Multiple Documents

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804
	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' OBJECTIONS TO DISCOVERY RULING NO. 5

October 10, 2018

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INTRODUCTION

Plaintiffs Summit County, City of Akron, Cuyahoga County, and City of Cleveland ("Plaintiffs") hereby object to Discovery Ruling No. 5 ("the Ruling"), issued by Special Master David Cohen on October 6, 2018. (A copy of the Ruling is Ex. 1 hereto.) In the Ruling, the Special Master ordered Plaintiffs to provide additional responses to three interrogatories, numbered 6, 7, and 10, propounded by the Manufacturer Defendants[1] in their First Set of Interrogatories; and to two interrogatories, numbered 2 and 3, propounded by the National Retail Pharmacy Defendants[2] in their First Set of Interrogatories. (Where pertinent, each interrogatory is referred to by its individual number. The five interrogatories that are the subject of the ruling are referred to collectively as the "Interrogatories.") As described more fully below, all of the Interrogatories call for Plaintiffs to identify specific prescriptions they claim were written in reliance on Defendants' marketing, that caused harm to patients, or that were medically unnecessary, and to provide detailed information on each of those prescriptions.

Plaintiffs respectfully submit that the Special Master's ruling was in error and should be overruled by this Court. The Special Master failed to consider that the

[1] As set forth in their interrogatories, the propounding Manufacturer Defendants are Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt LLC; SpecGx LLC; and Insys Therapeutics, Inc.

[2] As set forth in their interrogatories, the propounding National Retail Pharmacy Defendants are CVS Indiana, LLC; CVS Rx Services, Inc.; Rite-Aid of Maryland, dba as Mid-Atlantic Customer Service Center; Walgreens Boots Alliance, Inc.; and Walmart, Inc. dba Walmart Stores, Inc.

Interrogatories all call for Plaintiffs' contentions and/or for expert opinions, inappropriate prior to the completion of fact and expert discovery. The Special Master also failed to consider that, even if the Interrogatories should be answered now, each of them calls for information that requires the examination and analysis of business records (some possessed by Plaintiffs and some by Defendants), and that Plaintiffs have produced (or are in the process of producing) such records to the Defendants. The Special Master did not consider that the examination and analysis could be performed equally by Plaintiffs and Defendants, and, in particular, that it was more appropriate for Defendants to perform the examination and analysis in light of Plaintiffs' repeated representations that the information sought was not relevant to Plaintiffs' claims (because Plaintiffs intend to prove their case with aggregate proof). Thus, the Special Master ordered Plaintiffs to gather, analyze, and produce voluminous data and responses that they do not have and will not develop and on which they do not intend to rely. Moreover, much of the data underlying the Interrogatories is actually in the possession and/or control of the various defendants such that they can access and analyze it for purposes of developing their defenses. Ironically, some defendants have refused to provide Plaintiffs with the information that is the subject of these Interrogatories, namely, the opioid prescriptions they have filled, on the ground that it is not relevant to Plaintiffs' claims.

Thus, the Special Master erred in failing to consider *when* (if at all) the Interrogatories should be answered and failed to consider *how* and *by whom* the Interrogatories should be answered, in light of the need to examine and analyze business records in order to answer the questions. Yet, these were precisely the issues before him. Plaintiffs did not dispute that the Interrogatories were relevant to Defendants' defenses (although not to Plaintiffs' claims) and did not dispute that they would produce, and to a great extent already have produced, the records from which

the answers would, to the extent possible, be derived. The Special Master never addressed these arguments and never considered the underlying questions they raise.

Plaintiffs also note an additional ground for their objection. On October 5, 2018, Magistrate Judge Ruiz issued his Report and Recommendation ("R&R") with respect to Defendants' motions to dismiss Summit County's Second Amended Complaint. Ex. 4. As discussed below, the R&R's clarification of what Plaintiffs must, and need not, allege at the pleading stage is relevant to what information Plaintiffs can properly be required to provide before they receive complete discovery from the Defendants. The Special Master did not have the benefit of the R&R at the time he decided Defendants' motion to compel.[3] His ruling, requiring immediate identification of particular prescriptions, particular doctors, and particular patients, is at odds with the Magistrate Judge's conclusion in the R&R that Summit County was not required to plead these details in its Complaint. It would defeat the purpose of Rules 8 and 9 of the Federal Rules of Civil Procedure if Plaintiffs whose pleadings are deemed sufficient to survive a motion to dismiss could be immediately required to provide details absent from their pleading prior to having an opportunity to take discovery.

For all of these reasons, the Ruling should be reversed and this Court should hold that Plaintiffs may produce their records in lieu of answering the Interrogatories and that, to the extent that the Interrogatories seek Plaintiffs' contentions and or seek to discover opinion testimony as to which Plaintiffs should provide answers, the time for providing those answers should be deferred to the time of expert discovery.

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[3] The Special Master's decision was originally issued on October 2, 2018. The R&R was issued on October 5, 2018. Thereafter, on October 6, 2018, the Special Master formalized his October 2 ruling as Discovery Ruling No. 5. Thus, even though the Ruling was issued after the R&R, the Special Master did not have the benefit of the R&R when he made the initial ruling; the formalization of the ruling did not change the substance or the basis of the October 2 informal ruling.

PROCEDURAL BACKGROUND

The Interrogatories

The full text of each of the Interrogatories is provided in Exhibits 2 and 3. In brief, Interrogatory No. 6 calls for Plaintiffs to "[i]dentify and describe all prescriptions of opioids that were written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant," specifying details about each such prescription that must be provided. *See* Ex. 2at 4-5. Interrogatory No. 7 asks Plaintiffs to "[i]dentify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in [Plaintiff's jurisdiction]" and calls for Plaintiffs to provide a wealth of details about each person identified. *Id*. at 5. Interrogatory No. 10 asks Plaintiffs to "[i]dentify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful," and as is the case for Nos. 6 and 7, specifies details for each prescription that should be provided. *Id*. at 6.

Interrogatory No. 2 requires Plaintiffs to "Identify each prescription upon which you base, or which you contend supports, Your claims [against the National Retail Pharmacy Defendants] in this case." *See* Ex. 3 at 3. Interrogatory No. 3 calls for Plaintiffs to "[i]dentify each prescription the filling of which caused or led to harm for which you seek to recover in this case." *Id.*

Plaintiffs' Responses and Defendants' Motions to Compel

On May 25, 2018, Summit County provided its initial responses and objections to the Manufacturers' First Set of Interrogatories. *See* Ex. 5. Plaintiff objected to Interrogatories No. 6, 7, and 10 on a variety of grounds, including that the interrogatories were overbroad, irrelevant to Plaintiff's claims, were contention interrogatories, and called for information to be provided in expert reports. *Id.* On June 12, 2018, Summit County provided its First Amended Response to these interrogatories. *See* Ex. 6. Plaintiff reiterated its objections, but added a list of prescription opioids at

issue in the case and further added the following information: "Plaintiff further responds that the increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; 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." *See id.* at 36-38. The other Plaintiffs provided similar responses.

On August 4, 2018, the Manufacturer Defendants wrote to the Special Master seeking a ruling compelling Plaintiffs to provide further answers to Interrogatories No. 6, 7, and 10. Ex. 7. On August 17, 2018, Plaintiffs responded to the August 4 letter. Ex. 8. In connection with their August 17 letter, Plaintiffs provided Defendants another set of amended responses to the Manufacturers' First Set of Interrogatories. Ex. 9. Consistent with the position set forth in the August 17 letter, the amended responses invoked Rule 33(d) and identified records that had been, or would be, produced, from which the answers to the Manufacturers' questions could be derived. *See id.* at 49, 52.

On August 24, 2018, the Manufacturer Defendants wrote to the Special Master again, rejecting Plaintiffs' amended responses, reiterating their request for a ruling, and seeking oral argument on their motion to compel. Ex. 10.

In the meantime, on July 23, 2018, Summit County provided its initial responses to the National Retail Pharmacy Defendants' first set of interrogatories. Ex. 11. In the response, Summit County objected to Interrogatories 2 and 3 on the grounds, *inter alia*, that they were contention interrogatories and that the information was equally available to the defendants from business records in their possession or from records produced by the Plaintiffs. *Id.* at. 6. In response to Interrogatory No. 3, Summit County provided a list of pharmacies that had suspicious orders for opioids within Summit County, Ohio, and a separate list of pharmacies that the largest shipments of opioids into Summit County. *Id.* at 8-12.

On September 24, 2018, counsel for the National Retail Pharmacy Defendants wrote to the Special Master seeking a ruling compelling Plaintiffs to provide further answers to Interrogatories 2, 3, and 7 posed by the National Retail Pharmacy Defendants. Ex. 12. On September 26, 2018, Plaintiffs amended their responses to the National Retail Pharmacy Defendants' first set of interrogatories. Ex. 13. Plaintiffs continued their objections to Interrogatories 2 and 3, but provided, in response to Interrogatory No. 2, a list of documents, identified by Bates numbers, that contained responsive information. *See, e.g.*, Ex. 13 at 7.

On September 25, 2018, the Special Master set for hearing on September 28, 2018, the motion to compel with respect to the five Interrogatories at issue here.[4] Ex. 14.

The Ruling

The Special Master held a hearing on both the Manufacturers' and the National Retail Pharmacies' motions to compel on September 28, 2018 (the "Hearing"). (A transcript of the Hearing is Exhibit 15.) On October 2, 2018, the Special Master issued an informal ruling in an email. Ex. 16. On October 5, 2018, Plaintiffs requested that the Special Master issue a formal ruling. Ex. 17. On October 6, 2018, the Special Master filed Discovery Ruling No. 5, formalizing his October 2 order. Ex. 1.

In the Ruling, the Special Master did not address whether the Interrogatories were contention Interrogatories, nor did he address whether Plaintiffs could respond by producing their underlying documents. Instead, the Ruling re-wrote the Interrogatories and ordered Plaintiffs to respond promptly to the reformulated questions.

[4] The National Retail Pharmacy Defendants' motion with respect to their Interrogatory 7 was deferred for argument in connection with similar issues raised by the Distributor Defendants. Over Plaintiffs' objection, the Special Master decided to include the motion to compel with respect to Interrogatories 2 and 3 in the September 28 hearing, despite the fact that the National Retail Pharmacy Defendants had first raised the issue only four days previously and Plaintiffs had not had an opportunity to respond in writing to the motion.

In particular, where Interrogatory No. 6 called for identification of all prescriptions of opioids that were written in Plaintiff's jurisdiction in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant, the Special Master instead required Plaintiffs to identify 500 such prescriptions, at least 10 for each manufacturer. *Id*. at 2-3. Instead of identifying every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in Plaintiff's jurisdiction, as requested in Interrogatory No. 7, the Special Master ordered Plaintiffs to identify 300 such persons, again specifying that at least 10 must have been prescribed an opioid made by each of the Manufacturers. *Id*. at 3. Similarly, for Interrogatory No. 10, the Special Master modified Defendants' demand that Plaintiffs "[i]dentify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful," instead requiring Plaintiffs to identify 500 such prescriptions, at least ten for each Defendant. *Id*. at 4. The Special Master made similar edits to Interrogatories No. 2 and 3, calling for Plaintiffs to identify 500 prescriptions (instead of "each prescription") that Plaintiffs contend support their claims against the National Retail Pharmacies and 500 prescriptions (instead of "each prescription") "the filling of which caused or led to harm for which you seek to recover in this case." *Id*. at 4-5.

In addition, the Special Master ruled that Defendants could amend the Interrogatories to require Plaintiffs to state their contentions with respect to prescriptions and persons identified by the Defendants. Thus, the Ruling permits the Defendants to provide their own lists of 200 prescriptions (for Interrogatories No. 6 and 10) and 100 persons (for Interrogatory No. 7) and requires Plaintiffs to state whether each of the 200 prescriptions was written in reliance on Defendants' wrongdoing (for Interrogatory No. 6) or was medically unnecessary, ineffective, or harmful (for Interrogatory No. 10), or whether each person (for Interrogatory No. 7) became

addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s). *Id*. at 2-5.

Plaintiffs now object to the Ruling.

I. THE SPECIAL MASTER FAILED TO CONSIDER WHEN AND HOW THE INFORMATION REQUESTED IN THE INTERROGATORIES SHOULD BE PROVIDED

In Discovery Ruling No. 5, the Special Master ordered Plaintiffs to provide further responses to the Interrogatories without conducting the analyses required by Rule 33 of the Federal Rules of Civil Procedure, or considering the provisions of Rule 26 pertaining to expert disclosure which pertain to when and how information requested in interrogatories must be provided.

Two provisions of the Federal Rules are relevant to the issue of *when* particular information must be provided. First, Rule 33(a)(2) provides that, although "an interrogatory is not objectionable merely because it asks for an opinion or contention that relates to fact or the application of law to fact," the court may "order that the interrogatory need not be answered until designated discovery is complete, or until a pretrial conference or some other time." Fed. R. Civ. P. 33. In addition, Rule 26 requires that information about opinion testimony including "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them" must be disclosed "(i) at least 90 days before the date set for trial or for the case to be ready for trial; or (ii) if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B) or (C), within 30 days after the other party's disclosure." Fed. R. Civ. P. 26(a)(2)(A), (B), (D). The question whether Plaintiffs are required to answer the Interrogatories now or at some later date is thus governed by these provisions, but the Special Master failed in his Ruling to consider either of them.

Similarly, where information must be culled from records, Rule 33(d) provides:

> If the answer to an interrogatory may be determined by examining, auditing, compiling, abstracting, or summarizing a party's business records (including electronically stored information), and if the burden of deriving or ascertaining the answer will be substantially the same for either party, the responding party may answer by:
>
> (1) specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could; and
>
> (2) giving the interrogating party a reasonable opportunity to examine and audit the records and to make copies, compilations, abstracts, or summaries.

Fed. R. Civ. P. 33(d). As was the case with respect to the question of timing, the Special Master failed to consider in his Ruling *who* should do the work of analyzing the underlying information provided in discovery, by both sides, to determine, to the extent possible, the answers to the Interrogatories.

Because the Special Master failed to consider the effect of Rules 26 and 33 on when and how the interrogatories should be answered, this Court should undertake that analysis now. With respect to the timing of any answers, the Court should conclude that the Interrogatories in question are contention interrogatories and seek opinion testimony, and therefore Plaintiffs should not be required to answer them now, but, to the extent required, only at the close of discovery and/or in accordance with the deadlines set by the Court for the disclosure of expert opinion testimony. To the extent the Court believes, however, that the Interrogatories should be answered now, pursuant to Rule 33(d), the Court should find that Plaintiffs satisfied their discovery responsibilities by providing (and agreeing to continue to provide) to Defendants the records in their possession, custody, or control with the information from which the answers to the Interrogatories can be determined.

II. THE INTERROGATORIES ARE CONTENTION INTERROGATORIES AND SEEK OPINION TESTIMONY

A. The Interrogatories Call for Contentions, Including Contentions Plaintiffs Do Not Make

Each of the Interrogatories calls for Plaintiffs to state their contentions. Two of them—Interrogatories 10 and 2—explicitly use the term "contend." *See* Ex. 2 at 6, No. 10: ("Identify and describe all prescriptions of opioid(s) that Plaintiff *contends* were unauthorized, medically unnecessary, ineffective, or harmful") (emphasis added); Ex. 3 at 3, No. 2 ("Identify each prescription upon which you base, or which *you contend* supports, Your claims in this case.") (emphasis added). Although the word "contend" is absent from the other three, they similarly seek Plaintiffs' contentions. Interrogatory No. 7, for example, uses the term "allegedly" to seek Plaintiffs' contentions, asking that Plaintiff identify persons "who *allegedly* became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in [Plaintiff's jurisdiction]." Ex. 2 at 5 (emphasis added.) Similarly, "[i]dentify and describe . . . prescriptions of opioids that were written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant" (Interrogatory No. 6) is clearly a request to identify prescriptions that Plaintiffs *contend* were made in reliance. *Id.* at 4-5. Similarly, Interrogatory 3 calls for Plaintiffs to "[i]dentify each prescription the filling of which caused or led to harm for which you seek to recover in this case" and further requires Plaintiffs to "explain how [each identified prescription] supports Your claims."[5] Ex. 3 at 3.

[5] *See also*, Exhibit 7 at 7 where defendants state: "Plaintiffs have the capability to identify instances of opioid addiction and opioid overdoses and/or deaths in their jurisdiction and cross reference that information with state reimbursement data, medical records, and other information in Plaintiffs' possession to determine whether that individual was ever prescribed or abused a prescription opioid and if so, whether Plaintiffs claim that prescription was medically unnecessary or written by a prescriber that was misled by one of the Manufacturer Defendants."

Thus, not one of the Interrogatories calls for Plaintiffs to provide *factual* information to the Defendants. Indeed, that the Interrogatories all call for Plaintiffs' contentions is clear from Defendants' objections to Plaintiffs' invocation of Rule 33(d). In response to the proposition that the information was equally available to both parties and could be discovered by Defendants through examination of the records provided by Plaintiffs, the Defendants responded, in effect, that such a procedure would not tell them what Plaintiffs contend. *See* Ex. 10 at 4 (arguing that Rule 33(d) procedure was not appropriate because "Manufacturer Defendants cannot discern which, if any, opioid prescriptions Plaintiffs claim were medically unnecessary or written in reliance on an alleged misstatement."). Thus, the thrust of Defendants' argument is that they need Plaintiffs to provide answers in order to learn Plaintiffs' contentions.

The Federal Rules of Civil Procedure allow courts to defer answers to contention interrogatories because they "may create disputes between the parties which are best resolved after much or all of the other discovery has been completed." *Francis v. Lakewood Eng'g & Mfg. Co.*, No. 05-2429 MaV, 2006 U.S. Dist. LEXIS 102921, at *7-8 (W.D. Tenn. July 18, 2006); *see also United States v. Quebe*, No. 3:15-cv-294, 2017 U.S. Dist. LEXIS 9005, at *43 (S.D. Ohio Jan. 23, 2017) (*citing* Fed. R. Civ. P. 33(b) Advisory Committee's Note (1970)). The primary purpose of contention interrogatories, "is to narrow the issues for trial rather than providing the foundation for substantial follow-on discovery." *Lincoln Elec. Co. v. Travelers Cas. & Sur. Co.*, 2013 U.S. Dist. LEXIS 189111, at *188-89 N.D. Ohio Feb. 5, 2013) (*quoting Ross v. Abercrombie & Fitch Co.*, Nos. 2:05-cv-0819, 2:05-cv-0848, 2:05-cv-0879, 2:05-cv-0893, 2:05-cv-0913, 2:05-cv-0959, 2010 U.S. Dist. LEXIS 144383, at *10 (S.D. Ohio Feb. 4, 2010)).

Here, it is especially inappropriate to require Plaintiffs to provide their contentions at this stage of the case, for four reasons. First, Plaintiffs have very limited amounts of prescription data in their possession, custody, or control. Much of the information about prescriptions remains in the hands of the Defendants or third parties.

See, e.g., Ex. 15 at 33:19-36:25. Second, as explained by Magistrate Judge Ruiz in the R&R, Plaintiffs are not required to have this information at this stage of the case. *See* ex. 4 at 25 n.20, 30-31.[6] To require Plaintiffs to provide by interrogatory answer what they are not required to plead, without first allowing them to take discovery, would circumvent and undermine the federal pleading standards set forth in Rules 8 and 9.

Third, Plaintiffs are not required to identify specific prescriptions, doctors, or patients in order to prove their case. Rather, in analogous situations, courts have permitted aggregate proof, recognizing that conduct broadly directed at a community at large cannot be atomized into a series of individual decisions in order to obscure the larger picture. For example, in *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 29 (1st Cir. 2013), the First Circuit noted that "no physician in this case, or in the Neurontin MDL as a whole, testified that he or she prescribed Neurontin because of defendants' fraudulent off-label marketing." Instead, the plaintiffs in *Neurontin* relied on statistical, aggregate proof, explaining that plaintiffs' experts' "regression analysis found a causal connection between the fraudulent marketing and the quantity of prescriptions written for off-label indications." *Id.* at 29-30. The court further noted that such aggregate proof could in fact be "preferable" to individualized, prescription-by-prescription analysis:

> Dr. Rosenthal testified as to the well-recognized unreliability in the field of healthcare economics of asking doctors individually whether they were influenced by the many methods of off-label marketing. She said that self-reporting from physicians about patterns of practice that may be controversial shows both conscious reluctance and unconscious bias,

[6] Although the R&R suggests that "Defendants will certainly have the opportunity to request the identity of [specific doctors alleged in the complaint to have confirmed the deceptive marketing] during discovery, and Plaintiffs will need to support their theories with evidence to withstand a motion for summary judgment or persuade the trier of fact." Ex. 4 at 25 n.20, nothing in the R&R can be read to suggest that Plaintiffs ought to be required to make any such showing before receiving discovery from the Defendants and third-parties as needed.

> which lead them to deny being influenced. As a result, it is preferable "[t]o examine objectively the causal association between promotion and sales using ... econometric models." Dr. Rosenthal utilized the standard practice of using "aggregate data and . . . statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug." Dr. Rosenthal testified that it was "neither standard nor appropriate to look physician by physician."

Id. at 30. Notably, in the R&R, Magistrate Judge Ruiz cited and relied on *Neurontin*, specifically with respect to whether Plaintiffs were required to identify individual prescriptions at the pleading stage. *See* Ex. 4 at 30-31. Indeed, the R&R specifically finds "the rationale of *In re Neurontin* more compelling" than the authority cited by Defendants to support their claim that Plaintiffs ought to have identified individual prescriptions to the outset.[7]

While *Neurontin* involved claims by a third-party payor of fraudulent behavior by a pharmaceutical manufacturer, the court in *People v. ConAgra Grocery Prod. Co.*, 17 Cal. App. 5th 51 (Cal. Ct. App. 2017), *reh'g denied* (Dec. 6, 2017), *review denied* (Feb. 14, 2018), examined the issue of aggregate proof in the context of a nuisance claim. The court found that it was proper for each plaintiff to prove the existence of a nuisance in its jurisdiction by using aggregate data concerning the number of homes in each jurisdiction constructed before lead paint was banned, the number of housing units in each entity with lead paint hazards, and the total number of children who were

[7] At the Hearing, one of the lawyers for the Defendants argued that some individual depositions were taken of some individual doctors in the *Neurontin* litigation and that some individualized proof was offered (at least by the defendants). *See* Ex. 15 at 18:16-19:10. The actual scope of this discovery does not appear in the transcript, nor is it mentioned in the *Neurontin* court opinion. But nothing in the record suggests that plaintiffs were required to provide defendants with lists of prescriptions and patient and provider related data, so that defendants could pursue that individualized proof. Here, defendants are certainly free to rely on the voluminous information in their possession to depose health care providers to whom they marketed or who wrote prescriptions for their drugs and from they can submit expert opinions on the impact of their marketing and the appropriateness of their prescriptions. .

poisoned by lead in each jurisdiction. *See id.* at 113-16. The court also rejected the argument that plaintiffs must prove the location and identity of each coat of lead paint that was applied to any surface in the jurisdictions in order to succeed in their public nuisance claim. As these cases show, it is perfectly proper for Plaintiffs to prove their case through aggregate proof and to articulate a causal chain that recognizes the aggregate nature of the harms Defendants have caused.

Finally, it is especially inappropriate to require Plaintiffs to provide their contentions at this stage of the case because, for the most part, the Interrogatories pertain to *Defendants'* contentions, not Plaintiffs'. As already discussed, Plaintiffs intend to prove their case through aggregate proof. Moreover, in their opposition to the Motion to Compel, Plaintiffs expressly stated:

> Plaintiffs contend that Defendants' misrepresentations affected every prescription for opioid therapy, because, in light of Defendants' concealment of the truth, no doctor was able to perform a proper risk/benefit assessment without accurate information about either the risks or the benefits. *See* Summit SAC ¶¶ 146, 155-160, 174-76, 178, 351-56, 488-94, 714.[8] This does not mean that no prescriptions would have been written, but rather that every prescription was affected in some form by Defendants' misrepresentations and omissions—in whether to prescribe opioids, at what dosages, and for what length of time. Defendants' conduct also impacted what cautions were conveyed to patients, how patients were monitored, and how and whether doctors identified signs of addiction. *See, e.g.*, Summit SAC at ¶ 177.

Ex. 8 at 2-3. Thus, not only did the Special Master require Plaintiffs to provide their contentions at this stage of the case, he rejected, as inadequate, Plaintiffs' *actual* contention (that every prescription was influenced by the Defendants' misrepresentations). Requiring Plaintiffs to pick a set of 500 or 300 prescriptions from

[8] As set forth in Plaintiffs' letter opposition, each of the Plaintiffs had already disclaimed any intention of seeking reimbursement from the Defendants for prescriptions paid for by the Plaintiff based on the contention that the prescription for which reimbursement is sought was improper or not medically necessary. *See* Exhibit 8 at 2 n.4.

all of the prescriptions written in the jurisdictions, particularly when Defendants already have this data, and Plaintiffs do not, would do little to advance discovery.

The problem is even more significant in the context of Interrogatory No. 10. There, Defendants request that Plaintiffs identify prescriptions that "Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful." Ex. 2 at 6. As the R &R recognized, Plaintiffs' claims do not turn on the contention that specific prescriptions were unauthorized, medically unnecessary, or ineffective. Indeed, at the Hearing, Plaintiffs specifically explained that they made no such contention and, indeed, that the term "medically unnecessary" does not appear anywhere in the Amended Complaints. *See* Ex. 15 at 28:12-17, 50:7-13. (In this way, the claims in this case are distinct from those in the *City of Chicago* opioid litigation as originally pleaded. In that case, the claims include false claims allegations, which turned on whether a claim for medical reimbursement was false because the prescription was not medically necessary or appropriate, as required under the reimbursement plan. No such claims are asserted here.)[9] The National Retail Pharmacy Defendants' interrogatories are no

[9] Defendants argued, at the hearing, that even if Plaintiffs did not use the term "medically unnecessary," they did use the term "legitimate medical uses." *See* Ex. 15. at 56:21-57:7. But review of the Summit Second Amended Complaint shows that the term "legitimate medical use" has nothing whatsoever to do with the concept of "medical necessity." The term "legitimate medical use" appears in the SAC in two contexts, neither of which pertains to actual prescriptions. First, in the context of diversion, Plaintiffs allege that more opioids were shipped into particular jurisdictions than could be justified by legitimate medical use. *See* Ex. 18at ¶¶ 14, 396, 502, 555. These allegations do not suggest that particular prescriptions were influenced by the Manufacturers or were "medically unnecessary," but rather than the volume of pills was so great that it could be inferred that some of them were not for medical use at all. Second, Plaintiffs allege that *Defendants* assured doctors that addiction was rare in patients taking opioids for "legitimate medical use." *See, e.g., id.* at ¶¶ 15, 189, 196, 216, 219, 221, 230, 748. In this context, it would be more appropriate to ask Defendants what they meant by the term "legitimate medical use." In any event, the Interrogatories do not use the term "legitimate medical use" and thus do not seek Plaintiffs' contentions with respect to the term that does appear in the complaints.

better. Interrogatories 2 and 3 seek, respectively, identification of prescriptions that form the basis for, or support Plaintiffs' claims and prescriptions the filling of which led to harm for which Plaintiffs seek to recover. Ex. 3 at 3. These same defendants have refused to provide information about the opioid prescriptions they have filled, on the basis that the information is not relevant to Plaintiffs' claims. *See* Ex. 15 at 51-53. To the extent that Plaintiffs intend to prove that the National Retail Pharmacy Defendants filled prescriptions they should not have,[10] Plaintiffs should be able to obtain information in discovery about what prescriptions were filled before identifying particular problematic prescriptions.

As the Manufacturer Defendants made clear at the Hearing, they intend to defend these cases by demonstrating that particular individual prescriptions were necessary and beneficial; by presenting testimony of doctors who did not prescribe in reliance on Defendants' misrepresentations; and by demonstrating that individuals who were harmed by opioids were not harmed by any of Defendants' products. *See* Ex.15 at 7:13-23. The National Retail Pharmacy Defendants intend to show that even when they shipped suspicious orders, those suspicious orders did no harm. *Id.* at 26:16-27:9.[11] Defendants are, of course, entitled to mount these defenses.

What they are not entitled to do is to require Plaintiffs to create a strawman for them to knock down. The contentions Defendants seek are not Plaintiffs' contentions in this case, at least not at this stage of the case, based on the discovery so far available.

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[10] Summit County has specifically disclaimed any claim against the National Retail Pharmacy Defendants based on their retail dispensing opioids. *See* Ex. 19 at 75 n.47.

[11] Plaintiffs' claims against distributors, including the National Retail Pharmacy Defendants in their capacity as distributors, are not limited to the shipment of "suspicious orders," but arise more generally from the distributors' obligation and failure to prevent diversion of dangerous opioid products. *See, e.g.,* Ex. 18 Summit SAC ¶¶ 499, 502, 507, 524-25; Ex. 4 at 9, 77, 81.

Plaintiffs should not be required to make identifications that are not part of their case and do not reflect Plaintiffs' actual contentions, just so that Defendants can refute them.

Defendants do not need to know which prescriptions Plaintiffs believe were written in reliance on Defendants' misrepresentations, or which ones, if any, Plaintiffs believe were "medically unnecessary" in order to present evidence (if they can) that some prescriptions were not influenced or were proper or helpful. They can develop this evidence on their own, from the factual information provided by Plaintiffs in discovery, or already in their possession, or obtained from third-parties (or other Defendants) during discovery. It may be that Defendants will be entitled to know, before trial, whether there are particular prescriptions, patients, or doctors that Plaintiffs intend to use as examples. It may be that, at the close of fact discovery, Defendants will be entitled to know whether, after reviewing the evidence amassed in discovery, Plaintiffs still contend that all prescriptions were affected by Defendants' misrepresentations, or whether there is a more specific category of prescriptions Plaintiffs believe were not medically necessary. It may be that, before trial, the National Retail Pharmacy Defendants will be entitled to know which of the orders they shipped Plaintiffs contend should not have been shipped. But such information falls squarely within Rule 33's recognition that this kind of contention information is more appropriately provided at the close of discovery than in response to initial interrogatories. Nor should Plaintiffs be limited, at summary judgment or trial, to prescriptions or patients they happen to have information about now.[12]

[12] Plaintiffs note that the Advisory Committee Notes to the "contention interrogatory" provision of Rule 33 suggest that premature contention answers are not binding in any event. The Advisory Committee noted concerns about parties being "chained to misconceived contentions or theories," but found this not a significant concern in part because "[t]he general rule governing the use of answers to interrogatories is that under ordinary circumstances they do not limit proof." Advisory Committee Note, Fed. R. Civ. P. 33(b) (1970). The Advisory Committee further elaborated that "the interrogating party will ordinarily not be entitled to rely on the unchanging character of the answers (footnote continues on next page)

B. The Interrogatories Call for Opinions that Will Be the Subject of Expert Testimony

The Interrogatories also call for expert opinion, which pursuant to this Court's scheduling orders, need not be provided until February 8, 2019. The question whether a prescription is "medically necessary" is, for example, quintessentially a matter of opinion that can only be determined by expert testimony. Indeed, at the Hearing, counsel for the Manufacturers argued that Plaintiffs can "look at the prescriptions for which they've reimbursed . . . [a]nd they can tell us for those reimbursed prescriptions, which ones do they *think* should not have been written." Ex. 15 at 11:6-11 (emphasis added). Counsel further argued that "when you're talking about medically appropriate or medically proper prescriptions, there are criteria that one might use to determine based on [a person's] medical history whether the prescription written for two months or three months of opioids was appropriate given the medical circumstances." *Id.* at 14:21-25. She further argued that "We can't do that for them" because "*we don't know what criteria they're using*." *Id.* at 15:1-5 (emphasis added)[13]; *see also id*. at 10:17-22 ("There are prescriptions out there that everyone should be able to agree were fine, were medically appropriate, were written for a person who needed them by a doctor exercising their judgment . . . and we're entitled to know which ones are and which ones aren't."). These arguments make clear that what Defendants seek is expert, opinion testimony.

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he receives" and that "[t]he rule does not affect the power of a court to permit withdrawal or amendment of answers to interrogatories." *Id.* Thus, forcing Plaintiffs to identify their contentions now does not commit them to those contentions in any event, and thus is of little use to Defendants in preparing for summary judgment motions or trial. Answers provided at the end of discovery are, by contrast, more likely to reflect the actual contentions that will be at issue at summary judgment or trial.

[13] As noted above, this argument was especially problematic because Plaintiffs have not used the term "medically necessary" and thus have not had occasion to develop criteria for this.

Similarly, the question whether a particular individual was harmed by prescription opioids (the information called for in Interrogatory No. 7) is well recognized to be the subject of expert opinion testimony. Certainly an individual who brings a personal injury claim involving a prescription drug must present expert evidence to establish that he was harmed and that the harm was caused by the drug in question. *See, e.g., Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715, 724 (N.D. Ohio 2007); *In re Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004); *Silverstein v. Procter & Gamble Mfg. Co.*, 700 F. Supp. 2d 1312, 1316 (S.D. Ga. 2009). Plaintiffs' claims here do not turn on proof that a specific drug caused harm to a specific individual, but the Interrogatories do, and to the extent they seek information about the relation between Defendants' conduct and harms experienced in and by Summit County, that information is no less a matter of expert opinion than it would be in a personal injury case. Finally, as the First Circuit recognized in Neurontin, the question whether doctors were influenced by a pharmaceutical company's marketing is the subject of expert testimony; indeed, the court noted that expert testimony was the preferred method of addressing this question. *In re Neurontin,* 712 F.3d at 29-30.

The Interrogatories posed by the National Retail Pharmacy Defendants also call for opinions and expert conclusions. The National Retail Pharmacy Defendants argued that they needed to know which prescriptions were medically unnecessary in order to refute Plaintiffs' arguments that these defendants shipped suspicious orders. But whether particular orders shipped by these defendants as distributors ought not to have been shipped or whether particular prescriptions ought not to have been filled are matters of opinion.

The deadline for expert disclosures is still months away. To the extent that Plaintiffs experts will opine about medically unnecessary prescriptions, Plaintiffs should not be required to answer interrogatories on those subjects before their experts have had an opportunity to complete their analysis. In this respect, the Special Master

erred in requiring Plaintiffs to answer the Interrogatories now, rather than deferring the time to answer until the deadline for expert disclosures, as Rule 33 expressly permits.

C. The Special Master's Edits to the Interrogatories Do Not Justify Requiring Immediate Answers

The Special Master's edits to Defendants' Interrogatories does not make immediate answers any more appropriate. Although the Special Master relieved Plaintiffs of the burden to identify *every* prescription and *every* patient affected, he nonetheless required Plaintiffs to state their contentions with respect to 500 prescriptions, and 300 patients, of their own choosing. The questions still call for contentions and expert opinions and the answers are no less premature for being narrower in scope. Moreover, the Special Master *added* to the Interrogatories by permitting the Defendants to identify to Plaintiffs 200 prescriptions, and 100 patients, as to which Plaintiffs are required to formulate detailed contentions that do not now exist.

III. THE ANSWERS TO THE INTERROGATORIES ARE EQUALLY AVAILABLE TO DEFENDANTS FROM THE UNDERLYING FACTUAL MATERIAL

In their Second Amended Responses, Plaintiffs invoked the provisions of Rule 33(d), which permit them to respond to interrogatories by providing the records from which the information can be culled (to the extent it can be at all) so that Defendants could perform for themselves the analysis the Interrogatories called for. Ex. 9 at 49, 52. As noted above, Rule 33(d) permits a responding party to provide its records in lieu of extracting information from them "if the burden of deriving or ascertaining the answer will be substantially the same for either party." Rule 33(d). The rule provides an *option* at the election of the responding party. *See Daiflon, Inc. v. Allied Chem. Corp.*, 534 F.2d 221, 225 (10th Cir. 1976) (Rule 33 "gives the party served the option of producing records from which the answer can be obtained instead of preparing a direct answer"); Advisory Committee Notes, Fed. R. Civ. P. 33(c) (1970) ("The subdivision gives the

party an option to make the records available and place the burden of research of the party who seeks the information.").

"Interrogatories cannot require the responding party to make extensive investigations or conduct complex research." *Miller v. Pruneda*, 236 F.R.D. 277, 282 (N.D.W. Va. 2004). Rule 33(d) provides a mechanism by which the burden of such research can be placed on the party who will benefit from it. *See* Advisory Committee Notes, Fed. R. Civ. P. 33(c) (1970) ("without undermining the liberal scope of interrogatory discovery, [Rule 33(c)] places the burden of discovery upon its potential benefittee."). *See also Wilkinson v. Greater Dayton Reg'l Transit Auth.*, No. 3:11CV00247, 2012 WL 3527871, at *9 (S.D. Ohio, Aug. 14, 2012) (under FRCP 33(d), producing party was not required to perform analysis of a "gigantic number of documents" to provide individualized information based on requesting parties theory of the case); *Lunkenheimer Co. v. Tyco Flow Control Pac. Party Ltd.*, No. 1:11-CV-824 2015 WL 631045, at *2 (S.D. Ohio, Feb. 12, 2015) (answer to interrogatory not required when burden to derive answer was the same for both sides); *FenF, LLC v. Healio Health Inc.*, Case No. 5:08CV404, 2008 WL 11379993, at *3 (N.D. Ohio, 2008) (FRCP 33(d) satisfied when the "burden of reviewing those records would be equal upon Plaintiff as it would be on Defendants").

The only limit on the use of Rule 33(d) is the requirement that "the burden of ascertaining the answer be substantially the same for both sides." Advisory Committee Notes, Fed. R. Civ. P. 33(c) (1970). Here, Defendants' only argument that the burden was not substantially the same for both sides was that the Interrogatories seek Plaintiffs' *contentions*, not underlying factual information. *See* Ex. 7 at 7; *see also* Ex. 15. at 15:1-5. To the extent this is true, Plaintiffs should not be required to answer the Interrogatories until the close of discovery. But, to the extent Defendants seek factual information about prescriptions and patients to be derived from records in Plaintiffs' possession, there is no basis to conclude that the information is not equally available to the Defendants.

This is especially true because, as discussed above, the Interrogatories pertain to Defendants' defenses, not to Plaintiffs' claims, making it especially appropriate to impose the burden on them.

Indeed, in nearly identical circumstances, a district court in Tennessee rejected a nursing home's request to require the government to identify individual false claims. *United States ex rel. Glenda Martin v. Life Care Centers of America, Inc.*, Nos. 1:08-cv-251, 1:12-cv-64, 2015 WL 10987029, (E.D. Tenn. Feb. 18, 2015). In *Life Care*, the court had held (twice) that the government could prove its case through statistical sampling and extrapolation. *d.* at *2. Defendant subsequently sought to compel the Department of Justice to identify "each of the alleged claims, records or statements on which the Government intends to establish liability and damages" and "those submitted claims that resulted from, or were caused by Life Care's alleged corporate pressure." *Id.* at *1. In denying the motion, the court noted that: "Defendant is not simply requesting that the Government disclose discovery, they are essentially requesting that the Court impose an affirmative burden on the Government to identify each claim in the total universe of claims which could be categorized as false." *Id.* at *3. Like Defendants here, the nursing home claimed that the discovery was critical to its ability to investigate and develop its factual defenses. *Id.* "Simply because the Defendant may choose, among these options, to pursue a litigation strategy that relies on a claim-by-claim review does not justify placing the burden on the Government to be the party that performs that review." *Id.* Because the government produced the underlying claims data, defendant had the information to perform the analysis itself. *Id.* The court noted that defendant's complaints regarding the burden of conducting such a review "seems to reinforce the Court's earlier observation that insistence on such an individualized review by either party is not justified in this case." *Id.*

For the same reasons, this Court should reject the Special Master's rulings and, to the extent the Court believes the Interrogatories should be answered now, the Court

should hold that the answers already provided, including the designation of records from which the answers can be derived, is sufficient and no further answers are required.

CONCLUSION

For the foregoing reasons, this Court should overrule the Ruling of the Special Master and should deny Defendants' motion to compel further answers to the Interrogatories. To the extent the Court believes further answers are appropriate at a later date, the Court should set that date no sooner than the deadline for Plaintiffs to provide expert reports.

Respectfully submitted,

/s/ Elizabeth J. Cabraser

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EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	
	)	**SPECIAL MASTER COHEN**
THIS DOCUMENT RELATES TO: "*Track One Cases*"	)	
	)	
	)	**DISCOVERY RULING NO. 5**
	)	

This *Ruling* addresses Interrogatories propounded by defendants that ask plaintiffs to identify (1) specific, inappropriate opioid prescriptions, and (2) specific persons who became addicted due to those prescriptions. Plaintiffs insist this discovery is inappropriate and irrelevant, and also imposes an excessive burden. Defendants respond their Interrogatories are highly relevant and directed at the heart of plaintiffs' claims, and the burden is reasonable.

Having considered the parties' position statements, and also oral arguments related to similar topics, the Special Master concludes as follows. The plaintiffs' objections are upheld in part, to the extent that plaintiffs do not have to identify ***all*** prescriptions and ***every*** person, as requested in the Interrogatories. Rather, the Special Master rules that plaintiffs must respond to the five

Interrogatories at issue ***as rewritten below***.[1]

* * * * *

Manufacturer Interrogatory No. 6

Identify and describe all prescriptions of opioids that were written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission, or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement.[2]

Plaintiffs must answer this Interrogatory, but shall replace 'all prescriptions' with '500 prescriptions.' Plaintiffs' responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant. In addition, Manufacturer Defendants may amend this

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[1] The Special Master issued via email an informal ruling on this matter on October 2, 2018. Plaintiffs then timely asked the Special Master to formally document the ruling. *See Order of Appointment* (docket no. 69) at 5 ("If a Special Master issues an informal ruling or order that is not on the record (such as the resolution of a discovery dispute) either orally, via email, or through other writing, and a party wishes to object to that ruling or order, the party shall ask the Special Master to formalize the ruling or order by filing it on the docket or appearing before a court reporter. Such request shall be made within three days of issuance of the informal order or ruling, else the opportunity to object shall be waived.").

[2] In letters, defendants have characterized this Interrogatory as asking: "*Which prescriptions, if any, of each Defendant's opioids were written in Plaintiff's jurisdiction in reliance on any Defendant's alleged misrepresentations, omissions or other alleged wrongdoing?*"

Interrogatory to identify 200 specific prescriptions and require Plaintiffs to state whether each prescription was "written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant," and if so the details thereof (e.g. who made the misrepresentations and what they were).

Manufacturer Interrogatory No. 7

Identify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in [Plaintiff's jurisdiction]. Include in the identification of each such individual: (i) the particular type of alleged harm that the individual experienced, (ii) the particular opioid(s) that he or she took and/or was prescribed, (iii) when each prescription at issue was written, (iv) the condition for which each prescription was written, and (v) the allegedly false, misleading, or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.[3]

Plaintiffs must answer this Interrogatory, but shall replace 'every person' with '300 persons." Plaintiffs' responses must include information for at least 10 persons who were prescribed an opioid sold by each manufacturing defendant. In addition, Manufacturer Defendants may amend this Interrogatory to identify 100 specific persons in Plaintiff's jurisdiction and require Plaintiffs to state whether each person became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s).

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[3] Defendants have characterized this Interrogatory as asking: "*Who, if anyone, purportedly became addicted or was otherwise harmed as a result of such prescriptions in Plaintiff's jurisdiction?*

Manufacturer Interrogatory No. 10

Identify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful. Include in the response as to each such prescription the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the basis for your assertion that the prescription was unauthorized, medically unnecessary, ineffective or harmful; and whether, by whom, and for how much the prescription was approved for reimbursement.[4]

Plaintiffs must answer this Interrogatory, but shall replace 'all prescriptions' with '500 prescriptions.' Plaintiffs' responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant. In addition, Manufacturer Defendants may amend this Interrogatory to identify 200 specific prescriptions and require Plaintiffs to state whether those prescriptions were "unauthorized, medically unnecessary, ineffective, or harmful," and if so the basis therefor.

* * * * *

(The following Pharmacy Interrogatories are largely duplicative of the Manufacturing Interrogatories above, and so the rulings are essentially the same.)

Pharmacy Interrogatory No. 2

Identify each prescription upon which you base, or which you contend supports, Your claims in this case. For each prescription, identify the prescriber, dispensing pharmacy, dispensing pharmacist, and dispensing date, and explain how it supports Your claims.

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[4] Defendants have characterized this Interrogatory as asking: "*Which prescriptions, if any, were unauthorized, medically unnecessary, ineffective, or harmful?*

Plaintiffs must answer this Interrogatory, but shall replace 'each prescription' with '500 prescriptions.' Plaintiffs' responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant. In addition, Pharmacy Defendants may amend this Interrogatory to identify 200 specific prescriptions and require Plaintiffs to state whether and how each prescription supports Plaintiffs' claims.

Pharmacy Interrogatory No. 3

Identify each prescription the filling of which caused or led to harm for which you seek to recover in this case. For each prescription, identify the prescriber, dispensing pharmacy, dispensing pharmacist, and dispensing date, and explain how it supports Your claims.

Plaintiffs must answer this Interrogatory, but shall replace 'each prescription' with '500 prescriptions.' Plaintiffs' responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant. In addition, Pharmacy Defendants may amend this Interrogatory to identify 200 specific prescriptions and require Plaintiffs to state whether and how each prescription supports Plaintiffs' claims.

* * * * *

In addition, the Special Master clarifies as follows. For a given plaintiff: (1) the '500 prescriptions' referred to in Manufacturer Interrogatory Nos. 6 and 10 and Pharmacy Interrogatory Nos. 2 and 3 *may* all be the same 500 prescriptions; (2) the '200 specific prescriptions' referred to in Manufacturer Interrogatory Nos. 6 and 10 and Pharmacy Interrogatory Nos. 2 and 3 *must* all be the same 200 prescriptions; (3) the 300 persons identified in Manufacturer Interrogatory No. 7 *may* overlap with the 500 prescriptions; and (4) the '100 specific persons' identified in Manufacturer

Interrogatory No. 7 *may* overlap with the '200 specific prescriptions'.

Finally, the Special Master observes that, if any plaintiff expert or defense expert relies on any specific prescriptions, or specific persons who obtained prescriptions, those prescriptions and persons must be identified with specificity in the expert's disclosure and should also be identified to opposing counsel substantially before the deadline for non-expert discovery. The parties will negotiate this deadline.

In addition, I direct the parties to negotiate deadlines for responding to the re-written interrogatories. My suggestions are that: (a) plaintiffs should identify and provide information regarding prescriptions/persons within 28 days; (b) defendants should identify prescriptions/persons within 21 days, and plaintiffs should provide responsive information within 14 days thereafter.[5] If the parties cannot come to agreement regarding these deadlines on or before October 15, 2018, they must let me know and I will resolve it.

* * * * *

Given the amount of time left for fact discovery; the fact that these issues were first raised by defendants two months ago, on August 4, 2018; and that the parties have been negotiating and briefing this issue since then; the Special Master further orders as follows:

- objections to this *Ruling* must be filed on or before October 10, 2018;
- responses to objections must be filed on or before October 12, 2018; and
- regardless of whether any party files an objection, all parties remain obligated to negotiate the above-described deadlines and take actions consistent with this *Ruling* being affirmed

[5] Defendants' suggested deadline assumes plaintiffs have produced databases from which defendants can identify relevant prescriptions and persons.

by the Court. In other words, no party may rely on the filing of an objection to avoid or postpone any obligation described in this *Ruling*; these obligations remain in full force unless and until the Court modifies this *Ruling*.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: October 6, 2018

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

SUMMIT COUNTY COMBINED GENERAL HEALTH DISTRICT; CITY OF AKRON, OHIO; CITY OF BARBERTON, OHIO; VILLAGE OF BOSTON HEIGHTS, OHIO; BOSTON TOWNSHIP, OHIO; THE VILLAGE OF CLINTON, OHIO; COPLEY TOWNSHIP, OHIO; COVENTRY TOWNSHIP, OHIO; THE CITY OF CUYAHOGA FALLS, OHIO; THE CITY OF FAIRLAWN, OHIO; THE CITY OF GREEN, OHIO; THE VILLAGE OF LAKEMORE, OHIO; THE VILLAGE OF MOGADORE, OHIO; THE CITY OF MUNROE FALLS, OHIO; THE CITY OF NORTON, OHIO; THE VILLAGE OF PENINSULA, OHIO; VILLAGE OF RICHFIELD, OHIO; VILLAGE OF SILVER LAKE, OHIO; SPRINGFIELD TOWNSHIP, OHIO; THE CITY OF STOW, OHIO; CITY OF TALLMADGE, OHIO; and VALLEY FIRE DISTRICT,	)	
Plaintiff,	)	
v.	)	Case No. 1:18-op-45090
PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN	)	Hon. Judge Dan. A. Polster

PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; INSYS THERAPEUTICS, INC.; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; and JANE DOES 1-50	)
Defendants.	)

MANUFACTURER DEFENDANTS'
FIRST SET OF INTERROGATORIES TO PLAINTIFFS

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure as well as the Case Management Order in *In re National Prescription Opiate Litigation* (Dkt. No. 232 in No. 1:17-cv-2804), Manufacturer Defendants[1] hereby request that each Plaintiff in the above-captioned action individually respond to the following Interrogatories (the "Interrogatories") in accordance with their obligations under the Federal Rules of Civil Procedure. Responses to the Interrogatories shall be provided in the manner required by Rule 33(b), the Local Rules of the Northern District of Ohio, the Court's Case Management Order One, filed April 11, 2018, Doc. No. 232, and any other applicable law or rules, within thirty (30) days of the service of these Interrogatories.

In the interest of efficiency and cooperation, the Manufacturer Defendants have included only one brief Definition in conjunction with these Interrogatories. If any Plaintiff finds any term or other aspect of the Interrogatories vague, ambiguous, or otherwise objectionable and intends to

[1]The Manufacturer Defendants are Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; and Insys Therapeutics, Inc.

so object, counsel for the Manufacturer Defendants offer to promptly meet with counsel for Plaintiff to resolve any issues.

DEFINITION

1. "Identify" means:

a. With respect to a natural person, the complete name, date of birth, telephone number, occupation, last known place of employment, the street and mailing address for both home and business at the time in question, and (if different) the last known home and business street and mailing addresses as of the time of answering these Interrogatories; and

b. With respect to a document, its identification number, its title, its date, its location, its signatory, any authors and recipients, its description (e.g., memorandum, letter, contract, form), and the number of pages.

INSTRUCTION

1. Each Plaintiff must individually respond to each of these Interrogatories.

INTERROGATORIES

INTERROGATORY NO. 1:

Identify each and every doctor or other healthcare provider who Plaintiff alleges participated in "speaker programs" or "speakers' bureaus" on behalf of or in relation to any Defendant, as alleged in Plaintiff's Complaint. For each identified doctor or other healthcare provider, please also identify in the response the events or programs that Plaintiff alleges the doctor or other healthcare provider attended or spoke at and identify the amount of payment allegedly provided by each Defendant.

INTERROGATORY NO. 2:

Identify each entity or natural person, including without limitation healthcare providers, patients, addiction treatment specialists, alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, or any other third party, from whom Plaintiff

received or attempted to obtain documents, testimony, sworn affidavits, or any other form of information in connection with Plaintiff's investigation of any Defendant's advertising or marketing of opioids, or otherwise in connection with this litigation, and include in the response identification of all information sought or received from each entity or natural person.

INTERROGATORY NO. 3:

Identify any doctors, addiction treatment specialists, healthcare providers, and law enforcement and public health officials who Plaintiff contends agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic (as that term is used throughout the Complaint).

INTERROGATORY NO. 4:

Describe each cost, expenditure, damage, loss, or harm for which Plaintiff seeks equitable or monetary relief, including any penalty or fine, from each Defendant. For each cost, expenditure, damage, loss, penalty, fine or harm for which Plaintiff seeks relief, provide (i) the nature and amount of that cost, expenditure, damage, loss, penalty, fine or harm; (ii) the Defendant or Defendants from which the relief is sought; and (iii) how and by whom the cost, expenditure, damage, loss, penalty, fine, or harm was determined and calculated, and the specific conduct of that Defendant or those Defendants that allegedly caused the cost, expenditure, damage, loss, penalty, fine, or harm.

INTERROGATORY NO. 5:

Identify and describe all alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, and other third parties with whom any Defendant allegedly conspired or acted in concert in furtherance of the alleged misconduct described in the Complaint, including the identity of each Defendant that allegedly conspired and all facts supporting Plaintiff's contention that such Defendant(s) did so.

INTERROGATORY NO. 6:

Identify and describe all prescriptions of opioids that were written in the Plaintiff's county, city, village, or township in reliance on any alleged misrepresentations, omissions or other alleged

wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission; or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement.

INTERROGATORY NO. 7:

Identify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in the Plaintiff's county, city, village, or township. Include in the identification of each such individual: (i) the particular type of alleged harm that the individual experienced, (ii) the particular opioid(s) that he or she took and/or was prescribed, (iii) when each prescription at issue was written, (iv) the condition for which each prescription was written; and (v) the allegedly false, misleading, or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.

INTERROGATORY NO. 8:

Identify any "unbranded advertising" or "unbranded marketing" (as those terms are used throughout the Complaint) disseminated in the Plaintiff's county, city, village, or township in which any Defendant participated or to which any Defendant contributed in any way. Include in the response the identity of the Defendant(s) that participated or contributed and the identity of the person or persons to whom the "unbranded advertising" or "unbranded marketing" was distributed.

INTERROGATORY NO. 9:

Identify and describe all statements or omissions made or disseminated in the Plaintiff's county, city, village, or township by any Defendant (or any other person whose statements you attribute, in whole or in part, to a Defendant) that you claim were false, misleading, unfair, deceptive or otherwise actionable. Include in your identification of each statement or omission:

(i) the name, employer, and position(s) of the speaker, writer, or other person who issued the statement; (ii) the name(s) and position(s) of the recipient(s) of such statement; (iii) when and where the allegedly false, misleading, or deceptive statement was made; (iv) a description of the content of the statement; and (v) all reasons you claim the statement was false, misleading, or deceptive.

INTERROGATORY NO. 10:

Identify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful. Include in the response as to each such prescription the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the basis for your assertion that the prescription was unauthorized, medically unnecessary, ineffective, or harmful; and whether, by whom, and for how much the prescription was approved for reimbursement.

Date: April 25, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Mark S. Cheffo, among the liaison counsel for the Manufacturer Defendants, certify that on April 25, 2018, I caused the foregoing to be served via electronic mail on the individuals on the attached service list.

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EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE 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. 18-OP-45090	**Case No. 1:17-md-2804** **Hon. Dan A. Polster**

THE NATIONAL RETAIL PHARMACY DEFENDANTS' FIRST SET OF INTERROGATORIES TO COUNTY OF SUMMIT, OHIO

The National Retail Pharmacy Defendants named in the above-captioned Track One cases under Case Management Order No. 1 ¶ 3(a)[1] request Plaintiff County of Summit to respond to the following interrogatories pursuant to Federal Rules of Civil Procedure 26 and 33, the Local Rules of the Northern District of Ohio, and Case Management Order No. 1. If Plaintiff finds any term or other aspect of any of the Interrogatories objectionable and intends to object, counsel for the National Retail Pharmacy Defendants offer to promptly confer with counsel for Plaintiff to attempt to resolve any issues.

[1] The National Retail Pharmacy Defendants include the following defendants: CVS Indiana, LLC, CVS Rx Services, Inc., Rite Aid of Maryland, dba Mid-Atlantic Customer Service Center, Walgreens Boots Alliance, Inc., and Walmart Inc. F/K/A Wal-Mart Stores, Inc. Walgreens Boots Alliance, Inc. has filed a motion to dismiss this case for lack of personal jurisdiction and, by serving these requests, does not consent to jurisdiction or waive its position on jurisdiction in any respect. Because less than three months remain for fact discovery under the current schedule and it is uncertain when the Court will decide the personal jurisdiction motion (it is not even fully briefed), Walgreens Boots Alliance, Inc. risks losing the right to obtain necessary discovery – either on its own behalf, if the motion is denied, or on behalf of other entities that may be named in its place if further amendments of the complaints are permitted – if it abstains from participating until the motion is resolved.

DEFINITIONS

1. "Plaintiff" refers to Plaintiff County of Summit, including without limitation its agencies, offices, departments, divisions, commissions, agents, employees, boards, agents, boards, instrumentalities, vendors, administrators, executive and legislative branches, and anyone other person or entity acting on its behalf or controlled by it. Plaintiff further includes without limitation any health care systems or facilities owned, affiliated, operated or supported by or with Plaintiff. When the pronouns "You" or "Your" are used, the antecedent is the Plaintiff.

2. "Relevant Time Period" means the time period during which You claim any National Retail Pharmacy Defendant engaged in any conduct for which you seek damages, or such time period as the parties stipulate or the Court determines should apply to each side's discovery requests in this action.

3. "Prescription Opioids," as used in these Interrogatories, refers to the Prescription Opioids referenced in the Complaint as to which You seek to hold any National Retail Pharmacy Defendant liable.

4. "Suspicious Orders" means any order of Prescription Opioids placed by any source that You contend should have been reported to the DEA or state authorities, including the Board of Pharmacy or equivalent. Suspicious orders are not limited to those placed with the National Retail Pharmacy Defendants, but include those placed with any entity that has a regulatory reporting obligation.

INTERROGATORIES

1. State the years during which You claim each National Retail Pharmacy Defendant engaged in the conduct for which You seek damages.

2. Identify each prescription upon which You base, or which you contend supports, Your claims in this case. For each prescription, identify the prescriber, dispensing pharmacy, dispensing pharmacist, and dispensing date, and explain how it supports Your claims.

3. Identify each prescription the filling of which caused or led to harm for which you seek to recover in this case. For each prescription, identify the prescriber, dispensing pharmacy, dispensing pharmacist, and dispensing date, and explain how it supports Your claims.

4. Identify each person in Your geographic area who during the Relevant Time Period forged or otherwise improperly altered any prescription for any Prescription Opioid or who sought to obtain any Prescription Opioid through a forged or otherwise improper prescription.

5. Identify every instance during the Relevant Time Period in which You requested information relating to Prescription Opioids from the Ohio Automated Rx Reporting System (OARRS), including the date of the request, the subject matter of the request, the information You requested, the information You obtained in response to the request, and any action You took based on that information.

6. Identify each person employed by or associated with You, or whom You compensated, who possessed an account with OARRS, or otherwise had access to information on OARRS, during the Relevant Time Period. This includes but is not limited to all OARRS Supervisors and OARRS Officers for each of Your agencies that had access to OARRS. For each such person, state when access was first obtained and, if applicable, discontinued.

7. Identify all Suspicious Orders for Prescription Opioids shipped by any National Retail Pharmacy Defendant in Your geographic area during the Relevant Time Period, including for each the name and location of the pharmacy that placed the order, the distributor to whom it was placed, the respective dates that it was placed and shipped, the manufacturer, name and amount of the medication that was ordered and shipped, and the reason(s) why the order was suspicious.

8. Identify the "national comparative benchmarks and indefensible outliers" related to the Track One cases referred to in Paul Farrell's June 13, 2018 email to Mark Lynch.

9. Identify all physicians and any other health care providers who prescribed Prescription Opioids during the Relevant Time Period and who, at the time, were employed by You or practiced at facilities owned, operated, supported, or affiliated with You, including any public health care systems or facilities. For each individual, identify her or his place(s) of work and title(s) during the Relevant Time Period.

10. Identify all pharmacies that, during the Relevant Time Period, were owned, operated, supported, or affiliated with You, including through any public health care systems or facilities, and all pharmacists and pharmacy technicians who were employed by, compensated by, or otherwise worked in those pharmacies during the Relevant Time Period. For each individual, identify her or his place(s) of work and title(s) during the Relevant Time Period.

11. Identify each instance in which a person identified in response to Interrogatory Nos. 9 and 10 was involved in the diversion of Prescription Opioids during the Relevant Time Period—including without limitation the improper prescribing or filling of Prescription Opioids

or the submission to a distributor of a Suspicious Order. For each instance, identify the person, the nature of her or his involvement in the diversion, and the date of the diversion.

12. Identify all communications during the Relevant Time Period between any of the individuals identified in response to Interrogatory Nos. 9 and 10 and any National Retail Pharmacy Defendant, or anyone who You maintain was acting on behalf of or in concert with any National Retail Pharmacy Defendant, including the date of the communication, the substance of the communication, and the parties to the communication.

13. Identify any fees, reimbursements, honoraria, gifts or other items of value received in the Relevant Time Period by any individual identified in response to Interrogatory Nos. 9 and 10 from any Defendant named in Your Second Amended Complaint or from anyone who You maintain was acting on behalf of or in concert with any Defendant named in Your Second Amended Complaint.

14. Identify the individuals referenced anonymously in Your Second Amended Complaint as sources of information, including the name, address, and profession of each source.

15. Identify each instance during the Relevant Time Period in which You or anyone acting on Your behalf, including but not limited to Your health care and law enforcement agencies, communicated with any pharmacy in Your geographic area about Prescription Opioids. This includes without limitation each instance You or anyone acting on Your behalf notified any pharmacy in Your geographic area that You suspected or believed Prescription Opioids were being diverted from it. For each such communication, identify the pharmacy with which You had the communication, the substance of the communication, the date of the communication, and the persons who were party to it.

16. Identify each instance during the Relevant Time Period in which You or anyone acting on Your behalf, including but not limited to Your health care and law enforcement agencies, communicated with any distributor of Prescription Opioids about Prescription Opioids. This includes without limitation each instance You or anyone acting on Your behalf notified any such distributor that You suspected or believed that Prescription Opioids shipped by the distributor were being diverted in Your geographic area. For each such communication, identify the distributor with which you had the communication, the substance of the communication, the date of the communication, and the persons who were party to it.

17. Identify all persons (other than Your attorneys in this action) from whom you have obtained information about alleged diversion in Your geographic area by a National Retail Pharmacy Defendant during the Relevant Time Period. Describe the information that each person possesses and identify the National Retail Pharmacy Defendant to which it pertains.

18. Identify each employee, contractor or other person to whom You provided compensation during the Relevant Time Period (other than Your attorneys in this action) who worked on addressing, or who provided information to You about, the problems You experienced or expenses You incurred from the diversion of Prescription Opioids.

19. Identify each state or federal official or agency (including but not limited to the United States Drug Enforcement Administration, the United States Department of Justice, a United States Attorney's Office, the Ohio Department of Medicaid and its constituent providers, the Ohio Department of Public Safety, the Ohio Attorney General's Office, the State of Ohio Board of Pharmacy, and the State Medical Board of Ohio), insurer, or third party benefit manager who provided information to You about diversion of Prescription Opioids during the Relevant Time Period, including but not limited to information about Suspicious Orders,

improper prescriptions, or individuals responsible for diversion of Prescription Opioids. Include in Your response a description of the information and date it was provided.

20. Provide a computation of each category of damages, monetary sums, and injunctive relief that You seek from each National Retail Pharmacy Defendant.

Dated June 21, 2018

Respectfully submitted,

/s/ Eric R. Delinsky

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CERTIFICATE OF SERVICE

I, Eric R. Delinsky, do hereby certify that I caused a true and correct copy of the foregoing to be served by email on Plaintiffs' Liaison Counsel and Defendants Liaison Counsel pursuant to Case Management Order No. 1, ¶ 9(c).

/s/ Eric R. Delinsky

EXHIBIT 4

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

In Re: National Prescription Opiate Litigation	)	MDL No. 1:17-cv-02804
	)	
	)	CASE NO. 1:18-op-45090
COUNTY OF SUMMIT, OHIO, *et al.*,	)	
	)	JUDGE DAN AARON POLSTER
	)	
Plaintiffs,	)	MAGISTRATE JUDGE DAVID A. RUIZ
	)	
v.	)	
	)	**REPORT AND RECOMMENDATION**
PURDUE PHARMA L.P., *et al.*,	)	
	)	
Defendants.	)	

On May 25, 2018, the Distributor Defendants,[1] Pharmacy Defendants,[2] and Manufacturer Defendants[3] filed Motions to Dismiss the Second Amended Complaint. (R. 491, R. 497, R. 499).[4] On June 22, 2018, Plaintiffs filed an omnibus brief in opposition to the

[1] The motion to dismiss identifies the "Distributors" as AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. (R. 491, PageID# 7455).

[2] The motion to dismiss identifies the "Pharmacies" as Walmart Inc., Rite Aid Corp., Walgreens Boots Alliance, Inc., and CVS Health Corp. (R. 497, PageID# 7581).

[3] The motion to dismiss identifies the "Manufacturers" as Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. ("Purdue"); Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan/Actavis"); Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Teva Pharmaceuticals, USA, Inc., and Cephalon, Inc. ("Teva"); Johnson & Johnson ("J&J"); Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Janssen"); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. ("Endo"); Insys Therapeutics, Inc. ("Insys"); and Mallinckrodt LLC ("Mallinckrodt"). (R. 499, PageID# 7632).

[4] On May 18, 2018, Plaintiffs filed their Second Amended Complaint (R. 477), which included impermissible amendments. After the motions to dismiss were filed, Plaintiffs filed two "corrected" Second Amended Complaints on May 29, 2018—a redacted version (R. 513) and a sealed version. (R. 514). In order to maintain the integrity of the paragraph numbering from the document initially filed on May 18, 2018, the Special Master advised the parties that the

motions. (R. 654). On July 13, 2018, Defendants filed their reply briefs. (R. 742, 744, 746). This report and recommendation addresses all three motions.

I. Fed. R. Civ P. 12(b)(6) Standard

When ruling upon a motion to dismiss filed under Fed. R. Civ. P. 12(b)(6), a court must accept as true all the factual allegations contained in the complaint. *See Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007); *accord Streater v. Cox*, 336 Fed. App'x 470, 474 (6th Cir. 2009). Nonetheless, a court need not accept conclusions of law as true. Under Fed. R. Civ. P. 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief."

> As the Court held in [*Bell Atlantic Corp. v.] Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929, the pleading standard Rule 8 announces does not require "detailed factual allegations," but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. *Id.*, at 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (*citing Papasan v. Allain*, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (1986)). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." 550 U.S., at 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929. Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.*, at 557, 127 S. Ct. 1955, 167 L. Ed. 2d 929.
>
> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.*, at 570, 127 S.Ct. 1955. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.*, at 556, 127 S.Ct. 1955. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Ibid*. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.*, at

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subsequent "corrected" filings not delete the impermissible amendments, but rather use strike-through font to denote those portions that were no longer operative. Although the parties' briefs cite to R. 477, the court cites to R. 514 as it is the operative second amended complaint. For the sake of brevity, any reference to the "complaint" hereafter refers to R. 514. Public users unable to access the sealed version may refer to R. 513, where the paragraph numbers should parallel the citations to R. 514.

557, 127 S.Ct. 1955 (brackets omitted).

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (*quoting Twombly*, 550 U.S. 544).

A court "may dismiss a complaint for failure to state a claim 'only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 615 (6th Cir. 2004) (quoting *Swierzkiewickz v. Sorema N.A.*, 534 U.S. 506, 514 (2002); *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

II. Factual Allegations of the Complaint[5]

A. Increase in Opioid Use/Abuse and Overdose Deaths

The complaint alleges that the Manufacturers and Distributors of opioids began in the late 1990s to expand the use of opioids by developing a "deliberate marketing strategy" coupled with "deliberate efforts to evade restrictions on opioid distribution." (R. 514 at ¶¶3-4). Plaintiffs allege that annual deaths from opioid overdoses increased sharply from 8,000 in 1999 to 20,000 in 2009 and up to 33,000 in 2015. *Id* at ¶4. From 1999 through 2016, it is alleged that 350,000 individuals died from an opioid overdose. *Id* at ¶5. More than 200,000 of those deadly overdoses involved prescription opioids. *Id*. For others who overdosed from non-prescription opioids, such as heroin, it is estimated that 80 percent of people who began abusing heroin in the past decade started with prescription opioids. *Id*. at ¶6. By 2014, nearly 2 million Americans were addicted to prescription opioids with another 600,000 addicted to heroin. (R. 514 at ¶16).

[5] This report and recommendation provides only a brief overview of the voluminous factual allegations in the over 300 page complaint.

B. Allegations of an Intentional Campaign to Increase Opioid Use

Plaintiffs allege that the Manufacturers[6] initiated a massive marketing campaign based on false and misleading information to cause a dramatic increase in opioid prescriptions. (R. 514 at ¶10). Despite knowing the highly addictive properties of opioids, the Manufacturers sought to dramatically increase sales by means of publications, websites, and educational programs, resulting in a fourfold increase in opioid sales since 1999 and $9.6 billion in opioid sales in 2015 alone. *Id*. at ¶¶11-13. Plaintiffs allege the Manufacturers engaged in a series of marketing techniques that knowingly misrepresented both the risks and benefits of opioids for chronic pain treatment in order to "reverse the long-settled understanding of the relative risks and benefits of opioids." (R. 514 at ¶¶174-175).

1. Nine Categories of Misrepresentations

Plaintiffs allege the Manufacturers employed the following "nine categories of misrepresentations" concerning opioid treatment: (1) the risk of addiction from chronic opioid therapy is low; (2) such risk can be easily identified and managed; (3) signs of addiction are "pseudoaddiction," requiring more opioids; (4) withdrawal can be avoided by tapering; (5) dosage can be increased without additional risks; (6) long-term opioid use improves functioning; (7) alternative forms of pain relief are riskier; (8) OxyContin provides twelve hours of pain relief; and, (9) new formulas of certain opioids successfully deter abuse. (R. 514 at ¶177). Plaintiffs assert that all the above are false; that the Manufacturers knew them to be false; and, nonetheless, "set out to convince physicians, patients, and the public at large of the truth of each

[6] Plaintiffs' use of the term "Marketing Defendants" includes defendants that have "manufactured and sold" prescription opioids (R. 514 at ¶63), while those same defendants identify themselves as "Manufacturer Defendants" in their motion to dismiss. (R. 499). For the sake of consistency, the court refers to this category of defendants simply as "Manufacturers."

of these propositions in order to expand the market for their opioids." *Id*. at ¶178. The complaint proceeds to allege that each of the Manufacturers perpetuated the notion that the risk of addiction from opioid use is low. *Id*. at ¶¶180-232. The complaint also alleges how some of the other eight propositions were perpetuated.[7] *Id*. at ¶¶233-351.

2. Use of Front Groups, Key Opinion Leaders, and Continuing Medical Education Courses to Spread False and Misleading Information

Plaintiffs further allege that Manufacturers funded and controlled advocacy groups, which Plaintiffs label as "front groups," that distributed patient education materials and treatment guidelines that overstated the benefits of opioids for chronic pain treatment while understating the risks of addiction. (R. 514 at ¶¶350-354). The front groups were used to create the façade of "neutral and credible third parties" to influence opioid prescribing practices. *Id*. These front groups included both professional societies as well as patient advocacy organizations and received millions of dollars from the Manufacturers. *Id*. at ¶353. Plaintiffs further allege that individual executives, board members, and staff members of these front groups received substantial payments from the Manufacturers, many of whom were physicians on the Manufacturers' payroll, as consultants or speakers at medical events. *Id*. at ¶¶354, 363. These front groups minimized addiction risks while promoting opioid use for chronic pain, criticized existing CDC guidelines for opioid prescribing, and lobbied against existing laws that curbed opioid use. *Id*. at 355. The Manufacturers allegedly guided, reviewed, and approved false and misleading statements issued by the front groups. *Id*. at ¶356.

Plaintiffs identify numerous organizations that allegedly received funding from

[7] The Plaintiffs acknowledge that "not every Marketing Defendant" propagated each of the nine misrepresentations, but asserts that liability is not predicated upon every Manufacturer perpetuating all nine misrepresentations. (R. 514 at ¶179).

Manufacturers and served as front groups to distribute tens of thousands of pamphlets and other materials containing misrepresentations regarding opioids. Those entities included: American Pain Foundation (APF), an off-shoot of APF, the National Initiative on Pain Control (NIPC), American Academy of Pain Medicine (AAPM), American Pain Society, Alliance for Patient Access (APA), the U.S. Pain Foundation, and the American Geriatrics Society. (R. 514 at ¶¶357-395). Plaintiffs also allege that the Federation of State Medical Boards (FSMB), a trade organization representing various state medical boards, received grants from Manufacturers for specific opioid and pain management programs. *Id*. at ¶¶377-382. Beginning in 1998, the FSMB began "developing treatment guidelines for the use of opioids for the treatment of pain," that "was produced 'in collaboration with pharmaceutical companies.'" *Id*. at ¶379. It is alleged that the 1998 Guidelines, as well as a subsequent FSMB publication entitled *Responsible Opioid Prescribing*, "convey[ed] the alarming message that 'under-treatment of pain' would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented." (R. 514 at ¶¶381-382).

Plaintiffs also allege that the Manufacturers "paid and cultivated a select circle of doctors who were chosen and sponsored" for their pro-opioid messages in order "to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids." (R. 514 at ¶396). Plaintiffs label these doctors "key opinion leaders" (KOLs). *Id*. at ¶¶176, 398. They were used "to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals." *Id*. at ¶397. The publications of these physicians were funded by the Manufacturers as they supported the position that opioid treatment for chronic pain was appropriate, all while knowing these statements were false and

misleading. *Id*. at ¶¶401-403. According to the complaint, one of the KOLs later acknowledged in an interview that his earlier statements were "pseudoscience," the primary goal of which was to destigmatize opioids. *Id*. at ¶¶410-11.

The Manufacturers are alleged to have "created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors." (R. 514 at ¶446). Plaintiffs allege the literature originated from the Manufacturers' marketing departments and had no scientific research basis. *Id*. at ¶¶448-451. The Manufacturers "aggressively distributed their false message … through thousands of Continuing Medical Education Courses," (CMEs), that physicians attended to maintain their licenses. (R. 514 at ¶¶429-432). These CMEs allegedly "inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects," causing physicians that listened to these CMEs to be misled. *Id*. at ¶¶433, 440-41.

3. Branded and Unbranded Advertising and Marketing

Plaintiffs allege that the Manufacturers collectively spent more than $14 million on medical journal advertising of opioids in 2011, which included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo. (R. 514 at ¶442). These included journals targeting specialists, such as the *Journal of Pain and Clinical Journal of Pain*, as well as journals with a wider medical audience, such as the *Journal of the American Medical Association*. *Id*. It is further alleged that the Manufacturers promoted opioids through "unbranded advertising" that, in contrast to a "branded" advertisement, does not require the advertiser to include risks, possible side effects and contraindications. *Id*. at ¶444. Such advertising was directed at physicians and

consumers, as studies have shown that physicians are significantly more likely to prescribe a drug if a patient asks for it. *Id*. at ¶¶443-44. As an example one website contained testimonials from alleged pain advocates, who were paid significant sums by Defendant Purdue. *Id*. at ¶445.

It is further alleged that the Manufacturers' sales representatives met with "hundreds of thousands" of doctors "to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain." *Id*. at ¶¶452-455. The Manufacturers, in 2014 alone, spent "$166 million on detailing branded opioids to doctors. This amount is twice as much as the Manufacturers spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo." *Id*. at ¶¶455-461.

C. Distribution and Sales Allegations

Since 1999, the onset of the Manufacturers' alleged marketing actions, the amount of prescription opioids in the United States nearly quadrupled. (R. 514 at ¶12). Plaintiffs maintain that all Defendants were required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74. (R. 514 at ¶¶500-504). Plaintiffs allege the Defendants have a duty "to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions." *Id*. at ¶¶501-505. Plaintiffs allege these duties stem from multiple sources including state law, common law, an assumed duty, and as registrants with the Drug Enforcement Agency (DEA) as manufacturers and/or distributors of Schedule II controlled substances. *Id*.

Plaintiffs assert that the Controlled Substances Act (CSA) requires both the

Manufacturers and the Distributors[8] of Schedule II substances, such as opioids, to limit sales within a quota set by the DEA; register to manufacture or distribute opioids; maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and to design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA. *Id*. at ¶507. Plaintiffs allege Defendants failed to control the supply chain, prevent diversion, report suspicious orders, and halt shipments. *Id*. at ¶¶14, 518.

Plaintiffs allege Defendants worked together to increase the supply of opioids and fraudulently increased the quotas that governed the manufacture and distribution of prescription opioids. (R. 514 at ¶¶526-528). It is alleged that the Manufacturers engaged in the practice of paying rebates and/or "chargebacks" to the Distributors for sales of prescription opioids to boost sales and refine their marketing efforts. *Id*. at ¶529. Defendants worked together through trade or other organizations, such as the Pain Care Forum (PCF) or the Healthcare Distribution Alliance (HDA) to increase opioid sales. *Id*. at ¶531. The PCF, which included the previously described front groups, Manufacturers and Distributors, spent $140 million to lobby state and national legislatures on an array of issues, including opioids. *Id*. at ¶¶533-535.

Furthermore, Plaintiffs allege the HDA created a private network where representatives of the Manufacturers and Distributors could form relationships and create alliances between them and hold strategic business discussions between high-level executives. *Id*. at ¶¶535-540.

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[8] In the complaint, the Plaintiffs also classify the national retail pharmacy defendants as "Distributor Defendants." (R. 514 at ¶¶107, 111-112, 124-128). These defendants, however, moved separately to dismiss the complaint and, in the Analysis section, the court differentiates between these two categories of defendants by referring to them either as "Distributors" or "Pharmacies." For the purposes of this section only, the Plaintiffs' references to the Distributor defendants in the complaint may encompass the Pharmacies.

Thus, Plaintiffs allege that the Manufacturers and Distributors were "not two separate groups operating in isolation or two groups forced to work together in a closed system," but rather "operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids." *Id*. at ¶¶543-46. It is alleged the Defendants worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high to ensure that suspicious orders were not reported to the DEA thereby giving the DEA no basis to refuse to increase production quotas due to diversion. *Id*. at ¶¶550-552. Defendants, it is alleged, were "on notice" of the problems of abuse and diversion caused "inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain." *Id*. at ¶557.

Further, Defendants were "in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time." *Id*. at ¶¶558-563. It is also alleged that "Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings." *Id*. at ¶566. Plaintiffs allege Defendants also failed to report prolific prescribers, but instead focused their sales efforts on them to even further increase their prescribing. *Id*. at ¶¶569-578.

Plaintiffs also allege that several Distributors and Manufacturers have either admitted, been fined for, or been charged with failing to report suspicious orders. (R. 514 at ¶¶580-593, 595). The Defendants, through their trade associations, have acknowledged that "HDMA[9] and

[9] HDMA is the Healthcare Distribution Management Association, the predecessor of HDA. (R. 514 at ¶522).

NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society." *Id*. at ¶599. They further have stated in court filings that "Distributors take seriously their *duty* to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process." *Id*. (emphasis added).

It is alleged that the Manufacturers marketed their products and disseminated their misrepresentations in the state of Ohio, and their nationwide "policies, plans, and procedures that were the same in Summit County as they were across the country." (R. 514 at ¶¶671-672). Sales representatives from each of the Manufacturers visited prescribers in Summit County, which frequently coincided with payments to prescribers for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." *Id*. at ¶673. Summit County had an opioid prescription rate exceeding its population from 2008 to 2011—a rate that has remained higher than the national average.[10] *Id*. at ¶674.

III. Analysis

A. Counts One and Two: Federal RICO Claims

In Count One of the complaint, Plaintiffs allege a civil violation of the Racketeer Influenced and Corrupt Organizations (RICO) Act § 1961 *et seq.* based on a marketing enterprise theory against the Manufactures, specifically Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt, whom the Plaintiffs refer to as "Marketing Defendants." (R. 514, PageID# 11178).

[10] The complaint states that from 2010 to 2016, according to Ohio data, Summit County, whose population is 540,000 residents, averaged 36.4 million doses of opioids dispensed per year, with a high of 39.5 million. (R. 514 at ¶689).

In Count Two, Plaintiffs allege a civil RICO violation based on a supply chain enterprise theory against both the Manufacturers and Distributors, specifically Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen, whom Plaintiffs refer to as "Supply Chain Defendants." *Id*. at PageID# 11187.

The RICO Act includes a civil-suit provision that permits: "[a]ny person injured in his business or property by reason of" RICO's substantive provisions to "sue…in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee…." 18 U.S.C. § 1964(c). If a defendant "engages in a pattern of racketeering activity in a manner forbidden by these provisions, and the racketeering activities injure the plaintiff in his business or property, the plaintiff has a claim under § 1964(c)." *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 495 (1985). The Supreme Court has instructed that "the RICO statute provides that its terms are to be 'liberally construed to effectuate its remedial purposes.'" *Boyle v. United States*, 556 U.S. 938, 944 (2009) (citations omitted); *accord Ray v. Spirit Airlines, Inc.*, 836 F.3d 1340, 1349 (11th Cir. 2016). The Defendants' motions challenge Plaintiffs' RICO standing, allege they failed to plead causation and necessary RICO elements, and assert that Plaintiffs' supply chain enterprise theory attempts to bring a cause of action for violating the CSA for which they maintain there is no private right of action. (R. 491-1, PageID# 7477-7491, 499-1, PageID# 7664-7689).

1. Standing

"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 (as in this case) statutory limitations on who may sue, regardless of the merits of that person's claim." *Trollinger*, 370 F.3d at 612 (*citing Allen v. Wright*, 468 U.S.

737, 750-51 (1984)). In addition,"[b]ecause Congress modeled this provision on similar language in the antitrust laws (§ 4 of the Clayton Act and § 7 the Sherman Act) and because the antitrust laws have been interpreted to require that a private plaintiff show proximate cause in order to have standing to sue, RICO civil claims also require proximate cause." *Trollinger*, 370 F.3d at 612 (*citing Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 267–68 (1992); *Sedima*, 473 U.S. at 496).

The Defendants are correct in asserting that the standing requirements of a civil RICO claim require a plaintiff to allege (1) a direct injury,[11] and (2) the injury is to the plaintiff's "business or property." (R. 491-1, PageID# 7478-7486; R. 499-1, PageID# 7664). Plaintiffs summarize their alleged injuries into three categories: (1) public expenditures made in direct response to opioid use and trafficking; (2) lost tax revenue resulting from abuse, misuse, and addiction; and (3) losses caused by diminished property values. (R. 514 at ¶¶ 902, 934).

a. Business or Property

There is no dispute that a RICO claim requires injury to "business or property." *See, e.g.*, *Sedima*, 473 U.S. at 496 ("the plaintiff only has standing [under RICO] if, and can only recover to the extent that, he has been injured in his *business or property* by the conduct constituting the violation") (emphasis added); *accord Ray*, 836 F.3d at 1349. Plaintiffs do not contest that such a requirement exists, but rather argue that "[t]he harms that the Manufacturer and Distributor

[11] The court views the "direct injury" requirement as a consideration in the proximate cause inquiry and, therefore, addresses it below. *In re Neurontin Mktg. & Sales Practice Litig.*, 712 F.3d 21, 36 (1st Cir. 2013) (*citing Holmes*, 503 U.S. at 274 ("our use of the term 'direct' should merely be understood as a reference to the proximate-cause enquiry")); *see also Wallace v. Midwest Fin. & Mortg. Servs., Inc.*, 714 F.3d 414, 419 (6th Cir. 2013) (stating that RICO incorporated "many traditional proximate-cause considerations," and that "[o]ne such consideration is directness….").

Defendants caused, which also impact the Plaintiffs' revenue-generating function, are direct injuries to their 'business and property.'" (R. 654, PageID# 15747).

The Supreme Court in *Reiter v. Sonotone Corporation* analyzed the meaning of "business or property" under the Clayton Act and indicated that "monetary injury, standing alone, may be injury in one's 'property.'" 442 U.S. 330, 340 (1979). The *Reiter* court further noted in the most unambiguous terms that "Money, of course, is a form of property." *Id*. at 338; *see also Chattanooga Foundry and Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906) ("[a] person whose property is diminished by a payment of money wrongfully induced is injured in his property."). Plaintiffs have alleged loss of tax revenue and increased public expenditures as damages in both of their RICO claims. (R. 514 at ¶¶902, 934). "[I]njuries in the form of lost tax revenues and increased law enforcement costs…are at bottom, claims for lost money. Such inherently economic losses constitute injury to 'property' within the meaning of [RICO]." *European Community v. RJR Nabisco, Inc.*, 150 F.Supp.2d 456, 492-93 (E.D.N.Y. 2001) (citing *Reiter*). Moreover, courts have determined that a government entities' loss of tax revenue is a "business or property" interest under RICO. *City of New York v. FedEx Ground Package Sys.*, Inc., 91 F. Supp. 3d 512, 524 (S.D.N.Y. 2015); *City of New York v. Gordon*, 1 F. Supp. 3d 94, 113 (S.D.N.Y. 2013) (finding the city's complaint alleging lost tax revenue "easily satisfies [RICO's injury to business or property] element); *see also City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 445 (2d Cir. 2008) ("[L]ost taxes can constitute injury to 'business or property' for purposes of RICO...."), *rev'd on other grounds sub nom., Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010) (reversing on lack of proximate cause).

In a criminal action, the Supreme Court held that a government's "right to uncollected excise taxes … is 'property' in its hands. This right is an entitlement to collect money from

petitioners, the possession of which is 'something of value'…." *Pasquantino v. United States*, 544 U.S. 349, 355–56 (2005) ("Valuable entitlements [to collect excise taxes] are 'property' as that term ordinarily is employed") (*citing Leocal v. Ashcroft*, 543 U.S. 1, 9 (2004) ("When interpreting a statute, we must give words their ordinary or natural meaning" (internal quotation marks omitted); *Black's Law Dictionary* 1382 (4th ed. 1951) (defining "property" as "extend[ing] to every species of valuable right and interest")).

As such, Plaintiffs have alleged a facially plausible claim for injury to their property. Defendants, however, assert that a government entity, when suing as a plaintiff, "cannot rely on expenditures alone to establish civil RICO standing, and there is no indication that the County holds a property interest in the law enforcement or health care services that it provides to the public." *Canyon Cty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 976, 979 (9th Cir. 2008). (R. 491-1, PageID# 7480-7481; R. 499-1, PageID# 7665-7666)). Defendants, however, have not identified any Supreme Court or Sixth Circuit case directly on point with the facts of this case. Defendants rely almost exclusively on *Canyon County* and argue that RICO precludes the recovery of such government service expenditures. *Id*. This argument, however, is not persuasive on this record.

i. "Business or Property" as Commercial Interests

Canyon County determined that the "business or property language" found in both RICO and in the Clayton Act should be interpreted uniformly. 519 F.3d at 977. The court held to the view that an injury to business or property under the Clayton Act encompasses only "the interests of the [state] as a party to a commercial transaction." 519 F.3d at 977 (acknowledging, however, that courts have "often, though not invariably, interpreted the two statutory provisions in a like manner."); *see also Welborn v. Bank of New York Mellon Corp.*, 557 Fed. App'x 383, 387 (5th Cir. 2014) ("When a government sues under the civil RICO statute, the 'business or

property' element requires that the injury 'refer to commercial interests or enterprises.'"). The Defendants, however, do not cite any Supreme Court or Sixth Circuit authority explicitly stating that a civil RICO action by a governmental entity is limited to property interests that stem from a commercial transaction or commercial interests.

Indeed, the import of the phrase "business or property" in the Clayton Act context has been construed at one time to be limited to "commercial interests." *See, e.g., Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 264 (1972) ("[T]he words 'business or property,' … refer to commercial interests or enterprises" and a state may not seek damages for other injuries under the Clayton Act). The language in the *Hawaii* decision was greatly softened by *Reiter*, which also considered the meaning of the phrase "business or property" in the Clayton Act. The *Reiter* Court explained that the *Hawaii* Court's reference to "the phrase 'commercial interests or enterprises,' read [i]n context, in no sense suggests that only injuries to a business entity are within the ambit of [the Clayton Act]." *Reiter*, 442 U.S. at 339 (finding that Congress' use of the disjunctive in the phrase "business or property" indicates that "'business' was not intended to modify 'property,' nor was 'property' intended to modify 'business.'")[12] The Seventh Circuit Court of Appeals has acknowledged the *Hawaii* decision's interpretation of the "business and property" phrase under the Clayton Act as referring only to commercial interests and competitive injuries, but held that "this is not the case under RICO." *Illinois Dep't of Revenue v. Phillips*, 771

[12] The *Canyon County* decision appears to endorse a restrictive reading of *Hawaii* expressly rejected by *Reiter*. "[T]he language of an opinion is not always to be parsed as though we were dealing with language of a statute." 442 U.S. at 341-342 (explaining that a "central premise" in *Hawaii* was a "concern over duplicative recoveries" and noting that the state of Hawaii was essentially trying to recover injuries to the business or property of consumers who could recover their own damage).

F.2d 312, 314 (7th Cir. 1985). Other Circuit decisions also cautioned against reflexively applying the Clayton Act's antitrust principles to RICO. *See, e.g., Schacht v. Brown*, 711 F.2d 1343, 1357-58 (7th Cir. 1983), *cert. denied sub nom. Arthur Andersen & Co., v. Schacht*, 464 U.S. 1002 (1983); *Bennett v. Berg*, 685 F.2d 1053, 1059 (8th Cir. 1982) ("In a RICO context, there are few countervailing reasons to lessen the impact of RICO remedies by imputing the limitations on standing which apply to antitrust law."). The *Schacht* decision noted that "RICO was broadly aimed at 'striking ... a mortal blow against the property interests of organized crime," and, therefore, it was "reluctant to undermine that broad mission of RICO by engrafting onto its civil provisions a competitive injury requirement." 711 F.2d at 1358.

ii. Municipal Cost Recovery Rule

Canyon County also applied the municipal cost recovery rule, a tort doctrine developed under state common law, as a basis for concluding the public expenditures alone were insufficient to create RICO standing. 519 F.3d at 974, 979-980. "The 'municipal cost recovery rule,' also called the 'free public services doctrine,' is a common-law rule which provides that, absent specific statutory authorization or damage to government-owned property, a county cannot recover the costs of carrying out public services from a *tortfeasor* whose conduct caused the need for the services." 32 A.L.R.6th 261 (Originally published in 2008) (emphasis added). Although the Ninth Circuit acknowledged that "we are not dealing with state common law, but with a statutory cause of action created by Congress [RICO]," the court applied the common law tort doctrine. *Id*. at 980. Furthermore, relying on a prior Ninth Circuit decision—*Diaz v. Gates*, 420 F.3d 897, 900 (9th Cir. 2005)—*Canyon County* found that "[f]inancial loss alone, however, is insufficient" to establish an injury to business or property under RICO "'[w]ithout a harm to a specific business or property interest,'" and that said inquiry is "typically determined by

reference to state law." 519 F.3d at 975.

The Sixth Circuit, however, has expressed a different view, acknowledging that "some role" may exist for state law with respect to the question of "where to set the 'business or property' threshold" in RICO cases, but emphasizing that this question "depends on federal statutory purpose, and that purpose is likely to support a definition that is uniform throughout the country." *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013) (*quoting DeMauro v. DeMauro*, 115 F.3d 94, 96–97 (1st Cir.1997)).[13] The *Canyon County* court opted to apply the state law doctrine barring recovery of municipal costs based on the notion that had "Congress meant to disrupt settled expectations and alter the legislatively-chosen system of funding local government services[,]" and allow treble recovery "under RICO for injuries arising from [the] provision of governmental services[] …we believe that Congress would have been more explicit." 519 F.3d at 980.

The Sixth Circuit, in *Jackson*, however has stated:

> Concerns about the scope of RICO are not new. Courts have long recognized that RICO has evolved "into something quite different from the original conception of its enactors," who sought to "supplement old remedies and develop new methods for fighting crime." Nonetheless, the unexpected scope of RICO can largely be attributed to the terms of the statute itself. Congress chose "self-consciously expansive language" when it adopted RICO, defined the "predicate acts" necessary to establish a pattern of racketeering activity broadly, and directed courts to give the statute a liberal construction, Organized Crime Control Act of 1970. As a consequence, courts have frequently rejected arguments that RICO should be given constructions that prevent it from reaching conduct that Congress may not have intended it to reach. "[T]he fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth."
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[13] *See also Miller v. York Risk Servs. Grp.*, 2013 WL 6442764, at *3 (D. Ariz. Dec. 9, 2013) (distinguishing between the Sixth Circuit's federal statutory purpose inquiry and the Ninth Circuit's state-law based approach with respect to determining whether there has been a RICO injury to business or property), *adopted*, 2013 WL 11739992 (D. Ariz. Dec. 19, 2013).

> Another limitation in § 1964(c) that has its origins in the antitrust laws is the requirement that a plaintiff be "injured in his business or property" in order to bring a civil action. While the Supreme Court has yet to definitively interpret this phrase as it appears in § 1964(c), it has construed it in the context of the antitrust laws. In *Reiter v. Sonotone Corp.*, … the Court held that "consumers who pay a higher price for goods purchased for personal use as a result of antitrust violations sustain an injury in their 'business or property'" under § 4. In so doing, it rejected the respondents' argument that "the phrase 'business or property' means 'business activity or property related to one's business.'" While conceding the breadth of its ruling that "monetary injury, standing alone, may be injury in one's 'property,'" the Court pointed out that "[t]he phrase 'business or property' also retains restrictive significance.

Jackson, 731 F.3d at 563-564 (internal citations omitted).

In addition, the court finds instructive other decisions addressing the scope of the municipal cost recovery rule and declining to find that it creates an absolute shield for chronic wrongdoers engaged in a pattern of conduct that creates great public expense. For example, courts have found an exception when the government's costs are the product of a public nuisance. The Ohio Supreme Court was not persuaded that the municipal cost recovery rule barred Cincinnati's recovery of expenses for police, emergency, health, corrections, prosecution and other related public services, in an action brought against handgun manufacturers, trade associations, and handgun distributors—alleging tort claims of negligence, product liability, and public nuisance. *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002). The Ohio Supreme Court stated:

> Although a municipality cannot reasonably expect to recover the costs of city services whenever a tortfeasor causes harm to the public, it should be allowed to argue that it may recover such damages in this type of case. Unlike the train derailment that occurred in the *Flagstaff*[14] case, which was a single, discrete

[14] *Canyon County* relied upon *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 324 (9th Cir. 1983). The *Flagstaff* court applied the municipal cost recovery rule, but noted that it does not stand for the proposition that "a governmental entity may never recover the cost of its services. Recovery is permitted where it is authorized by statute or regulation … or

> incident requiring a single emergency response, the misconduct alleged in this case is ongoing and persistent. 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. Moreover, even the *Flagstaff* court recognized that recovery by a governmental entity is allowed "where the acts of a private party create a public nuisance which the government seeks to abate." *Flagstaff*, 719 F.2d at 324. We therefore reject the court of appeals' holding that appellant cannot recover its governmental costs.

Id. at 1149-50.

Similarly, in *City of Boston v. Smith & Wesson Corp.*, 2000 WL 1473568 (Mass. Super. Ct. 2000), the court held that said rule did not bar the city's claim to recover law enforcement and emergency services costs against the defendants—firearms manufacturers, distributors, sellers, and firearms industry trade associations. The court distinguished other decisions applying the doctrine, noting as follows:

> What each of these cases has in common is that the acts causing the damage were of the sort the municipality reasonably could expect might occur, and each of the results was a discrete emergency. Fires, fuel spills and ruptured gas mains are all frequent happenings which, while every effort is made to prevent them, can be expected to occur. Train derailments and airplane crashes are more unusual, but not so rare that a municipality can never expect to have to respond to such an emergency. The cases thus stand for the principle that such contingencies are part of the normal and expected costs of municipal existence, and absent legislation providing otherwise are costs to be allocated to the municipality's residents through taxes. In addition, in those cases there is no evidence that the specific defendants had engaged in a repeated course of conduct causing recurring costs to the municipality.

Id. at * 8; *see also James v. Arms Tech., Inc.*, 820 A.2d 27, 48-49 (N.J. App. Div. 2003) ("We do not accept the proposition that [the municipal cost recovery rule's] reasoning should apply in a case such as this, where the City claims a *repeated course of conduct* on defendants' part,

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required to effect the intent of federal legislation [or] … where the acts of a private party create a public nuisance which the government seeks to abate.").

requiring the City to expend substantial governmental funds on a continuous basis.")(emphasis added);[15] *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1145 (Ill. 2004) (citing *City of Flagstaff* and noting the public nuisance exception).

When balancing the fact that neither party has identified Supreme Court or Sixth Circuit precedent directly on point, with the Sixth Circuit's emphasis on federal statutory purpose over state-law based property rules and the jurisprudence confirming that the municipal cost recovery rule does not apply to preclude remedying a repeated course of conduct that allegedly injures a governmental plaintiff, the court is not persuaded that it is applicable to the present set of facts. Moreover, the Sixth Circuit has not indicated that it would concur with the Ninth Circuit's decision in *Canyon County* as it relates to the application of said rule.[16] The *Cincinnati v. Beretta* and *City of Boston* decisions declined to apply the doctrine to state law tort claims based on the persuasive reasoning that a doctrine that publicly spreads the costs caused by one-time tortfeasors, such as a negligent driver, is inappropriately applied where a defendant engages in a

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[15] The court determined the "Municipal Cost Recovery Rule does not apply to cases … where a municipality seeks to recover damages for the cost of abating a nuisance." Further, it also indicated that "if the City has a worthy claim, application of the Municipal Cost Recovery Rule would leave the City without a remedy." *Arms Tech., Inc.*, 359 N.J. Super. at 327-28. The court noted: "[i]f tortious conduct exists, the consequence is that the gun manufacturers are subsidized for their wrongful acts, and the cost of the governmental services must be borne by the taxpayers of the City. This result is fundamentally unfair, given the City's limited resources and strained ability to provide other essential services to its citizens. Application of the rule also serves as a disincentive; if culpable, the insulated defendants have no reason to obtain liability insurance to cover the cost of their conduct, or to take reasonable measures to eliminate, or at least reduce, the harm resulting from the use of their product." *Id.* at 328.

[16] The Sixth Circuit's citations to *Canyon County* in three decisions cannot be construed as endorsing its holding with respect to the "municipal cost recovery rule," as discussion of that doctrine is entirely absent from those cases. *See Saia v. Flying J. Inc.*, 2017 WL 6398013, at *3 (6th Cir. July 11, 2017), *cert. denied*, 138 S. Ct. 657, 199 L. Ed. 2d 533 (2018), *reh'g denied*, 138 S. Ct. 1182, 200 L. Ed. 2d 328 (2018); *Stooksbury v. Ross*, 528 F. App'x 547, 555 (6th Cir. 2013); *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496, 504, 506 (6th Cir. 2010).

course of repetitive conduct that causes harm of a substantial magnitude and imposes a repeated burden on government services. In addition, the court declines, in this case, to completely transplant that common law tort doctrine to defeat a claim arising under this federal statute. Doing so to defeat well pleaded allegations of an ongoing pattern of intentional racketeering activity is the antithesis of the construction of RICO that Congress designed it to have.[17]

b. Personal Injuries

The Defendants also argue that RICO's aforementioned limitation to recovery for an injury to "business or property" eliminates recovery for personal injuries or pecuniary damages flowing from such injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665) (*citing Doe v. Roe*, 958 F.2d 763, 767 (7th Cir. 1992); *Jackson*, 731 F.3d at 565). The *Jackson* court observed that "those regional circuits that have construed the phrase business or property have uniformly recognized that 'the ordinary meaning of the phrase injured in his business or property excludes

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[17] The court also notes that a recent New York supreme court decision addressed whether local governmental entities, who brought suit against opioid manufacturers, were barred from recovering the costs of governmental services by the municipal cost recovery rule. *In re Opioid Litigation*, 2018 WL 3115102 (N.Y. Sup. Ct., Jun. 18, 2018). The court found as follows:

> [A] review of the current state of the law revealed no case law supporting the Manufacturers' contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating "the normal provision of police, fire and emergency services," but to remedy public harm caused by an intentional, persistent course of deceptive conduct. The Manufacturers' argument that, despite allegations they designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids, the municipal cost recovery rule forecloses the plaintiffs from recovering the costs for services to treat residents suffering from prescription opioid abuse, addiction or overdose, or for the increased costs of programs implemented to stem prescription opioid-related criminal activities, if accepted, would distort the doctrine beyond recognition.

Id. (citations omitted).

personal injuries, including the pecuniary losses therefrom." 731 F.3d at 564-565 (internal quotation marks omitted); *accord Gucwa v. Lawley*, 731 Fed. App'x 408, 412 (6th Cir. 2018) ("Even though personal injuries may lead to monetary damages, such personal injuries and their associated pecuniary losses—including medical expenses—do not confer relief under § 1964(c).").

Plaintiffs do not contest that the law precludes recovering such damages, but rather argue that their "damages claims are not for personal injuries, but police and fire services, lost taxes, revenue and funding." (R. 654, PageID# 15747). They further argue that "[t]he harms that the Manufacturer and Distributor Defendants caused, which also impact the Plaintiffs' revenue-generating function, are direct injuries to their 'business and property.'" *Id*. Plaintiffs deny (and the court does not construe) the complaint as seeking to directly recover for the personal injuries sustained by opioid users/addicts. Nevertheless, the law also bars losses flowing from those personal injuries. Whether Plaintiffs' injuries flow from the personal injuries suffered by their residents is a crucial question in this litigation. Plaintiffs have alleged at least thirteen separate categories of damages with respect to their RICO claims in Counts One and Two. (R. 514, ¶¶902, 934).

The Defendants fail to meaningfully differentiate among the categories, contending they are all derivative of residents' personal injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665). Without a full record regarding the source of the various categories of damages, the court declines to paint with such a broad brush. While some of the claimed categories of damages may ultimately not survive if it is revealed through discovery that they fall into an area of prohibited recovery, the court cannot find at this preliminary stage in the proceedings that all thirteen categories are unrecoverable. For example, it is highly debatable whether Plaintiffs'

costs associated with training emergency personnel and first responders flow from an individual resident's personal injuries. (R. 514 at ¶¶902(c), 934(c)). Even further removed from any personal injuries are Plaintiffs' claimed losses associated with lost tax revenue and diminished property values. *Id*. at ¶¶902(k-n), 934(k-m).[18]

The Sixth Circuit has instructed that a court "may dismiss a complaint for failure to state a claim 'only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *Trollinger*, 370 F.3d at 615 (quoting *Swierzkiewickz*, 534 U.S. at 514). Defendants, as the moving party, have failed to meet their burden of demonstrating that all of Plaintiffs' claimed damages are purely derivative of personal injuries and, therefore, do not constitute an injury to "business or property." For the foregoing reasons, Defendants' motion to dismiss on these grounds is not well taken.

2. Causation

a. "But for" Cause

The Defendants assert that Plaintiffs have plead no facts establishing "but for" causation. (R. 491-1, PageID# 7516-7517; R. 499-1, PageID# 7666-7672, 7683-7684). First, they maintain that Plaintiffs have not alleged what they characterize as the "first step" in the causal chain—"that specific Ohio prescribers were exposed to the Manufacturers' alleged deceptive marketing" or that but for the Manufacturers' purported failure to monitor and report suspicious orders of prescription opioids to DEA Field Division Offices, Plaintiffs would not have suffered the

[18] The court's recommendation should not be misconstrued as an affirmative finding that none of Plaintiffs' claimed damages are premised upon pecuniary damages flowing from personal injuries. In addition, to the extent that Plaintiffs seek damages for losses of property value in their communities, such claims may, after discovery, be too speculative. *See, e.g. Ameriquest*, 615 F.3d at 505-506. However, in this case, such arguments are more appropriate after the record has been developed.

injuries associated with prescription opioid misuse, abuse, and addiction. *Id*. "But since 'we presume that general allegations embrace those specific facts … necessary to support the claim,'…causal weaknesses will more often be fodder for a summary-judgment motion under Rule 56 than a motion to dismiss under Rule 12(b)(6)." *Trollinger*, 370 F.3d at 615.[19]

Further, the complaint's allegations set forth a nationwide campaign targeting physicians throughout the United States to change their prescribing practices based on allegedly false statements and misrepresentations. The complaint alleges that the Marketing Defendants carried out this same marketing scheme in Ohio. (R. 514, PageID# 6966-6969, ¶¶671-683) ("The Marketing Defendants all marketed their products and disseminated their misrepresentations in the state of Ohio."). Plaintiffs also alleged that "sales representatives from each of the Marketing Defendants visited prescribers in Summit County." *Id*. at ¶673.[20] Thus, Defendants' first assertion is rejected.

Moreover, Defendants contend that Plaintiffs failed to allege that if they had reported suspicious orders to DEA, it would have led to enforcement actions and that would have averted prescription opioid diversion and "related societal harms in Summit County." (R. 491-1, PageID# 7516; R. 499-1, PageID# 7684). The court disagrees that Plaintiffs are required to

[19] To the extent Defendants argue that Plaintiffs allegations fail to satisfy Rule 9(b)'s pleading requirements, such argument is not persuasive, because courts have recognized that pleadings are sufficient so long as they provide enough detail to put the responding party on notice and enable a response. *See infra* Section III-A-4-a.

[20] To the extent Defendants maintain that Plaintiffs were required to name specific prescribers, this court disagrees. Where the alleged scheme is so broad in scope, no meaningful purpose would be served by merely naming a doctor or several doctors to serve as examples of physicians who were misled by Defendants' marketing scheme. The complaint alleges that Summit County physicians confirmed the existence of the alleged marketing scheme in Summit County. (R. 514 at ¶675). Defendants will certainly have the opportunity to request the identity of these doctors during discovery, and Plaintiffs will need to support their theories with evidence to withstand a motion for summary judgment or persuade the trier of fact.

divine the actions that the DEA would have taken had the Defendants properly reported the suspicious orders as alleged or that Plaintiffs would be required to foresee the alternate series of events had such actions been taken. Contrary to Defendants contention, "but-for" causation is rather easily satisfied by the allegations in the complaint. Reading the complaint's averments in favor of Plaintiffs, as required when considering a motion to dismiss, they assert but-for Defendants' allegedly deceptive marketing scheme that changed the way physicians prescribe opioids, coupled with the systemic undermining of quotas and institutional controls as well as the failure to report suspicious orders by both the Marketing and Distributor Defendants, the number of opioids would not have tripled or quadrupled thereby directly giving rise to the opioid epidemic—the costs of which have resulted in Plaintiffs' alleged injuries. Plaintiffs have sufficiently pled that the Defendants' alleged actions were the "but for" cause of their injuries as required by 18 U.S.C. § 1964(c) and under *Holmes*, 503 U.S. at 268, and *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 456-61 (2006).

b. Proximate Cause

The Defendants argue that Plaintiffs plead facts that are too attenuated and remote to establish proximate cause. They further contend that the causal chain is broken by: (1) the independent medical judgment of medical professionals who prescribe the opioid products; and (2) third-party criminal acts. (R. 491-1, PageID# 7481-7481; R. 499-1, PageID# 7667-7669). Defendants maintain that Plaintiffs fail to allege a direct relation between their injuries and the conduct of the Defendants. *Id*. Plaintiffs counter that their damages can be properly and efficiently apportioned among the Defendants, that their RICO damages cannot be sought or recovered by *any other party*, and that recovery is necessary to vindicate the purposes underlying RICO and deter future violations. (R. 654, PageID# 15749).

This court cannot say at this early stage of the proceedings that the Plaintiffs' injuries are so remote as to bar any potential recovery. Plaintiffs, local governments, have been impacted by the opioid epidemic. Their injuries, alleged to be caused by the Defendants' conspiracy to dramatically increase the usage and supply of opioids for off-label purposes, to some extent, stem from ills associated with opioid use and/or addiction. The connection between their injuries and the Defendants' alleged racketeering and fraudulent activity is not so attenuated, as their injuries plainly stem from opioid use/abuse and not some possible other source. This court cannot find, absent any discovery, that Plaintiffs' injuries were incidental to the alleged fraud or the oversupply/diversion of opioids. While Defendants' alleged actions caused harm to others (*i.e.* those who became addicted to opioids), the ensuing harm to Plaintiffs—the costs associated with responding to and working to stem the opioid epidemic—cannot be deemed incidental. Taking into consideration Plaintiffs' allegation that as many as 25 percent of patients who receive prescription opioids long-term for chronic pain in a primary care setting become addicted (R. 514 at ¶16), the costs associated with dealing with this surge in addictions cannot be described as incidental but, even if not inevitable in individual cases, it is inescapable in the aggregate.

The Supreme Court has addressed proximate cause under RICO in *Holmes*, 503 U.S. at 258, *Anza*, 547 U.S. at 451, and *Hemi Group LLC*, 559 U.S. at 1. The Manufacturers have asserted that *Anza* is analogous to the case at bar (R. 499-1, PageID# 7665), while the Distributors have asserted that *Hemi* is analogous. (R. 491-1, PageID# 7482-7483). While the court disagrees that any of these decisions are factually analogous to the case at bar, the decisions remain instructive in their application of the *Holmes* factors. The *Holmes* court identified the underlying rationale behind the need for proximate cause as follows: (1) "the less

direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors," (2) "recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries," and (3) "directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely." *Holmes*, 503 U.S. at 268.

i. Directness

Relying upon *Anza*, 547 U.S. at 460 and *Jackson*, 731 F.3d at 565, the Defendants, as discussed above, contend that Plaintiffs' injuries are barred because they are derivative of personal injuries suffered by third-party opioid users. (R. 491-1, PageID# 7479-7479; R. 499-1, PageID# 7665). Unsurprisingly, Plaintiffs respond that their damages were directly caused by the Defendants' actions; and, in addition, argue that the *Holmes* factors analysis weighs in favor of finding sufficient proximate cause at this early stage. The Supreme Court has cautioned that "the infinite variety of claims that may arise make it virtually impossible to announce a black-letter rule that will dictate the result in every case" and its use of "the term 'direct' should merely be understood as a reference to the proximate-cause enquiry …." *Holmes*, 503 U.S. at 274, n. 20 (citations omitted).[21] "The injurious conduct need not be the sole cause of the plaintiffs' injuries,

[21] Though not a RICO action, the Supreme Court recently addressed proximate cause under the Fair Housing Act (FHA). *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296 (2017). Significantly, the Court found that Miami's allegations—that the Defendant banks had discriminated against minorities leading to property tax and municipal spending injuries—arguably fell within the "zone of interests" protected by the FHA. *Id*. at 1303. Further, with respect to proximate cause, despite the fact that Miami's alleged injuries clearly went beyond the "first step" and flowed through individuals who had allegedly been the victims of racially discriminatory lending, the Supreme Court, rather than ordering dismissal, remanded the case for

but there must be 'some direct relation' between the conduct and the injury to sustain a claim." *Ray*, 836 F.3d at 1349 (*citing Williams*, 465 F.3d at 1287–88; *Anza*, 547 U.S. at 457).

The first of the *Holmes* factors requires the court to determine how difficult it would be to ascertain which portion of Plaintiffs' damages resulted from Defendants' allegedly unlawful conduct versus damages that may be attributable to other factors or to other parties. First, the court notes that injuries in *Holmes* and *Anza*, unlike the injuries asserted herein, were individualized, while the injury asserted herein is rather aggregative.[22]

Defendants suggest that there are too many possible intervening causes, identifying the "exercise of independent medical judgment" by physicians who acted as "learned intermediaries," as well as "intervening third-party criminal acts." (R. 491-1, PageID# 7483-7484; R. 499-1, PageID# 7669-7670). First, the notion that the physicians cut off the chain of causation ignores pertinent allegations in the complaint. While the complaint alleges that

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further analysis of proximate cause. *Id*. at 1306, 1311 ("The lower courts should define, in the first instance, the contours of proximate cause under the FHA and decide how that standard applies to the City's claims for lost property-tax revenue and increased municipal expenses.") Several lower courts have also noted that the fact that a plaintiff's increased costs/damages "runs through a separate injury" to a third party or parties "does not by itself require dismissal on proximate cause grounds." *Cty. of Cook, Illinois v. Wells Fargo & Co.*, 2018 WL 1469003, at *6 (N.D. Ill. Mar. 26, 2018); *City of Oakland*, 2018 WL 3008538 at *1 (N.D. Cal. June 15, 2018). Nor does the lack of a direct relationship between the plaintiff and defendant defeat nor necessarily frustrate proximate cause. The Sixth Circuit found there was sufficient directness where there is a "link between the scheme and the type of injury [plaintiff] suffered." *Wallace*, 714 F.3d at 420. "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.*, 2017 WL 4890594, at *9 (N.D. Cal. Oct. 30, 2017) (citations omitted).

[22] In *City of Oakland*, 2018 WL 3008538, at *1, a district court, when confronted with a proximate cause issue in a claim arising under the FHA, observed that "where damages are aggregative, precision is not expected. Invariably some approximation is required," but noted that "aggregative injury itself does not obviate proximate cause analysis…."

Defendants directly targeted patients with their advertising, the lion's share of the allegations point to a systematic campaign, based on allegedly false statements, that *specifically targeted physicians*. Not only is it alleged that Defendants, through their sales representatives, directly contacted hundreds of thousands of prescribers (R. 514, ¶¶452-455), it is also alleged that Defendants sponsored seminars, influenced medical associations, controlled third-party front groups to maintain the guise of impartiality, and finally directly paid KOLs—all to influence physicians' prescribing decisions and to abolish concern regarding opioid addiction/abuse. (*See generally* R. 514). In other words, the complaint alleges that prescribing physicians were also targets of the misrepresentations. Given these allegations, the court declines to find that the physicians' act of writing prescriptions breaks the causal chain, as a matter of law, when the very purpose of the Defendants' alleged scheme was to achieve exactly that result. The complaint further alleges that the Manufacturers and Distributors conspired to increase opioid sales through trade organizations such as the PCF or HAD; they were in a unique position to recognize the diversion of drugs and did in fact make such a recognition; and they concealed this information despite an obligation to report suspicious orders, all in order to further their supply chain scheme. (R. 514, ¶¶498-593, PageID# 6918-6947). Defendants have no cogent rationale explaining how the prescribing physicians would be an intervening cause with respect to the supply-side allegations.

The court also disagrees that the complaint's RICO claims are rendered deficient by the failure to specifically identify a prescribing physician who relied on Defendants' alleged fraudulent statements. The First Circuit Court of Appeals rejected a similar argument, in *In re Neurontin Litigation*, where the defendants had maintained that "its supposed misrepresentations went to prescribing doctors, and so the causal link to Kaiser [a healthplan provider and insurer]

must have been broken." 712 F.3d 21, 37 (1st Cir. 2013). Relying on the Supreme Court's holding in *Bridge*,[23] the circuit court rejected that argument. The court of appeals also rejected the argument that "no physician in this case, or in the Neurontin MDL as a whole, testified that he or she prescribed Neurontin because of defendants' fraudulent off-label marketing," an argument that mirrors Defendants' argument herein. *Id*. at 29. The court reasoned that plaintiffs had presented "other evidence" of causation to the jury, as well as "evidence as to why such individual [physician] testimony was unreliable."[24] *Id*. In addition, the defendants' "scheme relied on the expectation that physicians would base their prescribing decisions in part on [their] fraudulent marketing." 712 F.3d at 39.

Further, the court is unconvinced that Defendants' reliance on *Ind./Ky./Ohio Reg'l*

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[23] The Supreme Court in *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), held unanimously that a civil-RICO plaintiff does *not* need to show that it *detrimentally relied* on the defendant's alleged misrepresentations. *See also Wallace*, 714 F.3d at 420 ("While reliance is 'often used to prove ... the element of causation,' that does not mean it is the only way to do so, nor does that 'transform reliance itself into an element of the cause of action.'") (*citing Bridge*).

[24] The plaintiffs' primary evidence came from expert testimony from a health economics professor, who used "aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug." 712 F.3d at 30. The expert's regression analysis "found a causal connection between the fraudulent marketing and the quantity of prescriptions written for off-label indications. She also testified as to why Pfizer's proposed physician-by-physician analysis of causation was not a scientifically valid approach to causation." *Id*. The expert testified "as to the well-recognized unreliability in the field of healthcare economics of asking doctors individually whether they were influenced by the many methods of off-label marketing. She said that self-reporting from physicians about patterns of practice that may be controversial shows both conscious reluctance and unconscious bias, which lead them to deny being influenced." *Id*. Although such expert testimony is not before the court, this case cautions against prematurely determining, without a sufficiently developed record, that certain allegations must be present before causation can be determined to have been sufficiently pled. Defendants' reliance on *City of Chicago v. Purdue Pharma, L.P.*, for the proposition that the complaint must specifically identify doctors is misplaced, as the district court was addressing state law claims and found that the plaintiffs failed to allege sufficient detail about the false claims. 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015). Thus, the court finds that the absence "self-reports" from physicians in the complaint is not dispositive. In addition, the court finds the rationale of *In re Neurontin* more compelling.

Council of Carpenters Welfare Fund v. Cephalon, Inc. ("*Carpenters*") compels a different result. 2014 WL 2115498 (E.D. Pa. May 21, 2014). Defendants focus on the *Carpenters* court's observation that "physician-prescribers are presumed to have knowledge of a drug label's contents." *Id*. at *6 (*citing In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012)). However, the *Carpenters* decision was based on the finding that the allegations in the complaint were general and conclusory, it did not set forth a general rule that a physician's knowledge of a drug label insulates a drug manufacturer or distributor from liability for fraudulent marketing or unlawful distribution practices. *Id*. at **6-7. Defendants make no meaningful attempt to illustrate that the current complaint is similarly defective, beyond making generalized statements of insufficiency. (R. 499-1, PageID# 7675-7680). Conversely, in *In re Epogen*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008), a district court held that the plaintiff's RICO claims were essentially trying to "shoehorn allegations that Defendants have engaged in off-label promotion in violation of the FDCA into [a] RICO [action]." Although the claims therein were dismissed—with leave to amend—the court observed that "[t]he existence of the FDCA does not completely preclude injured parties from asserting claims of fraud or false advertising." *Id*. at 1290, 1292. In addition, the court observed that: "[Plaintiffs] *may* bring a RICO claim that is truly based on allegations of mail or wire fraud (in the form of deceptive advertising).…To the extent that Plaintiffs allege that Defendants made false statements or deliberately concealed material facts in order to mislead health care professionals and consumers about the safety of EPO, those claims are viable under RICO." *Id*. at 1290 (emphasis in original).

Second, Defendants' statement that third party criminal acts break the chain of causation (R. 491-1, PageID# 7517-7519; R. 499-1, PageID# 7669), even if accepted as true, would fail to

break the chain of causation for those damages that were caused by the legal prescription of opioids. The complaint alleges that out of 350,000 fatal overdoes during the relevant time span, more than 200,000 overdoses involved prescribed opioids rather than illicit heroin. (R. 514 at ¶5). It is further alleged that the vast majority of persons who began using heroin in the relevant time period turned to the drug after becoming addicted to prescription opioids.[25] (R. 514 at ¶6). Thus, under the facts pled, the criminal acts involving heroin or the illegal use/trade of legal prescriptions do not, as a matter of law upon consideration of a motion to dismiss, break the chain of causation. Even these actions can to some extent, given the allegations, be attributed and foreseeable to Defendants, who allegedly both flooded the market with opioids and created the demand for them.

Construing the allegations of the complaint as true, the court rejects Defendants' arguments and finds the first factor counsels in favor of proximate cause. The complaint contains sufficiently detailed allegations that a quantifiable causal link existed between Defendants' conduct and the damages suffered by Plaintiffs as a result of the opioid epidemic. The "direct causal connection" requirement has been met, as it is not apparent as a matter of law that "intricate, uncertain" inquiries are required to link the Defendants' alleged conduct to Plaintiffs' injuries. *Anza*, 547 U.S. at 460. Hence, the first of the *Holmes* factor weighs in favor of a finding that proximate cause has been sufficiently plead.

ii. Complexity of Apportioning Damages/Repetitive Recovery

The second *Holmes* factor is perhaps the easiest to apply to the allegations in the present

[25] The court recognizes that overdoses involving prescribed opioids may also include individuals who were not the prescribed user of the drug. The fact that this category may include both illicit users as well as those who were prescribed the opioids in question does not preclude proximate cause or warrant dismissal at this preliminary stage.

case. Plaintiffs' brief in opposition expressly states that they are *not* attempting to recover any of the following: (1) personal injuries incurred by individuals "suffering as a result of [opioid] over-prescription, overuse, and addiction," (2) funds expended by competitors or non-purchasing customers,[26] or (3) "monies for health insurance plan members required to pay increased health insurance premiums…." (R. 654, PageID# 15755). The court also does not construe the complaint as seeking to recover these costs. Plaintiffs' complaint seeks thirteen categories of damages, which can be summarized into three general categories—(1) public expenditures made in direct response to opioid use and trafficking; (2) reduced tax revenue resulting from that abuse, misuse, and addiction; and (3) losses caused by diminished property values—none of these damages are recoverable by those individuals who became addicted to opioids, as personal injuries. (R. 514 at ¶¶902, 934). These individuals cannot recover from Defendants the public expenditures of Plaintiffs, they cannot claim lost county or municipal tax revenue, and they cannot claim the diminished values of Plaintiffs' property, or the reduced tax income to Plaintiffs. By way of example, if Plaintiffs seek to recover the costs associated with providing police, firefighters or other emergency personnel with Naloxone to block a potentially fatal overdose (*Id*. at ¶902), this cost cannot be claimed by any other entity except Plaintiffs.[27]

Therefore, the second *Holmes* factor also weighs in favor of a finding that proximate cause has been sufficiently pled.

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[26] It is not entirely clear whether Plaintiffs are merely differentiating case law with this statement or disclaiming any interest in monies spent by private providers of emergency services. In any event, it does not meaningfully impact the court's conclusion.

[27] If discovery were to reveal that Plaintiffs routinely assessed these costs to the individuals who required them and/or to their insurers, and that Plaintiffs actually recovered such costs, Defendants would in no way be precluded from arguing that no damages were incurred.

iii. Other Injured Parties Vindicating the Law

The third and final *Holmes* factor is an inquiry into whether more directly injured victims can bring suit. Plaintiffs argue that if their suit is barred "few, if any, victims of the RICO conspiracy will be able to 'vindicate the law as private attorneys general.'" (R. 654, PageID# 15754) (*quoting Holmes*, 503 U.S. at 269-270). Of course, it is too early to determine whether any laws have been violated. Nevertheless, taking the allegations as true, the court agrees with Plaintiffs that no other category of potential plaintiff groups, aside from states and their political subdivisions, can be counted on to vindicate the law in the same manner.[28]

The court again finds *In re Neurontin* instructive. Although the plaintiff therein was an insurer and not a government entity, the court noted that there was no risk of duplicative recovery because "[n]either the individual physicians, nor the [Drug Information Service] members, nor the [Pharmacy and Therapeutics] Committee members—the parties to whom [defendant] directly made its misrepresentations—ever paid anything toward a Neurontin prescription, so there is no risk of multiple recoveries due to a suit by another of those actors." 712 F.3d at 37. Defendants have not shown that another party would be able to recover for the specific damages Plaintiffs sustained from Defendants' alleged enterprise. The third factor also favors a finding that proximate cause has been sufficiently pled.

Based on the application of the *Holmes* factors, the court concludes that the connection between Plaintiffs' injuries and the Defendants' alleged scheme—to vastly increase opioid sales by changing physician prescribing practices through fraud coupled with increasing the supply of

[28] Defendants have stridently asserted that civil RICO damages are unavailable for personal injuries. (R. 491-1, PageID# 7478-7479; R. 499-1, PageID# 7665). In such case, patients, who were inappropriately prescribed opioids and suffered physical or mental injuries as a result, would be precluded from bringing a RICO claim to recover for their personal injuries.

opioids by failing to report suspicious orders—"is not so indirect, unforeseeable, or illogical that the defendants must prevail as a matter of law." *Wallace*, 714 F.3d at 422.

3. Existence of an Enterprise

"The [RICO] statute does not specifically define the outer boundaries of the 'enterprise' concept but states that the term 'includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.'" *Boyle*, 556 U.S. at 944 (citing § 1961(4)). The *Boyle* court recognized that the definition of enterprises was "obviously broad" and ensure[d] that the definition has a wide reach. *Id.* Some structure, however informal, was found to be necessary, because: "it is apparent that an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Id.*

> [A]n association-in-fact enterprise is simply a continuing unit that functions with a common purpose. Such a group need not have a hierarchical structure or a "chain of command"; decisions may be made on an ad hoc basis and by any number of methods—by majority vote, consensus, a show of strength, etc. Members of the group need not have fixed roles; different members may perform different roles at different times. The group need not have a name, regular meetings, dues, established rules and regulations, disciplinary procedures, or induction or initiation ceremonies. While the group must function as a continuing unit and remain in existence long enough to pursue a course of conduct, nothing in RICO exempts an enterprise whose associates engage in spurts of activity punctuated by periods of quiescence.

Id. at 944, 948 (footnotes omitted).

Defendants contend that Plaintiffs have not alleged any facts that could establish the three requisite structural features. (R. 499-1, PageID# 7673-7674, 7685-7686; R. 491-1, PageID# 7490). Specifically, they argue that Plaintiffs have failed to allege that "each defendant had 'some part in directing the enterprise's affairs.'" *Id*. (*quoting United States v. Fowler*, 535 F.3d

408, 419 (6th Cir. 2008) (*citing Reves v. Ernst & Young*, 507 U.S. 170, 179 (1993)). Defendants also assert that the complaint fails to allege a "common purpose," and merely alleges profit-seeking activity by competitors. The court disagrees. First, pursuit of profit is not the exclusive province of legitimate commercial endeavors. Second, Plaintiffs clearly allege a vast scheme that had a fundamental overarching purpose—to materially expand prescription opioid use by altering the medical community's prescribing practices of opioids through repeated fraudulent statements and misrepresentations. The Defendants allegedly used front groups and KOLs, as well as their own sales representatives, to spread their false and misleading message. If such a conspiracy is established by the facts, a profit motive would not negate a common purpose. While Defendants would characterize the allegations as alleging merely "a pattern of crimes" "independently and without coordination," (R. 499-1, PageID# 7673), it is alleged that front groups, such as APF, AAPM, and APA, were funded and directed by multiple Defendants to spread their false message under the guise of a neutral third party. (R. 514 at ¶¶357-428).

On the supply side, the Distributors attempt to portray the allegations as establishing no more than "routine business relationships" or "membership in trade organizations." (R. 491-1, PageID# 7491). Defendants' contentions turn a blind eye to allegations that allege much more. It is alleged the PCF and the HDA created a private network where representatives of the Manufacturers and Distributors could form relationships and create alliances and hold strategic business discussions between high-level executives. (R. 514 at ¶¶534-553). Plaintiffs further allege that the Manufacturers and Distributors were "not two separate groups operating in isolation or two groups forced to work together in a closed system," but rather they "operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids." *Id*. at ¶¶543-546. Though Defendants may have competed over the ever-

mushrooming opioid market, that does not shield them from allegations of racketeering activity in furtherance of a scheme to grow that market.

Defendants assert that their mere participation in trade associations is insufficient to form an enterprise. (R. 744, PageID# 17655; R. 746, PageID# 17711). "In *Boyle*, the [Supreme] Court upheld an instruction that allowed a jury to find an association-in-fact enterprise 'form[ed] solely for the purpose of carrying out a pattern of racketeering acts' and instructed that '[c]ommon 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.'" *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 794 (6th Cir. 2012) (*citing Boyle*, 556 U.S. at 942). "[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]." *Id*. at 951. It is alleged, for example, that the Manufacturers and Distributors used the HDA to jointly increase production quotas, to stymie efforts that would prevent the diversion of opioids, and to coordinate their refusal to report suspicious orders, including those made by direct competitors. (R. 514 at ¶¶545-552). Defendants do not meaningfully explain how these relationships are insufficient as a matter of law. (R. 746).

An inability to describe the exact inner workings of these associations, without the benefit of discovery, is not dispositive at this stage. At the same time, the allegations in the complaint are significantly more detailed than a mere assertion that because the Defendants were members of a trade association that they must have been part of an illicit enterprise. Again, discovery may yield no fruit in this regard, but Plaintiffs should have an opportunity to prove the substance of their allegations.

Finally, Plaintiffs have alleged longevity sufficient to pursue the enterprise's purpose—

the 1990s to the present. (R. 514 at ¶¶829, 834).

4. Racketeering Activity

The Defendants argue that Plaintiffs fail to plead any actionable "racketeering activity." (R. 491-1, PageID# 7486-7490; R. 499-1, PageID# 7674-7678, 7686). "RICO takes aim at 'racketeering activity,' which it defines as any act 'chargeable' under several generically described state criminal laws, any act 'indictable' under numerous specific federal criminal provisions, including mail and wire fraud …." *Sedima*, 473 U.S. at 481. Plaintiffs allege Defendants engaged in mail and wire fraud under 18 U.S.C. §§ 1341 and 1343. (R. 514 at ¶¶888-890, 911-916).

a. Marketing Enterprise Claim

"When pleading predicate acts of mail or wire fraud, in order to satisfy the heightened pleading requirements of Rule 9(b), a plaintiff must '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 404 (6th Cir. 2012) (*citing Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008)). Nevertheless, a RICO plaintiff is *not* required to plead or prove first-party reliance on an allegedly false statement. *See Bridge*, 553 U.S. at 648. In addition, "courts have relaxed Rule 9(b)'s heightened pleading requirements in cases involving complex fraudulent schemes or those occurring over a lengthy period of time and involving thousands of billing documents." *In re U.S. Foodservice Inc. Pricing Litig.*, 2009 WL 5064468, at *18 (D. Conn. Dec. 15, 2009) ("dates, times and places need not be pleaded with absolute precision, so long as the allegations sufficiently put the defendant on notice as to the circumstances of the charged misrepresentations.") (citations omitted); *In re Sumitomo Copper Litig.*, 995 F. Supp.

451, 456 (S.D.N.Y. 1998) ("In complex civil RICO actions involving multiple defendants, therefore, Rule 9(b) does not require that the temporal or geographic particulars of each mailing or wire transmission made in furtherance of the fraudulent scheme be stated with particularity.").

The Manufacturers assert that the marketing enterprise and supply chain enterprise RICO claims are based entirely on allegations that they fraudulently marketed opioids, but the complaint fails to plead "any such fraudulent marketing anywhere in Summit County as to any Manufacturer Defendant with the particularity required by Rule 9(b)." (R. 499-1, PageID# 7678, 7688). They further aver that the so-called "nine categories of misrepresentations" alleged in the complaint do not satisfy the particularity requirements of Rule 9(b). *Id*. at PageID# 7679. They further contend that Plaintiffs impermissibly rely on the statements of third-parties. *Id*. at PageID# 7681. Plaintiffs point to *Williams v. Duke Energy Intern., Inc.*, wherein the Sixth Circuit Court of Appeals stated:

> [T]his court has held that "[i]t is a principle of basic fairness that a plaintiff should have an opportunity to flesh out her claim through evidence unturned in discovery. 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." *Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 680 (6th Cir. 1988). "Especially in a case in which there has been no discovery, courts have been reluctant to dismiss the action where the facts underlying the claims are within the defendant's control." *Id.*

681 F.3d 788, 803 (6th Cir. 2012). A recent decision from this district supports that notion and cautions that "Rule 9's pleading requirement of particularity 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 the requirements of Rule 9(b) have been met." *Ford v. Pa. Higher Educ. Assist. Agency*, 2018 WL 1377858 at *4 (N.D. Ohio Mar. 19, 2018) (Lioi, J.) (citations omitted); *see also In re Sumitomo Copper Litig.*, 995 F. Supp. at 456

("In cases in which the plaintiff claims that the mails or wires were simply used in furtherance of a master plan to defraud, the communications need not have contained false or misleading information themselves [and] a detailed description of the underlying scheme and the connection therewith of the mail and/or wire communications, is sufficient to satisfy Rule 9(b)."") (*citing Schmuck v. U.S.*, 489 U.S. 705, 715 (1989)).

Plaintiffs have sufficiently alleged that the Manufacturers engaged in an "Opioid Marketing Enterprise." At a minimum, they have sufficiently alleged that mail and wire communications were a "step in the plot" of the overarching fraudulent scheme.[29] It is alleged that the "[t]he pattern of racketeering activity used by the RICO Marketing Defendants … likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain…." (R. 514 at ¶¶839, 840-848). As set forth in the summary above, the complaint details nine categories of specific misrepresentations. It further sets out how the so-called misrepresentations were disseminated, including through speakers' programs, front groups, KOLs, and directly through sales representatives.

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[29] In *Schmuck*, 489 U.S. at 710-711, the Supreme Court explained that:

> The federal mail fraud statute does not purport to reach all frauds, but only those limited instances in which the use of the mails is a part of the execution of the fraud, leaving all other cases to be dealt with by appropriate state law." To be part of the execution of the fraud, however, the use of the mails need not be an essential element of the scheme. It is sufficient for the mailing to be "incident to an essential part of the scheme," or "a step in [the] plot."

(internal citations and footnotes omitted).

Whether these so-called misrepresentations were indeed false or misleading is an issue of fact. Defendants' motion to dismiss demands an untenable level of specificity above and beyond the pleading rules. Plaintiffs cannot be expected to plead the minutiae of their case without the benefit of discovery.[30] Further, the court finds compelling the reasoning of a decision from the Southern District of New York:

> [I]t is difficult to see any useful purpose in requiring that a RICO complaint specifically allege each mailing in furtherance of a complex commercial scheme, at least where, as here, the complaint alleges that numerous mailings of particular kinds were made in furtherance of the scheme. Once the plaintiff alleges with particularity the circumstances constituting the 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.

Spira v. Nick, 876 F. Supp. 553, 559 (S.D.N.Y. 1995) (footnotes omitted). Taking into consideration the clandestine nature of the alleged conspiracy to swell the market for opioids by undermining the medical community's apprehension towards prescribing them, it is unsurprising that Plaintiffs cannot connect each dot in the conspiracy without the benefit of discovery, as the evidence necessary to prove their allegations, if it exists, undoubtedly lies primarily in the hands of Defendants. Given the detailed allegations of the complaint, it cannot reasonably be deemed a fishing expedition.

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[30] Defendants repeated statement that Plaintiffs have failed to identify even one Summit County prescriber who relied on the misrepresentations is a red herring. Plaintiffs allege that interviews with Summit County doctors have confirmed that Defendants' sales representatives "carried the deceptive messages to local prescribers." (R. 514 at ¶675). Defendants will have ample opportunity to ascertain the identity of these doctors in discovery. The allegation that Ohio is one of the hardest hit states by the opioid epidemic, with 39.5 million opioid doses dispensed in Summit County in 2012 alone for a county-wide population of 540,000, coupled with the allegation that it leads the nation in overdose deaths per capita, when accepted as true, renders hollow any notion that the Defendants' more than a decade long nationwide push to expand prescription opioid use failed to permeate Summit County. *Id*. at ¶¶689, 714-719.

Finally, the Manufacturers' assertion that Plaintiffs are relying on statements made by third parties fails to read the complaint as a whole. (R. 499-1, PageID# 7681-7682). Plaintiffs have alleged that the Manufacturers spent millions of dollars on both advertising as well as direct contact with physicians through sales representatives, through which they spread their alleged misrepresentations concerning the safety and efficacy of opioids; that the Manufacturers created the body of literature to support false assertions; and that so-called third parties were merely front groups or KOLs sponsored and controlled directly by the Manufacturers. (R. 514 at ¶¶442-445, 448-455). Although the veracity of these allegations may be in dispute, they cannot be challenged in a 12(b)(6) motion.

b. Supply Chain Enterprise

i. Mail and Wire Fraud

The Distributors also assert that Plaintiffs have failed to allege with sufficient particularity any predicate acts of mail or wire fraud under RICO. (R. 491-1, PageID# 7486-7487). Without repeating the requirements of mail or wire fraud pleading set forth above, the complaint itself appears to concede that a high level of specificity is lacking, but asserts that "[m]any of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred." (R. 514 at ¶871). The complaint does broadly aver that the Distributors used the mail and/or the wires to ship the opioids themselves, to seek higher production/procurement quotas, to submit reports to the DEA that contained material omissions and/or misrepresentations, to transmit documents that facilitated the transport of the opioids, to process rebates and chargebacks, to make payments to

trade organizations such as the HDA—all while being aware that many of the orders were suspicious, exceeded any reasonable amount for legitimate purposes, and subject to diversion. *Id*. at ¶¶855-877.

Furthermore, all three of the moving Distributors are alleged to have paid millions of dollars in civil penalties and/or settlement agreements with the United States and/or the state of West Virginia involving similar allegations that they failed to report suspicious orders of controlled substances: in 2016 AmerisourceBergen Drug Corporation settled a lawsuit with West Virginia for $16 million (R. 514 at ¶585); in 2016 Cardinal Health, Inc. agreed to pay $44 million to the United States and $20 million to West Virginia (*Id*. at ¶¶584-585); and, in 2017 McKesson Corporation agreed to pay $150 million to the United States. (*Id*. at ¶¶581-582). While the court does not construe any of these allegations as admissions by the Distributors, these facts do bolster the plausibility of Plaintiffs' allegations.

Finally, as stated above, the specific evidence of a conspiracy, if indeed one existed, would lie in the hands of Defendants.

ii. Felonious Manufacture, Importation, Receiving, Concealment, Buying, Selling, or Otherwise Dealing in a Controlled Substance as a Predicate Act

The Defendants also challenge the alleged supply chain enterprise, asserting that Plaintiffs have failed to allege a predicate act under RICO. (R. 491-1, PageID# 7486, 7488-7489; R. 499-1, PageID# 7686-7687). "Section 1961(1) [of the RICO Act] contains an exhaustive list of acts of 'racketeering,' commonly referred to as 'predicate acts.'" *Beck v. Prupis*, 529 U.S. 494, 497 at n. 2 (2000). Under RICO, "racketeering activity" includes "the *felonious* manufacture, importation, receiving, *concealment*, buying, *selling*, or *otherwise dealing* in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances

Act), punishable under *any law* of the United States." 18 U.S.C. § 1961(1)(D) (emphasis added). The Manufacturers concede that "certain conduct involving the manufacture and distribution of controlled substances may constitute a predicate act if it is 'punishable by imprisonment for more than one year.'" (R. 499-1, PageID# 7686). They maintain, however, that the alleged "failure to monitor and report suspicious orders amounts to (at most) a violation of 21 U.S.C. § 842(a)(5)" and is not punishable by more than a year. (R. 499-1, PageID# 7687). Defendants fail to cite any authority that limits Plaintiffs' allegations to § 842, a position not compelled by the plain language of the code.[31] (R. 746, PageID# 17717).

Plaintiffs counter that Defendants' failure to report suspicious orders instead violates § 843, which makes it unlawful to "knowingly or intentionally … furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II…" (R. 654, PageID# 15770, *citing* 21 U.S.C. § 843(A)(4)(a)). Such a violation is punishable by up to four years imprisonment. 21 U.S.C. § 843(d)(1). Despite the admission in their motion to dismiss that the felonious dealing in a controlled substance constitutes a predicate act, Defendants assert that a violation of § 843(a)(4)(A) would not qualify as a predicate act because it is not specifically enumerated in § 1961(1)(D).[32] (R. 491-1, PageID# 7488; R. 499-1, PageID# 7694-

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[31] § 842 applies to persons who "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II…." The complaint alleges intentional conduct that goes well beyond negligence—that Defendants knew about suspicious orders from their own sales representatives and the exacting data they kept but concealed them. (R. 514 at ¶¶554-593).

[32] The Distributors cite one non-binding decision in their argument: *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008). (R. 491-1, PageID# 7488-7489). That case, however, is inapposite and contains no discussion at all as to whether a violation of § 843(a)(4)(A) may serve as a predicate act under the language of § 1961(1)(D). Further, the plaintiff therein alleged RICO liability solely on the basis of off-label

7695). Without relying on any binding case law to support their argument, Distributors assert that "[v]iolations of Section 843(a)(4) do not fall within that language [of 18 U.S.C. § 1961(1)(D)]" because providing false information or making material omissions does not constitute "buying, selling, or otherwise dealing" in controlled substances. (R. 491-1, PageID# 7488). First, the court is skeptical whether providing false information, as alleged, does not constitute "concealment" or "otherwise dealing in a controlled substance" as Distributors suggest. Second, the court takes note that in making the above assertion, the Distributors completely cut out the provision of § 1961(1)(D) that expressly references "concealment" of a controlled substance and furnishing false information as alleged may constitute concealment. Thus, the plain language of § 1961(1)(D) does not appear to preclude the use of a violation of § 843(a)(4)(A) as a predicate act. The argument that § 843 is not expressly enumerated as a predicate act by § 1961(1)(D) is untenable, as § 1961(1)(D) does not identify any single, specific section of the United States Code that would constitute a predicate act under the subsection. If Defendants' construction were adopted, the entirety of § 1961(1)(D) would be rendered a nullity.

While Defendants maintain their alleged conduct is more akin to a violation of § 842, the question of whether § 842, § 843, or neither was violated is ultimately an issue of fact that cannot

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marketing relying exclusively on mail and wire fraud as racketeering activities. *In re Epogen*, 590 F. Supp. 2d at 1287 ("Plaintiffs allege that Defendants' unlawful promotion of EPO for unsafe, off-label uses constituted a pattern of racketeering activity, including mail and wire fraud."). The district court did hold that "[a]llowing Plaintiffs to proceed on a theory that Defendants violated RICO by engaging in off-label promotion, without specific allegations that Defendants made false or misleading statements, would, in effect, permit Plaintiffs to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder." *Id*. at 1289-1290. Plaintiffs correctly note that "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." (R. 654, PageID# 15774). Defendants' attempt to portray *In re Epogen* as holding that a felony violation of either the FDCA or the CSA can never serve as a RICO predicate act under § 1961(1)(D) is far too broad and distorts the limited scope of the decision.

be resolved on a motion to dismiss. Plaintiffs' argument—that the Manufacturers and Distributors, by allegedly suppressing or refusing to identify and report suspicious orders effectively engaged in activity tantamount to "concealment" or "otherwise dealing in controlled substances"—is construed as true at this pleading stage. Thus, Plaintiffs have sufficiently pled a predicate act pursuant to section 1961(1)(D) with respect to their supply side RICO theory.

Alternatively, the Manufacturers argue that they "have no duty to monitor, prevent, or report the downstream diversion of prescription opioids at the pharmacy or physician level, where diversion occurs." (R. 499-1, PageID#7687). They maintain that under the "plain text" of 21 C.F.R. § 1301.74(b), their duty extends only to monitoring and reporting suspicious orders placed with them *by their direct customers* (*i.e.*, pharmaceutical distributors). *Id*. Plaintiffs counter that such an argument reads words into the text of the CSA and its regulations that do not exist. (R. 654, PageID# 15770). 21 C.F.R. § 1301.74(b) states:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

The plain text of the regulation is not so limiting, and does not state that a registrant's obligation to report suspicious orders applies only to orders from its direct customers. Rather, the plain text requires the registrant to report suspicious orders whenever one is "discovered by the registrant."[33] Further, Defendants cite no case law interpreting the provisions of § 1301.74(b) so

[33] Undoubtedly, a registrant manufacturer would have the most precise information about orders from its direct customers. However, the complaint alleges that the Manufacturers, in concert with the Distributors, collected vast amounts of data that, at least plausibly, led to Defendants' discovery of suspicious orders by parties other than their direct customers.

narrowly. Plaintiffs also fail to cite any authority interpreting the regulation, save for a DEA enforcement action against Mallinckrodt and Mallinckrodt's ensuing admission that "[a]s a registrant under the CSA, [it] had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." (R. 654, PageID# 15770, *citing* R. 514 at ¶520). Nonetheless, the onus is on Defendants as the moving party to demonstrate that Plaintiffs fail to state a claim.

For the forgoing reasons, it is recommended that the court deny the motions to dismiss Counts One and Two.

B. Preemption

The Manufacturers argue that all state law claims are preempted, as they conflict with the FDA's decisions regarding approval and labeling of medications. (R. 499-1, PageID# 7689-93).

1. Claims Involving Marketing of Opioids

The Manufacturers portray the complaint as alleging that they falsely represented opioids as safe and effective for the long-term treatment of chronic non-cancer pain. (R. 499-1, PageID# 76989-7690). They argue the FDA has approved this use, which demonstrates that it found "substantial evidence that the drug will have the effect it purports or is represented to have" and that the opioids in question are safe and effective for treating chronic pain. *Id*. *citing* 21 U.S.C. § 355(d). They cite cases holding that state law claims are preempted where a claim would require a drug manufacturer to make statements about safety or efficacy that differ from what the FDA required. *Id*. (*citing Rheinfrank v. Abbott Labs., Inc.*, 680 Fed. App'x 369, 386 (6th Cir. 2017); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42-43 (1st Cir. 2015); *Utts v. Bristol-Meyers Squibb Co.*, 251 F. Supp. 3d 644, 663-73 (S.D.N.Y. 2017)).

Conversely, Plaintiffs dispute that their claims are based on allegations that Defendants falsely claimed their medications were "safe and effective for the long-term treatment of chronic non-cancer pain." (R. 654, PageID# 15826). Rather, they insist their allegations revolve around Defendants' "false and misleading promotion of these drugs." *Id*. They argue that there is no preemptive conflict between their state law claims and federal law, because the latter did not require the Manufacturers to misleadingly promote their products. (R. 654, PageID# 15826). Plaintiffs assert that they do not seek to stop the Manufacturers from selling opioids, but only to stop their deceptive marketing. *Id*. Plaintiffs cite cases in support of the proposition that, "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.)" *Id.*, PageID# 15827 (*citing Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 819-20 (S.D. Ohio 2013) (state law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous promotion of generic drug were not preempted); *Priest v. Sandoz, Inc.*, 2016 WL 11162903, at *7 (W.D. Tex. Dec. 29, 2016), *report and recommendation adopted*, 2016 WL 8896188 (W.D. Tex. Jan. 31, 2017) (obligation to refrain from falsely promoting drugs does not make it impossible to comply with federal law regarding labelling); *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 143944, at *6 (D. Haw. Jan. 9, 2015) (no impossibility preemption for fraud claims); *Elmore v. Gorsky*, 2012 WL 6569760, at *3 (S.D. Tex. Dec. 17, 2012)).

The cases upon which Defendants rely are all distinguishable. *Rheinfrank* is inapposite because it was argued the defendant should have added a warning label the FDA had twice refused. 680 Fed. App'x at 384-388. In *In re Celexa*, it was argued that the FDA should not have

approved Lexapro, and that defendant should have shared negative efficacy information with the FDA. 779 F.3d at 36-43. Because the FDA had reviewed this information and approved the drug, the state law claim was in conflict with federal law. *Id*. In *Utts*, the plaintiffs' fraud-based claims were preempted, because they alleged a fraud upon the FDA. 251 F. Supp. 3d at 679-680 (*citing Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (holding that state law fraud on the FDA claims conflict with federal law and are impliedly preempted)). Herein, the state law claims are not premised upon inappropriate labeling or a fraud upon the FDA, but rather fraudulent marketing in the promotion and sale of their opioids.[34]

At this current stage of the proceedings, Defendants have not met their burden to show that Plaintiffs' claims are preempted.

2. Claims Involving Off-Label Uses

The Manufacturers also argue that claims related to the inappropriate promotion of opioids for off-label uses are preempted. (R. 499-1, PageID# 7689-7691). Preemption is required, they assert, because the FDA is invested with exclusive authority and a variety of enforcement options to address off-label promotion. *Id*. Moreover, the FDCA does not create a private right of action to enforce its provisions. *Perdue v. Wyeth Pharms., Inc.*, 209 F.Supp.3d 847, 851-52 (E.D.N.C. 2016); *see also McDaniel v. Upsher-Smith Pharms., Inc.*, 229 F.Supp.3d 707, 713 (W.D. Tenn. 2017).

Plaintiffs assert they are not suing to enforce FDCA off-label use rules, but rather contend that Defendants misrepresented the risks associated with off-label opioid use. (R. 514,

[34] The Manufacturers' reply characterizes Plaintiffs' brief as conceding that various claims are preempted. (R. 746, PageID# 17706-17707). The court does not construe Plaintiffs' brief as abandoning or conceding any of their state law claims as preempted. But after discovery, the Plaintiffs may narrow their claims and Defendants may renew their arguments upon a full record.

PageID# 6818-6869, ¶¶177-349). They argue that state law claims may proceed on such grounds even where the alleged wrongful conduct might also violate the FDCA. (R. 654, PageID# 15829-15830). Moreover, Plaintiffs assert that state law claims founded on violations of federal law duties are precluded 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*, 531 U.S. at 352-353. They rely upon cases in which state law claims proceeded on such grounds even where the alleged wrongful conduct might also have violated the FDCA. *Id.*; *see also Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576, 580 (6th Cir. 2013); *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); *Arters*, 921 F. Supp. 2d at 819-20.

The Sixth Circuit, in *Loreto*, indicated that "plaintiffs may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA." 515 Fed. App'x 576 at 579. The *Loreto* court explained its method for distinguishing between state law claims that seek to enforce the FDCA and those that actually arise under state law; only the former are preempted. *Id*. The *Loreto* court noted,

> [T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman.*

Id. The *Loreto* court found no preemption of a claim that a manufacturer's marketing materials misrepresented the health benefits of vitamin C in its over-the-counter cold remedy, ruling that the claim relied "solely on traditional state tort law predating the FDCA," even though the conduct also violated the FDCA. *Id.* at 580. In *Arters*, it was alleged that the defendants had

promoted Amiodarone as a routine treatment, rather than as a drug of last resort. 921 F. Supp. 2d at 819-820. The court held that claims arising from off-label promotion did not seek to enforce the FDCA, because plaintiff did not allege that defendants violated their duty on the ground that the promotion was off-label, but rather because it was fraudulent. *Id*.

Here, Plaintiffs do not seek to enforce the provisions of the FDCA, instead they allege that Defendants fraudulently and misleadingly promoted their opioids. These allegations are of the type that would traditionally be brought as state law claims and, therefore, are not preempted.

3. Obstacle Preemption

The Manufacturers next argue that Plaintiffs' diversion monitoring theory "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" under the FDCA. (R. 499-1, PageID# 7691, *citing Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000)). They frame the allegations as an assertion that the Manufacturers "had a duty not to sell their prescription opioids due to concerns with opioid diversion," and a prayer for damages and an injunction against any further violations. *Id*. at PageID# 7693. Defendants contend that "allowing these claims to proceed would undermine the FDA's decision to make (and keep) [the Manufacturers'] prescription opioids available to the public" and are thus preempted. *Id*. (internal quotation marks omitted).

The complaint cannot be reasonably construed as alleging that Defendants should have stopped selling opioids altogether, but rather alleges that they failed in their duty to prevent or actively concealed opioid diversion and misuse. Plaintiffs contend that their allegations focus on Defendants' "duty to use due care in selling their dangerous products and that they are liable for failing to use such care." (R. 654, PageID# 15832). Plaintiffs further argue that their diversion and monitoring claims are consistent with federal standards of care applicable to the sale of

opioids, and thus create no obstacle to the implementation of the FDCA. *Id*., PageID# 15830-15832.

Federal law preempts state law under the doctrine of obstacle preemption when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372-373. State tort actions related to the sale and marketing of pharmaceuticals raise the specter of obstacle preemption. In *Wyeth v. Levine*, the Supreme Court considered obstacle preemption in the context of a state tort claim alleging that the manufacturer of Phenergan had failed to provide adequate warnings about the risks of injecting the drug. 555 U.S. 555 (2009). The Supreme Court rejected Wyeth's obstacle preemption argument, noting that with limited resources to monitor the 11,000 drugs on the market, the FDA appears to view state tort law as a "complementary" form of drug regulation indicating:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express pre-emption provision for medical devices ... Congress has not enacted such a provision for prescription drugs. See *Riegel v. Medtronic, Inc.*, 552 U.S., at 327 (2008) ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.") Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (internal quotation marks omitted).

Wyeth, 555 U.S. at 574-575 (internal footnotes omitted).

The Manufacturers assert that one of Congress' core objectives in enacting the FDCA was to "ensure that any product regulated by the FDA is safe and effective for its intended use."

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000). They state that courts have consistently "held that this regulatory scheme preempts any state law claim seeking to prohibit drug manufacturers from selling their FDA-approved products as permitted by FDA." *See, e.g. Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *1-2 (D. Mass. Apr. 15, 2014); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (requiring a drug manufacturer "to stop production of a drug" "would directly conflict with" FDA's "sole authority ... to determine whether a drug may be marked."), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014). Both *Zogenix* and *Gross* are distinguishable because they, respectively, involved an attempt to enforce a state regulatory ban on the sale of certain drugs and a challenge to the adequacy of label warnings approved by the FDA. By contrast, Plaintiffs here seek to enforce an alleged state law duty to, for example, monitor the sale of drugs with due care—a claim that is not inconsistent with the purposes of the FDCA, and thus not preempted.

C. Statute of Limitations

Noting that the complaint is based on facts dating back to the 1990s, the Manufacturers assert that applying the most generous of the applicable statute of limitations—the 5-year period for an OCPA claim—would bar claims relying on conduct predating early 2013. (R. 499-1, PageID# 7708-7709). Plaintiffs counter that dismissal based on affirmative defenses at the pleading stage is inappropriate where issues of fact concerning tolling exceptions exist.

Resolving a motion to dismiss based on statute-of-limitations grounds is appropriate when the undisputed facts "conclusively establish" the defense as a matter of law. *Estate of Barney v. PNC Bank*, 714 F.3d 920, 926 (6th Cir. 2013); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012), *cert. denied*, 568 U.S. 1157 (2013). But where there are disputed factual questions, for example "relating to the accrual date, ... claims that the defendant fraudulently

concealed facts thereby preventing the plaintiff from learning of its injury, … and complex issues about whether information in the plaintiff's possession sufficed to alert it of the claim[,]" then a statute of limitations defense is more appropriately addressed in the context of a summary judgment motion or at trial. *Am. Premier Underwriters, Inc. v. Nat'l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016); *Lutz v. Chesapeake Appalachia, LLC*, 717 F.3d 459, 473-476 (6th Cir. 2013) (reversing and remanding to the district court to resolve issue of fraudulent concealment). Moreover, parties "are entitled to have their cause tried on the merits if they can prove that the doctrine of fraudulent concealment should be applied to their case." *Jones v. TransOhio Sav. Ass'n*, 747 F.2d 1037, 1043 (6th Cir. 1984) ("We are unprepared to hold, prior to any discovery on the issue, that Appellants can prove no set of facts consistent with these allegations sufficient to toll the statute of limitations.").

The complaint alleges that the fraudulent concealment and continuing violation doctrines extend the applicable limitations periods, because "Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic." (R. 514 at ¶¶770, 767-777). The complaint also alleges that Defendants, including the Manufacturers, purposefully concealed their unlawful conduct while assuring the government and the public that they were complying with applicable laws and cooperating with law enforcement to curb the opioid crisis, thereby, it is alleged, depriving Plaintiffs of any actual or implied notice of potential claims. (R. 514, ¶¶768-777). It further contends that Defendants' wrongful conduct has not ceased, continues to cause Plaintiffs' injuries, that the opioid epidemic continues to spread, and that the resulting claimed injuries are ongoing. *Id*. at ¶¶715, 718, 724, 727, 729, 744, 767-768, 780, 818, 827. These allegations are sufficient to raise a plausible

inference that the applicable limitation periods are subject to tolling.

D. Counts Three and Four: Ohio RICO Statute Claims

In Counts Three and Four, Plaintiffs allege a violation of Ohio's Corrupt Practices Act (OCPA), O.R.C. § 2923.31 *et seq*. against the Marketing Defendants and Supply-Chain Defendants respectively. (R. 514, ¶¶939- 973). OCPA, sometimes referred to as the "Ohio RICO" statute, is "patterned after" the federal RICO statute.[35] Consequently, Ohio courts look to federal case law applying RICO to determine how to apply OCPA. *O'Rourke*, 640 N.E.2d at 240; *Durrani*, 2014 WL 996471, at *8.

Defendants assert that Plaintiffs' OCPA claims must be dismissed for the same reasons as the federal RICO claims. (R. 491-1, PageID# 7489-7490; R. 499-1, PageID# 7693-7694). Because the court finds Plaintiffs have sufficiently pleaded the former, the court rejects Defendants' argument. Defendants, however, raise an additional argument: to establish a "pattern" of racketeering activity under the OCPA, a plaintiff must allege "at least one incident other than a violation of" federal mail, wire, or security fraud statutes. O.R.C. § 2923.34(A). Plaintiffs do not challenge the existence of such a requirement, but assert they also pleaded "telecommunications fraud," and "felony dealing in controlled substances pursuant to RICO section 1961(1)(D)." (R. 654, PageID# 15778). Plaintiffs have alleged a felony violation of the CSA, specifically § 843(a)(4)(A) ("to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II…"). *Id*. Defendants contention—that a violation of § 843 does not constitute a predicate act—was addressed and rejected above. Thus,

[35] *See, e.g., Aaron v. Durrani*, 2014 WL 996471, at *8 (S.D. Ohio Mar. 13, 2014) (*citing U.S. Demolition & Contracting v. O'Rourke*, 640 N.E.2d 235, 240 (Ohio Ct. App. 1994)).

Defendants' motion to dismiss the OCPA claims should be denied.

E. Ohio Product Liability Act and Abrogation

The Distributors, joined by the Pharmacies and Manufacturers, argue that Plaintiffs' common law negligence and public nuisance claims, as well as Plaintiffs' statutory public nuisance claim, should be dismissed because they are abrogated by the Ohio Product Liability Act (OPLA), O.R.C. §§ 2307.71 through 2307.80. (R. 491-1, PageID# 7492-7496, 7502-7505; R. 497-1, PageID# 7599; R. 499-1, PageID# 7695). OPLA, by its terms, abrogates a significant swath of common law tort litigation. O.R.C. § 2307.71(B) expressly states that "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." Pursuant to the statute, a product liability claim is defined as follows:

> "Product liability claim" means a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 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.
>
> "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.

O.R.C. § 2307.71(A)(13).[36] Thus, there are essentially two types of product liability claims that fall under OPLA's abrogation provisions: (1) product-related causes of action seeking compensatory damages for physical injury or for physical property damage (other than the product in question); and (2) public nuisance-type actions alleging unreasonable interference with a right common to the general public.[37]

1. Abrogation of Negligence Claim

The Distributors argue that Plaintiffs' common law negligence claim is, "at its core, a product liability claim—precisely the kind of claim abrogated by the OPLA." (R. 491-1, PageID# 7504, *citing Volovetz v. Tremco Barrier Sols., Inc.*, 74 N.E.3d 743, 753 (Ohio. Ct. App. 2016) (stating courts look to "[t]he essential nature of the substantive allegations of the plaintiff's claim, not the artificial label attached to the claim")). Plaintiffs argue that their negligence claim is not abrogated because they do not seek compensation for physical injuries caused by Defendants' products, but rather "to recover for economic harms inflicted on their communities by Defendants' conduct in marketing and distributing their products." (R. 654, PageID# 15799). Plaintiffs' negligence action does not implicate a Type 2 product liability claims, as it does not allege an unreasonable interference with a right common to the general public. It does, however, potentially implicate a Type 1 product liability claim, as Plaintiffs do not challenge that their action involves the "design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product." O.R.C. § 2307.71(A)(13)(a). Nevertheless,

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[36] The last paragraph emphasizing the inclusion of public nuisance claims was added by amendment and went into effect on August 1, 2007. *State ex rel. Ohio Gen. Assembly v. Brunner*, 873 N.E.2d 1232, 1235 (Ohio, 2007).

[37] For the sake of brevity, these will be referred to as "Type 1" and "Type 2" product liability claims respectively.

Plaintiffs assert that OPLA divides compensatory damages into two distinct categories: "harm" and "economic loss." (R. 654, PageID# 15798). They maintain that only claims for "harm" constitute "product liability claims" under OPLA, whereas, "claims solely for 'economic loss' are expressly exempted from the statute and remain available at common law." *Id*. The complaint alleges Defendants breached their duties resulting in "economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services," as well as "non-physical property damage, and damage to its proprietary interests."[38] (R. 514 at ¶¶1062-1063). Thus, the dispositive issue is whether Plaintiffs' negligence action seeks to recover damages for a loss defined as "harm" by OPLA.

The statute also clarifies that injuries defined as "harm" do not constitute "economic loss" under OPLA, O.R.C. § 2307.71(A)(2). OPLA defines "economic loss" as "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." *Id*. Damages that fall into this category are excluded from the definition of "harm." O.R.C. § 2307.71(A)(7). Type 1 product liability claims encompass claims for compensatory damages for death, physical injury to person, emotional distress, or physical damage to property other than the product in question—the same categories of injuries defined as "harm" by O.R.C. § 2307.71(A)(7).

These distinctions are crucial with respect to Type 1 actions, as another section of OPLA states that: "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 sections 2307.71 to 2307.79 of the Revised Code, but may occur under the common law of this state or other

[38] Though Plaintiffs allege an unreasonable interference with a right common to the general public with their common law public nuisance claim, pleading in the alternative is permissible.

applicable sections of the Revised Code." O.R.C. § 2307.72(C) (emphasis added). Because civil actions that implicate Type 1 product liability only fall within OPLA's ambit if they allege harm, a claim for solely economic loss by its very definition excludes harm and is not abrogated. This natural reading of the statutory language was confirmed by an Ohio Supreme Court decision, which predated the 2007 amendment:

> [O.R.C. §] 2307.72 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*, and that a failure to allege other than economic damages does not destroy the claim, but rather removes it from the purview of those statutes.

LaPuma v. Collinwood Concrete, 661 N.E.2d 714, 716 (Ohio 1996) (emphasis added); *Volovetz*, 74 N.E.3d at 752 (acknowledging *LaPuma*'s holding in a footnote, but finding that plaintiff's negligence claim was barred because it sought recovery for compensatory damages stemming from physical damage to property).

Because Plaintiffs' negligence claim seeks only damages for non-physical property damage and expenses related to governmental expenditures, it is not abrogated by OPLA to the extent it seeks recovery solely for economic loss and not for harm.[39]

2. Abrogation of Public Nuisance Claims

Plaintiffs' Fifth ("Statutory Public Nuisance") and Sixth ("Common Law Absolute Public Nuisance") Claims for Relief allege that Defendants created and maintained a public nuisance in the marketing and distribution of prescription opioids. (R. 514 at ¶¶974-1038). Defendants assert

[39] Defendants argue that framing Plaintiffs' injury as economic loss elevates form over substance, and that the personal injury to the users of opioids is the gravamen of the claim. (R. 744, PageID# 17663-17664). The court cannot find, without the benefit of any factual discovery, that *all* of Plaintiffs' claimed injuries stem from death, physical injuries, or physical damage to property.

that Plaintiffs' public nuisance claims are abrogated by OPLA and can only be brought as product liability claims under OPLA, if at all.[40] (R. 491-1, PageID# 7492-7496). OPLA was amended in 2007 to expressly include in the definition of a "product liability claim" "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." O.R.C. § 2307.71(A)(13).

a. Application to Statutory Public Nuisance Claim

Defendants contend that the reference to "*any* public nuisance claim" abrogates both common law *and* statutory public nuisance claims (R. 744, PageID# 17658-17659), while Plaintiffs contend that statutory public nuisances are not abrogated because the phrase "at common law" in the statute modifies both "public nuisance claim" and "cause of action." (R. 654, PageID# 15729). Under Ohio law, "[t]o determine the intent of the legislature," a court must "first look to the plain language of the statute," and if it is "plain and unambiguous," the statute should be applied as written. *State v. Gordon*, 2018 WL 2356650, at *2 (Ohio May 23, 2018) (citations omitted). The court finds the phrase "any public nuisance claim or cause of action at common law" to be ambiguous. Accordingly, the court looks to the legislative history, which notes:

> SECTION 3. The General Assembly declares its intent that the amendments made by this act to sections 2307.71 and 2307.73 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 2307.71 to 2307.80 of the Revised Code, as initially expressed in Section 3 of Am. Sub. S.B. 80 of the

[40] "Claims that are authorized by the Ohio Products Liability Act should be pled with reference to the applicable provision of the Act." *Greenway v. Kimberly-Clark Corp.*, 2016 WL 3460229, at *2 (N.D. Ohio June 24, 2016) (citations omitted).

> 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).

Given that the legislature explained it intended to abrogate "*common law* public nuisance causes of action," the court agrees with Plaintiffs' statutory construction. Therefore, Plaintiffs' *statutory* public nuisance claim in Count Five is not abrogated by OPLA.

b. Application to Common Law Absolute Public Nuisance Claim

Despite asserting that the 2007 amendment to OPLA intended to abrogate common law public nuisance actions, Plaintiffs aver that their self-styled "common law absolute public nuisance claim" is not abrogated by OPLA because their claim is an "equitable nuisance" claim. (R. 654, PageID# 15729). Plaintiffs rely on an observation from the Ohio Supreme Court in *State ex rel. Miller v. Anthony* that an abatement action was "not a common law action, but a summary proceeding more in the nature of a suit in equity." 647 N.E.2d 1368, 1371 (Ohio 1995) (*quoting Cameron v. United States*, 148 U.S. 301, 304 (1893)). The court does not construe the *dicta* from this decision as an affirmative finding that an absolute public nuisance claim is not a common law cause of action within the meaning of OPLA.[41] Moreover, "the distinction between legal and

[41] Notably, *State ex rel. Miller* did not involve an absolute public nuisance action, but instead considered whether a nuisance abatement action brought pursuant to statute—O.R.C. § 3719.10—required a jury trial under Ohio's constitution. The court concluded that a jury trial was not required because "the nuisance abatement provisions of R.C. Chapter 3767 are equitable in nature and not created by common law." 647 N.E.2d at 1371. Thus, it appears the court was focused on the equitable nature of the abatement remedy. Furthermore, by Plaintiffs' logic, the statutory-based nuisance action in *State ex rel. Miller* would not be considered a statutory nuisance claim simply because the court characterized the remedy as equitable in nature. The court declines to elevate form over substance.

equitable claims [has been] abolished." *Hodges v. Ettinger*, 189 N.E. 113, 115 (Ohio 1934). Finally, numerous courts, including a recent decision of the Sixth Circuit Court of Appeals, have recognized that an absolute public nuisance claim in Ohio is a common law action.

> Under Ohio law, *a common law public nuisance* is "an unreasonable interference with a right common to the general public." Examples of such rights, from Ohio and elsewhere, include: a right of public passage (e.g., obstruction of highways); a right to use public space (e.g., pollution of fisheries); a right to navigable waterways (e.g., obstruction of public streams); a right to public health (e.g., exposure to diseased animals); a right to public safety (e.g., negligent marketing/sale of dangerous weapons); a right to public morality (e.g., houses of ill-repute); a right to public peace (e.g., excessive noise); and a right to public comfort (e.g., excessive odors or fumes).
>
> *Ohio law recognizes two types of public nuisances: qualified and absolute*. A qualified public nuisance mirrors a negligence tort…. An absolute public nuisance, sometimes called nuisance per se, comes in two forms, one requiring more evidence of intent (akin to an intentional tort), the other requiring less (akin to a strict liability tort). The action thus requires either the "intentional" creation of a public nuisance or "an abnormally dangerous condition that cannot be maintained without injury to property, no matter what care is taken."

City of Cincinnati v. Deutsche Bank Nat'l Trust Co., 863 F.3d 474, 477 (6th Cir. 2017) (emphasis added); *see also Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *3 (Ohio Ct. App Mar. 21, 2013) (describing a public nuisance claim as a common law tort action used to vindicate interference with a general public right); *Brown v. Scioto Cty. Bd. of Commrs.*, 622 N.E.2d 1153, 1158 (Ohio Ct. App. 1993) (describing the common law elements of a public nuisance claim and recognizing that, in addition, there are also statutorily defined public nuisances).

Plaintiffs concede that a public nuisance claim, which they label as an "equitable" action, requires an unreasonable interference with a right common to the general public. (R. 654, PageID# 15719). The Sixth Circuit ascribed the same elements to common law public nuisance claims under Ohio law. *Deutsche Bank Nat'l Trust Co.*, 863 F.3d at 477. These are identical

causes of action that are not derived from statute. Under Plaintiffs' reasoning, common law public nuisance claims essentially do not exist in Ohio, because public nuisance claims are properly designated as suits arising in equity. Such a conclusion is untenable, as it would render the Ohio Legislature's 2007 amendment a nullity.[42] Furthermore, Plaintiffs' argument is contrary to the only Ohio decision that appears to have squarely addressed the operation of the 2007 amendment. S*ee City of Toledo v. Sherwin-Williams Co.*, 2007 Ohio Misc. LEXIS 5632, 2007 WL 4965044 (Ohio C.P. December 12, 2007) (finding that plaintiff's public nuisance claim was "expressly subsumed by the OPLA"). Thus, the court finds that Plaintiffs' absolute public nuisance claim constitutes a common law public nuisance claim and, therefore, falls within the purview of OPLA.

However, Plaintiffs raise an additional argument as to why their absolute public nuisance claim should not be construed as abrogated by OPLA—that the 2007 amendment that added the Type 2 product liability claims definition should be read as covering only those public nuisance actions that seek compensatory damages defined as harm elsewhere in the statute. (R. 654, PageID# 15730). This argument is similar to Plaintiffs' argument above with respect to OPLA's inapplicability to their negligence claim. Plaintiffs' argument here is contrary to the plain language of the statute. O.R.C. § 2307.71, as amended, abrogated Type 2 claims—public nuisance claims alleging that "the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product *unreasonably interferes with a right*

[42] In other words, Plaintiffs contend that non-statutory public nuisance actions in Ohio are equitable actions not common-law actions, and the 2007 amendment applies only to common law public nuisance actions. Such a result would completely frustrate the Ohio Legislature's clear intent to abrogate common-law public nuisance actions, as the amendment would have no applicability.

common to the general public." (emphasis added). Notably absent from the Type 2 product liability definition is the language contained in Type 1 claims that apply only to actions seeking compensatory damages for "death, physical injury to person, emotional distress, or physical damage to property other than the product in question" (*i.e.* "harm"). O.R.C. § 2703.71(A)(13). Thus, the distinction between harm and economic loss is conspicuously absent in the Type 2 definition of product liability claims.[43] Therefore, the issue of whether Plaintiffs' damages under its public nuisance theory are properly categorized as economic loss is immaterial.

Consequently, O.R.C. § 2307.72(C), which states that "[a]ny 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]…." is also inapplicable. The Ohio Supreme Court's holding in *LaPuma* interpreted OPLA as it existed in 1996; it did not create a judicial rule exempting product liability claims if they asserted only economic loss. 661 N.E.2d at 716. Before the 2007 amendment, only the Type 1 definition of product liability claims existed, and the definition expressly excluded claims for economic loss rather than harm. This distinction was not maintained with respect to the Type 2 definition. Therefore, Plaintiffs' argument—that its absolute public nuisance claim is not abrogated because it seeks to recover only economic loss—

[43] The argument that the harm requirements of Type 1 claims should be bootstrapped to Type 2 claims is not well taken. As noted above, the court should apply the plain language of the statute where it is unambiguous. Although this court above found that the statute was ambiguous with respect to the question of whether the term "common law" modified both the phrase "any public nuisance claim" and "cause of action," the decision not to include the preexisting language from the Type 1 definition into the Type 2 definition speaks volumes. Had the legislature intended such limiting language in the application of OPLA as it relates to public nuisance claims, it could easily have repeated the language contained in the Type 1 definition. It opted not to do so. It is also telling that the Type 2 definition was not made a subsection of the Type 1 definition, revealing a clear intent to create an alternative or additional definition of a "product liability claim."

does not exempt its common law public nuisance claim from OPLA. It is recommended that Count Six be dismissed.

F. Count Five: Statutory Public Nuisance

Count Five alleges a statutory public nuisance against all Defendants. (R. 514, PageID# 11208). It seeks "abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance," as well as "all other legal and equitable relief as allowed by law." *Id*. at ¶¶995-996.

The Pharmacies and Distributors assert that, among the Plaintiffs, only the Summit County Prosecutor may maintain a statutory public nuisance action brought pursuant to O.R.C. §4729.35. (R. 491-1, PageID# 7501; 497-1, PageID# 7608-7609; R. 742, PageID# 17613-17615). In addition, the Distributors and Manufacturers assert that Plaintiffs' remedies for a statutory public nuisance are limited to an injunction. (R. 491-1, PageID# 7501-7502; R. 499-1, PageID# 7700, n. 39). This latter argument does not provide a basis for dismissal. While the category of damages recoverable may be a legal issue proper for the court's consideration, Defendants have not identified any authority supporting their proposed statutory construction. *Id*.

1. Ohio Rules of Statutory Interpretation and Applicable Laws

First, under the express rules of Ohio statutory construction, a court should construe various statutes in harmony unless their provisions are irreconcilably in conflict:

> If a general provision conflicts with a special or local provision, they shall be construed, if possible, so that effect is given to both. If the conflict between the provisions is irreconcilable, the special or local provision prevails as an exception to the general provision, unless the general provision is the later adoption and the manifest intent is that the general provision prevail.

O.R.C. §1.51; *see also United Tel. Co. 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. ... [and] in the interpretation of related and co-existing statutes must harmonize and give full application to all such statutes unless they are irreconcilable and in hopeless conflict.") (citations omitted).

The following Ohio statutes address the issue of public nuisance and are relevant to the court's discussion. First, Chapter 3767 of the Ohio Revised Code addresses nuisances generally, and gives several definitions of a nuisance, including the following: "That which is defined and declared by statutes to be a nuisance." O.R.C. § 3767.01(C)(1). A separate chapter of the Ohio Revised Code, dealing with occupations and professions, identifies one such public nuisance:

> The violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011[44] of the Revised Code or the commission of any act set forth in division (A) of section 4729.16 of the Revised Code, is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance. The attorney general, the prosecuting attorney of any county in which the offense was committed or in which the person committing the offense resides, or the state board of pharmacy may maintain an action in the name of the state to enjoin such person from engaging in such violation. Any action under this section shall be brought in the common pleas court of the county where the offense occurred or the county where the alleged offender resides.

O.R.C. §4729.35. Returning to the general chapter on nuisances, O.R.C. § 3767.03 states that: "[w]henever a nuisance exists," an authorized party[45] "may bring an action in equity in the name of the state … to abate the nuisance and to perpetually enjoin the person maintaining the

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[44] O.R.C. §§ 3719.01(R) & 3719.011 define opiate as "a drug of abuse."

[45] O.R.C. § 3767.03 includes a significantly broader list of authorized parties who may maintain a public nuisance action than O.R.C. § 4729.35, as it includes the attorney general, the village solicitor, the city or township law director, the county prosecutor, or any person who is a citizen of the county in which the nuisance exists so long as the action is brought in the name of the state. The ramifications of this discrepancy is addressed below.

nuisance from further maintaining it."

2. Available Remedies

Defendants assert that any violation of O.R.C. § 4729.35 limits Plaintiffs' recovery to injunctive relief and that abatement costs are unrecoverable. (R. 491-1, PageID# 7501-7502; R. 499-1, PageID# 7700). However, Defendants' argument—that O.R.C. § 4729.35's provision that an authorized individual "may maintain an action in the name of the state to enjoin" a public nuisance is tantamount to a limitation on the remedies available—is an untenable interpretation of the plain text of the statute. Nothing in this statute can reasonably be construed as addressing or expressly limiting the categories of relief available for the nuisance. Rather, it identifies and defines a public nuisance, identifies who may bring the action to enjoin a nuisance, and finally where the claim should be brought. Further, Defendants' interpretation of the remedies available for a violation of O.R.C. § 4729.35 is not supported by any authority cited in their briefs.

Finally, Defendants' interpretation of O.R.C. § 4729.35 contravenes Ohio's laws on statutory construction, as stated above, that require a court to construe statutes so as to give effect to both the special and general provisions, and to construe all provisions of the Revised Code bearing upon the same subject as being in harmony. Defendants' construction does the opposite—it manufactures a conflict where none exists on the face of the statute. Because O.R.C. § 4729.35 is silent as to what remedies are available and the more general statute explains that an action seeking to abate a nuisance is equitable in nature, the court declines to recommend limiting the recovery or remedies available for a violation of O.R.C. § 4729.35 from what is typically recoverable in public nuisance actions.

3. City of Akron's Authority to Bring Public Nuisance Suit

Turning to the argument that the City of Akron is barred from bringing a nuisance claim, Defendants assert that O.R.C. § 4729.35 limits the authority for bringing an action to enjoin a violation of Ohio or federal drug laws to the state attorney general, the county prosecutor of the county in which the offense occurred, and the state board of pharmacy. Plaintiffs' contention that the City of Akron may, nevertheless, maintain a nuisance action for an ostensible violation of federal or Ohio drug laws based on other more generalized nuisance statutes flies in the face of the another portion of the Revised Code that they specifically rely upon—O.R.C. §1.47 ("In enacting a statute, it is presumed that: (B) The entire statute is intended to be effective").[46] Plaintiffs' position—that municipalities could maintain a statutory public nuisance action for violation of a state or federal drug law—would eviscerate the express statutory provision limiting who can bring suit. Plaintiffs' reliance on *State ex rel. DeWine v. Fred's Party Center, Inc*., 13 N.E.3d 699 (Ohio Ct. App. 2014) is misplaced. (R. 654, PageID# 15726). Therein, not only was the suit brought by the Ohio Attorney General, but the court's passing reference to O.R.C. § 4729.35 in a footnote neither states nor implies that any party, other than the attorney general,

[46] Plaintiffs also rely on O.R.C. § 715.44, which states as follows:

> A municipal corporation may:
>
> (A) Abate any nuisance and prosecute in any court of competent jurisdiction, any person who creates, continues, contributes to, or suffers such nuisance to exist;
>
> ***
>
> (C) Prevent injury and annoyance from any nuisance;
>
> ***

the county prosecutor, or the board of pharmacy is vested with authority to bring an action under that statute. *Id*. at n. 1. Although O.R.C. § 4729.35 is not the exclusive avenue for a municipal plaintiff to bring a public nuisance claim, the City of Akron cannot claim that the very nuisance it seeks to abate is the one caused by a violation of Ohio or federal drug laws, as set forth in O.R.C. § 4729.35, but then attempt to circumvent the limitations on who may bring such a suit as set forth in the same statute simply by claiming to rely on a different portion of the Revised Code. In the complaint, Plaintiffs, including the City of Akron, clearly identify the public nuisance they seek to enjoin as violations of Ohio or federal drug laws (or the rules of the board of pharmacy). (R. 514, PageID# 7068, ¶¶979, 983-984, 986, 988). As such, the City of Akron lacks standing to pursue a statutory public nuisance claim based on violations of Ohio or federal drug laws, or the rules of the board of pharmacy.

4. Sufficiency of the Factual Allegations

The Manufacturers argue that Plaintiffs' statutory nuisance claim should be dismissed for failure to allege facts demonstrating a statutory violation. *See Brown*, 622 N.E.2d at 1158 (explaining that Ohio statutes and regulations that define certain conduct as being a public nuisance "amount to a legislative declaration that the proscribed conduct is an unreasonable interference with a public right"); O.R.C. § 3767.01(C)(1) (defining "nuisance" as "that which is defined and declared by statutes to be a nuisance"). The Manufacturers' statement that they "have complied with all relevant federal and state controlled substances requirements" (R. 499-1, PageID# 7702) is merely an assertion of fact that is disputed by Plaintiffs and does not support dismissal at this stage. They also contend that the alleged violations of Ohio law apply only to distributors and not to pharmaceutical manufacturers. (R. 499-1, PageID# 7700-7701; R. 746, PageID# 17724-17725). Plaintiffs state that certain other laws and rules governing the

distribution of controlled substances do apply to the Manufacturers' alleged conduct, including those requiring them to maintain diversion controls and to create a system to disclose suspicious orders, report such orders, and adhere to sales quotas set by the DEA. (R. 654, PageID# 15726-15728, *citing* R. 514 at ¶¶504, 507, 510, 863, 915, 961). The complaint alleges that all Defendants have aided and abetted the violation of federal and state laws controlling the distribution of a drug of abuse as defined in O.R.C. § 3719.011.[47] (R. 514 at ¶¶981-986).

The complaint also alleges violations of O.R.C. § 2925.02(A)(1) and (3), which prohibit the administering, inducing, or causing another to use a controlled substance "[b]y force, threat, or deception" (§ 2925.02(A)(1)), as well as the administering, inducing, or causing another to use such a substance "by any means," with the additional requirement that the actions "cause serious harm" or "cause the other person to become drug dependent" (§ 2925.02(A)(3)). (R. 514 at ¶¶986-987). The Manufacturers argue that to the extent these violations are asserted in an attempt by Plaintiffs to hold them liable for failing to stop the sale of prescription opioids that have been approved by the FDA and are regulated by the DEA, any such claim is preempted. (R. 499-1, PageID# 7701-7702). But nowhere in the complaint is it alleged that the Manufacturers should be prevented from operating their business in a lawful manner; rather, Plaintiffs seek to abate the alleged public nuisance.

Like the Manufacturers, the Pharmacies assert that the complaint fails to allege specific details of nuisance-creating conduct on their part affecting Summit County or even the State of Ohio and that the complaint contains "no more than conclusory factual allegations …" (R. 497-1,

[47] The Manufacturers also assert that Plaintiffs' Opposition cites to statutory violations not specifically pled, but the complaint identifies specific statutes as bases for alleged liability and also states that the claimed violations include, but are not limited to, conduct proscribed by Ohio and federal law. (R. 514 at ¶984).

PageID# 7609-7610). They concede, however, that Plaintiffs have alleged several violations of Ohio and federal law, but protest that the allegations are not sufficiently specific with respect to recordkeeping defaults and contend the allegations that they failed to maintain effective controls against diversion or failed to disclose suspicious orders are implausible. *Id*. Indeed, the complaint contains allegations that the Pharmacies engaged in misconduct and violated federal and state laws, and references numerous fines and settlements involving the Pharmacies. (R. 514, ¶¶ 504, 612-659, 684-686). Furthermore, where the facts at issue may be in the control of others, dismissal prior to discovery is not appropriate. *Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 383 (6th Cir. 2016) (explaining that the pleading standards only require enough facts to demonstrate a reasonable expectation that discovery will reveal evidence to support the allegations).

5. Safe Harbor

"Ohio courts have long imposed the following concrete limitation on public nuisance claims: What the law sanctions cannot be held to be a public nuisance." *City of Cleveland v. Ameriquest*, 621 F. Supp.2d 513, 526 (N.D. Ohio 2009), *aff'd*, 615 F.3d 496 (6th Cir. 2010) (citations omitted). The Manufacturers claim that they are shielded from nuisance liability by virtue O.R.C. § 2925.02(B), which provides a "safe harbor" for persons whose conduct is in accordance with Ohio controlled substance regulations. (R. 499-1, PageID# 7001-7002). They assert that they "have complied with all relevant federal and state controlled substances requirements." *Id.*

But as *Ameriquest* makes clear, safe harbor immunity from nuisance liability is available only to those who perform in accordance with their applicable regulatory obligations. 621 F. Supp. 2d at 528 ("Under a long line of decisions, a showing that the challenged conduct is

subject to regulation and was performed in conformance therewith insulates such conduct from suit as a public nuisance"). The complaint alleges that all Defendants failed to do so. (R. 514 at ¶¶981-988). It also alleges misconduct unrelated to Defendants' respective regulated activities, for example, as to the Manufacturers, an extensive deceptive marketing scheme that intended to change the perception of opioids and boost sales by misleading doctors and the public about the risks of long-term opioid use. (R. 514 at ¶¶174-179, 989).

While regulatory oversight is a factor to be considered when determining the sufficiency of a public nuisance claim, "extensive regulation does not automatically bar a public nuisance claim." *City of Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, *6 (Ohio Ct. App. March 21, 2013); *Cincinnati v. Beretta*, 768 N.E.2d at 1143. The *Beretta* court rejected defendants' assertion that they were engaged in "legislatively authorized conduct," and were not subject to liability. 768 N.E.2d at 1143. The court concluded that "even though there exists a comprehensive regulatory scheme involving the manufacturing, sales, and distribution of firearms, ... the law does not regulate the distribution practices alleged in the complaint," *i.e.*, practices that "fostered the criminal misuse of firearms [and] helped sustain the illegal firearms market in Cincinnati …." *Id.* at 1140. Contrary to Manufacturers' contention that the complaint is defective because it fails to plead "any facts to show that any Manufacturer Defendant somehow deceived a particular resident in Summit County into using opioids, much less into becoming opioid dependent," that level of specificity is not required prior to discovery. (R. 499-1, PageID# 7702).

Accordingly, it is recommended that Defendants' motions to dismiss be partially granted to the extent they seek to bar the City of Akron from maintaining a statutory public nuisance action based on either: (1) a violation of an Ohio or federal drug law; or (2) any rule of the board

of pharmacy controlling the distribution of a drug of abuse. It is otherwise recommended that Defendants' motions to dismiss count five, or to limit Plaintiffs' statutory remedies, be denied.[48]

G. Count Seven: Negligence

The complaint alleges a negligence claim against all Defendants. (R. 514, PageID# 11220). A negligence claim must allege (1) a duty owed by the defendant to the plaintiff to conform to a certain standard of conduct, (2) that the defendant breached that duty, and (3) that the breach of the duty proximately caused the plaintiff's injury. *Cromer v. Children's Hosp. Med. Ctr. of Akron*, 29 N.E.3d 921, 928-929 (Ohio 2015). Defendants challenge the sufficiency of the complaint with respect to the first and third elements. (R. 491-1, PageID# 7505-7513, 7515-7519; R. 497-1, PageID# 7599-7608; R. 499-1, PageID# 7702-7703).

1. Duty of Care

"The existence of a duty is a question of law for a court to determine." *Mussivand v. David*, 544 N.E.2d 265, 270 (Ohio 1989) ("There is no formula for ascertaining whether a duty exists. Duty…is the court's expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.") (citations and quotations omitted). "The Ohio Supreme Court has explained that '[t]he existence of a duty depends on the foreseeability of the injury.'" *Jaycox v. Setty Family Veterans Residential Care Home*, 2004 WL

[48] Although the Distributors broadly argued that both Plaintiffs' negligence and nuisance claims should be dismissed based on the economic loss doctrine, they made no attempt to distinguish between common law public nuisance claims and statutory public nuisance claims. (R. 491-1, PageID# 7513-7514; R. 744, PageID# 17672-17673). "The doctrine bars tort plaintiffs from recovering purely economic loss that 'do not arise from tangible physical injury' to persons or property.'" *Deutsche Bank*, 863 F.3d at 477 (*quoting Queen City Terminals v. Gen. Am. Trans.*, 653 N.E.2d 661, 667 (Ohio 1995)). The movant has presented the court with no compelling reason to apply such a tort doctrine to a statutory claim, especially where it does not appear that Plaintiffs seeks any relief beyond that which is permitted by statute.

1171348, *3 (6th Cir. May 24, 2004) (quoting *Menifee v. Ohio Welding Products, Inc.*, 472 N.E.2d 707, 710 (Ohio 1984)). Moreover,

> The concept of foreseeability is an important part of all negligence claims, because "[t]he existence of a duty depends on the foreseeability of the injury." *Menifee* at 77, 472 N.E.2d 707. As a society, we expect people to exercise reasonable precautions against the risks that a reasonably prudent person would anticipate. *Commerce & Industry Ins. Co. v. Toledo*, 45 Ohio St.3d 96, 98, 543 N.E.2d 1188 (1989). Conversely, we do not expect people to guard against risks that the reasonable person would not foresee. *Menifee* at 77, 472 N.E.2d 707; Keeton, Dobbs, Keeton & Owen, Prosser and Keeton on the Law of Torts, Section 43, 280 (5th Ed.1984). 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. *See Gedeon v. E. Ohio Gas Co.*, 128 Ohio St. 335, 339, 190 N.E. 924 (1934). 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 ("The existence of an actor's duty to another person usually arises from the foreseeability of injury to someone in that other person's 'general situation.'") (*quoting Gedeon*, 190 N.E. at 926). The "foreseeability of harm usually depends on the defendant's knowledge." *Menifee*, 472 N.E.2d at 710. But 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. *Bohme, Inc. v. Sprint Int'l Comm. Corp.*, 686 N.E.2d 300, 303 (Ohio Ct. App. 1996); *Pavlides v. Niles Gun Show, Inc.*, 637 N.E.2d 404 (Ohio Ct. App. 1994) (holding that an actor cannot necessarily avoid the imposition of a legal duty merely because he did not foresee the exact consequences of his actions).

In *Cincinnati v. Beretta*, the Ohio Supreme Court addressed the question of whether gun manufacturers owed a duty of care to a local government concerning harms caused by negligent manufacturing, marketing and distributing of firearms. *Beretta* involved allegations that the defendants failed to exercise sufficient control over the distribution of their guns, thereby

creating an illegal secondary market in the weapons. The *Beretta* court concluded that the harms that resulted from selling these weapons were foreseeable—that Cincinnati was a foreseeable plaintiff. 768 N.E.2d at 1144. Plaintiffs argue that the harm caused by the marketing and distribution of opioids are similarly foreseeable.

Plaintiffs assert that Defendants have a common law duty "to not expose Plaintiffs to an unreasonable risk of harm[;] ... a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids." (R. 514 at ¶¶1040-1041). Defendants deny that they owed any common law duty to Plaintiffs. (R. 499-1, PageID# 7702-7703; R. 491-1, PageID# 7511-7512; R. 497-1, PageID# 7599-7601; R. 744, PageID# 17666-17667). Defendants claim that the common law does not recognize the duty of care that Plaintiffs assert; that Plaintiffs are actually alleging a statutory duty of care under the CSA which creates duties owed only to the DEA and the Ohio Board of Pharmacy, and which provides for no private right of action; that Plaintiffs are attempting to use negligence *per se* to plead around the absence of a private right of action; that there is no duty to prevent a third person from causing harm; and that the learned intermediary doctrine forecloses any duty running from Defendants to Plaintiffs. Moreover, Distributors deny any foreseeable harm caused by their actions and characterize themselves as mere "middlemen" who "do not write prescriptions or determine whether opioid medications are appropriate for patients" or "meet directly with patients and furnish them with opioids" as pharmacists do. (R. 491-1, PageID# 7511). The Pharmacies assert that Ohio imposes no common law duty "to exercise due care in the distribution of opioids, and specifically to detect, identify, or report suspicious orders." (R. 497-1, PageID# 7599).

Plaintiffs, for their part, do not argue that there is a private right of action under these

statutes, but rather argue that the complaint's references to statutes merely identified a statutory standard of care that they contend could serve as a basis to support their theories of a common law duty and breach. (R. 654, PageID# 15787). Here, Plaintiffs base their duty and breach arguments on Defendants' own conduct—failing to report suspicious orders or otherwise act to prevent diversion—which caused their harm. (R. 514 at ¶¶546, 568-569, 607-659, 989, 1046-1071). Plaintiffs' Opposition references allegations in their complaint to argue that Defendants sold opioids "without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids" (*id*. at ¶1050); that the Marketing Defendants disseminated deceptive marketing about the safety and addictiveness of opioids through front groups and KOLs (*id*. at ¶¶350-428); that Marketing Defendants funded CMEs to encourage doctors to increase their prescriptions of opioids (*id*. at ¶¶429-442); that Defendants marketed, distributed and sold opioids "in a way that created and fostered an illegal, secondary prescription opioids market that resulted in a foreseeable and unreasonable risk of harm to Plaintiffs" (*id*. at ¶1049); that Manufacturers knew of doctors who were writing large quantities of opioids "[b]ut ... were singularly focused on maintaining, capturing, or increasing their sales" (*id*. at ¶574); that the Pharmacies knew of oversupply of prescription opioids (*id*. at ¶607); that Marketing and Supply Chain Defendants were aware of suspicious orders from their facilities (*id*. at ¶¶763, 589); that Marketing Defendants provided incentives to sales representatives and ignored red flags of diversion during regular visits to pharmacies and doctors (*id*. at ¶¶516, 568-569); and their sales representatives frequently promoted opioids in Summit County (*id*. at ¶673).

Plaintiffs argue that these allegations are sufficient to establish that their resulting harm (*i.e.* dramatically increased expenditures on public health and safety) was the foreseeable and

likely result of Defendants' actions. (R. 654, PageID# 15783-15784). Taking Plaintiffs' allegations as true, Plaintiffs have stated a plausible claim that it was reasonably foreseeable that they would be forced to bear the public costs of increased harm from the over-prescription and oversupply of opioids in their communities if Defendants failed to implement and/or follow adequate controls in their marketing, sales, distribution, and dispensing of opioids.

Defendants argue, however, that Ohio law imposes no duty "to prevent a third person from causing harm to another absent a special relation between the parties." (R. 499-1, PageID# 7687; R. 497-1, PageID# 7600; R. 491-1, PageID# 7512). Defendants argue that Plaintiffs have not alleged any special relationship that would give rise to such a duty. *Id*. The defendants in *Cincinnati v. Beretta* raised a similar argument against municipal expenditures following the actions of firearm manufacturers. 768 N.E.2d at 1144-46. Therein, the city alleged that defendants marketed and distributed their firearms in such a way as to "ensure the widespread accessibility of the firearms to prohibited users" thereby fostering criminal misuse and an illegal aftermarket. *Id.* at 1140. The Ohio Supreme Court determined that the "special relationship rule [was] not determinative" because plaintiffs were not alleging a duty to control third persons. Instead, the court maintained that "the 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 a foreseeable injury." *Id.* In this case, Plaintiffs' do not assert a duty to prevent the actions of third persons, but rather a duty owed by Defendants to Plaintiffs to use reasonable care in, for example, marketing, monitoring, reporting, and selling their opioids. The wrongful conduct alleged is that of Defendants, and not of third persons.

The Pharmacies contend that they do not owe a duty as a result of the learned intermediary doctrine. The learned intermediary doctrine is not applicable as explained *supra* in

the RICO analysis. Distributors also argue that any duty they may owe to "report suspicious order is a duty that was created by statute, and the duty runs to the DEA and the Ohio Board of Pharmacy, not the County." This duty, they argue, is "unknown at common law." They maintain that when Plaintiffs assert a common law duty of care, they are actually seeking to enforce the CSA and Ohio's pharmacy regulations for controlled substances. (R. 491-1, PageID# 7505-7511; R. 497-1, PageID# 7602-05). Because the court finds that Plaintiffs have plausibly pleaded facts sufficient to establish that Defendants owed them a common law duty, the court does not reach this argument based upon the limited record before it.[49]

2. Proximate Cause

Plaintiffs must allege facts that, if proven, plausibly establish a causal link between Defendants' actions and Plaintiffs harm that is not too remote. The Ohio Supreme Court and the Sixth Circuit have employed the proximate cause test devised by the U.S. Supreme Court in *Holmes* in negligence cases like this one. 503 U.S. at 268-70; s*ee also Cincinnati v. Beretta*, 768 N.E.2d at 1147-49; *Ameriquest*, 615 F.3d at 504.

Plaintiffs argue that Defendants' alleged negligent sales practices, including failing to comply with obligations to monitor and report suspicious orders, halt suspicious orders, and implement effective diversion controls have led directly to the creation of a population of addicted patients and nourished the illegal secondary market, both of which lie at the root of the opioid crisis, resulting in complex and costly consequences to Plaintiffs' provision of public health, social, and criminal justice services. (R. 514 at ¶¶1040-1060).

[49] Nor is it necessary to address Defendants' arguments with regard to negligence *per se*, as those arguments presuppose Plaintiffs' failure to plead a common law duty.

Defendants insist that Plaintiffs' alleged injuries are far too remote and indirect to establish proximate cause. (R. 491-1, PageID# 7515-7518; R. 497-1, PageID# 7605-7608).[50] They argue that there are numerous intervening causes which break the causal link between their own actions and Plaintiffs' harms. These include the actions of prescribing doctors, criminals in the secondary market, and addicted users, among others. *Id*. Defendants also argue that Plaintiffs' harms were not proximately caused by Defendants actions, because those harms are derivative of harms sustained by third parties. Defendants urge the court to reach the same result on causation as the one reached by courts in the recent mortgage finance cases. *See JP Morgan Chase Bank*, 2013 WL 1183332, at *6*; Ameriquest*, 621 F. Supp. 2d at 536.

The Ohio Supreme Court has explained that in order to establish proximate causation, "there must be some direct relation between the injury asserted and the injurious conduct alleged." *Cincinnati v. Beretta*, 768 N.E.2d at 1148. The Ohio Supreme Court in *Beretta* adopted *Holmes*' analysis for remoteness and proximate cause, concluding that the complaint had set forth facts sufficient to establish proximate cause. As to the first factor, the court reasoned that concerns with the difficulty of proof were minimal, in part, because "the complaint…alleged that as a direct result of misconduct …[the city] has suffered 'actual injury and damages including but not limited to, significant expenses for police, health, prosecution, emergency, corrections and other services.'" *Id.* at 1148. The second factor did not pose a problem because there was "little risk of double recovery, since [the city] is seeking recovery for injuries to itself only." *Id.* Finally, invoking the deterrence principle embedded in the third *Holmes* factor, the court stated

[50] While asserting that Plaintiffs' negligence claim should be dismissed, the Manufacturers do not meaningfully develop any new argument and adopt earlier arguments. (R. 499-1, PageID# 7702). For the reasons stated elsewhere in this report and recommendation, such reiterated arguments, including the assertion that proximate cause is lacking, fail.

that "[a]lthough appellant is indirectly attempting to protect its citizens from the alleged misconduct by the gun manufacturers and trade associations, appellant is seeking recovery for its own harm. Under these circumstances, the general interest will be best served by having this plaintiff bring this lawsuit." *Id.* The court reversed the appellate court ruling that the city's claims were "too remote for recovery." *Id.*

Although the facts of this case differ in some respects from *Beretta*, its analysis of remoteness under *Holmes* is persuasive. Furthermore, the court has conducted a proximate cause analysis regarding the *Holmes* factors in section III-A-2-b above that need not be repeated here.[51]

Noting that Plaintiffs plead criminal acts, Defendants assert that their position is analogous to sellers who supply to independent retailers from whom drugs are obtained for diversion. *See, e.g., Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659, 663 and n.5 (8th Cir. 2009) (applying Arkansas law to find that intervening acts by retailers and methamphetamine cooks to whom they sold pseudoephedrine were independent causes relieving distributors of liability based on the legal sale of products later used for illicit purpose); *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 424 (3d Cir. 2002) (affirming dismissal of public nuisance claim against gun distributors because of the many "links that separate a manufacturer's sale of a gun to a licensee and the gun's arrival in the illegal market through a distribution scheme that is not only lawful, but also is prescribed by statute with respect to the manufacturers' conduct"). The

[51] Although the Pharmacies were not subject to the RICO claims addressed above, the differences between the allegations against them and the remaining Defendants do not compel a different result when addressing the issue of proximate cause. The Pharmacies are alleged to have "failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids [flowing] into communities across America," (R. 514 at ¶¶579, 607-626), and have been the subject of fines by the DEA for failing to do so. (*Id*. at ¶¶627-659). Moreover, the Pharmacies, the ultimate dispenser of opioids, are arguably a step closer to the injured parties than the other Defendants.

Distributors also argue that Plaintiffs plausibly allege that only Manufacturers could have foreseen that intervening criminal or intentional acts would occur and, therefore, do not establish that the alleged harm was foreseeable to Distributors. (R. 744, PageID# 17672, *citing Feichtner v. Ohio Dep't of Trans.*, 683 N.E.2d 112, 119-20 (Ohio Ct. App. 1995) (recognizing that there is no common law duty to anticipate or foresee criminal activity); *Volter v. C. Schmidt Co.*, 598 N.E.2d 35, 39 (Ohio Ct. App. 1991) ("Where the harm is intentionally caused by a third person and is not within the scope of the risk created by the actor's conduct, the intentional act is considered a superseding cause because such acts are typically not foreseeable.")).

Not only does the complaint allege that the opioid addiction epidemic and its attendant injury to government entities were foreseeable to all Defendants, it also alleges that even after Defendants were aware of the opiate addiction crisis they continued distributing commonly abused and diverted drugs in quantities and with frequency that they knew or should have known could not be justified by legitimate medical need and they manipulated quotas to evade reporting duties and maintain that inflated level of sale.[52] (R. 514 at ¶¶18, 518, 550, 557, 565, 579, 496, 606-08, 763, 929, 1012, 1019-1020). The Distributors' argument is also refuted by allegations that they conspired with the Manufacturers in a concerted scheme to expand the opioid market, to ensure that distribution quotas remained artificially high and that suspicious orders were not reported. (R. 514 at ¶¶760-766). In addition, Defendants' arguments concerning third-party intervening acts and alleged superseding events raise significant factual issues not suitable for resolution on a motion to dismiss.

[52] As the cited paragraphs illustrate, the Pharmacies' argument to the contrary is misplaced. (R. 742, PageID# 17611). The complaint does claim the Distributors could have foreseen, and were aware of, unnecessary prescriptions and the operation of pill mills, but nevertheless supplied them.

3. Economic Loss Rule

The Defendants argue that the economic loss doctrine requires dismissal of Plaintiffs' negligence claim. (R. 491-1, PageID# 7513-7514; R. 497-1, PageID# 7601-7602.).[53] They assert that the doctrine prohibits a negligence claim unless the plaintiff incurred a physical injury to person or property. *Id.*; *see Corporex Dev. & Constr. Mgt., Inc. v. Shook, Inc.*, 835 N.E.2d 701, 704 (Ohio 2005); *Floor Craft Floor Covering, Inc. v. Parma Cmty. Gen. Hosp. Ass'n*, 560 N.E.2d 206, 208 (Ohio 1990); *see also Deutsche Bank Nat'l Tr. Co.*, 863 F.3d at 477 (noting, "The premise of the economic loss rule is that tort law does not impose an independent duty to avoid consequential economic damages."); *Pavlovich v. Nat'l City Bank*, 435 F.3d 560, 569 (6th Cir. 2006). Defendants also rely upon, *Queen City Terminals, Inc. v. Gen. Am. Transp.*, in which the Ohio Supreme Court held that "in order to recover indirect economic damages in a negligence action, the plaintiff must prove that the indirect economic damages arose from tangible physical injury to persons or from tangible property damage. Indirect economic damages that do not arise from tangible physical injury to persons or from tangible property may only be recovered in contract." 653 N.E.2d 661, 667 (Ohio 1995); *see also Ashtabula River Corp. Grp. II v. Contrail, Inc.*, 549 F.Supp.2d 981, 987 (N.D. Ohio 2008) (R. 744, PageID# 17675).

Plaintiffs argue that the doctrine primarily applies to bar recovery in cases between parties in a contractual relationship. *See Corporex*, 835 N.E.2d at 701; *Chemtrol Adhesives, Inc. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624 (Ohio 1989); *Digiknow, Inc. v. PKXL Cards, Inc.*,

[53] Manufacturers make only cursory reference to the economic loss doctrine as a reason to dismiss Plaintiffs' negligence claim. (R. 499-1, PageID# 7702). They simply cite to *Corporex* in a bullet point, and then refer to a single paragraph of argument in their public nuisance section. Also, the Pharmacies adopt Distributors' arguments. (R. 742, PageID# 17613).

2011 WL 2899600, at *1 (Ohio Ct. App. July 21, 2011). Plaintiffs argue that the doctrine does not apply to their negligence claim because it is not based on the negligent performance of contractual duties. (R. 654, PageID# 15795-15797).

The Ohio Supreme Court in *Corporex* explained that the rule "stems from the recognition of a balance between tort law, designed to redress losses suffered by a breach of 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." 835 N.E.2d at 704 ("Tort law is not designed to compensate parties for losses suffered as a result of a breach of duties assumed only by agreement."). In other words, the economic loss rule recognizes that the risk of consequential economic loss is something that the parties can allocate by agreement when they enter into a contract. This allocation of risk is not possible where, as here, the harm alleged is caused by involuntary interactions between a tortfeasor and a plaintiff. Thus, courts have noted that in cases involving only economic loss, the rule "will bar the tort claim if the duty arose only by contract." *Campbell v. Krupp*, 961 N.E.2d 205, 211 (Ohio Ct. App. 2011). By contrast, "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." *Id.*; *see also Corporex*, 835 N.E.2d. at 705 ("When a duty in tort exists, a party may recover in tort. When a duty is premised entirely upon the terms of a contract, a party may recover based upon breach of contract."); *Ineos USA LLC v. Furmanite Am., Inc.*, 2014 WL 5803042, at *6 (Ohio Ct. App. Nov. 10, 2014) ("[W]here a tort claim alleges that a duty was breached independent of the contract, the economic loss rule does not apply.").

As discussed elsewhere in this opinion, Plaintiffs have pleaded facts which, if proven, plausibly establish the existence of a common law tort duty. Moreover, it would be premature on

this limited record to apply the economic-loss rule as Defendants have characterized Plaintiffs' economic damages as purely derivative of personal injuries, which if ultimately successful at summary judgment or before the trier-of-fact, could foreclose this argument. In addition, Plaintiffs have facially pled damages to their proprietary interests. (R. 514 at ¶1063). As such, Defendants have not shown that Plaintiffs' negligence claim runs afoul of the economic loss rule.

H. Count Eight: Fraud

In Count Eight, Plaintiffs assert a common law fraud claim against the Marketing Defendants. (R. 514, PageID# 11227). To state a cognizable cause of action for fraud under Ohio law, a complaint must plead the following elements:

> (a) a representation or, where there is a duty to disclose, omission of a fact; (b) which is material to the transaction at hand; (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred; (d) with the intent of misleading another into relying upon it; (e) justifiable reliance upon the representation or concealment; and (f) a resulting injury proximately caused by the reliance.

Lucarell v. Nationwide Mutual Ins. Co., 97 N.E.3d 458, 472 (Ohio 2018) (citations omitted).

The briefs focus on the element of justifiable reliance. Generally, whether a plaintiff justifiably relied on an allegedly fraudulent misrepresentation or omission is a question of fact and not appropriate for determination on a motion to dismiss. *See, e.g., Jewell Coke Co., L.P. v. ArcelorMittal USA, Inc.*, 756 F. Supp. 2d 858, 867 (N.D. Ohio 2010). The Manufacturers assert that because the claim is based on alleged misrepresentations made to third parties, it fails to plead the essential element of justifiable reliance (R. 499-1, PageID# 7703). Specifically, they contend that the misrepresentations and omissions alleged by Plaintiffs were made to induce reliance by third-party payors (R. 514 at ¶1074), or directed at state and federal regulators (*id.* at ¶856), and with intent that others rely on their omissions. *Id.* at ¶1075. As such, they contend

first-party reliance is lacking.

Plaintiffs respond that the complaint avers justifiable reliance and alleges that "Plaintiffs ... did in fact rightfully, reasonably, and justifiably rely on Marketing Defendants' representations and/or concealments both directly and indirectly ..." (R. 514 at ¶1081) and "proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants [and] [a]s a consequence, these Defendants prevented Plaintiffs from a more timely and effective response to the opioid crisis" (*id.* at ¶1082). (R. 654, PageID# 15801). In addition, they argue that Ohio recognizes a theory of recovery based on false statements made to third parties that are known or intended to deceive the pleader, *i.e.*,

> 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 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 of the Law (Torts) § 533 (2018). Plaintiffs also cite to authority from the Sixth Circuit and this court recognizing that a *prima facie* common fraud claim is stated based on that theory. *See Nernberg v. Pearce*, 35 F.3d 247, 250–51 (6th Cir. 1994) (stating that "[i]t is generally accepted that a plaintiff is not required to prove direct reliance on a fraudulent misrepresentation to state a claim for fraud."); *accord Lewis v. Horace Mann Ins. Co.*, 410 F. Supp. 2d 640, 664 (N.D. Ohio 2005) (denying summary judgment and

reasoning that reliance may be satisfied where a fraudulent statement or omission becomes known to a complainant who acts upon it, even if indirectly communicated by others) (also citing Oh. Jur.3d. Ed., Fraud & Deceit § 89, and *Lin v. Gatehouse Constr. Co.*, 616 N.E.2d 519, 524 (Ohio 1992)).[54]

The Manufacturers are correct in stating that the complaint alleges that they intentionally made misrepresentations and omissions to the medical community, patients, and government regulators with the intent of inducing reliance. (R. 499-1, PageID# 7703-7704). Their contention that this claim fails by not alleging any first-party reliance, however, is not well-taken, as noted above. In addition, Plaintiffs also aver that the Manufacturers knowingly set out to convince physicians, patients and the public at large that false propositions regarding the safety and efficacy of opioids were true (R. 514, *e.g.*, ¶¶177-178, 1076-1078); issued press releases falsely minimizing the risks of addiction and abuse potential of the drugs (*id. e.g.*, ¶¶190, 340-341); and in public outreach and pronouncements, falsely portrayed their compliance with regulatory obligations, cooperation with law enforcement, and commitment to preventing diversion (*id. e.g.*, ¶¶595-98, 601-606). The complaint further alleges:

> Defendants also concealed from Plaintiffs the existence of Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently

[54] The cases that defendants cite, as plaintiffs note, are distinguishable because there was a lack of evidence supporting reliance. *See Lucarell*, 97 N.E.3d at 473-474 (finding that plaintiff "failed to prove that any fraudulent representation had been made to her" where fraud claim was based on misrepresentation made by defendant to lender to induce lender to approve plaintiff's business loan); *Mike McGarry & Sons, Inc. v. Constr. Res. One, LLC*, 2018-Ohio-528, ¶ 78-79 (Ohio Ct. App. Feb. 9, 2018) (reversing denial of summary judgment, reasoning that fraud claim could not be maintained where party presented no evidence that it took action in reliance on the allegedly false statement).

> with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiffs, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

Id. at ¶772. These allegations support a reasonable inference that these Defendants intended to induce Plaintiffs to rely on their false assurances and omissions in order to deter potential liability for injuries such as those alleged in the complaint. Based on the foregoing, a genuine dispute of fact exists as to whether Plaintiffs' justifiably relied on alleged fraudulent statements and omissions, and it is not appropriately decided on a motion to dismiss.

I. Count Nine: Injury Through Criminal Acts

In Count Nine, Plaintiffs seek relief against all Defendants for injury through criminal acts pursuant to O.R.C. § 2307.60(A)(1), which states:

> 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.

O.R.C. § 2307.60(A)(1).[55] Defendants argue that the vast majority of courts have held that "a conviction for the alleged predicate criminal act" is required before a cause of action accrues. (R. 499-1, PageID# 7704; R. 497-1, PageID# 7614).[56] Defendants maintain that Plaintiffs have failed to allege the requisite criminal conviction against any of them and, therefore, their claims

[55] Defendants acknowledge the lone exception is inapplicable. (R. 499-1, PageID# 7704).
[56] *Citing Jane v. Patterson*, 2017 WL 1345242, at *4 (N.D. Ohio Apr. 12, 2017); *A.A. v. Otsego Local Sch. Bd. of Educ.*, 2016 WL 7387261, at *9 (N.D. Ohio Dec. 21, 2016); O*rtiz v. Kazimer*, 2015 WL 1400539, at *12 (N.D. Ohio Mar. 26, 2015), *aff'd*, 811 F.3d 848 (6th Cir. 2016); *Tri-State Comp. Exch., Inc. v. Burt*, 2003 WL 21414688, at *6 (Ohio Ct. App. June 20, 2003).

must be dismissed. *Id*. Conversely, Plaintiffs contend that the cases upon which Defendants rely are irreconcilable with a 2016 decision from the Supreme Court of Ohio—*Jacobson v. Kaforey*, 75 N.E.3d 203 (Ohio 2016). (R. 654, PageID# 15802-15805). Therein, the Ohio Supreme Court held that:

> 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).

Jacobson, 75 N.E.3d at 206 (emphasis in original). A few weeks before *Jacobson*, a decision from this district found that "Ohio Rev. Code § 2307.60(A)(1) clearly authorizes a civil action for damages for anyone injured by a criminal act, regardless of whether any person has pleaded guilty to or been convicted of a criminal offense." *Chem. Bank v. Kausmeyer*, 2016 WL 7178662, at *7 (N.D. Ohio Dec. 9, 2016) (Pearson, J.) (*citing Cuyahoga Hts. Local School Dist. v. Palazzo*, 2016 WL 4037309 (Ohio Ct. App. July 28, 2016)). In addition, a recent decision from this district observed that O.R.C. § 2307.60 authorizes a civil action for damages caused by criminal acts, noting:

> Interestingly, in 2007, the Ohio General Assembly amended ORC § 2307.60 to create a *presumption of civil liability* when the defendant had been convicted of a criminal violation. Am. Sub. S.B. 117. Had the General Assembly wanted to make a criminal conviction a condition precedent to establishing an ORC § 2307.60 claim, they presumably could have done so. However, the creation of this presumption does not conclusively establish that a conviction is not required for civil liability.
>
> Accordingly, the Court will deny the motion to dismiss at this time. Defendants may renew their challenge in the form of a motion for summary judgment after discovery and further research.

Buddenberg v. Weisdack, 2018 WL 3159052, at *5-6 (N.D. Ohio June 28, 2018) (Polster, J.) (emphasis in original).

Given that Defendants, as the moving party, bear the burden of demonstrating that Plaintiffs fail to state a claim, dismissal cannot be recommend at this time, especially given the not unreasonable inference from the Ohio Supreme Court's *Jacobson* decision that a conviction may not be a necessary prerequisite.

The Pharmacies also assert that Plaintiffs have not alleged any "injur[y]" to their "person or property" pursuant to O.R.C. § 2307.60(A)(1). (R. 497-1, PageID# 7615). They allege O.R.C. § 2307.60(A)(1) does not provide for recovery for purely economic loss, but cite no authority in support of this proposition, and the statute itself does not contain such an express limitation. *Id*. The only case cited by the Pharmacies is inapposite. *See Pavlovich*, 435 F.3d at 569 ("Under Ohio law, "[t]he economic-loss rule generally prevents recovery *in tort* of damages for purely economic loss.") (emphasis added). The *Pavlovich* decision contains no discussion concerning a statutory action brought under O.R.C. § 2307.60(A)(1), and Defendants cite no other authority suggesting claims arising under that section should be construed identically to tort claims.

Finally, the Pharmacies argue that they are "specifically excepted by law" from liability under § 2307.60, by virtue of O.R.C. §§ 2925.02(B), 2925.03(B). (R. 497-1, PageID# 7615). Defendants fail to meaningfully develop this argument. The complaint alleges that Defendants are not in compliance with multiple provisions of the Revised Code rendering any exceptions unavailable. (R. 514 at ¶¶1095-1097). The Pharmacies protest that "such unsupported and generic legal conclusions should be disregarded." (R. 497-1, PageID# 7615). This statement cannot be credited, as Plaintiffs' assertions or conclusions, as Defendants phrase it, cannot be construed in a vacuum ignoring the other voluminous allegations in the complaint that support the conclusion. To the extent Defendants merely reiterate the safe harbor argument addressed above, it fails for the same reasons.

J. Count Ten: Unjust Enrichment

In Count Ten, Plaintiffs assert an unjust enrichment claim against all Defendants. (R. 514, PageID# 11235). The following elements comprise a valid unjust enrichment cause of action: "(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 (Ohio 1984) (internal quotations omitted). Plaintiffs allege that they conferred a benefit upon Defendants "by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices," and that retention of that benefit would be unjust. (R. 514 at ¶¶1114-1115; 1108-1121).

The Defendants assert that Plaintiffs do not properly allege that they conferred a benefit upon them. (R. 491-1, PageID# 7519-7522; R.497-1, PageID# 7612; R. 499-1, PageID# 7705-7706). The Distributors argue that under Ohio law, "[i]t is not enough that a plaintiff suffers a loss and defendant receives a benefit; rather, 'a plaintiff must establish that a benefit has been conferred upon that defendant *by that particular plaintiff.*'" (R. 491-1, PageID# 7520-21) (quoting *Ohio Edison Co. v. Direct Energy Bus., LLC*, 2017 WL 3174347, at *3 (N.D. Ohio July 26, 2017) (emphasis in original); *Bihn v. Fifth Third Mortg. Co.*, 980 F. Supp. 2d 892, 904 (S.D. Ohio 2013)). Moreover, the Distributors construe *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005) and its progeny to announce a "rule of law" holding that unjust enrichment claims may only be sustained if they arise from an economic transaction between the parties.[57] (R. 491-1, PageID# 7520-21; R. 744, PageID# 17675-17676).

[57] The Manufacturers raise this same argument, citing *Randleman v. Fid. Nat'l Title Ins. Co.*, 465 F. Supp. 2d 812, 824 (N.D. Ohio 2006) in support. (R. 499-1, PageID# 7706).

Plaintiffs assert *Ohio Edison* is distinguishable, arguing that this case does not raise the same concerns—namely, an inability to allocate benefits and losses where multiple actors bought and sold from each other in a complicated market. They also argue that *Johnson* "is even farther afield" because its concern was that indirect purchasers would invoke unjust enrichment to accomplish an end-run around antitrust laws limiting recovery to direct purchasers. According to Plaintiffs, the reasoning does not mandate the same privity in this case. (R. 654, PageID# 15808). In the present action, Plaintiffs' theory of recovery is not based on a financial transaction, therefore the claim is not barred by *Johnson's* limiting indirect purchasers from maintaining unjust enrichment claims against parties other than those with whom they dealt with directly. *Johnson*, 834 N.E.2d at 799.

Further, the Pharmacies argue that the alleged expenditures did not save them any expense or loss, but rather the money benefited Plaintiffs' residents by increasing healthcare services and addiction treatment for opioid users. *City & Cty. of San Francisco v. Philip Morris, Inc.* 957 F. Supp. 1130 (N.D. Cal 1997) (finding that the City could not recover the costs of providing medical care to indigent smokers where there was no allegation that defendant tobacco company had a duty to cover those costs and plaintiff did not show that defendant was enriched); *Ashley Cty., Ark. v. Pfizer, Inc.*, 552 F.3d 659, 666 (8th Cir. 2009) (explaining that Arkansas law only implies a contract to pay for services when they were rendered in expectation of payment from a defendant, and finding that plaintiff had no expectation that the defendant drug manufacturer would pay for municipal services provided in dealing with the methamphetamine crisis). (R. 497-1, PageID# 7612; R. 742, PageID# 17617).

Plaintiffs assert that "[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." (R. 654, PageID # 15806-15807, *quoting White v. Smith & Wesson*, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (Nugent, J.)). Therein, the court found that a municipal plaintiff adequately plead an unjust enrichment claim where it was alleged that plaintiff "conferred a benefit upon Defendants, *i.e.*, that the City paid for what may be called the Defendants' externalities—the costs of the harm caused by Defendants' [conduct].").[58] *Id.* Courts applying *White's* analysis have arrived at the same result. *See, e.g.*, *City of Los Angeles v. Wells Fargo & Co.*, 22 F. Supp. 3d 1047, 1061 (C.D. Cal. 2014) (citing *White* and finding a sufficient restitution theory where plaintiff alleged the benefits conferred were "externalities—the costs of harm caused by Defendants' discriminatory lending that the City has had to shoulder"); *City of Los Angeles v. Bank of Am. Corp.*, 2014 WL 2770083, at *12–13 (C.D. Cal. June 12, 2014) (finding a valid claim for unjust enrichment where plaintiff alleged that the defendants' predatory lending resulted in their enrichment at plaintiffs' expense, which paid for defendants' "externalities, or costs of harm caused by its mortgage lending discrimination"); *City of Boston*, 2000 WL 1473568, at *18 (finding plaintiffs stated a claim for unjust enrichment by alleging that they "conferred a benefit upon Defendants by paying for the costs of the harm caused by Defendants' conduct ("externalities")").[59]

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[58] Because the Plaintiffs theory of recovery is not based on an economic transaction, the Distributors assertion that *White* was "effectively overruled" by *Johnson* does not follow. (R. 744, PageID# 17676).

[59] Plaintiffs also note that potential recovery under unjust enrichment and restitution theories are recognized where third parties have assumed costs of pollution remediation necessitated by defendant activities. *See, e.g., Little Hocking Water Ass'n, Inc. v. E.I. du Pont Nemours & Co.*, 91 F. Supp. 3d 940, 985-986 (S.D. Ohio 2015) (observing that unjust enrichment may serve as an alternative theory of recovery where actual damages are too difficult to determine, but it would be unjust to allow the defendant to benefit from the savings it enjoyed without payment to the plaintiff) (citing cases). (R. 654, PageID # 15807-08).

Distributors also argue that the complaint fails to plead that they had "knowledge" of the claimed benefit allegedly bestowed upon them, maintaining that alleging that "Defendants were aware of these obvious benefits …." (R. 514, ¶1115) is too vague and conclusory to state the element. (R. 491-1, PageID# 7521). An identical allegation has been recognized by this court as adequately supporting the unjust enrichment element of knowledge at the pleading stage. *White*, 97 F. Supp. 2d at 829. Distributors further argue that no injustice occurred because Plaintiffs are responsible for the alleged social service expenditures, but cite no authority for that proposition. (R. 491-1, PageID# 7522). Conversely, the *White* decision rejected a similar argument noting that "Defendants fail to cite a single case from Ohio that even comes close to advocating [the] view" that a municipality should be prohibited from recovering "for all governmental functions, such as police, medical, fire and emergency services, and other related expenditures, because these are the kinds of traditional services and functions that a municipality is expected to provide and which are most efficiently and fairly spread among the public." 97 F. Supp. 2d at 821-822 (internal quotations omitted). Here, the complaint pleads that the costs Plaintiffs assumed "are not part of the normal and expected costs of a local government's existence," and that "Defendants' alleged wrongful acts are neither discrete nor of the sort a local government can reasonably expect." (R. 514, ¶¶1118-1119).

Finally, the Defendants contend the claim should be dismissed, arguing they are derivative of Plaintiffs' other claims, and would permit "'an end run around policies' barring a plaintiffs' other failed claims." (R. 491-1, PageID# 7519-7520, *citing Johnson*, 834 N.E.2d at 799; R. 499-1, PageID# 7705). While that proposition is correct, the propriety of any application

to this case would be determined at a later stage of these proceedings. In addition, multiple causes of action based on the same conduct may be asserted alternatively. *PCA Minerals, LLC v. Merit Energy Co., LLC*, 725 F. App'x 342, 349 (6th Cir. 2018) ("nothing prohibits a plaintiff from pleading multiple claims when there are…multiple theories…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"); *Hutchings v. Nationstar Mortg. LLC*, 2013 WL 5670939 (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."); *Auto Chem Labs., Inc. v. Turtle Wax, Inc.*, 2008 WL 4372697, at *15 (S.D. Ohio Sept. 23, 2008) ("[A] party may plead alternative causes of action for the same matter, but may only prevail under one or the other.").

Based on the alleged facts in this case, Plaintiffs state a facially plausible unjust enrichment claim on the theory that they conferred a benefit upon all Defendants by alleging that they paid for the cost of harm caused by the defendant's conduct, *i.e.*, the defendant's externalities. *See, e.g., City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *9 (W.D. Wash. Sept. 25, 2017) (finding that plaintiffs' unjust enrichment claim based on their payment of the "so called externalities" of a defendant's conduct was not facially implausible). Accordingly, it is recommended that the court deny the motions to dismiss Count Ten of the complaint.

K. Count Eleven: Civil Conspiracy

Count Eleven of the complaint alleges a civil conspiracy claim against all Defendants. (R. 514, PageID# 11237). "An underlying unlawful act is required before a civil conspiracy claim can succeed." *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998). "Conspiracy in and of itself does not normally establish a basis for recovery in a civil action in Ohio; rather, there must be an actionable wrong committed as a result of the conspiracy." *Glassner v. R.J. Reynolds*

Tobacco Co., 223 F.3d 343, 354 (6th Cir. 2000) (*quoting NPF IV, Inc., v. Transitional Health Servs.*, 922 F. Supp. 77, 83 (S.D. Ohio 1996)); *Hale v. Enerco Grp., Inc.*, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (reciting the elements of a cognizable conspiracy claim as "(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") (citation and internal quotation marks omitted).

1. Unlawful Acts

Defendants argue that the cause of action should be dismissed "for failure to allege any actionable underlying tort" or an "underlying unlawful act." (R. 491-1, PageID# 7524; R. 497-1, PageID# 7613; R. 499-1, PageID# 7706-7708). With respect to the Manufacturers, as addressed above, Plaintiffs have sufficiently pled a claim for fraud—an intentional tort. In *Williams*, the Ohio Supreme Court found that the evidence supported a finding of a civil conspiracy where the defendants committed a fraud upon the plaintiff. 700 N.E.2d at 869. With respect to the other Defendants, Plaintiffs also note that under Ohio law, "the unlawful acts of any one member of the conspiracy will satisfy the underlying unlawful act requirement". (R. 654, PageID# 15814, *quoting Hale*, 2011 WL 49545, at *5 (citations and internal quotation marks omitted); *Williams*, 700 N.E.2d 868 ("[i]n a conspiracy, the acts of co-conspirators are attributable to each other.")). They contend that the complaint, moreover, alleges facts demonstrating that *each* Defendant engaged in unlawful acts supporting the causes of action therein. With the exception of the negligence claim, each of Plaintiffs' claims is based on alleged wrongful acts pursued "purposely, without a reasonable or lawful excuse" and therefore may serve to fulfill the underlying unlawful act element. *See Williams*, 700 N.E.2d at 868. Thus, the statutory public nuisance, Ohio RICO, and injury through criminal acts claims would also suffice.

2. Conspiratorial Agreement

Likewise, the Defendants' arguments that a conspiratorial agreement or malicious combination has not been alleged is not well taken. (R. 491-1, PageID# 7522-7524; R. 497-1, PageID# 7613-7614; 499-1, Page ID#7707). Pleading the existence of a malicious conspiracy requires "only a common understanding or design, even if tacit, to commit an unlawful act." *Gosden v. Louis*, 687 N.E.2d 481, 496-98 (Ohio Ct. App. 1996). "All that must be shown is that … the alleged coconspirator shared in the general conspiratorial objective ...." *Aetna Cas. & Sur. Co. v. Leahey Const. Co., Inc.*, 219 F.3d 519, 538 (6th Cir. 2000) (citation and internal quotation marks omitted). Direct evidence of an express agreement to undertake unlawful activity is rare and not required; a party may rely on circumstantial evidence to prove the claim. *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000). The complaint alleges,

> Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

(R. 514 at ¶1130, *see also* ¶¶552-553, 764-766). Plaintiffs note that conduct against economic self-interest is recognized as a "plus factor" that may support the plausibility of alleged conspiratorial behavior. (R. 654, PageID# 15812, citing *In re Polyurethane Foam Antitrust Litig.*, 152 F. Supp. 3d 968, 989 (N.D. Ohio 2015)). Furthermore, the complaint alleges that Defendants worked together to manipulate quotas (R. 514 at *e.g.* ¶¶526-528, 548, 550), and that their failure to comply with diversion prevention obligations (*id., e.g.*, ¶¶551-553, 565-566, 611-619) were mutually beneficial to all Defendants in the scheme to expand the opioid market (*id., e.g.* ¶¶760-766). The court has also discussed above the many allegations that the three sets of

Defendants acted in concert and need not repeat those discussions here. Although Defendants fault Plaintiffs for not pleading with pinpoint accuracy, it is alleged that Defendants' activities were clandestine and hidden from the public. Prior to discovery, such precision cannot reasonably be expected, and Defendants' position goes well beyond the *Twombly* and *Iqbal* pleading requirements. Defendant's motion to dismiss Count Eleven should, therefore, be denied.

L. Statewide Concern Doctrine

The Manufacturers and Distributors argue that Plaintiffs' claims should be dismissed under the "statewide concern" doctrine, which "is a fundamental principle of Ohio law that… a municipality may not, in the regulation of local matters, infringe on matters of statewide concern." *Reading v. Pub. Util. Comm.*, 846 N.E.2d 840, 845-46 (Ohio 2016) (quoting *State ex rel. Evans v. Moore*, 431 N.E.2d 311 (Ohio 1982) (prevailing-wage law superseded local wage regulation)); *see also State ex rel. Villari v. Bedford Hts.*, 465 N.E.2d 64 (Ohio 1984) (calculation of employee benefits), *overruled on other grounds*, *State ex rel. Adkins v. Sobb*, 496 N.E.2d 994 (Ohio 1986) (vacation-leave credits); *Cleveland Elec. Illum. Co. v. Painesville*, 239 N.E.2d 75 (Ohio 1968) (transmission of electricity through high-voltage lines); *State ex rel. McElroy v. Akron*, 181 N.E.2d 26 (Ohio 1962) (licensing of watercraft). Defendants cite Ohio Supreme Court cases recognizing the general doctrine, but have not cited any Ohio authority holding that the doctrine applies to preclude *lawsuits* brought to vindicate rights under federal or state law. For instance, in *JP Morgan*, an Ohio appellate court refrained from making any ruling on that ground, offering only *dicta* to suggest that litigation might, under certain circumstances, constitute regulation. 2013 WL 1183332, at *6 ("The existence of regulation should not, itself, preclude [a nuisance] cause of action. This will often require more evidentiary development than

available when ruling on a motion to dismiss.")

Plaintiffs argue that Ohio's Home Rule Amendment allows a sphere of joint authority where local regulation of police powers can co-exist with state regulation in general matters so long as the local regulation does not conflict with state law. Ohio Const. Art. XVIII, § 3; *American Financial Service Ass'n v. Cleveland*, 858 N.E.2d 776, 784 (Ohio 2005). Plaintiffs assert that they possess police powers, including the power to "adopt and enforce local health and safety measures" in order to "protect the public health, safety, or morals, or the general welfare of the public." *See Marich v. Bob Bennett Constr. Co.*, 880 N.E.2d 906, 911 (Ohio 2008). Therefore, Plaintiffs argue that this litigation presents no conflict with state law.

The Ohio Supreme Court has explained that even where the doctrine applies, it does not trump the state constitutional authority of municipalities to enact legislation pursuant to the Home Rule Amendment, provided that the local legislation is not in conflict with general laws. *American Financial Services*, on which Defendants rely, explains that "the Ohio Constitution's home-rule provision protects municipalities' authority to govern themselves, and it provides municipalities some authority to control local health and safety matters when the exercise of that authority does not conflict with general laws." 858 N.E.2d at 784. To determine 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." *Id*. The only such conflicts Defendants mention are with the Ohio Attorney General's lawsuit over the opioid crisis and Distributors' unexplained citation to O.R.C. §4729.01. (R. 499-1, PageID# 7662; R. 491-1, PageID# 7515). Defendants argue that if both of these suits proceed, they would impermissibly split the claims at issue and "risk inconsistent rulings and duplicative recoveries…." (R. 499-1, PageID# 7662). Defendants, however, have identified no Ohio Supreme Court authority holding

that, in such context, the statewide concern doctrine bars locally-originated municipal or county lawsuits seeking to remedy alleged injuries within their borders. Dismissal, therefore, is unwarranted.

M. Article III Standing

The Pharmacies move to dismiss to the complaint on the ground that Plaintiffs lack standing under Article III of the U.S. Constitution. (R. 497-1, PageID# 7595-7598). Article III standing requires: (1) an "injury in fact" (2) that is "fairly traceable to the challenged actions of the defendant, and not the result of the independent action of some third party not before the court" and (3) that is "likely to be redressed by the requested relief." *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1302 (2017); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The Pharmacies assert that Plaintiffs have not suffered an "injury in fact" but only a "generalized grievance" and that Plaintiffs' injury is not "fairly traceable" to the Pharmacies' conduct. (R. 497-1, PageID# 7596-7597). They do not contest the third element.

1. Injury in Fact

For purposes of Article III standing, an injury cannot be based on a "generalized grievance" that "no more directly and tangibly" affects the plaintiff "than it does the public at large." *Lujan*, 504 U.S. 555 at 574-575. Cases assessing "generalized grievances" typically involve citizens challenging the propriety of governmental action. *Id.* at 573, 576. The cases the *Lujan* court used to illustrate what is meant by "generalized grievance" involved taxpayer lawsuits—not suits brought by governmental entities. *See, e.g., Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 474 (1982) (no standing where taxpayer sued Department of Health, Education and Welfare for allegedly discounted conveyance of government property to a Christian college); *U.S. v. Richardson*, 418, U.S. 166

(1974) (holding taxpayers' challenge to the government's failure to disclose CIA expenditures was a "generalized grievance"). *Lujan* itself involved a suit by an environmental advocacy organization challenging a rule promulgated by the Secretary of the Interior, ruling that plaintiffs had alleged an injury to the species in question, but not to themselves. 504 U.S. 555 at 577-578.

The Defendants rely on *Richardson* and *Coyne v. American Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999) to support their conclusion that Plaintiffs allege only a generalized grievance. (R. 497-1, PageID# 7596). In *Coyne*, two Ohio local officials sued tobacco companies as private citizens—not in their representative capacities—alleging that the tobacco companies had caused the State of Ohio to expend public funds on health care costs caused by tobacco-related illnesses. *Id.* at 491. The Sixth Circuit held that these plaintiffs had asserted harms that affected the State as a whole and thus had only asserted a generalized grievance. The Pharmacies argue that Plaintiffs' alleged harms are like those in *Coyne.*

The court is not persuaded that Plaintiffs have alleged only a "generalized grievance." The plaintiffs in *Coyne, Lujan, Richardson,* and *Valley Forge Christian College* lacked standing because, as taxpayers, their harms were no different from those of all taxpayers. This is not the case here. Plaintiffs' allegations of extraordinary increases in public expenditures on hospitals, law enforcement, emergency and first responders, treatment of infants born with opioids-related medical conditions, and the criminal justice system constitute injury in fact. (R. 514 at ¶948).

2. Fairly Traceable

The Sixth Circuit has recently addressed the "fairly traceable" prong of the Article III standing test, explaining that it is a lower standard than proximate cause. *Parsons v. U.S. Dep't of Justice*, 701 F.3d 801 (6th Cir. 2015). The *Parsons* court noted that "even an attenuated line of causation to the eventual injury" would suffice. *Id.* at 713; *United States v. Students Challenging*

Regulatory Agency Procs. (SCRAP), 412 U.S. 669, 688 (1973). The court explained that causation in this context "means more than speculative, but less than but-for." *Parsons*, 801 F.3d at 714. In short, so long as the causal link is more than merely speculative, a plaintiff's injuries will be deemed fairly traceable to the actions of the defendant.

The Pharmacies argue that any link between Plaintiffs' alleged harm and their own alleged failure to monitor and report suspicious orders is wholly speculative and does not meet even the relaxed standard of causation associated with the "fairly traceable" requirement for Article III standing. Plaintiffs have alleged that all Defendants, including the Pharmacies, failed to monitor, report, and prevent the diversion of prescription opioids and that this failure has caused Plaintiffs to incur extraordinary municipal costs. (R. 514 at ¶¶555-556, 579-606, 607-659, 934). The court finds these allegations are sufficient. Because Plaintiffs have plausibly pleaded an injury in fact that is fairly traceable to the actions of Defendants, the claim that Plaintiffs lack Article III standing to bring this action should be denied.

IV. Conclusion

After fully considering the second amended complaint and the memoranda in support and against dismissal, it is recommended that the Manufacturers', Distributors' and Pharmacies' separate Motions to Dismiss (R. 491, R. 497, R. 499) be GRANTED in part and DENIED in part. Specifically, it is recommended that the motions be GRANTED with respect to the common law absolute public nuisance claim contained in Count Six, and GRANTED with respect to the

City of Akron's statutory public nuisance claim in Count Five to the extent it is based on violations of Ohio or federal drug laws, or the rules of the board of pharmacy. In all other respects, it is recommended that the motions be DENIED.

s/ *David A. Ruiz*
David A. Ruiz
United States Magistrate Judge

Date: October 5, 2018

OBJECTIONS

Any objections to this Report and Recommendation must be filed with the Clerk of Courts within fourteen (14) days after the party objecting has been served with a copy of this Report and Recommendation. 28 U.S.C. § 636(b)(1); Local Rule 72.3(b). Failure to file objections within the specified time may waive the right to appeal the district court's order. *See United States v. Walters*, 638 F.2d 947 (6th Cir. 1981); *Thomas v. Arn*, 474 U.S. 140 (1985), *reh'g denied*, 474 U.S. 1111 (1986).

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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

SUMMIT COUNTY, OHIO PLAINTIFF ENTITIES
INITIAL RESPONSES AND OBJECTIONS TO
MANUFACTURER DEFENDANTS' FIRST SET OF INTERROGATORIES

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and the Case Management Order in *In re National Prescription Opiate Litigation*, No. 1:17-cv-2804 (Dkt No. 232), the County of Summit, Ohio; the Summit County Combined General Health District; the City of Akron, Ohio; the City of Barberton, Ohio; the Village of Clinton, Ohio; Copley Township, Ohio; Coventry Township, Ohio; the City of Cuyahoga Falls, Ohio; the City of Fairlawn, Ohio; the City of Green, Ohio; the Village of Lakemore, Ohio; the Village of Mogadore, Ohio; the City of Munrowe Falls, Ohio; the City of Norton, Ohio, the Village of Peninsula, Ohio; the Village of Richfield, Ohio; the Village of Silver Lake, Ohio; Springfield Township, Ohio; the City of Stow, Ohio; the City of Tallmadge, Ohio; the City of New Franklin, Ohio; and the Valley Fire District (collectively "Plaintiff") hereby responds to the Manufacturer Defendants'[1] First Set of Interrogatories (the "Interrogatories" and, each individually, an "Interrogatory"), as follows:

[1] The Manufacturer Defendants are Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; and Insys Therapeutics, Inc.

OBJECTIONS

The following objections apply to each Interrogatory. To the extent that certain specific objections are cited in response to an individual Interrogatory, those specific objections are provided because they are applicable to that specific Interrogatory and are not a waiver of the other objections applicable to information falling within the scope of such Interrogatory.

1. Plaintiff objects to each Interrogatory to the extent they are overly broad, vague, unduly burdensome, seek information that is not relevant to any party's claim or defense, or seek to impose obligations or require actions beyond those required by the Federal Rules of Civil Procedure, the ESI Protocol entered in this matter or the Local Rules of the United States District Court of the Northern District of Ohio.

2. Plaintiff objects to each Interrogatory to the extent they seek information restricted from dissemination pursuant to court order, statute, or regulation. Further, any response made by Plaintiff to the Interrogatories is not intended to waive, and does not constitute any waiver of, any objection to the admissibility, authenticity, competency or relevance of the information produced or identified.

3. These responses are made solely for the purpose of and in relation to this action. Each answer is given subject to all appropriate objections, which would require the exclusion at trial of any statement contained or document provided herein. All such objections and the grounds therefore are hereby reserved.

4. No admission of any nature whatsoever is to be implied or inferred in these responses. The fact that any of the Interrogatories herein may have been answered should not be taken as an admission or a concession of the existence of any facts set forth or assumed by the Interrogatories, or that such answer constitutes evidence of any fact thus set forth or assumed.

5. Plaintiff objects to each Interrogatory to the extent Plaintiff has not yet completed its investigation of the facts relating to this action and has not yet completed its preparation for

trial. Accordingly, these responses are necessarily limited in nature, and reflect only that information known to Plaintiff at this time.

6. Plaintiff objects to each Interrogatory to the extent they purport to require Plaintiff to disclose information or produce documents that are in the public domain or otherwise available to Manufacturer Defendants as easily from other sources as from Plaintiff, and thus would impose an undue cost and burden on Plaintiff to collect such information.

7. Plaintiff objects to each Interrogatory to the extent they purport to state facts, assumptions, or characterizations that are disputed.

8. Plaintiff objects to each Interrogatory to the extent they seek information more appropriately obtained through other methods of discovery.

9. Plaintiff objects to each Interrogatory to the extent that they seek information that is proprietary or confidential or that is protected from discovery as attorney work product or attorney-client communication, information gathered or prepared in anticipation of litigation, the public interest privilege, law enforcement privilege, public official privilege, and/or by any other privilege or immunity from disclosure (collectively, "Privileged Information").

10. Plaintiff objects to each Interrogatory to the extent they seek confidential investigative, personal, or health information in Plaintiff's possession, custody, or control (collectively, "Confidential Information").

11. Whenever in the responses Plaintiff employs the phrase "subject to and without waiving all objections," Plaintiff is responding to the Interrogatory as it may be narrowed by its general and specific objections and without waiver of any objection.

12. Any response stating that Plaintiff will produce documents shall be deemed followed by the phrase "as are within Plaintiff's possession, custody, or control."

13. Plaintiff objects to each Interrogatory to the extent that they imply the existence of facts or circumstances that do not or did not exist, and to the extent that it states or assumes legal

conclusions. In providing these objections and responses, Plaintiff does not admit the factual or legal premise of any Interrogatory.

14. Plaintiff's lack of objection to any specific Interrogatory is not an admission that Plaintiff has possession, custody or control over any such information; and any statement by Plaintiff that it will search for or produce documents does not mean that Plaintiff has possession, custody or control of any responsive document, or that any such documents exist.

15. Plaintiff objects to each Interrogatory to the extent they seek information that is not within Plaintiff's possession, custody, or control, seek documents that do not already exist, or which purport to require a response by Plaintiff on behalf of an entity or individual other than Plaintiff.

16. Plaintiff intends to complete its responses by the time agreed upon by the parties for the completion of discovery, or by the date ordered by the Court. Upon request by the requesting party, Plaintiff is willing to meet and confer regarding its responses to the Interrogatories. All final decisions regarding whether any information will be withheld pursuant to any objection shall be made, and notice thereof provided, before the completion of written discovery.

17. Plaintiff objects to the Manufacturer Defendants' instruction that: "Each Plaintiff must individually respond to each of these Interrogatories." No federal rule prevents Plaintiff from submitting collective answers to Manufacturer Defendants' collective Interrogatories. Where the responses and objections to these Interrogatories are the same for each Plaintiff, a collective response herein will in no way prejudice Defendants. In each instance where the answers are not the same for each Plaintiff, any differences have been set forth herein with particularity.

NON-WAIVER

1. Plaintiff's responses are made without waiving its right to object (on the grounds of relevancy, hearsay, materiality, competency or any other ground) to the use of its responses in any subsequent stage or proceeding in this action or any other action.

2. If Plaintiff, in response to any Interrogatory, inadvertently discloses information that is or could be the subject of the objections stated herein, such disclosure is not intended to be, nor is it deemed to be, a waiver of the objections with respect to such information disclosed.

3. Plaintiff's failure to object to a specific Interrogatory on a particular ground or grounds shall not be construed as a waiver of its rights to object on any additional grounds.

4. Plaintiff responds herein based upon information it has been reasonably able to gather at the time of making these responses. Plaintiff reserves its right to amend and/or to supplement its objections and responses to the Interrogatories, consistent with further investigation and discovery.

SPECIFIC RESPONSES AND OBJECTIONS

INTERROGATORY NO. 1:

Identify each and every doctor or other healthcare provider who Plaintiff alleges participated in "speaker programs" or "speakers' bureaus" on behalf of or in relation to any Defendant, as alleged in Plaintiff's Complaint. For each identified doctor or other healthcare provider, please also identify in the response the events or programs that Plaintiff alleges the doctor or other healthcare provider attended or spoke at and identify the amount of payment allegedly provided by each Defendant.

PLAINTIFFS' RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests "each and every" doctor or healthcare provider who "participated" in "speaker programs" or "speakers' bureaus". Further objecting, Plaintiff objects to this Interrogatory as

overly broad and also to the extent it seeks information that is in Defendants' possession or publicly available, and thus seeks to impose an undue burden and unnecessary expense on Plaintiff. Each Defendant has, or should have, records that identify each and every doctor or other healthcare provider who participated in "speaker programs" or "speakers' bureaus" on behalf of or in relation to the subject Defendant. Therefore, Defendants have far superior access to this information which is also the subject of Plaintiff's discovery in this case. Notwithstanding and without waiving this objection, Plaintiff will conduct a reasonable and diligent search for and, if such information is in Plaintiff's possession, custody, or control, will produce documents that identify doctors and healthcare providers wo participated in "speaker programs" or "speakers' bureaus". Subject to and without waiving objections, once Plaintiff has this information, Plaintiff will provide it.

INTERROGATORY NO. 2:

Identify each entity or natural person, including without limitation healthcare providers, patients, addiction treatment specialists, alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, or any other third party, from whom Plaintiff received or attempted to obtain documents, testimony, sworn affidavits, or any other form of information in connection with Plaintiff's investigation of any Defendant's advertising or marketing of opioids, or otherwise in connection with this litigation, and include in the response identification of all information sought or received from each entity or natural person.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad, vague and ambiguous in that it fails to adequately or specifically define the term "entity or natural person" from whom each Plaintiff received information, and Plaintiff therefore will construe the term to exclude entities and natural persons who are part of the subject Plaintiff's governmental structure. Plaintiff also objects to

this Interrogatory on the grounds that it calls for production of information subject to the work-product doctrine, especially to the extent the Interrogatory seeks the identification of entities and natural persons from whom Plaintiff "attempted" to obtain information in furtherance of Plaintiff's "investigation." Disclosure of such information necessarily would reveal Plaintiff's and its counsel's mental impressions and legal strategies formed in anticipation of this litigation, and is therefore objectionable. Lastly, discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

Notwithstanding and without waiving all objections, Plaintiff received documents, evidence or other information from sources, including, but not limited to, the following individuals:

Name	Title	General description
Dr. William Reed	Doctor	Visited by drug reps: Nucynta, Purdue, Actiq, Opana, Kadian
Dr. William Lonsdorf	Doctor	Visited by Purdue, Opana, Nucynta,
Dr. Kendrick Bashor	Doctor	Visited by drug reps: Purdue
Dr. Michael Louwers	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta, Actiq/Fentora
Dr. Syed Ali	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta-Janssen/Depomed, Teva, Subsys, Endo, Cephalon, Xalgo, Kadian, Insys
Dr. Clayton Seiple	Doctor	Visited by drug reps: Purdue. Was a speaker for Endo, Depomed (Nucynta)
Bernie Rochford	Executive Vice President of Administrative Services and Business Relations, Oriana House	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Galen Sievert	Clinical Supervisor, Mature Services	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Laura Kidd	Behavioral Health Clinical Coordinator, AxessPointe Community Health Center at Arlington	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids

James Orlando	President of Summit Psychological Associates	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Brittney Becker	Doctor, Community Health Center	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Michael M. Hughes	President, Summa Health System, Barberton Campus	Illnesses related to opioid use
Joseph P. Myers	Doctor, Vice President of Medical Affairs, Summa Barberton and Summa Wadsworth-Rittman Hospitals	Illnesses related to opioid use
Roslyn Greene	Family member	Personal loss
Charlene Maxen	Pediatric oncologist nurse, Akron Children's Hospital	Personal loss
Travis Bornstein	Family member	Personal loss

INTERROGATORY NO. 3:

Identify any doctors, addiction treatment specialists, healthcare providers, and law enforcement and public health officials who Plaintiff contends agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic (as that term is used throughout the Complaint).

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vastly over-broad and unduly burdensome. Plaintiff objects to the extent it requests "any" doctors, addiction treatment specialists, health care providers and law enforcement and public health officials that agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic. Plaintiff further responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete, or until a pre-trial conference. See FRCP 33(a)(2). Plaintiff will construe the phrase "Plaintiff contends" to refer to any such contentions in Plaintiff's Second Amended Complaint, and Plaintiff refers Defendants to Plaintiff's Second Amended Complaint for this information.

Plaintiff objects to this Interrogatory as vague, ambiguous and calling for speculation in seeking information about the beliefs of individual third parties. Plaintiff notes that there is a vast amount of peer-reviewed and other literature, testimony before public entities, and on-line information in the public domain, equally available to Defendants, which may provide the answer, at least in large part, to Defendants' Interrogatory. Lastly, discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 4:

Describe each cost, expenditure, damage, loss, or harm for which Plaintiff seeks equitable or monetary relief, including any penalty or fine, from each Defendant. For each cost, expenditure, damage, loss, penalty, fine or harm for which Plaintiff seeks relief, provide (i) the nature and amount of that cost, expenditure, damage, loss, penalty, fine or harm; (ii) the Defendant or Defendants from which the relief is sought; and (iii) how and by whom the cost, expenditure, damage, loss, penalty, fine, or harm was determined and calculated, and the specific conduct of that Defendant or those Defendants that allegedly caused the cost, expenditure, damage, loss, penalty, fine, or harm.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad as propounded, to the extent that it is vague and ambiguous in failing to adequately and specifically define the term "harm," and in that it calls for Plaintiff to identify the specific conduct of each Defendant. Subject to and without waiving objections, for the identification of the Defendant or Defendants from which relief is sought, Plaintiff refers Defendants to Plaintiff's Second Amended Complaint. Plaintiff further responds as follows:

Subject to and without waiving all objections, Plaintiff will conduct a reasonable and diligent search for and will produce all non-privileged documents and communication that are sufficient to identify, describe and quantify the monetary and other relief Plaintiff seeks in this case.

In addition, Plaintiff's investigation of its damages caused by the Defendants is ongoing and will be the subject of fully-supported and detailed expert witness opinion(s) that will be disclosed in accordance with CMO No. 1 and the Federal Rules of Civil Procedure.

Further subject to and without waiving all objections, Plaintiff identifies the following non-exhaustive list of programs and other expenditures either that have been initiated because of the opioid crisis or which have experienced increased funding needs because of the opioid crisis. Such programs and expenditures include, but are not limited to, the following:

Jurisdiction	**Efforts to Address Opioid Epidemic**
Summit County	• Summit County Alcohol, Drug Addiction and Mental Health Board: Quick Response Teams, DAWN, Addiction Helpline; Opiate Task Force and the planning, maintaining and executing responses to the opioid epidemic; purchase of Narcan; manages waitlists for residential treatment facilities; additional training, education and treatment; • Summit County Medical Examiner: increased number of deaths caused by the opioid epidemic for the Summit County Medical Examiner's office to process and investigate; additional staffing and resources, additional costs for contractors/vendors; • Summit County Prosecutors: increased caseload and prosecutions relating to the opioid epidemic; • Summit County Court of Common Pleas (including probation and specialty courts, like drug court): increased caseload and probation services relating to the opioid epidemic; Opioid Unit in adult probation department; two drug court judges do community outreach re opioids and other drugs; Indigent Defense – increased County expenditures to fund this Court program for indigent defendants; • Summit County Juvenile Court (including probation and specialty courts): increase in number of parents participating in Family Reunification Through Recovery Court due to opioid use; increase in staff trainings related to opioid use;

	• Summit County Children Family Services: host Northeast Ohio Regional Training Center which provides trainings related to opioids, 25% of the staff trainings they do relate to opioids; social workers who exclusively deal with families and substance abuse issues; collaborate with juvenile court program, Family Reunifications through Recovery; Oriana House; provides licensure hours for Close Up which addresses opioids increased costs due to increased placement of children abused and neglected due to opioid addictions; • Summit County Sheriff: services, including but not limited to, training, investigations, staffing, jail expenses, dispatch services, task force as a result of the opioid epidemic; members of Quick Response Team; DARE education; drug task force members meet with community organizations to discuss opioids; drug take back days; implement House Bill 277 aka Good Samaritan Law; receive Narcan training; • Summit County General Health District: purchase of Narcan; Quick Response Team; Syringe Harm Reduction Program; educational campaigns, expanded medically assisted treatment programs; • Summit County Executive: Incident Management Assistance Team ("IMAT") coordinates activities of the Opiate Task Force and the Addiction Counsel
Akron	• Opioid-focused Quick Response Team (QRT); • Purchases of Narcan, drug testing kits, and Immunity Hearing Requirement forms; • Increased Police/Fire/EMS service calls for overdoses; • Increased Police Division services for opioid investigations, including training, detailing of staff to task forces; • Safety Communications handling of increased dispatches and related Police/Fire/EMS support; • Law Department Criminal Division's increased prosecutions relating to the opioid epidemic; • Municipal Court's increased caseload and probation load relating to the opioid epidemic; • Planning and executing a response to the opioid epidemic, including community educational awareness by Police, the Mayor's office, and other city departments; • Funding of third party entities that provide various support services related to the opioid epidemic, including Oriana House, Interval Brotherhood Home, Summit Co. Public Health, etc. http://www.akronohio.gov/

Barberton	• Increased Police/Fire/EMS service calls for overdoses http://www.cityofbarberton.com
Cuyahoga Falls	• Increased Police/Fire/EMS service calls for overdoses http://www.cityofcf.com
City of Fairlawn	• Increased Police/Fire/EMS service calls for overdoses http://www.cityoffairlawn.com
City of Green	• Increased Police/Fire/EMS service calls for overdoses https://www.cityofgreen.org
City of Stow	• Increased Police/Fire/EMS service calls for overdoses http://stowohio.org
City of Tallmadge	• Increased Police/Fire/EMS service calls for overdoses https://tallmadge-ohio.org
Village of Boston Heights	• Increased Police/Fire/EMS service calls for overdoses http://www.villageofbostonheights.com
Village of Clinton	• Increased Police/Fire/EMS service calls for overdoses http://clintonvillageohio.com
Village of Mogadore	• Increased Police/Fire/EMS service calls for overdoses http://mogadorevillage.org
Village of Peninsula	• Increased Police/Fire/EMS service calls for overdoses http://villageofpeninsula-oh.gov
Village of Richfiled	• Increased Police/Fire/EMS service calls for overdoses https://www.richfieldvillageohio.org
Boston Township	• Increased Police/Fire/EMS service calls for overdoses https://www.bostontownship.org

Copley Township	• Increased Police/Fire/EMS service calls for overdoses http://www.copley.oh.us
Coventry Township	• Increased Police/Fire/EMS service calls for overdoses http://www.coventrytownship.com
Valley Fire District	• Increased Police/Fire/EMS service calls for overdoses http://www.valleyfire.us
Summit County Combined General Health District	• Increased Police/Fire/EMS service calls for overdoses http://www.scph.org
Village of Lakemore	• Increased Police/Fire/EMS service calls for overdoses http://www.lakemoreohio.org
Munroe Falls	• Increased Police/Fire/EMS service calls for overdoses http://www.munroefalls.com
Norton	• Increased Police/Fire/EMS service calls for overdoses http://www.cityofnorton.org
Village of Silver Lake	• Increased Police/Fire/EMS service calls for overdoses http://www.villageofsilverlake.com
Springfield Township	• Increased Police/Fire/EMS service calls for overdoses http://www.springfieldtownship.us
City of New Franklin	• Increased Police/Fire/EMS service calls for overdoses http://www.newfranklin.org
Valley Fire District	• Increased Police/Fire/EMS service calls for overdoses http://www.valleyfire.us

INTERROGATORY NO. 5:

Identify and describe all alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, and other third parties with whom any Defendant allegedly conspired or acted in concert in furtherance of the alleged misconduct described in the Complaint, including the identity of each Defendant that allegedly conspired and all facts supporting Plaintiff's contention that such Defendant(s) did so.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad and unduly burdensome in that it seeks information that is uniquely in Defendants' possession, and thus imposes an undue burden and unnecessary expense on Plaintiff. Plaintiff further objects to this Request as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe all key opinion leaders, alleged front groups and other third parties. Further objecting, the Interrogatory contains a reference to several ambiguous phrases, namely, "alleged front groups," "allegedly conspired," "acted in concert," "in furtherance of," and "alleged misconduct".

Notwithstanding and without waiving this objection, Plaintiff states that discovery is ongoing, and refers Defendants to Plaintiff's Second Amended Complaint, which identifies key opinion leaders, alleged front groups, and other third parties acting in concert with Defendants. Plaintiff also responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete. See FRCP 33(a)(2). Furthermore, Plaintiff responds that discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 6:

Identify and describe all prescriptions of opioids that were written in the Plaintiff's county, city, village, or township in reliance on any alleged misrepresentations, omissions or other alleged

wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission; or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory because of its vast over breadth and in that it seeks information that is not relevant to any party's claim or defense, as Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act counts. Plaintiff also objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the marginal importance of the materials to the claims and defenses in this litigation, as described above, and (2) the substantial cost and burden to the Plaintiff to identify and describe responsive materials, and the substantial risk of harm to the privacy interests and rights held by the individuals whose private medical files are the subject of this request. Plaintiff also responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete, or until a pre-trial conference. See FRCP 33(a)(2). Furthermore, Plaintiff responds that discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 7:

Identify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in the Plaintiff's county, city, village, or township. Include in the identification of each such individual: (i) the particular type of alleged harm that the individual experienced, (ii) the particular opioid(s) that he or she took and/or was prescribed, (iii) when each prescription at issue was written, (iv) the condition for which each prescription was written; and (v) the allegedly false, misleading, or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.

PLAINTIFF'S RESPONSE:

See answer to Interrogatory No. 6. Plaintiff objects to this Interrogatory as grossly over-broad and unduly burdensome as propounded. Plaintiff objects because this Interrogatory seeks information not relevant to any party's claim or defense or the legal theories in this case. Subject to and without waiving objections, Plaintiff responds that Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act counts or other claims that justify the burden of an Interrogatory this broad in scope. Plaintiff objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the lack of relevance or importance of the materials to the claims and defenses in this litigation, as described above, and (2) the substantial cost and burden to identify and describe responsive materials, which would cause substantial harm to the privacy interests and rights held by the individuals whose private medical files are the subject of this request. Plaintiff further objects to the extent this Interrogatory calls for Confidential Information not in the Plaintiff's possession and protected by privacy laws, including but not limited to, the federal Health Insurance Portability and Accountability Act ("HIPAA").

INTERROGATORY NO. 8:

Identify any "unbranded advertising" or "unbranded marketing" (as those terms are used throughout the Complaint) disseminated in the Plaintiff's county, city, village, or township in which any Defendant participated or to which any Defendant contributed in any way. Include in the response the identity of the Defendant(s) that participated or contributed and the identity of the person or persons to whom the "unbranded advertising" or "unbranded marketing" was distributed.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify any "unbranded advertising" or "unbranded marketing" disseminated in Plaintiff's jurisdiction in which any Defendant participated or contributed. Plaintiff further objects to this Interrogatory to the extent it seeks information that is in Defendants' possession or publicly available, and thus imposes an undue burden and unnecessary expense on Plaintiff. Notwithstanding and without waiving this objection, Plaintiff states that discovery is ongoing, but Plaintiff's current information on this subject is contained in Plaintiff's Second Amended Complaint, and any additional information will be supplemented as discovery proceeds and pursuant to the Federal Rules of Civil Procedure. Plaintiff further responds that discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 9:

Identify and describe all statements or omissions made or disseminated in the Plaintiff's county, city, village, or township by any Defendant (or any other person whose statements you attribute, in whole or in part, to a Defendant) that you claim were false, misleading, unfair, deceptive or otherwise actionable. Include in your identification of each statement or omission:

(i) the name, employer, and position(s) of the speaker, writer, or other person who issued the statement; (ii) the name(s) and position(s) of the recipient(s) of such statement; (iii) when and where the allegedly false, misleading, or deceptive statement was made; (iv) a description of the content of the statement; and (v) all reasons you claim the statement was false, misleading, or deceptive.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe "all" statements or omissions made or disseminated in Plaintiff's jurisdiction by any Defendant that were false, misleading, unfair, deceptive or otherwise actionable. Further objecting, the Interrogatory contains a reference to an undefined phrase, "otherwise actionable."

Plaintiff further objects to the extent it seeks information that is in Defendants' possession or publicly available, and thus imposes an undue burden and unnecessary expense on Plaintiff. Notwithstanding and without waiving this objection, Plaintiff states that discovery is ongoing, and Plaintiff's current knowledge of this subject is reflected in Plaintiff's Second Amended Complaint, and any additional information will be supplemented as discovery proceeds pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 10:

Identify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful. Include in the response as to each such prescription the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the basis for your assertion that the prescription was unauthorized, medically unnecessary, ineffective, or harmful; and whether, by whom, and for how much the prescription was approved for reimbursement.

PLAINTIFF'S RESPONSE:

See answer to Interrogatory No. 6. Plaintiff objects to this Interrogatory as overly broad and unduly burdensome as propounded. Plaintiff objects because this Interrogatory seeks information not relevant to any party's claim or defense, or the legal theories in this case. Subject to and without waiving objections, Plaintiff responds that Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act counts or other claims that justify the burden of an Interrogatory this broad in scope. Plaintiff objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the lack of relevance or importance of the materials to the claims and defenses in this litigation, as described above, and (2) the substantial cost to identify and describe responsive materials, which would cause substantial harm to the privacy interests held by the individuals whose private medical files are the subject of this request. Plaintiff further objects to the extent this Interrogatory calls for Confidential Information not in the Plaintiff's possession and protected by privacy laws.

Dated: May 25, 2018

Respectfully submitted,

By: /s/ Linda Singer
Linda Singer

Joseph F. Rice
Jodi Westbrook Flowers
Anne McGinness Kearse
David I. Ackerman
Jeffrey C. Nelson
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
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CERTIFICATE OF SERVICE

I, Jeffrey Nelson, certify that on May 25, 2018, I caused the foregoing to be served via electronic mail on Defendant's Liaison Counsel pursuant to the Case Management Order in this case (ECF #232).

/s/ Jeffrey Nelson_____

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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

SUMMIT COUNTY, OHIO AND THE CITY OF AKRON, OHIO
FIRST AMENDED RESPONSES AND OBJECTIONS TO
MANUFACTURER DEFENDANTS' FIRST SET OF INTERROGATORIES

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and the Case Management Order in *In re National Prescription Opiate Litigation*, No. 1:17-cv-2804 (Dkt No. 232), the County of Summit, Ohio and the City of Akron, Ohio (collectively "Plaintiff") hereby respond to the Manufacturer Defendants'[1] First Set of Interrogatories (the "Interrogatories" and, each individually, an "Interrogatory"), as follows:

[1] The Manufacturer Defendants are Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; and Insys Therapeutics, Inc.

OBJECTIONS

The following objections apply to each Interrogatory. To the extent that certain specific objections are cited in response to an individual Interrogatory, those specific objections are provided because they are applicable to that specific Interrogatory and are not a waiver of the other objections applicable to information falling within the scope of such Interrogatory.

1. Plaintiff objects to each Interrogatory to the extent they are overly broad, vague, unduly burdensome, seek information that is not relevant to any party's claim or defense, or seek to impose obligations or require actions beyond those required by the Rules of Civil Procedure, the ESI Protocol entered in this matter or the Local Rules of the United States District Court of the Northern District of Ohio.

2. Plaintiff objects to each Interrogatory to the extent they seek information restricted from dissemination pursuant to court order, statute, or regulation. Further, any response made by Plaintiff to the Interrogatories is not intended to waive, and does not constitute any waiver of, any objection to the admissibility, authenticity, competency or relevance of the information produced or identified.

3. These responses are made solely for the purpose of and in relation to this action. Each answer is given subject to all appropriate objections, which would require the exclusion at trial of any statement contained or document provided herein. All such objections and the grounds therefore are hereby reserved.

4. No admission of any nature whatsoever is to be implied or inferred in these responses. The fact that any of the Interrogatories herein may have been answered should not be taken as an admission or a concession of the existence of any facts set forth or assumed by the Interrogatories, or that such answer constitutes evidence of any fact thus set forth or assumed.

5. Plaintiff objects to each Interrogatory to the extent Plaintiff has not yet completed its investigation of the facts relating to this action and has not yet completed its preparation for

trial. Accordingly, these responses are necessarily limited in nature, and reflect only that information known to Plaintiff at this time.

6. Plaintiff objects to each Interrogatory to the extent they purport to require Plaintiff to disclose information or produce documents that are in the public domain or otherwise available to Manufacturer Defendants as easily from other sources as from Plaintiff, and thus would impose an undue cost and burden on Plaintiff to collect such information.

7. Plaintiff objects to each Interrogatory to the extent they purport to state facts, assumptions, or characterizations that are disputed.

8. Plaintiff objects to each Interrogatory to the extent they seek information more appropriately obtained through other methods of discovery.

9. Plaintiff objects to each Interrogatory to the extent that they seek information that is proprietary or confidential or that is protected from discovery as attorney work product or attorney-client communication, information gathered or prepared in anticipation of litigation, the public interest privilege, law enforcement privilege, public official privilege, and/or by any other privilege or immunity from disclosure (collectively, "Privileged Information").

10. Plaintiff objects to each Interrogatory to the extent they seek confidential investigative, personal, or health information in Plaintiff's possession, custody, or control (collectively, "Confidential Information").

11. Whenever in the responses Plaintiff employs the phrase "subject to and without waiving all objections," Plaintiff is responding to the Interrogatory as it may be narrowed by its general and specific objections and without waiver of any objection.

12. Any response stating that Plaintiff will produce documents shall be deemed followed by the phrase "as are within Plaintiff's possession, custody, or control."

13. Plaintiff objects to each Interrogatory to the extent that they imply the existence of facts or circumstances that do not or did not exist, and to the extent that it states or assumes legal

conclusions. In providing these objections and responses, Plaintiff does not admit the factual or legal premise of any Interrogatory.

14. Plaintiff's lack of objection to any specific Interrogatory is not an admission that Plaintiff has possession, custody or control over any such information; and any statement by Plaintiff that it will search for or produce documents does not mean that Plaintiff has possession, custody or control of any responsive document, or that any such documents exist.

15. Plaintiff objects to each Interrogatory to the extent they seek information that is not within Plaintiff's possession, custody, or control, seek documents that do not already exist, or which purport to require a response by Plaintiff on behalf of an entity or individual other than Plaintiff.

16. Plaintiff intends to complete its responses by the time agreed upon by the parties for the completion of discovery, or by the date ordered by the Court. Upon request by the requesting party, Plaintiff is willing to meet and confer regarding its responses to the Interrogatories. All final decisions regarding whether any information will be withheld pursuant to any objection shall be made, and notice thereof provided, before the completion of written discovery.

17. Plaintiff objects to the Manufacturer Defendants' instruction that: "Each Plaintiff must individually respond to each of these Interrogatories." No federal rule prevents Plaintiff from submitting collective answers to Manufacturer Defendants' collective Interrogatories. Where the responses and objections to these Interrogatories are the same for each Plaintiff, a collective response herein will in no way prejudice Defendants. In each instance where the answers are not the same for each Plaintiff, any differences have been set forth herein with particularity.

NON-WAIVER

1. Plaintiff's responses are made without waiving its right to object (on the grounds of relevancy, hearsay, materiality, competency or any other ground) to the use of its responses in any subsequent stage or proceeding in this action or any other action.

2. If Plaintiff, in response to any Interrogatory, inadvertently discloses information that is or could be the subject of the objections stated herein, such disclosure is not intended to be, nor is it deemed to be, a waiver of the objections with respect to such information disclosed.

3. Plaintiff's failure to object to a specific Interrogatory on a particular ground or grounds shall not be construed as a waiver of its rights to object on any additional grounds.

4. Plaintiff responds herein based upon information it has been reasonably able to gather at the time of making these responses. Plaintiff reserves its right to amend and/or to supplement its objections and responses to the Interrogatories, consistent with further investigation and discovery.

SPECIFIC RESPONSES AND OBJECTIONS

INTERROGATORY NO. 1:

Identify each and every doctor or other healthcare provider who Plaintiff alleges participated in "speaker programs" or "speakers' bureaus" on behalf of or in relation to any Defendant, as alleged in Plaintiff's Complaint. For each identified doctor or other healthcare provider, please also identify in the response the events or programs that Plaintiff alleges the doctor or other healthcare provider attended or spoke at and identify the amount of payment allegedly provided by each Defendant.

PLAINTIFFS' RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests "each and every" doctor or healthcare provider who "participated" in "speaker programs" or "speakers' bureaus". Further objecting, Plaintiff objects to this Interrogatory as

overly broad and also to the extent it seeks information that is in Defendants' possession or publicly available, and thus seeks to impose an undue burden and unnecessary expense on Plaintiff. Each Defendant has, or should have, records that identify each and every doctor or other healthcare provider who participated in "speaker programs" or "speakers' bureaus" on behalf of or in relation to the subject Defendant. Therefore, Defendants have far superior access to this information which is also the subject of Plaintiff's discovery in this case. Notwithstanding and without waiving this objection, Plaintiff will conduct a reasonable and diligent search for and, if such information is in Plaintiff's possession, custody, or control, will produce documents that identify doctors and healthcare providers wo participated in "speaker programs" or "speakers' bureaus". Subject to and without waiving objections, Plaintiff responds:

Name	**Title**	**Event Description**	**Payment**
J. David Haddox	Doctor, Committee Chair of AAPM	A "consensus" statement issued in 1997 endorsing opioids to treat chronic pain and claiming the addiction risk to patients was low.	Unknown at this time
Russel Portenoy	Doctor, Chairman of the Department of Pain Medicine and Palliative Case at Beth Israel Medical Center in New York, Consultant to AAPM, spokesperson for Purdue	A "consensus" statement issued in 1997 endorsing opioids to treat chronic pain and claiming the addiction risk to patients was low.	Unknown at this time
Lynn Webster	Doctor, co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah, spokesperson for Cephalon, Endo and Purdue	Numerous Continuing Medical Education ("CME") programs	Over $2 million

Name	Title	Event Description	Payment
Perry Fine	Doctor, co-chair of APS/AAPM Opioid Guideline Panel, spokesperson for Endo and Johnson & Johnson	Numerous CMEs for Endo and promotional talks for Johnson & Johnson	$32,017 from Johnson & Johnson
Scott Fishman	Doctor, served as a board member of APF and president of AAPM	Participated in numerous CMEs	Unknown at this time
Steven Simon	Doctor at Mid-America Physiatrists in Overland Park, Kansas	Wrote prescriptions for Subsys and Fentanyl and was a designated paid "speaker" for Insys	> $200,000 from August 2013 to December 2015
Robert Yapundich	Neurologist in Hickory, NC	Board member of the Alliance for Patient Access and paid "speaker"	> $300,000 from 2013 to 2016
Howard Hoffberg	Doctor at Rosen-Hoffberg Rehabilitation and Pain Management Associates in Townson, Maryland	Wrote prescriptions for opioids and received "speaker" fees from Insys, Purdue and Teva	> $175,000 from 2013 to 2016
Heather Alfonso	Nurse practitioner in Connecticut	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys.	$83,000
Jerrold Rosenberg	Doctor in Rhode Island	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	> $188,000
Gordon Freedman	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> $100,000 annually
Jeffrey Goldstein	Doctor in New Rochelle, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> $100,000 annually
Todd Schlifstein	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for	> $100,000 annually

Name	Title	Event Description	Payment
		"speaker" fees from Insys	
Dialecti Voudouris	Doctor in New York, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> $100,000 annually
Alexandru Burducea	Doctor in Little Neck, New York	Wrote prescriptions for Fentanyl in exchange for "speaker" fees from Insys	> $100,000 annually
Michael Frey	Doctor in Florida	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	Unknown at this time
Jeffrey Kesten	Doctor in Boulder, Colorado	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	$294,000
Gordon Freedman	Doctor in White Plains, New York	Wrote prescriptions for Subsys in exchange for "speaker" fees from Insys	$283,000

In addition, Plaintiff identifies the following:

- Physicians identified by Insys Therapeutics, Inc. as having received compensation from Insys "for speaking about, endorsing or promoting SUBSYS in the State of Ohio." (*See* Insys Therapeutics, Inc.'s Responses and Objections to Plaintiff's First Set of Interrogatories);
- Physicians identified by Janssen Pharmaceuticals, Inc., its predecessor companies Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc., and its parent company Johnson & Johnson as having received compensation "for Nucynta IR and Nucynta ER speaker programs." (*See* Janssen Pharmaceuticals, Inc.'s Responses and Objections to Plaintiff's First Set of Interrogatories); and

- Physicians identified through ProPublica as payments publically disclosed in Ohio from August 2013 until December 2015.[2]

Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 2:

Identify each entity or natural person, including without limitation healthcare providers, patients, addiction treatment specialists, alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, or any other third party, from whom Plaintiff received or attempted to obtain documents, testimony, sworn affidavits, or any other form of information in connection with Plaintiff's investigation of any Defendant's advertising or marketing of opioids, or otherwise in connection with this litigation, and include in the response identification of all information sought or received from each entity or natural person.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad, vague and ambiguous in that it fails to adequately or specifically define the term "entity or natural person" from whom each Plaintiff received information, and Plaintiff therefore will construe the term to exclude entities and natural persons who are part of the subject Plaintiff's governmental structure. Plaintiff also objects to this Interrogatory on the grounds that it calls for production of information subject to the work-product doctrine, especially to the extent the Interrogatory seeks the identification of entities and natural persons from whom Plaintiff "attempted" to obtain information in furtherance of Plaintiff's "investigation." Disclosure of such information necessarily would reveal Plaintiff's and its counsel's mental impressions and legal strategies formed in anticipation of this litigation, and is therefore objectionable. Lastly, discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

[2] This document will be Bates labeled and produced to Defendants.

Notwithstanding and without waiving all objections, Plaintiff responds:

Name	Title	General description
Dr. William Reed	Doctor	Visited by drug reps: Nucynta, Purdue, Actiq, Opana, Kadian
Dr. William Lonsdorf	Doctor	Visited by Purdue, Opana, Nucynta,
Dr. Kendrick Bashor	Doctor	Visited by drug reps: Purdue
Dr. Michael Louwers	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta, Actiq/Fentora
Dr. Syed Ali	Doctor	Visited by drug reps: Purdue, Xtampza, Nucynta-Janssen/Depomed, Teva, Subsys, Endo, Cephalon, Xalgo, Kadian, Insys
Dr. Clayton Seiple	Doctor	Visited by drug reps: Purdue. Was a speaker for Endo, Depomed (Nucynta)
Bernie Rochford	Executive Vice President of Administrative Services and Business Relations, Oriana House	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Galen Sievert	Clinical Supervisor, Mature Services	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Laura Kidd	Behavioral Health Clinical Coordinator, AxessPointe Community Health Center at Arlington	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
James Orlando	President of Summit Psychological Associates	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Brittney Becker	Doctor, Community Health Center	Treatment center for those suffering from OUD, knowledgeable on trends, prevalence and impact of opioids
Michael M. Huges	President, Summa Health System, Barberton Campus	Illnesses related to opioid use
Joseph P. Myers	Doctor, Vice President of Medical Affairs, Summa Barberton and Summa Wadsworth-Rittman Hospitals	Illnesses related to opioid use
Roslyn Greene	Family member	Personal loss
Charlene Maxen	Pediatric oncologist nurse, Akron Children's Hospital	Personal loss
Travis Bornstein	Family member	Personal loss

Plaintiff also refers Defendants to its responses to Interrogatory No 5. Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 3:

Identify any doctors, addiction treatment specialists, healthcare providers, and law enforcement and public health officials who Plaintiff contends agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic (as that term is used throughout the Complaint).

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vastly overly broad and unduly burdensome. Plaintiff objects to the extent it requests "any" doctors, addiction treatment specialists, health care providers and law enforcement and public health officials that agree with the proposition that prescription opioids have caused or contributed to the opioid epidemic. Plaintiff further responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete, or until a pre-trial conference. See FRCP 33(a)(2). Therefore, Plaintiff will construe this phrase to refer to any such contentions in Plaintiff's Second Amended Complaint, and Plaintiff refers Defendants to Plaintiff's Second Amended Complaint for this information.

Plaintiff objects to this Interrogatory as vague, ambiguous and calling for speculation in seeking information about the beliefs or opinions of individual third parties. Plaintiff notes that there is a vast amount of peer-reviewed and other literature, testimony before public entities, and on-line information in the public domain, equally available to Defendants, which may provide the answer, at least in large part, to Defendants' Interrogatory. Notwithstanding and without waiving all objections, Plaintiff responds as follows:

Vivek H. Murthy, M.D., M.B.A., 19th U.S. Surgeon General;

Centers for Disease Control and Prevention;

National Institute on Drug Abuse;

Theodore J. Cicero, M.D.;

Robert M. Califf, M.D.;

Russell Portenoy, M.D.

Thomas Gilson, M.D.;

Andrew Kolodny, M.D.;

Special Agent David Schiller.

Plaintiff reserves the right to supplement or modify this list as discovery proceeds. As discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1.

INTERROGATORY NO. 4:

Describe each cost, expenditure, damage, loss, or harm for which Plaintiff seeks equitable or monetary relief, including any penalty or fine, from each Defendant. For each cost, expenditure, damage, loss, penalty, fine or harm for which Plaintiff seeks relief, provide (i) the nature and amount of that cost, expenditure, damage, loss, penalty, fine or harm; (ii) the Defendant or Defendants from which the relief is sought; and (iii) how and by whom the cost, expenditure, damage, loss, penalty, fine, or harm was determined and calculated, and the specific conduct of that Defendant or those Defendants that allegedly caused the cost, expenditure, damage, loss, penalty, fine, or harm.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad as propounded, and to the extent that it is vague and ambiguous in failing to adequately and specifically define the term "harm" and in that it calls for Plaintiff to identify the specific conduct of each Defendant. Subject to and without waiving objections, for the identification of the Defendant or Defendants from which

relief is sought, Plaintiff refers Defendants to Plaintiff's Second Amended Complaint. Plaintiff further responds as follows:

Subject to and without waiving all objections, Plaintiff will conduct a reasonable and diligent search for and will produce all non-privileged documents and communication that are sufficient to identify, describe and quantify the monetary and other relief Plaintiff seeks in this case.

In addition, Plaintiff's investigation of its damages caused by the Defendants is ongoing and will be the subject of fully-supported and detailed expert witness opinion(s) that will be disclosed in accordance with CMO No. 1 and the Federal Rules of Civil Procedure.

Further subject to and without waiving all objections, Plaintiff identifies the following non-exhaustive list of programs and other expenditures either that have been initiated because of the opioid crisis or which have experienced increased funding needs because of the opioid crisis. Such programs and expenditures include, but are not limited to, the following:

Jurisdiction	**Efforts to Address Opioid Epidemic**
Summit County	• Summit County Alcohol, Drug Addiction and Mental Health Board: Quick Response Teams, DAWN, Addiction Helpline; Opiate Task Force and the planning, maintaining and executing responses to the opioid epidemic; purchase of Narcan; manages waitlists for residential treatment facilities; additional training, education and treatment; • Summit County Medical Examiner: increased number of deaths caused by the opioid epidemic for the Summit County Medical Examiner's office to process and investigate; additional staffing and resources, additional costs for contractors/vendors; • Summit County Prosecutors: increased caseload and prosecutions relating to the opioid epidemic; • Summit County Court of Common Pleas (including probation and specialty courts, like drug court): increased caseload and probation services relating to the opioid epidemic; Opioid Unit in adult probation department; two drug court judges do community outreach re opioids and other drugs; Indigent Defense – increased County expenditures to fund this Court program for indigent defendants; • Summit County Juvenile Court (including probation and specialty courts): increase in number of parents participating in Family

Jurisdiction	Efforts to Address Opioid Epidemic
	Reunification Through Recovery Court due to opioid use; increase in staff trainings related to opioid use; • Summit County Children Family Services: host Northeast Ohio Regional Training Center which provides trainings related to opioids, 25% of the staff trainings they do relate to opioids; social workers who exclusively deal with families and substance abuse issues; collaborate with juvenile court program, Family Reunifications through Recovery; Oriana House; provides licensure hours for Close Up which addresses opioids increased costs due to increased placement of children abused and neglected due to opioid addictions; • Summit County Sheriff: services, including but not limited to, training, investigations, staffing, jail expenses, dispatch services, task force as a result of the opioid epidemic; members of Quick Response Team; DARE education; drug task force members meet with community organizations to discuss opioids; drug take back days; implement House Bill 277 aka Good Samaritan Law; receive Narcan training; • Summit County General Health District: purchase of Narcan; Quick Response Team; Syringe Harm Reduction Program; educational campaigns, expanded medically assisted treatment programs; • Summit County Executive: Incident Management Assistance Team ("IMAT") coordinates activities of the Opiate Task Force and the Addiction Counsel
Akron	• Opioid-focused Quick Response Team (QRT); • Purchases of Narcan, drug testing kits, and Immunity Hearing Requirement forms; • Increased Police/Fire/EMS service calls for overdoses; • Increased Police Division services for opioid investigations, including training, detailing of staff to task forces; • Safety Communications handling of increased dispatches and related Police/Fire/EMS support; • Law Department Criminal Division's increased prosecutions relating to the opioid epidemic; • Municipal Court's increased caseload and probation load relating to the opioid epidemic; • Planning and executing a response to the opioid epidemic, including community educational awareness by Police, the Mayor's office, and other city departments;

Jurisdiction	Efforts to Address Opioid Epidemic
	• Funding of third party entities that provide various support services related to the opioid epidemic, including Oriana House, Interval Brotherhood Home, etc.

Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 5:

Identify and describe all alleged key opinion leaders (as that term is used throughout the Complaint), alleged front groups, and other third parties with whom any Defendant allegedly conspired or acted in concert in furtherance of the alleged misconduct described in the Complaint, including the identity of each Defendant that allegedly conspired and all facts supporting Plaintiff's contention that such Defendant(s) did so.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as overly broad and unduly burdensome in that it seeks information that is uniquely in Defendants' possession, and thus imposes an undue burden and unnecessary expense on Plaintiff. Plaintiff further objects to this Request as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe all key opinion leaders, alleged front groups and other third parties. Further objecting, the Interrogatory contains a reference to several ambiguous phrases, namely, "alleged front groups," "allegedly conspired," "acted in concert," "in furtherance of," and "alleged misconduct".

Plaintiff responds that this Interrogatory is contention discovery more appropriately answered once discovery is complete. See FRCP 33(a)(2). Plaintiff responds discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure. Plaintiff also refers Defendants to Plaintiff's Second Amended Complaint, which identifies key opinion leaders, alleged front groups, and other third parties

acting in concert with Defendants. Notwithstanding and without waiving all objections, Plaintiff responds as follows:

Name	Title	Facts Alleged in Support
Russell Portenoy	Doctor, Chairman of the Department of Pain Medicine and Palliative Case at Beth Israel Medical Center in New York	In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy." Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids: *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.* According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy

Name	Title	Facts Alleged in Support
		in all but the most desperate cases of chronic nonmalignant pain." Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'" As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified." Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ." In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated

Name	Title	Facts Alleged in Support
		that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind: I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.* Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."

Name	Title	Facts Alleged in Support
Lynn Webster	Doctor, co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah	Another Key Opinion Leader, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon). Dr. Webster created and promoted the Opioid Risk Tool ("ORT"), a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's ORT appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Plaintiffs' communities. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or

Name	Title	Facts Alleged in Support
		addictive behaviors was more opioids: he prescribed staggering quantities of pills. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.
Perry Fine	Doctor, co-chair of APS/AAPM Opioid Guideline Panel	Dr. Perry Fine's ties to the Marketing Defendants are well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

Name	Title	Facts Alleged in Support
		Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from J&J for providing "educational" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction: > At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk. > Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study." In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management

Name	Title	Facts Alleged in Support
		of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain." The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small." Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain. He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."
Scott Fishman	Doctor, served as a board member of APF and president of AAPM	Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to

Name	Title	Facts Alleged in Support
		oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion." In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created: > Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins." In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict." The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

Name	Title	Facts Alleged in Support
American Pain Foundation ("APF")		The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.PainKnowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.PainKnowledge.com*. Endo estimated it would reach 60,000 prescribers through NIPC.

Name	Title	Facts Alleged in Support
		APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share [its] business interests. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between

Name	Title	Facts Alleged in Support
		APF and the Marketing Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence." In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

Name	Title	Facts Alleged in Support
American Academy of Pain Medicine and American Pain Society ("AAPM" and "APS," respectively)		The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed." AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet

Name	Title	Facts Alleged in Support
		with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine

Name	Title	Facts Alleged in Support
		toxicology testing, and claims of a low risk of addiction. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices." The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.
Federation of State Medical Boards ("FSMB")		The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

Name	Title	Facts Alleged in Support
		Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Summit County. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient

Name	Title	Facts Alleged in Support
		relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.
The Alliance for Patient Access ("APA")		Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care." It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon. APA's board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000

Name	Title	Facts Alleged in Support
		between 2013 and 2015 from pharmaceutical companies. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse." Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy: Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal. * * * In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . . We cannot merely assume that these programs will reduce prescription pain medication use and abuse. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills: Although well intentioned, many of the policies designed to address this problem have made it

Name	Title	Facts Alleged in Support
		difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication: Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs." The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward

Name	Title	Facts Alleged in Support
		members of Congress who have supported the APA's agenda. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences" and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The bill passed both houses of Congress and was signed into law in 2016.
The U.S. Pain Foundation ("USPF")		The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil *(i.e.*, Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

Name	Title	Facts Alleged in Support
American Geriatrics Society ("AGS")		The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009. AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant

Name	Title	Facts Alleged in Support
		proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 6:

Identify and describe all prescriptions of opioids that were written in the Plaintiff's county, city, village, or township in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission; or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory because of its vast over breadth and in that it seeks information that is not relevant to any party's claim or defense, as Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act or other individualized damage counts. Plaintiff also objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the marginal importance of the materials to the claims and defenses in this

litigation, as described above, and (2) the substantial cost and burden to the Plaintiff to identify and describe responsive materials on all prescriptions of opioids in Summit County, and the substantial risk of harm to the privacy interests and rights held by the individuals whose private medical files are the subject of this request. Plaintiff also responds that this Interrogatory is contention discovery more appropriately answered once written discovery is completed. See FRCP 33(a)(2). Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

Subject to and without waiving all objections, Plaintiff answers with the following list of prescription opioids at issue in the case:

OxyContin	MS Contin
Dilaudid	Dilaudid-HP
Butrans	Hysingla ER
Targiniq ER	Kadian
Norco	Actiq
Fentora	Duragesic
Nucynta	Nucynta ER
Opana ER	Opana
Percodan	Percocet
Generic Oxycodone	Generic Oxymorphone
Generic Hydromorphone	Generic Hydrocodone
Fentanyl	Exaglo
Roxicodone	Xartemis XR
Methadose	Generic Methadone Hydrochloride
Generic Morphine Sulfate Oral Solution	Generic Fentanyl Transdermal System
Generic Oral Transmucosal Fentanyl Citrate	Generic Oxycodone and Acetaminophen
Generic Hydrocodone Bitartrate and Acetaminophen	Generic Hydromorphone Hydrochloride
Generic Hydromorphone Hydrochloride ER	Generic Naltrexone Hydrochloride
Generic Oxymorphone Hydrochloride	Generic Methadone Hydrochloride
Generic Oxycodone Hydrochloride	Generic Buprenorphine and Naloxone

Plaintiff further responds that the increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; 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. Plaintiff also responds and incorporates the answers to Interrogatories No. 5 and No 9. Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 7:

Identify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in the Plaintiff's county, city, village, or township. Include in the identification of each such individual: (i) the particular type of alleged harm that the individual experienced, (ii) the particular opioid(s) that he or she took and/or was prescribed, (iii) when each prescription at issue was written, (iv) the condition for which each prescription was written; and (v) the allegedly false, misleading, or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as grossly overly broad and unduly burdensome as propounded. Plaintiff objects because this Interrogatory seeks information not relevant to any party's claim or defense or the legal theories in this case. Subject to and without waiving objections, Plaintiff responds that Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act counts or other individual claims that justify the burden of an Interrogatory this broad in scope. Plaintiff objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the lack of relevance or importance of the materials to the claims and defenses in this litigation, as described above, and (2) the substantial cost and burden to identify and describe responsive materials, which would cause substantial harm to the privacy interests and rights held by the individuals whose private medical files are the subject of this request. Plaintiff further objects to the extent this Interrogatory calls for

Confidential Information not in the Plaintiff's possession and protected by privacy laws, including but not limited to, the federal Health Insurance Portability and Accountability Act ("HIPAA"). Subject to and without waiving all objections, Plaintiff responds and incorporates the answer to Interrogatories No. 5 and No. 6. As discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1

INTERROGATORY NO. 8:

Identify any "unbranded advertising" or "unbranded marketing" (as those terms are used throughout the Complaint) disseminated in the Plaintiff's county, city, village, or township in which any Defendant participated or to which any Defendant contributed in any way. Include in the response the identity of the Defendant(s) that participated or contributed and the identity of the person or persons to whom the "unbranded advertising" or "unbranded marketing" was distributed.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify any "unbranded advertising" or "unbranded marketing" disseminated in Plaintiff's jurisdiction in which any Defendant participated or contributed. Plaintiff further objects to this Interrogatory to the extent it seeks information that is in Defendants' possession or publicly available, and thus imposes an undue burden and unnecessary expense on Plaintiff.

Notwithstanding and without waiving all objections, Plaintiff responds: Defendants Purdue, Endo and Teva sponsored a publication entitled, *Responsible Opioid Prescribing*, which promoted the prescription of opioids for non-cancer patients. This publication was distributed by Endo sales representatives throughout Plaintiff's jurisdiction with a special introductory letter from Dr. Scott Fishman. Purdue also promoted its pain-management website –

www.InTheFaceOfPain.com – which included testimonials from several paid "advocates" urging more pain treatment. Yet another Purdue unbranded website – Partners Against Pain – stated "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain." A Janssen unbranded website – www.PrescribeResponsibly.com – stated that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients." In 2012, Mallinckrodt promoted a book through its unbranded C.A.R.E.S. Alliance website entitled "Defeat Chronic Pain Now!" which stated false claims such as "Only rarely does opioid medication cause a true addiction when prescribed appropriately…" and "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

In addition, Defendants sponsored multiple CMEs in or near Plaintiff's jurisdiction to promote the use of opioids and downplay any risks or adverse effects; including Cephalon-sponsored CMEs made widely available through organizations such as Medscape LLC and a Teva-sponsored CME that was published in a supplement of *Pain Medicine News* in 2009.

Plaintiff reserves the right to supplement or modify this list as discovery proceeds. Plaintiff further responds discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1 and the Federal Rules of Civil Procedure.

INTERROGATORY NO. 9:

Identify and describe all statements or omissions made or disseminated in the Plaintiff's county, city, village, or township by any Defendant (or any other person whose statements you attribute, in whole or in part, to a Defendant) that you claim were false, misleading, unfair,

deceptive or otherwise actionable. Include in your identification of each statement or omission: (i) the name, employer, and position(s) of the speaker, writer, or other person who issued the statement; (ii) the name(s) and position(s) of the recipient(s) of such statement; (iii) when and where the allegedly false, misleading, or deceptive statement was made; (iv) a description of the content of the statement; and (v) all reasons you claim the statement was false, misleading, or deceptive.

PLAINTIFF'S RESPONSE:

Plaintiff objects to this Interrogatory as vague, overly broad and unduly burdensome to the extent it requests Plaintiff to identify and describe "all" statements or omissions made or disseminated in Plaintiff's jurisdiction by any Defendant that were false, misleading, unfair, deceptive or otherwise actionable. Further objecting, the Interrogatory contains a reference to an undefined phrase, "otherwise actionable."

Plaintiff further objects to the extent it seeks information that is in Defendants' possession or publicly available, and thus imposes an undue burden and unnecessary expense on Plaintiff. Notwithstanding and without waiving all objections, Plaintiff responds:

Falsehood	**Explanation**
The risk of addiction from chronic opioid therapy is low	When it launched OxyContin, Purdue cited in promotional and educational materials a single paragraph from a letter published in 1980 by Dr. Hershel Jick and Jane Porter in the New England Journal of Medicine as evidence of the low risk of addiction to opioids. In fact, Purdue included reference to this letter in a 1998 promotional video entitled, "I got my life back," in which Dr. Alan Spanos states, "In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%." Until April 2012, Endo stated on its website that "…patients treated with prolonged opioid medicines usually do not become addicted;" a statement echoed on the website of its close affiliate, APF. Endo also published and distributed multiple pamphlets and brochures downplaying addiction as it related to opioids, including but not limited to "Pain: Opioid Facts," "Understanding Your Pain: Taking Oral Opioid Analgesics" and "Pain: Opioid Therapy."

Falsehood	Explanation
	Janssen claimed on its unbranded website – www.PrescribeResponsibility.com – that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients." Janssen also published a patient education guide entitled "Finding Relief: Pain Management for Older Adults" describing opioid addiction as a myth and that "many studies show opioids are *rarely* addictive…" which, until recently, was available online. Cephalon sponsored a 2007 publication from APF entitled "Treatment Options: A Guide for People Living with Pain" which taught that opioid addiction is rare. Actavis published material that claimed it is "less likely" to become addicted to opioids in those who "have never had an addiction problem." The same publication notes that a need for a "dose adjustment" is the result of tolerance, and "not addiction." A 2007 guide for prescribers published under Actavis's copyright states that Kadian is more difficult to abuse and less addictive than other opioids. Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance in 2010 which promoted a book entitled "Defeat Chronic Pain Now!" in which opioids were stated to "rarely" cause addiction.
To the extent there is a risk of addiction, it can be easily identified and managed	Purdue and Cephalon sponsored the APF's publication, "Treatment Options: A Guide for People Living with Pain" in 2007, which falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed." Janssen stated on its website – www.PrescribeResponsibly.com – that opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors. Purdue also sponsored a 2011 webinar taught by Dr. Lynn Webster entitled "Managing Patient's Opioid Use: Balancing the Need and Risk" wherein prescribers were told that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." Endo paid for a 2007 supplement for continuing education credit in the "Journal of Family Practice" entitled "Pain Management Dilemmas in Primary Care: Use of Opioids" which recommended screening patients and the use of the Opioid Risk Tool.
Signs of addictive behavior are "psuedoaddiction," requiring more opioids	Cephalon, Endo and Purdue sponsored the Federation of State Medical Board's ("FSMB") publication entitled "Responsible Opioid Prescribing" in 2007 which stated that such behaviors as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to

Falsehood	Explanation
	obtain opioids and hoarding are all signs of "pseudoaddiction" (not genuine addiction). Purdue published an unbranded pamphlet entitled "Clinical Issues in Opioid Prescribing" in 2005 which was circulated through 2007 and available on its website through 2013. This pamphlet stated that "illicit drug use and deception" were not evidence of true addiction, but rather "pseudoaddiction." Endo sponsored a CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which promoted pseudoaddiction. Janssen sponsored, funded and edited a website entitled "Let's Talk Pain" which in 2009 stated that pseudoaddiction "…refers to patient behaviors that may occur when pain is undertreated…"
Opioid withdrawal can be avoided by tapering	Endo sponsored an educational program entitled "Persistent Pain in the Older Adult" which claimed that withdrawal symptoms could be avoided by simply tapering a patient's opioid dose over ten days. Similarly, Purdue sponsored APF's publication "A Policymaker's Guide to Understanding Pain & Its Management" which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation." Neither Defendant explained the significant hardships associated with cessation of use.
Opioid doses can be increased without limit or greater risks	Purdue omitted the increased risk of respiratory distress and death from increasing opioid dosage from its 2010 "Risk Evaluation and Mitigation Strategy" for OxyContin. Endo published on its website a patient education pamphlet entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" that responds to the question, "If I take the opioid now, will it work later when I really need it?" with "The dose can be increased…You won't 'run out' of pain relief." Purdue and Cephalon also sponsored APF's 2007 "Treatment Options: A Guide for People Living with Pain" which taught patients that opioids have "no ceiling dose" and are therefore safer than NSAIDs.
Long-term opioid use improves functioning	Janssen promoted Duragesic through an ad campaign as improving a patient's functioning and work productivity. Janssen's "Let's Talk Pain" website featured a video interview claiming that opioids were what allowed a patient to "continue to function." Similarly, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association stating, "There Can Be Life With Relief" and implying that OxyContin would help users' function; however the FDA noted that Purdue failed to warn that patients could die from taking OxyContin. Purdue also ran advertisements in medical journals in 2012 touting that OxyContin would help a "writer with osteoarthritis of the hands" work more effectively. Since May 2011, Endo has

Falsehood	Explanation
	distributed and made available on its website – www.Opana.com – a pamphlet implying that patients with physically demanding jobs would achieve long-term pain relief and functional improvement. Mallinckrodt's website claims that "[t]he effective pain management offered by our [opioids] helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."
Alternative forms of pain relief pose greater risks than opioids	Purdue and Cephalon sponsored APF's publication entitled "Treatment Options: A Guide for People Living with Pain" warning of increased risks if NSAIDs are "taken for more than a period of months;" falsely attributing 10,000 to 20,000 deaths annually to NSAID overdoses when the figure is closer to 3,200. In 2009, Janssen sponsored a publication entitled, "Finding Relief: Pain Mangement for Older Adults" which listed dose limitations as "disadvantages" of other pain medicines. It also listed a number of serious health effects as disadvantages of NSAIDs while only listing "upset stomach or sleepiness" and constipation as disadvantages of opioids. Purdue and Endo sponsored a CME issued by the AMA in 2003, 2007, 2010 and 2013 entitled "Overview of Management Options" which taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.
OxyContin provides twelve hours of pain relief	In 2000, Purdue advertised that OxyContin provides "Consistent Plasma Levels Over 12 Hours;" however the oxycodone does not enter the body at a linear rate, releasing a greater proportion upon administration and gradually tapering over 12 hours. These 12-hour dosing advertisements ran in the *Journal of Pain* in February 2005 and the *Clinical Journal of Pain* in 2006.
New formulations of certain opioids successfully deter abuse	Purdue presented an article in 2013 based on a review of data from poison control centers concluding that its ADF OxyContin can reduce abuse, but failed to acknowledge that abuse merely shifted to other drugs and that there were actually more harmful exposures to opioids after the reformulation. In 2016, Dr. J. David Haddox, VP of Health Policy for Purdue, falsely claimed that the evidence does not show Purdue's ADF opioids are being abused in large numbers. Endo's promotion of its Opana ER also tended to omit material facts according to a May 2012 letter from the FDA to Endo. Endo submitted a citizen petition asking the FDA for permission to label Opana ER as abuse-resistant, and also went so far as to sue the FDA to force expedited consideration of this change. Endo falsely promoted Opana ER as having been designed to be crush-resistent, knowing that this would (falsely) imply that it was actually crush-

Falsehood	Explanation
	resistant and less likely to be abused (as stated in a June 14. 2012 press release). Endo initiated journal advertisements that appears in April 2013 stating Opana ER was "designed to be crush resistant." Likewise, Actavis copyrighted a guide for prescribers representing that Kadian is more difficult to abuse and less addictive than other opioids. Mallinckrodt promoted both Exalgo and Xartemis XR as specifically formulated to reduce abuse, going so far as to state, "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."

Plaintiff reserves the right to supplement or modify this list as discovery proceeds.

INTERROGATORY NO. 10:

Identify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful. Include in the response as to each such prescription the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the basis for your assertion that the prescription was unauthorized, medically unnecessary, ineffective, or harmful; and whether, by whom, and for how much the prescription was approved for reimbursement.

PLAINTIFF'S RESPONSE:

See answer to Interrogatory No. 6. Plaintiff objects to this Interrogatory as overly broad and unduly burdensome as propounded. Plaintiff objects because this Interrogatory seeks information not relevant to any party's claim or defense, or the legal theories in this case. Subject to and without waiving objections, Plaintiff responds that Plaintiff is not representing the interests of any individuals who were harmed by opioids or the interests of any payor of opioid prescription costs; nor has Plaintiff alleged any False Claims Act counts or other claims that justify the burden of an Interrogatory this broad in scope. Plaintiff objects to this Interrogatory because it is not proportional to the needs of the case considering (1) the lack of relevance or importance of the materials to the claims and defenses in this litigation, as described above, and

(2) the substantial cost to identify and describe responsive materials, which would cause substantial harm to the privacy interests held by the individuals whose private medical files are the subject of this request. Plaintiff further objects to the extent this Interrogatory calls for Confidential Information not in the Plaintiff's possession and protected by privacy laws.

As discovery continues and Plaintiff will produce a trial witness list and expert reports pursuant to CMO No. 1. Subject to and without waiving all objections, Plaintiff will comply with the procedure and deadline as set forth in ¶ 9(1)(iii) of Case Management Order No. 1.

Dated: June 12, 2018

Respectfully submitted,

By: /s/ Linda Singer
Linda Singer

Joseph F. Rice
Jodi Westbrook Flowers
Anne McGinness Kearse
David I. Ackerman
Jeffrey C. Nelson
MOTLEY RICE LLC
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CERTIFICATE OF SERVICE

I, Jeffrey Nelson, certify that on June 12, 2018, I caused the foregoing to be served via electronic mail on Defendant's Liaison Counsel pursuant to the Case Management Order in this case (ECF #232).

/s/ Jeffrey Nelson

Verification

I, Deborah S. Matz, declare:

I am the Law Director for the County of Summit, Ohio. I am authorized to make this verification on behalf of Plaintiff the County of Summit, Ohio. The foregoing **Plaintiff's Entities First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories** represents a municipal corporate response, based on information, in part, assembled by the County of Summit, Ohio employees and/or representatives. Because the matters stated in the document identified above constitute a corporate response, they are not all necessarily within my personal knowledge, or within the personal knowledge of any single individual. Subject to these limitations, the information contained in the foregoing response is, to the best of the County of Summit, Ohio's knowledge, true and correct. The County of Summit, Ohio reserves the right to make any changes should it appear that any omissions or errors have been made.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Summit, Ohio on this 13th day of June, 2018

Deborah S. Matz
Signature

Deborah S. Matz
Print Name

Law Director
For Summit County

Verification

I, Charles Twigg, declare:

I am the Deputy Chief, Fire Administration for the City of Akron, Ohio. I am authorized to make this verification on behalf of Plaintiff the City of Akron, Ohio. The foregoing **Plaintiff's Entities First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories** represents a municipal corporate response, based on information, in part, assembled by the City of Akron, Ohio employees and/or representatives. Because the matters stated in the document identified above constitute a corporate response, they are not all necessarily within my personal knowledge, or within the personal knowledge of any single individual. Subject to these limitations, the information contained in the foregoing response is, to the best of the City of Akron, Ohio's knowledge, true and correct. The City of Akron, Ohio reserves the right to make any changes should it appear that any omissions or errors have been made.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Akron, Ohio on this 13 day of June, 2018

Deputy Chief Charles Twigg
Akron Division of Fire

Sworn to before me and subscribed in my presence on this 13th day of June, 2018.

Notary Public

KAROL E. HATCH
Resident of Summit County
Notary Public, State of Ohio
My Commission Expires 8/16/19

Verification

I, Mike Caprez declare:

I am the Deputy Chief of Police for the City of Akron, Ohio. I am authorized to make this verification on behalf of Plaintiff the City of Akron, Ohio. The foregoing **Plaintiff's Entities First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories** represents a municipal corporate response, based on information, in part, assembled by the City of Akron, Ohio employees and/or representatives. Because the matters stated in the document identified above constitute a corporate response, they are not all necessarily within my personal knowledge, or within the personal knowledge of any single individual. Subject to these limitations, the information contained in the foregoing response is, to the best of the City of Akron, Ohio's knowledge, true and correct. The City of Akron, Ohio reserves the right to make any changes should it appear that any omissions or errors have been made.

I declare under penalty of perjury that the foregoing is true and correct.

Executed at Akron, Ohio on this 14th day of June, 2018

Deputy Chief Michael Caprez
Akron Division of Police

Sworn to before me and subscribed in my presence on this 14th day of June, 2018.

NOTARIAL SEAL STATE OF OHIO

Marlene E. Long
Resident Summit County
Notary Public, State of Ohio
My Commission Expires: April 18, 2022

Marlene E. Long
Notary Public

EXHIBIT 7

KIRKLAND & ELLIS LLP
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August 4, 2018

Via Electronic Mail

Special Master David Cohen
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, OH 44113-1837
david@specialmaster.law

CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER

Re: *In re National Prescription Opiate Litigation*, MDL No. 2804
County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-OP-45090
City of Cleveland, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-OP-451312
County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-OP-45004

Dear Special Master Cohen:

I write on behalf of Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) ("Allergan Finance") and the Manufacturer Defendants[1] regarding the Track 1 Plaintiffs' refusal to provide information in response to Interrogatory Nos. 6, 7 and 10, and their refusal to produce documents responsive to RFP No. 10. These discovery requests seek information that go to the heart of the Manufacturer Defendants' defenses and, we believe, are also essential to Plaintiffs' claims—namely, whether any prescriber in Plaintiffs' jurisdictions wrote a prescription for any Manufacturer Defendant's prescription opioid in reliance on any alleged misrepresentations, whether any prescriber in Plaintiffs' jurisdictions wrote a prescription for any such opioid that was medically unnecessary, and, if so, what harm resulted. These requests go to the core elements of Plaintiffs' claims. Indeed, we have never been involved in a case where plaintiffs asserting fraud-based claims have refused even to identify the parties who supposedly

[1] The Manufacturer Defendants include Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. ("Teva Defendants"); Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. ("Purdue"); Johnson & Johnson ("J&J") and Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Janssen"); Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. ("Endo"); Insys Therapeutics, Inc. ("Insys"); and Mallinckrodt LLC ("Mallinckrodt").

received and relied upon the alleged fraudulent statements, much less identify what fraudulent statements were made to them and explain the basis for alleging that that fraud caused plaintiffs harm. Because this information is critical both to this litigation and to the parties' ongoing settlement discussions, the Manufacturer Defendants request a Ruling requiring Track 1 Plaintiffs to provide it.

Procedural History. Manufacturer Defendants first wrote to Track 1 Plaintiffs on June 22, 2018, to address the wholesale deficiencies in Plaintiffs' responses to Interrogatory Nos. 6, 7 and 10 and RFP No. 10.[2] Initially, Plaintiffs cited relevance and burden as their reasons for refusing to identify any of the information requested in these Interrogatories. The parties met and conferred on these issues on June 29, and Plaintiffs suggested the requests were overbroad because they sought information and documents relating to all opioids. At Manufacturer Defendants' request, Plaintiffs agreed to consider narrowed requests to provide information related to the specific prescriptions written for the Manufacturer Defendants' opioids in their jurisdictions.

On July 6, Plaintiffs contended that they do not have the requested information, but stated generally "[i]t is possible" that some of the requested information is somewhere in the documents Plaintiffs have produced or may produce in the future.[3] On July 10, Manufacturer Defendants responded, noting that Plaintiffs are either unable or unwilling to identify any specific prescription for any Manufacturer Defendant's FDA-approved medication that they contend was written in reliance on any Defendant's alleged misstatements, was medically inappropriate, and resulted in harm to any of the bellwether jurisdictions—identified by Plaintiffs either during their pre-suit investigations or since. In response to certain contentions in their July 6 letter, the Manufacturer Defendants also asked Plaintiffs to respond to certain clarifying questions, such as whether:

- Plaintiffs control the information held by the third parties who administer medical insurance and workers' compensation plans for the Plaintiffs' employees and their families;
- Plaintiffs have received the information they requested from their insurers or when they can expect to receive it;
- Plaintiffs or their counsel have received any individual prescription information from third parties;

[2] *See* Ex. 1 (June 22, 2018 D. Welch Ltr. to D. Ackerman).

[3] Ex. 2 (July 6, 2018 D. Ackerman Ltr. to D. Welch).

- Plaintiffs can identify a single prescription written for any of the Manufacturer Defendants' opioids that is responsive to Interrogatory Nos. 6 or 10; and

- Plaintiffs can identify a single individual in their jurisdictions harmed by a prescription to a Manufacturer Defendant's opioid, or the allegedly false, misleading or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.[4]

They have failed to respond.

Interrogatory Nos. 6, 7 and 10. These Interrogatories seek information that goes to the heart of these cases:

- **No. 6:** Which prescriptions, if any, of each Defendant's opioids were written in Plaintiff's jurisdiction in reliance on any Defendant's alleged misrepresentations, omissions or other alleged wrongdoing?[5]

- **No. 7:** Who, if anyone, purportedly became addicted or was otherwise harmed as a result of such prescriptions in Plaintiff's jurisdiction?[6]

[4] Ex. 3 (July 10, 2018 D. Welch Ltr. to D. Ackerman).

[5] *See, e.g.*, Ex. 4 (Cuyahoga's First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories) at Interrogatory No. 6 ("Identify and describe all prescriptions of opioids that were written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission, or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement.").

[6] *Id.* at Interrogatory No. 7 ("Identify every person who allegedly became addicted to any substance or was otherwise harmed as a result of any prescription of an opioid(s) in [Plaintiff's jurisdiction]. Include in the identification of each such individual: (i) the particular type of alleged harm that the individual experienced, (ii) the particular opioid(s) that he or she took and/or was prescribed, (iii) when each prescription at issue was written, (iv) the condition for which each prescription was written, and (v) the allegedly false, misleading, or deceptive statement or omission that purportedly caused the healthcare provider to write the prescription.").

- **No. 10:** Which prescriptions, if any, were unauthorized, medically unnecessary, ineffective, or harmful?[7]

In response, none of the three Track 1 Plaintiffs has produced any substantive information with respect to any of the separately named Manufacturer Defendants. None has identified a single wrongful prescription of any Manufacturer Defendant's opioid product connected in any way to that Manufacturer Defendant's alleged wrongdoing. None has identified a single prescription of any Manufacturer Defendant's opioid that was medically inappropriate. And none has identified a single individual harmed by any Manufacturer Defendant's opioid medication. In order to provide concrete examples to illustrate a point that applies equally to all Manufacturer Defendants, Allergan Finance and Teva provided specific information identifying the extremely small number of prescriptions written for their respective opioids in Ohio (for Allergan Finance, there were 617 prescriptions for Kadian® in all of Ohio in 2015, 469 in 2016 and 186 in the first half of 2017; for Teva, based upon its latest data received since the last submission, there were 69 prescriptions for ACTIQ® in Cleveland and Cuyahoga County and 52 in Summit County for the more than seven year period from 2011 through the first half of 2018).[8] Still, Plaintiffs have not identified a single allegedly unnecessary prescription from even this small set of prescriptions.

As an initial matter, if Plaintiffs cannot at this time identify a single prescription of a Manufacturer Defendant's opioid that was improper and connected in some way to that Defendant's conduct, they are required to say so in their sworn responses. *See* Fed. R. Civ. P. 33(b)(3) ("Each interrogatory must, to the extent it is not objected to, be answered separately and fully in writing under oath."). We believe that Plaintiffs' refusal to identify a single instance where any Manufacturer Defendant's act or omission caused harm in their geographic territory is not only an abdication of their discovery responsibilities under the Federal Rules, but also evidences a fatal flaw in their underlying case against each Defendant. As Judge Polster recognized in CMO-1 and you recognized in Discovery Ruling No. 1, this is undoubtedly true for Track 1 Plaintiffs' claims that "allege[] money damages based upon unnecessary prescriptions."[9] Because Plaintiffs have already failed to identify this information required under CMO-1 ¶ 9(l)(iii),[10] they have "forfeit[ed]

[7] *Id.* at Interrogatory No. 10 ("Identify and describe all prescriptions of opioid(s) that Plaintiff contends were unauthorized, medically unnecessary, ineffective, or harmful. Include in the response as to each such prescription the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the basis for your assertion that the prescription was unauthorized, medically unnecessary, ineffective or harmful; and whether, by whom, and for how much the prescription was approved for reimbursement..").

[8] Ex. 1 (June 22, 2018 D. Welch Ltr. to D. Ackerman).

[9] CMO-1 (Dkt. 232) ¶ 9(l)(iii); Discovery Ruling No. 1 (Dkt. 606) at 6.

[10] *See* Exs. 5-7 (July 16, 2018 letters from each Track 1 Plaintiff contending that CMO-1 ¶ 9(l)(iii) does not apply to their claims); Ex. 8 (July 27, 2018 Response from Manufacturing Defendants).

any claim for money damages based upon unnecessary prescriptions," as you warned them they would.[11]

But regardless of Plaintiffs' apparent decision to forfeit their damages claims, this information is plainly relevant to the Manufacturer Defendants' defenses in these cases, and thus we are entitled to it. Indeed, you clarified this when you sent the parties an email stating, Discovery Ruling No. 1 (Dkt. 606) "was not intended to preclude defendants' from obtaining specific, well-defined discovery needed to address and challenge plaintiffs' experts or method of analysis of damages, or ***discovery necessary to support or challenge plaintiffs' claims or defendants' defenses***." (emphasis added).[12] As you also recognized, Defendants will be able to argue "that the lack of this evidence also breaks a necessary link in the chain of causation for some or all claims."[13] Indeed, there can be no other conclusion.[14] And while a lack of any evidence sustaining the causal chain is fatal to Plaintiffs' claims, a corollary is equally true: the requested discovery, and other evidence it may lead to, can disprove causation (and other elements of Plaintiffs' claims). Under Fed. R. Civ. P. 26, the Manufacturer Defendants are entitled to this discovery and all other discovery that is relevant to our defenses: "[T]he scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim ***or defense***…." (emphasis added).

This is a fundamental point that Plaintiffs miss. While Defendants cannot dictate to Plaintiffs how they might try to go about attempting to prove their claims, Plaintiffs cannot dictate to Defendants how they get to defend themselves. For example, Plaintiffs cannot avoid inconvenient facts (including the inconvenient fact that they lack evidence to support their claims) simply by declaring that they intend to pursue a novel theory of causation that depends on inferences rather than proof. Defendants are still entitled to discovery, including answers to interrogatories, that will refute Plaintiffs' inferences. To conclude otherwise would read out one half of the standard for relevant discovery and deprive Manufacturer Defendants of Due Process.

Put simply, even if Plaintiffs are allowed to try to prove causation with statistical or aggregate proof, Manufacturer Defendants still are entitled to explore, and potentially use at summary judgment or trial, the evidence concerning the chain of causation between any allegedly wrongful conduct by each Manufacturer Defendant, on the one hand, and any injury or damages suffered by Plaintiffs, on the other, to demonstrate that the Manufacturer Defendant's conduct

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[11] Discovery Ruling No. 1 at 6.

[12] *See* Ex. 9 (June 22, 2018 Email from Special Master Cohen).

[13] *Id.*

[14] *See infra* nn. 15-16.

could not have caused the harm Plaintiffs claim. Even ignoring intervening illegal acts like diversion, that causal chain necessarily includes: (i) an alleged misstatement to a prescriber; (ii) the prescriber's reliance on that misstatement; (iii) a prescription for opioids that Plaintiffs claim should not have been written, (iv) a physician or other prescriber who wrote that prescription, (v) an individual who was purportedly harmed by that prescription, and (vi) resulting harm to Plaintiffs.[15] While now is not the time to decide definitively whether Plaintiffs are able to use aggregate evidence and statistics to prove causation in these cases (as you've noted), the Court cannot allow Plaintiffs' novel causation theory to artificially limit relevant discovery, particularly when the weight of relevant authority—in our view, controlling precedent—requires more

[15] *See, e.g.*, *City of Cincinnati v. Deutsche Bank Nat'l Tr.*, 863 F.3d 474, 480 (6th Cir. 2017) ("Proximate cause requires some reasonable connection between the act or omission of the defendant and the damage the plaintiff has suffered. In addition to foreseeability, it requires some direct relation between the injury and the injurious conduct…. The failure to tether the damages to nuisance-related problems on Wells Fargo's properties prevents us from assessing the 'directness' of the relationship between the two. That is particularly true for the City's attenuated theories of damage: decreased tax revenue, increased police and fire expenditures, and increased administrative costs. When tied only to a general 'policy' of non-conformance, these damages are difficult to connect to Wells Fargo's actions and nearly impossible to disaggregate from other potential causes of these costs.") (internal quotation marks and citations omitted); *City of Cleveland v. Ameriquest Mort. Sec., Inc.*, 615 F.3d 496, 502–03 (6th Cir. 2010) ("[T]he Supreme Court's application of *Holmes* in its subsequent decision *Anza* is instructive and consistent with how we believe the Ohio Supreme Court would consider this matter because the Ohio Supreme Court has previously adopted the directness requirement precedent of the United States Supreme Court…. [In *Anza*] [t]he Court held that the complaint did not satisfy the directness requirement because the [defendant's] alleged violation [of law] did not lead directly to the plaintiff's injuries."); *see also Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1062 (N.Y. 2001) ("Such broad liability, potentially encompassing all gunshot crime victims, should not be imposed without a more tangible showing that defendants were a direct link in the causal chain that resulted in plaintiffs' injuries, and that defendants were realistically in a position to prevent the wrongs. Giving plaintiffs' evidence the benefit of every favorable inference, they have not shown that the gun used to harm plaintiff Fox came from a source amenable to the exercise of any duty of care that plaintiffs would impose upon defendant manufacturers.").

particularized proof of causation.[16] The Manufacturer Defendants are entitled to full discovery regarding each step in that causal chain.[17]

Plaintiffs have suggested in prior discussions that it would be impossible for them to supply the requested data and information—we disagree. Plaintiffs have the capability to identify instances of opioid addiction and opioid overdoses and/or deaths in their jurisdiction and cross reference that information with state reimbursement data, medical records, and other information in Plaintiffs' possession to determine whether that individual was ever prescribed or abused a prescription opioid and if so, whether Plaintiffs claim that prescription was medically unnecessary or written by a prescriber that was misled by one of the Manufacturer Defendants.

Notwithstanding Plaintiffs' counsel's posturing, during the recent deposition of Dr. Lisa Kohler, the Summit County Chief Medical Examiner, Dr. Kohler testified the Medical Examiner's Office maintains detailed information about all overdose deaths that enable them to identify whether a person's overdose involved prescription opioids or, as in the vast majority of cases, illegal opioids such as heroin and illicit fentanyl. *See* Ex. 10 (Kohler Dep. Tr.) at 52:9-53:6; *id.* at Ex. 1. With this information, Plaintiffs are easily able to dispel the claim that a death was caused by a prescription opioid. In the small percentage of deaths where prescription opioid medications are detected in toxicology reports, Dr. Kohler also testified that her office reviews a person's

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[16] *See, e.g.*, *In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 487 (6th Cir. 2013) ("The Supreme Court has repeatedly held that plaintiffs attempting to assert an injury 'by reason of' a RICO violation must demonstrate both but-for causation and proximate causation."); *Uland v. S.E. Johnson Companies*, 1998 WL 123086, at *5 (Ohio Ct. App. Mar. 13, 1998) ("A qualified nuisance derives from negligence. To be actionable, the harm must be proximately caused by the defendant's act. Similarly, nuisance *per se* requires proximate causation."); *see also Chance v. BP Chemicals, Inc.*, 1995 WL 143827, at *5 (Ohio Ct. App. Mar. 30, 1995) (plaintiffs failed to prove that defendants' actions "constituted extreme or outrageous conduct which proximately caused" the injuries); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787, 792 (S.D. Ohio 2009) (recovery under the OPLA requires a showing that the product defect "was a proximate cause of harm for which the plaintiff seeks to recover compensatory damages."); *In re Zyprexa Products Liability Litig.*, 254 F.R.D. 50, 52 (E.D.N.Y. 2008) (in states' action stemming from alleged unlawful marketing, "[i]t is plainly evident that, given the disputed issue of causation, disclosure of the medical records is 'reasonably calculated to lead to the discovery of admissible evidence.'") (citation omitted).

[17] *See City of Los Angeles v. Wells Fargo & Co.*, 22 F. Supp. 3d 1047, 1054 (C.D. Cal. 2014) ("The City's lengthy Complaint relies on a regression analysis to support its claims and theory of causation…. In contrast to the City, Defendants describe the alleged causal chain as having seven 'links' …. While the issues raised by Defendants' causal chain may be subject to proof at a later stage in the litigation, the pleading standards for Article III standing are not so burdensome. The City must be afforded an opportunity to conduct discovery and obtain more property-specific information to meet its burden of actually proving its claims."); *see also Planned Parenthood Fed'n of Am., Inc. v. Ctr. for Med. Progress*, 214 F. Supp. 3d 808, 827 (N.D. Cal. 2016) ("How far the actual causal link stretches for each category of damages plaintiffs' allege is something that will need to be developed in discovery and tested on summary judgment."); *In re Zyprexa Products Liability Litigation*, 254 F.R.D. at 51 (in states' action stemming from alleged unlawful marketing, "[i]t bears repeating, then, that the [medical] records are in fact relevant to [Defendant's] defenses.").

relevant medical records and checks the Ohio Automated Rx Reporting System ("OARRs") database to determine whether the decedent was properly prescribed the medication. *See* Ex. 10 (Kohler Dep. Tr.) at 53:12-54:2. This is critically important information that is already contained in the Medical Examiner records that Plaintiffs have in their possession, custody, and control.

Furthermore, to the extent that Plaintiffs claim a decedent previously was prescribed or abused a prescription opioid that led to their larger opioid addiction, Dr. Kohler also testified that when investigating suspected drug overdose deaths, the Medical Examiner's office is supposed to, and does, inquire into a person's medical and prescription history, including (1) obtaining recent medical records, (2) consulting with healthcare providers, (3) interviewing a decedent's friends and family, and (4) checking the OARRs database to determine whether the individual has a history of being prescribed prescription opioids or possibly abusing them. *See* Ex. 10 (Kohler Dep. Tr.) at 41:12-23 ("If we know there was a physician treating that person, we can request records from that office. We can make inquiries to the local hospitals and ask if they have discharge summaries available."); *id.* at 125:2-15 ("In practice what we do is we request a list of medications and the problem list and the recent progress notes and evaluate it based upon the information that's provided to us to assess the cause and the manner of death of that individual."); *see also id.* at Ex. 7 (memo from Dr. Kohler to staff instructing them to investigate various aspects of a person's "medication history" in instances involving "overdose deaths").

While the Medical Examiner's office is not responsible for determining whether or not a past opioid prescription was medically necessary, Dr. Kohler's testimony confirms that Plaintiffs are at least able to readily identify a discrete sub-set of individuals whose deaths were allegedly associated with either prescription or illicit opioids. In 2015, for example, there were 213 overdose deaths in Summit County, which have all been investigated and tracked by Dr. Kohler's office at the time of death. Therefore, for each of those 213 individuals, Plaintiffs and their experts have the capacity—and in many instances, already have the information—to determine a decedent's relevant medical and prescription history. This discernable universe of overdose victims confirms that Plaintiffs are capable, and required to, pursue information concerning these individuals' opioid prescription and abuse history as part of Plaintiffs' discovery obligations. Plaintiffs cannot claim that the Manufacturer Defendants caused an epidemic in Summit or Cuyahoga County leading to numerous overdose deaths while at the same time refusing to use readily available information to connect an allegedly improper prescription to a single death that took place in those communities.

Furthermore, any burden to provide substantive responses is also lessened by the Manufacturer Defendants' agreement to narrow the requests to information regarding prescriptions written for their opioids—for example, as discussed above, there is a very limited number of

prescriptions of Allergan Finance's and Teva's opioids in Ohio and the Track 1 jurisdictions.[18] In any event, Plaintiffs should be held to no less than their own recently articulated standard:

> [I]f the time-period is too short for [Plaintiffs] to disclose the relevant information . . . the solution is not to deny [Defendants] vital discovery. If the Court finds the burden of discovery in the time remaining to be undue, Plaintiffs believe that the proper solution is a short extension of the deadline for production (and related deadlines). Such an extension, and not a truncation of the scope of discovery that would deny [Defendants] information critical to [defending] [Plaintiffs'] claims, would be the proper approach to burden arguments [Plaintiffs] raise.[19]

Each Manufacturer Defendant is entitled to information regarding which of the prescriptions for its specific FDA-approved opioids—if any—Plaintiffs contend were improper, and how, if at all, each specific Manufacturer Defendant's conduct was connected to those prescriptions. If there were no such prescriptions with respect to Allergan Finance, Teva, or any other Manufacturer Defendant, Plaintiffs are obligated simply to state that in a sworn interrogatory response. If there were, Plaintiffs must identify them now so Manufacturer Defendants can investigate, and, if necessary, pursue additional discovery, including third-party discovery, regarding any such prescriptions

In light of the aggressive schedule in this case, Plaintiffs' continued delay and refusal to provide substantive responses is depriving Manufacturer Defendants of our right to defend ourselves.[20] Manufacturer Defendants need this information promptly in order to engage in meaningful discovery with respect to Plaintiffs' claims, including pursuing potential third-party discovery. As you have recognized, heavy production burdens have been placed on Defendants in this case, and we are expending enormous effort to get Plaintiffs the documents and information they requested as expeditiously as possible. Manufacturer Defendants' efforts stand in stark

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[18] Plaintiffs cannot avoid their discovery obligations by arguing that the number of prescriptions at issue is too large. As the examples provided by Allergan Finance and Teva illustrate, that is not the case at all—and it is certainly not true for every Defendant. In any event, it is Plaintiffs, not Defendants, who chose to file the expansive claims that they did against the long list of defendants they sued (based upon whatever pre-suit investigation they did). And, at least one of the purposes of setting bellwether trials was to test the ability of a small subset of plaintiffs to prove their claims.

[19] Dkt. 812 at 8.

[20] *See, e.g.*, *In re Textron, Inc.*, 2012 WL 12876091, at *2 (D.R.I. Apr. 11, 2012) ("Plaintiffs have shown no compelling reason for relieving them of the duty to review the interrogatories and provide Textron with the most complete answers they can at this time. Furthermore, having basic information regarding the elements of a plaintiff's claim may very well provide the defendants with a 'roadmap' for further discovery decreasing the time and cost of litigation." (citations, internal quotation marks, and bracket omitted)).

contrast to Plaintiffs' flat refusal to identify discrete sets of critical information that we expect will refute the allegations in their complaints. "Discovery, of course, is not a one-way proposition,"[21] nor is it dictated by what Plaintiffs want to try to prove their claims and nothing more.

RFP No. 10. Manufacturer Defendants also have requested "[a]ll Documents and communications relating to any evaluation, assessment, analysis, modeling, or review of any cost or financial or economic impact associated with the alleged improper prescribing of Opioids." Plaintiffs have limited their production thus far to evaluations, assessments, analyses, and reviews "performed by Plaintiff[s]," although they subsequently agreed to produce any such responsive documents in their custody and control.[22] Plaintiffs, however, have never confirmed whether they are still withholding responsive communications related to the evaluations, assessments, analyses, models or reviews themselves, and have never provide details regarding the custodial and non-custodial sources of documents they are searching for responsive records, as requested.

* * *

For these reasons, Manufacturer Defendants respectfully request a Ruling requiring Track 1 Plaintiffs to **(i)** respond fully to Interrogatory Nos. 6, 7 and 10 within 10 days; and **(ii)** produce all documents in their possession, custody or control responsive to RFP No. 10, including communications, and provide Manufacturer Defendants with detail about the custodial sources they are searching for responsive documents.

Sincerely,

/s/ *Donna M. Welch*
Donna M. Welch

Counsel for Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.)

[21] *Hickman v. Taylor*, 329 U.S. 495, 507 (1947).

[22] *See* Ex. 11 (June 28, 2018 D. Ackerman Letter to D. Welch).

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