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 Three Cases	)	
	)	**OPINION AND ORDER DENYING HBC SERVICE COMPANY AND GIANT EAGLE'S MOTION FOR SUMMARY JUDGMENT**

Before the Court is Defendants HBC Service Company ("HBC") and Giant Eagle's (collectively, "the GE Defendants") Motion for Summary Judgment. (Doc. #: 3862). Plaintiffs filed an opposition brief. The GE Defendants filed a reply in support of their motion. Upon careful consideration of the parties' briefs and supporting evidence, for the reasons set forth below, the Motion is **DENIED**.

Legal Standard

The Court incorporates the legal standards set forth in the Court's Opinion and Order regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act ("CSA"). *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575, at *1–*2 (N.D. Ohio Aug. 19, 2019) (Doc. #: 2483 at 2–4).

Analysis

Plaintiffs assert common law public nuisance claims based on an alleged failure by the GE Defendants to maintain effective controls against the diversion of prescription opioids. The GE Defendants seek summary judgment, asserting: (1) they are entitled to "safe harbor" immunity for having fully complied with all relevant regulatory obligations involving anti-diversion laws; (2)

Plaintiffs cannot establish the GE Defendants caused the alleged nuisance; and (3) at the very least, the GE Defendants are entitled to partial summary judgment with respect to their Giant Eagle Rx Distribution Center ("GERX") facility, because there is no evidence the GERX facility violated any regulation. The Court addresses each of these arguments in turn.

Safe Harbor Immunity

Plaintiffs and the GE Defendants jointly acknowledge the CSA requires all registrants to maintain effective controls and procedures to guard against the diversion of controlled substances, including the (i) establishment and (ii) proper use of an efficacious suspicious order monitoring system ("SOMS"). The parties disagree, however, about whether the GE Defendants met these requirements.

The GE Defendants argue they have been in "full compliance" with all applicable anti-diversion laws for over a decade. As evidence of this, they point to at least seven inspections by the Drug Enforcement Agency ("DEA") and ninety-two inspections by the Ohio Board of Pharmacy ("OBOP") during the relevant period; the GE Defendants claim all of these inspections concluded they were acting lawfully and in compliance with applicable regulations. Motion at 4–11. This record of passed inspections, the GE Defendants argue, entitles them to safe harbor immunity from nuisance liability: "Giant Eagle reasonably relied to its detriment on the DEA's repeated assurances that its security systems were in 'full compliance' with the CFR's security regulations," so it would be unfair to now allow "a jury to overrule the favorable on-the-ground determinations made by these agencies and impose a post-hoc finding" of liability. Motion at 20, 21.

In response, however, Plaintiffs offer extensive evidence demonstrating possible violations of anti-diversion laws that DEA and OBOP inspectors did not find ***and which GE Defendants***

knew about. For example, Plaintiffs assert the GE Defendants failed to provide their pharmacists with effective, available tools and information necessary to exercise their corresponding responsibility to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose. This alleged failure included withholding relevant guidelines regarding the dispensing of suspicious prescriptions. Response at 8–14.[1] Also, Plaintiffs point to expert testimony demonstrating that Giant Eagle pharmacies repeatedly filled obvious "red flag" prescriptions,[2] and did so without performing the necessary due diligence. *Id.* at 17–18. Additionally, Plaintiffs point to numerous documented instances of potential diversion in Lake and Trumbull Counties allegedly resulting from the GE Defendants' failure to implement effective controls, such as the filling of fraudulent prescriptions, prescription theft, and the loss of thousands of opioid tablets.[3] *Id.* 18–19.

Furthermore, Plaintiffs present evidence that the scope of the DEA and OBOP inspections was limited, and GE Defendants knew this. Plaintiffs maintain that, "[c]ontrary to the GE Defendants' assertions, the DEA inspections at issue were quite limited in scope. The investigators were simply looking at whether the GE Defendants had a SOM system. They did not analyze whether that system was being implemented in accordance with the CSA and its regulations." *Id.* at 25. Plaintiffs assert "[t]he same is true for the Ohio BOP inspections cited by the GE Defendants.

[1] Plaintiffs assert: "In June 2013, Giant Eagle's compliance department drafted a detailed 47-page 'Giant Eagle Pharmacy Controlled Substances Manual' (the 'Manual') containing approximately 20 pages on dispensing red flags and due diligence in order to address what Giant Eagle recognized as the 'epidemic' created by the 'abuse of prescription drugs,'" but "Giant Eagle *never* implemented this policy and never provided the Manual to its pharmacies or pharmacists." Response at 8–9 (emphasis in original).

[2] Such red flags are identified in the expert report of Dr. Carmen Catizone. Internal company documents show the GE Defendants understood these to be red flags as well. Response at 17, n. 62.

[3] The GE Defendants dismiss these violations as "some random technical violation of DEA or Ohio BOP regulations," which "occur from time-to-time in all pharmacies and are self-reported to responsible authorities," and do not "negate the application of 'safe harbor' immunity." Motion at 18, n.21.

Those inspections were also extremely limited in scope. The inspector's findings were based only on what he or she was able to observe during the few hours of the inspection and the limited information provided by the pharmacist in response to the inspector's questions." *Id.* at 27. Plaintiffs contend the GE Defendants knew the limited scope of these inspections and knew the inspectors did not conduct an independent review of underlying facts, but "were relying on information provided to them, and the GE Defendants certainly knew what information they were, and more significantly were not, providing to those inspectors." *Id.* at 32, n.93. Simply passing DEA and OBOP inspections, Plaintiffs maintain, is relevant but does not and cannot prove, by itself, that the GE Defendants substantially complied with all relevant anti-diversion laws.

Defendants cite *City of Cleveland v. Ameriquest Mortgage Securities, Inc.*, 621 F. Supp. 2d 513 (N.D. Ohio 2009) and *Hager v. Waste Technologies Industries*, No. 2000-CO-45, 2002 WL 1483913 (Ohio App. 7 Dist. June 27, 2002) for the proposition that "conduct that complies with regulations cannot be a nuisance." *Ameriquest*, 621 F. Supp. 2d 513, 528. However, these cases say no more than what this Court has repeatedly instructed: safe harbor immunity is available ***only*** to those who perform in accordance with their regulatory obligations. *See, e.g., In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d 773, 808 (N.D. Ohio 2020), *motion to certify appeal denied*, No. 1:17-MD-2804, 2020 WL 2128450 (N.D. Ohio May 5, 2020) (by Distributor Defendants), and *motion to certify appeal denied*, No. 1:17-MD-2804, 2020 WL 2128462 (N.D. Ohio May 5, 2020) (by Manufacturer Defendants) (Doc. #: 3177 at 47); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3737023, at *10 (N.D. Ohio June 13, 2019) (Doc. #: 1680 at 17–18). Both *Ameriquest* and *Hager* draw an important distinction between: (1) the "mere existence or operation" of a company, in a regulated industry, operating within the limitations of the regulatory scheme (which cannot constitute an absolute public nuisance), *Hager*,

2002 WL 1483913, at *10; and (2) conduct by a regulated company that operates beyond its statutory authorization (which was not at issue in either *Ameriquest* or *Hager*).

For example, in *Ameriquest*, the court rightly found that, "if the challenged conduct is subject to regulation ***and the defendant complied with the regulatory structure***, that conduct is not actionable under Ohio law as a public nuisance." *Ameriquest*, 621 F. Supp. at 528 (emphasis added). Logically then, if the defendant ***did not*** comply with the regulatory scheme, the conduct ***is*** actionable as a public nuisance. The plaintiffs in *Ameriquest* did not challenge the defendants' compliance with the applicable mortgage lending regulations. In the present case, however, Plaintiffs have identified evidence that tends to show the GE Defendants were not in compliance with the CSA. What's more, Plaintiffs point to evidence that tends to show the GE Defendants ***knew*** they were not in full compliance.[4] Because there are material facts in dispute regarding the GE Defendants' compliance, they cannot qualify for safe harbor immunity.

A registrant's regulatory obligations under the CSA, analogous Ohio laws, and those laws' implementing regulations do not require strict compliance. Only substantial compliance is required. *See* 21 C.F.R. § 1301.71(b); OAC-4729-9-05. A determination of substantial compliance, however, is a fact-intensive inquiry. This Court has previously concluded that whether a defendant has substantially complied with the CSA is a question of fact. *See In re Opiate*, 2019 WL 3917575, at *15 (Doc. #: 2483 at 29).[5]

[4] Plaintiffs' have identified internal GE documents suggesting the GE Defendants' SOMS were ***incapable*** of stopping suspicious orders prior to shipping them, and that ***they knew this to be the case***. *See* Response, Ex. 6 at 6–7 (HBC_MDL00046224–25) ("It is the belief of the business that Giant Eagle's suspicious order monitoring is 75 to 85 percent of where it needs to be. The missing 15 to 25 percent of the necessary functionality needed to bring Giant Eagle into full compliance with CFR 1301.74(b) can be achieved through the following: [listing features]," which included a "tool [that] will provide GE with the ability to block orders that exceed the set threshold."); *see also* Response, Ex. 10 at 2 (HBC_MDL00028498) ("At the end of the day, the only thing it did that our current system would not do, was stop the orders physically if there was a threshold.").

[5] In that Order, the roles of the parties were reversed. Plaintiffs in *Track One* asked this Court for summary judgment that the defendants' compliance with the CSA fell short of substantial compliance. The Court refused: "[c]onstrued in

In this case, the GE Defendants do not and cannot (and need not) assert that their compliance with the CSA was perfect. However, here, as before, where it is uncontested that a defendants' compliance with the CSA was not complete,[6] and where Plaintiffs have submitted evidence tending to show material non-compliance with the CSA and related state obligations,[7] the Court concludes that the ultimate determination of whether a defendants' compliance was substantial, or whether it falls somewhere short of that mark, is best left to a jury. In the end, it will be for the factfinder to determine how much weight to give the GE Defendants' DEA and OBOP inspections and how much weight to give Plaintiffs' evidence that, despite those inspection results, the GE Defendants, in fact, violated their statutory duties to guard against diversion.[8]

The GE Defendants argue they reasonably relied upon the results of the DEA and OBOP inspections. "[W]hether [a defendant's] reliance was reasonable is beyond doubt a question of fact for a jury to decide, and not a fit subject for judgment as a matter of law." *Bass v. Janney Montgomery Scott, Inc.*, 210 F.3d 577, 590 (6th Cir. 2000). There is no question the GE Defendants knew, as registrants under the CSA, they were always required to maintain effective controls against diversion. As described above, Plaintiffs have presented sufficient evidence that the scope of the DEA and OBOP inspections was limited ***and*** the GE Defendants knew at least some of their

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a light most favorable to [defendant], the record presents genuine issues of material fact regarding . . . whether [defendant] 'substantially' complied with its duties under the CSA." *Id*.

[6] *See* Motion at 18, n.21 (acknowledging the existence of "minor incidents and thefts that occur from time-to-time in all pharmacies and are self-reported to responsible authorities"); *see also* Reply at 14-19 (describing diversion incidents that the GE Defendants characterize as "isolated incidents" that fall "far short of what is necessary to defeat summary judgment").

[7] *See* Response at 30-31 (listing alleged incidents).

[8] Among other things, Plaintiffs raise important questions involving: (1) the adequacy of the resources the GE Defendants provided to pharmacists in assessing possible risk of diversion of controlled substances; (2) the filling of suspicious prescriptions without requisite due diligence; and (3) documented instances of possible diversion of controlled substances. A reasonable jury could find by a preponderance of the evidence that, far from substantial compliance, the GE Defendants, in fact, violated anti-diversion laws.

controls against diversion were not, in fact, effective. The Court concludes there are triable issues of material fact with respect to whether the GE Defendants' compliance with the CSA and state regulations was substantial and whether their reliance on passed DEA and OBOP inspections was reasonable.

Finally, the GE Defendants argue they were not on notice they could be held liable for not maintaining effective controls against diversion. Although the GE Defendants couch their arguments about notice in Constitutional terms, the Court views the notice issue as an aspect of reliance, and not as a matter of due process. While the GE Defendants rely on excerpted deposition statements of DEA agents to support their argument that they justifiably relied on DEA inspection reports, they also note in their trial brief their opposition to "Plaintiffs' likely invocation of several informal agency statements or publications that do not have the force of law, ***are accorded no weight in this lawsuit***, and do not impose controlling legal requirements on anyone beyond the entity involved in the particular agency adjudication." GE Tr. Br. at 8 (Doc. #: 3880) (emphasis added). The GE Defendants cannot have it both ways; their objections to informal agency statements undercut their reliance and notice arguments, especially in light of evidence that their SOMS and other anti-diversion efforts were less than fully efficacious.

Causation

The GE Defendants also contend they are entitled to summary judgment because Plaintiffs cannot offer evidence that the GE Defendants proximately caused the alleged public nuisance. In particular, they point to the impact of other actors in Lake and Trumbull Counties, such as drug gangs and pill mills, as being the true causes of the opioid epidemic. Motion at 29–31.

Plaintiffs correctly point out, however, that when multiple wrongdoers contribute to a combined harm, a plaintiff may still demonstrate causation by a defendant if that defendant's

conduct was a *substantial factor* in producing the harm. Response at 45. The threshold inquiry is whether the defendant's wrongful conduct had "a substantial as distinguished from a merely negligible effect . . ." RESTATEMENT (SECOND) OF TORTS § 431, cmt. b (1965). Accordingly, it is not sufficient for the GE Defendants to assert there were other bad actors who contributed to the opioid crisis.

The Court has previously denied motions for summary judgment on proximate causation grounds, concluding that, based on the "massive increases in the supply of prescription opioids into [the relevant 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." *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4178617, at *4 (N.D. Ohio Sept. 3, 2019) (Doc. #: 2561 at 8); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 425830, at *2 (N.D. Ohio Jan. 27, 2020) (Doc. #: 3101 at 5). The Court declines to deviate from this position.

Ultimately, questions of proximate cause are typically left to the trier of fact. *See, e.g.*, *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 636 (N.D. Ohio 2020), clarified on denial of reconsideration, No. 1:17-MD-2804, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020) (Doc. #: 3403 at 32) ("Ohio law instructs that proximate cause is ordinarily a question of fact for the jury.") (citing *Brondes Ford, Inc. v. Habitec Sec.*, 38 N.E.3d 1056, 1086 (Ohio Ct. App. 2015)); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 7330956, at *2 (N.D. Ohio Dec. 9, 2020) (Doc. #: 3579 at 3–4) ("[T]he quintessential questions ***for the jury*** in this case are: (i) whether a public nuisance exists; and (ii) if so, was any defendant a substantial factor in causing it?") (emphasis in original).

The question of causation is best left to a jury. Accordingly, the GE Defendants are not entitled to summary judgment on this ground.

The GERX Facility

The GE Defendants argue they are at least entitled to partial summary judgment for all conduct related to their GERX facility because there is no evidence the facility violated any regulation. Plaintiffs, however, respond there is such evidence: the SOMS in place at GERX did not fully comply with CSA regulations from 2016–2017. Specifically, Plaintiffs state the GERX SOMS flagged orders "above a specified threshold" on a daily report, but that "the thresholds were set at 3 times the rolling 12 month *chain-wide* average for a given chemical/ingredient," so that "each store was measured according to a chain-wide average regardless of a particular pharmacy's order history, frequency, or the population it served." Response at 3–4 (emphasis in original). As a result of this allegedly improper threshold level, Plaintiffs assert the GE Defendants "systematically ignored [the GERX's] threshold reports and continued to ship opioids to pharmacies that exceeded the thresholds," such as by sending 21,500 units of generic hydrocodone to a single pharmacy in Trumbull County when the chain-wide threshold was 4,895 units, the smaller figure already being triple the size of the national monthly average. *Id.* at 5.

Once again, Plaintiffs raise genuine issues of material fact; a reasonable jury could conclude there were violations of anti-diversion laws by the GE Defendants emanating from the GERX facility. Accordingly, partial summary judgment on this ground is inappropriate.

Conclusion

Despite the GE Defendants' impassioned insistence that, having passed numerous DEA and OBOP inspections, they cannot now be held liable, Plaintiffs present evidence and 30(b)(6) testimony that would allow a jury to conclude the GE Defendants knew their controls against

diversion were not effective. Indeed, Plaintiffs offer evidence that the GE Defendants' SOMS systems were incapable of stopping suspicious orders before shipping, and the company knew this. The fact that audits by DEA and OBOP inspectors did not reveal alleged serious compliance deficiencies does not now insulate the GE Defendants.[9]

In sum, despite having received passing grades from government inspections, there are material facts in dispute that, when viewed in a light most favorable to Plaintiffs, would allow a jury to find the GE Defendants were not in compliance with the CSA and their actions substantially contributed to a public nuisance in Lake and Trumbull Counties.

For those reasons, the GE Defendants' Motion for Summary Judgement (Doc. #: 3862) is **DENIED**.[10]

IT IS SO ORDERED.

/s/ Dan Aaron Polster September 1, 2021
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

[9] The Court offers this real-life analogy: Jones drives on a highway from tollbooth A to tollbooth B, passing four police officers en route. Each police officer records Jones' speed as being within the legal limit. These four "passing inspections" tend to show Jones did not speed during his trip. Upon arriving at tollbooth B, however, it is revealed that Jones ***must*** have been speeding at some point during his drive, given the total time he took to travel the distance between tollbooths. Jones violated the speed limit, and knew or should have known he did; he wasn't caught by the police officers, but damning evidence is provided by the tollbooth timer. Jones cannot complain he cannot be given a speeding ticket because he relied to his detriment on the four police officers' recordings. Similarly, that the GE Defendants passed their inspections does not prove they were in substantial compliance with the CSA (although it is favorable evidence), and does not insulate them from liability. The fact that other evidence, not discovered by the inspectors, tends to prove knowing, material non-compliance means that summary judgment is not appropriate.

[10] Plaintiffs alternatively request that, should the Court refuse to deny summary judgment regarding the above claims, it should instead defer determination until discovery related to Giant Eagle's due diligence of red flag prescriptions is complete. Because the Court denies summary judgment, Plaintiffs' request is moot.