

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

**IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**MDL No. 2804**

**Case No. 17-MD-2804**

This document relates to:

**Judge Dan Aaron Polster**

All Cases

**DEFENDANTS' BRIEF OPPOSING PUBLIC DISCLOSURE OF ARCOS DATA  
PROVIDED ONLY FOR LITIGATION AND LAW ENFORCEMENT PURPOSES**

The Chain Pharmacy, Distributor and Manufacturer Defendants respectfully move the Court for an order enjoining Plaintiffs from publicly disclosing, in response to public records requests, confidential and sensitive ARCOS data that the Drug Enforcement Administration (“DEA”) produced to Plaintiffs only subject to a strict Protective Order entered by the Court. The Chain Pharmacy, Distributor, and Manufacturer Defendants also join DEA’s brief opposing disclosure of the data.<sup>1</sup>

**BACKGROUND**

**A. The ARCOS Protective Order and the Court’s ARCOS Production Orders**

On March 6, 2018 this Court entered its Protective Order re DEA’s ARCOS/DADS Database (Doc. No. 167) (“ARCOS Protective Order”), in which the Court “determined that any . . . disclosure” of ARCOS data “shall remain confidential and shall be used only for litigation

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<sup>1</sup> While the Court called for this briefing based on public records requests made to Plaintiffs Cabell County, Summit County, and Cuyahoga County, Defendants have subsequently received notice of other public records requests. As the Court observed, this issue is likely to recur, and it makes sense for the Court to issue one generally applicable ruling, rather than addressing separate requests piecemeal. Briefing Order re Public Records Requests (Doc. No. 611) (June 13, 2018). Accordingly, Defendants seek an order that covers the produced ARCOS data generally, rather than an order specific to any particular Plaintiff.

purposes or in connection with state and local law enforcement efforts.” *Id.* at 1. To that end, the ARCOS Protective Order limited disclosure to the parties, their counsel, and state attorneys general. *Id.* The order also expressly stated that ARCOS data “shall not be used by the parties, counsel for the parties, or any other authorized persons . . . for any purpose whatsoever other than (1) to mediate, settle, prosecute, or defend the above-captioned litigation, or (2) for law enforcement purposes.” *Id.* ¶ 5.

Even with these confidentiality protections in place, DEA objected on numerous grounds to producing transaction-level ARCOS data that discloses, among other things, specific information about every sale of certain medications by a manufacturer to a wholesale distributor or by a wholesale distributor to a retail pharmacy, including the amount sold and the identity and location of the distributor or pharmacy. The Court overruled DEA’s objections and ordered production of all transaction-level ARCOS data for a period of nine years, first with an order that concerned just six states, Order Regarding ARCOS Data (Doc. No. 233) (April 11, 2018), and then with a second order that required a nationwide production, Second Order Regarding ARCOS Data (Doc. No. 397) (May 8, 2018).

Both production orders stressed that the “[u]se of the ARCOS database shall be limited to this litigation and for State and local law enforcement purposes only,” and that “[n]o person shall disclose the data or allow use of the data except as necessary for a submission to the court or at trial.” Order Regarding ARCOS Data, at 22; Second Order Regarding ARCOS Data, at 3.

**B. The Public Records Requests**

On June 7, 2018, Plaintiffs Cabell County, Cuyahoga County, and Summit County notified DEA and Defendants that they had received requests under Ohio and West Virginia public records laws for the confidential ARCOS data that DEA has produced to Plaintiffs.<sup>2</sup>

In accordance with the Protective Order, DEA, the Chain Pharmacy and Distributor Defendants, and the Manufacturer Defendants filed objections to any production of the ARCOS data by Plaintiffs in response to these requests. *See* DEA Objection to Disclosure of ARCOS Data (Doc. No. 603) (June 11, 2018); Distributor Defendants Objection to Disclosure of ARCOS Data (Doc. No. 605) (June 11, 2018); Manufacturer Defendants Objection to Disclosure of ARCOS Data (Doc. No. 621) (June 13, 2018). Because “these objections raise[d] issues that are likely to recur,” the Court issued a briefing order to enable it to “rule on this issue only once (to be applied in all similar circumstances).” Briefing Order re Public Record Requests, at 2 (Doc. No. 611) (June 13, 2018). That order also “suspend[ed] the obligation of DEA or Defendants to file objections” to any additional public records requests. *Id.*

**C. Federal Regulation of ARCOS Data**

ARCOS is a creature of federal law, maintained by DEA in accordance with 21 U.S.C. §§ 827, 831, 958; *see also* 5 U.S.C. § 552a; 21 C.F.R. § 1304. It is “an automated, comprehensive drug reporting system [that] monitors the flow” of certain controlled substances, including opioids, “from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level” so that “Federal and state government

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<sup>2</sup> Paragraph 13 of the ARCOS Protective Order requires that “[i]f Plaintiffs receive [public record] 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.”

agencies” can “identify the diversion of controlled substances into illicit channels of distribution.” *ARCOS: Background*, DEA DIVERSION CONTROL DIVISION, available at <https://www.deadiversion.usdoj.gov/arcos/> (last visited June 21, 2018). To effect that purpose, federal law requires manufacturers and distributors to submit ARCOS reports containing specific information about each transaction of opioids from manufacturer, to distributor, to pharmacy. *See, e.g.*, 21 C.F.R. § 1304.33. With respect to each transaction, the reports contain, *inter alia*, the type, quantity, and strength of each drug shipped as well as the particular pharmacy to which it was shipped.

The ARCOS data that distributors are required to submit is sensitive from the perspective of both the pharmacies and distributors because it is confidential business information, and it is sensitive from the perspective of DEA because it is crucial to its law-enforcement efforts. Consistent with those concerns, extensive federal laws and regulations limit the circumstances in which DEA may disclose ARCOS data. For example, federal regulations permit DEA to release information it obtains “to Federal, State, and local officials” only if they are “engaged in the enforcement of laws related to controlled substances” or “the institution and prosecution of cases before courts and licensing boards related to controlled substances.” 28 C.F.R. § 0.103(a)(1)-(2).

Federal law affords distributors significant protections against federal Freedom of Information Act requests for ARCOS data. For example, FOIA exempts from public disclosure any confidential commercial information, the disclosure of which is likely to cause substantial competitive harm. *See* 5 U.S.C. § 552(b)(4); *Canadian Commercial Corp. v. Dep’t of Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008). If information falls within this exemption, it also falls within 18 U.S.C. § 1905 and must be withheld from disclosure. *See CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1151-52 (D.C. Cir. 1987) (“It is our considered view . . . that the scope of the [Trade

Secrets] Act is at least co-extensive with that of Exemption 4 of FOIA, and that, in the absence of a regulation effective to authorize disclosure, the [Trade Secrets] Act prohibits [an agency] . . . from releasing any information . . . that falls within Exemption 4.”). And when DEA receives a FOIA request, it is required to provide distributors pre-disclosure notice so that the distributors “may object to the disclosure of” the information. Exec. Order 12,600, 52 Fed. Reg. 23,781 (June 23, 1987). DEA must then “give careful consideration” to any objection raised by the distributors. *Id.*

### ARGUMENT

Because Plaintiffs have not stated what (if any) ARCOS information is in their own possession, rather than in the possession of the outside counsel they share with any number of other entities, it is unclear just what data is subject to these public records requests. By way of example, Plaintiffs have not provided notice whether the public records requests at issue would obligate them, but for this Court’s Protective Order, to make a responsive production of just data for their own geographic territories or whether they possess nationwide data. Defendants similarly do not know what (if any) data fields have been provided to the Plaintiffs receiving public records requests, what (if any) fields the Plaintiffs believe they would be required to produce in response to the requests, and what (if any) redactions Plaintiffs plan to make.

By necessity, then, this brief addresses only general objections to disclosure of the entire ARCOS dataset.<sup>3</sup> Even at the highest level of generality, however, it is clear that disclosure of ARCOS data pursuant to any state public records laws would nullify this Court’s ARCOS

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<sup>3</sup> For the same reasons, declarations in support of this brief would be premature at best. Any potential declarants could speak only in general terms about the harms discussed in this brief.

Protective Order and circumvent federal law. The Court should therefore bar Plaintiffs from disclosing the data pursuant to any current and future public records requests.

**I. Disclosure Would Be Inconsistent with this Court's Orders and Federal Law.**

The Court should prevent Plaintiffs from disclosing ARCOS data pursuant to any state public records requests because doing so would undermine this Court's Orders and federal law.

Information disclosed pursuant to state public records statutes may be freely disseminated to other parties or the public at large. *See, e.g.*, Ohio Rev. Code § 149.43, *et seq.*; W. Va. Code Ann. § 29B-1-1, *et seq.* As a result, if ARCOS data were to be disclosed pursuant to state public records requests, those disclosures would render meaningless this Court's limits on the use of such data. That is, the ARCOS data would become available to the public without restriction, despite this Court's repeated requirement in the ARCOS Protective Order and subsequent orders that ARCOS data was to be disclosed exclusively for use in this litigation and for law enforcement purposes.

Disclosure pursuant to state public records laws would also give those seeking the data a ready path for circumventing the extensive federal scheme governing the collection and use of ARCOS data. As noted, confidential commercial information is exempt from federal FOIA requests insofar as it is likely to cause substantial competitive harm. 5 U.S.C. § 552(b)(4); *Canadian Commercial*, 514 F.3d at 39. And if information falls within that exemption, it also falls within 18 U.S.C. § 1905 and *must* be withheld from disclosure. *CNA Fin.*, 830 F.2d at 1151-52. If disclosed, the ARCOS dataset produced by DEA in this litigation would cause significant competitive harm to the Chain Pharmacies and Distributors. The dataset includes *every* shipment of the products at issue from every wholesale distributor across the country to

each of the almost 62,000 retail pharmacies in the United States over a period of nine years.<sup>4</sup>

Any competitor familiar with the industry could draw highly accurate inferences from that data about overall traffic and sales volumes for each distributor and each store.<sup>5</sup> That information is closely guarded in the highly competitive and fragmented wholesale distribution and retail pharmacy marketplaces.<sup>6</sup> The potential utility of disclosure of this data to a competitor is enormous. Competitors could use the data to determine market shares, to identify trends in ordering patterns, and to predict future behavior.

Importantly, the value of this data and the potential competitive harm is not limited to opioids. Rather, the level of distribution indicated in the ARCOS data serves as a proxy for the overall activity in a pharmacy, generally corresponding to overall traffic through the entire store. A competitor can thus use this information judge the potential profitability of opening its own store in the area. This competitive harm explains why pharmacies keep their sales and dispensing information confidential not just as to opioids, but as to all medications and other products sold at drug store, and why distributors are not permitted to share the information they know about their customers' sales.

It is not just the Chain Pharmacies and Distributors whose sensitive business information would be opened to the public by disclosure of the ARCOS data, but also thousands of parties, most of which are not before the Court and thus have no opportunity to object to disclosure. The

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<sup>4</sup> According to third-party market research, there are 61,722 pharmacies in the United States. *See* IQVIA, National Pharmacy Market Summary, at 3 (June 2018).

<sup>5</sup> In addition, however, there appear to be aberrations in the data with the potential to lead to inaccurate inferences, which could also be problematic.

<sup>6</sup> As an indication of how fragmented the retail pharmacy market is, even the 25 largest chains still account for just 56% of retail pharmacies, while 37% of all pharmacies are independently owned. *Id.* at 2-3.

Chain Pharmacy Defendants currently represent 46% of American retail pharmacies. National Pharmacy Market Summary, at 2. Other chains account for more than 10,000 additional pharmacies across the country, and over 23,000 independently owned pharmacies round out the market. *Id.* at 2-3. These tens of thousands of small businesses and chains rely on DEA's representations that the ARCOS data is not public information. Similarly, the Distributor Defendants are a fraction of the total number of distributors included in the ARCOS data.

Moreover, permitting disclosure of ARCOS data pursuant to state public records laws would effectively strip distributors of the procedural protections that federal law affords them, namely the requirement that DEA provide distributors pre-disclosure notice upon receipt of a FOIA request seeking ARCOS data so to allow distributors to object to specific FOIA request at issue. Exec. Order 12,600, 52 Fed. Reg. 23,781 (June 23, 1987). When submitting ARCOS data, distributors have relied on this and other carefully drawn federal protections. Allowing disclosure pursuant to state law would upset those reliance interests.

Finally, public disclosure of ARCOS data would frustrate effective federal law enforcement efforts by straining relations between DEA and private companies. If unrelated local government entities filing lawsuits can obtain through discovery confidential business information shared with DEA to support law-enforcement efforts, and then must disclose that information to the public by means of state public records laws, business entities will be far more reluctant to share confidential information and can be expected to resist such requests, all to unnecessary detriment of effective law enforcement.

## **II. Disclosure Is Not Permitted Under the State Laws Currently at Issue.**

At a minimum, the Court should prevent Plaintiffs Cabell County, Cuyahoga County, and Summit County from disclosing the ARCOS data they have received from DEA to those who



have submitted public records requests pursuant to Ohio and West Virginia law. Like the federal FOIA, the public records statutes of both Ohio and West Virginia expressly exempt from disclosure certain types of information, including the ARCOS data at issue here.

The Ohio Public Records Act contains at least two applicable exemptions. First, the Act exempts from disclosure “[r]ecords the release of which is prohibited by state or federal law.” Ohio Rev. Code § 149.43(A)(1)(v). That exemption squarely covers federal court orders prohibiting disclosure, such as this Court’s ARCOS Protective Order, as well as trade secrets, including competitively sensitive business information, which are protected by both Ohio state law and federal law. *See Salemi v. Cleveland Metroparks*, 49 N.E.3d 1296, 1301-02 (Ohio 2016) (state law); *Canadian Commercial*, 514 F.3d at 39 (federal law). Second, the Ohio Public Records Act includes an exemption for “confidential law enforcement investigator records.” Ohio Rev. Code § 149.43(A)(1)(h). That exemption encompasses the narrow law-enforcement use of ARCOS data contemplated by this Court’s orders. Similarly, the West Virginia Freedom of Information Act provides exemptions for “[t]rade secrets,” which the statute defines broadly, W. Va. Code § 29B-1-4(a)(1), and “[r]ecords of law-enforcement agencies,” *id.* § 29B-1-4(a)(4)(A).

### CONCLUSION

For these reasons, the Chain Pharmacies, Distributors, and Manufacturers respectfully request an order enjoining all Plaintiffs in this litigation from disclosing any ARCOS data pursuant to public records requests arising under state law. In the alternative, and at a minimum, the Court should enter an order enjoining Plaintiffs Cabell County, Cuyahoga County, and Summit County from disclosing any ARCOS data pursuant to public records requests and reinstate the process for objecting to future requests under the ARCOS Protective Order.

Dated: June 25, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this 25th day of June, 2018, I electronically filed a copy of the foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to all counsel of record.

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