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

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| IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION | ) | CASE NO. 1:17-MD-2804 |
| | ) | JUDGE DAN AARON POLSTER |
| This document applies to All Cases. | ) | |

**REPORT BY MDL PLAINTIFFS**
**ON STATUS OF ARCOS/DADS DISCLOSURE DISCUSSIONS WITH DOJ/DEA**

COME NOW the MDL Plaintiffs, by the undersigned, and submit this report on the status of discussions with the United States Department of Justice and the Drug Enforcement Agency (DOJ/DEA) related to the disclosure of the Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS) (69 FR 51104-02) pursuant to the ORDER RE: ARCOS/DADS DATABASE (Doc #: 112) entered on February 2, 2018. A meeting of the stakeholders was conducted at U.S. Department of Justice in Washington, DC, on February 22, 2018.

In order to facilitate a productive discussion, in advance of the meeting, the MDL Plaintiffs requested certain preliminary information from the DOJ/DEA, such as available data fields and the format and size of the requested data. The DOJ/DEA never responded to these requests. Accordingly, the meet and confer occurred without the MDL Plaintiffs having knowledge of certain elementary information.

Instead of providing the information necessary to facilitate a meaningful discussion, the DOJ/DEA offered to produce only certain very limited data. The DOJ/DEA's proposal is problematic because the limited data would not allow the MDL Plaintiffs or the Court to identify the specific manufacturers and distributors that sold and/or distributed the prescription opioids into specific communities, nor would it allow the MDL Plaintiffs or the Court to identify the amount of prescription opioids distributed into a particular state, county, or city. The information offered by the DOJ/DEA is insufficient for the MDL Plaintiffs and the Court to determine the relevant defendants or the relationship between any current or potential defendant's activities and a given geographic area or the extent of any current or potential defendant's activities in a given geographic area. The information which the DOJ/DEA has refused to provide is necessary to effectively address the opioid epidemic as currently postured before this Court.

Procedural History

1. On October 2, 2017, a nineteen (19) page *Touhy* letter was issued to ARCOS Unit Chief Alan N. Drumheller at DEA Headquarters in Springfield, Virginia, on behalf of the City of Cincinnati and some fourteen (14) southern Ohio governmental entities with cases pending before

Chief Judge Edmond Sargus in the United States District Court for the Southern District of Ohio. [1] *See* Exhibit 1.

2. On October 11, 2017, United States Attorney for the Southern District of Ohio, on behalf of the DEA, refused the *Touhy* demand as not "appropriate under the rules of procedure governing the case." *See* Exhibit 2. As a result, the Southern District of Ohio Plaintiffs sought and received permission from the Court to issue a subpoena duces tecum. (Doc #: 67).

3. On October 30, 2017, the Court entered an Order authorizing the issuance of a subpoena duces tecum upon the DEA for the ARCOS database and set a briefing schedule. *City of Cincinnati v. Amerisourcebergen Drug Co., et al.*, (Case: 2:17-cv-00713-EAS-EPD Doc #: 75 Filed: 10/30/17). On October 31, 2017, the City of Cincinnati issued its Notice to serve the subpoena duces tecum. (Doc #: 81).

4. On November 27, 2017, the DOJ/DEA filed objections to the issuance of the subpoena. (Doc #: 101).

5. On December 12, 2017, the *City of Cincinnati* (Doc #: 104) case was transferred to MDL2804 *In re: National Prescription Opiate Litigation* in the United States District Court for the Northern District of Ohio. After that point, the Southern District of Ohio Plaintiffs began working together with the other MDL Plaintiffs to obtain the relevant information from the DOJ/DEA.

6. On December 19, 2017, the MDL Plaintiffs were advised the Assistant U.S. Attorney for the Northern District of Ohio, James R. Bennett, would serve as the contact person regarding any discovery requests to the DOJ/DEA under the DEA's Touhy regulations. The MDL Plaintiffs initiated telephone calls with Mr. Bennett on January 10 and 13, 2018. The DOJ/DEA was invited but declined to attend a January 31, 2018, "information session to educate the Court and each other on supply-chain dynamics and other issues relevant to resolving this MDL, and to further pursue settlement discussions." *In re: National Prescription Opiate Litigation*, MDL2804 (Case: 1:17-md-02804-DAP Doc #: 70).

7. On February 2, 2018, this Honorable Court entered its ORDER RE: ARCOS/DADS DATABASE (Doc #: 112) directing "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." The Court directed the MDL Plaintiffs and the DOJ/DEA to file a report detailing their

[1] *Clermont County Board of County Commissioners v. AmerisourceBergen Drug Corporation, et al.* (2:17-cv-662); *Belmont County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-663); *Brown County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-664); *Vinton County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-665); *Jackson County Board of Commissioners v. AmerisourceBergen Drug Corporation, et al.* (2:17-cv-680); *Scioto County Board of Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-682); *Pike County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-696); *Ross County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-704); *City of Cincinnati v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-713) *City of Portsmouth v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-723); *Gallia County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-768); *Hocking County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-769); and *Lawrence County Board of County Commissioners v. AmerisourceBergen Drug Corporation, Inc., et al.* (2:17-cv-770).

agreement (or lack thereof) no later than 12:00 noon on Friday, February 23, 2018. The MDL Plaintiffs initiated a telephone conference with AUSA Bennett on the same day welcoming the opportunity to meet and confer.

8. On February 5, 2018, the MDL Plaintiffs forwarded correspondence to AUSA Bennett restating and referencing prior communications, requested some basic information,[2] and formally offered to "to meet by phone or in person at [the DOJ/DEA's] earliest availability." *See* Exhibit 3. The MDL Plaintiffs sent emails on February 7 and February 10, 2018, asking for the opportunity to meet and confer.

9. AUSA Bennett responded by correspondence on February 12, 2018, attached as Exhibit 4, as well as email stating:

> Mr. Ferrell:
>
> Thank you for your e-mail and your suggestion to schedule a meeting. While the Department of Justice remains willing to discuss the disclosure of ARCOS data, it needs a summary of the information being sought by the parties and its relevancy to the settlement proceedings to begin the review process as explained in the attached letter. The Department of Justice would be happy to consider a meeting once it receives and reviews the summary and the statement of relevance.

The MDL Plaintiffs responded by correspondence dated February 13, 2018, attached as Exhibit 5, reminding the DOJ/DEA of the procedural history and attempting to provide additional information.

10. On February 19, 2018, AUSA Bennett invited the stakeholders to a meeting on February 22 (the day before the Court imposed deadline) in Washington DC.

11. In summary, the MDL Plaintiffs respectfully submit the DOJ/DEA has been on notice request since October 2, 2017, of the full extent of the data requested. On February 2, 2018, this Honorable Court directed the MDL Plaintiffs and the DOJ/DEA to meet and confer in an attempt to reach an agreement by February 23, 2018. The MDL Plaintiffs have attempted to initiate such discussions on multiple occasions by placing telephone calls, sending email reminders and sending formal correspondence. The DOJ/DEA's first available opportunity to meet and confer was set for February 22, 2018.

12. The February 22, 2018, meeting was attended by: Paul T. Farrell, Jr., Greene, Ketchum, Farrell, Bailey & Tweel, LLP, Peter J. Mougey, Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A. and David Ackerman, Motley Rice LLC; Alvin Lee Emch, Jackson Kelly,

[2] The MDL Plaintiffs requested the DOJ/DEA answer a list of basic and foundational questions, including: (1) What is the native format of the database? and (2) Which data fields are included in the database?

PLLC [Counsel for AmerisourceBergen] and Jennifer G. Wicht, Williams & Connolly LLP [Counsel for Cardinal Health] on behalf of the Defendants; and Alex Haas, Chief of Staff, DOJ Civil Division, Gustav Eyler, Acting Director, DOJ Consumer Protection Branch, Jacqueline Snead, DOJ Federal Programs Branch, Mary Daly, DOJ Office of the Deputy Attorney General, Sandra Stevens, DEA Assistant Deputy Chief Counsel Litigation & Policy and James Bennett, Assistant U.S. Attorney, Northern District of Ohio.

Data requested by the MDL Plaintiffs and Response by the DOJ/DEA

The following parameters for the data disclosure were discussed during the February 22, 2018, meet and confer:

(a) **Format.** The MDL Plaintiffs requested the data be produced in native format and that the data reflect any routine quality control or validation process conducted by DEA.

The DOJ/DEA ***refused*** the request to produce the data in its native format. Instead, DOJ/DEA offered to produce limited portions of the data in Excel spreadsheets if an agreement could be reached on the remaining parameters.

(b) **Timeframe.** The MDL Plaintiffs requested the production of data between January 1, 2006 and January 1, 2015.

The DOJ/DEA ***refused*** the request and offered to produce only a two (2) year span if an agreement could be reached on the remaining parameters.

(c) **Geography.** The MDL Plaintiffs requested the production of data nationwide (including Puerto Rico).

The DOJ/DEA agreed to produce nationwide data if an agreement could be reached on the remaining parameters.

(d) **Transactions.** The MDL Plaintiffs requested data related to all transactions and returns between manufacturers and distributors, distributors and distributors, and distributors and retailers (pharmacies and practitioners).

The DOJ/DEA agreed to produce data showing the dates and occurrences of the transactions within the limited offered two-year time period, if an agreement could be reached on the remaining parameters. However, the DOJ/DEA refused to produce information sufficient to identify the identities of the manufacturers, distributors, and/or retailers party to any of the transactions.

(e) **Opioids.** The MDL Plaintiffs requested data related to all prescription oxycodone, hydrocodone, hydromorphone, and fentanyl transactions reflected in the ARCOS/DADS database, including combination products.

The DOJ/DEA agreed to produce limited data related to all prescription opioid transactions in the ARCOS/DADS database within the restricted time period, the request if an agreement could be reached on the remaining parameters.

(f) **Data fields.** The MDL Plaintiffs requested production of data for the following fields:

(1) Date of each transaction.
(2) Seller's name, DEA registrant number, business activity, state, transaction code.
(3) Buyer's name, DEA registrant number, business activity, county, state, and zip code.
(4) Drug code, manufacturer, dosage units, grams weight, quantity.

• The DOJ/DEA agreed to produce the date of each transaction an agreement could be reached on the remaining parameters.

• The DOJ/DEA ***refused*** to provide the identities of any of the purchasers and/or sellers, including the manufacturers, distributors, and pharmacies who were party to those transactions. Instead, the DOJ/DEA proposed providing a code or numeric identifier for each purchaser and seller, without providing a key which would allow the MDL Plaintiffs or the Court to determine the identities of those entities.

• The DOJ/DEA ***refused*** to provide the state, county, or city to which the drugs were distributed or sold. The DOJ/DEA will only provide the first three digits of the postal code for the distribution or sale location, information which is insufficient to determine the county and city to which the drugs were distributed or sold.

• The DOJ/DEA ***refused*** to provide the National Drug Code ("NDC") for the prescription opioids reflected in the transaction data and/or the identity of the manufacturer for those opioids, which would allow the Court and the MDL Plaintiffs to identify market share.

(g) **Redactions.** MDL Plaintiffs and the DOJ/DEA agreed that the address of any commercial locations where large amounts of controlled substances are stored shall not be disclosed to the public.

(h) **Protective Order**: The MDL Plaintiffs opposed the entry of a broad protective order and recommended the data be disclosed leaving to the discretion of the Court the ability to share data and/or reports generated therefrom with (a) the defendants, (b) the clients, (c) the Attorneys General and (d) the media.[3]

[3] "While the release of information for the purpose of influencing a trial is, of course, always improper, there are valid reasons for making available to the public information about the administration of the law. The task of striking a fair balance between the protection of individuals accused of crime or involved in civil proceedings with the Government and public understandings of the problems of controlling crime and administering government depends largely on the exercise of sound judgment by those responsible for administering the law and by representatives of the press and other media." 28 C.F.R. § 50.2(a)(2).

The DOJ/DEA ***refused*** and insisted on the entry of a protective order providing for the confidentiality of all of the data and preventing disclosure of any of the data.

LEGAL ANALYSIS

The MDL Plaintiffs submit the legal analysis related to the disclosure of the data is set forth in the pleadings in the *City of Cincinnati v. Amerisourcebergen Drug Co., et al.*, (Case: 2:17-cv-00713-EAS-EPD) including the Touhy letter, subpoena duces tecum and attachments and the DOJ/DEA objections and attachments. The creation of MDL2804 rendered some of the objections moot. The remaining disagreements fall into one of four categories:

First, the MDL Plaintiffs and the DOJ/DEA disagree on applicable law governing the data request. The MDL Plaintiffs argue that the rules of civil procedure govern disclosure. *In re Packaged Ice Antitrust Litig.*, 2011 WL 1790189, at *2 (E.D. Mich. May 10, 2011) (concluding 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) (citations omitted). The government argues that Section 706 of the Administrative Procedure Act ("APA") should apply. That statute requires the Court to uphold an agency's decision unless it is arbitrary and capricious. See, e.g., *COMSAT Corp. v. Nat. Sci. Found.*, 190 F.3d 269, 277 (4th Cir. 1999); *Moore v. Armour Pharm. Co.*, 927 F.2d 1194, 1197 (11th Cir. 1991).

Under Rule 45(3)(A), a court may quash or modify a subpoena if it subjects a person to undue burden. If this standard would apply, the United States would have to prove that the subpoena subjects it to an undue burden. Conversely, under section 706 of the APA, a court may set aside an agency action if it is arbitrary or capricious or if it is in excess of the agency's authority[4]. *In re Vioxx Prod. Liab. Litig.*, 235 F.R.D. 334, 344 (E.D. La. 2006).

This Court need not resolve this issue. In the present case, the MDL Plaintiffs respectfully assert they complied with both the *Touhy* regulations as well as the Federal Rules of Civil Procedure. The DOJ/DEA has failed to carry its burden of proof under either standard. Moreover, this Honorable Court is vested with the broad authority broad authority over pretrial proceedings. The purpose of the MDL statute is to "promote the just and efficient conduct" of numerous complex cases with common questions of fact through "coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). The phrase "pretrial proceedings" has been broadly interpreted to give the transferee judge control over any and all proceedings before trial. *See In re Korean Air Lines Co.*, 642 F.3d 685, 698–99 (9th Cir. 2011); *In re Phenylpropanolamine (PPA) Products Liability Litigation*, 460 F.3d 1217, 1230–31 (9th Cir. 2006) (citing Stanley A. Weigel, The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts, 78 F.R.D. 575, 578–79 (1978)); *In re Neurontin Mktg., Sales Practices, and Prods. Liab.*, 245 F.R.D. 55, 57 (D.Mass. 2007). This is because a "district judge charged with the responsibility of 'just and efficient conduct' of the multiplicity of actions in an MDL proceeding must have discretion to manage them that is commensurate with the task." *In re Phenylpropanolamine (PPA) Prods. Liab.*

[4] "[The reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

*Litig.*, 460 F.3d at 1231. The task of a transferee judge requires "broad discretion to structure a procedural framework for moving the cases as a whole as well as individually, more so than in an action involving only a few parties and a handful of claims." *Id*. at 1231–32.

Second, the DOJ/DEA objects to the production of the requested information because "[d]isclosure would reveal investigatory records compiled for law enforcement purposes, and would interfere with enforcement proceedings or disclose investigative techniques and procedures the effectiveness of which would thereby be impaired." 28 C.F.R. § 16.26(b)(5). DOJ/DEA refuses to make a proffer on how or why the raw data is an "investigatory record" and/or how the historical data could possibly interfere with enforcement proceedings.

The data requested is not an "investigative record." This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 826(d)) and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971. 69 FR 51104-02. To be clear, the MDL Plaintiffs are requesting historical data mandated by federal law to be reported to the federal government. The MDL Plaintiffs are not requesting the investigatory records and/or work product generated from the database by the DOJ/DEA. Moreover, the data from the past three (3) years has been excluded which renders moot any possibility that disclosure of data interferes with an ongoing enforcement proceeding. Mere "barren assertions" that a document is exempt is insufficient. *Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 452 (8th Cir. 2015). The DOJ/ DEA has failed to comply with its obligations under *Touhy* and failed to meet its burden of proof to withhold disclosure under 28 C.F.R. § 16.26(b)(5).

Third, the DOJ/DEA objects to the production of the requested information under the Touhy regulations (28 C.F.R. § 16.26(b)(6)) because disclosure would improperly reveal trade secrets without the owners' consent. The DOJ/DEA argues that production of this data would reveal specific details regarding the scope and breadth of market share which is likely to cause manufacturers and distributors substantial competitive harm. Again, "barren assertions" that a document is exempt is insufficient. *Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 452 (8th Cir. 2015).

The DOJ/DEA fails to proffer how the historical data subject to disclosure is a trade secret and/or will result in substantial competitive harm. This defect was emphasized in *Madel* when the 8th Circuit Court of Appeals remanded the case with a mandate for an express finding on segregability. *Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 454 (8th Cir. 2015). Notably, on remand, U.S. District Court Judge Paul Magnuson entered a Memorandum and Order holding "company-specific information by the buyer's county, business activity, drug type, transaction date, dosage units, and total grams for the years Madel requests is not exempt from disclosure under [FOIA]." *Madel v. United States*, No. CV 13-2832 (PAM/FLN), 2017 WL 111302, at *4 (D. Minn. Jan. 11, 2017). The court concluded:

> The Court has given [the DEA] the benefit of the doubt throughout this litigation, and [the DEA] have time and again failed to establish that they deserve that benefit. Whether by refusing to negotiate with Madel in good faith, or by publicly releasing data that they had mere

> months before insisted was too sensitive to ever make public, [the DEA] have lost their credibility with this Court. The Eighth Circuit was clear: it is [the DEA]'s burden to show that information responsive to Madel's requests is not reasonably segregable from information not subject to disclosure. Broad pronouncements and general explanations will not suffice to meet this burden, and [the DEA] have offered nothing more than that here. [The DEA] have failed to establish that there is no non-exempt information responsive to Madel's requests that is not segregable from exempt information.

*Madel v. United States*, at *3.

Nearly nine months later, the parties sought clarification from the Court on the meaning of its prior ruling which resulted in the Court finding:

> The information Madel requests is now more than five years old. […] It is no longer a trade secret, if it ever was. Nor is it protected from disclosure under any exemption to the FOIA. Madel is correct: the non-exempt information in the spreadsheets includes the name of the supplier companies as well as the other information identified in the Court's previous Order.

*Madel v. United States*, No. CV 13-2832 (PAM/FLN), Document 127, available on PACER (D. Minn. Aug. 30, 2017).

The requested data is not a "trade secret." Courts of Appeals have embraced varying versions of a "convoluted test" that rests on judicial speculation about whether disclosure will cause competitive harm to the entity from which the information was obtained. *New Hampshire Right to Life v. Dep't of Health & Human Servs.*, 136 S. Ct. 383, 384, 193 L. Ed. 2d 412 (2015). The *National Parks* test has received widespread acceptance which involves a two-part test:

> [C]ommercial or financial matter is "confidential" ... if disclosure of the information is likely ... either ... (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.

*Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 873 (D.C. Cir. 1992) (en banc). The MDL Plaintiffs set forth in great detail the National Parks factors in its Touhy letter. DOJ/DEA has yet to respond in kind.

Fourth, and finally, the DOJ/DEA objects to the production of the requested information because it would violate the Privacy Act, 5 U.S.C. § 552a. However, a statutory exception permits disclosure "pursuant to the order of a court of competent jurisdiction." 5 U.S. Code § 552a(b)(11).

This Honorable Court is a court of competent jurisdiction. The entry of an appropriate order renders this objection moot.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the 23rd day of February, 2018, the foregoing was filed using the Court's CM/ECF filing system and will be served *via* the Court's CM/ECF filing system on all attorneys of record.

/s/ Paul T. Farrell, Jr.
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