UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	**JUDGE POLSTER**
	)	**ORDER REGARDING ARCOS DATA**

For the reasons and to the extent stated below, the Court now **ORDERS** the United States Drug Enforcement Agency ("DEA") to produce to the parties, no later than the close of business on Friday, April 20, 2018, certain data contained in the DEA's Automated Records and Consolidated Orders System/Diversion Analysis and Detection System ("ARCOS/DADS") database. Specifically, the DEA shall produce to the parties complete transactional ARCOS data, and also all Suspicious Order Reports, for the States of Ohio, West Virginia, Illinois, Alabama, Michigan, and Florida, for the period of January 1, 2006 through December 31, 2014. The ARCOS data produced pursuant to this Order shall be governed by the Protective Order previously entered at docket no. 167. Additional details regarding the scope and methods of production are discussed below.

I. Background.

One of the hundreds of cases that has been transferred by the Judicial Panel on Multidistrict Litigation to this MDL Court is *City of Cincinnati v. AmeriSourceBergen Drug Corp.*, case no. 2:17-CV-713 (S. D. Ohio) (MDL case no. 1:17-OP-45041) (hereinafter, "*Cincinnati*"). In October of 2017, when *Cincinnati* was still pending before the Honorable Edmund A. Sargus, the Court

authorized plaintiffs to send to DEA a "formal *Touhy* request" for "production of electronically stored information contained within the ARCOS/DADS database." Docket no. 81-1 at 2.[1] Plaintiffs sent to DEA a 19-page *"Touhy* letter," explaining precisely the information they sought and why they believed their request was consistent with *Touhy* regulations adopted by the Department of Justice at 29 C.F.R. §16.21-29. *Id.* Judge Sargus subsequently "granted [plaintiffs] permission to file a subpoena to be served upon the DEA for ARCOS database information," and also set a briefing schedule for objections to the subpoena. Docket no. 75 at 3. Judge Sargus specifically noted he was purposefully "teeing up" for early resolution – either by himself or, if the *Cincinnati* case was transferred into an MDL, the transferee court – the question of whether any objections to the subpoena were valid. *Id.* at 3-4.

The DEA did file objections, but also indicated it was "willing to continue discussions with Plaintiff concerning the disclosure of ARCOS data consistent with disclosures it has made to other requestors, e.g., state and local government entities." Docket no. 101 at 9. Accordingly, on February 2, 2018 – after *Cincinnati* was transferred into the MDL – this Court directed the "MDL Plaintiffs and the DEA to meet to see if they can reach agreement on what part of the ARCOS/DADS database the DEA will produce." MDL docket no. 112 at 2. The undersigned observed that "[t]here is a legitimate need for Plaintiffs to obtain this data, but the Court believes that production must be tailored – perhaps through a protective order – in a way to address the DEA's concerns regarding breadth, years in question, potential interference in investigations and enforcement actions, and divulging the location of warehouses where opioids are stored." *Id.* The

[1] In this Order, citations to "docket no." refer to the *Cincinnati* case docket, case no. 17-OP-45041 (N.D. Ohio), while citations to "MDL docket no." refer to the master MDL docket, case no. 17-MD-2804 (N.D. Ohio).

Court indicated the Plaintiffs and DEA should meet over the next three weeks and, on February 23, 2018, "file a report detailing their agreement or, if agreement has not been reached, the issues that remain to be resolved." *Id.* The Court further stated, "[i]f they are unable to reach agreement, the Court will hold a hearing . . . on Monday, February 26, 2018 at 3:00 p.m. to resolve the matter." *Id.*

On February 5, 2018, three days after the Court directed the parties to confer, Plaintiffs sent a letter to the government that: (1) reminded the government that Plaintiffs had earlier sent the 19-page *Touhy* letter, (2) asked for a prompt meeting, and (3) listed topics for discussion. *See* MDL docket no. 137-3. The topic list addressed the scope and process of data production, including: (a) data format; (b) data fields; (c) time limitations; (d) geographic limitations; (e) types of transactions by party; and (f) types of transactions by drug. *Id.* at 2-3.

As time passed with no response, Plaintiffs sent emails to government counsel on February 7 and February 10, 2018, again asking for the opportunity to meet and confer. On February 12, 2018, the government finally responded by reminding Plaintiffs that their request was "governed by the United States Department of Justice's *Touhy* regulations" and asking for "a summary of the information sought and how such information is relevant to the ongoing settlement discussions in the case," because "[y]our letter of February 5, 2018, did not provide that information." MDL docket no. 137-4 at 1-2. The boilerplate language in the government's letter did not address any of the substantive topics for discussion listed by Plaintiffs, did not acknowledge the 19-page *Touhy* letter the DEA had received four months earlier, and did not in any way serve to "continue discussions . . . concerning the disclosure of ARCOS data consistent with disclosures it has made to other requestors." Docket no. 101 at 9.

The next day, on February 13, 2018, Plaintiffs responded with a brief recapitulation of their earlier *Touhy* letter. By this time, over half of the three weeks the Court had given the parties to confer had passed. Plaintiffs continued to send emails asking for a meeting and reiterating their topics for discussion. Still another nine days expired before DEA finally agreed to meet and confer with Plaintiffs on February 22, 2018 (the day before the due date for the parties to report to the Court).

The parties' reports revealed small pockets of agreement. *See* MDL docket nos. 137 & 139. For example, regarding **geographic scope**, Plaintiffs requested the production of data nationwide, and DEA agreed; regarding **types of transactions by drug**, Plaintiffs requested the production of data related to all prescription oxycodone, hydrocodone, hydromorphone, and fentanyl transactions, including combination products, and DEA agreed; and Plaintiffs and DEA agreed that the data would be **redacted** so that the address of any commercial locations where large amounts of controlled substances are stored would not be disclosed. Plaintiffs and DEA also agreed on the protocol of how DEA would actually transfer any ARCOS data to the Plaintiffs, including: (a) using an encrypted portable storage device; and (b) delivery to a secure third-party consultant, who would house the data on a computer not connected to the internet.

But Plaintiffs and DEA could not agree on other aspects of data production including:

- **data format** – Plaintiffs wanted native format; DEA wanted to produce data in Excel spreadsheets.
- **timeframe** – Plaintiffs wanted data between January 1, 2006 and January 1, 2015; DEA wanted to produce only data between January 1, 2012 and December 31, 2013.
- **data fields** – for *each transaction*, Plaintiffs wanted the following data:
  (1) date;
  (2) seller's name, DEA registrant number, business activity, State, transaction code;
  (3) buyer's name, DEA registrant number, business activity, county, State, zip code; and
  (4) drug code, manufacturer, dosage units, grams-weight, quantity.

> In contrast, DEA wanted only to produce transaction *date*, and very limited identifying data regarding buyer and seller (such as the first three digits of their zip codes, and only made-up code numbers for each buyer and seller).[2]

The DEA offered the following explanation for why it could not reach agreement with Plaintiffs regarding the aspects of data production listed above:

> The parties were unable to reach an agreement because Plaintiffs desire production of the ARCOS database in its native format from January 1, 2006 through January 1, 2015, notwithstanding the attendant security, privacy, law-enforcement sensitive, and business proprietary concerns with doing so. Plaintiffs also would not agree that any production of ARCOS data should be covered by a protective order, but rather acknowledged that any produced data eventually would reach Plaintiffs' clients, state and local governmental entities, and the news media.

MDL docket no. 139 at 2-3.

As promised, the Court held "a hearing . . . on Monday, February 26, 2018 at 3:00 p.m. to resolve the matter." MDL docket no. 112 at 2. In addition to asking questions and hearing oral argument, the Court reviewed carefully all of the correspondence between Plaintiffs and DEA, DEA's written objections to the Plaintiffs' subpoena (docket no. 101), DEA's *Touhy* Authorization

(continued)

[2] DEA explained it wanted to produce only: (1) a list (alphabetical, not by sales volume) of all manufacturers in each State comprising 95% or more of the market share for opioid drugs, which would still enable Plaintiffs to identify additional potential defendants; and (2) spreadsheets showing ***de-identified*** transaction data – replacing buyer and seller names with numbers – which would still allow Plaintiffs to see general patterns of broad locations where the largest amounts of drugs were sent, and whether sales from or to a given (de-identified) entity appear especially problematic. The DEA added it would consider subsequent requests for ***actual*** identities of buyers or sellers if Plaintiffs successfully mined the data to show special need.

Letter (MDL docket no. 145-1),[3] and position statements from defendant distributors and manufacturers.

Ultimately, the Court concluded it would largely adopt the DEA's position ***at that time***. Specifically, the Court ordered that DEA would: (a) provide Excel spreadsheets to Plaintiffs that (b) identified the top manufacturers and distributors who sold 95% of the prescription opiates (c) to each State (d) during the time period of January 1, 2006 through December 31, 2014 (e) on a year-by-year and State-by-State basis, along with (f) the aggregate amount of pills sold and (g) the market shares of each manufacturer and distributor. The Court also ordered that the parties would adhere to a protective order strictly limiting access to this data. *See* docket entry no. 155.

In so ruling, the Court denied Plaintiffs' requests that the data be produced in native format, and also denied access to data regarding each transaction.[4] This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Wal-Mart, and Miami-Luken; but there is no way to know whether (or how much) any

[3] DEA's Authorization Letter, which was filed shortly before the hearing, recapitulates in greater detail DEA's objections and the positions it set out in its report to the Court.

[4] As promised at the hearing, DEA has recently produced very limited, ***de-identified*** transactional data for 2013 and 2014 only, showing only the first three digits of the buyers' zip codes, and the buyers' and sellers' names replaced with numbers. *See* hearing tr. at 13-14, 60; *see also* MDL docket no. 139 at 2.

of these five entities distributed oxycodone into Seneca County, Ohio[5] (or any other particular venue).

At the time of the hearing, the Court was focused strictly on pursuing settlement. DEA and the defendants argued successfully the ARCOS data was not necessary for settlement. But DEA and defendants also conceded the data was relevant and necessary to litigation.[6] And since then, the defendants have asserted forcefully that they cannot reach final settlement without litigating certain matters. To address this impediment, the Court recently entered Case Management Order, docket no. 232**,** creating a bellwether briefing and trial process for cases in Ohio, West Virginia, Illinois, Alabama, Michigan, and Florida.

Arguably, only circumscribed information within the ARCOS database is necessary to facilitate ***settlement***. But it is certain that all of the detailed information in the database is necessary

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[5] Seneca County is an MDL plaintiff. *See Seneca County Bd. of Cty. Commissioners v. AmerisourceBergen Drug Corp.*, case no. 18-OP-45290. Seneca does name Cardinal Health, AmerisourceBergen, and McKesson as defendants, but not Wal-Mart or Miami-Luken. Even with the de-identified transactional data that DEA produced, Seneca County cannot know for sure whether any of these five defendants distributed oxycodone within its boundaries, or how much. For example, Seneca County has 14 ZIP Codes, all of which start with 448; but ZIP Codes beginning with these three digits are also found in Ashland, Crawford, Erie, Hancock, Huron, Richland, Wood, and Wyandot Counties. Thus, *even if the data revealed the distributors' names*, instead of disguised code-numbers, the data showing transactions involving sales to 448xx ZIP Codes would still be unhelpful to Seneca County.

[6] *See* hearing transcript at 42 (counsel for defendant Cardinal Health: "On the litigation front, I respectfully suggest, Your Honor, that what's being asked for in ARCOS goes deep into discovery. It is, in fact, part of the litigation, it's not part of the resolution information that's necessary now."); *id.* at 47 (counsel for defendant Cardinal Health: "The information that the plaintiffs are seeking in this [case], where they seek the ARCOS data, is discovery information. It's not the information necessary for the settlement, especially the discussions for prospective relief going forward."); *id.* at 64-65 (counsel for Purdue making the same distinction between data needed for resolution versus litigation); *id.* at 33-34 (counsel for AmerisourceBergen making the same distinction between data needed for resolution versus litigation).

for ***litigation***, as the defendants recognized. Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiffs' claims, but also to the Court's understanding of the width and depth of this litigation. Given the parties' agreement that ARCOS data is relevant and necessary to litigate these cases, the Court must examine anew DEA's objections to production.[7]

As explained below, the Court concludes that DEA's objections are not well-taken, and Plaintiffs are entitled to production from DEA of the ARCOS/DADS data in the six bellwether States without the limitations DEA seeks to impose, as well as any Suspicious Order Reports DEA received.

II. Legal Standard.

"A federal-court litigant . . . can seek to obtain the production of documents from a federal agency by means of a federal subpoena." *Houston Bus. Journal, Inc. v. Office of Comptroller of Currency, U.S. Dep't of Treasury*, 86 F.3d 1208, 1212 (D.C. Cir. 1996). Courts of appeals are divided, however, "on the question of what standard of review to apply to an agency's decision not to comply with a subpoena." 9A C. Wright & A. Miller, Fed. Prac. & Proc. Civ. §2463.2 (3rd ed. Sept. 2017). Some Circuits review the agency's decision under the "arbitrary and capricious" standard of Section 706(2)(A) of the Administrative Procedure Act ("APA"), while others apply the more stringent standard of review found in Fed. R. Civ. P. 45, "under which the party refusing to comply bears the burden of showing good cause." *Id.*

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[7] Notably, the Court forecast this possibility at the hearing. *See* hearing tr. at 74 ("[W]e'll see exactly what [ARCOS data] we're getting [from DEA for now] and whether that's going to be satisfactory for this for the present. And if it's not, I'll have to order something more . . . .").

Several years ago, an MDL Court in the Sixth Circuit faced the question of which standard to apply when plaintiffs served a subpoena on the DOJ seeking certain tape recordings and transcripts obtained during an antitrust investigation. *In re Packaged Ice Antitrust Litig.*, 2011 WL 1790189 (E.D. Mich. May 10, 2011). The MDL court concluded "that the Sixth Circuit would join the opinions of those courts, mostly in this century, that have concluded that Federal Rule of Civil Procedure 45 and various available privilege rules provide sufficient limitations on discovery to adequately address legitimate governmental interests in objecting to a motion to compel compliance with a valid federal court subpoena." *Id.* at *2. This Court agrees. *See also In re Bankers Trust Co.*, 61 F.3d 465, 470 (6th Cir. 1995) ("Congress did not empower the Federal Reserve to prescribe regulations that direct a party to deliberately disobey a court order, subpoena, or other judicial mechanism requiring the production of information."); *Gardner v. Michigan State Univ.*, 2013 WL 5320282 at *1 (W.D. Mich. Sept. 20, 2013) (agreeing with the conclusion in *Packaged Ice*); *Houston Bus. Journal*, 86 F.3d at 1212 ("neither the Federal Housekeeping Statute nor the *Touhy* decision authorizes a federal agency to withhold documents from a federal court"); *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 780 (9th Cir. 1994) ("district courts should apply the federal rules of discovery when deciding on discovery requests made against government agencies . . . . Under the balancing test authorized by the rules, courts can ensure that the unique interests of the government are adequately considered.").

Accordingly, the Court examines the DEA's objections under the standard set out in Fed. R. Civ. P. 45(d).

III. The *Madel* Case.

Before turning to the DEA's objections to Plaintiffs' subpoena, the Court reviews the case of *Madel v. U.S. Dep't of Justice*, 784 F.3d 448 (8th Cir. 2015), which has much in common with this case. As seen below, recent events in *Madel*, following remand from the Eighth Circuit Court of Appeals, are especially instructive.

In *Madel*, the plaintiff "submitted [Freedom of Information Act] requests to DEA seeking information on oxycodone transactions in Georgia by five private companies," and also "requested seven reports from DEA's Automation of Reports and Consolidated Orders System (ARCOS)." *Id.* at 451. DEA produced some of the requested information, but withheld: (1) an ARCOS report, known as "report 1," that "includes data on every state and over 1,260 DEA registrants" and sets forth "quarterly and annual drug distributions to individual retail registrants (for example, retail pharmacies or hospitals) by three-digit zip code;" and also (2) "four spreadsheets of oxycodone sales, one each for Cardinal Health, Walgreens, AmerisourceBergen, and McKesson," which identify sales "by each company, identifying every buyer, location of sale, and amount of drug." *Id.*

The basis for DEA's refusal to produce these documents was that they contained "confidential commercial information." *Id.* Specifically, DEA asserted: (1) "the data in the withheld spreadsheets could be used to determine the companies' market shares, inventory levels, and sales trends in particular areas;" and (2) competitors could use the spreadsheet data and also the ARCOS report to "'target specific markets, forecast potential business of new locations, or to gain market share in existing locations,' thereby gaining competitive advantage." *Id.* at 453.

The plaintiff challenged DEA's refusal to produce the ARCOS report and spreadsheets, but the district court granted summary judgment to DEA. Plaintiff appealed, and the Eighth Circuit ruled "[t]he district court did not err in holding that [some of the] information in the withheld documents" was confidential commercial information. *Id.*

The appellate court further ruled, however, that DEA could "not automatically withhold an ***entire*** document when ***some*** information is exempt from production, but rather must [produce] '[a]ny reasonably segregable portion.'" *Id.* (emphasis added) (quoting 5 U.S.C. § 552(b)). The court added that DEA "has the burden to show that exempt portions are not segregable from non-exempt portions." *Id.* The Eighth Circuit observed that DEA had not carried this burden, which required a showing that ***all*** of the withheld data was either confidential commercial information or thoroughly mingled with confidential information:

> [The DEA does not explain] how disclosure of the data from, say, 2007, leads to the proffered substantial competitive harms of a competitor "target[ing] specific markets" or "forecast[ing] potential business of new locations." The claims of harm are undermined by DEA's public release of four charts showing total dosage units sold per month by Cardinal Health to four named buyers in Florida over four years. The Declaration also does not address whether disclosing only distributions over 100,000 or 200,000 units per year, as Madel offered, would have the same competitive harm as disclosing all the data. The case is remanded to the district court for an express finding on segregability.

Id. at 454.

After remand in 2015, Madel and the DEA attempted to negotiate a resolution. As the district court wrote one year ago, however, there is some question whether this negotiation was in good faith. "In the fall of 2015, [DEA] informed Madel that ***none*** of the information he sought was segregable, including any information from ARCOS report 1. However, in February 2016, the DEA

publicly released ARCOS report 1 in its entirety," revealing "quarterly drug-distribution totals by zip code for every drug and every state in the United States, for the period 2006 to 2015." *Madel v. United States*, 2017 WL 111302 at *2 (D. Minn. Jan. 11, 2017) (emphasis added). This left at issue only the four spreadsheets.

The DEA moved for summary judgment, asserting the entirety of the data in the spreadsheets was "completely exempt from disclosure and . . . non-segregable." *Id.* The district court did not merely overrule the DEA, it eviscerated its arguments. For example, the court wrote that, in support of its contention of non-segregability, DEA

> rel[ied] almost solely on the four [distributor] companies' objections to the spreadsheets' disclosure. These objections are stated in broad terms without any specific detail, or even specific justification that the release of any portion of the data will cause the companies competitive harm. The claims of competitive harm are undermined by the fact that the information Madel seeks is at least five years, and up to 11 years, old. Neither the Government nor the companies credibly explain how the release of distribution levels from 2006, for example, would cause any current harm.

Id. Further, DEA provided the district court with sorted spreadsheets, conclusively rebutting its own assertion "that it is not possible or practicable to filter the spreadsheets to remove competitively sensitive data." *Id.* at 3. After cataloging DEA's other actions, the district court went so far as to write that it had "given [DEA] the benefit of the doubt throughout this litigation, and [DEA] ha[d] time and again failed to establish that [it] deserve[s] that benefit. * * * [DEA has] lost [its] credibility with this Court." *Id.*

Even more recently, the *Madel* district court rejected new contentions by DEA that: (1) information in the spreadsheets was protected by the Trade Secrets Act; and (2) only names of ***buyers*** of opioids should be disclosed, not names of ***suppliers***. *See Madel*, case no. 13-CV-2832 (D.

Minn), docket no. 127 at 1 (Aug. 30, 2017) ("the Government contended previously that 'the only information on the spreadsheets that can be provided without causing competitive harm is the name and locations of the ***supplier*** companies.' It is curious that the Government has reversed its position now that the Court has ordered other information on the spreadsheets released.") (emphasis added).

Ultimately, then, the lessons *Madel* teaches are that, when assessing DEA's attempts to narrow or reject Plaintiffs' discovery requests: (1) it is DEA's burden to show that information responsive to Plaintiffs' subpoena is not reasonably segregable from information that is exempt from disclosure; (2) broad pronouncements, conclusory assertions, and general explanations will not suffice to meet this burden; and (3) relevant information must be produced, absent undue burden or other good cause.

IV. Analysis of DEA's Objections.

Plaintiffs' initial request of DEA was "Data from the Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS) national database in its native format, including all fields of information commonly stored, **for the time period of January 1, 1995 to the present**." Docket no. 81-4 at 4 (subpoena) (emphasis added). As noted earlier, Plaintiffs have modified this request, now seeking data between January 1, 2006 and January 1, 2015.

Before the Plaintiffs met with DEA on February 22, 2018, the DEA asserted 12 different objections to Plaintiffs' subpoena. Some of these objections are now moot; others are not well-taken, either entirely or in large part. The principal reason the Court overrules DEA's objections

below is that the Plaintiffs have agreed to limit their request to data that is now over three years old. This resolves numerous concerns. The Court addresses each objection below.

1. Begin-date of data. DEA notes that the ARCOS database includes data only from 2006 to the present, but Plaintiffs originally sought data beginning from January 1, 1995, which simply does not exist. Plaintiffs have since amended the "begin-date" of their demand to January 1, 2006, so this objection is moot.

2. Geographic scope and non-parties. DEA next asserts a two-prong objection, arguing Plaintiffs' request is "overly broad, unduly burdensome and irrelevant, since it requests [i] information pertaining to jurisdictions outside Ohio and [ii] data relating to manufacturers and distributors that are not parties to this litigation." Docket no. 101 at 4.

Regarding the first prong of this objection, the subpoena was initially issued before the *Cincinnati* case was transferred to the MDL, which now includes cases from across the country. Accordingly, the DEA now recognizes its objection to geographic scope is not well-taken and withdraws it.

Regarding the second prong, the DEA seems to recognize it is reasonable and appropriate for Plaintiffs to obtain data allowing them to identify ***manufacturers*** that are not parties to this litigation. *See* docket no. 139 at 1-2 (DEA agrees to produce "an alphabetical list of all manufacturers in each state who comprised 95% or more of the market share for manufacturing [opioids] to enable the Plaintiffs to identify additional parties to join as defendants"). For exactly the same reason, it is appropriate for Plaintiffs to obtain data allowing them to identify ***distributors and retailers*** that are not parties to this litigation. DEA's objection that some of the ARCOS data relates to entities not yet parties to the litigation is overruled. Moreover, it is also appropriate for

Plaintiffs to obtain data allowing them to understand not only the identity of each potential defendant, but the ***extent*** to which each defendant and potential defendant engaged in the allegedly fraudulent marketing of opioids, filling of suspicious orders, and diversion of drugs, which can be revealed only by all of the data.[8]

3. Drugs besides opioids. DEA notes that the ARCOS database tracks data related to many types of drugs, not just opioids. *Id.* at 4 (noting the database collects information on "all controlled substances in Schedules I and II, all narcotic controlled substances in Schedule III, and selected psychotropic controlled substances in Schedules II and IV"). DEA asserts that "[i]nformation regarding non-opioid drugs is not relevant to Plaintiff's claims and DEA objects to their production now or in the future." *Id.* at 4-5. This objection has been resolved, as DEA and Plaintiffs now agree DEA will produce data related only to all prescription oxycodone, hydrocodone, hydromorphone, and fentanyl transactions, including combination products.

4. Open Access. DEA "objects to providing Plaintiff open access to the ARCOS system." *Id.* at 5. This objection has been resolved, as the DEA and Plaintiffs now agree that DEA will transfer ARCOS data to a secure third-party consultant. This mitigates any security concerns.

5. Privacy Act. DEA objects to production "under DOJ's *Touhy* regulations (28 C.F.R. §16.26(b)(1)), because it would violate the Privacy Act, 5 U.S.C. § 552a." *Id.* The statute, however, states that "No agency shall disclose any record which is contained in a system of records . . . to any

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[8] Detailed ARCOS data evidence is relevant not only to prove culpability but also possibly for purposes of allocation of settlement funds. Distributors assert that DEA's offer of limited, de-identified information is sufficient to address the Court's immediate focus on "forward-looking initiatives and actions to help ameliorate the opioid crisis," but this ***initial*** objective does not make irrelevant discovery going to the merits of Plaintiffs' claims and their burden of proof. MDL docket no. 142 at 2 (Distributors' ARCOS report). Evidence relevant to trials and settlement remains critical to the orderly progress of this MDL.

person . . . unless disclosure of the record would be . . . pursuant to the order of a court of competent jurisdiction." 5 U.S.C. §552a(b)(11). This Order removes any concern of a violation of the Privacy Act. Moreover, disclosure is allowed "to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual." *Id.* §552a(b)(8). President Trump has declared the opioid epidemic a national emergency; the circumstances in this case, which affect the health and safety of the entire country, are certainly compelling.

6. Investigatory Records. DEA "objects to the production of the requested information under DOJ's *Touhy* regulations (28 C.F.R. §16.26(b)(5)) because disclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings." Docket no. 101 at 5. This objection fails for three reasons. First, Plaintiffs seek ARCOS data with an end-date of January 1, 2015. Given that the most recent data is over three years old, it is untenable that exposure of the data will actually or meaningfully interfere with any ongoing enforcement proceeding. Second, the ARCOS data are not pure investigatory records compiled for law enforcement purposes. Rather, the data is simply business records of defendants; these "[c]ompanies are legally required to submit the information" to ARCOS, the database does not include any additional DEA analysis or work-product, and the records are used for numerous purposes besides law enforcement. *Madel*, 784 F.3d at 452. Indeed, Plaintiffs assert that part of the reason for the opioid epidemic is ***lack*** of law enforcement. And third, simply saying that disclosure of ARCOS records dating back to 2006 would detrimentally affect law enforcement does not make it so. It is certain at least ***some*** of the requested data is responsive and relevant; DEA's conclusory

pronouncement that disclosure of ***any*** data would be harmful does not carry its burden of showing non-segregability.

That said, if DEA truly believes release of certain, specific data would interfere with a particular, pre-existing and ongoing enforcement proceeding, DEA can move the Court for relief from release of that particular data (and make an in camera submission, if necessary).

7. Market share. DEA "objects to the production of the requested information under DOJ's *Touhy* regulations (28 C.F.R. § 16.26(b)(6)) because disclosure would improperly reveal trade secrets without the owners' consent." Docket no. 101 at 6. Specifically, DEA asserts the data would reveal "details regarding the scope and breadth of [each manufacturer's and distributor's] market share, which is likely to cause [them] substantial competitive harm." *Id.* The *Madel* court explicitly rejected this argument, noting the assertion was conclusory and also that market data over three years old carried no risk of competitive harm. This objection is overruled.

8. Ongoing Investigations. DEA "objects to the production of the requested information because disclosure would violate DOJ's policy which prohibits the release of information related to ongoing matters." *Id.* at 7. The same reasons for overruling objection number 6 apply here. It is highly unlikely exposure of data more than three years old will actually or meaningfully interfere with any ongoing matter, and DEA's conclusory pronouncement that disclosure of ***any*** data would be harmful to an ongoing matter does not carry its burden of showing non-segregability.

9. Warehouse locations. DEA objections that "ARCOS data can be used to identify commercial locations where large amounts of controlled substances are stored," so releasing the data could aid criminals. This objection is not well-taken on the facts, as Plaintiffs produced evidence at the hearing showing that locations of the manufacturers' and distributors' warehouses are already

publicly available through numerous sources (including websites operated by DEA and the defendants, themselves).

10. Database size. DEA notes the requested ARCOS data includes hundreds of millions of transactions: "For example, in 2016 alone, registrants reported nearly 80 million ARCOS transactions." *Id.* at 8. Thus, DEA objects that the subpoena is "overbroad and unduly burdensome" because the "amount of information is too large to fit into excel spreadsheets." *Id.* This objection is mooted by DEA's giving the data to Plaintiffs in native format, and shifting the burden and expense of data mining and extraction to Plaintiffs – DEA need not produce any spreadsheets at all. To oversimply only slightly, the burden of producing the ARCOS database requires merely downloading it to "an encrypted portable storage device, encrypted to AES 256 standards," and delivering it to the third-party consultant. Email from Plaintiffs to Government regarding data transfer (February 21, 2018). The expense and effort of examining the data then falls on Plaintiffs. In addition, although there is probably little real difference in burden on the DEA, the Court is directing DEA to download and produce data for only six States, not the entire country.

11, 12. Availability. Finally, DEA objects that the ARCOS data is "publically available" and/or "readily available from other sources; namely, the Defendants." These assertions are simply not true. Small portions of the ARCOS data have been made available to the public – such as occurred in the *Madel* case – but only after struggle and delay, and the scope of the data made public is insufficient to establish national, regional or local market share and market conduct necessary to reflect the merits *vel non* of the Plaintiffs' claims, or to facilitate settlement discussions. Indeed, if the data was publicly available, DEA would not be objecting to its production based on privacy concerns.

Moreover, it is not a valid objection to insist the data is available elsewhere, in small pieces. It would be unduly burdensome (if not impossible) to force Plaintiffs to recreate the ARCOS data by pursuing each defendant and potential defendant. Each defendant operates a separate Suspicious Order Monitoring System (SOMS), but they all submit the same data in a unified format for ARCOS inclusion, which is aggregated and validated by the DEA. The necessary breadth and depth of data Plaintiffs need to pursue their claims and settle this litigation is held only by DEA.

In sum, the Court concludes DEA's objections to production of the requested ARCOS data are not well-taken. In relevant part, Rule 45(d) directs the Court to quash or modify a subpoena if it "requires disclosure of privileged or other protected matter," or "subjects a person to undue burden," or calls for "disclos[ure of] a trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 45(d)(3). As modified (with data requested between January 1, 2006 and January 1, 2015), the Plaintiffs' subpoena does none of these things. Moreover, as discussed in Section VI below, the Court provides the data will be covered by the existing protective order. Accordingly, the Court orders the DEA to produce the information described above on or before April 20, 2018.

V. Arbitrary and Capricious Standard.

As discussed in Section II, some Circuits analyze objections to a subpoena issued to a federal agency using the good cause / undue burden standard embodied in Fed. R. Civ. P. 45, while other Circuits use the "arbitrary and capricious" standard set out in the Administrative Procedure Act ("APA"). The Court adds here that it would reach the same conclusions even if it used the latter

standard. To support this conclusion, the Court relies on *In re Vioxx Prod. Liab. Litig.*, 235 F.R.D. 334 (E.D. La. 2006).

In *Vioxx*, the MDL Plaintiffs issued a subpoena *ad testificandum* to an employee of the United States Food and Drug Administration ("FDA"). After the FDA moved to quash, the Honorable Eldon Fallon had to determine whether to "review the motion to quash under Rule 45 or APA standards." *Id.* at 343. After noting the split in authority, the court concluded it "need not resolve the issue" because the FDA did not meet either standard. Among other reasons, the *Vioxx* court focused on the overriding public interest in disclosure of the information sought. The court's discussion of this factor bears repeating here:

> [T]his Court fails to see how disclosure of this information is not in the public interest. Vioxx is a drug that was used by millions of patients and is currently the subject of thousands of lawsuits.
>
> Although it has many purposes and goals, litigation is a fact-finding device designed as a search for the truth. With this in mind, it is vitally important to every plaintiff in this litigation to know the truth surrounding Vioxx, including what the FDA knew, when the FDA knew it, what if anything was kept, intentionally or unintentionally, away from the FDA, and what, if anything, the FDA kept from the public. Similarly, this information is important to those people who used Vioxx, were injured, and may have a claim against Merck, but are still contemplating the filing of a formal suit. This information is also important to Merck, who is now spending countless dollars trying to vindicate itself and its product and who, after voluntarily removing Vioxx from the market, most likely desires to place Vioxx, which it believes is safe and effective, back on the market. This information is also important to those people who took Vioxx, suffered no injury, and who still wish they could take Vioxx, but cannot because it has been voluntarily removed from the market.
>
> [] Dr. Graham's deposition would further the objectives of the FDA and the FDCA. The objective of the FDA and FDCA is the protection of the public. The FDA protects the public by enacting regulations governing the sale and marketing of pharmaceutical products and, based upon those regulations, approving and monitoring pharmaceutical products for sale and marketing. Any improvements

> deriving from such a reevaluation would promote the protection of the public—the FDA's ultimate goal.

Id. at 346.

Unfortunately, the public health emergency caused by addiction to opioids greatly overshadows the medical issues related to Vioxx. There is overwhelming need for the Plaintiffs in this case to learn the truth surrounding marketing and distribution of opioids, including what the manufacturers, distributors, retailers, and DEA knew and when they knew it; what, if anything, was kept, intentionally or unintentionally, away from the DEA and the public by defendants; and what, if anything, the DEA kept, intentionally or unintentionally, from the States, counties, and cities that have filed the MDL lawsuits.

Moreover, disclosure of the years-old ARCOS data will further the objectives of the DEA without damaging its ability to continue to pursue those objectives. The objective of the DEA is protection of the public and regulation of dangerous drugs. As in *Vioxx*, producing the requested information will only serve to strengthen those objectives by revealing ways the system failed, so that deficiencies may be fixed. DEA's submissions and arguments show that: (a) it failed to consider important aspects of many factors underlying the opioid epidemic; (b) it offered explanations that run counter to the evidence; and (c) the arguments it offers in support of the limitations it seeks on production of ARCOS data are so implausible that it cannot be ascribed to a difference in view or the product of agency action. Therefore, the Court finds that DEA's bases for refusal to produce the requested data are arbitrary and capricious. *Id.*

In closing, the Court observes that the vast oversupply of opioid drugs in the United States has caused a plague on its citizens and their local and State governments. Plaintiffs' request for the ARCOS data, which will allow Plaintiffs to discover how and where the virus grew, is a reasonable

step toward defeating the disease. *See Buckley v. Valeo*, 424 U.S. 1, 67 ("Sunlight is said to be the best of disinfectants.") (quoting Justice Brandeis, *Other People's Money* 62 (1933)). DEA's objections to production of the requested data are denied.

VI. Protective Order.

Having overruled DEA's objections, DEA shall produce the requested information for the States of Ohio, West Virginia, Illinois, Alabama, Michigan, and Florida. Use of the ARCOS database shall be limited to this litigation and for State and local law enforcement purposes only. No person shall disclose the data or allow use of the data except as necessary for a submission to the court or at trial. The ARCOS data produced pursuant to this Order shall be governed by the Protective Order previously entered at docket no. 167.

IT IS SO ORDERED.

/s/ Dan Aaron Polster
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: April 11, 2018