

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

**IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION**

Case No. 2:18-md-2846

**JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson**

**This document relates to:
ALL ACTIONS.**

CASE MANAGEMENT ORDER NO. 33

On May 27, 2022, Defendants C.R. Bard, Inc. and Davol Inc. filed a Motion for a Docket Control Order (“*Lone Pine* motion”) (ECF No. 627). Defendants request an order requiring plaintiffs in this multidistrict litigation (“MDL”) to “provid[e] fundamental proof of a legally cognizable injury[.]” (ECF No. 627 at PageID #7760.) Defendants ask that plaintiffs be required to produce “evidence of a medical diagnosis of compensable injury, proof of implant with a covered device for this MDL, and certification that plaintiff’s counsel has conducted an assessment of basic issues that bear on whether a case should be pending in this proceeding.” (*Id.* at PageID #7778.) According to Defendants, there are a “considerable number” of pending cases with one or more of the following issues:

- 1) The plaintiff is suing over a Bard device that is still in place;
- 2) The plaintiff is suing over an incidental finding discovered during an unrelated procedure;
- 3) The plaintiff is suing over an alleged injury that produced no physical symptoms;
- 4) The plaintiff is suing over a device not made by Bard or otherwise outside of the scope of this MDL;

- 5) The plaintiff's claims are plainly barred by applicable statutes of limitations and/or repose;
- 6) The plaintiff has multiple cases arising out of the same operative facts pending in this MDL; and
- 7) The plaintiff's claims have been resolved in other litigation or are subject to a prior dismissal with prejudice.

(*Id.* at PageID #7759.) According to Defendants, these “continuously increasing” cases are impediments to this MDL and such cases need to be rooted out so that the litigation can focus on the remaining cases. (*Id.*)

Plaintiffs respond that existing procedural devices are sufficient to address Defendants' stated concerns and note that “a *Lone Pine* order should only occur where existing procedural devices . . . have been exhausted or where they cannot accommodate the unique issues of this litigation.” (ECF No. 630 at PageID #7860 (citing *Ripley v. Sunoco, Inc.*, 287 F.R.D. 300 (E.D. Pa. 2012)).) Plaintiffs claim that Defendants can, and often do, utilize existing procedural devices such as motions to compel and motions to dismiss to address the concerns at hand. Additionally, Plaintiffs argue that the issuance of a *Lone Pine* order based on Defendants' seven stated issues would be burdensome, unprecedented, unnecessary, and/or contrary to applicable law.

In an unpublished opinion from 1986, the Superior Court of New Jersey issued a case management order requiring the plaintiffs to provide certain facts about their case via expert reports or risk dismissal of their case. *Lore v. Lone Pine Corp.*, No. L-33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986). In *Lone Pine*, homeowners brought suit against hundreds of defendants for personal injury and property damage resulting from polluted water during the operation of Lone Pine's landfill. *Id.* The Environmental Protection Agency “had prepared a Record of Decision (R.O.D.) which was a summary of sixteen studies on the Lone Pine Landfill. The R.O.D. cataloged and evaluated all the information available on the Lone Pine

problem and the location of the resulting pollution.” *Id.* at *1. The EPA R.O.D. “indicate[d] that there was no problem with ground water contamination, nor indeed with the transport of pollution by air, ground water or surface water.” *Id.* at *2. The court issued a case management order requiring the plaintiffs to put forth expert evidence that their injuries were caused by the landfill. *Id.* at *1–2. The plaintiffs failed to comply with the court’s order, and the case was subsequently dismissed. *Id.* at *4. “Consequently, the concept of using case management orders to require plaintiffs to set forth evidence of causation early in a case was recognized and became known as *Lone Pine* orders.” *Manning v. Arch Wood Prot., Inc.*, 40 F. Supp. 3d 861, 863 (E.D. Ky. 2014).

A *Lone Pine* order is “viewed as [an] extraordinary remed[y] that should be issued only in exceptional cases ‘after the defendant has made a clear showing of significant evidence calling into question the plaintiffs’ ability’ to produce evidence to establish the critical elements of causation and damages.” *Hostetler v. Johnson Controls, Inc.*, No. 3:15-CV-226-JD-MGG, 2017 WL 359852, at *4 (N.D. Ind. Jan. 25, 2017) (quoting *McManaway v. KRB, Inc.*, 265 F.R.D. 384, 388 (S.D. Ind. 2009)). “[T]he vast majority of cases granting *Lone Pine* motions did so only when there was a refusal to comply with discovery requests or when plaintiffs failed to allege a *prima facie* case.” *Manning*, 40 F. Supp. 3d at 864 (citing *Simeone v. Girard City Bd. of Educ.*, 171 Ohio App.3d 633, 872 N.E.2d 344, 351 (2007)). *Lone Pine* orders “have been criticized because they give ‘courts the means to ignore existing procedural rules and safeguards.’” *Hostetler*, 2017 WL 359852 at *4 (quoting *Simeone*, 171 Ohio App.3d at 642). Notably, “a central element supporting the original *Lone Pine* order was the EPA report casting serious doubt on the alleged pollution by those defendants;” Defendants have pointed to no analogous evidence here. *Russell v. Chesapeake Appalachia, L.L.C.*, 305 F.R.D. 78, 84 (M.D. Pa. 2015) (citing *Lone Pine*, 1986 WL 637507 at *1).

In support of their *Lone Pine* motion, Defendants point to several cases that can be distinguished from the circumstances of this MDL, which the Court will now address. Defendants point to the requirement for plaintiffs to submit “a specific form or report” in a docket control order in *In re 3M Combat Arms Earplug Products Liability Litigation*. MDL No. 2885, May 6, 2022 (ECF No. 3076). However, as Plaintiffs point out, the docket control order in *3M* required a form confirming the military service of a plaintiff, much like the Plaintiff Profile Forms (“PPFs”) that are required in this MDL. The circumstances under which the court issued a *Lone Pine* order in *In re Fosamax Products Liability Litigation* are not analogous to this case. In *Fosamax*, after denying two such requests, the court granted the defendant’s third request for a *Lone Pine* order after “more than 50% of the cases set for trial ha[d] been dismissed, and some 31% of cases that ha[d] been selected for discovery ha[d] been dismissed.” *Fosamax*, No. 06 MD 1789 JFK, 2012 WL 5877418, at *3 (S.D.N.Y. Nov. 20, 2012). The court reasoned that “Plaintiffs’ habit of dismissing cases after both parties have expended time and money on case specific discovery demonstrate[d]” the need for a *Lone Pine* order. *Id.* In *In re Zostavax (Zoster Vaccine Live) Products Liability Litigation*, the court issued a *Lone Pine* order noting that “[t]here is compelling medical authority that a laboratory test of the shingles rash of a person who has had chickenpox is the only way to tell whether the shingles was caused by the virus strain contained in Zostavax or by the wild-virus strain from chickenpox latent in a person’s body.” *Zostavax*, No. CV 18-MD-2848, 2022 WL 952179, at *2 (E.D. Pa. Mar. 30, 2022). There is no analogous definitive medical test for causation in this MDL. The court issued a narrow *Lone Pine* order in *In re: Zimmer NexGen Knee Implant Products Liability Litigation* applicable to claims involving “high flexion activities of an MIS tibial component which was implanted with a drop down stem.” *Zimmer*, No. 1:11 -CV-05468, 2016 WL 3281032, at *1 (N.D. Ill. June 10, 2016). The order related to a very

specific subset of injuries and was entered in the context of the court’s “commitment to have full resolution of the[] consolidated proceedings” by a specific date. *Id.*

Additionally, several of the cases cited by Defendants relate to *Lone Pine* orders issued to assist in the administrations of settlements, and there is currently no such settlement administration in this MDL. See *In re Vioxx Prod. Liab. Litig.*, 557 F. Supp. 2d 741 (E.D. La. 2008), *aff’d*, 388 F. App’x 391 (5th Cir. 2010); *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 2007-MD-1871, 2010 WL 4720335 (E.D. Pa. Nov. 15, 2010); *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 1:14-CV-01748, 2018 WL 6258898 (N.D. Ill. June 11, 2018); and *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. 2:19-CV-14669, 2021 WL 493069 (E.D. La. Feb. 10, 2021).

Finally, Defendants also cite to a number of toxic tort cases in support of their motion. These cases are also distinguishable, as toxic tort cases (such as *Lone Pine* itself) present unique circumstances in which plaintiffs must prove their exposure to certain chemicals, often through complicated environmental and epidemiological testing. For example, in *McManaway v. KBR, Inc.*, the court noted that “[a] *Lone Pine* order should issue only in an exceptional case and after the defendant has made a clear showing of significant evidence calling into question the plaintiffs’ ability to bring forward necessary medical causation and other scientific information.” *McManaway*, 265 F.R.D. 384, 388 (S.D. Ind. 2009). The *McManaway* court delved into a specific analysis of the use of *Lone Pine* orders in toxic tort cases, and the concerns that relate to determining a plaintiff’s exposure to the chemical at issue. *Id.*; see also *Baker v. Chevron USA, Inc.*, No. 105-CV-227, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007) (requiring information regarding “the alleged manner of exposure [to the toxic chemical at issue], and the date, duration, and dose of the exposure”); *Burns v. Universal Crop Prot. All.*, No. 4:07CV00535 SWW, 2007

WL 2811533, at *2 (E.D. Ark. Sept. 25, 2007) (requiring “evidence on product identification and exposure issues”); *Acuna v. Brown & Root Inc.*, 200 F.3d 335, 338–340 (5th Cir. 2000) (affirming district court’s *Lone Pine* order for “injuries occurring over a span of up to forty years” with “a range of injuries as well as durations and intensities of exposure” from uranium mines and processing plants via several different types of exposure such as employment, wind, and groundwater); *Trujillo v. Ametek, Inc.*, No. 3:15-CV-1394-GPC-BGS, 2016 WL 3552029 (S.D. Cal. June 28, 2016) (requiring information regarding the identity of hazardous substances and exposure in a toxic tort medical monitoring case).

These MDL cases are not toxic tort cases involving proof of exposure to a specific hazardous substance. The cases involve the use of specific medical products manufactured and sold by Defendants. Defendants only mention Plaintiffs “suing over a device not made by Bard or otherwise outside the scope of this MDL” in passing, and their arguments are not similar to the proof of exposure issues present in a toxic tort case. Defendants do not provide any evidence that a significant number of cases do not involve a device at issue in this MDL.

In addition to the fact that the cases cited by Defendants are readily distinguishable, the Sixth Circuit “has not had occasion to address the nature and appropriateness of *Lone Pine* orders.” *Adkisson v. Jacobs Eng’g Grp., Inc.*, No. 3:13-CV-505-TAV-HBG, 2016 WL 4079531, at *3 (E.D. Tenn. July 29, 2016) (denying *Lone Pine* motion because the defendant “ha[d] not demonstrated that th[e] litigation present[ed] case management needs that [were] so extraordinarily unique as to require deviation from the usual procedural vehicles and case management tools utilized in civil actions”).

The Sixth Circuit has, however, made clear that the law and Civil Rules apply in MDLs as they do in any other case:

[T]he law governs an MDL court’s decisions just as it does a court’s decisions in any other case. The Supreme Court illustrated precisely that point in *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 40, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998). There, a unanimous Court stopped in its tracks the MDL courts’ nascent practice of conducting trials in cases where, under the plain terms of 28 U.S.C. § 1407, the MDL courts lacked power to conduct them. *See* 28 U.S.C. § 1407(a) (authorizing the transfer of cases to an MDL court for only “pretrial proceedings”). That some observers thought it “more desirable” that MDL courts should have that power was beside the point—because the relevant law made clear they did not. *Id.* at 40, 118 S.Ct. 956.

Here, the relevant law takes the form of the Federal Rules of Civil Procedure. Promulgated pursuant to the Rules Enabling Act, 28 U.S.C. § 2072, those Rules are binding upon court and parties alike, with fully the force of law. *See Bank of Nova Scotia v. United States*, 487 U.S. 250, 255, 108 S.Ct. 2369, 101 L.Ed.2d 228 (1988); *In re Pangang Grp. Co.*, 901 F.3d 1046, 1055 (9th Cir. 2018); *Winston & Strawn, LLP v. McLean*, 843 F.3d 503, 506 (D.C. Cir. 2016). . . . [T]he requirements of the Civil Rules in an MDL case . . . “are the same as those for ordinary litigation on an ordinary docket.” *In re Korean Air Lines Co.*, 642 F.3d 685, 700 (9th Cir. 2011). . . . MDLs are not some kind of judicial border country, where the rules are few and the law rarely makes an appearance. For neither § 1407 nor Rule 1 remotely suggests that, whereas the Rules are law in individual cases, they are merely hortatory in MDL ones.

In re Nat’l Prescription Opiate Litig., 956 F.3d 838, 844 (6th Cir. 2020). “A complaint need only contain ‘a short and plain statement of the claim showing that the pleader is entitled to relief.’ ‘Rule 11 does not require conclusive proof of causation prior to filing suit.’” *Adkisson*, 2016 WL 4079531 at *4 (quoting Fed. R. Civ. P. 8(a)(2); *Manning*, 40 F. Supp. 3d at 865). Those who file cases in this MDL are already required to “complete and serve upon Defendants via email a completed PPF, the form of which has been agreed to by the parties and approved by the Court, . . . along with all duly executed authorizations for the release of relevant medical records, within 60 days after Defendants serve their Short Form Answer upon a Plaintiff.” (Case Management Order (“CMO”) No. 8, ECF No. 57.) The PPF includes information such as the date of the hernia mesh implant, the reason for the implant, information regarding any explant surgery, the outcome or injuries the Plaintiff attributes to the hernia mesh, and the Plaintiff’s medical history and healthcare providers. (*Id.*) There are also procedures in place in the case of a Plaintiff’s failure to

submit a PPF. (*Id.*) Additionally, Plaintiffs in the bellwether pool were required to submit a more detailed Plaintiff Fact Sheet. (CMO No. 14, ECF No. 109.) Therefore, Plaintiffs in this MDL are already required to provide details, medical records, and authorizations in support of their claims.

As this Court noted in *In re: E.I. du Pont de Nemours and Company C-8 Personal Injury Litigation* (“C-8”), the *Lone Pine* court “determined that, upon the face of the Complaint, no prima facie claim for personal injuries or property damage appear[ed].” (Case No. 13-md-2433, CMO No. 24, ECF No. 5143 at PageID #120712 (citing *Lone Pine*, 1986 WL 637507 at *1).) The information submitted in *Lone Pine* was “so inadequate as to be deemed unbelievable and unreal.” (*Id.* (quoting *Lone Pine*, 1986 WL 637507 at *3).) As in C-8, no such findings can be made here. Defendants argue that many cases do not claim a “compensable injury” and many cases involve a product still in place. However, as Plaintiffs point out, “there has been no definition or negotiation of just what a ‘compensable injury’ entails,” and “just because a product has not been removed does not mean that the case is not meritorious as there are many reasons why a product that has caused significant injury to a patient is still in the patient’s body (*e.g.*, too dangerous to remove, etc.).” (ECF No. 630 at PageID #7864.)

For the reasons stated above, the Court believes that “entry of a *Lone Pine* order under the circumstances here amounts to an unprecedented condition precedent to filing a claim and insertion of defense counsel screening of a plaintiff’s claims.” (Case No. 13-md-2433, CMO No. 24, ECF No. 5143 at PageID #120714.) Under the circumstances of this case, such a course is neither permitted nor required by the Federal Rules of Civil Procedure or this Court’s Local Rules.

Defendants' *Lone Pine* motion is **DENIED** without prejudice to refiling.

IT IS SO ORDERED.

7/5/2022
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE