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	)	**ISSUE RULING FIVE REGARDING DILIGENCE**

In *Issue Ruling One* (docket no. 6306), the Court stated it would publish a series of "Issue Rulings" to resolve common arguments raised by the parties in connection with plaintiffs' numerous pending motions for leave to amend complaints.[1] This *Issue Ruling Five* addresses defendants' arguments concerning whether plaintiffs were diligent in meeting the Court's amendment deadline. Specifically, the Court addresses two aspects of diligence raised by defendants: (1) whether the information necessary to identify and add these defendants was available to plaintiffs prior to their case-specific amendment deadlines; and (2) whether plaintiffs demonstrated a lack of diligence by failing to promptly pursue amendment after the relevant information became available. The reader can learn the "bottom line" by skipping to the Summary section at the end of this Ruling.

The Court begins its analysis with a recapitulation of the deadlines it set, and re-set, for amendment of complaints.

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[1] *See Issue Ruling One* at 2 ("Future Issue Rulings are deemed to incorporate by reference this [Legal Standards] Section of Issue Ruling One.").

I. Procedural Background of Amendment Deadlines.

A. The Moratorium.

At the outset of this MDL, the Court issued a temporary moratorium on substantive filings. *See* docket no. 4 at 4 (ordering "a **moratorium** on all filings . . . for 60 days") (emphasis in original); docket no. 70 at 2 ("the Court hereby **continues the moratorium on all substantive filings**") (emphasis in original). As relevant here, this moratorium included motions for leave to amend complaints.

The Court then changed the moratorium from temporary to standing. Specifically, on April 11, 2018, the Court issued its first Case Management Order ("CMO-1"). Docket no. 232. In CMO-1, the Court ordered that "No party may file any motion not expressly authorized by this Order absent further Order of this Court or express agreement of the parties." *Id.* ¶ 6.g at 11. CMO-1 also provided that "Plaintiffs shall file any amended pleading, including any amendment to add a party to a case, **no later than Friday, May 25, 2018**. After that date, no complaint shall be amended by Plaintiffs to add a party or otherwise, absent leave of Court or stipulation of the parties." *Id.* ¶ 6.b at 9 (emphasis in original).[2]

Later, the Court clarified these provisions of CMO-1, stating:

> [I]f a plaintiff in an MDL case wants to file an amended complaint without leave of Court, it must do so by May 25, 2018. Thereafter, all cases . . . are stayed until further order of [the] Court. If a case is later designated as a bellwether for motion practice or trial, a separate CMO will be entered that will provide for another opportunity to amend. And, plaintiffs retain the right to move to file further

[2] CMO-1 added that "[t]he deadline ***for Defendants*** to add a party without leave of Court shall be **45 days before the close of fact discovery** applicable to a particular case" *Id*. (italicized emphasis added). No fact discovery has commenced in any of the stayed cases seeking leave to amend ("MTA Cases").

> amended pleadings if deemed appropriate, such as because additional defendants were identified by ARCOS data.

Docket no. 371 at 1–2. This clarification created the "Bellwether Exception" to the amendment deadline: it allowed any plaintiff whose case is chosen as a bellwether to amend their complaint upon bellwether designation. The Bellwether Exception implicitly included, pursuant to the underlying language it clarified, a plaintiff's right to "add a party."[3]

Thus, as of May 26, 2018, the MDL-wide rule was that a plaintiff was allowed to amend its complaint to add a party only pursuant to: (1) stipulation, (2) order of the Court, or (3) designation as a bellwether.

B. The First Tranche of ARCOS Data.

On May 8, 2018, the Court ordered the U.S. Drug Enforcement Administration ("DEA") to "produce to the parties complete transactional ARCOS data, and also all Suspicious Order Reports, for the entire United States, for the period of January 1, 2006, through December 31, 2014." Docket no. 397 at 2.[4] The Court ordered that "production of the ARCOS data shall take place on or before May 25, 2018." *Id.* On June 26, 2018, after a brief review of the produced ARCOS data, the Court ordered the DEA to expand the data production to include 10 additional opioid drugs. *See* docket no. 668 at 2.

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[3] As discussed further below, plaintiffs' right to add a party pursuant to the Bellwether Exception was upheld by the Sixth Circuit. *See In re Nat'l Prescription Opiate Litig.*, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022).

[4] "ARCOS—which stands for Automation of Reports and Consolidated Orders System—is 'an automated, comprehensive drug reporting system [overseen by DEA] which monitors the flow of DEA controlled substances [such as opioids] from [1] their point of manufacture through [2] commercial distribution channels to [3] point of sale or distribution at the dispensing/retail level.'" Docket no. 5115 at 2 (citation omitted, brackets added by Court).

Upon production of the expanded ARCOS data, it became clear that plaintiffs needed more time to analyze it to amend their complaints to add parties, the deadline for which had already passed. Thus, the Court modified its CMO-1 amendment deadline on two separate occasions.

First, on July 13, 2018—in response to a request from plaintiffs to indefinitely stay the Court's amendment deadline while they worked to synthesize the ARCOS data—the Court ruled that "Plaintiffs are entitled to additional time to file amended complaints after reviewing and analyzing the ARCOS data," but refused to grant an indefinite stay. Docket no. 739 at 3. The Court ordered the Plaintiffs' Executive Committee ("PEC") to create and provide to all MDL Plaintiffs,[5] on or before July 19, 2018, reports "derived from the ARCOS data" (hereinafter "ARCOS Reports") that disclosed "the *identity* of entities that manufactured, distributed, or sold opioids in the counties." *Id.* at 4 (emphasis in original). At the same time, pursuant to the DEA's and defendants' request, the Court prohibited the ARCOS Reports from revealing "any data regarding the *amounts or types of opioids* distributed." *Id.* (emphasis in original). The Court then extended the deadline to amend complaints to November 16, 2018, to give the PEC time to generate and disseminate the ARCOS Reports to MDL Plaintiffs, and to allow each plaintiff to then "amend their complaints to properly name 'various entities who *should* be named as defendants' and also to remove claims 'against defendants who should *not* be named.'" *Id*. at 1 (quoting docket no. 397 at 2) (emphasis in original). The Court again reiterated that, "if a given MDL case is later set for full discovery and trial, then any necessary corrections [to the amended complaints] . . . can be made at that time." *Id.* at 4, n.3.

[5] The Court uses "MDL Plaintiffs" to refer to all plaintiffs in the MDL, whether they have moved for leave to amend their complaint or not. The Court uses "MTA Plaintiffs" to refer to any plaintiff who has joined any of the PEC's motions for leave to amend their complaint.

On July 19, 2018, as ordered by the Court, the PEC filed its first Notice of ARCOS Disclosure.[6] Docket no. 767. These first ARCOS Reports contained only the identities of each manufacturer, distributor, and pharmacy registrant that had conducted any opioid business in a given county. Recognizing that the mere presence of a potential defendant in a plaintiff's jurisdiction would, by itself, not provide a sufficient basis upon which a plaintiff could amend its complaint, the Court on November 8, 2018 ordered the PEC to make a minor modification to the ARCOS Reports. *See* docket no. 1106 ("Modification Order"). The minor modification was that the ARCOS Reports were to include only those **manufacturers** and **distributors** who had more than a 5% market share of opioid business in each county. The Court did not require a 5% market share threshold for a **pharmacy** business. Instead, the Court ordered that the ARCOS Reports should reflect "all opioid shipments to each pharmacy in the relevant county." *Id.* at 2.

The Court then extended the deadline for amending complaints to "the later of: [i] March 16, 2019, [ii] the applicable deadline under Fed. R. Civ. P. 15(a)(1), or [iii] 90 days following transfer into this MDL." Docket no. 1106 at 3, n.7. The Court's moratorium remained otherwise in effect. Thus, except for the Bellwether Exception, this provision in the Modification Order became MDL Plaintiffs' final deadline to amend their complaints without further leave of Court.

C. The Short-Form Amendment Process.

On January 18, 2019, after the PEC was able to synthesize the ARCOS data and produce and disseminate the modified ARCOS Reports, the Court granted a request by the PEC to allow MDL Plaintiffs to meet the March 16, 2019 amendment deadline by using a Short-Form

[6] On August 8, 2019, the PEC filed an Amended Notice of ARCOS Disclosure describing a change in the procedure for counsel to obtain the ARCOS Reports, but that change did not substantively modify the information presented in the reports. Docket no. 859.

Amendment Process. *See* docket no. 1282. The primary focus of the Short-Form Amendment Process was for each MDL Plaintiff to use the ARCOS Reports to amend its complaint to add or delete defendants. Although the Court approved the use of the Short-Form Amendment Process, the Court appreciated that litigation in the MDL would continue to evolve and that further amendments to complaints would likely be necessary. Accordingly, the Short-Form Amendment Order again reiterated that MDL Plaintiffs would get another opportunity to amend if and when their case was "set for trial." *See id*. at 3 ("Should any of those cases [that utilize the Short-Form Complaint] subsequently be set for trial, purported deficiencies with the complaints can be addressed at that time by subsequent Court order.").

The Court notes this "set for trial" language is broader than its previous language "if … designated as a bellwether." The Short-Form Amendment Order expressly contemplated further opportunities for all MDL Plaintiffs to "clean up" their complaints.[7] As this Court has previously explained:

> Although the Short Form Complaint Order permitted plaintiffs to amend their complaints "for matters both relying on and beyond the ARCOS data," it recognized that the short form complaints were intended to be a one-size-fits-all solution to "streamline the amendment process, reduce the burden on the parties and the Court, and increase judicial efficiency." *Id.* at 3. The Court expressly provided that, "should any of those cases subsequently be set for trial, purported deficiencies with the complaints can be addressed at that time by subsequent Court

[7] The Court recognized then and continues to recognize that a case filed years ago and immediately stayed, with virtually no opportunity to actively litigate for nearly a decade, will likely require some modifications to its complaint before it can be considered "trial ready." Thus, by "clean up," the Court means that a plaintiff whose complaint has been stayed for many years and whose case is later chosen as a bellwether or remanded may need to amend its complaint to, among other things: (1) remove settled or bankrupt defendants; (2) remove theories of liability that are no longer viable; (3) add subsequently developed legal theories; and/or (4) add updated factual allegations identified through bellwether discovery. The Federal Rules, with the recent addition of Fed. R. Civ. P. 16.1(c), recognize the necessity of this type of flexibility in MDLs. *See* Fed. R. Civ. P. 16.1(c) cmt. ("Because active judicial management of MDL proceedings must be flexible, the court should be open to modifying its initial management order in light of developments in the MDL proceedings.").

> order." *Id.* At ***all*** other times, no MDL plaintiff could amend its complaint without first being selected as a bellwether.

Docket no. 5319 at 2–3 (emphasis in original).

D. The ARCOS Data Becomes Publicly Available.

On April 12, 2019, shortly after the amendment deadline had passed, the Court issued an updated ARCOS Protective Order that would allow the PEC to share with MDL Plaintiffs for the first time "the entirety of the unprocessed ARCOS data," as well as county-level reports showing detailed market share analyses.[8] Docket no. 1545 at 2. This information would only be shared with plaintiffs who signed an Acknowledgment of Protective Order and Agreement to be Bound. On May 7, 2019, the PEC filed a Second Notice of ARCOS Disclosure describing the procedure a plaintiff could use to request the ARCOS data and/or the PEC's analyses thereof. *See* docket nos. 1612; 1613.

Then, on June 20, 2019, the Sixth Circuit issued a decision vacating this Court's ARCOS Protective Order. *See In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919 (6th Cir. 2019). In response to the Sixth Circuit's mandate, on July 15, 2019, this Court partially lifted its protective order with respect to the 2006–2012 ARCOS data, *see* docket no. 1845; and on November 5, 2019, the Court lifted the protective order with respect to the final two years of the complete 2006–2014 ARCOS dataset. *See* docket no. 2909. The ARCOS data produced by the DEA thus became publicly available in its entirety in late 2019. By the time the ARCOS data was fully publicly

[8] These reports still do not appear to have contained a true pharmacy market share. Rather, they provided, among other analyses: "For the top 100 pharmacies in the county ranked by MME . . . the percentile rank of this pharmacy's receipts of opioids compared to all pharmacies in the state." Docket no. 1545 at 4.

available, however, the amendment deadline had passed for the vast majority of MDL Plaintiffs, who were prevented from moving to further amend their complaints by the Court's moratorium.[9]

E. The JPML's Order.

On April 8, 2022, the Judicial Panel on Multidistrict Litigation ("JPML") concluded that "inclusion of . . . any future actions in MDL No. 2804 is no longer necessary to achieve the just and efficient conduct of the litigation" and stopped transferring new cases into the MDL. *In re: Nat'l Prescription Opiate Litig.*, MDL No. 2804, docket no. 9586 at 1 (J.P.M.L. Apr. 8, 2022) (citing 28 U.S.C. § 1407(a)). Accordingly, the last possible date on which any MDL Plaintiff could amend its complaint without leave of Court was July 7, 2022—that is, 90 days after the final transfer date of April 8, 2022.[10]

F. The Bellwether Exception Applied.

Of course, even after the JPML Transfer Ruling, the Court's Bellwether Exception remained in force. And the Court in fact applied this Exception when it chose several bellwether cases, allowing those bellwether plaintiffs to amend their complaints to add defendants as appropriate.

Most notably, after Montgomery County, Ohio was chosen as a bellwether plaintiff in Track Seven, it added Meijer as a "new defendant" in its amended complaint. Meijer challenged

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[9] The only MDL Plaintiffs that ***could*** amend their complaints without leave of Court, after the ARCOS data was made fully public, were: (1) those that were transferred into the MDL and could still take advantage of the Court's earlier Order allowing amendment "90 days following transfer into this MDL," docket no. 1106 at 3, n.7; and (2) those selected as a bellwether.

[10] *See* footnote 9.

the viability of the Court's Bellwether Exception, ultimately seeking relief from the Sixth Circuit via petition for writ of *mandamus*. The Sixth Circuit upheld the Bellwether Exception:

> Meijer rightly points out that the district court's scheduling order fits somewhat uncomfortably with Rule 16's requirement that scheduling orders "limit the time to join other parties." Fed. R. Civ. P. 16(b)(3)(A). The scheduling order allowed plaintiffs to amend whenever their case was selected as a bellwether, so there was no cutoff date for amendments. That unusual aspect of the scheduling order did not clearly violate Rule 16 because it provided some limit (when a case was selected as a bellwether), although the order went right to the edge of the district court's discretion under Rule 16.

In re Nat'l Prescription Opiate Litig., 2022 WL 20701236, at *1.[11] The Sixth Circuit also noted that, although Meijer was "new" to the Track Seven case, it had been in the MDL for several years. *See In re Nat'l Prescription Opiate Litig.*, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022) ("Meijer was added to this case before discovery ever started. Going back even further, Meijer has been a party to the MDL since at least 2019.").

G. The Second Tranche of ARCOS Data.

On July 14, 2023, the Court granted a motion by the PEC to enforce a subpoena served on the DEA for new, updated ARCOS data—that is, the Court ordered the DEA to produce another five years of data regarding opioids. *See* docket no. 5115. On August 14, 2023, the DEA produced the raw ARCOS data from 2015–2019 to the PEC. *See* docket no. 5565-2 at 2 (Decl. of P. Mougey). After conducting its analysis on the new ARCOS data, the PEC provided updated ARCOS Reports to all MDL Plaintiffs on September 12, 2023. *See id.* at 5.

[11] Although not in effect at the time the Sixth Circuit issued this ruling, the applicability of Fed. R. Civ. P. 16(b)(3)(A) to MDLs has been altered by new Fed. R. Civ. P. 16.1(c). *See* Fed. R. Civ. P. 16.1(c) cmt. ("There is no requirement under Rule 16.1 that the court set specific time limits or other scheduling provisions as in ordinary litigation under Rule 16(b)(3)(A)."). So, while the Sixth Circuit ultimately upheld the Court's Bellwether Exception, the Exception would plainly be permissible under the current Rules.

H. The Final Amendment Process.

On April 22, 2024, the PEC moved to lift the Court's moratorium and permit all MDL Plaintiffs to file motions for leave to amend their complaints, to add new defendants. Docket no. 5411. The Court granted the motion, but stated: "This will be plaintiffs' final opportunity to amend their complaints." Docket no. 5455 at 2.[12] The Order then set forth the present Final Amendment Process that is the subject of these *Issue Rulings*.

II. Analysis.

A. Legal Standard.

"The primary measure of Rule 16's 'good cause' standard is the moving party's diligence in attempting to meet the case management order's requirements." *Helena Agri-Enterprises, LLC v. Great Lakes Grain, LLC*, 988 F.3d 260, 272 (6th Cir. 2021) (citation omitted). "Good cause is a flexible concept," *Powell v. Fugate*, 2018 WL 4088029, at *2 (E.D. Ky. Aug. 27, 2018), and "trial courts have considerable discretion in determining what kind of showing satisfies this . . . good cause standard." *Tesone v. Empire Mktg. Strategies*, 942 F.3d 979, 988 (10th Cir. 2019) (citation omitted). "What constitutes good cause sufficient to justify the modification of a scheduling order necessarily varies with the circumstances of each case." Charles Alan Wright *et al*., 6A Fed. Prac. & Proc. § 1522.2 (3rd ed.).

[12] Later, the Court clarified that this "final opportunity" to amend complaints did not abrogate the Court's Bellwether Exception, but it did preclude plaintiffs from ***adding new defendants*** in later bellwether amendments. *See* docket no. 5656 at 2–3 ("The Court ***may*** later allow amendment of complaints by a newly-chosen bellwether plaintiff to update allegations or to add claims, but it will not allow any further amendment by any MDL Plaintiff to add a new defendant.") (emphasis in original). This rule will also apply to any remanded case that is "cleaned up" to become trial-ready, *see* footnote 7.

The "due diligence requirement does not impose on a plaintiff the burden to exhaust all avenues to discover information that may serve as the basis of a claim." *O'Neal v. Denn-Ohio, LLC*, 2020 WL 210801, at *2 (N.D. Ohio Jan. 14, 2020). And "the time at which certain information became available to [the movant is not] dispositive of diligence, rather [it is] a factor to be considered." *NOCO Co. v. Lapidus*, 2022 WL 1803039, at *2 (N.D. Ohio June 2, 2022) (Polster, J.). "A party seeking to modify a scheduling Order need not show perfect diligence, but can establish good cause when it can show that it has been reasonably diligent." *Reed v. Hope Depot U.S.A., Inc.*, 2017 WL 5202684, at *2 (S.D. Ohio May 15, 2017).

B. Assessing Plaintiffs' Diligence.

The parties' briefing presents two distinct aspects of diligence, each arising from the unique procedural posture of the MTA Plaintiffs' cases. In order to address these two aspects, the Court refers below to what it will call the "Information Date"—that is, the date when: (a) sufficient information became available for a plaintiff to know it had a basis for a claim against a specific defendant, ***and*** (b) a reasonably diligent plaintiff could have identified, understood, and acted upon that information. As discussed further below, the Information Date is different for different defendants.

1. Diligence in Seeking Court Permission.

The first aspect of diligence—raised by a number of the MTA Defendants—is whether plaintiffs showed a fatal lack of diligence by failing to seek Court permission to amend their complaints promptly after the relevant Information Date. Defendants, while conceding that some information only became available after the amendment deadline had passed, argue that MTA Plaintiffs demonstrated a lack of diligence by not more quickly moving for leave to file motions

to amend their complaints, instead waiting several months or more after obtaining the information. This argument fails.

The Court's moratorium on substantive filings operated as a constraint throughout the entire relevant period. That moratorium completely foreclosed any non-bellwether MDL Plaintiff from filing any substantive motion—including motions seeking leave to amend—since the MDL's inception. Defendants assert MTA Plaintiffs could have, nonetheless, moved for leave to file motions to amend at any time, which they eventually did on April 22, 2024. Defendants argue that MTA Plaintiffs' failure to so move earlier, immediately after MTA Plaintiffs had obtained information sufficient to add a specific defendant, shows a lack of due diligence.

But as the Court has previously observed, the PEC regularly sought the Court's guidance on whether the moratorium might be lifted to permit MDL Plaintiffs to file amendment motions; and on each occasion (until the last) the Court declined. *See* docket no. 5598 at 21, n.14 ("[D]uring several status conferences over the years, the PEC regularly (if informally) took the Court's temperature on lifting its moratorium to permit MDL plaintiffs to move to [amend their] complaints. Until recently, *see* docket no. 5455, the Court always demurred."). And those few plaintiffs who did formally attempt to seek leave to amend during the moratorium period were all rebuffed. *Id.* at 21 (citing docket no. 5319 at 3, n.2). Diligence does not require a plaintiff to repeatedly ask the Court for permission after having been directed, both explicitly and implicitly, not to ask. Under these circumstances, the time elapsed between plaintiffs' obtaining new information about a defendant and the filing of the motion to lift the moratorium cannot fairly be characterized as a lack of diligence.

Furthermore, the Court has addressed the diligence question in the context of the Court's moratorium on two prior occasions and reached the same conclusion both times. First, when

addressing four bellwether plaintiffs' motions for leave to amend, the Court observed that "the moratorium foreclosed any plaintiff . . . from filing any substantive motion—including amending or seeking leave to amend their complaints." *See* docket no. 5319 at 2–3. Because those plaintiffs had no earlier opportunity to amend, the Court held their motion for leave to amend was not untimely.

Second, in the context of a motion to dismiss filed by certain new PBM defendants, the Court applied an equitable tolling analysis and reached the same conclusion. *See* docket no. 5598. The Court noted that: (1) the moratorium "was a legal order that completely foreclosed Plaintiffs' ability to timely amend their complaints;" (2) the "Plaintiffs could not add claims against the 'New Defendants' between 2019 and 2024 because the Court forbade it;" and (3) "[i]n the unusual, idiosyncratic circumstances presented here, the Court's own moratorium order prevented Plaintiffs from timely filing claims against New Defendants any earlier." *Id.* at 19–21. The Court concluded that "Plaintiffs acted with reasonable diligence in pursuing amendment of their complaints to add the New Defendants and did so promptly at their first opportunity." *Id.* at 21.

These holdings and the circumstances supporting them apply with equal force here. The Court concludes the MTA Plaintiffs were diligent in moving to lift the moratorium and pursue amendment to add defendants, after the relevant information became available.

2. Diligence in Meeting the CMO's Amendment Deadline.

The second aspect of diligence is the standard established by Rule 16: whether a party was diligent in attempting to meet the pleading amendment deadline. Under this Court's Case Management Order (as modified), the deadline to amend complaints without leave of court was "the later of: [i] March 16, 2019, [ii] the applicable deadline under Fed. R. Civ. P. 15(a)(1), or [iii] 90 days following transfer into this MDL." Docket no. 1106 at 3, n.7. Because transfers to this

MDL ceased on April 8, 2022, the last possible plaintiff-specific amendment deadline was July 7, 2022—ninety days after that final transfer date.

Accordingly, if the Information Date for a defendant was ***after July 7, 2022***, then every MTA Plaintiff now seeking to add that defendant was reasonably diligent as to that defendant, because no plaintiff was permitted to act on that information prior to the amendment deadline.[13] *See Rapp v. Forest City Techs., Inc.*, 2021 WL 4713394, at *3-4 (N.D. Ohio June 17, 2021) ("Because this evidence was not reasonably available to Rapp until well after the [amendment] deadline date passed, Rapp could not reasonably have met the deadline despite due diligence.").

Conversely, if the Information Date was ***before March 16, 2019***—the date the Court set earlier as a deadline for amendment using the Short Form Amendment Process—then the MTA Plaintiff will have a much more difficult time demonstrating reasonable diligence.

Finally, if the Information Date falls between those two dates, then diligence *vel non* will depend on a comparison of the Information Date and the individual plaintiff's case-specific amendment deadline (which is 90 days after their transfer date). Thus, for example, if the Information Date for "Defendant X" is June 1, 2020, then a plaintiff whose case was transferred into the MDL on January 1, 2020—and who therefore had an amendment deadline of March 31, 2020—"could not reasonably have met the deadline despite due diligence," because the Information Date came after the amendment deadline. *Id*. In contrast, a plaintiff whose case was transferred into the MDL on May 1, 2020, could have amended to add Defendant X before its case-specific deadline of July 30, 2020; the plaintiff had the necessary information before the deadline to amend.

[13] An exception to this rule could exist if a MTA Plaintiff ***direct-filed*** its case in the MDL after July 7, 2022. If this circumstance exists, the parties should address it in a meet-and-confer, *see* footnote 18.

Of course, identifying the Information Date is not simply a matter of asking whether critical information existed *somewhere*. Given the millions of documents produced into the MDL Discovery Repository, the Court cannot simply examine whether information was theoretically accessible at a given moment. Rather, the more meaningful question is whether a reasonably diligent plaintiff would have had reason to look for the information and, upon finding it, would have recognized it as a basis to add a particular defendant. The Information Date is, therefore, the point at which a sufficient nucleus of available information existed for a sufficient amount of time regarding a specific defendant or defendant group such that a reasonable plaintiff, exercising reasonable diligence, would have identified, understood, and acted upon the information to add that defendant.

As set forth above, if a plaintiff's case-specific amendment deadline fell ***before*** the Information Date for a given defendant group, then that plaintiff did not have sufficient information to amend to add any particular defendant from that defendant group prior to their deadline; accordingly, the Court will overrule the contention that such a plaintiff was not diligent. If a plaintiff's case-specific amendment deadline fell ***after*** the Information Date, however, that plaintiff had an opportunity to act. In most instances—absent a showing of some extenuating circumstances not readily apparent in the record—the Court will deny that plaintiff's motion for leave to amend to add any defendant from that defendant group.

That said, the Court recognizes that the Information Dates described below are benchmarks, not bright lines. There may be close calls—for example, where a plaintiff's case-specific amendment deadline fell only days after the applicable Information Date. The Court will address such close calls, to the extent they exist and the parties cannot resolve them, after the parties have met and conferred and applied this *Issue Ruling* (as described below).

3. The Information Dates Applicable to the Different Defendant Groups.

There are three groups of defendants that MTA Plaintiffs seek to add to their complaints through this Final Amendment Process: (1) Generic Manufacturers; (2) Pharmacies; and (3) Pharmacy Benefit Managers ("PBMs"). Each group presents distinct facts bearing on the applicable Information Date. The Court addresses each in turn.

Generic Manufacturers

MTA Plaintiffs assert each Generic Manufacturer: (1) had less than a 5% market share as calculated from the 2006–2014 ARCOS data; (2) was, therefore, unknown to MTA Plaintiffs as of the first amendment deadline;[14] (3) had greater than a 5% market share in the 2015–2019 ARCOS data; and (4) was, therefore, an "opportunistic seller" of opioids, taking advantage of recent decreases in opioid production by other sellers. MTA Plaintiffs thus declare they did not have sufficient information to add the Generic Manufacturers as defendants until the PEC received and analyzed the 2015–2019 ARCOS data in September of 2023.

The Generic Manufacturers respond that the MTA plaintiffs were not diligent in seeking leave to amend their complaints because the MTA plaintiffs: (1) could have and should have sought the 2015–2019 ARCOS data sooner; and (2) disregarded ***other*** information they had in their possession before the March 2019 amendment deadline.

More specifically, the Generic Manufacturers first contend the MTA plaintiffs were not diligent because they should have attempted to obtain the 2015–2019 ARCOS data from the DEA sooner. This argument is slightly different from the one rejected above. There, the argument was:

[14] As described above, the initial ARCOS data was not provided in a fully accessible format. Instead, only the *identities* of manufacturers with more than a 5% market share were provided in the ARCOS Reports. Therefore, the Generic Manufacturers' names would not have been known to MTA Plaintiffs from the first tranche of ARCOS data prior to the first amendment deadline.

once the MTA Plaintiffs had obtained the information, they should have ***acted*** on it sooner, despite the moratorium. Here, the argument is: the MTA Plaintiffs should have sought to ***obtain*** the information sooner. This argument is also unavailing.

As described above, the Generic Manufacturers' identities were not disclosed to any MDL Plaintiff in the initial ARCOS Reports.[15] Each MTA Plaintiff would have needed the "second tranche" of 2015–2019 ARCOS data in hand, prior to its plaintiff-specific amendment deadline, to assess whether it had a claim against any Generic Manufacturer defendant. But the DEA consistently refused to produce ARCOS data to plaintiffs absent Court Order, and this Court would not have ordered production of any additional ARCOS data before July 14, 2023, when it ordered production of the second tranche. The reason for this, which the Court has applied consistently, was to avoid potential interference with ongoing DEA investigations.

To explain: the Court ordered production of the first tranche of ARCOS data in 2018. And even though that production was under a protective order, the first tranche was for the period of 2006–2014. The Court purposefully chose a nearly four-year gap between the end-date of the data and the production date, to avoid any adverse impact on ongoing DEA investigations. *See* docket no. 5115 at 11 ("Given that the most recent data is over three years old, it is untenable that exposure of the data will actually or meaningfully interfere with any ongoing enforcement proceeding.") (quoting docket no. 233). Put simply, the Court issued a very strong signal it would not order the DEA, at any time, to produce ***recent*** data.

Having laid down this approach, plaintiffs were certainly reasonable in waiting until 2023 to seek the release of the 2015–2019 ARCOS data. This is all the more true given that the Court

[15] To state it more accurately, an individual plaintiff *may* have known of the *existence* of a Generic Manufacturer, but the plaintiff would not have known whether that entity did any business in its jurisdiction.

explicitly warned the parties against seeking "piecemeal enlargements of ARCOS data production." *See* docket no. 5115 at 6. The timing of the PEC's 2023 subpoena, therefore, reflected reasonable litigation judgment grounded in the Court's prior Orders regarding ARCOS data. It does not reflect a lack of diligence in obtaining updated information.

The Generic Manufacturers next contend the MTA Plaintiffs had sufficient non-ARCOS information to name them as defendants by the amendment deadline. In support, the Generic Manufacturers observe that many MDL Plaintiffs named other opioid manufacturers as defendants before receiving any ARCOS data. But this observation actually cuts against the Generic Manufacturers' position. In their early complaints, MDL Plaintiffs primarily named only the very largest opioid manufacturers. Naming only manufacturers whose opioids had the strongest likelihood of being present in their jurisdiction reflects precisely the kind of reasonable, good-faith pleading practice that courts expect. The Generic Manufacturers' argument would require a plaintiff to name nearly every opioid manufacturer, however small or regionally limited, on the speculative possibility that (1) a non-trivial amount of each manufacturer's pills had reached the plaintiff's jurisdiction, or (2) each manufacturer might later increase its market share in their jurisdiction. The Court, in fact, expressly wished to discourage such a "name them all" practice; that is why the Court imposed the 5% market share limit in its November 2018 CMO-1 Modification Order. The Court wanted each plaintiff to limit its case to defendants that had most likely contributed to the alleged local effects of the opioid crisis, and not to list every potential defendant.

The Generic Manufacturers also assert, perhaps as a corollary to the above argument, that MTA plaintiffs could have examined the discovery produced: (1) in other case tracks, (2) by other

defendants,[16] and (3) from other jurisdictions; and then extrapolate to add the Generic Manufacturers to MTA plaintiffs' own cases in their own jurisdictions. The Court cannot fathom how this might be possible, and the Generic Manufacturers offer nothing more than conclusory assertions that plaintiffs could have figured it out and done it before the amendment deadline. *See* Generic Manufacturer Response at 8 (docket no. 5899) ("The Plaintiffs' Executive Committee ("PEC") took discovery [in other case tracks], and Amending Plaintiffs ***could*** have reaped the benefits of that discovery as to the Generic Manufacturers, but chose to do nothing with this information.") (emphasis added). Moreover, even if it were somehow possible for an Arizona Plaintiff (for example) to use discovery produced by KVK-Tech regarding its conduct in West Virginia (for example) as a basis to assert a claim against KVK-Tech (or any of the other Generic Manufacturers), the "due diligence requirement does not impose on a plaintiff the burden to exhaust all avenues to discover information that may serve as the basis of a claim." *O'Neal*, 2020 WL 210801, at *2. Reasonable diligence is what the Federal Rules require, and such extrapolation would be unreasonable, if not impossible.

Finally, the Generic Manufacturers narrow their focus to third-party payor plaintiffs ("TPPs") and suggest the TPPs, at least, each had sufficient access to their own claims data to identify the Generic Manufacturers as defendants prior to their amendment deadlines. This argument is offered without meaningful elaboration or evidentiary support and does not convince the Court that the TPPs should be treated any differently than any other MTA Plaintiff.

[16] The Generic Manufacturers assert that "Amending Plaintiffs cannot deny that they have long had access to discovery produced into the DR-22 repository, including information produced by ***some*** of the Generic Manufacturers." Generic Manufacturer Response at 8 (docket no. 5899) (emphasis added). One of the Generic Manufacturers, KVK-Tech, was indeed in Track Two and may have produced some limited discovery in that case before it was remanded to West Virginia as a distributor bellwether. It is highly unlikely, however, that such limited discovery would have provided any other plaintiff information sufficient to determine whether KVK-Tech potentially contributed to the opioid crisis in their own jurisdiction; and in any event, KVK-Tech does not set forth details sufficient to show any individual plaintiff actually had sufficient information.

Accordingly, the Court finds that the appropriate Information Date for the Generic Manufacturers is September 12, 2023, the date the PEC provided its analysis of the updated ARCOS data to the MDL Plaintiffs; and this Information Date applies also to TPPs.[17] Because the Generic Manufacturer Information Date is after the last possible amendment deadline of July 7, 2022, the Court finds that: (1) no MTA Plaintiff seeking to add a Generic Manufacturer could have reasonably moved for leave to amend its complaint before its amendment deadline; and (2) all MTA Plaintiffs have, therefore, demonstrated reasonable diligence in pursuing their amendments against the Generic Manufacturers. The Court will not deny any MTA Plaintiffs' motion for leave to amend to add any of the Generic Manufacturers for a lack of diligence.

Pharmacies

Regarding the Pharmacies, MTA Plaintiffs assert they were diligent in seeking leave to amend because: (1) they did not have (and could not have had) market share information for the Pharmacies until, at the earliest, after the ARCOS data was made publicly available in May 2019, which was after the March 16, 2019 amendment deadline; and (2) even if they could have made dispensing market share calculations prior to the amendment deadline—for example, with the 2006–2014 ARCOS data—they had no reason to do so until the dispensing theory of liability was identified and developed, which could not have happened until dispensing-related discovery was conducted and analyzed in Track Three.

[17] This September 12, 2023 date is probably earlier than it should be, because it includes no time for a MTA Plaintiff to digest the PEC's ARCOS data analysis and file an appropriate motion. But even this "early" date is after the last possible amendment deadline of July 7, 2022, so adding some additional time to take action would not change the analysis. The Court took the same "early date" approach below, in favor of non-movants, when calculating the Information Dates applicable to other defendants.

The Pharmacies respond that, because the PEC's market-share analysis relies on data drawn from both the 2006–2014 and 2015–2019 tranches of ARCOS data without distinguishing between the two datasets, MTA plaintiffs have provided no reason why they could not have used the earlier dataset to identify pharmacy defendants by the March 2019 amendment deadline. The Court is not persuaded.

First, the ARCOS Reports generated from the 2006–2014 ARCOS data did not contain market share information of any kind with respect to pharmacies. Notwithstanding the language in the Modification Order requiring the PEC to provide "Pharmacy Reports reflecting all opioid shipments to each pharmacy in the relevant [jurisdiction]," docket no. 1106 at 2, the Reports as actually produced contained only the names and addresses of DEA-registered pharmacies located within each plaintiff's jurisdiction. *See* docket no. 739 at 4 (directing that "the report shall set forth only the *identity* of entities that manufactured, distributed, or sold opioids in the counties"); docket no. 859 at 2 (describing the pharmacy list as containing "the name and address for all DEA registrants identified as a [pharmacy] located within the county that purchased any of the 8 opioid drug families from a distributor according to the 2006–2014 DEA's ARCOS data"). *See also* docket no. 5565-2 at 4 (Decl. of P. Mougey) ("The only information that the PEC was permitted to provide about dispensers [from the ARCOS Reports] was a pharmacy's presence in the jurisdiction; no dispensing market share information was provided at this time."). In other words, the ARCOS Reports amounted to little more than a simple directory of pharmacies operating within each jurisdiction. No plaintiff could reasonably have derived dispensing market share, distribution market share, or any other metric to determine what, if any, allegedly wrongful conduct may have been committed by a pharmacy from that list. The Pharmacies' argument that

plaintiffs should have used the 2006–2014 ARCOS data to identify them as defendants therefore presupposes an analytical capability that the available Reports simply did not support.

Second, and independently, the dispensing theory of liability underlying plaintiffs' claims against the pharmacy defendants was so embryonic as of the March 2019 amendment deadline that MTA Plaintiffs cannot reasonably be charged with a lack of diligence for failing to pursue it. The gravamen of the dispensing claim is that a pharmacy, upon receiving opioid prescriptions bearing objective indicia of fraud or potential diversion (*i.e.*, "red flags"), nonetheless filled those prescriptions without appropriate review. The only records that would reveal whether a pharmacy engaged in such conduct are the pharmacy's own prescription logs and dispensing records.

The ARCOS data provides no insight whatsoever into the quality of a pharmacy's prescription review. The difference between lawful dispensing and the allegedly culpable dispensing conduct underlying plaintiffs' claims only became apparent when plaintiffs began to receive and analyze dispensing-specific document and deposition discovery in the earliest bellwether tracks. Prior to that discovery, plaintiffs lacked both the factual basis to identify which pharmacies had engaged in wrongful dispensing conduct and, relatedly, a sufficiently developed legal theory on which to base such a claim. While the statutory and regulatory framework underlying plaintiffs' dispensing theory of liability was arguably available, the viability of that novel theory as applied to the opioid epidemic was, at best, unsettled prior to the bellwether track litigation.

The question for the Court, then, is: What is the appropriate Information Date for the MTA Pharmacy Defendants? To answer that question, the Court will briefly review the genesis of Plaintiffs' dispensing claims.

Dispensing-related discovery began in Track One-B. All defendants except the pharmacy defendants settled the Track One claims against them on or before October 21, 2019, the day the Track One trial was scheduled to begin. On October 29, 2019, Track One Plaintiffs moved for leave to amend the Track One complaint to add dispensing claims against the pharmacies that remained. *See* docket no. 2880. After receiving briefing from the parties, the Court granted plaintiffs' motion on November 19, 2019, creating Track One-B and allowing the Track One-B Plaintiffs to add dispensing claims. *See* docket no. 2940. On December 10, 2019, the Court ordered the Track One-B Pharmacy Defendants to "produce transactional dispensing data for the entire United States from 1996 forward," docket no. 2976 at 2, and discovery into pharmacy dispensing conduct began. That discovery was stayed by the Sixth Circuit, however, and on April 15, 2020, the Sixth Circuit instructed this Court to strike the dispensing claims from Track One-B. *See* docket no. 3262.

So, on April 30, 2020, the Court created a new bellwether track, Track Three, to test dispensing claims against pharmacy defendants. *See* docket no. 3282. On June 2, 2020, the Court granted the Track Three Plaintiffs' motion for leave to amend their complaints to add dispensing claims. *See* docket no. 3314. Because the same pharmacy defendants were in Track Three that had been in Track One-B, dispensing related discovery resumed and on June 8, 2020, the Court ordered that "all discovery propounded or produced in Track 1 ("CT1") shall be deemed propounded and/or produced in Track 3." Docket no. 3329.

On August 6, 2020, the Court denied a motion to dismiss by the Track Three Pharmacy Defendants, which effectively confirmed the legal (but not factual) viability of plaintiffs' red-flag theory of dispensing-related liability against pharmacies. *See* docket no. 3403; docket no. 3499 (denying motion for reconsideration). Plaintiffs' red-flag theory of dispensing-related liability

continued to evolve, however. *See* docket no. 3735 at 2 (case management order setting May 19, 2021 deadline for plaintiffs to "serve their amended expert reports . . . with revisions permitted only relating to Plaintiffs' ***revised*** red-flag methodology") (emphasis added). The Court ultimately denied a motion for summary judgment brought by Track Three Pharmacy Defendants. *See* docket no. 3913.

The Court's difficult task is to pick a precise Information Date for the MTA Pharmacy Defendants, being when a plaintiff: (1) had enough information from the ARCOS data to understand which pharmacies had meaningful market share in their jurisdiction, and also (2) had sufficient understanding of and confidence in the legal viability of the red-flag theory of dispensing-related liability to responsibly add the appropriate pharmacy defendants. Upon review of the above procedural history, the Court finds that the most appropriate Information Date for asserting dispensing claims against the MTA Pharmacy Defendants is September 22, 2020, the date when the Court denied reconsideration of and upheld its opinion denying the Track Three Pharmacies' motion to dismiss. Docket no. 3499. At that point, a reasonably diligent plaintiff whose amendment deadline had not yet passed could: (1) look at the available ARCOS data for 2006–2014, which was then publicly available, *see* docket no. 3259 (April 13, 2020 Revised Notice of Public Disclosure of ARCOS Data); (2) review and analyze the Track Three litigation; (3) understand that there was a viable dispensing-based theory of liability; and (4) add pharmacy defendants to its complaint based on that information.

Because September 22, 2020, falls before the final amendment deadline of July 7, 2022, it is possible that some MTA Plaintiffs had amendment deadlines that fell after the Pharmacy Information Date. The parties will have to meet and confer to review the case-specific deadlines for amendment for each case and determine whether the deadline falls before or after the

Information Date. If the plaintiff's amendment deadline falls before the Pharmacy Information Date, the Court ***will not*** deny that plaintiff's motion for leave to amend for lack of diligence. If the plaintiff's amendment deadline falls after the Pharmacy Information Date, the Court ***will*** deny the plaintiff's motion for leave to amend for lack of diligence, absent extenuating circumstances (which will be rare).[18]

Pharmacy Benefit Managers

Unlike the Generic Manufacturers and Pharmacies, whose inclusion in the amended complaints proposed by MTA Plaintiffs is grounded in the ARCOS data, the PBMs present a distinct evidentiary picture. MTA Plaintiffs do not rely on the ARCOS data as the basis for their claims against the PBMs. Rather, they assert that information sufficient to name the PBMs as defendants came from discovery produced by the PBMs in *Jefferson County v. Dannie E. Williams, M.D., et al.*, No. 1922-CC00203 (Mo. Cir. Ct.) (the "*JeffCo* litigation"), which was subsequently re-produced into the MDL Discovery Repository pursuant to Discovery Ruling No. 22 ("DR-22"). The PBMs began making DR-22 productions in January 2023. If Plaintiffs are correct, they were all sufficiently diligent, because January 2023 falls after the last possible plaintiff-specific amendment deadline of July 7, 2022.

The PBMs contend the MTA Plaintiffs are wrong, and Plaintiffs had sufficient information to bring claims against them far earlier than January 2023. PBMs argue this is shown most clearly

[18] It now falls to the parties to apply this ruling to each individual case where the plaintiff seeks to add a Pharmacy Defendant and report the results back to the Court. Specifically, the parties should meet and confer and come to as much agreement as possible on how this *Issue Ruling* applies to each case where a motion for leave to amend to add a Pharmacy Defendant was filed, and then submit to the Court a chart listing their agreed conclusions. If the parties cannot agree on how this *Issue Ruling* applies to a given case, they shall: (1) so note in their chart; and (2) submit a statement explaining their position. A party's position statement shall not be longer than 2 pages per case, nor longer than 15 pages total.

by the fact that several attorneys, including members of the PEC, had clients who had already sued the PBMs before the March 16, 2019 amendment deadline, and at least one attorney had filed a letter on this Court's docket urging examination of the PBMs' role in the opioid crisis. *See* docket no. 168.

The great problem with this argument is that the PBMs, themselves, insisted these early claims against them were so devoid of legal or factual support that they were frivolous. Specifically, on May 18, 2021, counsel for PBM Defendant OptumRx sent a letter to the *JeffCo* plaintiffs warning that their pleading lacked any "discernible evidentiary basis" and threatening that both "[plaintiffs' counsel] and the [client] County have likely committed sanctionable conduct." *See* docket no. 5547-2 at 3 (Conrod Decl.). This highlights the tension at the heart of the PBMs' position. Rule 11—the Rule upon which the OptumRx letter was based—prohibits the filing of a pleading that lacks a sufficient evidentiary basis. *See* Fed. R. Civ. P. 11. Rule 16 requires a showing of good cause—which includes reasonable diligence—to modify a scheduling order and permit late amendment. *See* Fed. R. Civ. P. 16. These two rules operate in different directions, but they share a common premise: A party's litigation conduct must be evaluated against the evidentiary record actually available to it at the relevant time. Put differently, a party cannot be found to lack diligence under Rule 16 for declining to file a pleading that Rule 11 would prohibit. If, as the PBMs argued in May 2021, there was no discernible evidentiary basis to name them as

defendants, then MTA Plaintiffs cannot be faulted for waiting until there was one. The PBMs cannot have it both ways.[19]

In the face of the PBMs' threat that a plaintiff pursuing an opioid claim against them would be met with a motion for sanctions, the MTA Plaintiffs did not lack diligence for waiting until they were confident they could defeat that motion. Accordingly, the Court finds that the appropriate Information Date for the PBM Defendants is, at the earliest, January 2023, when the PBMs began making DR-22 productions available through the MDL Discovery Repository. As that date falls after the last possible plaintiff-specific amendment deadline of July 7, 2022, the Court concludes that no MTA Plaintiff lacked diligence by failing to name the PBMs before its amendment deadline.

[19] The Court also disagrees with the PBMs' *present* insistence (which is contrary to their former assertion in *JeffCo*) that, well before the DR-22 *JeffCo* production, MTA Plaintiffs had sufficient information to seek amendment and bring claims against the PBMs. PBMs assert: (1) the *JeffCo* documents did not contain new information; (2) the relevant information was already available in the MDL Discovery Repository; and (3) the exemplar complaint against the PBMs relies predominantly on documents produced by other MDL defendants, not the *JeffCo* documents. But the PBMs' business practices, corporate structures, and relationships with other participants in the pharmaceutical supply chain are, by all accounts, unusually opaque. This Court previously observed it has "had difficulty understanding clearly the PBMs' complicated corporate structure and complex business model." Docket no. 5598 at 36. The Court is not alone in that assessment. *See Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, FTC Interim Staff Report at 1 (Jul. 2024) ("PBMs oversee critical decisions about access to and affordability of medications without transparency or accountability to the public. Indeed, PBM business practices and their effects remain extraordinarily opaque."). It was not until the *JeffCo* discovery was produced into the MDL that MDL Plaintiffs had sufficient information to understand how the PBMs connected to the other defendants in this litigation, and what the factual basis for claims against the PBMs might be. That some plaintiffs chose to assert claims against the PBMs before then does not establish that the evidentiary foundation to do so was well-established or broadly available.

III. Summary.

This Court has "considerable discretion in determining what kind of showing" of diligence satisfies Rule 16's good cause standard. *Tesone*, 942 F.3d at 988. Having considered thoroughly the parties' arguments on the common diligence issues discussed above, the Court rules as follows:

- The applicable Information Date for the Generic Manufacturer Defendants is September 12, 2023—the date the PEC provided its analysis of the 2015–2019 ARCOS data to MDL Plaintiffs. A plaintiff was not diligent only if it could have, but did not, move for leave to amend after September 12, 2023. Because that date falls ***after*** the last possible court-allowed, plaintiff-specific amendment deadline of July 7, 2022, no motion for leave to amend to add a Generic Manufacturer Defendant will be denied for lack of diligence.

- The applicable Information Date for the PBM Defendants is January 2023—when the PBMs began making DR-22 productions into the MDL Repository. A plaintiff was not diligent only if it could have, but did not, move for leave to amend after January 2023. Because that date falls ***after*** the last possible court-allowed, plaintiff-specific amendment deadline of July 7, 2022, no motion for leave to amend to add a PBM Defendant will be denied for lack of diligence.

- The applicable Information Date for the Pharmacy Defendants is September 22, 2020—the date this Court denied reconsideration of its opinion denying the Track Three Pharmacies' motion to dismiss plaintiffs' dispensing-related claims. A plaintiff was not diligent only if it could have, but did not, move for leave to amend after September 22, 2020. Because that date falls ***before*** the last possible court-allowed, plaintiff-specific amendment deadline of July 7, 2022, there may be some plaintiffs who fail this test for diligence. Accordingly, the parties shall: (a) meet and confer and come to as much agreement as possible on how this Issue Ruling applies to each case where a motion for

leave to amend to add a Pharmacy Defendant was filed, and then (b) submit to the Court a chart listing their conclusions, *see* footnote 18.

IT IS SO ORDERED.

/s/ Dan Aaron Polster April 27, 2026
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE