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 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.,
Case No. 17-op-45004 (N.D. Ohio)

"Track One-B Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

PHARMACY DEFENDANTS' MOTION FOR RECONSIDERATION OF THE COURT'S ORDER REGARDING SCOPE OF TRACK ONE-B AND SUPPORTING MEMORANDUM

Pursuant to Federal Rule of Civil Procedure 54(b), Pharmacy Defendants[1] hereby move for reconsideration of the Court's December 10, 2019 Order Regarding Scope of Track One-B (Doc. 2976) ("Order"), requiring Pharmacy Defendants to produce to Plaintiffs highly sensitive patient information in the form of detailed records of prescriptions dispensed by Pharmacy Defendants across the entire United States for the last twenty-three years. The Order was entered without any briefing, argument, or process and runs afoul of the Federal Rules of Civil Procedure and applicable law.

[1] "Pharmacy Defendants" are CVS Rx Services, Inc., CVS Indiana, L.L.C., CVS Pharmacy, Inc., and Ohio CVS Stores, L.L.C. ("CVS"), Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center, Rite Aid of Ohio, Inc., and Rite Aid Hdqtrs. Corp. ("Rite Aid"), Walgreen Co. and Walgreen Eastern Co. ("Walgreens"), HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"), Discount Drug Mart ("DDM"), and Walmart Inc. ("Walmart").

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STATEMENT OF ISSUES AND SUMMARY OF ARGUMENT

The Plaintiffs in the cases that have been designated as "Track 1B" are two Ohio counties—Cuyahoga and Summit. The Order requiring Pharmacy Defendants to "produce transactional dispensing data for the entire United States from 1996 forward" is grossly disproportionate to the needs of these Track 1B Plaintiffs and was imposed without due consideration of "whether the burden or expense of the proposed discovery outweighs its likely benefit," as Federal Rule of Civil Procedure 26(b)(1) requires. The Court clearly erred by ordering a vast and unprecedented production of private personal medical records without any consideration for the privacy interests at stake, the geographically narrow needs of the Track 1B cases, or whether the burden on Pharmacy Defendants is appropriate, particularly given that the relevant data could be more efficiently obtained by subpoena from the State of Ohio's Automated Rx Reporting System ("OARRS").

The Court gave two reasons for ordering Pharmacy Defendants to produce over two decades of records of every single prescription filled—nationwide—for a host of medications. Both are premised on mistakes of fact. First, the Court suggested that it was just matching for Pharmacy Defendants the nationwide discovery burden that Distributor Defendants bore in Track 1, but that is incorrect. In fact, Distributor Defendants *did not disclose nationwide data in Track 1*. On the contrary, the Court ordered Distributor Defendants to produce customer-specific information only for Cuyahoga and Summit Counties, a limited geographic scope this Court found proportional to the needs of the case. Doc. 762 at 3. Pharmacy Defendants' discovery burden likewise should be limited to the two Plaintiff Counties. Second, this Court attempted to explain its ruling by drawing an analogy to DEA's production of transaction-level ARCOS distribution data in Track 1. Doc. 2976 at 2. That analogy is flawed, however, because this

Court ordered DEA to produce transaction-level ARCOS data dating only *from 2006 to 2014*—*not* back to 1996, and *not* after 2014. Doc. 233 at 1. It directed the production of only eight, not twenty-three, years of data.

Beyond these foundational mistakes of fact, the analogy between distribution and dispensing is entirely inapt. For at least three reasons, discovery of transaction-level dispensing records must be ordered narrowly and with particular care.

First, transaction-level dispensing data implicates substantial individual interests in medical privacy—interests protected by both constitutional and statutory frameworks. Unlike wholesale-distribution records, which involve transactions between *wholesalers* and pharmacies, dispensing records involve highly sensitive transactions between *individuals* and pharmacies. Dispensing records held by pharmacies are protected health information under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and various state regimes, which means that pharmacies should limit disclosures to the "minimum necessary" to accomplish the disclosure's purpose. 45 C.F.R. § 164.502(b). Despite these critical privacy interests, the Court ordered the maximum possible disclosure.

Second, Plaintiffs have shown no need whatsoever for data outside their counties. No matter how Plaintiffs attempt to prove their case, they will have to show that Pharmacy Defendants improperly filled prescriptions *in Cuyahoga and Summit Counties*—not elsewhere. Prescriptions filled in Portland, Phoenix, Pittsburgh, or Pensacola are irrelevant to Plaintiffs' claims. Pharmacy Defendants also have the right to take discovery at the prescription level: Whatever supposed red flags Plaintiffs attribute to particular prescriptions, Pharmacy Defendants must have the opportunity to show that licensed prescribers wrote them for legitimate medical purposes, and that patients used them appropriately, without causing harm to Plaintiffs. Indeed,

Pharmacy Defendants' defense depends on such discovery. But the scope of discovery will quickly spiral beyond the Court's vision for the case if Plaintiffs intend to dispute the propriety of twenty-three years' worth of prescriptions filled from coast to coast. Indeed, it will spiral even if twenty-three years' worth of prescriptions are at issue in the two counties alone. And the fact that the Track One-B cases are part of a larger MDL is no justification for ordering sweeping nationwide production, because the proper parameters of discovery are based on factors specific to each case.

Third, ordering Pharmacy Defendants to compile individual dispensing transactions is many orders of magnitude more burdensome than ordering DEA to produce an already-centralized database of wholesale distribution transactions. Not only are there exponentially more individual dispensing transactions, but also each record must be anonymized and assembled and prepared for production in a way that protects patient confidentiality. The Federal Rules of Civil Procedure require courts to limit the extent of discovery if what is sought "can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C). Because the data Plaintiffs need already resides in a single place—the OARRS database—and thus could easily be anonymized and produced in a standardized way, there is no reason to impose the time-consuming, costly burden on Pharmacy Defendants to assemble data sets from numerous computer systems. Moreover, only the OARRS database will provide prescription information from the large portion of the market *not* captured by Pharmacy Defendants—the independent pharmacies and other dispensers whom Plaintiffs chose not to sue but which dispensed a significant share of the prescription opioids in Cuyahoga and Summit Counties in the relevant timeframe.

Pharmacy Defendants respectfully ask this Court to amend its Order to require a more proportional production, and submit that, at this juncture, it would be appropriate to order Plaintiffs first to seek the requested Ohio dispensing data from OARRS.[2] To the extent that Plaintiffs show a need to supplement the OARRS data, Pharmacy Defendants submit that production of transaction-level dispensing data from the pharmacies should be limited to three years within the Plaintiff Counties, dating back from November 20, 2019, when Plaintiffs served their amended complaints after receiving leave, *see* Doc. 2940. Prescriptions filled outside of Cuyahoga and Summit Counties for patients who do not even in live in or travel to the counties are, by definition, irrelevant to Plaintiffs' claims. Likewise, prescriptions filled more than three years ago have little relevance to the remedy Plaintiffs will be seeking—abatement of an alleged nuisance as it exists at the time of trial. And in any event, if data on in-county prescriptions went back more than three years, the amount of third-party discovery the Pharmacy Defendants would be entitled to take certainly would massively outstrip the Court's stated vision for the case.

BACKGROUND

Plaintiff Counties seek discovery on dispensing claims that they expressly, repeatedly, and "purposefully" disavowed throughout 18 months of litigation. Doc. 2921 at 6; *see* Doc. 2924 at 1-5, 8-9 (reciting history of Plaintiffs' disavowals). Pharmacy Defendants opposed Plaintiffs' motion for leave to add dispensing claims because Plaintiffs could not show good cause for any amendment, as clear Sixth Circuit precedent requires. *See id.* at 7-8.

Plaintiffs propounded discovery requests on their amended claims on October 29, 2019—before the Court granted leave for their proposed amendments. *See* Doc. 2925-3 (discovery

[2] In fact, Pharmacy Defendants have already served a subpoena for the OARRS data on the Ohio Board of Pharmacy and will pursue the appropriate process to the extent the Board has refused to produce the data in a usable form.

requests); Doc. 2940 (leave to amend granted November 19, 2019). Among many other things, the requests sought "all dispensing data . . . related to the dispensing of opioids and 'cocktail drugs' dispensed from all pharmacies from January 1, 1996, to the present." Doc. 2925-3 at 2. The discovery requests demanded that Pharmacy Defendants "identify the drug name, prescription number, NDC number, date filled, quantity dispensed, dosage form, days' supply, MME, prescriber's name, prescriber's DEA number, dispensing pharmacist, patient's full name and address, patient's identification number, quantity prescribed, number of refills authorized (if any), diagnostic code, method of payment, patient paid amount, and whether the prescription was covered by third party payors." *Id*. Plaintiffs specified that their request for "electronically maintained dispensing transactional data" applied nationwide and extended "from 1996 through the present." *Id*. at 1.

On November 19, 2019—without holding a case management conference, and thus without receiving any input from any Pharmacy Defendants—the Court entered a Track One-B Case Management Order. Doc. 2940. The Order contemplated that document discovery would be "substantially complete" by January 31, 2020. *Id.* at 4. The Court set a schedule under which expert reports are due March 16, 2020, dispositive motions are due June 19, 2020, and jury selection begins October 7, 2020. *Id.* at 4-5. Pharmacy Defendants then requested a case management conference, Doc. 2952, which the Court held on Wednesday, December 4, 2019. *See* Minute Entry, Entered Dec. 5, 2019.

At the conference, the Court indicated that discovery would have to be limited to a reasonable scope and urged the parties to confer to agree to an appropriate approach. *See* Doc. 2966 at 55, 61. The Court further stated that twenty years of discovery would not qualify as reasonable, as the effort required to produce records for that period could well take several years.

See Doc. 2966 at 55-56, 61. Plaintiffs did not contest the point and suggested a number of possible cut-off dates, including 2006 or 2004. *Id.* at 56, 66.[3]

Following the case management conference, Special Master Cohen held additional proceedings with the parties concerning discovery. At the conference, the Special Master stated that, notwithstanding the Court's contrary statements, he was inclined to require discovery extending back to 1996. *See* Tr. of Procs. Before Special Master (Dec. 4, 2019), at 31.[4] The Special Master also indicated that he was inclined to expand discovery to a geographic area encompassing three states. *Id.* The Special Master stated that this was a starting presumption, which would be open to modification based on further information from the parties concerning the burdens associated with production. *Id.*

Then, on Monday, December 9, 2019, Special Master Cohen informed the parties by email that "[t]he Judge finally concluded that discovery of transactional data from the pharmacies should generally be analogous to the Track 1 transactional data discovery from the distributors—that is, the ARCOS data."[5] *See* E-mail from Special Master David R. Cohen to Counsel (Dec. 9, 2019), Ex. 1 at 1. Special Master Cohen then stated that "[t]he temporal scope will be back to 1996 (despite [the Judge's] suggestion otherwise at Friday's conference)." *Id.* And "[t]he geographic scope will be national." *Id.* The Court had apparently reached this

[3] Defendants also submitted a motion to ensure that ordinary rules regarding *ex parte* communications with the Court and Special Masters, including the Special Master charged with overseeing discovery, would be followed as the litigation proceeded. Doc. 2963. The Court denied the motion, stating that it would continue to meet on an *ex parte* basis with Plaintiffs to discuss issues related to settlement. Doc. 2966 at 71, 75.

[4] This transcript has not been docketed.

[5] As explained *supra* pp. 1-2, the ARCOS data was produced not by Distributor Defendants but by DEA, and was limited to 2006–2014. Distributor Defendants' transaction-data production was limited to the two Plaintiff counties.

conclusion *sua sponte*, for Pharmacy Defendants had not yet even asserted objections to Plaintiffs' written discovery requests and Plaintiffs had filed no motion to compel.

The next day, with no notice to or briefing from Pharmacy Defendants—and no filing with the Court from Plaintiffs—the Court issued an Order Regarding Scope of Track One-B (Dec. 10, 2019), Doc. No. 2976 ("Order"). On the scope of discovery, the Court stated that "[t]he ARCOS data that the Court ordered the government to produce in Track One, which included distribution data from all of the Distributor Defendants, extended backwards to 1996 and was national in scope." *Id*. at 2. "Accordingly," the Court ordered, "the Pharmacy Defendants shall produce transactional dispensing data for the entire United States from 1996 forward." *Id*.[6] "As quickly as possible," Pharmacy Defendants were instructed to "first produce Ohio data; then nearby regional data, including West Virginia and Kentucky; and then roll out data for the rest of the country." *Id.*

STANDARD

"District courts have authority both under common law and [Fed. R. Civ. P.] 54(b) to reconsider interlocutory orders and to reopen any part of a case before entry of final judgment." *Rodriguez v. Tennessee Laborers Health & Welfare Fund*, 89 F. App'x 949, 959 (6th Cir. 2004). Reconsideration is warranted where, among other things, "there is . . . a need to correct a clear error or prevent manifest injustice." *Louisville/Jefferson Cty. Metro Gov't v. Hotels.com, L.P.*, 590 F.3d 381, 389 (6th Cir. 2009) (quoting *Rodriguez*, 89 F. App'x at 959). A court may grant a

[6] In fact, the federal government (not Distributor Defendants) produced transaction-level ARCOS aggregate shipment data only from 2006 to 2014. *See* Doc. 1899-13 (McCann Report) at 14 ("The DEA produced a subset of ARCOS Data reflecting transactions in drug products containing one or more of fourteen drugs . . . from January 1, 2006, to December 31, 2014."); Doc. 233 at 1 (ordering the DEA to produce complete transactional ARCOS data "for the period of January 1, 2006 through December 31, 2014").

motion for reconsideration if it "calls . . . attention to an argument or controlling authority that was overlooked or disregarded in the original ruling, presents evidence or argument that could not previously have been submitted, or successfully points out a manifest error of fact or law." *Jackson v. City of Cleveland*, 219 F. Supp. 3d 639, 642 (N.D. Ohio 2016) (internal quotation marks omitted).

ARGUMENT

Under Federal Rule of Civil Procedure 26(b)(1), discovery must be "proportional to the needs of the case," considering both the "importance of the discovery in resolving the issues" and "whether the burden or expense of the proposed discovery outweighs its likely benefit." The discovery ordered here is the opposite—in the extreme. It sets the stage for an unprecedented invasion of personal privacy, bears no relation to Plaintiffs' burden of proof on their dispensing claims, and exceeds in breathtaking fashion the appropriate temporal and geographic scope.

I. The Order Requires A Massive Invasion Of The Medical Privacy Of Millions of Americans.

Unlike wholesale-distribution data, transaction-level dispensing data reveals an individual patient's intimate medical information. Congress recognized as much in protecting this information under HIPAA, and states have done so with similar laws. When a government entity seeks this information, as Plaintiff Counties do in this case, the Fourth Amendment (along with state constitutional equivalents) also protects patients' privacy interests. In addition, despite this Court's protective order and all efforts to anonymize the data covered by the Order, a massive assemblage of data is at risk of public disclosure. If disclosure were to occur, identities may be revealed from the data. In issuing the Order, this Court took no account of the risk of a large-scale invasion of medical privacy, and accordingly made no effort to tailor the ordered production to minimize that risk.

A. HIPAA and its Implementing Regulations Recognize The Importance of Protecting the Privacy of Patients' Health Care Data.

An individual's prescription records reveal substantial private medical information that goes well beyond the fact that the medication was prescribed. The transaction-level dispensing data covered by the Order includes prescription records for a number of frequently prescribed medications used to treat a wide range of serious (and, in some cases, stigmatized) medical conditions, including cancer, chronic and acute pain, opiate addiction, and fibromyalgia. Plaintiffs have requested that transaction-level dispensing data include not just information about the dosage and quantity of a particular drug, but also patients' full names and addresses, prescribers' names, fill dates, method of payment, and, where available, the diagnostic code associated with every prescription. *See supra* p. 5. Even without all of that data, diagnoses may be inferred from information contained in prescription records. *See Douglas v. Dobbs*, 419 F.3d 1097, 1102 (10th Cir. 2005). And even if anonymized, the data might readily be pieced back together into profiles that would invade individual patients' privacy. *See, e.g.*, Boris Lubarsky, *Re-Identification of "Anonymized" Data*, 1 GEO. L. TECH. REV. 202, 212 (2017) (explaining how "today's techniques of re-identification can nullify scrubbing and compromise privacy"); Natasha Lomas, *Researchers Spotlight the Lie of "Anonymous" Data*, TechCrunch (July 24, 2019), techcrunch.com/2019/07/24/researchers-spotlight-the-lie-of-anonymous-data (reporting research suggesting that "no 'anonymized' and released big data set can be considered safe from re-identification").

For good reason, this sensitive personal information is protected health information under HIPAA, *see* 45 C.F.R. § 160.103 (defining "protected health information"), and is also protected under similar state laws, *see,* Ohio Admin. Code § 4729:5-3-05 (Ohio regulation governing confidentiality of patient records held by certain licensed pharmacies); *see also, e.g.*, Cal. Civ.

Code §§ 56 *et seq.* (California Confidentiality of Medical Information Act); Tex. Health & Safety Code §§ 181.001 *et seq.* (Texas Medical Privacy Act). As such, the use, disclosure, and transmission of this information is tightly regulated, including under the HIPAA Privacy Rule. *See* 45 C.F.R. Parts 160 & 164. A central aspect of the Privacy Rule is the principle that the disclosure of protected health information should be limited to the "minimum necessary" to accomplish the intended purpose of the disclosure. 45 C.F.R. § 164.502(b). Even if this Court has the power to authorize the production of HIPAA-protected information, *see id.* § 164.512(e), the motivating purpose of HIPAA demands that the production of that information to be narrowly tailored to minimize the risk to patients' medical privacy.

B. The Fourth Amendment Protects Patients' Privacy Interest In Their Aggregated, Digitized Prescription Records from Unjustified Government Intrusion.

In ordering an arbitrarily expansive production of private personal medical information, this Court overlooked not only the applicable privacy-protecting statutory regime but also the applicable constitutional framework. The Fourth Amendment's "basic purpose . . . is to safeguard the privacy and security of individuals against arbitrary invasions by government officials." *Carpenter v. United States*, 138 S. Ct. 2206, 2213 (2018) (quoting *Camara v. Municipal Court of City and County of San Francisco*, 387 U.S. 523, 528 (1967)); *see also Katz v. United States*, 389 U.S. 347, 351 (1967) ("the Fourth Amendment protects people, not places"). It protects against invasive government action whenever a reasonable expectation of privacy exists, *see Smith v. Maryland*, 442 U.S. 735, 740 (1979), and an individual has such an expectation, the Supreme Court has recently made clear, in "detailed" and "encyclopedic" "digital data [about an individual] . . . maintained by a third party," *Carpenter*, 138 S. Ct. at 2214, 2217.

The privacy interests in sensitive patient information go without saying. *See, e.g.*, *Douglas*, 419 F.3d at 1102 (recognizing that "privacy in prescription records falls within a protected 'zone of privacy' and is thus protected as a personal right either 'fundamental' to or 'implicit in the concept of ordered liberty'" (citation omitted)); *Turk v. Oiler*, 732 F. Supp. 2d 758, 770 (N.D. Ohio 2010) ("As a general rule, an individual's medical records are confidential."). And the Sixth Circuit has recognized that "where [an] individual privacy interest is of constitutional dimension," that privacy interest must be balanced against "the public's interest in and need for the invasion of privacy." *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1061 (6th Cir. 1998).

Moreover, discrete information takes on a different character under the Fourth Amendment when—enabled by modern computing—it is aggregated and retroactively analyzed over a long period of time. *See Carpenter*, 138 S. Ct. at 2215 (citing *United States v. Jones*, 565 U.S. 400, 415 (2012) (Sotomayor, J., concurring)); *id.* at 2217 ("Mapping a cell phone's location over the course of 127 days provides an all-encompassing record of the holder's whereabouts. . . . These location records 'hold for many Americans the privacies of life.'" (quoting *Riley v. California*, 573 U.S. 373, 403 (2014)); *see also Riley*, 573 U.S. at 393 (recognizing that the "immense storage capacity" of modern cell phones means that they "implicate privacy concerns far beyond those implicated by the search of [physical items that might be found on an arrestee's person, such as] a cigarette pack, a wallet, or a purse").

Applying these principles to the Order, patients are entitled to Fourth Amendment protection in the transaction-level prescription data that Pharmacy Defendants have been ordered to produce to government entities—the Plaintiff Counties. The Order calls for the comprehensive production of decades of prescription records. Each individual record reveals

intimate medical information about the patient. And in the aggregate, a "deep repository of historical . . . information," *Carpenter*, 138 S. Ct. at 2218, presents a still greater threat to privacy, even if it is anonymized, given the risk of re-identification. *See supra* p. 9. Considering the irrelevance of the overwhelming majority of *nationwide* prescription records dating back *twenty-three years* to the case at hand, *see infra* Part II.A, the Order authorizes an unreasonable—and likely unconstitutional—search.

C. Because Production of Nationwide Prescription Records Implicates the Privacy Interests of Millions of Americans, It is Essential That This Production Be Reasonably Tailored to the Needs of This Case.

The Court's protective order can only reduce but not eliminate the grave risk to the medical privacy of the millions of Americans whose prescription history is contained within the ordered production. There is no assurance that this data—once assembled and handed over to Plaintiffs—will be secure from public release. This could happen by means of either a public records request, *see In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919, 926, 931 (6th Cir. 2019) (as Counties, Plaintiffs are subject to public records requests under Ohio law and good cause did not exist to prevent ARCOS data from being disclosed pursuant to such a request), or an unauthorized data breach, *see, e.g.*, *In re U.S. Office of Personnel Mgmt. Data Sec. Breach Litig.*, 928 F.3d 48, 49-50 (D.C. Cir. 2019) (recounting how "cyberattackers breached multiple [OPM] databases and allegedly stole the sensitive personal information [of twenty-one million] past, present, and prospective government workers"). Indeed, to safeguard against the risk of unauthorized data breaches, the HIPAA Security Rule tightly regulates how protected health information may be electronically stored and transmitted by covered entities. *See* 45 C.F.R.

§ 164.306.[7] Consistent with their legal obligations, Pharmacy Defendants are committed to good stewardship of their customers' privacy. *See* Arends Decl., Ex. 4 ¶ 7; Tsipakis Decl., Ex. 5 ¶¶ 6-8; Jones Decl., Ex. 7 ¶ 11. Plaintiffs, however, are not covered entities under HIPAA, *see* 45 C.F.R. § 160.103 (defining "covered entity"), and therefore are not subject to the same stringent requirements to safeguard data privacy and security. Plaintiffs may not be equipped to maintain these records under the high standards of confidentiality and security that Pharmacy Defendants employ.

If publicly released, the scale of the potential privacy invasion is staggering. Given the fields of data requested by Plaintiffs, *see supra* p. 5, nothing would prevent enterprising third parties from piecing together the opioid prescription history of any individual whose data was included—whether a public figure or a private citizen—or using the data for nefarious purposes. In light of these concerns, the Court should appropriately tailor the scope of any transaction-level dispensing data production. In issuing the Order, however, the Court conducted no tailoring analysis and provided no opportunity for Pharmacy Defendants to object to its scope.

II. The Burdens Imposed By The Order Bear No Relation to the Needs of the Case And Are Vastly Disproportionate To Its Benefits.

Finally, the geographic and temporal scope of the Order exceeds anything conceivably necessary to resolve Plaintiffs' claims. Nationwide discovery greatly magnifies the amount of data at issue: For instance, CVS has 82 stores in the Plaintiff Counties, but more than 9,900 stores nationwide; Rite Aid has 27 stores in the Plaintiff Counties, but approximately 2,443 stores nationwide; Walgreens has 52 stores in the Plaintiff Counties, but approximately 9,277 stores nationwide; and there are 11 Walmart pharmacies in the Plaintiff Counties, but more than

[7] No such law imposes standards governing the storage or transmission of transaction-level distribution data.

4,650 nationwide. *See* Boyd Decl., Ex. 2 ¶¶ 2-3 (CVS); Teague Decl., Ex. 3 ¶ 2 (Rite Aid); Arends Decl., Ex. 4 ¶ 2 (Walgreens); Jones Decl., Ex. 7 ¶ 4 (Walmart). And these burdens are all the greater given that the Order requires data for *all* these stores over a period of *twenty-three years*.

The Federal Rules emphasize that discovery must be "*proportional to the needs of the case*," Fed. R.. Civ. P. 26(b)(1), but Plaintiffs have shown *no* need for nationwide data dating back twenty-three years. First and foremost, Plaintiffs have shown no need for data from outside their counties. And even if they had, the burdens of such a production are out of all proportion to any such benefits. Pharmacy Defendants estimate that querying and processing such a large amount of information from their databases will take, at minimum, several months. By contrast, producing three years' worth of data for prescriptions dispensed in Cuyahoga and Summit Counties could likely be done within approximately six weeks, requiring substantially less delay in the briefing and trial schedule set for the Track One-B cases. *See infra* p. 19. Finally, the Ohio Board of Pharmacy already keeps the needed data in a single database, and could provide more complete data—including dispensing data for non-party pharmacies—at far less expense.

A. Plaintiffs Have Shown No Need for Dispensing Data From Outside Their Counties.

The Order fails Rule 26's proportionality requirement at the outset because Plaintiffs have identified *no* need for the data. Nor could they. Plaintiffs are challenging the filling of prescriptions *in Cuyahoga and Summit Counties*—not in Anchorage or Tulsa or Miami. After all, it is in their own counties that Plaintiffs allege the dispensing conduct created a public nuisance. What is more, regardless of how Plaintiffs attempt to prove their case, there is no dispute that Pharmacy Defendants have the right to take discovery at the prescription level to show that, regardless of any supposed red flags Plaintiffs may attribute to particular

prescriptions, licensed prescribers wrote them for legitimate medical purposes, and patients used them appropriately, without causing harm to Plaintiffs. This proof is entirely local, and no need exists for data from farther afield. And this is to say nothing of the burdens of producing needless data.

B. Extending Discovery To 1996 Will Impose Significant Burdens On The Parties, But Will Yield Slight Benefits To Plaintiffs.

The staggering temporal scope of the Order—requiring nationwide data for a period of *twenty-three years*—will impose extraordinary burdens. But the first and most significant defect in the Order's temporal scope is that it appears to be based on a misunderstanding. The Order states that "[t]he ARCOS data that the Court ordered the government to produce in Track One . . . extended backwards to 1996." Doc. 2976 at 2. But that is not so. Rather, the DEA's production of ARCOS data covered a period from January 1, 2006, through December 31, 2014, *see* Doc. 1899-13 at 14 (ECF pagination), which appears to be why the allegations in the Interlineated Complaint focus on that same period, *see* Doc. 2943 at 1. If the Court wanted to ensure that dispensing data was congruent with distribution data, the appropriate discovery period would likewise extend from 2006 to 2014.

In any event, there is no reason why dispensing and distribution data need to cover the same period, and critical differences necessitate a more limited approach. First, distribution data concerns wholesale orders, each of which is used to fill multiple prescriptions. Dispensing data, by contrast, covers many more transactions; includes more information on each transaction (since each involves a particular patient); and is therefore more voluminous, and costly to process, by orders of magnitude. *See* Boyd Decl., Ex. 2 ¶ 2 (CVS Pharmacy Data Warehouse contains data on well over 10 billion prescription fills, including numerous data fields for each); Teague Decl., Ex. 3 ¶ 4 (estimating that Rite Aid's data warehouse contains data on more than 3

billion prescription fills); Arends Decl., Ex. 4 ¶ 4 (Walgreens dispensing data includes more than 8.4 billion prescriptions); Tsipakis Decl., Ex. 5 ¶ 5 (in the year 2017 alone, Giant Eagle pharmacies dispensed medications pursuant to a prescription more than 22.7 million times); Jones Decl., Ex. 7 ¶ 6 (one year's worth of Walmart's dispensing data includes approximately 310 million to 480 million unique rows of data). Moreover, with ARCOS, the Court was dealing with a single, centralized database in a single entity's possession (the federal government's), meaning the cost of production was relatively contained. By contrast, because not all Pharmacy Defendants' current computer systems have data extending back for years, the requested data does not all exist in transferable form, and compiling the data will be a time-consuming process. *See* Miller Decl., Ex. 6 ¶ 5. *See, e.g.*, *U.S. ex rel. Carter v. Bridgepoint Educ., Inc.*, 305 F.R.D. 225, 239 (S.D. Cal. 2015) (explaining that archived data may be "inaccessible" insofar as the "expenditure of resources required to access the contents is itself unreasonable"); *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 320 (S.D.N.Y. 2003) (similar). Producing many years of dispensing data, far from being achieved by the click of a button, would require months of work by IT professionals. *See* Boyd Decl., Ex. 2 ¶ 5; Teague Decl., Ex. 3 ¶¶ 6-8; *see also infra* pp. 19-20.

This burden is magnified further by the fact that much of the requested data is protected health information subject to HIPAA and state analogs. *See, e.g.*, *Lillard v. Univ. of Louisville*, No. 3:11-CV-554-JGH, 2014 WL 12725816, at *18 (W.D. Ky. Apr. 7, 2014) (discovery would not be ordered where request was "unduly burdensome and involves a potential HIPAA violation"). The imperative of protecting patient privacy is relevant to the scope of the discovery burden imposed on Pharmacy Defendants because it will require Defendants to develop systems to anonymize the data and then to double-check the data to ensure it was fully anonymized. *See*

Arends Decl., Ex. 4 ¶¶ 7-8; Jones Decl., Ex. 7 ¶¶ 11-13. Producing the data covered by the Order will also likely require some Pharmacy Defendants to work with third-party vendors to compile the data and prepare it for production. *See* Boyd Decl., Ex. 2 ¶ 5; Teague Decl., Ex. 3 ¶ 8; Miller Decl., Ex. 6 ¶ 5. Ensuring that these vendors have appropriate security controls in place to protect patient privacy increases the burden still more. *See* Tsipakis Decl., Ex. 5 ¶¶ 6-10.

Meanwhile, against all these burdens, Plaintiffs have made no showing as to why they would need this extraordinary amount of data. *See, e.g.*, *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, No. 11 CIV. 0071 (PGG), 2015 WL 13649823, at *4 (S.D.N.Y. July 29, 2015) (rejecting discovery beyond time period alleged in complaint and citing cases in accord). None of the dispensing-related allegations in the Interlineated Complaint focus on conduct from 1996; to the contrary, the very first paragraph of the Interlineated Complaint frames its allegations as focused on a period "from 2006 to 2014." Doc. 2943 at 1; Doc. 2944 at 1. The Interlineated Complaint includes specific factual allegations over roughly that same period. *See, e.g.*, Doc. 2943 at ¶¶ 16, 20, 29, 31, 37, 39, 50, 54, 59, 69, 83, 93, 98, 102. And even for periods encompassed by the allegations in the Interlineated Complaint, Plaintiffs have not made any showing that they actually require data for *all* transactions from the *entire* period to prove their case. Perhaps for this reason, when this Court initially indicated that discovery would not extend back so far, Plaintiffs did not even attempt to object. *See supra* pp. 5-6.

On top of all this, the burdens associated with the Order's temporal scope will be magnified many times over by the individualized nature of the inquiry in the dispensing context. If the Order's temporal scope suggests that Plaintiffs can pick out individual prescriptions from 1996 and argue that those prescriptions were erroneously filled, then fairness will dictate that

Pharmacy Defendants must have an opportunity to conduct discovery to prove the opposite. Even setting aside the difficulty of that kind of historical inquiry—where witnesses may be unavailable, memories may have faded, and medical records may have been destroyed[8]—the sheer volume of discovery Pharmacy Defendants will need to take will proliferate in a way that will necessarily exceed the volume of discovery the Court envisions for the case.

As explained below, to the extent that Plaintiffs and the Court believe it is important to obtain transaction-level dispensing data, the most cost-effective way to do so would be to order the Ohio Board of Pharmacy to comply with the subpoena Pharmacy Defendants have already served. *See infra* pp. 22-23. And, to the extent that Plaintiffs need to supplement the data produced with data obtained directly from Pharmacy Defendants, it would be reasonable to limit that discovery to the needs of the case, given the privacy interests at stake and the burden involved. To that end, Defendants have proposed discovery extending back for a period of three years, which, in addition to significantly narrowing the privacy interests at stake, would greatly reduce the cost (in both time and dollars) associated with the Order.

C. Nationwide Discovery Is Completely Disproportionate To Plaintiffs' Claims In The Track One Suits.

The Order's temporal scope is exceeded only by its geographic scope, as the Order directs Pharmacy Defendants to produce data for all their stores across the entire country, even though these Track One suits concern just two counties in Ohio.

First and most important, the Order's geographic scope (like its temporal scope) is based on a misunderstanding of the scope of previous discovery. While ARCOS data is indeed national in scope, that data was obtained from the federal government, which maintains a

[8] Under Ohio law, doctors are not required to keep their records for more than six years. *See* Ohio Admin. Code § 3701-83-11(F).

national database—not from the Distributor Defendants. The Court's prior discovery orders limited discovery of Defendants' distribution data to only Cuyahoga and Summit Counties, explaining that a broader geographic scope was "not proportional to the greatest needs and burdens of the parties." Doc. 762 at 3. If the Court seeks to align distribution and dispensing discovery, discovery here should likewise be limited to the Plaintiff Counties.

As in the context of distribution, nationwide discovery would impose burdens entirely out of proportion to the needs of the case. *See, e.g.*, *United States ex rel. Conroy v. Select Med. Corp.*, 307 F. Supp. 3d 896 (S.D. Ind. 2018) (rejecting proposed nationwide discovery as unduly burdensome and citing other cases in accord). Nationwide discovery greatly magnifies the amount of data at issue, in some cases increasing the number of stores at issue more than a hundred-fold. *See supra* pp. 13-14.

An average pharmacy store records as many as 2,000 prescription-filling transactions each week, or approximately 100,000 per year. *See, e.g.,* Jones Decl., Ex. 7 ¶ 6. Pharmacy Defendants estimate that it will take several weeks to collect and process information concerning three years' worth of prescriptions dispensed in Cuyahoga and Summit County alone. *See* Teague Decl., Ex. 3 ¶ 6; Tsipakis Decl., Ex. 5 ¶ 9; Jones Decl., Ex. 7 ¶ 9. On a nationwide basis, however, the number of prescriptions—and corresponding amount of data—increases exponentially. Production of nationwide data would be expected to take several months, at the very least. *See* Boyd Decl., Ex. 2 ¶ 5 (estimating six to nine months for CVS to collect and produce nationwide data); Teague Decl., Ex. 3 ¶ 7 (estimating three to five months for Rite Aid to collect and produce nationwide data); Arends Decl., Ex. 4 ¶ 8 (estimating six to eight months for Walgreens to collect and produce nationwide data); Jones Decl., Ex. 7 ¶ 10 (estimating four to eight months for Walmart to collect and produce nationwide data). A request of this

magnitude will tax Pharmacy Defendants' computer systems and will have to be carefully engineered to prevent interfering with normal pharmacy operations. Having never before been required to query and process such a large amount of information from their active databases, Pharmacy Defendants might encounter unforeseen obstacles, further increasing the time needed. *See* Arends Decl., Ex. 4 ¶ 8; Jones Decl., Ex. 7 ¶¶ 7-10. And, again, these burdens are magnified further by the need to ensure that all this data protects patients' privacy, through appropriate anonymization.

The Court has previously suggested that nationwide discovery is justified by the fact that discovery is being ordered in the context of an MDL, but the existence of an MDL cannot justify discovery untethered from the needs of a particular case. "[W]hen the purpose of a discovery request is to gather information for use in proceedings other than the pending suit, discovery properly is denied." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 352 n.17 (1978); *see also In re Korean Air Lines Co., Ltd.*, 642 F.3d 685, 699 (9th Cir. 2011) ("A district judge exercising authority over cases transferred for pretrial proceedings inherits the . . . pretrial jurisdiction that the transferor district judge would have exercised if the transfer had not occurred." (internal quotation marks and citation omitted)). Not every Pharmacy Defendant is a defendant in a case in every State; to the contrary, some Pharmacy Defendants are not properly named as parties to *any* cases outside of Ohio. *See* Tsipakis Decl., Ex. 5 ¶ 3. Likewise, many jurisdictions have brought suits against Pharmacy Defendants in state court and thus outside of this MDL, and in most cases discovery has not commenced. Because the Order directs discovery without first considering whether it is proportional to the needs of a particular case, it will impose discovery burdens that are unrelated to *any* active case—in the MDL or elsewhere—and is thus unreasonable on its face.

Moreover, nationwide discovery is particularly inappropriate because Plaintiffs have never sought to proceed with their claims on a nationwide basis. Plaintiffs have never filed a consolidated master complaint in the MDL, even though that is a common procedure. *See, e.g.*, *Gelboim v. Bank of Am. Corp.*, 135 S. Ct. 897, 904 n.4 (2015). And that is for good reason: Plaintiffs have brought different claims in different states, based on different laws and common law doctrines, and cannot proceed based on the same legal theories in every case. In the dispensing context, for instance, regulation of pharmacists varies state to state, and dispensing is an inherently local practice insofar as it depends on an individual pharmacist's assessment of an individual prescription. *See supra* pp. 14-15. Absent some showing by Plaintiffs that they actually need nationwide discovery to pursue their claims in these disparate actions, the Court cannot simply assume that is the case.

Even beyond these considerations, the Order also makes the burdens on the parties wildly asymmetrical: While Plaintiffs are allowed nationwide discovery, Pharmacy Defendants will be allowed to take discovery from two Ohio counties at best. *See Swanson v. Citibank, N.A.*, 614 F.3d 400, 411 (7th Cir. 2010) (Posner, J., dissenting in part) (discussing concerns with "asymmetric discovery burdens"). This asymmetry gives rise to serious due process concerns: Plaintiffs will no doubt seek to draw inferences based on this nationwide discovery, which they will then use in an attempt to impose liability in this case and to extract a global settlement, but Pharmacy Defendants will have no corresponding opportunity to develop a nationwide factual record to counter Plaintiffs' claims.

Given all the above, a more appropriate scope for discovery would be to order production of transactional data related to the two Plaintiff Counties, while preserving the right of Plaintiffs to craft more limited discovery requests seeking more targeted information at a national level.

This more limited scope would be appropriately tailored to the actual allegations in the case and symmetrical with both previous discovery in this case and the discovery available to Pharmacy Defendants.

D. Where Relevant Information Is Available From A State Board Of Pharmacy, Pharmacy Defendants Should Not Be Required To Produce It.

Finally, under the Federal Rules, "the court *must limit* the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that . . . the discovery sought . . . can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C) (emphasis added). Accordingly, the "amount of discovery of electronically stored information that should be permitted . . . will be a function of . . . whether the discovery sought is available from alternative sources that are less burdensome." *Hopson v. Mayor & City Council of Baltimore*, 232 F.R.D. 228, 244 (D. Md. 2005).

To the extent that Plaintiffs do need the data in question, the appropriate way for them to get it is for this Court to enforce the subpoena that has already been served on the Ohio Board of Pharmacy for OARRS data—just as Plaintiffs subpoenaed ARCOS data from the Department of Justice. *See supra* p. 4 n.2. OARRS provides a far superior source of the relevant information than Pharmacy Defendants. Not only would it be less burdensome to obtain the data from an existing database, but the information maintained by the Ohio Board of Pharmacy (or by the board of pharmacy for any other state that this Court might find to be relevant to Plaintiffs' case) is also far more complete because it includes non-party pharmacies. It is impossible to get a meaningful picture of the marketplace based on information that only includes the particular companies Plaintiffs have selected as defendants, particularly as Plaintiffs have not sued the independent pharmacies most likely to engage in misconduct. *See, e.g.*, Doc. 1983-17 (Ranazzisi

Dep. Tr.) at 198:23-25 (discussing "rogue pharmacies . . . that were operating independently in the neighborhoods and communities"). Where complete data is available, it makes no sense to force Pharmacy Defendants to undertake extraordinary efforts to assemble a less-complete data set.

CONCLUSION

For the foregoing reasons, Pharmacy Defendants ask this Court to amend its Order. The data Plaintiffs seek should be obtained, if at all, from OARRS. Then, if necessary, the Court should order a more proportional production from Pharmacy Defendants of three years of dispensing data covering Summit and Cuyahoga Counties.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on December 20, 2019.

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