

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION)
)
) **MDL 2804**
) **Case No. 1:17-md-2804**
)
THIS DOCUMENT RELATES TO:) **Judge Dan Aaron Polster**
)
All Cases) **OPINION AND CONSOLIDATED**
) **ARCOS PROTECTIVE ORDER**

By Order of this Court filed March 6, 2018, the Court entered an initial Protective Order re the DEA ARCOS/DADS Database.¹ Doc. #: 167. On May 8, 2018, the Court entered an Amendment to Protective Order to make such Order expressly applicable to Suspicious Order Reports (“SORs”) produced by DOJ and/or DEA. Doc. #: 400. These two Orders are collectively referred to as the “ARCOS Protective Order.” With the agreement of the Department of Justice (“DOJ”), Drug Enforcement Administration (“DEA”) and the Co-Lead Counsel for the Plaintiffs in MDL No. 2804 (“MDL Counsel”), on March 15, 2019, Plaintiffs filed a Motion to Modify the Court’s ARCOS Protective Order. Doc. #: 1447. At that time, there remained some disagreement between MDL Counsel and DEA regarding the scope of the modification, and Defendants had not been afforded the opportunity to express their view.² Thus, the Court provided for additional briefing from the parties. On March 19, 2019, Hospitals filed a brief in support of Plaintiffs’ proposed modification. Doc. #: 1455. On March 29, 2019, various defendants filed responses to Plaintiffs’ proposed modification.³ Doc. #: 1488, 1494. Finally, on April 5, 2019, DEA filed its response to Plaintiffs’ proposed modification of the ARCOS Protective Order. Doc. #: 1522.

¹ All references to “Doc. #:” refer to the master docket in *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP) (N.D. Ohio).

² DEA opposed Plaintiffs’ Modification as filed because it included provisions for sharing ARCOS data with hospitals. *See* Doc. #: 1447-1.

³ There were two separate responses filed: Certain Defendants’ Opposition to Plaintiffs’ Motion to Modify Protective Order Re: DEA’s ARCOS/DADS Database, Doc. #: 1488, was filed by Defendants AmerisourceBergen

Having carefully considered the briefs on the matter, the Court hereby issues the following ARCOS Protective Order, which consolidates and supersedes the Court's prior ARCOS Protective Orders. Doc. ## 167, 400, 602.⁴

Accordingly, it is hereby **ORDERED**:

1. Purpose. The Court enters this Protective Order to govern the disclosure of official Department of Justice ("DOJ") information collected and maintained by the DEA in its ARCOS database, as well as Suspicious Order Reports collected and maintained by the DEA.

2. Scope. This Order applies to all documents or electronically stored information ("ESI") provided by the DEA to the Court, counsel, or any parties in the above-captioned litigation, including but not limited to: any data produced directly from DEA's ARCOS database; any reports generated from DEA's ARCOS database; any information collected and maintained by DEA in its ARCOS database; and any derivative documents that the parties or their employees, agents or experts create using ARCOS data (collectively, "ARCOS Data") and Suspicious Order Reports produced by DOJ and/or DEA.

This Order also applies to the following categories of information:

1) (A) The entirety of the SORs previously produced in this litigation by the DEA; (B) the entirety of the unprocessed ARCOS data previously produced in this litigation by the DEA; (C) county level SLCG⁵ Processed ARCOS data; and/or (D) county⁶ level reports⁷ as identified below:

1. County Level Distributor Reports that include the following information:
 - i. State level summary distributor market share by MME;

Drug Corporation, Cardinal Health, Inc., McKesson Corporation, and Walgreens Boots Alliance, Inc.; and Response to Plaintiffs' Motion to Modify Protective Order Re: DEA's ARCOS/DADS Database, Doc. #: 1494, was filed by CVS Indiana, LLC, Discount Drug Mart, Inc., HBC Service Company, Kroger Co., Rite Aid of Maryland, Walgreens Boots Alliance Inc., and Walmart Inc. (These latter pharmacy defendants also joined the earlier filed opposition brief).

⁴ In addition to the two ARCOS Orders described above, Doc. ##: 167 and 400, the Court also issued an Order re Alternate Exhibit A to 167 ARCOS Protective Order. Doc. #: 602.

⁵ Securities Litigation and Consulting Group, Inc.

⁶ As used herein the term county includes parishes.

⁷ The county level reports include data for all drugs for which the DEA provided ARCOS data except the two treatment drugs, specifically, methadone and buprenorphine.

- ii. State level summary distributor market share by dosage units;
 - iii. State level summary distributor market share by dosage units by distribution center;
 - iv. State versus county level market share comparison by total dosage units;
 - v. County level summary distributor market share⁸ by MME;
 - vi. County level summary distributor market share by dosage units;
 - vii. County level distributor summary chart;
 - viii. County level summary distributor market share by dosage units by distribution center;
 - ix. County level per capita total dosage units;
 - x. Chart of county level market share and total dosage units per capita;
 - xi. County level market share by distributor;
 - xii. Charts of county level market share by distributor.
2. County Level Labeler Reports that include the following information:
- i. County level labeler⁹ market share by MME total for 2006 through 2014;
 - ii. County level labeler market share by dosage units total for 2006 through 2014;
 - iii. County level labeler market share by MME by year;
 - iv. County level labeler market share by dosage units by year;
 - v. County level labeler market share data by MME;
 - vi. County level market share data by dosage units.

⁸ Distributor market shares aggregate the market shares attributable to distribution centers owned by the same distributor.

⁹ Labeler information was derived using the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration code for each drug and cross referencing against the Food and Drug Administration, National Drug Code Directory and list of NDC/NHRIC Labeler Codes. A list of NDC/NHRIC Labeler Codes is available at:

www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm.

Food and Drug Administration, National Drug Code Directory available at:

www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt; www.deadiversion.usdoj.gov/arcos/ndc/readme.txt.

Additionally, the ARCOS Registrant Handbook provides the following definitions relating to labeler:

A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e., relabeler). The “relabel” term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. Registrant Handbook at 6-2, available at:

www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook.

Labeler market shares aggregate the market shares attributable to FDA labeler names which reflect slight variations in a parent company name.

3. County Level Pharmacy Reports that include the following information:
 - i. County level summary of opioid shipments of twelve opioid drugs to retail and chain pharmacies¹⁰ within the county by total dosage units, weight in mgs and total MME;
 - ii. For the top 100 pharmacies in the county ranked by MME, pharmacy reports, which provide:
 - a. opioid shipments by distributor band distribution center by year;
 - b. average purchased opioid MME of pharmacies in the county and in the state as well as the percentile rank of this pharmacy's receipts of opioids compared to all pharmacies in the state;
 - c. chart of total dosage units by drug family shipped to pharmacy;
 - d. chart of total MME by drug family shipped to pharmacy.

2) County level SLCG Processed ARCOS data and county level reports, as enumerated in (C) and (D) above, will be provided to counsel as follows:

- (A) State Attorneys General – county level SLCG Processed ARCOS data and county level reports for all counties in the state;
- (B) Cities – county level SLCG Processed ARCOS data and county level reports for the county in which the city is located;
- (C) Counties – county level SLCG Processed ARCOS data and county level reports for that county;
- (D) Native American Tribes – county level SLCG Processed ARCOS data and county level reports for all counties included, in whole or in part, within its territorial boundaries;
- (E) MDL Plaintiff Hospitals – county level SLCG Processed ARCOS data and county level reports for the county in which the hospital is physically located.

3. Form and Timing of Designation. Prior to the production or disclosure of documents, MDL Counsel and/or the DEA shall designate all documents as confidential and restricted in disclosure under the Order by stamping “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” on the document in a manner that will not interfere with the legibility of the document and that will permit complete removal of the CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER designation. The designation “CONFIDENTIAL – SUBJECT TO

¹⁰ Included pharmacies are those identified as Retail Pharmacy or Chain Pharmacy in ARCOS field BUYER_BUS_ACT.

PROTECTIVE ORDER” under this Order does not constitute a finding that the document or information has any status or protection by statute or otherwise except to the extent and for the purposes of this Order. If MDL Counsel and/or the DEA produces ESI that cannot itself be marked with one of these two designations, MDL Counsel and/or the DEA shall place the designation on the physical media used to produce the ESI or in the title of any secure server, link, or file used to produce the ESI.

4. Inadvertent Production. If MDL Counsel or the DEA inadvertently produces any document without a confidentiality designation, they do not forfeit the right to later stamp the document(s) with a confidentiality designation and obtain for the document(s) the full protection of this Order.

5. Authorized Use. The Suspicious Order Reports and/or ARCOS Data designated “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” under this Order (collectively, “Designated Information”) shall not be used by the parties, counsel for the parties, or any other authorized entities or persons identified in ¶¶ 6 or 7 for any purpose whatsoever other than (1) to mediate, settle, prosecute, or defend litigation in any court throughout the United States involving the marketing, distribution, sale or use of Opioid related drugs (“Opioid Litigation”), or (2) for law enforcement purposes. Specifically, Designated Information shall not be used by any person or entity for commercial purposes, in furtherance of business objectives, or to gain a competitive advantage.

6. Authorized Individuals. Documents and/or ESI designated “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” shall be available only to the authorized parties described in this **Paragraph 6 (Authorized Individuals)** and attorneys for the authorized parties. The Court concludes that disclosure of the materials identified in **Paragraph 2 (Scope)** above may be made

to counsel for State Attorneys General, cities, counties, Native American Tribes, and hospitals to the extent that such hospitals are plaintiffs in the above-captioned MDL (“MDL Plaintiff Hospitals”). The parties and counsel for the parties shall not disclose or permit the disclosure of any Designated Information to any third person or entity except:

- a. Employees and agents of counsel assisting with the Litigation who have a need to view the Designated Information in connection with the Litigation;
- b. Court reporters in the Litigation, the judge and his employees or clerks working on the Litigation, and Special Masters assisting with the Litigation;
- c. Experts employed to assist in the Litigation, but only after completing the certification contained in Attachment B or C, Acknowledgement of Protective Order and Agreement to be Bound, the original of which shall be retained by counsel until the above-captioned case is conclusively resolved;
- d. State and local law enforcement including State Attorneys General; and
- e. Other persons only upon order of the Court and on such conditions as may be agreed or ordered, as set out in the paragraph below concerning “Public Records Requests.”

Any person to whom disclosure is made shall be bound by the terms of this Order. Designated Information shall not be communicated to the public or media in any way or form without prior approval of the Court. Counsel shall take measures to prevent unauthorized disclosure of Designated Information.

7. Copies. All copies of Designated Information shall thereafter be entitled to the protection of this Order.

8. Filing Documents Containing Designated Information. If contained in a pleading, motion, or other document filed with this Court, any Designated Information must be marked with the applicable confidentiality designation, designated as “Subject to Protective Order,” and filed under seal with prior Court authorization. Only the portions of the filed document containing Designated Information are subject to being filed under seal, and a party shall file both a redacted version for the public docket and an unredacted version for sealing.

9. Deposition Testimony Concerning the Designated Information. Deposition testimony concerning the Designated Information, and exhibits to depositions containing the Designated Information, shall be deemed CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER only if designated within ten days of the deposition. Such designation shall be specific as to the portions of the transcript or any exhibit to be designated as CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER. Thereafter, the deposition transcripts and any of those portions so designated shall be protected as CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER, pending objection, under the terms of this Order.

10. Use of Designated Information at Trial. All trials are open to the public. Absent order of the Court, there will be no restrictions on the use of any document that may be introduced by any party during the trial. If a party intends to present at trial CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER documents or information derived therefrom, such party shall provide advance notice to the other parties and to the DEA at least five (5) days before the commencement of trial by identifying the documents or information at issue as specifically as possible (i.e., by Bates number, page range, deposition transcript lines, etc.) without divulging the actual CONFIDENTIAL–SUBJECT TO PROTECTIVE ORDER documents or information. The Court may thereafter make such orders as are necessary to govern the use of such documents of information at trial. Any and all documents that may have been subject to sealing during discovery or motion practice will not enjoy a protected or confidential designation if the matter comes on for hearing, argument, or trial in the courtroom. The hearing, argument, or trial will be public in all respects.

11. De-Designation of Documents Stamped “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” under this Order. Any Designated Information is subject to challenge

by any party or nonparty with standing to object (hereafter, “party”). Before filing any motions or objections to a confidentiality designation with the Court, the objecting party shall have an obligation to meet and confer in a good faith effort to resolve the objection by agreement. If agreement is reached confirming or waiving the CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER designation as to any documents subject to the objection, the designating party shall serve on all parties a notice specifying the documents and the nature of the agreement.

12. Obligations on Conclusion of Litigation. Designated Information shall at all times remain the property of DOJ, subject to DEA control. Unless otherwise agreed upon or ordered, this Order shall remain in force after dismissal or entry of final judgment not subject to further appeal. Within thirty days after dismissal or entry of final judgment not subject to further appeal, all Designated Information and copies thereof shall be returned to the DEA, through its DOJ counsel, unless: (1) the document has been offered into evidence or filed without restriction as to disclosure, or (2) the parties agree to destruction in lieu of return. Notwithstanding the above requirements to return or destroy documents, counsel may retain attorney work product, but it shall continue to be subject to this Order. After dismissal or entry of final judgment not subject to further appeal, the Clerk may elect to return or, after notice, destroy documents filed under seal or offered at trial.

13. Public Record Requests. Because many of the Plaintiffs in this litigation are governmental entities, they may be subject to Public Records Laws, including, but not limited to, the Freedom of Information Act (collectively, “Public Records Laws”). As such, the Plaintiffs may receive requests for the Designated Information under applicable Public Records Laws (“Public Records Requests”). If Plaintiffs receive such requests, they shall immediately notify the DEA and Defendants of the request. Plaintiff will provide the notification to the DEA and Defendants via

email to counsel of record for the Defendants and for the DEA in this litigation pursuant to Plaintiffs' Notice of Procedures for Public Records Requests for ARCOS Data. Doc. #: 202. Should Defendants or the DEA decide to challenge the Public Records Request, the challenging party must, within two business days after notification of the existence of the request, file an appropriate action in this Court, opposing production of the records. Where such a challenge is filed with this Court, Plaintiffs shall not release any Designated Information without order of this Court.

14. The MDL Counsel are hereby authorized to transfer the data identified herein and subsequently provide access to counsel as outlined above.

15. The entirety of the data described in **Paragraph 2 (Scope)** will be transferred via a secured website. Such secured site shall be set up pursuant to Attachment A to this Order.

16. All counsel requesting data outlined in **Paragraph 2 (Scope)** must read the Consolidated ARCOS Protective Order and ensure that the Acknowledgement of Protective Order and Agreement to be Bound, which is attached at Attachment B or C to this Order, is signed by both the counsel making the request, as well as a representative of his or her client.

IT IS SO ORDERED.

/s/ Dan Aaron Polster April 11, 2019
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE