

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP, BI-
LEVEL PAP, AND MECHANICAL
VENTILATOR PRODUCTS LIABILITY
LITIGATION

This Document Relates To:

All Litigating Plaintiff Cases

Master Docket: Misc. No. 21-01230

MDL No. 3014

DOCKET MANAGEMENT ORDER FOR CLAIMS OF LITIGATING PLAINTIFFS

This Case Management Order (the “Order”) applies to all Litigating Plaintiffs, who are defined as individuals asserting Personal Injury Claims against one or more of the Philips Defendants who do not register for the Settlement Program by the Registration Deadline set forth in the May 9, 2024 Master Settlement Agreement (“MSA”).¹ An individual who has asserted such claims on or prior to the Registration Deadline becomes a Litigating Plaintiff as of the Registration Deadline. An individual who first asserts such claims after the Registration Deadline becomes a Litigating Plaintiff as of the date of the filing of such claims.

Consistent with the Court’s inherent authority to manage these proceedings, and in light of the Settlement Program agreed to after years of litigation and complex and extensive discovery and motion practice before this Court and the Special Masters, the Court finds it appropriate at this time to exercise its discretion to enter this Order to fairly, effectively and efficiently manage the cases of any Litigating Plaintiffs. This Order requires all Litigating Plaintiffs to produce certain

¹ Terms not defined herein have the same meaning as in the MSA. The MSA is available on the website of the Settlement Administrator, MDLCentrality.com/CPAP, and will be publicly available at RespirationPISettlement.com.

specified information regarding their claim(s), including medical records and evidence relating to device usage, their alleged injury(ies), and causation, and provides deadlines to meet those requirements prior to further proceedings, including any further discovery, motion practice, or trial on the merits. Litigating Plaintiffs shall be bound by the requirements of this Order and shall fully comply with all obligations required by this Order. The Court expects complete and full compliance with this Order and reserves its ability to dismiss a Litigating Plaintiff's case with prejudice for failure to adhere to the terms of this Order.

I. BACKGROUND AND STATUS OF PROCEEDINGS

1. On June 14, 2021, Philips RS North America LLC voluntarily recalled certain prescription medical devices, including certain Continuous Positive Airway Pressure ("CPAP"), Bi-Level Positive Airway Pressure ("BiPAP"), and mechanical ventilator devices (the "Recall" and the "Recalled Devices").

2. On October 8, 2021, the United States Judicial Panel on Multidistrict Litigation ("JPML") established MDL 3014 to centralize cases concerning the Recalled Devices. More than 800 cases have been filed in or removed to this MDL to date, and more than 58,000 potential claimants entered the Census Registry.

3. District courts have inherent authority to manage their dockets. This is especially true in large litigations, such as this MDL.² A district court's power extends to, for example, "controlling and scheduling discovery, including orders affecting disclosures and discovery under

² See, e.g., *In re Asbestos Prods. Liab. Litig.*, 718 F.3d 236, 246 (3d Cir. 2013) ("[D]istrict judges must have authority to manage their dockets, especially during [a] massive litigation.") (quoting *In re Fannie Mae Sec. Litig.*, 552 F.3d 814, 823 (D.C. Cir. 2009)); see also *Ramirez v. T&H Lemont, Inc.*, 845 F. 3d 772, 776 (7th Cir. 2016) ("[A] court has the inherent authority to manage judicial proceedings and to regulate the conduct of those appearing before it.").

Rule 26 and Rules 29 through 37,” “adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems,” and “facilitating in other ways the just, speedy, and inexpensive disposition of the action.” Fed. R. Civ. P. 16(c)(2)(F), (L) & (P).

4. This Court is granted wide discretion with regard to case management,³ and has the authority to streamline litigation in complex cases through rigorous Case Management Orders, particularly in mass tort cases.⁴

³ As the U.S. Court of Appeals for the Third Circuit has recognized, “multidistrict litigation ‘presents a special situation, in which the district judge must be given wide latitude with regard to case management in order to effectively achieve the goals set forth by the legislation that created the [JPML].’ This wide latitude applies, in particular, to issuing discovery orders, and to dismissing actions for non-compliance with such orders.” *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 687 F. App’x 210, 214 (3d Cir. 2017) (citation omitted); *see also In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 496 F.3d 863, 866 (8th Cir. 2007) (affirming MDL court’s dismissal of claims for failure to comply with discovery orders); *In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1229 (9th Cir. 2006) (“*In re PPA*”) (“[A]dministering cases in multidistrict litigation is different from administering cases on a routine docket.”; finding no abuse of discretion in MDL court’s dismissal of claims for failure to comply with discovery and product identification case management orders); *Freeman v. Wyeth*, 764 F.3d 806, 809 (8th Cir. 2014) (affirming MDL court’s dismissal of claims for failure to provide medical authorizations); *In re Asbestos Prods. Liab. Litig.*, 718 F.3d at 246 (“[A]dministering cases in multidistrict litigation is different from administering cases on a routine docket.”) (quoting *In re PPA*, 460 F.3d at 1229).

⁴ *In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008) (internal citations omitted). Appellate courts have regularly upheld these sorts of Case Management Orders in MDL proceedings. *See, e.g., In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1232 (9th Cir. 2006) (stating that “[c]ase management orders are the engine that drives disposition on the merits,” and finding no abuse of discretion in MDL court’s dismissal of claims for failure to comply with discovery and product identification case management orders); *United States v. Graf*, 610 F.3d 1148, 1169 (9th Cir. 2010) (*citing United States v. W.R. Grace*, 526 F.3d 499, 508-09 (9th Cir. 2008) (en banc)) (“A district court has broad authority to enter pretrial case management orders to ensure that the trial proceeds efficiently.”); *In re Avandia*, 687 F. App’x at 214 (affirming MDL court’s dismissal for failure to comply with an order requiring that future plaintiffs provide an expert report); *Dzik v. Bayer Corp.*, 846 F.3d 211, 216 (7th Cir. 2017) (affirming MDL court’s dismissal for plaintiff’s failure to comply with discovery order and stating that “[d]istrict courts handling complex, multidistrict litigation ‘must be given wide latitude with regard to case

5. The broad discretion afforded to the Court enables it to enter case management orders after substantial discovery has taken place in a mature mass tort or multidistrict litigation where, as here, a defendant has taken steps to settle a significant portion of the claims pending against it.⁵ Many MDL courts have exercised their discretion and inherent authority to enter orders establishing discovery and other requirements for future cases filed against settling defendants in mass tort litigation.⁶

6. In the nearly three years since this MDL was formed, the parties and the Court have expended extraordinary resources to effectively and expeditiously manage these matters. Among other things: The parties and the Court have participated in a Science Day. The Parties have briefed various motions to dismiss, including motions to dismiss amended master complaints, and this Court (with the assistance of a Special Master) has determined various aspects of those

management’ in order to achieve efficiency”) (citation omitted); *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) (“*Lone Pine* orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed. R. Civ. P. 16.”).

⁵ See *Avila v. Willits Env’t Remediation Tr.*, 633 F.3d 828, 833 (9th Cir. 2011) (noting such orders are authorized by district judge’s “broad discretion to manage discovery and to control the course of litigation under Federal Rule of Civil Procedure 16”).

⁶ See, e.g., *In re Am. Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2325, Pretrial Order # 239, ECF No. 4272 (S.D.W. Va. June 7, 2017) (establishing requirements for future claims against a defendant due to “recent settlement developments” of thousands of claims after more than three years of litigation); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, Case Management Order No. 126, ECF No. 2716 at 1-2 (N.D. Ill. June 11, 2018) (finding it appropriate to enter an order to manage remaining litigation in light of the parties’ settlement agreements entered after years of litigation); *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. CV 18-MD-2848, 2022 WL 952179, at *2-3 (E.D. Pa. Mar. 30, 2022) (quoting 28 U.S.C. § 1407(a)) (“A *Lone Pine* management order is the only viable way that ‘will promote the just and efficient conduct of [these] actions.’”); *In re Proton-Pump Inhibitor Prods. Liab. Litig. (No. II)*, MDL 2789, Case Management Order No. 109, ECF 955 (D.N.J. Oct. 2, 2023) (recognizing the utility of docket control orders “when a defendant has taken steps to settle a significant portion of the claims pending against it”) (collecting cases).

motions, in whole or in part. The parties successfully settled the economic loss claims on a class-wide basis. The Census Registry has been active since September 2022, and more than 58,000 potential claimants have registered. This Court has provided notice of the Census Registry on the Court's website since September 2022. The Personal Injury Plaintiffs have been participating in the Short Form Complaint and Plaintiff Fact Sheet process since October 2022, submitting over 170,000 documents to MDL Centrality. The Philips Defendants have submitted nearly 600 Defendant Fact Sheets. The parties have taken more than 50 depositions, including of third parties, and exchanged millions of documents on all relevant issues, including extensive testing relating to general causation, both prior to and after the Recall. The Discovery Special Master has resolved many discovery disputes among the parties. The Court has heard argument on privilege issues, jurisdictional issues, and numerous rounds of dispositive motions, and the parties have participated in numerous conferences with the Court and the Special Masters. In short, proceedings in this MDL are very mature.

7. Recognizing that continued litigation in pursuit of remaining claims will require enormous strain on the parties and the judiciary, and without admission of fault or liability, the parties entered into the MSA, which creates a program to resolve those Personal Injury Claims for which Plaintiffs' Negotiating Counsel believe there is any expert and/or scientific support (*i.e.*, claims asserting Qualifying Injuries).

8. For these and other reasons, the Court orders as follows:

II. STAY OF PROCEEDINGS PENDING SETTLEMENT REGISTRATION PROCESS

9. So as to afford plaintiffs the opportunity to consider the Settlement Program, and to ensure the orderly and effective administration of the Settlement Program, all deadlines for the Personal Injury and Medical Monitoring Tracks set in this Court's Order of April 16, 2024 (ECF

No. 2727) are hereby vacated. Further, absent agreement of the Philips Defendants and Plaintiffs' Negotiating Counsel, all Personal Injury Claims against one or more of the Philips Defendants are hereby stayed through and including the Registration Deadline.

10. If after the Registration Deadline, any cases remain for which a Litigating Plaintiff has moved to remand to state court, the Court will set a schedule for those motion(s), including oral argument, following the Registration Deadline.

11. In light of the withdrawal of the Philips Defendants from the Census Registry Program Agreement and the termination of the Census Registry Program, the Clerk is hereby directed to remove the Census Registry Program Agreement from the Court's website.

III. PRESERVATION NOTICE REQUIREMENTS

12. No later than 30 days after the date on which an individual becomes a Litigating Plaintiff as defined above, counsel for the Litigating Plaintiff (or, if unrepresented, the *pro se* Litigating Plaintiff) shall notify the following individuals or entities, in writing, that they may have records relevant to the Litigating Plaintiff's claims and that any records relating to the Litigating Plaintiff must be preserved pending collection by the Litigating Plaintiff (the "Notice" or "Notices"):

- a. All physicians and/or other healthcare providers who treated the Litigating Plaintiff, including mental health treatment providers for a Litigating Plaintiff alleging injury related to mental health;
- b. All physicians and/or other healthcare providers who prescribed the Recalled Device(s) to the Litigating Plaintiff;
- c. Any person (if not the Litigating Plaintiff) in possession, custody or control of the Recalled Device(s);

- d. For Litigating Plaintiffs alleging death, all pathologists and coroners; and
- e. If a Litigating Plaintiff is seeking lost wages, all of his or her employers for the period from three years prior to the date for which he or she is seeking lost wages, through the last day for which the Litigating Plaintiff is seeking lost wages.

13. All copies of the Notices shall be preserved by counsel for the Litigating Plaintiff or the *pro se* Litigating Plaintiff for so long as the claim remains pending. Counsel for the Litigating Plaintiff or the *pro se* Litigating Plaintiff shall also serve a statement, or serve a supplement to their Plaintiff Fact Sheet, identifying the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a signed certification that the Notices were sent as required by this Order with their Plaintiff Fact Sheet.

14. Litigating Plaintiffs may not seek to introduce into evidence at trial any document or information from anyone to whom Notice was required to be provided if a Notice was not sent to such person as required by this Order, except with leave of Court for good cause shown.

IV. LITIGATING PLAINTIFFS' REQUIREMENTS TO PRODUCE CERTAIN SPECIFIED INFORMATION REGARDING THEIR CLAIMS

15. All Litigating Plaintiffs shall serve the following documents and/or information upon counsel for Defendants within the timeframe provided in Section V. All Litigating Plaintiffs' productions shall comply with the search, production, and certification requirements of Pretrial Order No. 18 (ECF No. 660).

a. Litigating Plaintiffs' Production Requirements⁷

- i. All disclosures required by Fed. R. Civ. P. 26(a)(1).
- ii. Litigating Plaintiff Fact Sheet. Each Litigating Plaintiff must prepare and submit to Defendants a Fact Sheet and all accompanying authorizations for the release of records, in the forms attached to the Litigating Plaintiff Fact Sheets, signed under penalty of perjury.
- iii. Medical Records. All medical records relating to the Litigating Plaintiff from any time before, during and after the Litigating Plaintiff's use of the Recalled Device, including mental health records if Litigating Plaintiff alleges an injury related to mental health.
- iv. Autopsy Reports and Death Certificates. For all Litigating Plaintiffs alleging death, all autopsy reports regarding the deceased, as well as any accompanying notes or records.
- v. Records Relating to Use of the Recalled Device and any CPAP, BiPAP, or mechanical ventilator acquired to replace the Recalled Device (a "Replacement Device"). All documents evidencing any use (or non-use) of the Recalled Device or Replacement Device, including but not limited to DreamMapper data, photos, videos,

⁷ All documents produced pursuant to Section 12(a) will be deemed "Confidential" under the Amended Stipulated Protective Order, ECF No. 765, in the first instance, subject to a later process of re-designating these materials and challenges to any re-designation.

messages, emails, chats, social media, materials indicating instructions or habits with respect to cleaning the Recalled Device or Replacement Device, or other communications relating to the use or non-use of the Recalled Device or Replacement Device.

- vi. Record Collection Production. The Litigating Plaintiff and his/her counsel shall affirmatively collect and produce such records from all available sources in the Litigating Plaintiff's possession, custody, or control, which includes but is not limited to any relevant records that can be collected from the Litigating Plaintiff's medical facilities and health care providers that treated the Litigating Plaintiff. Counsel for the Litigating Plaintiff (or the *pro se* Litigating Plaintiff) shall be responsible for submitting necessary authorizations or other requests required to obtain the Litigating Plaintiff's medical records, personnel files and other documents required by this Order. Because of the need to ensure timely and thorough collection and production and review of all relevant records by the parties, a Litigating Plaintiff and his/her counsel, if any, must **both collect and produce records** **and** provide authorizations in order to comply with this Order.
- vii. Declaration. A Declaration under penalty of perjury signed by the Litigating Plaintiff's counsel attesting (i) that the Litigating Plaintiff has provided a Litigating Plaintiff Fact Sheet, executed under penalty of perjury; (ii) that all available records in the Litigating

Plaintiff's possession, custody or control described in the foregoing sections have been collected and produced; (iii) that the Litigating Plaintiff's production complies with all of the requirements of Pretrial Order No. 18; and (iv) that counsel has met with the Litigating Plaintiff, personally investigated the merit of Litigating Plaintiff's claim(s) and satisfied himself or herself that the claim(s) is/are meritorious, and discussed with the Litigating Plaintiff their claims and likelihood of success. If any of the documents or records described in the foregoing sections do not exist or exist but cannot be obtained, the signed affidavit by the Litigating Plaintiff's counsel shall state that fact and the reasons why such materials do not exist or cannot be obtained, and shall provide a "No Records Statement" from each records custodian (or proof of return to sender from the United States Postal Service if the last known address of the medical provider is no longer valid).

b. Litigating Plaintiffs' Proof of Injury Requirements

16. All Litigating Plaintiffs shall serve upon Defendants, within the timeframe provided in Section V, all medical records that document the Litigating Plaintiff's alleged diagnosis and related injuries, including but not limited to a contemporaneous statement from the diagnosing physician that the Litigating Plaintiff was diagnosed with the alleged injury, all diagnostic reports, x-rays, CT scans, PET scans, laboratory reports, treatment plans, Emergency Room and Urgent Care records, and pharmaceutical records.

c. Litigating Plaintiffs' Expert Reports

17. All Litigating Plaintiffs shall serve upon counsel for Defendants, within the timeframe provided in Section V, expert report(s) in compliance with Federal Rule of Civil Procedure 26, including, but not limited to, on the following topics:

- i. an opinion that the Litigating Plaintiff has a specified personal injury both generally and specifically caused by a Recalled Device, and how the Recalled Device both generally and specifically caused such Litigating Plaintiff's alleged personal injury;
- ii. an opinion ruling out alternative causes for the Litigating Plaintiff's alleged personal injury;
- iii. a detailed description of facts, medical and scientific literature, testing, and any other authorities relied upon by the expert to support such opinions;
- iv. a description of all of the Litigating Plaintiff's alleged damages; and
- v. a complete set of records relied upon in forming the expert's opinions, including any medical records and test results.

18. Form or template reports are not permitted and will be stricken by the Court.

V. COMPLIANCE

a. Deadline

19. The items required by Section IV shall be produced no later than 60 days after the date on which an individual becomes a Litigating Plaintiff, except that expert reports shall be produced no later than 90 days after such date.

b. Failure to Comply

20. The Court has entered this Order establishing requirements and setting deadlines for the purpose of ensuring that further pretrial litigation against the Defendants in this mature MDL will progress as smoothly and efficiently as possible. Should any Litigating Plaintiff fail to fully comply with the obligations of this Order, such Litigating Plaintiff's case is subject to dismissal with prejudice.

21. In the event any Litigating Plaintiff fails to fully comply with the requirements of this Order, Counsel for Defendants shall notify the Court of the alleged deficiencies, and the Court shall enter an Order to Show Cause why the Litigating Plaintiff's case should not be dismissed with prejudice. Counsel for Litigating Plaintiffs (or, if unrepresented, the *pro se* Litigating Plaintiffs) shall have 21 days to respond to said Order to Show Cause. If any of the Litigating Plaintiffs fail to cure the deficiencies or show good cause why their case should not be dismissed with prejudice within 21 days of the entry of the Order to Show Cause, those Litigating Plaintiffs' claims will be dismissed with prejudice.

VI. ADDITIONAL CASE-SPECIFIC DISCOVERY AND RELATED MOTION PRACTICE FOR INDIVIDUAL LITIGATING PLAINTIFFS

22. If a Litigating Plaintiff provides all the materials contemplated by this Order, the Court shall set further deadlines for management of the case, including deadlines (i) for Defendants' expert reports on general causation, (ii) for motion practice on general causation, including under Rule 702, (iii) for additional case-specific discovery following decision(s) on general causation, and (iv) for motion practice on remaining issues, including specific causation and summary judgment.

23. Based upon the outcome of these motions, if appropriate, the Court will set Case Management Conferences to determine whether any non-duplicative discovery, including

additional expert disclosures, is necessary and to discuss other case management issues. The filing and briefing of summary judgment motions and Rule 702 motions (which the Court will schedule) shall not prejudice or otherwise foreclose the opportunity for any party to file later, non-duplicative summary judgment and Rule 702 motions after completing any additional discovery. Any party seeking to file non-duplicative dispositive motions, including motions related to personal jurisdiction, must first file a motion seeking to file the non-duplicative dispositive motions and requesting a Case Management Conference. At the Case Management Conference, the Court, if the motion to file non-duplicative dispositive motions is granted, will set deadlines for filing and responding to such motions. The filing of serial summary judgment motions is disfavored by the Court.

24. Upon the expiration of the Registration Deadline, counsel for the Philips Defendants shall promptly notify the Court that the deadline for registration in the Settlement Program has expired and shall request a conference with the Court within 60 days thereafter.

SO ORDERED, on this 9th day of May 2024.

/s/ Joy Flowers Conti
Joy Flowers Conti
Senior United States District Judge