

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE: SUBOXONE (BUPRENORPHINE/ NALOXONE) FILM PRODUCTS LIABILITY LITIGATION  This document relates to: All Actions	Case No. 1:24-md-03092-JPC  Judge J. Philip Calabrese
---	---

**Plaintiffs' Brief on Benefits of Tolling Agreement and Request for  
Defendants to Answer Complaints**

Since November 2023, Plaintiffs worked to persuade Defendants of the benefits of a tolling agreement to ensure this MDL is administered efficiently. The PLC proposes a tolling agreement where every potential claimant would supply proof of use from pharmacy or medical records to guarantee that this MDL includes only people who used Suboxone film. On May 8, Defendants advised that they will not consider tolling at this time.

As of this filing, 486 cases are pending in this MDL. Absent tolling, there will be hundreds, if not thousands, of cases filed over the next month as plaintiffs rush to ensure compliance with statutes of limitations in several states.<sup>1</sup> Claims that are not fully vetted will be filed, state-court litigation will commence, and an initial census will be difficult to complete. The combination of these factors will inject unnecessary obstacles into this MDL. The Court can encourage cooperative administration of this MDL by requiring Defendants to answer the complaints they insist Plaintiffs file.

---

<sup>1</sup> Plaintiffs do not waive any claim to equitable tolling or otherwise concede that a statute of limitations would bar any cases in any states.

### RELEVANT FACTUAL BACKGROUND

In January 2022, the FDA announced that it would require a warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medications dissolved in the mouth (including Suboxone film).<sup>2</sup> On June 17, 2022, Defendants updated the Suboxone film prescribing information to warn of the risk of dental injuries.<sup>3</sup>

The label change has potential implications for statutes of limitations. Although calculating limitations periods differs state-to-state and case-to-case based on the interpretation of the discovery rule and learned-intermediary doctrine, more than 20 states generally apply two-year statutes of limitations to products-liability actions, and the majority of the remaining states apply three-year statutes. *See* AM. L. PROD. LIAB. 3d § 47:2 (May 2024). All told, prospective plaintiffs in approximately 40 states face potential limitations periods that expire in June of 2024 or 2025.

Suboxone film monopolized the buprenorphine drug market for years thanks to its orphan-drug exclusivity. Per the CDC, about 16,000,000 buprenorphine prescriptions were dispensed annually from 2019 to 2022.<sup>4</sup> As a result, there are likely thousands of injured people who have yet to file claims but whose filing deadlines could be just weeks away. On the eve of this potential limitations period,

---

<sup>2</sup> FDA, Drug Safety Communication, at 1 (Jan. 12, 2022) (available at <https://www.fda.gov/media/155352/download?attachment>) (last accessed May 9, 2024).

<sup>3</sup> Suboxone film prescribing information (available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/022410s046s047lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022410s046s047lbl.pdf)) (last accessed May 9, 2024).

<sup>4</sup> *See* CDC, *United States Dispensing Rate Maps*, tbl. 1 (Dec. 11, 2023) (available at <https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>) (last accessed May 9, 2024).

Defendants, by refusing to enter a tolling agreement, insist that all prospective plaintiffs file their complaints per the Federal Rules of Civil Procedure.

### ARGUMENT

#### **I. MDLs are created for efficiency. Tolling agreements help make MDLs efficient by streamlining the proceedings to common issues.**

The JPML established this MDL to “promote the just and efficient conduct” of these actions. *See In re Suboxone (Buprenorphine/Naloxone) Film Prods. Liab. Litig.*, MDL No. 3092, 2024 WL 437218, at \*1 (J.P.M.L. Feb. 2, 2024). The efficiency goals in MDLs are “to manage discovery and otherwise efficiently prepare the cases for trial, taking care to identify pretrial opportunities to resolve key issues or to achieve settlements.” BOLCH JUD. INST., GUIDELINES & BEST PRACTICES FOR LARGE & MASS-TORT MDLS at 1 (2d ed. 2018) (“MDL GUIDELINES”). An efficient MDL provides fairness by enabling “all parties to have a fair test of the merits of their claims and defenses” and achieving “consistent, predictable, and cost-effective outcomes” across similar cases. MANUAL COMPLEX LITIG. § 22.2 (4th ed. 2023).

Of course, MDLs are civil litigation at scale, and their “sheer volume” creates a “need for special judicial management.” *Id.* § 22.1. MDL judges “must efficiently and fairly manage hundreds, even thousands, of related cases without unduly disrupting the court’s other work.” *Id.* This reality encourages judges to “tailor case-management procedures to the needs of the particular litigation and to the resources available from the parties and the judicial system,” *id.* § 10.1, and the JPML has repeatedly stated that an MDL judge “can employ any number of techniques . . . to

manage pretrial proceedings efficiently.” *In re Baby Food Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, MDL No. 3101, 2024 WL 1597351, at \*2 (J.P.M.L. Apr. 11, 2024).

But the “[f]air and efficient resolution of complex litigation” does not require only the Court’s managerial buy-in. MANUAL COMPLEX LITIG. § 10. It equally requires that “the judge and counsel collaborate to develop and carry out a comprehensive plan for the conduct of pretrial and trial proceedings.” *Id.* The entire point of centralization is “to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of case and a minimum of inconvenience to all concerned.” *In re Baldwin-United Corp. Litig.*, 581 F. Supp. 739, 741 (J.P.M.L. 1984).

One way that counsel often collaborate to assist the court early in an MDL is with a tolling agreement. This is often done in exchange for certain evidence establishing the plaintiff possesses a meritorious claim (as the PLC has proposed for months). Statutes of limitations can be tolled only by agreement, and MDL defendants commonly enter these agreements because tolling benefits them. “When there is a mass of claims,” there are good reasons why “a defendant may wish to not have them all file suit.” RHEINGOLD, LITIGATING MASS TORT CASES § 6:35 (Aug. 2023). Some of the benefits pertain to managing the litigation’s effects (“the pendency of a suit make[s] the situation look worse,” *id.*). Others pertain to managing the litigation itself; after all, every pending suit “also entails defense costs.” *Id.*

Tolling agreements inure to the Court’s benefit as well. By “hold[ing] down mass filings of cases simply to protect the statute of limitation,” a tolling agreement

“allows for meaningful work in the MDL to occur”—and “takes the pressure off the clerk’s office in the MDL court district.” 1 PHARM. & MED. DEVICE LITIG. § 7:38 (Nov. 2023). The Court can in turn “promote the settlement process by advancing the litigation so that factual and expert development occurs and the cases become ripe for settlement discussions.” MDL GUIDELINES at 96. In short, with a tolling agreement in place, all involved can focus on the efficiency goals for which the MDL was created.

- In the **Vioxx MDL**, about 14,000 plaintiffs entered tolling agreements with Merck upon certain threshold showings; the MDL court explained that it deployed these agreements “to achieve the efficiencies celebrated by *American Pipe [ & Construction Co. v. Utah*, 414 U.S. 538 (1974)],” which articulated the class-action tolling doctrine. *In re Vioxx Prods. Liab. Litig.*, 522 F. Supp. 2d 799, 806 n.11 (E.D. La. 2007).
- The parties entered a tolling agreement early in the **3M MDL**, which ended up with over 250,000 cases, and the court expressed its “appreciat[ion for] their hard work and cooperation in this regard, as these agreements will facilitate a more accurate and informative initial census.” CMO No. 4, *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 3:19-md-02885, ECF No. 651 at p.2 (N.D. Fla. Aug. 27, 2019).
- Similarly in the **Zantac MDL**, the parties conferred “[a]t the Court’s request . . . to formulate an initial census process to assist in overall effective case management.” Pretrial Order No. 5, *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 20-md-2924, 2020 WL 1640021, at \*1 (S.D. Fla. Apr. 2, 2020). That process provided tolling to census participants. *See id.* at \*5.
- The parties entered a tolling agreement in the **Welding Rod MDL**. *See In re Welding Rod Prods. Liab. Litig.*, 1:03-cv-17000, ECF No. 229, PageID # 2856 (N.D. Ohio May 25, 2004) (ordering parties to submit executed tolling agreement); *id.*, ECF No. 235-1 (June 2, 2004) (tolling agreement); *id.*, Order (non-document) (June 14, 2004) (approving and adopting tolling agreement).
- In the **CPAP MDL**, the court ordered that the tolling agreement be filed for other parties to use. *See In re Philips Recalled CPAP, Bi-Level PAP, & Mech. Ventilator Prods. Litig.*, 2:21-mc-01230, ECF No. 382 (W.D. Pa Feb. 8, 2022) (order); *id.*, ECF No. 383 (Feb. 8, 2022) (agreement).

In all of these cases, the courts allowed plaintiffs to voluntarily dismiss certain already filed claims to participate in the tolling agreement. Here, implementing a tolling agreement would also benefit the parties and the Court by facilitating the conduct of an early census process.<sup>5</sup>

**II. Rule 11 allows inefficient “blind filing” to protect clients’ claims from expiring statutes of limitation. Tolling will avoid this waste of judicial and party resources.**

Given Defendants’ refusal to toll, many plaintiffs will be forced to “blind file” to avoid potential statutes-of-limitations defenses. Plaintiffs are permitted to allege claims based on information and belief following “an inquiry reasonable under the circumstances.” Fed. R. Civ. P. 11(b). This expressly includes authorization to file claims where “the factual contentions . . . will likely have evidentiary support after a reasonable opportunity for further investigation.” Fed. R. Civ. P. 11(b)(3).

Where a plaintiff hires a lawyer on the eve of an expiring limitation period, the investigation required to satisfy Rule 11 amounts to little more than the client’s representation she used Suboxone and suffered tooth loss as a result. While independent confirmation is preferred, time constraints in the face of an expiring

---

<sup>55</sup> This is important here, given the PLC intends to ask the Court to establish a protocol requiring that the parties discuss settlement from Day 1—a practice that is increasingly being adopted by MDL Courts. *See In re: Abbott et al., Preterm Infant Nutrition Prods. Liab. Litig.*, MDL No. 3026, Case No: 1:22-cv-0071, ECF No. 463 at PageID #: 7031; *In re: Tepezza Mktg., Sales Practices, and Prods. Liab. Litig.*, MDL No. 3079, N.D. Ill. Case No. 1:23-CV-3568 ECF No. 10, PageID #: 99; *In re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Prods. Litig.*, MDL No. 3014, W.D. Pa. Case No. 2:21-mc-01230, ECF No. 4, ¶ 14.B.1.c.iii at p. 8 (emphasizing counsel’s responsibility to “explore, develop and pursue all settlement options pertaining to any claim or portion thereof of any case filed in this litigation” from day one) Absent accurate information, the ability to discuss resolution will be hampered significantly.

statute require the lawyer to trust the client's account. For example, a physician might advise her patient she was prescribed Suboxone film when the pharmacy actually dispensed a generic drug. Obtaining pharmacy records is therefore necessary to confirm product identification. But that takes time, which is precisely why Rule 11 affords parties the right to state allegations on "information and belief." Unfortunately, many of those cases will, "after a reasonable opportunity for further investigation" turn out to lack merit requiring their dismissal.

Defendants know that the parties and Court will need to parse through scores of claims to uncover which are viable and which are not. This is a problem for all parties in this litigation. Absent tolling, "blind filed" cases *will* be filed, additional cost *will* be imposed on the parties, the Court *will* waste resources opening cases that will soon leave its docket. A docket with too many non-compensable cases on file is not one that is likely to readily yield precise metrics for an assortment of topics including bellwether selection. Providing adequate time to secure records confirming that each client used brand-name Suboxone film is in all parties' best interests.

**III. Competing state-court litigation will launch absent a tolling agreement to secure recovery for non-diverse plaintiffs.**

The absence of a tolling agreement interjects a new dimension into this litigation: competing state court cases. The PLC thus far has been able to head off such litigation pending negotiation of a tolling agreement. But absent such an agreement, the PLC will be unable to persuade lawyers with non-diverse clients from filing cases in various state venues. Virginia, New Jersey and Delaware are homes to Defendants and operate under a two-year statute. It is a near certainty at least one

of these state-court fronts will develop. Under *Mallory v. Norfolk Southern Railway Co.*, 600 U.S. 122 (2023), several Defendants are also subject to general jurisdiction in Pennsylvania and Georgia—more two-year states—because they are registered to do business there as foreign corporations. *See also Sloan v. Burist*, No. 2:22-CV-76, 2023 WL 7309476, at \*4–6 (S.D. Ga. Nov. 6, 2023) (upholding and applying Georgia’s *Mallory* statute). Managing this MDL will be more difficult with up to five fronts of state-court litigation.

The competing state-court litigation that will result from Defendants’ decision carries risk of substantial inefficiency. For example, in the *In re Abbott Preterm Infant Litigation*, notwithstanding the MDL leadership’s best efforts, the parties were unable to secure coordination between the state and federal litigants. As a result, witnesses were deposed in both state and federal proceedings because the courts recognized their respective jurisdiction afforded them limited options to compel cooperation. That is a realistic concern here if lawyers not currently before this Court start to file cases in remote state-court venues.

Competing state proceedings will subvert this MDL’s ability to efficiently run this litigation given the competing state court plaintiffs may not be subject to this Court’s jurisdiction. Absent tolling, the best way for the PLC to attempt to secure coordination of state and federal proceedings is for PLC firms to play a substantial role in any state litigation. And even in those instances where the state-court cases are filed by PLC members, there is no guarantee any state court will adopt, let alone compel, coordination as it manages its own docket. A tolling agreement immediately



mitigates against this risk by disincentivizing the need to file non-diverse state court cases.

**IV. If Defendants insist that each plaintiff file a separate complaint per the civil rules, Defendants should answer each complaint per the civil rules.**

Per the stipulated direct-filing order, every case filed into the MDL “must be initiated by opening a new case.” Amended CMO 3, ECF No. 52, ¶ II.C, PageID #: 487 (Mar. 27, 2024). Defendants currently are not required to respond to any complaint “until so ordered by the Court or until such time as an order is entered governing the procedure for filing short-form pleadings.” *Id.* at ¶ III.D, PageID #: 496. Considering the expected volume of this litigation, the task of appearing in, monitoring, and answering those complaints will be formidable. Given plaintiffs are forced by the absence of a tolling agreement to initiate new cases with full individual complaints, the PLC can, and should, fairly insist on full answers, particularly where Defendants’ refusal to agree to tolling amounts to nothing more than a gamble that plaintiffs’ counsel will have neither the time nor resources to file a separate complaint for each client.

But that bet hardly advances this MDL’s ability to achieve “consistent, predictable, and cost-effective outcomes.” MANUAL COMPLEX LITIG. § 22.2. Defendants are not likely to face fewer claims if they decline to toll. Quite the contrary. Absent a tolling agreement, competent counsel will file scores of cases based on their clients’ “information and belief.” Conversely, a tolling agreement, and an accompanying obligation to produce product identification, ensures that *only* valid claims will be included in this MDL. If the just and efficient determination of the issues is the

collective objective here, tolling claims makes sense. Inadequate—or nonexistent—cooperative tolling on the front end guarantees the inefficiencies MDLs were designed to avoid.

In the three weeks since the last CMC, the number of cases in this MDL nearly *doubled*. That trend will continue. The question is not whether Defendants will face the same number of claims absent tolling. The question is whether Defendants will face more filed cases where there was insufficient time to fully vet claims. The odds of that result are a near certainty. In short, Defendants’ decision refusing to agree to tolling will leave the parties (and the Court) to sort through the myriad of cases that must be filed without the benefit of a full investigation. And all the while, hopes of efficient discovery, merits determinations, and settlement negotiations will slide further down the calendar.<sup>6</sup> Conversely, a tolling agreement, and its accompanying benefits, will eliminate this threat. Such an agreement would serve the efficiency goals that Plaintiffs presented to the JPML and that the JPML (and Defendants) agreed with. *See In re Suboxone*, 2024 WL 437218, at \*1 (noting that “[c]entralization” here “offers an opportunity to substantially streamline pretrial proceedings”).

---

<sup>6</sup> This is not to suggest the PLC does not intend to push the pace of this litigation. On the contrary, Defendants’ one-sided approach to litigation is nearing its end. Specifically, by the time of the next CMC, the PLC intends to seek dates to implement a Wave 1 Bellwether Protocol; an ESI Protocol; and Custodial and Non-Custodial Production Protocols. In short, the PLC intends to advance this litigation in a significant and substantial way to align with other MDLs whose preliminary schedules contemplate trial in less than three years from inception.

## CONCLUSION

If Defendants agree to toll claims through an administrative process in this MDL, this MDL's efficiency can be maximized, product identification can be independently confirmed pre-suit, and competing state-court litigations may be avoided. Tolling can apply to all claims regardless of diversity. And the MDL can remain the sole situs for litigating Suboxone film cases. This is the PLC's preference and inures to the benefit of all. It avoids the flood of cases that will impede this MDL's efficient operation.

The chaos that will ensue for failure to enter a tolling agreement can be laid entirely at Defendants' feet. Since Defendants chose to litigate in a multiverse where hundreds of cases must be filed in the next month in various courts, and insisted that this MDL will be governed "by the Rules," the PLC seeks an Order from this Court—consistent with NDOH's Local Rules—requiring that Defendants answer each and every currently filed Complaint within 30 days of this Order or 30 days of service for cases filed subsequent to such an Order. The PLC suspects that such an Order will nudge this MDL on to the path of efficiency that the undersigned has been advocating since November.

Dated: May 10, 2024

Respectfully submitted,

/s/ Ashlie Case Sletvold

Ashlie Case Sletvold  
PEIFFER WOLF CARR KANE CONWAY &  
WISE, LLP  
6370 SOM Center Road, Suite 108  
Cleveland, OH 44139  
(216) 589-9280  
[asletvold@peifferwolf.com](mailto:asletvold@peifferwolf.com)  
*Plaintiffs' Co-Lead Counsel and Court's  
Liaison*

/s/ Alyson Steele Beridon

Alyson Steele Beridon  
HERZFELD, SUETHOLZ, GASTEL, LENISKI, &  
WALL, PLLC  
600 Vine Street, Suite 2720  
Cincinnati, OH 45202  
(513) 381-2224  
[alyson@hsglawgroup.com](mailto:alyson@hsglawgroup.com)  
*Plaintiffs' Liaison Counsel*

/s/ Erin Copeland

FIBICH, LEEBRON, COPELAND & BRIGGS  
1150 Bissonnet Street  
Houston, TX 77005  
(713) 424-4682  
[ecopeland@fibishlaw.com](mailto:ecopeland@fibishlaw.com)

/s/ Timothy J. Becker

Timothy J. Becker  
JOHNSON // BECKER, PLLC  
444 Cedar Street, Suite 1800  
St. Paul, MN 55101  
(612) 436-1800  
[tbecker@johnsonbecker.com](mailto:tbecker@johnsonbecker.com)

/s/ Trent B. Miracle

Trent B. Miracle  
FLINT COOPER LLC  
222 East Park Street, #500  
Edwardsville, IL 62025  
(618) 288-4777  
[tmiracle@flintcooper.com](mailto:tmiracle@flintcooper.com)  
*Plaintiffs' Co-Lead Counsel*