UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

		MDL 2804
IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	**Judge Dan Aaron Polster**
ALL CASES NOT DESIGNATED IN PARAGRAPHS 2 OR 3 OF CMO-1	)	**ORDER REGARDING PLAINTIFF'S MOTION FOR MODIFICATION OF CMO-1**

Before the Court is Plaintiffs' Motion for Modification of CMO-1 Regarding ARCOS Market Share Data and Amending Complaints. **Doc. #: 1077**. After reviewing Plaintiffs' Motion, the United States' Response,[1] Doc. #: 1097, Defendants' Response, Doc. #: 1099, and Plaintiffs' Reply, Doc. #: 1102, the Court has determined that minor modifications to its July 13, 2018 Order Regarding Plaintiffs' Motion for Modification of CMO-1, Doc. #: 739 are necessary, specifically with regard to the PEC ARCOS reports. Therefore, the Court **GRANTS** Plaintiffs' Motion, and modifies its July 13, 2018 Order as follows:

On or before November 19, 2018, the PEC shall make available reports derived from the ARCOS data that list, for every county or county equivalent,[2] all manufacturers, distributors and pharmacies that manufactured, distributed or sold of the prescription opioids distributed in that county. The reports shall be disseminated according to the procedures set out in the Amended

[1] The U.S. Department of Justice and U.S. Drug Enforcement Agency do not object to Plaintiffs' Motion.
[2] The PEC states there are about 3,007 counties and 137 county-equivalents in the United States.

Notice of ARCOS Disclosure.[3] Doc. #: 859. The reports provided by the PEC shall include the following:

(1) Manufacturer Reports reflecting the names of all labelers[4] (as identified by NDC code) who manufactured and/or labeled more than five percent (5%) of the market share of opioids distributed in the relevant county or county-equivalent in at least three of the nine years available in the ARCOS data;

(2) Distributor Reports reflecting the name of each distributor who distributed more than five percent (5%) of the market share of opioids distributed in the relevant county or county-equivalent in at least three of the nine years available in the ARCOS data; and

(3) Pharmacy Reports reflecting all opioid shipments to each pharmacy in the relevant county or county equivalent. Plaintiffs in MDL cases[5] may then use this information to amend

[3] Plaintiffs' Amended Notice of ARCOS Disclosure includes the requirement to be bound by this Court's protective orders.

[4] The PEC states that 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:
https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm.

Food and Drug Administration, National Drug Code Directory available at:
https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt
https://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:
https://www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook.

[5] This Order applies only to those cases not designated in paragraphs 2 or 3 of CMO-1.

their complaints,[6] and must do so on or before March 16, 2019 (that is, within 120 days from PEC's filing of the reports).[7]

IT IS SO ORDERED.

/s/ Dan Aaron Polster *November 8, 2018*
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

[6] The Court recognizes that the entities who manufactured, distributed, or sold opioids in "County Y" may not be exactly the same entities that manufactured, distributed, or sold opioids in "City X" that is located in "County Y." Because creating a more granular, city-level report would be extremely burdensome, the Court concludes the county-level report can serve as a reasonable approximation, allowing for a sufficiently accurate identification of appropriately named defendants. Amended complaints may then refer to the PEC's report. If a given MDL case is later set for full discovery and trial, then any necessary corrections—including altering defendants plead by a city—can be made at that time. Finally, the Court reiterates its view that participation by a City or County in any eventual class or aggregate settlement is not contingent on having filed a complaint.

[7] The deadlines in this Order apply to cases transferred into this MDL as of the date of entry of this order. With respect to cases transferred into this MDL after the entry of this Order, any amended complaints to be filed without seeking leave of Court must be filed the later of March 16, 2019, the applicable deadline under Fed. R. Civ. Pro. 15(a)(1), or 90 days following transfer into this MDL.