

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
All Cases)
) **ISSUE RULING SIX**
) **REGARDING PREJUDICE**
)

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.2d1117, 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.