

EXHIBIT 1

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

IN RE: NATIONAL PRESCRIPTION)	CASE NO. 1:17-MD-2804
OPIATE LITIGATION)	
)	SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)	
<i>“Track One Cases”</i>)	
)	
)	<u>DISCOVERY RULING NO. 1</u>
)	

In Case Management Order One (“CMO-1”), the MDL Court chose three “Track One” cases for discovery and trial: (1) *The County of Summit, Ohio v. Purdue Pharma L.P.*, Case No. 18-OP-45090 (N.D. Ohio); (2) *The County of Cuyahoga v. Purdue Pharma L.P.*, Case No. 17-OP-45004 (N.D. Ohio); and (3) *City of Cleveland v. AmerisourceBergen Drug Corp.*, Case No. 18-OP-45132 (N.D. Ohio). The Manufacturer-Defendants served their first set of requests for production (“RFPs”) on Plaintiffs. Plaintiffs objected to RFPs 6, 7, and 11 and, according to defendants, “refused to produce entire categories of plainly relevant and responsive documents.” Letter from Liaison Counsel Mark Cheffo to Special Master David R. Cohen (June 5, 2018) (“Cheffo letter”). Accordingly, the undersigned engaged in an on-the-record discovery teleconference and heard argument regarding these three RFPs. The Special Master now rules on Plaintiffs’ objections.

The common theme of the three RFPs at issue is that defendants seek highly detailed information related to all individuals who received or were harmed by opioids. This includes: (a) medical records, insurance records, pharmacy records, and test results for “any person [whom]

Plaintiff claims was harmed in any way by any Defendant;” (b) documents referring to “any patient[s] whom Plaintiff believes received, obtained, or were harmed by any improper or medically unnecessary prescription for an Opioid;” and (c) the full history of claims submitted to Medicaid “for all patients who received” an opioid prescription. RFPs 6, 7, 11.¹

Plaintiffs interpose three principal objections. First, Plaintiffs object that producing individualized medical information would “cause substantial harm to the strong privacy interests held by the individuals whose private medical files are legally protected under HIPAA and similar State laws. Response to RFP 6. The Special Master overrules this objection for the simple reason that the MDL Court entered a Protective Order, which was negotiated by the parties, that addresses these concerns. *See, e.g.* CMO-2 §XII (discussing discovery of “Protected Health Information”) (docket no. 441). The parties have agreed upon – and, if necessary, can agree upon additional – procedural mechanisms, such as redaction, to produce the requested discovery while protecting individuals’ privacy interests.²

Second, Plaintiffs object that the information requested simply has “no relevance to the claims and defenses in this litigation.” Response to RFP 6. Plaintiffs explain they are “not claiming any damages for *personal harm* suffered by any individual or group of individuals who were harmed by Defendants’ conduct, and the claims asserted by Plaintiff do not require a showing that

¹ The full text of RFPs 6, 7, and 11, and Plaintiffs’ responses thereto, is set out at the end of this *Discovery Ruling*.

² Plaintiffs recently wrote a letter to defendants setting out what information they believed they were allowed to “produce in light of the complex set of federal and state statutes, regulations and case law governing medical privacy, and to determine whether additional safeguards are necessary,” and “welcom[ing] further discussion.” Letter from David Ackerman to various defense liaison counsel at 1 (June 11, 2018) (“Ackerman Letter”). The Special Master directs the parties to continue to meet and confer in order to address and resolve these issues.

any third-party individuals were harmed.” *Id.* (emphasis added). Thus, Plaintiffs’ assert, Defendants simply do not need “information on every person who received a prescription of opioids, . . . every person who became addicted to opioids, . . . every ‘improper or medically unnecessary’ opioid that made its way into the [plaintiff] jurisdictions[, and] information on every single . . . [opioid] prescription that was ever written at any time in the jurisdictions.” Letter from Liaison Counsel Paul Hanly, Jr. to Special Master David R. Cohen at 15 (July 5, 2018) (“Hanly letter”).

This objection is largely well-taken: Defendants RFPs are clearly overbroad. *See, e.g.*, RFP 6 (requesting “with respect to **any** person that Plaintiff claims was harmed in **any** way by **any** Defendant, **all** Documents concerning each such person’s medical history [and] medical treatment . . . and **any** other records relating to the use of **any** prescription or over-the-counter medications or illicit drugs”) (emphasis added). The question that remains, however, is to what extent Defendants are entitled to **some** of what they seek. Ultimately, this question implicates the issue of causation: to prove some or all of their claims (and damages flowing therefrom), do Plaintiffs have to show defendants instigated specific doctors to write individual opioid prescriptions that were improper or medically unnecessary, and show how that prescription caused harm to the plaintiff jurisdiction? If so, the individual patient medical records are arguably relevant. Or is it sufficient for Plaintiffs to adduce aggregate evidence and statistics showing defendants caused doctors’ overall prescribing practices to become increasingly improper or medically unnecessary? If so, individual patient medical records are of limited relevance. Plaintiffs state they intend to pursue the latter course. *See* Hanly letter at 17 (“Plaintiffs will prove causation through aggregate proof demonstrating the link between Defendants’ . . . conduct and the exponential increase in prescribing and diversion of opioids and the resulting harms on a jurisdiction-wide basis.”); *id.* at 19 (“it is likely that Plaintiffs

will rely on expert testimony and statistical and aggregate evidence”). There is case law suggesting this approach may be permitted. *See People v. Conagra Grocery Prod. Co.*, 227 Cal. Rptr. 3d 499, 557 (Ct. App. 2017) (affirming the trial court’s determination that defendants’ promotion of lead-based paint for interior residential use caused a public nuisance, and rejecting manufacturers’ contention that they were denied due process when the trial court rejected discovery “to inspect each individual property and defend against their liability on a residence-by-residence basis.”).³

The ultimate question of the requisite level of proof is an issue the Court may have to answer at a future stage of litigation, perhaps through orders resolving summary judgment or *Daubert* motions. At this juncture, it is possible only to observe that Plaintiffs’ current discovery productions must equal or surpass the proofs that will eventually be required. In other words, if Plaintiffs are correct that statistical and aggregate evidence is sufficient, then Plaintiffs must now produce all available statistical and aggregate evidence, and enough supporting particulars to allow the Court

³ The *Conagra Grocery* court also noted that discovery into each residence with interior lead-based paint would be so expensive that it was inappropriate to require plaintiffs to produce it. *See id.* at 558 (“Plaintiff established the existence of a public nuisance by proving that these conditions are pervasive in the 10 jurisdictions, but the enormous cost of discovering each and every one of the specific locations where remediation is necessary must be borne by the wrongdoers, in this case defendants.”). Plaintiffs in this case make a similar “cost argument” regarding discovery of records related to each opioid prescription and patient. *See* Response to RFP 7 (“Plaintiff objects that the burden of responding to this Request is not proportional to the needs of the case considering: (i) the marginal importance of the materials to the claims and defenses in this litigation, and (ii) the substantial cost to produce responsive materials.”).

Defendants cite class action cases for the proposition that they are “entitled not only to the damages information that Plaintiffs choose to produce as part of their damages calculations, but also to materials that relate to those claimed damages, such that Defendants can evaluate and test Plaintiffs’ claims.” Cheffo letter at 4, 3 (citing *Fox v. Cheminova, Inc.*, 2006 WL 5080807 (E.D.N.Y. Mar. 1, 2006) and *Powell v. Tosh*, 2011 WL 13210026 (W.D. Ky. Aug. 2, 2011)). The Track One cases are not class actions, however, and *Conagra* rejected class action principles as support for the contention that aggregate discovery was insufficient. *See Conagra*, 227 Cal. Rptr. 3d at 558 (individualized discovery is not appropriate because “[t]his is not a class action, and [like the Track One cases] no individuals seek to recover anything from defendants.”).

and Defendants and the parties' experts to understand the fundamental bases for those statistics and aggregated data; but Plaintiffs need not produce *all* discovery regarding *every* patient or *every* opioid prescription. This quantum of evidence is certainly less than what Defendants have requested, but also much more than nothing at all. Conversely, if Plaintiffs are incorrect, and the Court ultimately requires more granular proof of causation than Plaintiffs produce in discovery, then Defendants will rightly point to Plaintiffs' responses to the RFPs as a basis for defense judgment.

This leads to Plaintiffs' third principal objection: the RFPs are "not proportional to the needs of the case considering: (i) the marginal importance of the materials to the claims and defenses in this litigation, and (ii) the substantial cost to produce responsive materials." Response to RFP 11. The Special Master agrees that, because the RFPs are overbroad, and because retrieving much of the requested information would be very expensive, the RFPs as drafted are not proportional to the needs of the case. The Special Master also agrees with Defendants, however, that, at the very least, aggregate and statistical data addressing the information sought through RFPs 6, 7, and 11 is relevant. Indeed, Cuyahoga County has already produced charts and analyses of opioid deaths and overdoses, and has promised more detailed information underlying these summaries, and agrees that this evidence is relevant.

In the end, the Special Master cannot simply overrule nor sustain Plaintiffs' objections. Defendants request too much, and Plaintiffs have so far produced too little. Rather, the Special Master can only issue the following directives. Plaintiffs must accelerate their responsive discovery production, and must produce to defendants all relevant aggregate data and statistics. Plaintiffs must also undertake a good-faith effort to produce sufficient supporting particularized evidence to allow Defendants and their experts to understand the fundamental bases for these statistics and aggregated

data.⁴ If the parties later have more detailed disputes, the Special Master will address them at that time. When Plaintiffs later seek to prove causation or damages at trial, whether through expert testimony regarding a statistical model or otherwise, Plaintiffs may not rely affirmatively or defensively on any evidence or data they did not produce during discovery.

Finally, the Special Master notes that ¶9.1.iii of CMO-1 sets out the following requirement: each Plaintiff in a Track One case “that alleges money damages based upon unnecessary prescriptions shall identify: (a) the prescriptions that each Plaintiff asserts were medically unnecessary or medically inappropriate, to whom they were written, and whether Plaintiff reimbursed for them; (b) the physicians or healthcare providers who wrote the prescriptions; and (c) Plaintiff’s basis for identifying the prescriptions that it asserts are medically unnecessary or medically inappropriate.” This requirement remains in place. A plaintiff who fails to fulfill this requirement: (1) forfeits any claim for money damages based upon unnecessary prescriptions; and (2) may face argument that the lack of this evidence also breaks a necessary link in the chain of causation for some or all claims.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen

David R. Cohen
Special Master

Dated: June 11, 2018

(RFPs 6, 7, and 11, and Plaintiffs’ responses thereto, are set out in the following pages)

⁴ Plaintiffs’ recent offer to produce de-identified medical claims data is a good start. Ackerman Letter at 4-5.

RFP No. 6

With respect to any person that Plaintiff claims was harmed in any way by any Defendant, all Documents concerning each such person’s medical history, medical treatment, medical examinations, medical tests, therapy, injuries, diagnoses, or medical condition during the last ten years, including any Health Care Provider’s reports, records, summaries, test results, medical records, insurance records, pharmacy records, and any other records relating to the use of any prescription or over-the-counter medications or illicit drugs.

Response to RFP No. 6:

Plaintiff objects to this request as overly broad and improper in that the materials sought have no relevance to the claims and defenses in this litigation. Plaintiff is not claiming any damages for personal harm suffered by any individual or group of individuals who were harmed by Defendants’ conduct, and the claims asserted by Plaintiff do not require a showing that any third-party individuals were harmed. Moreover, producing such individualized medical information would waste resources and cause substantial harm to the strong privacy interests held by the individuals whose private medical files are legally protected under HIPAA and are the subject of this Request.

To the extent Plaintiff misunderstands the documents and communications sought by this Request, Plaintiff seeks to resolve these issues during the meet and confer process with Defendants. Also, the Request is overly broad and unduly burdensome and seeks information beyond Plaintiff’s possession, custody, and control. Further objecting, the Request contains a reference to several undefined terms and phrases, namely, “over-the-counter medications” and “illicit drugs.”

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.

RFP 7

All Documents and communications identifying, referring to, or concerning any Patient whom Plaintiff believes received, obtained, or were harmed by any improper or medically unnecessary prescription for an Opioid.

Response to RFP No. 7:

Please see Response to Request No. 6.

Plaintiff objects to this Request to the extent that it calls for information beyond Plaintiff’s possession, custody, and control. To the extent that there are any non-privileged, responsive documents in Plaintiff’s possession, custody or control, Plaintiff objects that the burden of responding to this Request is not proportional to the needs of the case considering: (i) the marginal importance of the materials to the claims and defenses in this litigation, and (ii) the substantial cost to produce responsive materials. The materials have marginal—if any—importance to the claims and defenses in this litigation because Plaintiff is not claiming any damages on behalf of any individual or group of individuals who were harmed by Defendants’ conduct, and the claims asserted by Plaintiff do not require a showing that any third-party individuals were harmed. Moreover, producing such information would cause substantial harm to the strong privacy interests held by the individuals whose private and legally protected medical files are the subject of this Request.

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.

RFP 11

Participant-level claims data showing the full Medicaid or other Program claims history for prescriptions and other health care services submitted to Medicaid or any other Program, whether reimbursed or not, for all Patients who received a prescription for one or more of the Opioids at issue in this litigation.

Response to RFP No. 11:

Plaintiff incorporates its answer to RFP No. 6.

Plaintiff objects to the extent that this Request is overly broad and improper in that it seeks information protected by statute(s) or ordinance(s) that restrict Plaintiff's ability to disclose the requested information. Plaintiff further objects to this Request to the extent that it calls for disclosure of Privileged and Confidential Information. Plaintiff objects insofar as the Request seeks information that is not relevant to any party's claim or defense. Also, the Request contains an undefined term, "other health care services" and calls for disclosure of Privileged and Confidential Information. In order to respond to such Request, Plaintiff would have to undertake an incredibly time consuming and expensive review process and burden not relevant to the claims or proportional to the needs of discovery.

To the extent that Plaintiff will seek damages relating to the participant-level claims that are the subject of this Request, Plaintiff already will provide information that it lawfully may disclose regarding such claims in response to Request No. 2.

To the extent Plaintiff does not seek damages relating to such participant-level claims, Plaintiff objects that the burden of responding to this Request is not proportional to the needs of the case considering: (i) the marginal importance of the materials to the claims and defenses in this litigation, and (ii) the substantial cost to produce responsive materials. The materials will have marginal relevance—if any—should Plaintiff choose not to pursue damages relating to such claims, because in such circumstance, the individual Program claims submitted by individuals will not be a factor in proving or defending Plaintiff's claims. Conversely, there would be substantial cost in gathering the many thousands of claims and de-identifying the personally identifiable information that would be necessary for disclosure. Therefore, Plaintiff is unable to produce documents pursuant to this Request.

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.