Eli Lilly & Co.,* 82 Ohio St. 3d 347, 351-355, 696 N.E.2d 187, 190-192 (Ohio 1998) (the Ohio Products Liability Act does not provide for market-share liability, *i.e.* a plaintiff cannot recover from defendants who did not supply the product that caused the harm).

Accordingly, the Court concludes the Manufacturers are not entitled to summary judgment on the fraudulent marketing claims.

B. Failure to Maintain Effective Controls Against All Defendants.

Defendants assert Plaintiffs cannot show their alleged failure to maintain effective controls against diversion proximately caused harm to Plaintiffs. *See* Man. Brief. at 11-15 (Doc. #: 1894-1); Dist. Brief at 6-20 (Doc. #: 1920-1); Pharm. Brief at 4-11 (Doc. #: 1885-1). This Court has found that, as a matter of law, the Controlled Substance Act and its implementing regulations require registrants to: (1) design and operate a system to disclose to the registrant suspicious orders ("SOMS"); (2) inform the DEA of suspicious orders when discovered by the registrant; and (3) not ship a suspicious order unless due diligence reasonably dispels the suspicion. *See* Order on Pls. MSJ re CSA at 15, 18-19 (Doc. #: 2483) (citations omitted).

1. SOMS Claims Against the Manufacturers.

The Manufacturers assert the SOMS claims against them fail because Plaintiffs have no evidence to show the Manufacturers failed to maintain effective controls against diversion. *See id.* at 12-15. Specifically, the Manufacturers assert that, at most, Plaintiffs' evidence on this issue is only against the *Distributors*. *See id.* The Manufacturers are mistaken. Plaintiffs' expert, James Rafalski, is a former DEA Investigator with expertise in identifying methodologies available to flag potentially suspicious orders. *See* Order re Mtn. to Exclude Rafalski at 12 (Doc. #: 2494).[7]

[7] Except for statements about what the law requires or whether Defendants' conduct violated the law, the Court overruled Defendants' motion to exclude Rafalski's testimony. *See* Doc. #: 2549.

Rafalski reviewed each of the Manufacturers' SOMS and due diligence procedures and determined that each failed to contain key components that are necessary to maintain effective controls against diversion. *See* Rafalski Rpt. at ECF pp. 145-187 (Doc. #1999-21). Based on this evidence, a jury could reasonably conclude the Manufacturers, and each of them, failed to maintain effective controls against diversion. *See also* Pls. Opp. at 19-22 (citing evidence regarding specific Manufacturers' failure to maintain effective controls).

The Manufacturers next contend Plaintiffs cannot show their alleged failure to maintain effective controls caused excess shipments of prescription opioids into the *Track One* Counties. Specifically, the Manufacturers assert Plaintiffs have failed to identify a single order they should not have shipped. *See* Man. Brief at 12-15 (Doc. #: 1894-1). For reasons similar to those stated above, the Court finds Plaintiffs' aggregate proof of causation sufficient to overcome summary judgment. In particular, given the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests there was a complete failure by Defendants to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs. *See Pang*, 559 N.E.2d at 1324. Because Plaintiffs have presented evidence that shows they have suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct, Plaintiffs have demonstrated that summary judgment is unwarranted on this issue. *See, e.g., BCS Servs.*, 637 F.3d at 758.

2. SOMS Claims Against the Distributors and Pharmacies.

The Distributors and Pharmacies similarly assert the SOMS claims against them fail because Plaintiffs cannot show their alleged failure to maintain effective controls caused the

alleged injury to Plaintiffs. More specifically, the Distributors and Pharmacies assert Plaintiffs have not shown their alleged injury resulted from the diversion of suspicious orders, as opposed to an increase in good faith prescriptions based on the Manufacturers' alleged fraudulent marketing practices. *See* Dist. Brief at 7-14; Pharm. Brief at 5-11. This argument overlooks the fact that whether the alleged harm was caused by fraudulent marketing or ineffective controls, or a combination of both, involves questions of disputed facts for the jury to resolve. As with the SOMS claims against the Manufacturers, given the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs. *See Pang*, 559 N.E.2d at 1324. Because Plaintiffs have presented evidence that shows they have suffered the sort of injury that would be an expected consequence of the alleged wrongful conduct, Plaintiffs have done enough to withstand summary judgment on this issue. *See, e.g., BCS Servs.*, 637 F.3d at 758.[8]

[8] The Court rejects the Distributors' arguments that Plaintiffs' claims fail, as a matter of law, due to the fact that diversion involves intervening criminal conduct. For reasons stated, a jury could reasonably conclude diversion is a foreseeable consequence of the alleged misconduct. *See* Dist. Brief at 14-15. Likewise, the Distributors' arguments about the extent of harm caused by alleged wrongdoing involves questions of material fact for the jury to decide. *See* id. at 19-22.

IV. Conclusion.

For the reasons stated above, the Court **DENIES** Defendants' Motions for Summary on Causation (**Docs. #: 1885, 1894 and 1920**). In so ruling, the Court notes that, at trial, it will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted. *See* Fed. R. Civ. P. 50.

IT IS SO ORDERED.

/s/ Dan Aaron Polster *Sept. 3, 2019*
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE