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No. 26-____

In the United States Court of Appeals for the Sixth Circuit

OPTUMRX, INC., UNITEDHEALTH GROUP INCORPORATED, OPTUM, INC., OPTUMINSIGHT, INC., OPTUMINSIGHT LIFE SCIENCES, INC., OPTUMRX DISCOUNT CARD SERVICES, LLC, OPTUM PERKS, LLC, OPTUMHEALTH CARE SOLUTIONS, LLC, OPTUMHEALTH HOLDINGS, LLC, OPTUM HEALTH NETWORKS, INC., EXPRESS SCRIPTS, INC., EXPRESS SCRIPTS ADMINISTRATORS, LLC, MEDCO HEALTH SOLUTIONS, INC., ESI MAIL ORDER PROCESSING, INC., ESI MAIL PHARMACY SERVICE, INC., EXPRESS SCRIPTS PHARMACY, INC., EVERNORTH HEALTH, INC., AND EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.,

Petitioners.

United States District Court for the
Northern District of Ohio (No. 1:17-md-2804-DAP)
(Hon. Dan Aaron Polster)

PETITION FOR WRIT OF MANDAMUS

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INTRODUCTION

This is a textbook case for mandamus. For the second time in this multidistrict litigation, the District Court ignored Federal Rules of Civil Procedure 15 and 16 by allowing plaintiffs, this time 800 of them, to amend years after the deadline and without requiring any individualized showing of good cause. Six years ago, this Court granted mandamus relief to other defendants in this MDL after the District Court allowed plaintiffs to amend their claims in two cases 19 months after the deadline without properly analyzing diligence. The Court struck the amendments, because “an MDL court must find efficiencies within the Civil Rules, rather than in violation of them,” and “whether to grant a motion to amend in an individual case depends on the record in that case and not others.” *In re Nat’l Prescription Opiate Litig.* (CVS), 956 F.3d 838, 845 (6th Cir. 2020).

Notwithstanding this Court’s decision in CVS, the District Court committed the same error again—this time on a *much* larger scale. It granted 800 plaintiffs across 704 cases leave to amend their respective complaints to add claims against pharmacy benefit managers (PBMs) OptumRx, Inc., Express Scripts, Inc., and 16 of their affiliates. This

represents a *tenfold* increase in the number of plaintiffs against these defendants. The District Court did so again without requiring any individualized showing of good cause and without examining the record in each individual case. Instead, it created a first-of-its-kind omnibus briefing process, permitting *hundreds* of moving plaintiffs to submit a single brief of less than 20 pages against each group of defendants making generalized arguments supporting amendment.

The District Court's order plainly violates Rules 15 and 16 by holding, without any case-by-case analysis, that 800 plaintiffs across 704 cases were diligent in amending their complaints years after the deadline. Indeed, the First Circuit recently affirmed dismissal of a materially identical case against OptumRx and Express Scripts as time-barred at the pleading stage, holding as a matter of law that plaintiffs were not diligent in pursuing their claims because "undisputed public documents," including "at least seventy-four lawsuits" filed against PBMs from 2018 to 2019, provided "ample means to discover the facts to support a claim against PBMs." *City of Boston v. OptumRx, Inc.*, 169 F.4th 58, 62-63 (1st Cir. 2026).

Remarkably, the District Court recognized that its departure from “normal procedure” was legally wrong. At a hearing, Judge Polster told the parties that “the Sixth Circuit would reverse [him] in a heartbeat” if he “allow[ed] 800 amendments adding the PBMs.” 9/10/2025 Tr., R.6273, PageID#695081:5-20. But he later did just that, allowing 800 plaintiffs to amend *en masse* without undertaking the individualized analysis that Rules 15 and 16 require. As in *CVS*, Judge Polster tried to excuse his failure to follow the Civil Rules by saying that case-specific analyses would demand “colossal resources” and not achieve the “efficiency goals of an MDL.” Issue Ruling 4, R.6428, PageID##707424-707425.

As this Court already held in *CVS*, there is no “MDL exception” to the Federal Rules. The District Court’s clear error reflects a “persistent disregard” of Rules 15 and 16, *John B. v. Goetz*, 531 F.3d 448, 457 (6th Cir. 2008), for which there is no adequate remedy through the ordinary appeals process. To “avoid repeated errors of this magnitude,” *In re Am. Med. Sys.*, 75 F.3d 1069, 1089 (6th Cir. 1996), this Court should grant the petition. The PBMs have no other adequate means of obtaining relief and otherwise face the hydraulic pressure of litigating hundreds of new

cases years after the MDL closed its doors and the deadline for amendments passed.

ISSUES PRESENTED

1. Did the District Court err by granting leave to amend to 800 plaintiffs *en masse* after the amendment deadline without making individualized findings based on each plaintiff's pleadings, allegations, and showings of diligence, as Rules 15 and 16 require?

2. Did the District Court err under Rule 16 by permitting 800 plaintiffs to amend after the amendment deadlines, even though all those plaintiffs indisputably knew the facts underlying their claims for years?

STATEMENT OF FACTS

A. Between 2018 And 2019, Scores Of Plaintiffs Sued PBMs For Claims Concerning Prescription Opioid Abuse.

This petition arises from *In re National Prescription Opiate Litigation*, MDL No. 2804, an MDL pending before Judge Polster in the Northern District of Ohio since December 2017. The MDL includes thousands of lawsuits filed by state and local governments alleging harms from prescription opioids. Defendants include manufacturers, distributors, pharmacies, and PBMs.

OptumRx and Express Scripts are PBMs that process claims for insurance coverage of prescription medications. *Rutledge v. Pharm. Care Mgmt. Ass’n*, 592 U.S. 80, 83-84 (2020). PBMs help “secure lower prices for prescription drugs” for their clients by negotiating discounts from drug manufacturers for covered medicines. *McKee Foods Corp. v. BFP Inc.*, 173 F.4th 242, 251-252 (6th Cir. 2026).

For more than eight years, OptumRx and Express Scripts have been defendants in the MDL. In January 2018, Webb County, Texas, sued several PBMs, including OptumRx and Express Scripts, claiming that they and other defendants “caused an opioid epidemic that has resulted in economic, social, and emotional damage to virtually every community in the United States and tens of thousands of Americans.” Compl., R.108-1 ¶ 1. Webb County’s counsel also represents at least 60 of the 800 plaintiffs who waited until 2024—six years after the *Webb County* complaint—to seek leave to amend in this MDL. List of Cases, R.6636-1, PageID##713816-713867.

Right after filing its complaint, Webb County notified the MDL’s Plaintiffs’ Executive Committee (PEC) of its lawsuit, which it said “describe[d] in detail the nature of PBMs’ [alleged] role in the scheme.”

Letter, R.978-6, PageID#21682; *see Boston*, 169 F.4th at 63. Webb County filed that letter and several others on the public MDL docket in 2018, spotlighting PBMs as an allegedly “critical defendant group,” which it said were “necessary parties to any effort to abate the opioid crisis.” R.108, PageID#558; *see* R.168, PageID#945.

Many other plaintiffs then filed copycat opioid lawsuits against PBMs, including in the MDL. In 2018 and 2019, “at least seventy-four lawsuits, all a matter of public record,” were filed against PBMs. *Boston*, 169 F.4th at 63; *see* Am. Opp., R.6163, PageID##684440-684443 (listing cases). These lawsuits included the 2019 MDL bellwether complaint by the City of Huntington and Cabell County, West Virginia, R.2582, signed by PEC members and other attorneys who serve as counsel for at least 340 of the 800 moving plaintiffs. The 2018 and 2019 actions also included lawsuits by two New York cities, Rochester and Ogdensburg, that were later selected in the MDL as PBM bellwethers; their counsel represents at least 26 of the 800 moving plaintiffs. Compl., *City of Rochester v. Purdue Pharma L.P.*, No. 1:19-op-45853 (N.D. Ohio June 28, 2019), ECF No. 1-5; Compl., *City of Ogdensburg v. Purdue Pharma L.P.*, No. 1:19-op-45852 (N.D. Ohio June 7, 2019), ECF No. 1-4; *see Boston*, 169 F.4th at 63.

The District Court afforded MDL plaintiffs substantial opportunity to amend their complaints to add claims against PBMs. Plaintiffs could “file any amended pleading, including any amendment to add a party,” by March 16, 2019, after which the District Court imposed a moratorium on further substantive filings in non-bellwether cases. Order, R.1106, PageID##27482-27483. Plaintiffs in later-filed cases could amend their complaints as a matter of right within 90 days after their transfer to the MDL. *Id.*, PageID#27483 n.7. All told, 44 plaintiffs amended their complaints in 2019 to add claims against the PBMs and their affiliates in the MDL. Am. Opp., R.6163, PageID##684440-684441.

In April 2022, the Judicial Panel on Multidistrict Litigation closed the MDL to new cases. *In re Nat’l Prescription Opiate Litig.*, 2022 U.S. Dist. LEXIS 65760, at *2-3 (J.P.M.L. Apr. 8, 2022); *see also* Order Denying Transfer, *In re Nat’l Prescription Opiate Litig.*, MDL No. 2804 (J.P.M.L. Aug. 7, 2026), ECF No. 9673 (reaffirming MDL’s closure). As of July 7, 2022—the last possible date to amend for transferred cases—111 plaintiffs had sued the PBMs in the MDL.

B. Between 2019 And 2023, OptumRx And Express Scripts Litigated Opioid Claims In Missouri State Court.

In August 2018, Jefferson County, Missouri sued OptumRx and Express Scripts in state court. *Jefferson County v. Purdue Pharma L.P.*, No. 1822-CC10883 (Mo. Cir. Ct.). In 2020, the trial court twice denied the PBMs' motions to dismiss. Order, *Jefferson County v. Williams*, No. 20JE-CC00203-01 (Mo. Cir. Ct. July 8, 2020); Order, *Jefferson County v. Williams*, No. 20JE-CC00203-01 (Mo. Cir. Ct. Dec. 3, 2020). OptumRx and Express Scripts began producing documents in *Jefferson County* in February 2021. Conrod Decl. (Optum), R.5547-2 ¶ 7; Conrod Decl. (Express Scripts), R.5548-2 ¶ 7. Many of the documents—including *every* document cited in plaintiffs' omnibus motions for leave to amend—duplicated information already available to plaintiffs and their counsel, either publicly or as part of the MDL record, *as early as July 2018*. Am. Opp., R.6163, PageID##684462-684463; Hatchett Decl., R.5892; Cooper Decl., R.5890.

C. In April 2024, More Than 2,000 Plaintiffs Moved To Add Claims Against PBMs In The MDL.

On April 22, 2024, the PEC pressed the District Court to lift its moratorium on new motions so plaintiffs could seek leave to amend their

complaints to add claims against OptumRx, Express Scripts, and their affiliates. Mot. to Lift Moratorium, R.5411. Plaintiffs' stated goal was to exert settlement pressure on the PBMs. By 2024, the PEC had reached settlements with most defendants in the MDL for over \$50 billion.¹ When the PBMs refused to enter broad settlements, the PEC moved to lift the moratorium, citing the PBMs' "reticence to reach broader settlements because only limited numbers of cases are pending against them in the MDL." *Id.*, PageID#635513 n.1.

For years, the District Court repeatedly reaffirmed the finality of its amendment deadlines. For example, in August 2023, the court acknowledged that "to say that the plaintiffs should go ahead and amend complaints in hundreds of cases" would not "make sense," because the court had to "follow the Sixth Circuit[s]" opinion in *CVS*. 8/30/2023 Tr., R.5168, PageID#621885:2-6; *see also* 10/10/2023 Order, R.5217, PageID#623913 (similar).

But after plaintiffs claimed that they needed more leverage to obtain global settlements with the PBMs, the District Court reversed

¹ *Global Settlement Tracker*, OPIOID SETTLEMENT TRACKER, <https://www.opioidsettlementtracker.com/globalsettlementtracker> (last visited Aug. 26, 2026).

course. At a May 2024 hearing, the District Court suggested “hav[ing] the PEC file a motion for each Defendant for which it wants to amend complaints, listing all the cases for that Defendant that they want to add.” 5/22/2024 Tr., R.5471, PageID#638224:17-20. The PBMs objected that the contemplated process “would violate the [Civil Rules] and the Sixth Circuit precedent,” and that “[e]ach Plaintiff should file its own motion” so the PBMs could “oppose based on the unique facts of that [p]laintiff.” *Id.*, PageID#638234:5-11.

The District Court nevertheless authorized the PEC to “file a *single* motion to amend the complaints of *all* plaintiffs who wish to add that defendant.” Order Lifting Moratorium, R.5455, PageID#637947. Over the PBMs’ objection, the District Court also excused plaintiffs from filing proposed amended complaints because its “focus” was not “the specific allegations in the complaint” or “a defect in any particular complaint.” 5/22/2024 Tr., R.5471, PageID#638246:9-12. But the court did instruct plaintiffs to include in their omnibus motions (i) “any plaintiff-specific factual allegations,” (ii) “any jurisdiction-specific claims,” and (iii) “the reasons amendment should be permitted in each individual case.” Order Lifting Moratorium, R.5455, PageID#637948.

In July 2024, more than 2,000 plaintiffs joined omnibus motions to add claims against OptumRx, Express Scripts, and 16 affiliates. Omb. Mot. (Optum), R.5547; Omb. Mot. (Express Scripts), R.5548; Omb. Roadmap, R.5546. Plaintiffs included municipalities across three dozen states ranging in size from small rural towns (like Cherokee, Alabama) to major American cities (like Detroit and Cleveland), as well as health plans, hospitals, school districts, tribes, and individuals.

Despite the District Court’s instruction that the motions should include plaintiff- and jurisdiction-specific allegations and individualized good-cause arguments, *see* Order Lifting Moratorium, R.5455, plaintiffs’ omnibus motions—only 18 and 17 pages against the Optum and Express Scripts defendants, respectively—included *none* of those case-specific allegations and arguments. Instead, the motions, on behalf of thousands of plaintiffs, referred collectively to the “Amending Plaintiffs” and said that, once leave was granted, they intended “to supplement their operative pleadings” with “allegations and claims for relief . . . substantially identical” to those in the *City of Rochester* bellwether case. Omb. Mot. (Optum), R.5547, PageID#640472; Omb. Mot. (Express Scripts), R.5548, PageID#640597.

OptumRx and Express Scripts filed an extensive opposition brief that addressed each plaintiff separately, as the Rules require. R.5885; R.5885-1. In accordance with Rules 15 and 16, the opposition made different arguments against different proposed amendments based on the actual facts of the individual plaintiffs.

After filing their opposition, the PBMs learned that many moving plaintiffs never authorized their counsel to join the omnibus motions. Through public-records requests, the PBMs uncovered evidence that many plaintiffs' attorneys had signed the motions without ever consulting their clients. Mot. to Strike, R.5941; Supp. Mot. to Strike, R.5952. As a result, hundreds of plaintiffs withdrew from the motions. Am. Opp., R.6163, PageID#684446.

At the District Court's direction, the PBMs filed an amended opposition brief that removed arguments about the withdrawn plaintiffs and painstakingly explained (in another voluminous filing) why each of the hundreds of remaining plaintiffs should be denied leave to amend. R.6163; R.6172. For each plaintiff, the PBMs demonstrated, based on that plaintiff's individual case record, why leave to amend should be denied, including, for example, (i) each plaintiff's notice of its purported

claims and lack of diligence in pursuing them (*e.g.*, if the plaintiff or its counsel previously had filed opioid-related claims against PBMs), (ii) prejudice to the PBMs if the court were to allow each proposed amendment (*e.g.*, loss of evidence from a plaintiff's failure to implement a timely litigation hold), and (iii) whether each plaintiff's claims would be futile under the applicable substantive law (*e.g.*, if the claims are time-barred or foreclosed by state supreme court rulings). *See* Am. Opp Pt. II, R.6172, PageID##685636-688896. The PBMs provided this individualized evidence and argument even though plaintiffs' cursory omnibus motions (and lack of proposed amended complaints) forced them to guess what claims and allegations each plaintiff might allege.

The PBMs also demonstrated that all the purportedly new facts in the 2023 reproduction of documents from *Jefferson County* had been available publicly or through productions by other defendants in the MDL *as early as 2018*. For example, plaintiffs claimed that information about the PBMs' rebate contracts with opioid manufacturers was not available until "the JeffCo Action production." Omb. Mot., R.5547, PageID#640480; Conrod Decl., R.5547-2 ¶ 21a. In fact, plaintiffs long had access to dozens of rebate contracts that both Express Scripts and

opioid manufacturers (like Purdue) had produced in the MDL in 2018. *See* Am. Opp., R.6163, PageID##684463-684467; Cooper Decl., R.5890.

In reply, plaintiffs conceded that—*for years*—they had access to many, if not all, of the documents and facts on which their proposed amendments were based. In plaintiffs’ own words, there was “no dispute” that “previously produced documents contained important evidentiary support for [p]laintiffs’ now-asserted allegations.” Reply, R.6257, PageID##694731-694732. Nevertheless, plaintiffs claimed this access was irrelevant because they had no obligation to review the documents *in their possession* “with an eye toward the PBMs’ liability.” *Id.*, PageID#694730.

After the PBMs filed their amended opposition, plaintiffs continued to withdraw from the omnibus motions. All told, more than 1,000 plaintiffs withdrew their unauthorized amended claims against the PBMs, leaving 800 moving plaintiffs when the District Court granted leave to amend. List of Cases, R.6636-1, PageID##713816-713867; List of Withdrawals, R.6636-2, PageID##713903-713933. Of the 800 plaintiffs, at least 426 are represented by counsel that previously sued PBMs in 2018 or 2019. And at least 60 of those had *themselves* asserted

claims against the PBMs in the MDL, and sought leave to amend only to add new claims or affiliated entities as defendants. *See* Sur-Reply, R.6265, PageID#695047; List of Cases, R.6636-1, PageID##713816-713867; Am. Opp., R.6163, PageID##684458, 684493.

D. The District Court Granted 800 Plaintiffs Leave To Amend.

At a hearing on plaintiffs' motions in September 2025, the District Court acknowledged that this Court's precedent would not permit 800 amendments adding the PBMs:

Everyone knows or should have known that *I'm not going to allow 800 amendments adding the PBMs*, nor am I going to allow zero. Okay? And if I did one or the other, *the Sixth Circuit would reverse me in a heartbeat*. So that isn't going to happen.

9/10/2025 Tr., R.6273, PageID#695081:17-21 (emphasis added). But in July 2026, the court did just that, granting leave to amend to 800 plaintiffs following six "issue rulings" that categorically rejected the PBMs' arguments without addressing any individual plaintiff.² Order,

² Of the 800 plaintiffs granted leave to amend, 799 are suing Express Scripts and its affiliates, and 787 are suing OptumRx and its affiliates. List of Cases, R.6636-1, PageID##713816-713867.

R.6650. Two of those issue rulings are particularly relevant to this Petition.

First, the District Court rejected the PBMs' argument that plaintiffs' failure to make individualized arguments and allegations, including their failure to provide proposed amended complaints, violated the Civil Rules and deprived the PBMs of fair notice of the proposed claims. In the court's view, plaintiffs had to point only to preexisting "exemplar complaints" as a preview of the "substance" of their claims. Issue Ruling 4, R.6428, PageID##707421-707424. The District Court recognized that it was not following "normal procedure" under the Rules but deemed the omnibus process "sufficient" because it struck a "reasonable balance between the efficiency goals of an MDL and the required retention of each individual case's character." *Id.*, PageID##707424-707425.

Second, the District Court ruled categorically that "no motion for leave to amend to add a PBM Defendant will be denied for lack of diligence." Issue Ruling 5, R.6553, PageID#711239. Instead of addressing the individual circumstances of any moving plaintiff, the District Court issued a blanket ruling that none had been on notice until January 2023, when the PBMs began reproducing discovery from *Jefferson County* into

the MDL. *Id.*, PageID##711222, 711238. The District Court primarily relied on a May 2021 letter sent by OptumRx—but not Express Scripts—to Jefferson County reserving the right to seek sanctions after the County insisted in discovery that it did not have any facts satisfying the heightened causation standard for one of its state-law claims. *Id.*, PageID##711236-711238; *see* R.5547-2, PageID##640587-640592. Based on this one non-public OptumRx letter, sent on behalf of just one of the eighteen Petitioners and which resulted in no sanctions motion (let alone actual sanctions), the District Court reasoned that no plaintiff in any jurisdiction could have reasonably asserted any claims against OptumRx, Express Scripts, or their affiliates for fear of sanctions. Issue Ruling 5, R.6553, PageID##711236-711238.

The other four issue rulings addressed other arguments against granting leave to amend in a similarly generalized fashion. R.6306, R.6379, R.6418, R.6599. For example, in Issue Rulings 3 and 6, the District Court rejected the PBMs' futility and prejudice arguments without conducting an individualized inquiry into any proposed amendment. R.6418; R.6599.

On July 27, 2026, after its sixth and final issue ruling, the District Court granted leave to amend to *all* 800 remaining plaintiffs in 704 separate cases. R.6650. Remarkably, the District Court did not deny leave to amend to any plaintiffs, except for those whose motions were moot because the plaintiffs had earlier withdrawn.

LEGAL STANDARD

Mandamus relief is warranted when a party (1) asserts a “clear and indisputable” right, (2) has “no other adequate means to attain the relief [it] desires,” and (3) demonstrates that relief “is appropriate under the circumstances.” *Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 380-381 (2004); *In re FirstEnergy Corp.*, 154 F.4th 431, 440 (6th Cir. 2025). It is especially appropriate in cases involving a “judicial usurpation of power” or a “clear abuse of discretion.” *Cheney*, 542 U.S. at 380; *see CVS*, 956 F.3d at 842. In deciding whether to grant mandamus, this Court considers, among other factors, whether the petition presents a “question[] of unusual importance necessary to the economical and efficient administration of justice” or seeks to correct “a persistent disregard of the federal rules.” *Goetz*, 531 F.3d at 457.

REASONS TO GRANT THE PETITION

All the factors supporting mandamus relief are present here. Before ruling on plaintiffs’ omnibus motions, the District Court recognized that “the Sixth Circuit would reverse [it] in a heartbeat” if it “allow[ed] 800 amendments adding the PBMs,” and that “there isn’t any way that any such ruling would be affirmed.” 9/10/2025 Tr., R.6273, PageID##695081:17-20, 695082:7-8. But, ten months later, the District Court granted leave to amend to 800 plaintiffs in 704 separate cases without conducting any of the individualized analysis required by Rules 15 and 16.

This Court should grant mandamus to correct the District Court’s “clear abuse[s] of discretion.” *Cheney*, 542 U.S. at 380. Unless this Court acts now, the PBMs will face pressure to settle for enormous sums or litigate for years hundreds of cases filed long after the amendment deadlines.

I. THE PBMS HAVE A CLEAR AND INDISPUTABLE RIGHT TO MANDAMUS RELIEF.

“MDLs are not some kind of judicial border country, where the rules are few and the law rarely makes an appearance.” *CVS*, 956 F.3d at 843-846. Cases in an MDL do not “meld . . . into a single unit.” *Gelboim v.*

Bank of Am. Corp., 574 U.S. 405, 414 (2015); accord *CVS*, 956 F.3d at 845 (“cases within an MDL retain their separate identities”). As this Court has held, “the requirements of the Civil Rules in an MDL case—indeed, the requirements for granting a motion to amend in particular—are the same as those for ordinary litigation on an ordinary docket.” *CVS*, 956 F.3d at 844; see *In re Korean Air Lines Co.*, 642 F.3d 685, 700 (9th Cir. 2011) (“[W]hen it comes to motions that can spell the life or death of a case, such as . . . a motion to amend pleadings, it is important for the district court to articulate and apply the traditional standards governing such motions.”).

Rules 15 and 16 require an individualized, case-by-case analysis: “a district court’s decision whether to grant a motion to amend in an individual case *depends on the record in that case and not others*.” *CVS*, 956 F.3d at 845 (cleaned up) (emphasis added). These requirements cannot be loosened to achieve efficiencies in an MDL. “[A]n MDL court must find efficiencies within the Civil Rules, rather than in violation of them.” *Id.*³

³ Other circuits agree that the Civil Rules do not take a back seat to expediency in MDLs. See, e.g., *In re Aqueous Film-Forming Foams Prods.*

This is not the first time that the District Court has ignored these bedrock requirements in this MDL. Six years ago, it allowed two county plaintiffs to amend their complaints to add claims against pharmacy defendants “19 months after the court’s deadline for amendments to the Counties’ complaints, and more than 10 months after discovery had closed.” *Id.* at 842. Because “[n]either the Counties nor the district court ha[d] even attempted to show that the Counties demonstrated diligence as required by Rule 16(b),” this Court granted mandamus relief. *Id.* at 843. If the District Court’s disregard of the Civil Rules for the two plaintiffs in two cases was sufficient to grant mandamus in CVS, it is all the more so for the 800 plaintiffs in 704 cases at issue here.

A. The District Court Flouted Rules 15 And 16 By Granting Leave To Amend Without Individualized, Plaintiff-Specific Analysis.

Rules 15 and 16 specify the requirements that plaintiffs must satisfy when seeking to amend a complaint. Under Rule 16(b), a plaintiff seeking leave to amend after the court-ordered deadline must

Liab. Litig., 169 F.4th 436, 444-445 (4th Cir. 2026); *Hamer v. LivaNova Deutschland GmbH*, 994 F.3d 173, 177 (3d Cir. 2021); *In re Korean Air Lines*, 642 F.3d at 700.

demonstrate “good cause.” This requirement “ensures that at some point both the parties and the pleadings will be fixed,” permitting changes only when plaintiffs can demonstrate that “despite their diligence they could not meet the original deadline.” *CVS*, 956 F.3d at 843; *see Leary v. Daeschner*, 349 F.3d 888, 907-909 (6th Cir. 2003). Only if a plaintiff meets this threshold diligence requirement can a court consider granting leave under Rule 15(a), which requires courts to consider the specific allegations and claims that a plaintiff proposes to assert—*i.e.*, “the substance of the proposed amendment.” *Beydoun v. Sessions*, 871 F.3d 459, 469 (6th Cir. 2017).

1. The District Court committed clear legal error by granting leave to amend to 800 plaintiffs without undertaking any of the plaintiff- and case-specific inquiries Rules 15 and 16 require. Instead of evaluating each plaintiff’s request individually, based on “the record in that case,” *CVS*, 956 F.3d at 845, the District Court entered a series of “issue rulings” addressing broad categories of arguments—like diligence, futility, and prejudice—for all 800 plaintiffs as a monolith. Nor did the District Court consider how multiple issues affecting an individual plaintiff might compound and together demonstrate a lack of good cause.

Indeed, many plaintiffs' proposed amendments suffered from multiple independent defects.

The District Court's ruling on diligence underscores its legal error. Issue Ruling 5, R.6553. Rule 16(b)'s diligence requirement turns on an individualized inquiry into when a specific plaintiff became "aware of the facts underlying the proposed amendment" and the plaintiff's "explanation" for why it could not "move to amend the complaint before the deadline." *Ross v. Am. Red Cross*, 567 F. App'x 296, 306 (6th Cir. 2014).

The reason for individualized analysis is clear. Two different plaintiffs bringing the same claims at the same time after a deadline may have different explanations for their delay, and there is no necessary or categorical reason to view their diligence the same. The District Court's blanket finding of diligence for 800 different plaintiffs across 704 separate cases cannot be squared with its obligation to assess good cause for each "individual case" based on "the record in that case and not others." *CVS*, 956 F.3d at 845.

Plaintiffs' caveated and vague language in describing their own claims and diligence confirms why their generalized assertions cannot

support individual findings of good cause. For example, all 800 plaintiffs claimed that they were not on notice of their claims in 2018 and 2019—even though at least 74 opioid cases were already filed against the PBMs by then, *see* Am. Opp., R.6163, PageID##684440-684443, including a complaint in a bellwether case, *see* R.2582—because those cases and subsequent public reporting did not “*necessarily* persuade[]” them of the merits of pursuing similar claims. Reply, R.6257, PageID##694734-694735. The 800 plaintiffs improperly conflated a claim’s underlying merits with notice of its availability. *See infra* Section I.B. Even worse, no individual plaintiff specified in any way when or even *whether* it had reached that conclusion.

The District Court erred in accepting 800 plaintiffs’ conclusory and impermissibly collective assertion that *all* of them were justified in “waiting until they were confident” in their claims without engaging in any individualized assessment of each plaintiff’s diligence. Issue Ruling 5, R.6553, PageID#711238. In fact, in 2018 or 2019, 51 of the moving plaintiffs had *already* brought claims against the PBMs in the MDL, which they presumably believed to be meritorious. *See* Sur-Reply, R.6265, PageID#695047; Am. Opp., R.6163, PageID##684458, 684493.

Nor did the District Court meaningfully address the fact that at least 426 plaintiffs are represented by the *same lawyers* who sued the PBMs years earlier. Sixty of those plaintiffs are represented by the same attorneys who filed the *Webb County* case in 2018. R.6636-1, PageID##713816-713867. Twenty-six are represented by the same attorneys who filed 2019 actions against PBMs in Rochester and Ogdensburg, which later became PBM bellwethers. *See* R.5231; R.5834. And 340 are represented by PEC members and other attorneys who signed a 2019 MDL bellwether complaint against Express Scripts and OptumRx, among others, alleging that PBMs serve as “gatekeepers” in the industry. R.2582, PageID#413087 ¶ 284; R.6636-1, PageID##713816-713867.

The District Court also neglected other case-specific facts, such as that many moving plaintiffs were clients of Express Scripts with first-hand knowledge of the PBMs’ business model and thus more knowledgeable about potential PBM claims. *See* Am. Opp. Part II, R.6172; Issue Ruling 5, R.6553, PageID##711236-711238. Simply put, the District Court did not analyze each individual plaintiff’s diligence on a case-by-case basis, in violation of the Civil Rules.

2. The District Court’s flawed categorical rulings were the result of the flawed process it imposed over the PBMs’ objections. The District Court never required any moving plaintiff to submit a proposed amended complaint or to make any plaintiff-specific allegations; the only case-specific information before it was each plaintiff’s name, case number, and state. *See* R.5547-1; R.5548-1. Instead, plaintiffs collectively pointed to the City of Rochester’s complaint and represented that their amended claims would be “substantially identical.” Omb. Mot. (Optum), R.5547, PageID#640472; Omb. Mot. (Express Scripts), R.5548, PageID#640597. That vague cross-reference could not convey the “substance of the proposed amendment[s]” required by Rule 15. *Beydoun*, 871 F.3d at 469.

“[W]ithout viewing the proposed amendment, it is impossible for the district court to determine whether leave to amend should have been granted.” *Islamic Ctr. of Nashville v. Tennessee*, 872 F.3d 377, 387 n.7 (6th Cir. 2017). That is why the failure to submit a proposed amended complaint is ordinarily, by itself, a basis to deny leave to amend. *See Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 444 (6th Cir. 2014) (affirming denial of leave to amend where “plaintiffs did not present an adequate motion and . . . did not attach a copy of their amended

complaint”); *Doe v. Carson*, 2020 WL 2611189, at *1 (6th Cir. May 6, 2020) (affirming denial of leave to amend where plaintiff “failed to submit a proposed amended complaint”); *Harris v. Davidson County Sheriff*, 2019 WL 7573883, at *4 (6th Cir. Dec. 11, 2019) (same).

Here, plaintiffs’ short omnibus motions covering hundreds of distinct plaintiffs did not provide notice of each plaintiff’s claims. The 800 plaintiffs hailed from more than three dozen states—including Ohio, Maryland, and Oklahoma, where state supreme courts have rejected the public-nuisance theory pressed by the City of Rochester, New York, and where an individualized inquiry would thus have revealed that those amendments were “futile.” *See* Order, R.6650; List of Cases, R.6636-1; *see also Express Scripts, Inc. v. Anne Arundel County*, 353 A.3d 1084 (Md. 2026); *In re Nat’l Prescription Opiate Litig.*, 265 N.E.3d 1 (Ohio 2024); *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719 (Okla. 2021). Some moving plaintiffs are municipalities ranging from rural towns with fewer than 1,000 people; others are not even municipalities but are health plans, hospitals, school districts, tribes, and individuals. R.6163, PageID#684504; *see, e.g.*, R.6172, PageID##685991, 686065, 686855, 686871. It is therefore unclear which of Rochester’s claims and

allegations each moving plaintiff seeks to press against the PBMs; whether those claims are futile would require a case-by-case and plaintiff-by-plaintiff analysis.

The District Court recognized that “the normal procedure” is for each plaintiff to submit “a proposed amended complaint.” Issue Ruling 4, R.6428, PageID##707424-707425. But the District Court believed that such individualized pleadings would demand “colossal resources” without serving the “efficiency goals of an MDL.” *Id.* In *CVS*, this Court could not have been clearer that an MDL judge may not “distort or disregard the rules of law” for efficiency’s sake. 956 F.3d at 841. “[A]n MDL court must find efficiencies within the Civil Rules, rather than in violation of them.” *Id.* at 845. By disregarding the Rules for perceived efficiency, Judge Polster doubled down on the very error that caused this Court to grant mandamus relief six years ago in this MDL.

B. The District Court’s Decision To Grant Leave To Amend Based On Information Long Available To Plaintiffs Was Clearly Erroneous.

Beyond the District Court’s clear failure to follow the Rules, its ruling was wrong on the merits because, as a matter of law, the 800 moving plaintiffs did not meet their burden of demonstrating “good

cause” for their belated amendments. The First Circuit recently affirmed the dismissal of substantively identical claims against OptumRx and Express Scripts as time-barred at the pleading stage, based primarily on public records showing that the plaintiffs knew or should have known of their claims years earlier. *Boston*, 169 F.4th at 62-63.

This Court has repeatedly held that a party lacks good cause for an untimely amendment where, as here, it was “aware of the basis of the claim” but “nonetheless failed to pursue the claim” within the time allotted. *Leary*, 349 F.3d at 908; *see Garza v. Lansing Sch. Dist.*, 972 F.3d 853, 879 (6th Cir. 2020) (affirming denial of leave to amend where plaintiff “had all the information [she] needed to timely allege” her claim). Applying this rule “is not optional” and reflects the principle that, at some point in a litigation, “both the parties and the pleadings will be fixed.” *CVS*, 956 F.3d at 843.

Under that settled rule, diligence turns on when a plaintiff had access to the facts underlying its claim—not when it decides that those facts can, in its view, ground a meritorious claim. *Garza*, 972 F.3d at 879. A plaintiff cannot amend after the deadline if it “could have developed [its] claim . . . much sooner” based on “information plainly available,” even

where the issue is “complex” and it “could not be certain” that the claim had merit. *Profitt v. Highlands Hosp. Corp.*, 2024 WL 3622448, at *4 (6th Cir. Aug. 1, 2024).

Ignoring these fundamental requirements, the District Court concluded that *all* 800 plaintiffs acted diligently—notwithstanding their years-long delay—based on its conclusion that all 800 plaintiffs did not have “information sufficient to name the PBMs” until January 2023, when discovery materials from *Jefferson County* were reproduced in the MDL. Issue Ruling 5, R.6553, PageID#711236. That finding was contrary to the record and the law.

1. The record before the District Court makes clear that, for two reasons, all 800 plaintiffs were on notice of their claims before the applicable amendment deadlines.

First, the MDL’s public docket shows that plaintiffs were on notice of their claims since at least 2018. Dozens of plaintiffs sued PBMs, including OptumRx and Express Scripts, in 2018 and 2019. Beginning in January 2018 with Webb County, Texas, at least 74 opioid cases were publicly filed against the PBMs during those two years. *See supra* pp. 5-6; Am. Opp., R.6163, PageID##684440-684443. Those lawsuits were

highlighted on the MDL docket in 2018 through publicly filed letters describing the PBMs as a “critical defendant group” and “necessary parties to any effort to abate the opioid crisis and address the legal issues presented” in the MDL. R.108, PageID#558; R.168, PageID#945; *see also* R.978-6, PageID#21682. In 2019, an MDL bellwether complaint filed against PBMs was signed by counsel who collectively represent nearly half of the 800 moving plaintiffs. R.2582, PageID##413486-413488; R.6636-1, PageID##713816-713867.

The First Circuit’s recent decision in *Boston* confirms that these public records defeat a showing of good cause as a matter of law. Reviewing the same public filings, the First Circuit held at the pleading stage that materially identical claims filed in January 2024 against OptumRx, Express Scripts, and their affiliates were time-barred because Boston “had ample reason to know of [alleged] PBM wrongdoing and had ample means to discover the facts to support a claim against PBMs before 2021.” 169 F.4th at 62-64. It was “not plausible” that a plaintiff was unaware of the dozens of public lawsuits and MDL bellwether cases naming the PBMs in 2018 and 2019. *Id.* at 63.

The First Circuit’s conclusion was “further bolstered by” the fact that plaintiffs’ own counsel were aware from the MDL of claims against PBMs. *Id.* That is equally true here. Hundreds of moving plaintiffs were represented by the *same lawyers* who sued the PBMs years earlier on behalf of other clients. *See* R.6265, PageID#695047; R.6636-1, PageID##713816-713867; R.6163, PageID#684458; *Daniel v. Cantrell*, 375 F.3d 377, 386 (6th Cir. 2004) (“We know of no good reason to depart from the well-established rule that the knowledge of an agent is imputed to his principal.”). As a matter of law, the moving plaintiffs cannot meet their burden to show diligence and good cause for their delay. *CVS*, 956 F.3d at 844-846.

Second, moving plaintiffs conceded that they had access to all the “new” information on which they purported to rely as justifying the delay in their proposed amendments. *See* Am. Opp., R.6163, PageID##684462-684471. As the PBMs demonstrated below, documents containing the *same* information—in some instances, exact duplicates—have long been available publicly or in the MDL since *at least August 2018*, nearly six years before the 800 plaintiffs moved to amend. *Id.*; *see, e.g.*, R.5547, PageID#640480; R.6163, PageID##684463-684467.

In reply, plaintiffs conceded that early MDL productions “contained important evidentiary support” for their new allegations. Reply, R.6257, PageID##694731-694732. Rochester’s complaint, which plaintiffs offered as a model, draws extensively on documents produced by other MDL defendants before the amendment deadline. *See* Am. Opp., R.6163, Tables 1 & 2. The fact that plaintiffs sat on these documents for years before seeking leave to amend is the opposite of diligence. *See Bank of Am., N.A. v. Corporex Realty & Inv. Corp.*, 661 F. App’x 305, 317 (6th Cir. 2016) (affirming denial of leave to amend where party “fail[ed] to explain why it neglected to assert [its] new claims after it received the bulk of relevant discovery”).

It was plaintiffs’ burden to demonstrate that “despite their diligence they could not meet the original deadline.” *CVS*, 956 F.3d at 843. Yet plaintiffs all but admitted that they had the information they needed to bring claims against PBMs years earlier—as dozens of other plaintiffs did. That alone warranted denial of their motions. *See Leary*, 349 F.3d at 907-908 (“It comes as no surprise” that leave to amend is denied when plaintiffs were “obviously aware of the basis of the claim for many months.”). Indeed, the District Court never found that any particular

piece of information on which plaintiffs relied was “new.” It is clear error to hold that Rule 16 was satisfied on that record.

2. The District Court nevertheless rejected the PBMs’ arguments for two erroneous reasons.

First, the District Court clearly erred in relying on a discovery letter OptumRx’s counsel sent to Jefferson County in May 2021—more than two years *after* the MDL amendment deadline applicable to most plaintiffs—reserving the right to seek sanctions against Jefferson County for lacking factual information to support the heightened causation standard applicable to one of the County’s state-law claims. Issue Ruling 5, R.6553, PageID##711236-711238. The District Court believed “the PBMs’ threat that a plaintiff pursuing an opioid claim against them would be met with a motion for sanctions” meant that the plaintiffs “did not lack diligence for waiting until they were confident they could defeat that motion,” which the court concluded was not until “January 2023” when discovery materials from *Jefferson County* were reproduced in the MDL. *Id.*, PageID#711238.

That conclusion was clearly wrong for several reasons. In the first place, the letter was from OptumRx—not Express Scripts or any of the

other sixteen Petitioners, *id.*, PageID#711237—so it provides no basis for the district court to assert that “the PBMs” collectively threatened sanctions or to find that plaintiffs were justified in delaying claims against Express Scripts, its affiliates, or even OptumRx’s affiliates.

In addition, the District Court misread the letter. The letter did not address the facial sufficiency of Jefferson County’s pleadings, which had already survived two motions to dismiss under Missouri’s “rigorous” fact-pleading requirements. *Agnello v. Walker*, 306 S.W.3d 666, 678 (Mo. Ct. App. 2014). Rather, it addressed Missouri state-law claims subject to an additional heightened standard that discovery revealed Jefferson County had no basis to bring. *See Letter*, R.5547-2, PageID##640587-640592. Moreover, although OptumRx’s letter reserved the right to seek sanctions against Jefferson County, it did not threaten sanctions against any other plaintiff, let alone each of the 800 moving plaintiffs at issue here. Nor did any court, state or federal, ever agree with OptumRx’s position. That letter was not even conceivably a “threat” that could deter all other legitimate filings.

Indeed, this letter did not stop dozens of other plaintiffs across the country from filing opioid claims against OptumRx and Express Scripts

in 2018, 2019, and later years, including in the MDL. *See* Am. Opp., R.6163, PageID##684440-684443; *Forbes v. Eagleson*, 19 F. Supp. 2d 352, 375-376 (E.D. Pa. 1998) (threat of Rule 11 sanctions did not preclude plaintiffs from timely bringing suit where public news articles “gave notice of both the existence of plaintiffs’ potential claim and sources of whom plaintiffs could have inquired for verification and further information”).

Worse still, the District Court did not find that any moving plaintiff (let alone all of them) even knew about the non-public *Jefferson County* letter, much less relied on it in deciding whether to sue the PBMs before the amendment deadline. Issue Ruling 5, R.6553, PageID##711237-711238. The letter was not sent until May 2021—*after* the applicable amendment deadline for 765 of the 800 plaintiffs, *see* Am. Opp. Part II, R.6172—so it could not possibly have influenced their decision-making. And the District Court’s generalized assertions about a hypothetical plaintiff’s decision-making violated Rule 16, which this Court has emphasized “depends on the record” in each “individual case.” *CVS*, 956 F.3d at 845.

Second, the District Court erred in excusing all 800 plaintiffs’ lack of diligence because PBMs’ business practices are, in its view, “unusually opaque.” Issue Ruling 5, R.6553, PageID#711238 n.19. That is wrong as a factual matter. PBMs’ practices are hardly opaque; indeed, they were described in detail on the public docket years ago. At least 74 opioid complaints were publicly filed against PBMs in 2018 and 2019, including a bellwether complaint, all of which lay out in public filings precisely how to allege claims against the PBMs. *See* Am. Opp., R.6163, PageID##684440-684443. These complaints—many drafted by the same lawyers who represent over half of the 800 moving plaintiffs—demonstrate that the District Court clearly erred in holding that plaintiffs were not on notice until 2023.

In any event, this Court’s decision in *Profitt* confirms the District Court’s legal error. There, this Court rejected a plaintiff’s argument that she did not have sufficient notice of medical malpractice claims by the amendment deadline because the medical records long in her possession were too “complex” for “a layperson . . . [to] reasonably assess.” 2024 WL 3622448, at *3-4. This Court held that the plaintiff was not diligent because the information was “plainly available” before the amendment

deadline, and her claim “could have [been] developed” “much sooner.” *Id.* at *4. That the claim involved “complicated” issues did not relieve the plaintiff of her Rule 16(b) obligations. *Id.* Diligence does not turn on whether the subject matter is “complex”; it turns on whether information was “available” to put the plaintiff on notice of its claim. *Id.*

II. THE PBMS HAVE NO OTHER ADEQUATE MEANS OF OBTAINING RELIEF.

Mandamus relief is necessary because the PBMs have “no other adequate means to obtain relief” from the extraordinary litigation burdens that will result from the District Court’s flagrant (and now repeated) disregard of the Civil Rules. *CVS*, 956 F.3d at 845. By granting leave to amend *en masse* to 800 plaintiffs at this late stage of the MDL, the District Court has forced the PBMs to defend against claims by 800 additional plaintiffs.

There is more. The District Court has foreclosed the PBMs’ ability to obtain review of moving plaintiffs’ legally deficient claims at the pleading stage by imposing a moratorium on substantive filings, even though, in the District Court’s own words, many of the newly asserted claims “would not survive a motion to dismiss.” Issue Ruling 3, R.6418, PageID#707377. To cite just one example, every state supreme court to

consider the issue has rejected the state-law public-nuisance theories that plaintiffs seek to press, but the PBMs are barred from bringing any pleading-stage challenge. *See supra* p. 27.

That prejudice cannot be remedied after final judgment. As this Court has held, defendants forced to litigate improperly allowed amendments are “prejudiced in a way not correctable on appeal,” *CVS*, 956 F.3d at 845-846, because the resulting litigation burdens cannot be undone, and appellate review would come only after years of unnecessary effort and expense.

Immediate appellate review is critical because the District Court clearly erred in allowing 800 plaintiffs to bring new claims. The PBMs should not have to wait until hundreds of cases are remanded to courts around the country to correct the District Court’s clear and dispositive procedural error common to all of them.

Finally, it is clear that plaintiffs seek to leverage this massive crush of new cases to try to coerce the PBMs into unwarranted settlements. *See Mot. to Lift Moratorium*, R.5411, PageID#635513 n.1. The Supreme Court has warned against such “blackmail settlements” that can occur when defendants are forced to litigate meritless claims in the shadow of

“the possibility of colossal liability” because of delayed appellate rights. *Coinbase, Inc. v. Bielski*, 599 U.S. 736, 743 (2023).

III. MANDAMUS RELIEF IS APPROPRIATE.

For two reasons, mandamus relief is particularly appropriate here.

First, the District Court’s decision below not only is “plainly incorrect as a matter of law,” but also reflects a “persistent disregard of the federal rules.” *CVS*, 956 F.3d at 843 (quotation omitted); *see Goetz*, 531 F.3d at 457. Mandamus is “appropriate” when “the district judge in [a] case has a history” of making “repeated errors.” *In re Am. Med. Sys.*, 75 F.3d at 1089. This is now the second time that the District Court has made the same error, treating Rules 15 and 16 as optional in this MDL.

Second, the District Court’s disregard of the Rules implicates “questions of unusual importance.” *Goetz*, 531 F.3d at 457. MDL litigation is a fast-growing part of the federal civil docket, comprising around *half* of the civil docket in federal courts today, up from only 16% in 2002.⁴ That growth will be further fueled if MDL courts are permitted

⁴ *Federal Judicial Caseload Statistics 2025*, U.S. COURTS, <https://www.uscourts.gov/data-news/reports/statistical-reports/federal-judicial-caseload-statistics/federal-judicial-caseload-statistics-2025> (398,121 pending civil cases); Bloch Judicial Inst., Duke L. Sch., *Guidelines and Best Practices for Large and Mass-Tort MDLs*, at vii.

to prioritize efficiency over fair application of the Rules, as the District Court did here. As this Court has recognized, “in the MDL context” consequential procedural errors “often evade appellate review.” *CVS*, 956 F.3d at 845. That makes mandamus relief all the more important and appropriate here.

CONCLUSION

The Court should grant a writ of mandamus, vacate the order granting leave to amend, and direct the District Court to deny plaintiffs’ omnibus motions for leave to amend.

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AUGUST 26, 2026

CERTIFICATE OF COMPLIANCE

This Petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 21(d)(1) because, excluding accompanying documents and the parts of the petition exempted by Rule 32(f), it contains 7,786 words. This petition complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

A handwritten signature in cursive script, reading "Robert J. Giuffra, Jr.", positioned above a horizontal line.

Robert J. Giuffra, Jr.

Dated: August 26, 2026

CERTIFICATE OF SERVICE

I certify that, on August 26, 2026, the foregoing was filed electronically with the Clerk of Court using the Court's CM/ECF system.

I certify that, on August 26, 2026, a copy of the foregoing was served upon the District Court by email and mail and on Plaintiffs' Counsel by email.



Robert J. Giuffra, Jr.

Dated: August 26, 2026

DESIGNATION OF DISTRICT COURT DOCUMENTS

R. No.	Description	PageID
108	Jan. 31, 2028 Letter to Hon. Dan A. Polster filed by Webb County, TX	558–559
108-1	Attachment: Webb County Complaint	560–674
168	Mar. 6, 2018 Letter to Hon. Dan A. Polster from J. Cicala re PBMs filed by Webb County, TX	945
978-6	Jan. 26, 2018 Letter from Webb County to PEC	21680–21688
1106	Order Granting Plaintiffs' Motion for Modification of CMO 1	27481–27483
2582	Cabell County Commission and City of Huntington Third Amended Complaint	413019–413488
5168	Transcript of Status Conference by Zoom Held on August 30, 2023	621874–621922
5217	Order Denying Joint Motion to Disqualify Special Master Cohen	623906–623916
5231	Order Confirming the PBM Bellwether Process	624062–624063
5411	PEC Motion to Lift Moratorium on Substantive Filings to Permit Plaintiffs to File Motions for Leave to Amend to Add Defendants	635512–635515
5455	Order re PEC Motion to Lift Moratorium on Substantive Filings to Permit Plaintiffs to File Motions for Leave to Amend to Add Defendants	637947–637949
5471	Transcript of Motion Hearing Held on May 22, 2024	638221–638252
5546	Roadmap Overview for Motions for Leave to Amend	640192–640218
5547	PEC Omnibus Motion Leave for Amend to Add Optum Defendants and Memorandum of Law in Support	640468–640490
5547-1	Exhibit A – Chart	640491–640578
5547-2	Exhibit B – Declaration	640579–640592

R. No.	Description	PageID
5548	PEC Omnibus Motion for Leave to Amend to Add Express Scripts Defendants and Memorandum of Law in Support	640593– 640614
5548-1	Exhibit A – Chart	640615– 640701
5548-2	Exhibit B – Declaration	640702– 640706
5834	PBM Bellwether Case Track 22 Case Management Order	659241– 659250
5885	Opposition Part 1 to Omnibus Motions for Leave to Amend to Add Express Scripts Defendants and Optum Defendants	660586– 660701
5885-1	Opposition Part 2 to Omnibus Motions for Leave to Amend to Add Express Scripts Defendants and Optum Defendants	660702– 667211
5890	Declaration of Jonathan G. Cooper	667705– 667710
5892	Declaration of Andrew Hatchett	667721– 667725
5941	PBM Motion to Strike Certain Plaintiffs from the Omnibus Motions for Leave to Amend and for Sworn Certifications Regarding Joinder to the Omnibus Motions	670380– 670387
5952	The PBMs’ First Supplemental Motion to Strike Certain Plaintiffs from the Omnibus Motions for Leave to Amend	670732– 670737
6163	Amended Opposition Part I to Omnibus Motions for Leave to Amend to Add Express Scripts Defendants and Optum Defendants	684415– 684532
6172	Amended Opposition Part II to Omnibus Motions for Leave to Amend to Add Express Scripts Defendants and Optum Defendants	685588– 688898
6257	PEC Reply in Response to the PBMs’ Joint Opposition to Motions for Leave to Amend	694707– 694829
6265	PBM Sur-Reply re: Plaintiffs’ Reply in Support of Their Omnibus Motions for Leave to Amend	695043– 695050

R. No.	Description	PageID
6273	Transcript of Status Conference held on 9/10/2025	695072–695086
6306	Issue Ruling Order No. 1 Re: Motions to Amend	697097–697110
6379	Issue Ruling Order No. 2 Re: Motions to Amend	704587–704593
6418	Issue Ruling Order No. 3 Re: Motions to Amend	707369–707378
6428	Issue Ruling Order No. 4 Re: Motions to Amend	707421–707430
6553	Issue Ruling Order No. 5 Re: Motions to Amend	711212–711240
6599	Issue Ruling Order No. 6 Re: Motions to Amend	712265–712274
6636-1	Exhibit 1 - 1A through 1M	713774–713867
6636-2	Exhibit 2 - 2A through 2L	713868–713933
6650	Order Regarding Plaintiffs' Motions for Leave to Amend	714156–714162

ATTACHMENT A

(R. 6306, Issue Ruling Order No. 1)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION	)	CASE NO. 1:17-MD-2804
OPIATE LITIGATION	)	
	)	JUDGE POLSTER
THIS DOCUMENT RELATES TO:	)	
“All Cases”	)	
	)	<u>ISSUE RULING ONE</u>
	)	<u>REGARDING</u>
	)	<u>MOTIONS TO AMEND</u>

I. Introduction.

On April 22, 2024, the PEC filed a motion asking the Court to lift its moratorium on substantive filings and permit all MDL plaintiffs to file motions for leave to amend complaints to add defendants. Docket no. 5411. Following briefing and oral argument, the Court granted the PEC’s motion. *See Amendment Order* at 2 (docket no. 5455) (noting “[t]his will be plaintiffs’ final opportunity to amend their complaints.”).

The Court set forth certain directives regarding the timing and format of the motions to amend and related briefing, among other things. *See, e.g., id.* at 1 (“For each defendant the PEC wishes to add to any case, the PEC shall file a *single* motion to amend the complaints of *all* plaintiffs who wish to add that defendant.”) (emphasis in original). In the 16-month period following the Court’s *Amendment Order*, the parties have filed dozens of motions and responsive briefs that, including attached exhibits, total many thousands of pages. The chart attached to the end of this Order lists the principal documents. The Court has also carefully reviewed and considered all related documents, Orders, transcripts, and so on.

The parties’ briefs raise a plethora of arguments, many of which are common across the

various motions to amend. For example, several defendants argue that, if a plaintiff failed to file or to update a Plaintiff Fact Sheet (“PFS”), that plaintiff should be denied leave to amend. Given this commonality, the Court has determined that the best way to address all of the motions to amend is to publish “Issue Rulings” that resolve common issues, rather than to publish rulings on one motion at a time. This is the first such Issue Ruling.

In this and future Issue Rulings, the Court will direct the parties to: (1) meet and confer and come to agreement on how the Ruling applies to each case where a motion to amend was filed; and (2) submit to the Court an agreed case list showing their conclusion. For example, Section III of the instant Issue Ruling addresses the parties’ arguments regarding PFSs. As explained further in Section IV, the Court expects the parties to come to agreement that application of this Ruling works to deny the motion to amend in certain, specific cases, but not others. Upon receiving the parties’ agreed list, the Court will make case-specific docket entries accordingly.

II. Legal Standards.

The Court sets out here the general legal standards it will apply to the motions to amend. Future Issue Rulings are deemed to incorporate by reference this Section of Issue Ruling One. Future Issue Rulings may also set forth additional legal standards specific to certain issues.

* * * * *

The MDL Court’s first Case Management Order (“CMO-1”) set a deadline of May 25, 2018 for all plaintiffs (with certain specifically-identified exceptions) to “file any amended pleading, including any amendment to add a party to a case.” Docket no. 232 at 9. Subsequent Orders extended this deadline for all existing MDL cases to March 16, 2019. Docket no. 1106 at 3. As for cases not

yet transferred to or filed in the MDL, the Court ordered that “any amended complaints to be filed without seeking leave of Court must be filed [by] the later of March 16, 2019 . . . or 90 days following transfer into this MDL.” *Id.* at 3 n.7.

On April 8, 2022, the Judicial Panel on Multidistrict Litigation (“JPML”) discontinued transferring new cases to this MDL. *In re Nat’l Prescription Opiate Litig.* (J.P.M.L. Apr. 8, 2022) (case no. 2804, docket no. 9586). Thus, the last possible date for virtually every MDL plaintiff to amend its complaint without leave of Court was approximately July 8, 2022.¹

On July 29, 2024, more than 2,000 plaintiffs joined and filed omnibus motions seeking to amend their complaints to state claims against various additional defendants. Numerous plaintiffs subsequently withdrew from some of those motions, leaving roughly 1,200 moving plaintiffs at this time.

Amendment of complaints is governed by Rules 15 and 16 of the Federal Rules of Civil Procedure. The two Rules set forth somewhat different standards. Rule 15 states that, if a party seeks to amend its pleading, “[t]he court should freely give leave when justice so requires.” Rule 16 requires a court to enter a scheduling order setting (among other time limits) a deadline for amendment of pleadings, and this “schedule may be modified only for good cause and with the

¹ The MDL Court’s docket shows the JPML’s last conditional transfer order was filed on March 21, 2022. *See* docket no. 4318 (CTO no. 217). Only about 40 cases were direct-filed in the MDL after that date. The MDL docket shows a total of 3,169 “member cases,” some of which are already closed.

judge's consent." Fed. R. Civ. P. 16(b)(3, 4).²

The Sixth Circuit has explained how these two directives intersect: If a plaintiff files a "motion to amend . . . after the scheduling order's deadline, plaintiff must first demonstrate good cause under Rule 16(b) before [the court] will consider whether amendment is proper under Rule 15(a)." *Leary v. Daeschner*, 349 F.3d 888, 906 (6th Cir. 2003) (quoting *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1419 (11th Cir. 1998)) (cleaned up). *See also Armatas v. Haws*, 2021 WL 5356028, at *3 (6th Cir. Nov. 17, 2021) ("the moving party must meet a 'higher threshold' in showing good cause under Rule 16 than it would under Rule 15") (citation omitted).

Because the moving plaintiffs filed their omnibus motions years after the March 16, 2019 deadline for amendments, these plaintiffs must first satisfy Rule 16's higher threshold. Rule 16 provides that "the district judge . . . must issue a scheduling order" that, among other things, "must limit the time" during which the parties may "join other parties" or "amend the pleadings." Fed. R.

² There is some question whether the "good cause" requirement in Rule 16 will still hold in MDL cases. Proposed Rule 16.1, which is the first federal rule to provide specific guidance for MDL cases, and which is scheduled to become effective on December 1, 2025, states only that the MDL court's scheduling order "controls the course of the proceedings unless the court modifies it." There is no mention of "good cause." Further, the advisory committee notes on this new proposed rule state:

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) [which requires, among other things, a deadline for parties to amend pleadings]. 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.

Fed. R. Civ. P. 16.1(c) cmt. (proposed); *see* October 17, 2024 Memorandum Summary of Proposed New and Amended Federal Rules of Procedure, available at https://www.uscourts.gov/sites/default/files/2024_scotus_package_final.pdf.

In any event, the Court's analysis of the pending motions to amend **does** include application of the good cause requirement.

Civ. P. 16(b)(1), (3)(A). After that deadline, a party can amend the pleadings only if it shows “good cause.” *Id.* at 16(b)(4). “[T]he application of Rule 16(b)’s good-cause standard is not optional.” *In re CVS*, 956 F.3d 838, 843 (6th Cir. 2020) (quoting *Sherman v. Winco Fireworks, Inc.*, 532 F.3d 709, 716 (8th Cir. 2008)). Indeed, “when it comes to motions that can spell the life or death of a case, such as . . . a motion to amend pleadings, it is important for the district court to articulate and apply the traditional standards governing such motions.” *Id.* at 845 (citing *In re Korean Air Lines Co.*, 642 F.3d 685, 700 (9th Cir. 2011)).

“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) (quoting 3 James Wm. Moore, *Moore’s Federal Practice – Civil* § 16.14[1][b] (3rd ed. 2019)). “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.). Thus, the “decision whether to grant a motion to amend in an individual case depends on the record in that case and not others.” *In re CVS*, 956 F.3d at 845.

Courts consider two principal factors in assessing “good cause”: the diligence of the party seeking leave to amend and undue prejudice to the opposing side. *Andretti v. Boria Performance Indus., Inc.*, 426 F.3d 824, 830 (6th Cir. 2006); *Leary*, 349 F.3d at 906. Both factors must be considered. *See Korn v. Paul Revere Life Ins. Co.*, 382 F. App’x 443, 450 (6th Cir. 2010) (absence of prejudice alone does not demonstrate good cause). Regarding the latter factor, “[t]he longer the delay, the less prejudice the opposing party will be required to show.” *Garza v. Lansing Sch. Dist.*, 972 F.3d 853, 880 (6th Cir. 2020) (citation omitted). But a court may also consider whether any

prejudice can be cured by allowing a continuance, and whether “refusing to grant the continuance would create a substantial risk of unfairness to [the moving] party.” 3 Moore’s Federal Practice, §16.14[1][c] at 16-72.1; *Deloitte Tax LLP v. Murray*, 2022 WL 44661, at *1 (N.D. Ohio Jan. 4, 2022). An appellate court “review[s] for abuse of discretion a district court’s decision to amend its scheduling order to allow a late filing.” *Andretti*, 426 F.3d at 830.

“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). The moving party must “demonstrate[] that ‘despite their diligence they could not meet the original deadline.’” *In re CVS*, 956 F.3d at 843 (citation omitted). Thus, a court may conclude “a party cannot show diligence when it is ‘aware of the basis of a claim for many months’ and fails to pursue that claim.” *Profitt v. Highlands Hosp. Corp.*, 2024 WL 3622448, at*4 (6th Cir. Aug. 1, 2024) (quoting *Leary*, 349 F.3d at 908).

In contrast, if the moving party only learned of the facts supporting its proposed amendment after the amendment deadline, diligence will generally be found. *See, e.g., Salerno v. Fam. Heritage Life Ins. Co. of Am.*, 2024 WL 2235772, at *2 (N.D. Ohio May 17, 2024) (“Sixth Circuit courts regularly grant leave for a party to amend its pleadings when discovery ‘apparently confirmed [the party’s] suspicions so that the company could assert [additional] claims.’”); *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 deadline date passed, Rapp could not reasonably have met the deadline despite due diligence.”); *Joseph v. Joseph*, 2017 WL 5953119, at *2 (S.D. Ohio Jan. 10, 2017) (finding good cause existed when “the documents upon which the proposed

amendment [was] largely based were not produced until more than two months after the . . . motion to amend deadline”). And 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. Instead, Plaintiffs were entitled to presume they would discover this kind of information the way many litigants routinely do, through discovery.” *O’Neal v. Denn-Ohio, LLC*, 2020 WL 210801, at *2 (N.D. Ohio Jan. 14, 2020).

Moreover, “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.); *see Yukech v. Cal. Transp., LLC*, 2022 WL 15523495, at *1 (S.D. Ohio Oct. 27, 2022) (“Notably, a plaintiff’s ‘possession of relevant information prior to the amendment deadline is only one factor tending to show a lack of diligence.’”).

If a plaintiff does show good cause under Rule 16, the Court should then proceed to “consider whether amendment is proper under Rule 15(a).” *Leary*, 349 F.3d at 909. Under Rule 15, a “court should freely give leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). The Sixth Circuit has explained that Rule 15 reflects a “liberal amendment policy.” *Brown v. Chapman*, 814 F.3d 436, 442–43 (6th Cir. 2016). “[T]he thrust of Rule 15 is to reinforce the principle that cases ‘should be tried on their merits rather than the technicalities of pleadings.’” *Moore v. City of Paducah*, 790 F.2d 557, 559 (6th Cir. 1986) (quoting *Tefft v. Seward*, 689 F.2d 637, 639 (6th Cir. 1982)). Certain circumstances, however, may counsel against allowing amendment: “In deciding whether to grant a motion to amend, courts should consider undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous

amendments, undue prejudice to the opposing party, and futility of amendment.” *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005).³ Some of these factors are subsumed in the Rule 16 good cause analysis.

“Notice and substantial prejudice to the opposing party are critical factors in determining whether an amendment should be granted” under Rule 15(a). *Head v. Jellico Hous. Auth.*, 870 F.2d 1117, 1123 (6th Cir. 1989) (citation omitted). Rule 15(a) requires an amending plaintiff to “act with due diligence if it intends to take advantage of the Rule’s liberality.” *United States v. Midwest Suspension & Brake*, 49 F.3d 1197, 1202 (6th Cir. 1995). As with Rule 16, “[t]he longer the delay, the less prejudice the opposing party will be required to show” under Rule 15. *Dubuc v. Green Oak Township*, 312 F.3d 736, 752 (6th Cir. 2002).

In addition, a Court will disallow proposed amendments under Rule 15 if they are “futile.” *Stanley v. W. Mich. Univ.*, 105 F.4th 856, 867 (6th Cir. 2024). A proposed amendment is futile if it fails to present any claim that could survive a Rule 12(b)(6) motion to dismiss. *Id.* To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. Plaintiff Fact Sheets.

The Court now turns to an argument raised by several defendants, which is that: (1) certain plaintiffs failed to comply with the Court’s Orders mandating the filing of Plaintiff Fact Sheets

³ No defendant asserts a moving plaintiff engaged in bad faith or failed repeatedly to cure deficiencies by previous amendments.

(“PFSs”); and (2) this failure compels denial of those plaintiffs’ motions to amend. For the reasons and to the extent stated below, the Court finds this argument well-taken.

Over two years ago, in its *PFS Failures Order*, the Court recapitulated the history of the requirement that every governmental subdivision plaintiff in this MDL must submit a PFS. *See* docket no. 4985 at 1-2. The final thrust of the *PFS Failures Order* is set out in these two sentences: (1) “The Court has [previously] expressly required plaintiffs to exchange or provide PFSs numerous times;” and (2) “This Order, therefore, acts as a final warning that continued failure to submit a PFS into the PFS Repository will result in **dismissal with prejudice**” for failure to prosecute *Id.* at 5, 6 (emphasis in original). The Court gave every MDL plaintiff a final deadline of 45 days to submit a PFS. *Id.* at 6. Dismissal of cases thereafter for failure to submit a PFS would not be automatic, but would occur if a defendant moved for dismissal for failure to comply with the Order. *Id.* at 7.⁴

Certain defendants argue that a plaintiff’s failure to submit a PFS should now preclude them from amending their complaint. For example, the PBM Defendants assert:

16 Moving Plaintiffs never submitted a Government Plaintiff Fact Sheet. In addition, 288 submitted substantially incomplete Fact Sheets, and 509 submitted Fact Sheets before January 1, 2020, and have not updated any of the information since.

PBM Part I Response at 66–67 (docket no. 6163). The PBM Defendants argue these failures cause them undue prejudice, so none of these allegedly noncompliant plaintiffs should be allowed to amend their complaints. The Generic Manufacturer Defendants offer different statistics, but make the same point. *See* GM Joint Response at 15 (docket no. 5899) (asserting that “127 [plaintiffs] have

⁴ Because there are several thousand cases in the MDL, the Court relied on defendants to identify PFS failures and move to dismiss those plaintiffs’ cases, rather than attempting, itself, to identify those plaintiffs. Thus, there apparently remain cases in the MDL where the plaintiff did not submit a PFS, but no defendant moved to dismiss.

not filed fact sheets as this Court required,” and arguing that “a plaintiff’s failure to submit plaintiff fact sheets in contravention of a court order constitutes prejudice”).

The Court does not agree that a plaintiff’s failure to submit a PFS will cause or has caused any defendant undue prejudice under Rule 15 or Rule 16. The cases where plaintiffs seek leave to amend have been stayed and discovery has not yet begun. *See In re Meijer*, No. 21-4051, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022) (finding no substantial prejudice where “[defendant] was added to this case before discovery ever started.”). *See also NOCO*, 2022 WL 1803039, at *3 (Polster, J.) (granting leave to amend and rejecting defendant’s assertion of prejudice where “discovery [was] still ongoing and dispositive motions [were] not due for another seven months”).

5

As noted in Section II above, however, undue prejudice is just one of the two principal factors a Court must use to assess “good cause” under Rule 16(b); the other factor is the diligence of the party seeking leave to amend. Defendants have not shown undue prejudice, but they have certainly described lack of diligence. As the Court already concluded over two years ago in the *PFS Failures Order*, any plaintiff who was required to submit a PFS but failed to do so has not been diligent in prosecuting its case. *A fortiori*, that plaintiff cannot demonstrate the requisite diligence to now be allowed to amend its complaint.

Still, there is a difference between: (i) a plaintiff’s complete failure to submit a PFS, and (ii) a plaintiff’s submission of a PFS that a defendant asserts is incomplete or out-of-date. The former is black-and-white. The latter is largely subjective and does not show the degree of failure of

⁵ Numerous Defendants have pointed in their opposition briefs to various putative sources of prejudice as a reason to deny the motions to amend. The Court addresses in this Issue Ruling only the argument that failure to submit a PFS caused a defendant undue prejudice.

attention that mandates denial of a motion to amend. Moreover, there is simply no *prejudice* to a party in not having the most up-to-date factual information about a plaintiff in whose case the party is not presently named. If a plaintiff's motion to amend is granted, a newly-added defendant may raise any deficiencies with that plaintiff's PFS through the procedure set forth in the Court's Fact Sheet Implementation Order (docket no. 638).

Accordingly, the Court hereby **DENIES** leave to amend sought by any plaintiff that has not submitted a PFS. This denial applies *in toto*, prohibiting amendment to add any and every party the plaintiff sought to add as a defendant. Conversely, the Court will *not* deny leave to amend sought by a plaintiff on the basis that the plaintiff's PFS is somehow inadequate.

IV. Application of this Issue Ruling.

For the reasons and to the extent stated above, the Court rules that a motion to amend filed by a plaintiff that did not submit a PFS is **DENIED**. It now falls to the parties to apply that ruling to each individual case 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 to amend 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.

IT IS SO ORDERED.

/s/ Dan Aaron Polster
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: October 1, 2025

(Chart on following pages)

Motion to Amend Briefing Chart ^{1, 2}					
Defendant	Motion		Response	Reply	Sur-Reply
	5565	Plaintiffs' Roadmap			
Pharmacy Defendants					
Ahold Delhaize	5566	Omnibus Motion to Amend to Add Ahold Delhaize	5879 Ahold Delhaize Response		
Albertsons	5567	Omnibus Motion to Amend to Add Albertsons	5898 Albertsons Response		
Costco	5568	Omnibus Motion to Amend to Add Costco	5883 Costco Response	6214 Plaintiffs' Reply re Costco	
Discount Drug Mart	5569	Omnibus Motion to Amend to Add Discount Drug Mart	5875 Discount Drug Mart Response ³	6212 Plaintiffs' Reply re Discount Drug Mart	
Publix	5570	Omnibus Motion to Amend to Add Publix	5881 Publix Response	6213 Plaintiffs' Reply re Publix	
Target	5571	Omnibus Motion to Amend to Add Target	5886 Target Response		
Winn-Dixie	5572	Omnibus Motion to Amend to Add Winn-Dixie	5880 Winn-Dixie Response		
			5888 Certain Pharmacies Joint Response ⁴	6211 Plaintiffs' Reply re Certain Pharmacies ⁵	

¹ In this chart, the Court lists the principal substantive briefs on Plaintiffs' fourteen Motions to Amend. The parties submitted, and the Court reviewed, many additional documents pertaining to these Motions—for example, motions to strike, motions for extension of time, affidavits in support, and so on. The Court does not list those additional documents here, but may refer to them in its Issue Rulings if relevant.

² Individual Plaintiff Masiowski also filed a separate Motion to Amend his complaint. *See* docket no. 5582. Masiowski's motion is differently situated than the plaintiffs' motions identified in this chart. To the extent the Court's Issue Rulings are applicable to Masiowski's Motion, he and the defendants should attempt to implement them. However, the Court intends to rule on Masiowski's Motion separately.

³ Discount Drug Mart filed a separate Response to plaintiffs seeking leave to amend that are located outside the State of Ohio. *See* docket no. 5874. Those Plaintiffs have since withdrawn from Plaintiffs Motion for Leave to Add Discount Drug Mart. *See* docket no. 6212 at 1, n.2. Discount Drug Mart's separate Response is thus moot and not listed in the chart.

⁴ Pharmacy Defendants Ahold Delhaize, Albertsons, Target, and Winn-Dixie filed a joint opposition in addition to their individual opposition briefs.

⁵ Plaintiffs' Reply addresses the joint and individual oppositions of Ahold Delhaize, Albertsons, Target, and Winn-Dixie.

Defendant	Motion		Response		Reply		Sur-Reply	
Generic Manufacturer Defendants								
Alvogen	5550	Omnibus Motion to Amend to Add Alvogen ⁶	5891	Alvogen Response				
Aurolife	5551	Omnibus Motion to Amend to Add Aurolife	5889	Aurolife Response				
KVK-Tech	5552	Omnibus Motion to Amend to Add KVK-Tech	5900	KVK-Tech Response				
Lupin	5553	Omnibus Motion to Amend to Add Lupin	5884	Lupin Response				
Tris Pharma	5554	Omnibus Motion to Amend to Add Tris Pharma	5887	Tris Pharma Response				
			5899	Generic Manufacturers Joint Response ⁷	6171	Plaintiffs’ Reply re Generic Manufacturers ⁸	6225	Generic Manufacturers’ Sur-Reply
Pharmacy Benefits Manager Defendants								
Express Scripts	5548	Omnibus Motion to Amend to Add Express Scripts	6163	PBM Joint Response (Part I) ⁹	6257 Plaintiffs Reply re PBMs		6265 PBMs’ Sur-Reply	
OptumRx	5547	Omnibus Motion to Amend to Add OptumRx	6172	PBM Joint Response (Part II)				

⁶ Presently, Plaintiffs' Motion to Amend to Add Alvogen remains a live motion. Although Plaintiffs indicated they intend to withdraw this motion, *see* footnote 8 below, the Court has not received notice of such withdrawal.

⁷ Generic Manufacturer Defendants Alvogen, Aurolife, KVK-Tech, Lupin, and Tris Pharma filed a joint opposition in addition to their individual opposition briefs.

⁸ Plaintiffs' Reply addresses the joint and individual oppositions of Aurolife, KVK-Tech, Lupin, and Tris Pharma. Plaintiffs' Reply states that Alvogen reached an agreement to settle Plaintiffs' claims and that Plaintiffs' Motion for Leave to Add Alvogen will be withdrawn. *See* docket no. 6171 at 1, n.1.

⁹ PBM Defendants OptumRx and Express Scripts jointly filed a Response to Plaintiffs' two Motions. *See* docket no. 5885. The PBMs then began filing separate motions to strike various plaintiffs from joining the motions. *See* docket nos. 5941, 5952. To prevent piecemeal briefing of the Motions to add the PBMs, the Court permitted the PBMs to incorporate those motions into a second supplemental opposition brief to Plaintiffs' Motions. *See* Order, docket no. 6022. The PBMs' second Response was submitted in two Parts, docket nos. 6163 and 6172, and these supersede and replace docket no. 5885.

ATTACHMENT B

(R. 6379, Issue Ruling Order No. 2)

**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
<i>All Cases</i>	)	
	)	<u>ISSUE RULING TWO REGARDING</u>
	)	<u>PROCEDURAL DEFICIENCIES</u>
	)	

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 the numerous pending motions for leave to amend complaints. This *Issue Ruling Two* addresses arguments concerning several procedural issues identified primarily by the Pharmacy Benefit Manager defendants (“PBMs”).

At the outset, the Court is mindful that many counsel—particularly those on the Plaintiffs’ Executive Committee—manage large inventories of plaintiffs and cases. The administrative burden associated with those inventories is significant, and the Court recognizes that, on occasion, inadvertent clerical errors or other oversights may occur. The Court has generally been understanding of these realities and has permitted parties to cure administrative defects promptly once identified. *See, e.g., Order Granting Motions to Correct Inadvertent Omissions* (docket no. 5682); *Order Regarding Service Failures* (docket no. 4986); *but see* docket no. 5749 (denying motion to correct additional inadvertent omissions). The Court expects the parties will continue to work together in good faith to correct scrivener’s errors, inadvertent mistakes, and the like. The rulings in this Order are not meant to prohibit or vitiate such corrections.

Nevertheless, certain procedural deficiencies cannot be overlooked. And, as the Court explains further below, where these deficiencies exist and cannot be readily corrected, the Court will not allow amendment of complaints.

PBMs' Asserted Procedural Deficiencies

The PBMs contend that many of the moving plaintiffs' motions to amend are procedurally improper. PBMs identify four categories of alleged defects and argue these defects preclude certain plaintiffs from amending their complaints:

1. **Duplicate Plaintiffs:** PBMs assert "[a] significant number of the Moving Plaintiffs appear as plaintiffs in two or more cases." PBM Part I Response at 73 (docket no. 6163). PBMs argue that "[t]he same plaintiff cannot bring duplicate claims in multiple cases against the same defendant," so those plaintiffs' motions to amend must be denied. *Id.*
2. **Unnamed Plaintiffs:** PBMs assert the motions to amend "sweep in numerous plaintiffs *that are not even named* in the cases for which they purportedly seek leave to amend." *Id.* at 74 (emphasis in original). PBMs argue these plaintiffs' motions to amend must be denied because their motions "violat[e] Rule 15's requirement that the movant be a party to the case in which it seeks leave to amend." *Id.*
3. **Lack of Jurisdiction:** PBMs assert "several Moving Plaintiffs improperly seek leave to amend in cases that have been closed, dismissed, or remanded." *Id.* PBMs argue this Court no longer has jurisdiction over these cases, so those plaintiffs' motions to amend must be denied. *Id.*
4. **Other Lawsuit:** PBMs assert some "Moving Plaintiffs already filed and dismissed claims against the PBMs outside the MDL." *Id.* at 75. PBMs argue that, "[b]y suing the PBMs outside the MDL, those Moving Plaintiffs unequivocally admit that they possessed facts

sufficient to assert claims against the PBMs before moving to amend in the MDL, which precludes a showing of good cause.” *Id.*

The Court’s review of Part II of the PBM’s Response (docket no. 6172) shows the PBMs identified approximately 91 duplicate plaintiffs, 37 unnamed plaintiffs, 8 plaintiffs in cases where this Court allegedly lacks jurisdiction, and 12 plaintiffs who previously filed and dismissed actions outside the MDL.¹

Many of the alleged procedural defects appear to be simply administrative mistakes, such as scrivener’s errors or inadvertent mis-listings, that can be easily corrected. Indeed, plaintiffs’ Reply indicates that in a great many of the identified instances, corrections have already been made. *See* Plaintiffs’ PBM Reply at 97–104 (docket no. 6257). Where this has occurred, the PBMs’ objections to amendment of the complaints are now moot.

To the extent the PBMs’ objections are not moot, the Court rules on the four alleged procedural defects below.

¹ In Part I of their Response, the PBMs allege there are “85 instances of duplicate plaintiffs spread across 13 cases.” PBM Part I Response at 73–74. In its own independent review of Part II of the PBMs’ Response, the Court counted 91 such instances. Similarly, PBMs allege there are 16 plaintiffs who previously filed and dismissed actions outside the MDL, but the Court counts only 12. It appears the plaintiffs’ counts may be different still. These discrepancies provide further support for the conclusion that the parties should continue to meet and confer and come to as much agreement as possible on the status of each case, including through agreed correction of inadvertent or mistaken listings by plaintiffs.

Duplicate Plaintiffs²

PBMs point out that several entities appear as plaintiffs in more than one case seeking to add the PBMs. PBMs argue this is impermissible claim splitting.³ The Court agrees that no plaintiff can be allowed to maintain two separate cases asserting the same claims against the PBMs. The complaints in the cases against the PBMs in this MDL—and the amended complaints, if ultimately allowed—are all virtually identical. Any plaintiff who appears in more than one such case is **ordered** to withdraw at least one of them from the applicable omnibus motions to amend. If a plaintiff fails to do so, the Court will deny leave to amend both cases.

Unnamed Plaintiffs

PBMs point out correctly that Federal Rule of Civil Procedure 15 requires a movant seeking leave to amend to be a party to the case in which amendment is sought. Fed. R. Civ. P. 15(a)(2) (“a *party* may amend its pleading only with . . . the court’s leave.”) (emphasis added). The Court is doubtful—based on the structure of plaintiffs’ motions—that any movant intentionally seeks to amend in a case where it is not a party. But, whatever the cause of misalignment in the motions for leave between the listed movants and the listed cases, the thrust

² Plaintiffs state the duplicate or incorrect cases listed in the motion for leave to amend were due mostly to a scrivener’s error, and “[e]ach of these errors has been corrected in [attached exhibits].” Plaintiffs’ PBM Reply at 100. Plaintiffs also state some of the cases identified by PBMs as duplicates are in fact independent actions; for example, in Louisiana, “sheriffs and parishes can [] sue[] separately.” *Id.* at 102. The Court’s ruling here regarding duplicate plaintiffs applies only to entities that are completely identical.

³ “[C]laim splitting is the same as res judicata, but with a presumption of a final judgment instead of an actual final judgment.” *Waad v. Farmers Ins. Exch.*, 762 F. App’x 256, 260 (6th Cir. 2019). *See also Katz v. Gerardi*, 655 F.3d 1218 (10th Cir. 2011) (“The proper question is whether, assuming the first suit was already final, the second suit would be precluded under res judicata analysis.”).

of PBMs' argument is correct. The Court hereby **denies** a motion to amend a complaint in any case where the moving entity is not an existing plaintiff in that case.⁴

Lack of Jurisdiction

PBMs are certainly correct that the Court cannot grant a plaintiff's motion to amend its complaint if the Court lacks jurisdiction over the case. This circumstance may exist, for example, if the plaintiff's case was earlier remanded in its entirety to state court or to the transferor court. *See, e.g., Cook v. Lankford*, 17 F. App'x 351, 352 (6th Cir. 2001) ("A remand to state court pursuant to § 1447(c) divests the federal district court of jurisdiction."); *In re Welding Fume Prods. Liab. Litig.*, 2010 WL 7699456, at *18 (N.D. Ohio June 4, 2010) ("once the order of remand [to a transferor court] is entered, this MDL Court loses jurisdiction over the remanded case").⁵

Furthermore, this Court normally does not have jurisdiction to decide a motion for leave to amend filed in a case that the Court earlier dismissed, or otherwise closed, in its entirety.⁶

The PBMs do not make entirely clear which cases: (1) have a still-pending motion for leave to amend (e.g., the motion was not withdrawn); and (2) were remanded, dismissed, or otherwise closed, such that the Court no longer has jurisdiction to decide that still-pending motion. The

⁴ As stated at the outset of this *Issue Ruling*, the Court still expects the parties will continue to meet and confer and agree to correct scrivener's errors or other inadvertent mis-listings. Plaintiffs who already joined the motions to amend are permitted to correct their case name or number where those items were recorded incorrectly due to an administrative mistake.

⁵ Of course, this MDL Court may retain jurisdiction over a case if the Judicial Panel on Multidistrict Litigation remands to the transferor court only certain, severed claims, as has occurred several times. *See, e.g.*, docket nos. 2990 & 3059 (in Track Two, severing and remanding only claims against distributor defendants to the transferor court, while retaining jurisdiction over claims against other defendants).

⁶ Even after a case is dismissed, however, a federal court may retain ancillary jurisdiction over certain matters, such as a motion for sanctions or a motion to enforce a settlement agreement. *See Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 396 (1990) (a trial court may still decide a motion for sanctions "after the principal suit has been terminated"); *Moore v. U.S. Postal Serv.*, 369 F. App'x 712, 716-17 (6th Cir. 2010) (a district court "retains jurisdiction over the settlement contract for the purpose of its enforcement" if there is "inclu[ded] in the order of dismissal . . . a separate provision retaining jurisdiction over the settlement agreement").

Court cannot state broadly (as PBMs seem to request) that it denies *every* motion for leave to amend brought by a plaintiff in a case that was previously remanded, closed, or dismissed. The Court can enter only this more tailored order: the Court hereby **denies** any motion for leave to amend brought by a plaintiff in a case that was earlier (a) remanded *in its entirety* to state court or to a transferor court, or (b) dismissed with prejudice *in its entirety*.

Other Lawsuit⁷

PBMs argue a motion to amend is procedurally improper if the plaintiff previously filed and dismissed a similar case against the PBMs outside the MDL. Specifically: “By suing the PBMs outside the MDL, those Moving Plaintiffs unequivocally admit that they possessed facts sufficient to assert claims against the PBMs before moving to amend in the MDL, which precludes a showing of good cause.” PBM Part I Response at 75.

The Court does not address this argument in this *Issue Ruling*. The argument raises the substantive question of whether plaintiffs can show due diligence or good cause in pursuing amendment. The instant *Issue Ruling* addresses only alleged procedural defects. The Court will address the PBMs’ arguments regarding good cause in a subsequent *Issue Ruling*.

The Court further notes that the PBMs’ “other lawsuit” argument tangentially touches upon a second question: whether there is any preclusive effect of a prior dismissal. For example, it is possible a plaintiff sued the PBMs in another case outside the MDL and the case was dismissed with prejudice. In such circumstances, it *could* be appropriate for this Court to deny that plaintiff’s motion to amend. But that would depend upon, among other things, exactly which claims and

⁷ Plaintiffs state that, of 16 plaintiffs identified by PBMs that previously filed cases outside the MDL, ten were dismissed without prejudice and six have withdrawn. Plaintiffs’ PBM Reply at 97–99. Plaintiffs further state that some of the other identified plaintiffs with previously dismissed claims are “entities that have been assigned the rights to assert the claims of a collection of third-party payers” and the assignees dismissed some, but not all, of the claims of their assignors. *Id.* at 103.

allegations were advanced in the other case, and which parties appeared, and whether the judgment was on the merits. The PBMs do not address these details for any given plaintiff. Accordingly, the Court does not reach that issue.

Conclusion

The Court appreciates the PBMs' detailed effort in identifying various procedural issues that need to be cleaned up or otherwise resolved. Although other defendants did not also raise the specific arguments made by the PBMs, the same alleged procedural deficiencies may exist in other omnibus motions to amend—and the plaintiffs may have already corrected some of those deficiencies. The rulings issued above apply equally to motions to amend seeking to add other defendants.

As stated in *Issue Ruling One*, it now falls to the parties to meet and confer and apply these rulings to each individual case and report back to the Court with their results. *See* docket no. 6306 at 11–12. The Court will decide individually any cases where the parties cannot agree on the application of this *Issue Ruling*. *Id.* The Court notes its rulings above agreeing with plaintiffs' positions do not mean the motions to amend filed by the relevant plaintiffs are granted, because defendants have raised other arguments upon which the Court has not yet ruled.⁸

IT IS SO ORDERED.

/s/ Dan Aaron Polster November 17, 2025
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

⁸ For example, the Court has not yet addressed whether amending plaintiffs have met Rule 16's good cause standard; this will be the subject of a future *Issue Ruling*. In contrast, the ruling above denying a motion to amend in any case that was previously remanded in its entirety to state court applies forthwith, regardless of the merits of the parties' other arguments.

ATTACHMENT C

(R. 6418, Issue Ruling Order No. 3)

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

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL 2804
	)	
THIS DOCUMENT RELATES TO:	)	Case No. 1:17-md-2804
	)	
<i>All Cases</i>	)	Judge Dan Aaron Polster
	)	
	)	<u>ISSUE RULING THREE</u>
	)	<u>REGARDING FUTILITY OF CLAIMS</u>
	)	

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 the numerous pending motions for leave to amend complaints. In this *Issue Ruling Three*, the Court addresses several arguments raised by defendants sharing the common theme that plaintiffs’ motions to amend are futile and should therefore be denied.

The defendants’ futility arguments are somewhat tangled, not only because defendants assert numerous reasons why plaintiffs’ proposed amendments are futile, but also because different sets of defendants assert arguments against different sets of plaintiffs. The complexity arises because there are so many motions to amend and so many proposed new defendants. For example, some of defendants’ futility arguments apply broadly to *all plaintiffs in certain jurisdictions*. See, e.g., PBM Part I Response at 75–79 (docket no. 6163) (asserting that public nuisance claims are futile in some States because that legal theory has been disallowed as a means to address the opioid crisis); see also Generic Man. Joint Response at 28–29 (docket no. 5899) (same). Other futility arguments apply broadly to *every plaintiff asserting a specific claim*. See, e.g., PBM Part I Response at 83 (docket no. 6163) (arguing that all RICO claims are time-barred and therefore

futile). And some arguments apply *only to one specific plaintiff (or a small set of plaintiffs)*. See, e.g., PBM Part I Response at 63–64 (docket no. 6163) (arguing that certain plaintiffs have entered into contracts with a certain defendant, and those contracts preclude those plaintiffs from litigating any claims against that defendant, thus rendering all of those plaintiffs’ claims futile).

Given the breadth and complexity of the many futility arguments, and for the reasons set forth below, the Court concludes defendants’ futility arguments do not support denial of the motion for leave to amend filed by any plaintiff. But the Court enters this ruling without prejudice; specifically, the Court further concludes that, “[u]nder these circumstances, whether the proposed amendments are futile and whether Plaintiff’s claims are subject to dismissal under Rule 12(b)(6) would be best handled in a single motion to dismiss [filed in the individual case], where the arguments are cleanly and plainly presented before the Court.” *Cleveland Commc’ns, Inc. v. Lorain Cnty. Bd. of Commissioners*, 2024 WL 3878308, at *3 (N.D. Ohio Aug. 20, 2024).

Legal Standard

In *Issue Ruling One*, the Court set forth the general legal standards applicable to this and other subsequent Issue Rulings. See *Issue Ruling One* at 2–8 (docket no. 6306) (“The Court sets out here the general legal standards it will apply to the motions to amend.”). There, the Court wrote:

[A] Court will disallow proposed amendments under Rule 15 if they are “futile.” *Stanley v. W. Mich. Univ.*, 105 F.4th 856, 867 (6th Cir. 2024). A proposed amendment is futile if it fails to present any claim that could survive a Rule 12(b)(6) motion to dismiss. *Id.* To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Id. at 8.

Further, “[i]n considering Defendant’s futility argument, ‘[a]t this stage of the litigation [before the commencement of discovery], this Court is charged with determining whether the futility of an amendment is so obvious that it should be disallowed.’” *Zlozower v. Rock & Roll Hall of Fame & Museum, Inc.*, 2025 WL 1822570, at *3 (N.D. Ohio July 2, 2025) (quoting *Bear v. Delaware Cnty.*, Ohio, 2015 WL 1954451, at *3 (S.D. Ohio Apr. 28, 2015)). “A proposed amendment . . . must be frivolous or legally insufficient on its face to warrant denial of leave to amend on that ground.” *McNeill v. Bagley*, 2018 WL 3348876, at *8 (N.D. Ohio July 9, 2018) (Polster, J.).

Finally, “[t]hough futility is a permissible basis for denying a motion to amend a pleading, the Supreme Court in *Foman v. Davis*[,] 371 U.S. 178 (1962),] did not mandate that a court must deny a proposed amendment if it is futile. Rather, ‘even if a claim may be futile, the Court is not required to disallow the amendment.’” *All Pro Brace, LLC v. United States Dep’t of Health & Hum. Servs.*, 2022 WL 17067459, at *3 (N.D. Ohio Nov. 17, 2022) (quoting *Aladdin Temp-Rite, LLC v. Carlisle FoodService Prods. Inc.*, 2014 WL 12774872, at *2 (M.D. Tenn. June 16, 2014)). When a defendant argues an amended pleading should not be allowed because the new claim would be futile, “rather than determining the actual legal sufficiency of the claim, in many cases it would suffice to determine if there is a substantial argument to be made on that question and, if so, to allow the amended pleading to be filed with the understanding that a motion to dismiss for failure to state a claim may follow.” *Aladdin Temp-Rite*, 2014 WL 12774872, at *3.

Here, the Court concludes the better approach is not to disallow the proposed amended pleadings based on futility, with the understanding that defendants may later file motions to dismiss or even motions for summary judgment that raise anew their futility arguments.

Analysis

Upon careful review of the entire array of Defendants’ futility arguments, three major themes emerge. The allegedly futile claims fall into one of three categories: (1) claims whose legal sufficiency has already been tested and ruled on in a prior Court order; (2) claims based partly or predominantly on disputed facts; and (3) claims that are facially or obviously futile. The Court addresses each of these categories in turn.

A. Claims That Have Already Been Tested.

Early in this MDL, the Court recognized “it [would] be efficient and informative to proceed with briefing on threshold legal issues on common claims.” CMO-1 at 2 (docket no. 232). The Court chose nine cases where defendants were permitted to file bellwether motions to dismiss, to test plaintiffs’ legal theories. *Id.* at 2-4. The Court ruled on each of these early motions, and then later ruled on additional dismissal motions filed in more than a score of subsequent bellwether cases. Throughout this lengthy process, the Court remained consistent: “as it has repeatedly said it would, the Court has assiduously stood by those prior rulings.” *In re Nat’l Prescription Opiate Litig.*, 2024 WL 4912429, at *12 (N.D. Ohio Aug. 22, 2024) (docket no. 5598 at 22–23). *See also*, *In re Nat’l Prescription Opiate Litig.*, 452 F. Supp. 3d 745, 763 (N.D. Ohio 2020) (docket no. 3253 at 12) (“Nothing in the parties’ briefs convinces the Court to revisit any of its prior analysis of the applicable RICO standard.”); *Order Denying CT7 MTD* (docket no. 3767 at 2) (“the Court has already carefully reviewed, considered, and rejected all of the [] Defendants’ arguments listed above and hereby does so again by incorporation of its prior rulings on those arguments.”); *Order Resolving PBM CMO Disputes* (docket no. 5268 at 2) (“the Court intends to rely heavily on its prior rulings.”).

At least two of defendants’ present futility arguments have been addressed in the Court’s prior rulings. Those arguments include: (1) plaintiffs’ RICO claims are futile due to the four-year RICO statute of limitations, *see, e.g.*, PBM Part I Response at 79–83 (docket no. 6163) (issue resolved to the contrary in *In re Opiate Litig.*, 2024 WL 4912429, at *4–*15 (docket no. 5598 at 6–28)); and (2) plaintiffs’ claims against certain “related defendants” must fail because their motions refer to “all of these separate companies collectively as [a single corporate family entity],” Ahold Response at 8 (docket no. 5879) (issue resolved to the contrary in *Order Denying PBM MTD for PJ* at 7–9 (docket no. 6235)).

Defendants’ latest arguments do not convince the Court it should reach different conclusions than it has in the past. The Court continues to hold with its prior rulings and therefore finds the claims associated with these arguments neither facially nor obviously futile.

The better approach in this instance is to adhere to the Sixth Circuit’s liberal amendment policy and permit plaintiffs to amend their complaints. At the appropriate time, defendants may seek dismissal of those claims by filing a motion dedicated to fully briefing those issues. Other courts in this district have taken a similar approach. *See Donahue v. Travelers Companies, Inc.*, 2024 WL 4534250, at *3 (N.D. Ohio Oct. 21, 2024) (“Any challenges to the claims presented in Plaintiffs’ amended complaint are better presented in a later filed Rule 12 motion to dismiss that fully addresses all of the allegations and applicable legal standards.”); *Cleveland Commc’ns*, 2024 WL 3878308, at *3 (permitting amendment and observing that, “[e]ven if Plaintiff’s claims are ultimately dismissed on the merits for failure to state a claim, that does not necessarily mean that the claims were frivolous or entirely baseless.”). Further, “the Sixth Circuit noted that ‘another round of motion practice . . . does not rise to the level of prejudice that would warrant denial of

leave to amend.” *Zlozower*, 2025 WL 1822570, at *2 (quoting *Morse v. McWhorter*, 290 F.3d 795, 801 (6th Cir. 2002)).

The Court will not deny any motion to amend based on an argument the Court has previously found not well-taken.¹ Similarly, the Court is very unlikely in the future to grant a motion to dismiss based on an argument the Court has previously rejected. Accordingly, the better course of action is as follows: if a defendant believes it is so differently situated from prior MDL defendants that a prior ruling allowing a claim to proceed does not apply, or if there has been an intervening change in the law, then that defendant should, at the appropriate time, file a Rule 12 motion fully addressing the legal issues and applicable legal standards. *See Donahue*, 2024 WL 4534250, at *3.

B. Claims Involving Disputed Facts.

Some of defendants’ futility arguments rely on statements of fact, which allegedly show a plaintiff’s claim would only be made in vain. But the appropriate vehicle to resolve these disputes is a motion for summary judgment, after the factual record has been fully developed. *See Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 421 (6th Cir. 2000) (“The test for futility . . . does not depend on whether the proposed amendment could potentially be dismissed on a motion for summary judgment; instead, a proposed amendment is futile only if it could not withstand a Rule 12(b)(6) motion to dismiss.”). The Court cannot evaluate at this juncture a factual dispute that underpins a futility argument.

The following are examples of futility arguments made by defendants that depend upon disputed facts:

¹ There is an exception to this ruling, discussed in Section C below, where an intervening development in the law necessarily renders a claim that was previously found sufficient now to be facially and obviously futile.

- Many defendants disagree with plaintiffs' market share data or calculations and assert their market share was so small they cannot possibly be held liable. These data and calculations will be fully fleshed out in discovery, and plaintiffs' market share calculations will be tested by experts. The Court will not attempt to analyze market share on less than a full factual record and cannot reach futility in the context of a motion to amend when the facts are disputed.
- The plaintiffs and the generic manufacturers disagree whether, and the extent to which, the generic manufacturers engaged in any form of opioid marketing. *See* Generics Response at 27 (docket no. 5899). This is also a factual dispute best resolved on a motion for summary judgment.²
- The PBMs assert some of the plaintiffs seeking leave to amend had contracts requiring arbitration. *See* PBM Part I Response at 64 (docket no. 6163). Without seeing the specific contracts, the Court cannot evaluate the PBMs' assertions; and in any event, plaintiffs' motions to amend are not the appropriate vehicle for resolution of this argument. The PBMs can and should raise these arguments again in a motion to dismiss or for summary judgment.
- Some defendants assert that certain plaintiffs failed to properly authorize their joinder with the motions to amend. *See* Publix Response at 8 (docket no 5881); PBM Part I Response at 92 (docket no. 6163). Whether authorization was proper (or an alleged failure is curable and was cured) is best left for a more fully developed factual record.

In sum, the Court will not deny any motion to amend based on a defendant's recitation of facts, especially if only cursorily addressed in opposition to motions to amend. The Court

² This argument also may fall under the analysis in Section A above, as it has been previously tested and resolved at least in part. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 4895856, at *22-*25 (N.D. Ohio Oct. 5, 2018) (docket no. 1025 at 48-54) (discussing claims involving marketing of opioids and off-label uses).

concludes the better course is to address defendants’ factual assertions: (1) with a complete factual record, (2) within the context of a single case, and (3) through a motion dedicated to those issues.

C. Claims That Are Obviously Futile.

The last category of defendants’ futility arguments has some merit. The most obvious argument in this category pertains to the public nuisance claims alleged by plaintiffs in jurisdictions where the State supreme court (most notably in Oklahoma and Ohio) ruled that public nuisance is not a viable theory for addressing the opioid crisis. Public nuisance claims in these jurisdictions are now certainly futile, and an amended complaint should not contain such a claim.

However, even if the Court were to carefully strike from each complaint or otherwise prohibit these obviously futile claims in the relevant jurisdictions, that would not support wholesale denial of those plaintiffs’ motions to amend given the presence of plaintiffs’ *other* potentially viable claims. So, while it is true that at least one of the claims (*i.e.*, nuisance) in at least two jurisdictions (*i.e.*, Oklahoma and Ohio) is no longer legally viable, defendants’ futility arguments—when considered in total—fail to convince this Court that Oklahoma and Ohio plaintiffs have *no* viable claims. *See Issue Ruling One* at 8 (quoting *Stanley*, 105 F.4th at 867) (“A proposed amendment is futile if it fails to present *any* claim that could survive a Rule 12(b)(6) motion to dismiss.”) (emphasis added). And in any event, “even if the Court were to find that all the proposed amendments were futile, the Court is not required to deny leave to amend.” *Cleveland Commc’ns*, 2024 WL 3878308, at *2.

Moreover, the moving plaintiffs have represented that, if the Court ultimately does give them leave to amend, they will not advance any plainly futile claims when filing their amended complaints. *See Plaintiffs’ Generics Response* at 31 (docket no. 6171) (“Plaintiffs do not intend to assert claims that are expressly precluded by statute or controlling state supreme court

precedent.”). Assuming the Court does allow a plaintiff to file an amended complaint, if that plaintiff persists in stating a plainly futile claim, defendants can file a motion to dismiss it (and refer the Court to plaintiff’s representation that the futile claim would not be brought).

Ultimately, although defendants have identified some claims asserted by some plaintiffs that would not survive a motion to dismiss, there appear to be other claims stated by each such plaintiff that could. The defendants have not identified—or otherwise convinced the Court that there exists—any specific case that will not contain a single viable claim against a proposed new defendant.

Although the Court could conceivably identify each of the cases that would contain a futile claim and prohibit now any amendment to state those claims, the result would not yield denial of any plaintiff’s motion to amend in its entirety. The Court’s effort would largely be a waste of judicial resources. Instead, the Court trusts that plaintiffs will, if granted leave to amend, not state any plainly futile claim in their amended complaints. Any such claim that does appear can be addressed through a later-filed motion to dismiss.

Conclusion

If the Court ultimately grants a motion to amend in a given case, the plaintiff will be required to file an amended complaint. Defendants (both existing and new) will have the right to move to dismiss the claims in that case.³ The Court concludes that a proper, thorough analysis of any claim the defendants believe is futile “would be best handled in a single motion to dismiss, where the arguments are cleanly and plainly presented before the Court.” *Cleveland Commc’ns*,

³ In light of the Court’s moratorium, any such motion to dismiss will only be allowed if the defendant obtains leave, which is likely only if the case is selected as an MDL bellwether or is remanded. *See* docket no. 5319 at 2 (discussing orders related to the moratorium).

2024 WL 3878308, at *3. The Court “finds that Defendants have not met their burden of establishing that the proposed amendments would be futile *in their entirety*,” so the Court will not deny any motion to amend on futility grounds. *Donahue*, 2024 WL 4534250, at *3 (emphasis added).

IT IS SO ORDERED.

/s/ Dan Aaron Polster February 2, 2026
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

ATTACHMENT D

(R. 6428, Issue Ruling Order No. 4)

**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 FOUR**
) **REGARDING THE SUFFICIENCY OF**
) **CLAIMS AND ALLEGATIONS**

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 to amend complaints.¹ This *Issue Ruling Four* addresses defendants’ arguments concerning the sufficiency of plaintiffs’ claims and allegations against them. Specifically, the Court considers below:

(1) whether plaintiffs were required to append proposed amended complaints to their motions to amend;

(2) whether a proposed defendant is sufficiently put on notice of the claims and allegations against it if the plaintiff incorporates by reference an Exemplar Complaint² in which the proposed defendant is not named; and

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

² Moving plaintiffs identified “a bellwether pleading for [each] defendant or a similarly situated defendant . . . that the Amending Plaintiffs plan to base their supplemental and amended allegations and claims for relief upon.” Plaintiffs’ Roadmap at 2–4 (docket no. 5565). The Court refers to these bellwether pleadings, on which plaintiffs purport to base their supplemental and amended allegations, as “Exemplar Complaints.”

(3) whether a proposed defendant is sufficiently put on notice of the claims and allegations against it if the plaintiff is of one category (*e.g.*, a third-party payor) and incorporates by reference an Exemplar Complaint filed by a plaintiff of another category (*e.g.*, a municipality).

Background

On May 23, 2025, the Court conditionally lifted its moratorium on substantive filings and permitted plaintiffs to file motions for leave to amend their complaints. *See Amendment Order* (docket no. 5455). Pursuant to the *Amendment Order*, thousands of plaintiffs joined one or more of fourteen separate omnibus motions for leave to add fourteen different defendants to their complaints.³ Those fourteen defendants fall, generally, into three categories: (1) pharmacy benefit managers (“PBMs”); (2) manufacturers of generic opioids (“Generic Manufacturers”); and (3) Pharmacies. *See Issue Ruling One* at 13–14 (briefing chart) (docket no. 6306).

The Court set certain conditions on plaintiffs’ filing of motions for leave to amend. *See Amendment Order* at 1 (“the Court will lift the moratorium to permit plaintiffs to move to amend their complaints; however, the PEC and plaintiffs must adhere to the following directives.”). The Court required each defendant-specific motion to “address[] plaintiff-specific facts and law against that defendant.” *Id.* at 2. Specifically, the plaintiff-specific portion of each motion was required to contain:

(1) a list of ***all*** cases seeking to add that defendant; (2) any plaintiff-specific factual allegations pertinent to ***each individual*** case; (3) any jurisdiction-specific claims the plaintiff seeks to add to (or dismiss from) ***each individual*** case; and (4) good cause for the proposed amendments, stating with particularity the reasons amendment should be permitted in ***each individual*** case.

Id. (emphasis in original).

³ Of course, not all—and in fact maybe none—of the moving plaintiffs joined ***all*** of the omnibus motions to amend.

In their effort to comply with these requirements, plaintiffs: (1) provided, with each motion, a chart listing every plaintiff and case that joined the motion; (2) set forth in those charts “relevant plaintiff-specific information,” such as (a) the State and County in which the plaintiff is located, and (b) where applicable, certain opioid-related, market-share information derived from “new” ARCOS data;⁴ (3) identified “a bellwether pleading [Exemplar Complaint] for that defendant or a similarly situated defendant . . . that the Amending Plaintiffs plan to base their supplemental and amended allegations and claims for relief upon”; and (4) provided collectively, in each motion, a discussion of “[the] circumstances that demonstrate good cause for all plaintiffs, or for all plaintiffs in a particular subset.” Plaintiffs’ Roadmap at 2–4 (docket no. 5565).

With respect to the Court’s requirement that plaintiffs must set forth in their omnibus motions to amend “any jurisdiction-specific claims the plaintiff seeks to add to (or dismiss from) *each individual* case,” *Amendment Order* at 2 (emphasis in original), Plaintiffs state that *if* the Court grants any individual plaintiff leave to amend its complaint, that plaintiff would then “file supplemental and amended allegations that will add to, but not supersede or replace, the plaintiff’s existing operative pleading.” Plaintiffs’ Roadmap at 3. Further, Plaintiffs explain that “[t]he jurisdiction-specific claims, and the basis for them, are in the underlying operative pleading originally filed by each plaintiff, which will remain operative even when supplemented by the additional allegations and claims.” *Id.*

⁴ ARCOS—which stands for Automation of Reports and Consolidated Orders System—“tracks every single opioid pill from its point of manufacture, through the distribution chain, to its destination at a doctor’s office, hospital or pharmacy.” Docket no. 5115 at 2. Before August 14, 2023, Plaintiffs only had access to ARCOS data from the years 2006–2014. On July 14, 2023, the Court granted a motion by the PEC “seeking to enforce a subpoena it served upon the United States Drug Enforcement Administration (“DEA”) for production of *updated* ARCOS data.” *See id.* at 1 (emphasis added). On August 14, 2023, the DEA produced to the PEC raw ARCOS data from 2015–2019, which until that time had not been available to plaintiffs. *See* decl. of P. Mougey at 2 (docket no. 5565-2). This updated ARCOS data allowed plaintiffs to identify “additional entities, beyond those they already named as defendants, [that plaintiffs assert were] among those responsible for the continuing opioid crisis in their jurisdictions.” Plaintiffs Roadmap at 15–16.

Analysis

Defendants argue plaintiffs' proposed application of the Court's procedures for amending their complaints is insufficient to put defendants on notice of the claims against them, and offer three primary bases for this assertion.

First, defendants insist that "the failure to supply a proposed amended complaint is, by itself, grounds to deny leave for [sic] amend." PBM Part I Response at 19 (docket no. 6163). The Court finds this position is not well-taken. Defendants are correct that submission by plaintiff of a proposed amended complaint is the normal procedure. *See Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 444 (6th Cir. 2014) ("Normally, a party seeking an amendment should attach a copy of the amended complaint."). Doing so does aid judicial review. Nonetheless, the Federal Rules of Civil Procedure do not explicitly require a plaintiff to submit with a motion to amend a proposed amended pleading. To the contrary, Rule 15, as interpreted by the Sixth Circuit, requires only that "the court must have before it ***the substance*** of the proposed amendment." *Beydoun v. Sessions*, 871 F.3d 459, 469 (6th Cir. 2017) (emphasis added); *see also Moore v. State of Ind.*, 999 F.2d 1125, 1131 (7th Cir. 1993) ("***the motion itself*** may be acceptable so long as it puts the opposing party on notice of the content of the amendment") (emphasis added) (citing Charles A Wright, *et al.*, 6 Fed. Prac. & Proc. Civ. § 1485 (2nd ed.)).

Here, the procedure proposed by plaintiffs is sufficient to provide defendants and the Court with the substance of the proposed amendments. This is especially true in the broad context of this MDL, where each existing complaint is hundreds of pages long and gives every defendant a substantial and particularized understanding of plaintiffs' claims and allegations. In view of the colossal resources that would be required for plaintiffs to create and attach thousands of proposed individual amended complaints, the Court finds the PEC's proposed procedure a reasonable

balance between the efficiency goals of an MDL and the required retention of each individual case's character.

Accordingly, plaintiffs' failures to attach thousands of proposed amended complaints—one by each plaintiff to its motion for leave to amend—is not, by itself, fatal to their motions for leave to amend.

Second, defendants argue a plaintiff's reference to and incorporation of an Exemplar Complaint in the plaintiff's motion to amend is, in some circumstances, still insufficient. Specifically, defendants assert a proposed defendant is not provided with adequate notice of the claims and allegations against it if the plaintiff incorporates by reference an Exemplar Complaint in which the proposed defendant is not even named and in which there are no defendant-specific factual allegations. *See, e.g.*, Generic Manufacturers' Joint Response (docket no. 5899) at 17, n.9 (noting that plaintiffs intend to supplement their claims through incorporation of the *City of San Francisco* Track 4 bellwether complaint, but "the *City of San Francisco* plaintiffs have not sued any of the Generic Manufacturers;" thus, the *City of San Francisco* Exemplar Complaint provides no defendant-specific allegations to any Generic Manufacturer). Here, the Court agrees.

Plaintiffs' approach to amendment in this instance tests the balance between the efficiency goals that justify multidistrict litigation and the fundamental fairness owed to each litigant. In effect, plaintiffs' plan is to stitch together: (1) jurisdiction-specific claims from the underlying operative complaint; (2) a few, insubstantial defendant-specific factual allegations from the motion for leave to amend; and (3) generalized, non-defendant-specific allegations of wrongful conduct from the incorporated Exemplar Complaints. This approach falls short: with regard to many of the proposed new defendants, the **totality** of these proposed claims and allegations simply do not identify or even suggest misconduct specific to that defendant.

The Court's *Amendment Order* cannot be read to permit plaintiffs to rely on Exemplar Complaints that contain **general** factual allegations of misconduct against certain named defendants broadly, but no **specific** factual allegations whatsoever that the proposed new defendant violated the CSA or engaged in other prohibited conduct. As the Sixth Circuit has made clear, efficiency must not become a substitute for the pleading discipline required by the Federal Rules or by this Court's directives. *See In re CVS*, 956 F.3d 838, 845 (6th Cir. 2020) ("a party's rights in one case [cannot] be impinged to create efficiencies in the MDL generally.").

As described in *Issue Ruling One*, Rule 15's liberal amendment standard incorporates principles of fairness and notice. Those principles are strained to excess when, as with several motions to amend here, a plaintiff merely incorporates by reference a complaint that neither names nor alleges any **specific** misconduct by a proposed defendant. The Court concludes plaintiffs' approach fails in some cases to satisfy the requirement imposed by Rule 15 that the Court and the proposed defendant "have before [them] the substance of the proposed amendment." *Beydown*, 871 F.3d at 469. Of no less importance, plaintiffs' approach also fails to meet the procedural requirements this Court imposed as a condition of lifting its moratorium (quoted at page 2 above).

The Court is mindful that MDL proceedings, by their nature, often rely upon representative pleadings and coordinated motion practice. *See In re CVS*, 956 F.3d at 845 (the Court retains "broad discretion to create efficiencies and to avoid unnecessary duplication in its management of pretrial proceedings in the MDL."); *see also Short Form Order* at 3 ("The goal of the Short-Form Complaint is to streamline the amendment process.") (docket no. 1282). But the MDL process cannot be used to excuse a complete absence of particularized allegations of wrongdoing. Plaintiffs

were required to provide something more.⁵ At this late stage of the MDL, simply stating a defendant has an opioid market share above 5% is not sufficient where there are no other specific factual allegations in the motion for leave to amend or the Exemplar Complaint indicating the defendant engaged in any prohibited conduct.⁶ By contrast, when the Exemplar Complaint includes specific allegations of wrongful conduct by the proposed new defendant, the incorporation by reference of those allegations, combined with the basic factual allegations in plaintiffs' motion, is sufficient to satisfy the requirements of Rule 15.

Thus, although the Court concludes each plaintiff is not required to attach an individualized proposed amended complaint, plaintiffs were obligated, at a minimum, to have made (or incorporated by reference via Exemplar Complaint) *some* defendant-specific factual allegations that could plausibly support a finding that the proposed new defendant, itself—and not a different

⁵ Plaintiffs seek to excuse the absence of defendant-specific allegations by referring to the Court's prior use of the short-form amendment process in 2019. *See, e.g.*, PEC Reply to Generic Manufacturers Joint Response at 23–24 (docket no. 6171). During the short-form amendment process, the Court stated that “purported deficiencies with the [short-form] complaints can be addressed [when the case is set for trial] by subsequent Court order.” *Short Form Order* at 3 (docket no. 1282). In contrast, as the MDL enters its ninth year, the Court ordered that “[t]his will be [non-bellwether] plaintiffs’ final opportunity to amend their complaints.” *Amendment Order* at 2. At this juncture, unless a specific case is later chosen as a bellwether, Plaintiffs may not rely on yet another, future amendment to clarify and fully state their allegations and claims. *See In re: Meijer*, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022) (ruling that plaintiffs can amend their complaints when selected as a bellwether).

⁶ Ultimately, each plaintiff proposes to combine: (1) the allegations and claims stated in its existing, operative complaint; (2) a few defendant-specific allegations set out in the motion for leave to amend; and (3) additional factual allegations and claims from the Exemplar Complaint. While the Court concludes plaintiffs’ “combination” approach *may* generally provide adequate notice to a defendant of the claims and allegations against it, plaintiffs are still obligated to provide *some* allegations that *each* individual proposed new defendant engaged in wrongful conduct. An Exemplar Complaint that does not even name the proposed new defendant obviously contains no defendant-specific factual allegations. If there are also no defendant-specific factual allegations of misconduct in the motion for leave to amend, the Court cannot grant the motion.

For many of the defendants, plaintiffs did not cite to an Exemplar Complaint that names the proposed new defendant and also did not include any defendant-specific factual allegations of misconduct in the motion for leave to amend. Instead, plaintiffs merely included a “factual background” section in the motion that contains little more than a statement that the defendant’s market share of opioid sales increased according to the updated ARCOS data. That is insufficient. One notable exception is in plaintiffs’ motion to add Generic Manufacturer Lupin: plaintiffs allege Novel, a wholly owned Lupin subsidiary, “committed violations of the CSA by failing to account for approximately 3.1 kg oxycodone, 7.7 kg hydrocodone, and 30 kg Temazepam.” Docket no. 5553 at 4. This is sufficient and the motions to amend to add Lupin will *not* be denied for failure to allege wrongful conduct.

defendant—engaged in some prohibited conduct.⁷ A plaintiff that did not do so fails to meet the legal standard set by Rule 15 and does not meet the balance the Court must strike between efficiency in the MDL and maintenance of an individual party’s rights in each case.

Third, defendants argue a plaintiff’s incorporation of an Exemplar Complaint is, in some circumstances, still insufficient for yet another reason: a proposed defendant is not given adequate notice of the claims and allegations against it if the plaintiff is of one category (*e.g.*, a third-party payor) and incorporates by reference an Exemplar Complaint filed by a plaintiff of another category (*e.g.*, a municipality). Unlike the focus of defendants’ second argument above, which was on the absence of *defendant*-specific allegations, the focus of defendants’ third argument is the nature of the moving *plaintiff*. The Court concludes this third argument is not well-taken.

Defendants contend that “[t]he absence of particularized facts is especially problematic for non-municipal Moving Plaintiffs because those plaintiffs provide *no indication whatsoever* of the kind of allegations that may appear in their future amended complaints against the [defendant].” PBM Part I Response at 72 (emphasis added). But this is not true. Plaintiffs explained in their Roadmap that “[t]he jurisdiction-specific claims, and the basis for them, are in the underlying operative pleading originally filed by each plaintiff, which will remain operative even when

⁷ For example, the *Cobb County* complaint includes a section for *every named defendant* that contains factual allegations specific to that named defendant. More concretely, Cobb County names CVS and alleges it “lacked a genuine suspicious order monitoring system for much of the relevant time”—conduct that, if proven, would violate the CSA. *See, e.g., Cobb County* Compl. at §I.C.5.a.i (docket no. 3787). However, there is no equivalent section in the *Cobb County* complaint making a similar specific allegation against, for example, Ahold Delhaize, even though the amending plaintiffs purport to rely on the *Cobb County* complaint to “supplement their existing pleadings with claims substantially similar to those asserted against chain pharmacies [such as CVS].” Docket no. 5566 at 1. As to Ahold Delhaize, supplementation via the *Cobb County* complaint is simply not enough, even when assessed in light of Rule 15’s “liberal amendment policy.” *Brown v. Chapman*, 814 F.3d 436, 442–43 (6th Cir. 2016).

supplemented by the additional allegations and claims.” Plaintiffs’ Roadmap at 2–4.⁸ Between the particularized, defendant-specific factual allegations in the Exemplar Complaint and the plaintiff- and jurisdiction-specific claims (and the bases for them) in the underlying operative complaint, the proposed new defendants and the Court are sufficiently informed of the substance of the operative claims and allegations; and the Court has more than enough information to evaluate the merits of the omnibus motions. Moreover, that the defendants and the Court are sufficiently informed remains true even regarding motions filed by non-municipal plaintiffs.⁹

Accordingly, the Court will not deny the motions for leave to amend solely on the basis that the moving plaintiff, though not itself a municipality, incorporates by reference into its motion to amend an Exemplar Complaint filed by a municipality. This ruling applies to plaintiffs that are third-party payors, hospitals, Tribes, and so on.

Summary

Having considered all of the parties’ arguments on the common issues discussed above, the Court: (1) **overrules** defendants’ argument that a motion for leave to amend must be denied if the plaintiff did not attach a proposed amended complaint; (2) **denies** plaintiffs’ motions for leave

⁸ The Court understands this assertion—that each plaintiff’s jurisdiction-specific claims are stated in the underlying operative pleadings—to limit and define the universe of claims that each plaintiff intends to pursue. Accordingly, if leave to amend is ultimately granted, the Court will not permit any plaintiff to add additional claims that do not already appear in its underlying operative complaint. For example, if a plaintiffs’ underlying complaint does not include state-specific unfair trade practices claims, that plaintiff will not be allowed to amend to add unfair trade practices claims, whether those claims exist in the Exemplar Complaint or not. The defendants are entitled to know what claims are being brought against them.

⁹ For example, in *Local 404 Teamsters Health Service and Insurance Plan v. Purdue Pharma*, case no. 1:18-OP-45001, the underlying operative complaint asserts claims for violations of RICO, 18 U.S.C. §1962 *et seq.* (among others). In the *Rochester* complaint—from which the TPP asserts it will supplement its underlying operative complaint with substantially identical allegations—there are ample factual allegations against the PBMs to plausibly support a RICO claim. *See* docket no. 5598 (denying PBMs’ motion to dismiss *Rochester* complaint). The Court can readily apply the factual allegations from the *Rochester* complaint to the *Local 404 Teamsters* operative complaint—and the jurisdiction-specific claims contained therein—and evaluate the merits of the Local 404 Teamsters motion for leave to amend.

to amend if the plaintiff presented no defendant-specific factual allegations, in either the Exemplar Complaint or the motion itself, that the defendant engaged in prohibited conduct; and (3) **overrules** defendants' argument that a motion for leave to amend must be denied if a non-municipality plaintiff incorporated an Exemplar Complaint filed by a municipality.

The Court notes that rulings one and three above do not mean the motions to amend filed by the relevant plaintiffs are granted, because defendants have raised other arguments upon which the Court has not yet ruled.¹⁰

As stated in *Issue Ruling One*, it now falls to the parties to meet and confer and apply these rulings to each individual case and report back to the Court by **noon on Thursday, March 5, 2026**, with their results. *See* docket no. 6306 at 11–12.

IT IS SO ORDERED.

/s/ Dan Aaron Polster February 12, 2026
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

¹⁰ For example, the Court has not yet addressed whether amending plaintiffs have met Rule 16's good cause standard; this will be the subject of a future Issue Ruling. In contrast, ruling two above applies to deny a plaintiff's motion for leave regardless of the merits of the parties' other arguments.

ATTACHMENT E

(R. 6553, Issue Ruling Order No. 5)

**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
<i>All Cases</i>	)	
	)	<u>ISSUE RULING FIVE REGARDING</u>
	)	<u>DILIGENCE</u>
	)	

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.

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.

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

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

ATTACHMENT F

(R. 6599, Issue Ruling Order No. 6)

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

IN RE: NATIONAL PRESCRIPTION	)	MDL 2804
OPIATE LITIGATION	)	
	)	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:	)	
	)	Judge Dan Aaron Polster
<i>All Cases</i>	)	
	)	<u>ISSUE RULING SIX</u>
	)	<u>REGARDING PREJUDICE</u>
	)	

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 their complaints.¹ This *Issue Ruling Six* addresses defendants’ arguments that permitting plaintiffs to amend their complaints now—nearly a decade into this MDL and approximately seven years after the first, original amendment deadline—would cause substantial and undue prejudice to the defendants. Specifically, the Court addresses potential prejudice from: (1) the passage of time, (2) alleged loss of evidence, and (3) the amendment process itself.

As explained below, the Court finds that defendants have not demonstrated the kind of concrete prejudice that warrants denial of leave to amend.

Background

The Court incorporates by reference the background sections of all its prior *Issue Rulings*. As explained in great detail in *Issue Ruling Five*, and as explained further below, the most

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

important factor in the Court’s prejudice analysis is that every case at issue has been continuously subject to the Court’s moratorium on substantive filings. *See Issue Ruling Five* at 2–3 (docket no. 6553). This means that no discovery has commenced in any of the cases at issue. The parties in each one of those cases stand in exactly the same procedural and evidentiary position they would have occupied had the defendants been added by the original amendment deadline.

Legal Standard

To briefly review, Federal Rule of Civil Procedure 16 requires a court to enter a scheduling order and permits modification of that order “only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(3) and (4). “Courts consider two principal factors in assessing good cause: the diligence of the party seeking leave to amend *and* undue prejudice to the opposing side.” *Issue Ruling One* at 5 (docket no. 6306) (quoting *Andretti v. Boria Performance Indus., Inc.*, 426 F.3d 824, 830 (6th Cir. 2006); *Leary v. Daeschner*, 349 F.3d 888, 906 (6th Cir. 2003)). “Both factors must be considered.” *Id.* (quoting *Korn v. Paul Revere Life Ins. Co.*, 382 F. App’x 443, 450 (6th Cir. 2010)). However, “[t]he 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.” *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002) (citing *Bradford v. DANA Corp.*, 249 F.3d 807, 809 (8th Cir. 2001)).

In *Issue Ruling Five*, this Court resolved the diligence inquiry predominantly, though not entirely, in plaintiffs’ favor.² Defendants correctly observe, however, that analysis of diligence

² *Issue Ruling Five* set forth a careful analysis of precisely when new information pertaining to discreet categories of defendants became available to plaintiffs (the “Information Date”). The Court then held that a plaintiff was sufficiently diligent if the Information Date fell after the plaintiff-specific amendment deadline. The Court directed the parties to apply its analysis to each plaintiff to determine which, if any, were diligent under the Court’s *Ruling*. It is the Court’s impression that most plaintiffs, but perhaps not all, were sufficiently diligent under the *Issue Ruling Five* analysis.

alone is insufficient: “If the PEC has been sufficiently diligent, then prejudice to the defendants may still weigh in favor of denying amendment.” Pharmacy Response at 7 (docket no. 5888).

The question of prejudice is also raised by Federal Rule of Civil Procedure 15. The rule instructs that leave to amend should be “freely give[n] when justice so requires,” but “this liberal amendment policy is not without limits.” *DeCrane v. Eckart*, 2018 WL 916520, at *1 (N.D. Ohio Feb. 16, 2018). “‘Notice and substantial prejudice to the opposing party are critical factors in determining whether an amendment should be granted’ under Rule 15(a).” *Issue Ruling One* at 8 (quoting *Head v. Jellico Hous. Auth.*, 870 F.2d 1117, 1123 (6th Cir. 1989)). This Court resolved the question of notice in *Issue Ruling Four* (docket no. 6428).³ This leaves the question of prejudice.

As described in *Issue Ruling One*, Rules 15 and 16 overlap, but are meaningfully different. To summarize, Rule 16 requires the Court to assess whether modifying its scheduling order will cause **undue** prejudice to the side opposing modification, while Rule 15 requires the Court to examine whether allowing a plaintiff to amend its complaint would cause **substantial** prejudice to the defendant. However, when the proposed modification of the scheduling order under Rule 16 is for the express purpose of allowing belated amendment of complaints, the Court’s assessment of prejudice to the opposing party focuses on the more restrictive standard required under Rule 16. *See Armatas v. Haws*, 2021 WL 5356028, at *3 (6th Cir. Nov. 17, 2021) (“the moving party must meet a ‘higher threshold’ in showing good cause under Rule 16 than it would under Rule 15”). In this *Ruling*, the Court’s examination of whether defendants make a showing of undue prejudice includes examination of whether defendants make a showing of substantial prejudice.

³ *Issue Ruling Four* worked to deny plaintiffs’ motions for leave to amend “if the plaintiff presented no defendant-specific factual allegations, in either the Exemplar Complaint or the motion itself, that the defendant engaged in prohibited conduct,” but otherwise rejected defendants’ arguments for denial of leave. *See Issue Ruling Four* at 9–10. *Issue Ruling Four* is the subject of a currently pending motion for reconsideration filed by plaintiffs. *See* docket no. 6477.

In sum, the Court must determine whether defendants have shown that permitting plaintiffs to amend their complaints would cause substantial or undue prejudice under the Federal Rules. The Court has broad discretion in making this determination. *See Issue Ruling One* at 5 (citing *Tesone v. Empire Mktg. Strategies*, 942 F.3d 979, 988 (10th Cir. 2019) (“trial courts have considerable discretion in determining what kind of showing satisfies this . . . good cause standard.”)). For the reasons explained below, the Court concludes defendants have not met their burden.

Discussion

Defendants raise two principal categories of prejudice arguments:⁴ (1) prejudice from the passage of time; and (2) prejudice from potential loss of evidence, including from litigation hold failures and alleged spoliation. The PBM Defendants also raise some procedural prejudice arguments. The Court addresses each of the three categories in turn.

A. Prejudice Due to the Passage of Time

Several defendants argue that permitting amendment now—years after the original deadline—would be unduly prejudicial simply by virtue of the time that has elapsed. This contention, standing alone, is insufficient.

Fundamentally, the Court must assess the degree, if any, to which being added as a party now places the defendants in a worse position than they would have occupied if they had been added before the original amendment deadline. The answer, on the record before the Court, is no.

⁴ Defendants raise several arguments regarding potential prejudice that the Court already addressed in its prior *Issue Rulings*, so these arguments will not be revisited in this *Ruling*. For example, some defendants contend: (1) plaintiffs could have sought amendment earlier (addressed in *Issue Ruling Five*); (2) defendants are prejudiced due to plaintiff’s alleged failure to submit a plaintiff fact sheet (addressed in *Issue Ruling One*); (3) defendants could be prejudiced every time new ARCOS data is released (addressed in *Issue Ruling Five*); and (4) defendants are prejudiced by a lack of notice of claims and allegations against them (addressed in *Issue Ruling Four*).

Typically, a belated amendment can prejudice a defendant by frustrating the efficient progression of discovery and motion practice leading to a trial. A continuance, therefore, is the usual mechanism by which a Court can cure potential prejudice caused by a late amendment. *See Issue Ruling One* at 5–6 (“a court may [] consider whether any prejudice can be cured by allowing a continuance”) (quoting 3 Moore’s Federal Practice, §16.14[1][c] at 16-72.1); *see also In re Nat’l Prescription Opiate Litig.*, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022) (“*Meijer*”) (“If [the defendant] suffered any specific prejudice, it could have asked the district court for a tailored remedy, like . . . a delay in the trial schedule.”). No trial schedule has been set and no discovery has occurred in any of the stayed cases, so a continuance is moot. In the unlikely event any of these cases are ultimately set for trial, only then will the parties commence discovery, and all parties will do so from the exact same starting point regardless of when a particular defendant was added to the case. In this light, the moratorium essentially prevented prejudice from materializing in the first place because, when the moratorium is lifted in any given case, all parties will begin litigating at the same starting line. There will be no prejudice stemming from discovery and motion practice having already occurred.

Defendants also argue that permitting them to be named in additional cases now will require them to expend significant additional resources. The Court is not persuaded this carries any prejudice. No defendant even attempts to show how being added to stayed cases in which no discovery has commenced will require any “additional” expense materially different from or greater than what they would have faced had they been added by the original amendment deadline. “[A]ny amendment, regardless of when it is filed, is likely to result in additional litigation cost and expenses.” *Deloitte Tax LLP v. Murray*, 2022 WL 44661, at *6 (N.D. Ohio Jan. 4, 2022). “Courts do not dismiss [or refuse to permit the filing of] valid legal claims simply because defending

against them would be costly and time consuming.” *Id.* (quoting *In re Varner*, 2014 WL 4988236, at *4 (Bankr. N.D. Ohio Oct. 7, 2014) (bracketed alteration in original)). The Sixth Circuit’s holding in *Meijer* is, therefore, not just instructive, but dispositive. See *In re Nat’l Prescription Opiate Litig.*, 2022 WL 20701236, at *1 (6th Cir. Nov. 10, 2022) (finding no prejudice from an amendment where a defendant “was added to th[e] case before discovery ever started”); compare *Leary v. Daeschner*, 349 F.3d 888, 907 (6th Cir. 2003) (defendant would suffer “significant prejudice” because “the time for discovery and dispositive motions had passed and a summary judgment motion had been filed”) (discussing *Duggins v. Steak ’N Shake, Inc.*, 195 F.3d 828, 834 (6th Cir. 1999)). Defendants have made no showing of undue prejudice due to the passage of time.

B. Prejudice Due to Alleged Loss of Evidence

Defendants also contend that evidence pertinent to the amended claims may have been lost or degraded over time. This argument does not demonstrate the kind of concrete prejudice a defendant must show to warrant denial of leave to amend.

Here, the passage of time poses the same risk of evidentiary loss as it would if the defendants had been added by the original amendment deadline. As described above, the parties in the stayed cases have not conducted any discovery. Evidence available today will be equally available—or unavailable—to a defendant named from the outset as to the same defendant added now.⁵ Defendants do not establish that they are unduly prejudiced by being added to cases now, as compared to being added via amendments they contend should have been filed earlier. The long

⁵ The same should be true for plaintiffs. The PBM defendants were named in some of the first MDL cases, and so presumably put into place litigation holds. The nucleus of discovery available to a plaintiff who adds PBMs as defendants now should be essentially the same as that available to a plaintiff who named the PBMs eight years ago.

pendency of these cases in this MDL is unfortunate, but it has been unavoidable, and amendment of these cases now does not work to change or increase any prejudice to defendants.

Defendants further argue that plaintiffs' failure to timely implement litigation holds prejudices them and constitutes an independent ground to deny leave to amend. The Court rejects this contention.

The Court has previously addressed litigation holds, stating that "implementation of a litigation hold is not a strict precondition for allowing amendment." *See* Docket no. 5517 at 2; *see also* docket no. 5766 at 1 (same). Although those Orders expressly contemplated defendants addressing the topic of litigation holds in their responses to motions for leave to amend, nothing in defendants' responses convinces this Court that plaintiffs' litigation hold failures were intentional or are incurable.

Federal Rule of Civil Procedure 37(e) specifically governs the failure to preserve electronically stored information (ESI). That rule provides a carefully calibrated framework: "**only** upon finding that the party acted **with the intent to deprive another party** of the information's use in the litigation" may a Court impose sanctions, such as adverse inferences or dismissal. Fed. R. Civ. P. 37(e)(2) (emphasis added). No defendant has even attempted to make a showing that any plaintiff acted with the requisite intent to warrant sanctions. Absent a finding of that intent—and only upon a finding of concrete prejudice⁶—may the Court impose "measures no greater than necessary to cure the prejudice." Fed. R. Civ. P. 37(e)(1).

Moreover, defendants' concerns about hypothetical evidentiary loss present, at best, factual disputes better resolved in individual cases on a more fully developed record, consistent with the

⁶ "The rule leaves judges with discretion to determine how best to assess prejudice in particular cases." Fed. R. Civ. P. 37, advisory committee's notes to 2015 amendment.

rubric the Court applied in *Issue Ruling Three* (docket no. 6418). Put differently, without a more fully developed factual record, the Court cannot make fact-intensive determinations regarding: (1) a plaintiff's intent in failing to implement a litigation hold, or (2) the measures necessary to cure yet unknown evidentiary deficiencies. *See Mann v. CSX Transp., Inc.*, 2009 WL 3766056, at *6 (N.D. Ohio Nov. 10, 2009) (Polster, J.) (to justify sanctions, "the destruction of evidence must have caused prejudice to the party alleging spoliation. Prejudice occurs where [one party's] actions impair the [other party's] ability to go to trial or threaten to interfere with the rightful decision of the case," and "the severity of the sanctions should correspond with the degree of fault.") (citations omitted). As the Court stated in *Issue Ruling Three*, "the better course is to [grant leave to amend, and then] address defendants' factual assertions: (1) with a complete factual record, (2) within the context of a single case, and (3) through a motion dedicated to those issues." *Issue Ruling Three* at 8.

In sum, the Court concludes defendants have not made a showing of undue prejudice caused by the alleged loss of evidence.

C. The Final Amendment Process and Expansion of the MDL

The PBMs also expressly object to the Court's Final Amendment Process.⁷ They contend the process itself is prejudicial. The Generic Manufacturers note the Court itself stated three years ago that, "if Plaintiffs seek to amend complaints years after their cases were filed and made part of this MDL, it will raise some real concern." Docket no. 5115 at 12.

The Court implemented this Final Amendment Process to thoroughly and systematically work through each concern raised by every defendant, and the Court has done so carefully and

⁷ The Court uses "Final Amendment Process" to refer to the present process of amending MDL complaints as described in *Issue Ruling Five* at 10 (citing docket no. 5455 at 2).

thoughtfully in its six *Issue Rulings*. As described in *Issue Ruling Four*, the Court's Final Amendment Process strikes the appropriate balance between the efficiency goals of an MDL and the required retention of each case's individual character. *See Issue Ruling Four* at 2–4. To the extent any party believes the Court's Final Amendment Process is legally defective, the appropriate remedy is to file an appeal in an individual case at the appropriate juncture. Having carefully considered the defendants' concerns, the Court remains convinced that the Final Amendment Process is fair, reasonable, appropriate, and begets no prejudice.

Finally, the PBMs assert that granting leave to add them to plaintiffs' cases would constitute a dramatic expansion of the MDL. This argument is without merit and has already been considered and rejected in the Court's Order Granting PBM Bellwether Plaintiffs Leave to Amend. Docket no. 5319 at 7. Fundamentally, all of these cases already exist in the MDL, so granting leave to amend will not alter the number of plaintiffs, the number of defendants, or the nature of the claims pending in this MDL. True, the PBMs will be named in more cases, but that is a consequence of the allegations against them, not of any structural change to the MDL itself.

Conclusion

Having considered the full record and the arguments of the parties, the Court concludes the defendants have not demonstrated the kind of concrete, undue or substantial prejudice that would warrant denial of plaintiffs' motions for leave to amend. In each case where a motion for leave to amend has been filed, the defendants are in the same position they would have occupied had they been added by the original amendment deadline. No discovery has occurred. No trial is imminent. The concerns defendants raise are either foreclosed by prior rulings of this Court, reserved for individual case proceedings on a fully developed factual record, or insufficient as a matter of law to constitute the type and amount of prejudice required to deny amendment. The Court recognizes

that significant time has elapsed since the original amendment deadline; however, the Sixth Circuit is clear that mere delay, unaccompanied by actual prejudice, does not justify denial of leave to amend. *See Moore v. City of Paducah*, 790 F.2d 557, 559-62 (6th Cir. 1986); *Leary*, 349 F.3d at 906-09.

Accordingly, the Court will not deny any plaintiff's motion for leave to amend based on defendants' assertions of prejudice.

The Court believes that, with this *Issue Ruling Six*, it has resolved *all* of the issues raised in defendants' oppositions to plaintiffs' motions for leave to amend. It is now incumbent upon the parties to apply all six *Issue Rulings* and report to the Court: (1) which of plaintiffs' motions the parties agree should be denied; (2) which motions they agree should be granted; and (3) which motions require a definitive ruling from the Court because the parties cannot agree.⁸ Where the parties do not agree, each side may include a concise summary of their disagreement consisting of not more than half a page per case, describing the bases for their disagreement. This process should have already begun per direction of prior *Issue Rulings*. The parties shall jointly submit this report to the Court on July 17, 2026.

IT IS SO ORDERED.

/s/ Dan Aaron Polster June 8, 2026
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

⁸ The Court understands that PBMs, and possibly other defendants, object to the Final Amendment Process. The Court acknowledges that a defendant does not waive this objection by engaging in the *Ruling*-application and reporting process required here.

ATTACHMENT G

**(R. 6650, Final Order Regarding
Plaintiffs' Motions for Leave to Amend)**

**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
<i>All Cases</i>	)	
	)	<u>ORDER REGARDING PLAINTIFFS’</u>
	)	<u>MOTIONS FOR LEAVE TO AMEND</u>
	)	

For a few years, during various status conferences, the PEC inquired whether the Court would be willing to lift its moratorium and allow plaintiffs to amend their complaints. *See, e.g.*, 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.”). On May 23, 2024, in response to a formal motion by the PEC, the Court initiated a process that would finally and firmly fix the defendants that would be named in each MDL case. Docket no. 5455 (“Final Amendment Order”). The Court made clear this process would provide plaintiffs their “final opportunity to amend their complaints.” Final Amendment Order at 2. The Final Amendment Order directed that, “[f]or each defendant the PEC wishes to add to any case, the PEC shall file a *single* motion to amend the complaints of *all* plaintiffs who wish to add that defendant.” *Id.* at 1 (emphasis in original). Ultimately, the PEC filed 14 defendant-specific motions for leave to amend (“MLAs”).

Since issuing the Final Amendment Order, the Court has received thousands of pages of briefing on every conceivable issue pertaining to whether the Court should grant or deny plaintiffs’ MLAs. *See* Issue Ruling One at 13–14 (providing a chart of all the substantive briefs). To resolve

each of the many issues raised, the Court released a series of six “Issue Rulings.” *See* docket nos. 6303 (“Issue Ruling One”); 6379 (“Issue Ruling Two”); 6418 (“Issue Ruling Three”); 6428 (“Issue Ruling Four”);¹ 6553 (“Issue Ruling Five”); 6599 (“Issue Ruling Six”). These Issue Rulings resolved, one by one, every argument raised by any defendant against granting plaintiffs’ MLAs.

In its final Issue Ruling, the Court directed the parties to apply all of its Issue Rulings to the pending MLAs and report back to the Court on which motions: (a) the parties agreed should be denied (or withdrawn), (b) the parties agreed should be granted, and (c) the parties could not agree and thus required a definitive ruling by the Court. *See* Issue Ruling Six at 10. On July 17, 2026, the parties filed their joint Report. Docket no. 6636 (“Report”). In the Report, the parties broadly describe three groups into which the defendants named in the 14 MLAs fall: (1) defendants as to which every plaintiff has withdrawn from the MLA seeking to add that defendant; (2) defendants that are actively and productively engaged in settlement discussions with the PEC; and (3) defendants that some plaintiffs still seek to add and that are not actively engaged in settlement discussions with the PEC. The Court discusses each group in turn.

The first group consists of those defendants as to which every plaintiff has withdrawn from the MLA. This group consists of four defendants: (1) Alvogen, (2) Costco, (3) Target, and (4) Tris Pharma. *See* Report at 2. Because there are no longer any plaintiffs seeking to add any of these defendants, these motions are all **DENIED** as moot.²

The second group consists of defendants who are actively and productively engaged in a resolution process with the PEC; their settlement discussions are at various stages, ranging from

¹ Issue Ruling Four is currently the subject of a motion for reconsideration filed by the PEC. *See* docket no. 6477. The Court also addresses this motion below.

² Those motions are docket nos. 5550 (Alvogen) (already ruled moot, *see* docket no. 6532); 5568 (Costco); 5571 (Target); 5554 (Tris Pharma).

nearly finalized to making progress. *See* Report at 2–3. This group consists of seven defendants: (1) Aurolife, (2) Albertsons, (3) Discount Drug Mart, (4) Lupin, (5) Winn-Dixie, (6) Ahold Delhaize, and (7) KVK-Tech. The parties jointly request that the Court hold the relevant MLAs in abeyance and allow settlement discussions to continue.³ Full resolution would cause these MLAs to become moot. Accordingly, the Court grants the parties’ joint request to have these group two MLAs **HELD IN ABEYANCE**.⁴ These parties should promptly notify the Court when and if they reach full settlement or instead finally conclude they cannot do so.

Last, the third group consists of defendants that some plaintiffs still seek to add to their case and that are not actively pursuing settlement with the PEC. These MLAs require a ruling on the merits. This group consists of three defendants: the two PBMs, (1) OptumRx and (2) Express Scripts; and (3) Publix. Publix is somewhat differently situated than the two PBMs. The Court first addresses the good-cause showing common to all three defendants and then turns to Publix and the PBMs in turn.

Through its six Issue Rulings, the Court resolved each issue raised by defendants in the negative. That is, the Court carefully analyzed each issue and determined whether it provided a basis to deny an MLA; the Court necessarily reserved affirmatively *granting* any MLA until after it determined conclusively that there existed no issue warranting *denial* of any plaintiff’s motion.

As this process unfolded, plaintiffs did not wait for the Court to release its very last Issue Ruling; rather, when the Court released an Issue Ruling that forecast an eventual formal denial of

³ As mentioned in footnote 1, there remains a pending motion for reconsideration of Issue Ruling Four. Docket no. 6477. For the reasons provided in footnote 2 of the Report, the parties also jointly ask that the Court hold off on ruling on the PEC’s motion for reconsideration. Any such ruling would affect only this second group of defendants. Accordingly, the Court will also hold in abeyance its ruling on the PEC’s motion for reconsideration until the parties’ settlement efforts are final.

⁴ Those motions are docket nos. 5551 (Aurolife); 5567 (Albertsons); 5569 (Discount Drug Mart); 5553 (Lupin); 5572 (Winn-Dixie); 5566 (Ahold Delhaize); 5552 (KVK-Tech).

a plaintiff's motion, that plaintiff voluntarily withdrew from the respective omnibus MLA. *See, e.g.,* Report at Exhibit 2A–2M (listing thousands of plaintiffs withdrawing from the various motions).⁵ Thus, the only plaintiffs with MLAs still pending are those where the Court has concluded, via the six Issue Rulings, that there is no basis for denial of the MLA. Put differently, the Court understands there are no remaining MLA plaintiffs that: (1) still seek leave to add the PBMs or Publix; and (2) against which the Court has resolved any issue in favor of denial. *See* Report at 3 (“Publix does *not* contend that the Court’s issue rulings dictate that the 5 pending plaintiffs’ MLAs against it must be denied”) (emphasis in original); *id.* at 5 (“the PBMs acknowledge that the Court’s issue rulings, standing alone, do not require *denial* of any pending MLAs.”) (emphasis in original).

Because the Court has resolved none of the group three defendants’ arguments in favor of denying any remaining plaintiffs’ motion, the Court concludes there is good cause to grant the respective motions. Throughout its Issue Ruling process, the Court has decided, among many other things, that: (1) each of the now-remaining plaintiffs has been diligent; and (2) the defendants will not be unduly prejudiced if the plaintiff’s particular motion is granted. *See* Issue Ruling One at 5 (“Courts consider two principal factors in assessing ‘good cause’: the diligence of the party seeking leave to amend and undue prejudice to the opposing side.”) (citing *Andretti v. Borla Performance Indus., Inc.*, 426 F.3d 824, 830 (6th Cir. 2005)).

Accordingly, the Court concludes that each of the remaining plaintiffs has demonstrated good cause and their motion for leave to amend should be **GRANTED**. *See id.* at 7 (“Under Rule

⁵ The Court notes for completeness that the charts provided in Exhibits 2A–2M do not provide the reason for a plaintiff’s withdrawal. The Court recognizes that its issuance of a Ruling that would work to deny a plaintiff’s motion based on the specific factual circumstances present in that individual case was just one of many possible reasons a plaintiff might choose to withdraw from an MLA.

15, a ‘court should freely give leave [to amend] when justice so requires.’”) (quoting Fed. R. Civ. P. 15(a)(2)).

The Court now turns to the differently situated defendants in group three. Publix is currently “out” of the MDL. That is, there are no active MDL cases in which Publix is a named defendant. But there are five MDL cases seeking to add Publix that, with the instant ruling, bring Publix back “in” to the MDL.

As cited above, Publix concedes that none of the Issue Rulings provide a basis to deny any plaintiff’s motion for leave to amend. *See* Report at 3. In Publix’s view, however, the best procedure to handle the five plaintiffs with MLAs would be to deny their motions and let them refile their complaints in a different court in an appropriate jurisdiction. The PEC responds that the better procedure would be to grant the MLA in favor of the five plaintiffs and allow Publix the option of either: (1) attempting to resolve its cases within the structure of the MDL, or (2) asking the Court to remand (or suggest remand of) each of the five cases to the appropriate venue. Publix could then seek to resolve the cases however it sees fit.

The Court agrees with the PEC’s proposed approach. As Publix points out, the Court recently transferred the last remaining active Publix case out of the MDL. *See* Case no. 23-op-45004, docket no. 4 (transferring venue of last active case naming Publix to the Middle District of Tennessee). The Court can, if Publix so requests, simply do the same for these five “new” Publix cases. To that end, the Court will shortly schedule a status conference with counsel for Publix and the plaintiffs in these five cases to determine how they would like to proceed.

Accordingly, MLAs in the five cases identified in Exhibit 1H seeking to add Publix are **GRANTED**.⁶

⁶ The motion is docket no. 5570.

The two PBM Defendants are distinct from Publix in that there is active bellwether litigation in the MDL against the PBMs. But this is a distinction without a difference as measured by the standard for granting an MLA; the general good-cause analysis set forth above applies with equal force.

In the Report, the PBMs again voice their objection to the Court's process. *See* Report at 5–7; *but see* Issue Ruling 6 at 10, n.8 (“The Court understands that PBMs, and possibly other defendants, object to the Final Amendment Process. The Court acknowledges that a defendant does not waive this objection by engaging in the Ruling-application and reporting process required here.”). Those objections are noted for the record but remain overruled. “Having carefully considered the defendants’ concerns, the Court remains convinced that the Final Amendment Process is fair, reasonable, appropriate, and begets no prejudice.” Issue Ruling Six at 9.

Accordingly, the MLAs of each of the plaintiffs identified in Exhibits 1L (Express Scripts) and 1M (OptumRx) are **GRANTED**.⁷

Finally, there are two additional issues raised in the Report that the Court addresses briefly. First, as mentioned above, the Report contains two exhibits. Exhibit 1 (1A–1M) lists plaintiffs who maintain their MLA with respect to the corresponding defendant. Exhibit 2 lists plaintiffs who have withdrawn from the corresponding MLA. For the avoidance of doubt, in case the Court has not clearly already so ruled, the motions for leave to amend of the withdrawing plaintiffs identified in any of the Exhibit 2s (2A–2M) are hereby **DENIED** as moot.

Second, the PEC now proposes the Court adopt a procedure that will require each amending plaintiff to file a short-form complaint. The PBM Defendants request that, if the Court adopts the

⁷ Those motions are docket nos. 5548 (Express Scripts); 5547 (OptumRx).

PEC proposal, they be provided an opportunity to participate in the development and drafting of the short-form complaint. On this matter, the Court **ORDERS** as follows:

The PEC shall, as soon as reasonably possible, draft a proposed short-form complaint and share it with the PBM Defendants and Publix. The parties shall then meet and confer and attempt to reach agreement on the substance and content of the proposed short form complaint.

If the parties reach agreement, they shall, **by September 25, 2026**, at the latest (and earlier if possible), jointly submit a proposed order for the short-form complaint, and the Court will review and likely adopt it.

If the parties cannot reach full agreement, then on **October 9, 2026**: (1) the PEC shall file its proposed short form complaint, identify points of disagreement, and set forth its positions on those points; and (2) the PBM Defendants and Publix shall simultaneously file a brief identifying the points of disagreement, set forth its positions on those points, and offer counterproposals.

The Court will then consider the parties' positions and issue an order.

IT IS SO ORDERED.

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