

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*
Case No. 18-op-45090

*The County of Cuyahoga, et al. v. Purdue
Pharma L.P., et al.*
Case No. 17-op-45004

CASE NO.1:17-MD-2804

Hon. Dan Aaron Polster

**DEFENDANTS’ “POSITION PAPER” REGARDING ARCOS AND SUSPICIOUS
ORDER REPORTS PROTECTIVE ORDER**

Defendants¹ submit that the Court should maintain its Protective Orders regarding both ARCOS data and Suspicious Order Reports. While the Sixth Circuit found that there was no good cause for a “permanent[] and categorical[]” order protecting disclosure of the ARCOS data, the Sixth Circuit’s pronouncement is not the last word on this issue. Just two business days after the Sixth Circuit issued its ruling in this case, the United States Supreme Court issued an opinion in *Food Marketing Institute v. Argus Leader Media*, -- S.Ct.---, 2019 WL 2570624 (June 24, 2019). In that case, the Supreme Court rejected the “competitive harm” test relied upon by both this Court and the Sixth Circuit in deciding whether Defendants had shown “good cause” for the ARCOS Protective Order. Under the *Food Marketing* analysis, ARCOS data and Suspicious

¹ On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join this Position Paper.

Order Reports are “confidential” and exempt from disclosure under FOIA and also qualify for a protective order under Rule 26(c)(G)(1), which, like FOIA, protects “confidential . . . commercial information.” Furthermore, because information that falls within Exemption 4 also falls within the Trade Secrets Act, 18 U.S.C. § 1905, government officials must protect the information from disclosure, and there is no occasion for the Court to engage in any balancing of interests in disclosure.

At a minimum, the Court should maintain the status quo and keep the Protective Order in place until the Sixth Circuit has time to consider whether to rehear this issue and revise its opinion regarding ARCOS data in light of the Supreme Court’s decision. The Sixth Circuit’s opinion did not address Suspicious Order Reports (“SORs”) because no media entity sought disclosure of those reports, but those reports also are exempt from disclosure pursuant to the rule of *Food Marketing*.

As also set forth below, the written directions provided by the Special Master for redacting discovery information in briefs is inconsistent with *Food Marketing*. See Dkt. 1719. Those instructions also are inconsistent with the Court’s June 28, 2019 order that “all existing Protective Orders are reaffirmed and shall remain in place until the Court issues a ruling determining the scope of a new Protective Order.” The Court therefore also should maintain the status quo as to such discovery information and keep all applicable protective orders in place until the Sixth Circuit determines how to proceed.

BACKGROUND

Issuance of the Protective Order. After Plaintiffs issued subpoenas to DEA for ARCOS data, the Court ultimately ordered DEA “to produce transactional data for all 50 States and several Territories from its Automation of Reports and Consolidated Orders System (‘ARCOS’)

database.” Dkt. 800. In assessing whether the ARCOS data ought to be disclosed to Plaintiffs, this Court considered whether production of the ARCOS data would cause Defendants “substantial competitive harm.” Dkt. 233 at 17. The Court relied on *Madel v. United States Dep’t of Justice*, 784 F.3d 448 (8th Cir. 2015), and *Madel v. United States*, No. 13-cv-2832, 2017 WL 111302 (D. Minn. Jan. 11, 2017), cases in which the courts analyzed whether certain limited ARCOS data was exempt from public disclosure pursuant to Exemption 4 of FOIA because release of the data would cause wholesale distributors and pharmacies competitive harm. Dkt. 233 at 10–13. FOIA Exemption 4 shields from disclosure “trade secrets and commercial or financial information obtained from a person and privileged *or confidential*.” 5 U.S.C. § 552(b)(4) (emphasis added). In analyzing whether the requested ARCOS data was “confidential,” the *Madel* courts applied the “substantial competitive harm” test and held that the information was exempt under FOIA only if “disclosure is likely . . . to cause substantial harm to the competitive position of the person from whom the information was obtained.” *Madel*, 784 F.3d at 452; *Madel*, 2017 WL 111302, at *3.

This Court noted that ARCOS data is “confidential business information” and that “the DEA does not release ARCOS data publicly.” Dkt. 800 at 1. This Court also noted that “[e]xtensive federal laws and regulations limit the circumstances in which the DEA may disclose ARCOS data” and that “federal regulations permit the 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.’” *Id.* at 10 (quoting 28 C.F.R. § 0.103(a)(1)-(2)). The Court further acknowledged that “[f]ederal law allows distributors of prescription opiates significant protections against FOIA requests for ARCOS data. FOIA exempts from public

disclosure any confidential commercial information, the disclosure of which is likely to cause substantial competitive harm,” and “[i]f information falls within this exemption, it also falls within 18 U.S.C. § 1905, and its dissemination may result in fines and/or imprisonment.” *Id.* (citations omitted).

Nevertheless, citing *Madel*, this Court concluded that producing ARCOS data from 2006 to 2014 *to Plaintiffs* (local governments) would not carry a significant risk of competitive harm to Defendants. Dkt. 233 at 217. The Court rejected DEA’s objection that production of the ARCOS data *to Plaintiffs* would interfere with ongoing DEA investigation efforts. *Id.* The Court did, however, enter a Protective Order governing use and disclosure of the ARCOS data, under which the ARCOS data would remain “confidential” and disclosure of the data could be made only to governmental plaintiffs and State Attorneys General “for this litigation and/or law enforcement purposes.” Dkt. 167 at 1. The Court later extended the ARCOS Protective Order to cover SORs produced by or to the parties in the litigation. Dkt. 397.²

The Intervenors’ Requests. After obtaining ARCOS data through discovery, several of the MDL plaintiffs received public records requests under state disclosure laws from various media companies, which sought disclosure of the ARCOS dataset so that they could publish it in their newspapers. DEA and Defendants objected to disclosure on numerous grounds. The Court permitted the media companies to intervene in the MDL litigation for the limited purpose of addressing their public records requests, and after considering the arguments for and against disclosure, pursuant to Federal Rule of Civil Procedure 26(c)(1), this Court found good cause on three grounds to preserve the confidentiality of the commercially-sensitive ARCOS data: (1) the

² The Court subsequently has amended the ARCOS Protective Order to permit disclosure of ARCOS data to additional government entities and plaintiffs in the MDL. Dkt. 1545, 1725. These amendments do not substantively affect the arguments made herein.

data is not a public record of the local government plaintiffs subject to disclosure under state public records laws; (2) disclosure would cause competitive harm to Defendants; and (3) disclosure would threaten DEA law enforcement objectives. Dkt. 800. The Intervenor appealed the Court's ruling to the Sixth Circuit.

The Sixth Circuit Decision. On June 20, 2019, the Sixth Circuit issued its opinion, in which it held that “the district court abused its discretion in finding that good cause existed to permanently and categorically prevent the ARCOS data from being disclosed pursuant to public records requests.” *In re: Nat’l Prescription Opiate Litigation*, --F.3d---, 2019 WL 2529050, at *13 (6th Cir. June 20, 2019). The Sixth Circuit found that the public’s interest in disclosure of the ARCOS data outweighed any interest in nondisclosure by DEA or Defendants. The court found the interest of Defendants’ only “slight” because “[t]he ARCOS data does not contain sensitive information like trade secrets, and the age of the data makes the risk of anticompetitive harm slight and speculative.” *Id.* at *12. The Sixth Circuit emphasized that Defendants had not demonstrated “commercial harm” from the publication of previous limited portions of ARCOS data and held that Defendants’ competitive interests therefore were “far outweighed by the specific, concrete interest” provided by Intervenor and the public, and good cause had not been shown. *Id.* at *12–13. The court did not dispute that ARCOS data is kept confidential by both the reporting companies and DEA.

ARGUMENT

GOOD CAUSE EXISTS TO PROTECT ARCOS, SUSPICIOUS ORDER REPORTS, AND OTHER DISCOVERY MATERIAL FROM PUBLIC DISCLOSURE.

A. The Supreme Court’s *Food Marketing* Opinion.

On June 24, 2019, two business days after the Sixth Circuit issued its ARCOS opinion in this case, the Supreme Court issued its opinion in *Food Marketing Institute v. Argus Leader*

Media, -- S.Ct.--, 2019 WL 2570624 (June 24, 2019). There, a newspaper filed a FOIA request with the United States Department of Agriculture (“USDA”) seeking disclosure of the names and addresses of retail stores that participate in the national food-stamp program, as well as food-stamp data, from 2005 to 2010. *Id.* at *2. The USDA resisted disclosure under FOIA Exemption 4, *id.*—the same exemption at issue in *Madel*. In *Food Marketing*, the trial court and Eighth Circuit had given significant attention to whether disclosure would inflict “competitive harm” to participating retailers, *id.* at *2–3, just as the Eighth Circuit did in *Madel* and this Court and the Sixth Circuit did in this case.

The Supreme Court rejected the “competitive harm” test, however, holding that there is no statutory support—or support in “dictionary definitions, early caselaw, or any other usual source”—for grafting the requirement of competitive harm onto the definition of “confidential” found in Exemption 4. *Id.* at *5. The Court held that the introduction of the “substantial competitive harm” test in *National Parks & Conservation Assn. v. Morton*, 498 F. 2d 765 (D.C. Cir. 1974), and in other cases like it, was based on a “casual disregard of the rules of statutory interpretation” and was “a relic from a bygone era of statutory construction.” 2019 WL 2570624, at *5 (quotation marks and citation omitted). The Court held that the “term ‘confidential’ meant then [in 1966, when FOIA was enacted], as it does now, ‘private’ or ‘secret.’” *Id.* at *4. Thus, at a minimum, to be “confidential” under Exemption 4, the relevant information must “customarily [be] kept private, or at least closely held, by the person imparting it.” *Id.* The Court further suggested that confidentiality might also require an assurance from the government that the information would remain secret, but ruled that “there’s no need to resolve that question in this case because the retailers before us clearly satisfy this condition too.” *Id.*

Given those two circumstances, the Court held that, “[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is ‘confidential’ within the meaning of Exemption 4” and exempt from disclosure. *Id.* at *7. There is no need for a company resisting public disclosure of confidential business data under FOIA Exemption 4 to demonstrate any competitive harm, much less “substantial” competitive harm. *Id.* at *6. Nor did the Supreme Court indicate that any “balancing” of interests in disclosure versus non-disclosure is appropriate in determining whether information is “confidential” and exempt from disclosure under FOIA.

B. There is Good Cause to Exempt ARCOS Data from Public Disclosure.

The Sixth Circuit found that this Court did not have good cause to enter a protective order preventing the disclosure of ARCOS data to the public because, *inter alia*, any “competitive” risk to Defendants from disclosure was “slight.” But the Supreme Court’s decision in *Food Marketing* now makes clear that data such as ARCOS is “confidential” under Exemption 4, and therefore exempt from public disclosure, whether or not the disclosure would work any competitive harm to the companies that supply the data to the government. ARCOS data meets the *Food Marketing* standard because the record makes it clear that Defendants keep the data confidential, and the government not only agrees to keep it confidential, but is **required by law** to keep it so except in narrow circumstances not at issue here. *See supra* at 3–4.

This Court’s task is to consider whether “good cause” exists pursuant to Rule 26(c)(1) to restrict the production or use of ARCOS data, which the Court ordered DEA to produce over its objections. Rule 26 authorizes protective orders, *inter alia*, “requiring that a trade secret or other confidential . . . commercial information not be revealed or that it be revealed only in a specified

way.” Fed. R. Civ. P. 26(c)(1)(G). In applying Rule 26, this Court and the Sixth Circuit were guided by FOIA. There can be no question after *Food Marketing* that, if Intervenors requested the ARCOS data directly from DEA pursuant to a FOIA request,³ the data would be exempt from disclosure. Furthermore, because Rule 26(c)(1)(G) uses the same language as Exemption 4,⁴ that language should be given the same meaning as the Supreme Court gave to it in Exemption 4.

Whether there is good cause under Rule 26 to prevent disclosure of the data through the vehicle of this litigation is resolved by the Trade Secrets Act, 18 U.S.C. § 1905. Courts have long recognized that the Trade Secrets Act’s prohibitions are at least as broad as Exemption 4 and are mandatory. *See, e.g., 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.”). In other words, if information falls within Exemption 4, the Trade Secrets Act requires that it be withheld. Now that the Supreme Court has clarified the meaning of Exemption 4 to cover commercial information that “is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy,” *Food Marketing*, 2019 WL 2570624, at *7, and because the Trade Secrets

³ DEA and Defendants maintain that that was the proper procedural vehicle for the media companies to seek the ARCOS data because ARCOS is a federal record and is in the possession of local governments only because they received the data as part of discovery in civil litigation. Neither ARCOS, nor suspicious order reports, are records ordinarily available to or in the possession of local governments.

⁴ Rule 26(c)(1)(G) (“confidential . . . commercial information”); Exemption 4 (“commercial . . . information [that is] confidential”).

Act requires government officials to protect such information from disclosure, there is ample good cause for this Court's existing protective order.

Nor is there any occasion for balancing competing interests in disclosure because, in the case of confidential commercial information, Congress in the Trade Secrets Act has struck the balance in favor of non-disclosure. And even if balancing were appropriate, the "balancing" of interests engaged in by the Sixth Circuit is no longer valid under *Food Marketing*. The Sixth Circuit found that the companies' interests in non-disclosure were slight because it focused only on whether there would be competitive harm to the companies from disclosure. Under *Food Marketing*, that is not a proper consideration and certainly not a proper basis on which to conclude that no confidentiality protections ought to attach to the ARCOS data.

C. There is Good Cause to Exempt Suspicious Order Reports from Public Disclosure.

The Court also should maintain the Protective Order over Suspicious Order Reports ("SORs"). First, those reports indisputably meet the *Food Marketing* "confidentiality" test: both Defendants and DEA maintain SORs data as confidential business data that is not shared with the public. For the reasons stated above, this alone is sufficient to support a good cause finding under Rule 26(c)(G)(1) preventing disclosure.

Second, as the Court notes, the Sixth Circuit did not address SORs because Intervenors did not seek disclosure of those reports, and the Sixth Circuit therefore did not order that any modifications of the Protective Order be made regarding those reports. Dkt. 1725. Third, SORs have been produced only through discovery and have not been included on the Court's docket. As both the Sixth Circuit and this Court have noted, "there is a lower requirement for protective orders relating to discovery, during which secrecy is permitted, than for orders to seal court records, which carry a strong presumption of openness." *In re Nat'l Prescription Opiate Litig.*,

2019 WL 2529050, at *9 (citing *Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016)).

Fourth, because no third party has sought disclosure of SORs, no one has demonstrated a public interest in those documents. The Sixth Circuit found that the public has a significant interest in disclosure of ARCOS data because that data “provid[es] invaluable, highly-specific information regarding historic patterns of opioid sales.” 2019 WL 2529050, at *10 (quoting Dkt. 397). The court also found that “[t]he ARCOS data will aid us in understanding the full enormity of the opioid epidemic and might thereby aid us in ending it.” *Id.* Based on arguments made by Intervenors, the court also found that the public has an interest in knowing how many prescription opioids were shipped to which pharmacies and in what dosages. *Id.* SORs do not provide any of that information. They do not reveal historic patterns of opioid sales or show which pharmacies or practitioners got what pills in what dosages. If SORs are made public, hundreds or thousands of local pharmacies and individual practitioners will be revealed to have had orders reported to DEA as “suspicious” under the terms of the CSA’s implementing regulation. These entities and individuals no doubt will be subject to media scrutiny even though a reported SOR does not necessarily reflect any wrongdoing by any pharmacy or practitioner, and certainly not every SOR reflects a shipment that was likely to be, or was, ever diverted or caused anyone any harm. SORs are a tool used by distributors and manufacturers to aid DEA in its law enforcement duties. Because SORs do not tell the public anything about what actually happened with respect to opioid distributions or sales “on the ground,” the public has no, or at most, a very minimal, interest in disclosure of those documents.

Thus, even if the Court were to engage in a balancing of the public's interest in disclosure versus Defendants' interests in confidentiality, the public's interest is minimal, if any, and outweighed by the confidentiality protections afforded the reports.

D. There is Good Cause to Exempt Additional Confidential Business Data from Public Disclosure.

Food Marketing also impacts the written directions provided by the Special Master for redacting information contained in briefs and exhibits—directions that expressly are based on the Sixth Circuit opinion. *See* Dkt. 1719 at 1 n.1. The Special Master's directions state: “Information that is considered ‘business confidential’ but that is not a bona fide trade secret does not qualify for redaction.” *Id.* at 3 n.4. This standard implicitly is rejected by *Food Marketing*, which, as noted above, preserved confidentiality for material that is “customarily kept private, or at least closely held, by the person imparting it.” *Food Marketing*, 2019 WL 2570624, at *4. As also noted above, the Supreme Court interpreted the same terms—confidential commercial information—as appear in Rule 26(c)(1)(G). Thus, the Special Master's directions on sealing briefs are not consistent with *Food Marketing* and should be revised accordingly.

E. At a Minimum, the Court Should Maintain Its Protective Orders in Effect Until the Sixth Circuit Has an Opportunity to Decide Whether To Revisit Its Ruling In Light of *Food Marketing*.

With the benefit of *Food Marketing*, the Sixth Circuit may have affirmed this Court's order, or at the very least remanded for this Court to determine good cause in light of *Food Marketing*. Both this Court and the Sixth Circuit found that the ARCOS data was confidential, and both the Sixth Circuit and this Court relied on the *Madel* cases that utilized the “substantial competitive harm” standard that *Food Marketing* rejected. Under *Food Marketing*, it makes no

difference whether the competitive harm to Defendants from disclosure of ARCOS is “slight and speculative.”

Under Federal Rule of Appellate Procedure Rule 41(b), the Court of Appeals mandate does not issue until seven days after the time for a rehearing petition elapses. And under Rule 40(a)(1), the parties have 45 days after the entry of judgment to seek rehearing by the panel or an *en banc* rehearing. DEA and Defendants should be allowed an opportunity to exercise that right in light of *Food Marketing*. If this Court orders ARCOS data to be released to the public before that 45 days has expired—or, if a petition for rehearing is sought, before the Sixth Circuit has time to consider it—the Court effectively will have denied DEA and Defendants their ability to seek rehearing and denied the Sixth Circuit the opportunity to consider its ruling in light of binding Supreme Court precedent.

Defendants therefore ask the Court to maintain the status quo at least until the rehearing process has time to play out in the Sixth Circuit. For the same reasons, the Court should defer any decision to unseal confidential business data attached to court filings pending the conclusion of the appeal process in the Sixth Circuit.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court maintain its Protective Orders regarding all ARCOS data, SORs, and discovery material attached to court filings at this time.

Dated: July 3, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Ashley W. Hardin, hereby certify that the foregoing document as served via the Court's ECF system to all counsel of record.

/s/ Ashley W. Hardin
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