2018 WL 6258898
Only the Westlaw citation is currently available.
United States District Court, N.D. Illinois, Eastern Division.

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION
This document relates to all cases
Master Dkt. Case No. 1:14-cv-01748
|
MDL No. 2545
|
Signed 06/11/2018

CASE MANAGEMENT ORDER NO. 126 (Docket Control Order For Future Cases Against Eli Lilly, Endo, Auxilium, & GSK)

MATTHEW F. KENNELLY, UNITED STATES DISTRICT JUDGE

***1** This Case Management Order ("CMO") applies to all Plaintiffs alleging personal injury (and related) claim(s) against Eli Lilly and Company, Lilly USA, LLC, Acrux Commercial Pty Ltd., and Acrux DDS Pty Ltd. (individually an "Eli Lilly Defendant" and collectively the "Eli Lilly Defendants"), and/or against Auxilium Pharmaceuticals, LLC (f/k/a Auxilium Pharmaceuticals, Inc.), Endo Pharmaceuticals Inc., and/or GlaxoSmithKline LLC (individually an "Endo Defendant" and collectively the "Endo Defendants") who have cases pending against the Eli Lilly Defendants and/or the Endo Defendants as of the date this CMO is entered and elect not to settle under the voluntary settlement program, and all Plaintiffs with cases alleging personal injury (and related) claim(s) against the Eli Lilly Defendants and/or the Endo Defendants that are newly filed in, removed to, or transferred to this MDL after the entry of this CMO ("Litigating Plaintiffs") (collectively, the "Parties").

Consistent with the Court's inherent authority to manage these judicial proceedings, and in light of the respective Master Settlement Agreements that the Eli Lilly Defendants and Plaintiffs' Counsel and the Endo Defendants and Plaintiffs' Counsel entered after over four years of litigation, the Court finds it appropriate at this time to exercise its discretion to enter this CMO in order to efficiently manage any cases against the Eli Lilly Defendants and the Endo Defendants by Litigating Plaintiffs, while separately managing the litigation against the remaining defendants that are not subject to settlement agreements and/or a related stay.

This CMO requires all Litigating Plaintiffs to produce certain specified information regarding their claim(s) and provides for expedited bifurcated discovery on statute of limitations, other time-based defenses, and causation issues, and related dispositive motion practice, prior to any further discovery. Litigating Plaintiffs who represent themselves *pro se* shall be bound by the requirements of this CMO and shall fully comply with all obligations required of counsel by this CMO, unless otherwise stated.

A. Background and Status of Proceedings

1. In June 2014, the United States Judicial Panel on Multidistrict Litigation ("JPML") established MDL No. 2545 to centralize cases against several defendants, including the Eli Lilly Defendants and the Endo Defendants, alleging injuries arising from the use of testosterone replacement therapy ("TRT") products. *In re Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014). Over 7,700 cases have been filed in, removed to, or transferred to the MDL, and of these, over 500 cases have named one or more of the Eli Lilly Defendants, and over 1,300 cases have named one or more of the Endo Defendants.

2. As the Seventh Circuit has recognized, "a court has the inherent authority to manage judicial proceedings and to regulate the conduct of those appearing before it." *Ramirez v. T&H Lemont, Inc.*, 845 F. 3d 772, 776 (7th Cir. 2016). This power extends to, for example, "controlling and scheduling discovery, including orders affecting disclosures and discovery under 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).

***2** 3. Case management is of the utmost importance in proceedings of this size, and MDL courts have even "greater discretion to organize, coordinate and adjudicate [their] proceedings." *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); *see also* *In re Phenylpropanolamine Prod. Liab. Litig.*, 460 F.3d 1217, 1229 (9th Cir. 2006) ("*In re PPA*") ("administering 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). This is particularly true with respect to managing discovery and taking actions designed to move the cases "in a diligent fashion toward resolution by motion, settlement or trial." *In re PPA*, 460 F.3d at 1232.

4. During the course of these MDL proceedings, this Court has exercised its discretion and inherent authority and has established "separate discovery ... tracks for the various products" at issue in this MDL. Fed. R. Civ. P. 1; Fed. R. Civ. P. 16(c); *see also In re Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379-80 (J.P.M.L. 2014).

5. The Court is aware that, without admission of fault or liability, the Eli Lilly Defendants and the Endo Defendants have separately entered into Master Settlement Agreements to resolve cases alleging personal injury (and related) claims against them related to TRT products. Because the Eli Lilly Defendants and Plaintiffs' Counsel entered a Memorandum of Understanding regarding settlement, the Court entered CMO 92 on December 21, 2017, staying proceedings involving the Eli Lilly Defendants [Dkt. No. 2313], and on February 6, 2018, the Court extended the stay [Dkt. No. 2359]. Because the Endo Defendants and Plaintiffs' Counsel entered a Memorandum of Understanding regarding settlement, the Court entered CMO 98 on February 23, 2018, staying proceedings involving the Endo Defendants [Dkt. No. 2377]; on March 12, 2018, the Court entered CMO 103 clarifying the stay [Dkt. No. 2399]; on April 9, 2018, the Court entered CMO 111 extending the stay through May 24, 2018 [Dkt. No. 2435]; and on May 25, 2018, the Court entered CMO 122 extending the stay through June 4, 2018 [Dkt. No. 2670]. Proceedings in this MDL have not been stayed against the remaining defendants, and bellwether trials are scheduled involving these defendants.

6. Docket Control Orders "have been routinely used by courts to manage mass tort cases." *In re Vioxx Prod. Liab. Litig.*, 557 F. Supp. 2d 741, 743 (E.D. La. 2008) (Fallon, J.). Appellate courts have regularly upheld their use in MDL cases. *See, e.g.*, *Dzik v. Bayer Corp.*, 846 F.3d 211, 216 (7th Cir. 2017) (affirming MDL court's dismissal for failure to comply with discovery order; "District courts handling complex, multidistrict litigation must be given wide latitude with regard to case management in order to achieve efficiency.") (internal quotation marks omitted); *In re Avandia Marketing, Sales Practices & Prods. Liab. Litig.*, 687 F. App'x 210, 2017 WL 1401285, at *214 (3d Cir. Apr. 19, 2017) (affirming MDL court's dismissal for failure to comply with an order requiring future plaintiffs to provide an expert report; "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 Judicial Panel on Multidistrict Litigation' ") (citation omitted); *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) (such "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").

***3** 7. Though earlier in this litigation this Court exercised its discretion and denied requests to enter so-called "*Lone-Pine*" orders as premature and unnecessary based on, among other things, other available discovery mechanisms, such orders may be particularly appropriate when a defendant has taken steps to settle a significant portion of the claims pending against it. *See, e.g., In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, MDL No. 2385 (S.D. Ill. May 29, 2014), *available at* http://www.ilsd.uscourts.gov/documents/mdl2385/CMO78.pdf (in settlement context, requiring non-settling plaintiffs to produce causation expert reports); *see also In re Vioxx Prods. Liab. Litig.*, MDL No. 1657 (E.D. La. 2008), Pretrial Order No. 28 (*available at* http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto28.mdl.pdf) and Pretrial Order No. 29

(*available at* http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto29.mdl.pdf).

8. Moreover, this Court finds it particularly appropriate to enter this Docket Control Order so the Court can efficiently manage an MDL that is proceeding on a settlement front with certain defendants. Another MDL court recently exercised its discretion and inherent authority to enter an order establishing certain discovery and other requirements for future cases filed against certain settling defendants (but not against other non-settling defendants) in tort litigation regarding transvaginal mesh. *In re American Medical Systems, Inc. Pelvic Repair Systems Prods. Liab. Litig.*, MDL No. 2325 (S.D. Va. June 7, 2017) (the "AMS Mesh MDL"). The AMS Mesh MDL is one of seven centralized MDL proceedings pending before Judge Goodwin in the Southern District of West Virginia arising from different mesh products manufactured by different defendants. The court explained that it was establishing these requirements for future claims against the AMS defendants only due to "recent settlement developments," in particular a "dramatic[ ]" decline in the number of cases against AMS on the active docket "[a]s a result of AMS's efforts and those of multiple counsel for plaintiffs." *Id.* at 1-2. The Court recognized that:

> [C]ase management is of the utmost importance and the Court is vested with substantial discretion to manage discovery and set deadlines that will help secure "the just, speedy, and inexpensive determination of every action and proceeding."

Id. at 2 (citation omitted). The parties' significant progress in resolving existing claims made it appropriate to establish requirements for the speedy and just resolution of any future claims. *See id.* at 2. These requirements included expert disclosures regarding causation, among other items, for newly filed cases. *See id.* at 3-7. Those requirements were not at that time applied to claims against non-settling defendants.

For the foregoing reasons, and other good cause appearing therefor, it is Ordered as follows:

B. Litigating Plaintiffs' Requirements To Produce Certain Specified Information Regarding Their Claims

9. **Litigating Plaintiffs' Production Requirements:** Litigating Plaintiffs shall serve the following documents and/or information upon counsel for the Eli Lilly Defendants and/or the Endo Defendants, as applicable, in the service manner described in Third Amended CMO 9:

> a. **Third Amended CMO 9 Obligations:** If not already completed, executed, and served, the Litigating Plaintiff must comply with all requirements of Third Amended CMO 9, including but not limited to producing all medical records that document the Litigating Plaintiff's, or if different the associated TRT user's ("Associated User's"), alleged TRT-related injury/injuries, and pharmacy records/medical records for the Litigating Plaintiff's or the Associated User's TRT prescription(s) and/or samples.
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> ***4** b. **Pharmacy Records:** All pharmacy records and medical records regarding the dispensation of any prescription medication and/or samples to the Litigating Plaintiff or the Associated User for the period from five (5) years prior to the date of the alleged injury to the present.
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> c. **Medical Records:** All medical records relating to the Litigating Plaintiff or the Associated User from health care providers for the period from five (5) years prior to the date of the Litigating Plaintiff's or the Associated User's first use of TRT to the present.
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> d. **Record Collection Production**: The Litigating Plaintiff and his/her counsel shall affirmatively collect and produce such Pharmacy and Medical Records from all available sources in the Litigating Plaintiff's possession, custody or control, which includes but is not limited to any relevant Pharmacy and Medical records that can be collected from the Litigating Plaintiff's or the Associated User's medical facilities, health care providers, and/or pharmacies that treated and/or dispensed drugs to, or for, the Litigating Plaintiff or the Associated User. A Litigating Plaintiff and his/her counsel shall not be in compliance with this CMO by producing only records in the Litigating Plaintiff or his/her counsel's current possession, or by only producing authorizations to allow the Eli Lilly Defendants and Endo Defendants to collect such records.
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> e. **Affidavit:** An affidavit signed by the Litigating Plaintiff and his/her counsel (i) attesting that the

Litigating Plaintiff has complied with all requirements of Third Amended CMO 9; (ii) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Litigating Plaintiff or the Associated User covered by paragraph B.9.b; (iii) attesting that all medical records described in paragraph B.9.c. have been collected; and (iv) attesting that all records collected have been produced pursuant to this CMO. If any of the documents or records described in Sections B.9.a., B.9.b., or B.9.c. do not exist, the signed affidavit by the Litigating Plaintiff and the Litigating Plaintiff's counsel shall state that fact and the reasons, if known, why such materials do not exist, and shall provide a "No Records Statement" from the pharmacy, medical facilities, and/or other healthcare provider.

f. **Expert Reports:** Expert reports in compliance with Federal Rule of Civil Procedure 26 as follows:

i. A Rule 26(a)(2) expert report on general causation concerning the alleged injury/injuries.

ii. A Rule 26(a)(2) case-specific expert report concerning the causation of the Litigating Plaintiff's or the Associated User's alleged injury/injuries. The reports required by Sections B.9.f.i and B.9.f.ii may be combined in a single report by a single expert.

iii. A Rule 26(a)(2) expert report on the basis for liability concerning the Eli Lilly Defendants and/or Endo Defendants—*e.g.*, support for allegations that the Eli Lilly Defendants' and/or Endo Defendants' warning label(s) were inadequate, that they failed to adequately test and/or monitor the safety of their TRT product(s), and/or that they marketed their TRT product(s) off-label.

10. Deadline to comply:

a. For each Litigating Plaintiff with personal injury (and related) claims pending against one or more of the Eli Lilly Defendants and/or the Endo Defendants as of the entry of this CMO who elects not to settle under the voluntary settlement program, the items required by paragraph B.9 shall be produced no later than 90 days after the date such Litigating Plaintiff elects not to settle his/her claims.

***5** b. For each Litigating Plaintiff with personal injury (and related) claims newly filed in, removed to, or transferred to this MDL against one or more of the Eli Lilly Defendants and/or the Endo Defendants after the entry of this CMO, the items required by paragraph B.9 shall be produced no later than 90 days after the case is filed in, removed to, or transferred to this MDL.

11. **Failure to comply:** The Court has established the foregoing deadlines for the purpose of ensuring that pretrial litigation against the Eli Lilly Defendants and the Endo Defendants will progress as smoothly and efficiently as possible. Accordingly, the Court expects strict adherence to these deadlines. Should any Litigating Plaintiff fail to comply with the obligations of paragraphs B.9, B.10, and C.12 or should the Eli Lilly Defendants and/or the Endo Defendants deem the Litigating Plaintiff's compliance with this CMO deficient, counsel for the Eli Lilly Defendants and/or the Endo Defendants, as applicable, shall notify the Court of the alleged deficiency, and the Court shall issue an "Order To Show Cause Why the Case Should Not Be Dismissed With Prejudice and/or Sanctions Ordered." Litigating Plaintiff's counsel shall have 21 days to respond to said Order To Show Cause, which includes the ability to cure the alleged discovery deficiency. There shall be no imposition of a sanction for any Litigating Plaintiff who cures a deficiency within 21 days after entry of an Order to Show Cause. If the Litigating Plaintiff fails to show cause within 21 days of entry of the Court's Order To Show Cause, the Court shall dismiss the Litigating Plaintiff's case with prejudice and may impose additional sanctions the Court deems appropriate. *See, e.g., Freeman*, 764 F.3d at 810; *In re PPA*, 460 F.3d at 1232.

C. Discovery For Cases Filed, Removed to or Transferred to This MDL After The Date of This CMO

12. Litigating Plaintiffs whose claims against the Eli Lilly Defendants and/or the Endo Defendants are filed in, removed to, or transferred to this MDL after the entry of this CMO must, within 80 days of the claims being filed in, removed to, or transferred to this MDL, serve upon counsel for the Eli Lilly Defendants and/or the Endo Defendants, as applicable, in the manner described in Third Amended CMO 9 an affidavit signed by the Litigating Plaintiff and his/her counsel, providing the

following information: (1) the date the Litigating Plaintiff first learned his or the Associated User's alleged injury/injuries may be related to TRT use; (2) how the Litigating Plaintiff first learned his or the Associated User's alleged injury/injuries may be related to TRT use; (3) the date the Litigating Plaintiff or the Associated User first spoke to or corresponded with an attorney about potential litigation related to TRT use; and (4) the date the Litigating Plaintiff first retained counsel for litigation related to TRT use. The Eli Lilly Defendants and Endo Defendants are permitted to serve written discovery on Litigating Plaintiffs related to these topics (and others), and Litigating Plaintiffs must respond to the discovery prior to the Eli Lilly Defendants' or the Endo Defendants' depositions of Litigating Plaintiff or the Associated User and Litigating Plaintiff's or the Associated User's prescribing and treating healthcare providers, provided that Litigating Plaintiff shall have at least 30 days to respond to such discovery.

D. Expedited Case-Specific Bifurcated Discovery On Statute of Limitations, Other Time-Based Defenses, and Causation Issues And Related Dispositive Motion Practice

***6** 13. If a Litigating Plaintiff complies with the production requirements outlined above in paragraphs B.9, B.10, and C.12, then the Parties, as applicable, shall submit a proposed Scheduling Order to the Court that: (a) grants the Parties 180 days from the entry of the Scheduling Order to conduct expedited bifurcated discovery on case-specific statute of limitations, other time-based defenses, and causation issues ("Expedited Discovery"); and (b) sets a briefing schedule that gives the Parties 45 days from the close of Expedited Discovery for the Parties to submit summary judgment motions and *Daubert* motions, 28 days for responses, and 28 days for replies.

14. The Parties shall have 180 days to conduct expedited bifurcated discovery on statute of limitations, other time-based defenses, and causation issues, which includes the adequacy of the Eli Lilly Defendants' and Endo Defendants' TRT labels at various times. During such expedited discovery, the Parties are permitted to: (a) serve written discovery related to statute of limitations, other time-based defenses, and causation issues specific to the Litigating Plaintiff; (b) take the depositions of the Litigating Plaintiff, the Litigating Plaintiff's or Associated User's spouse, and any other non-party fact witness specific to the Litigating Plaintiff identified in the Plaintiff Fact Sheet or through other discovery for up to seven hours each, with counsel for the Eli Lilly Defendants or the Endo Defendants, as applicable, questioning first at each deposition; (c) take the depositions of each of the Litigating Plaintiff's or Associated User's prescribing and treating healthcare providers, with counsel for the Eli Lilly Defendants or the Endo Defendants, as applicable, questioning first at each deposition. If a Litigating Plaintiff serves any written discovery upon the Eli Lilly Defendants or the Endo Defendants pursuant to clause (a) above, the Parties shall meet and confer about an appropriate deadline for responding to such discovery, which deadline shall be at least 60 days after service of such discovery. The Court's use of the term "specific to the Litigating Plaintiff" is intended to express the Court's intention not to permit additional "generic" discovery against the Eli Lilly Defendants and the Endo Defendants, as that discovery has already been completed in the MDL. No other depositions, including depositions of current and former sales representatives and managers of the Eli Lilly Defendants and the Endo Defendants, may be taken during the expedited discovery period absent prior leave granted by the Court upon a showing of good cause.

15. If a case survives the Eli Lilly Defendants' and/or the Endo Defendants' summary judgment motions, as applicable, the Court will set a Case Management Conference to determine whether any non-duplicative additional discovery is necessary and to discuss other case management issues. The filing and briefing of summary judgment motions and *Daubert* motions after the Expedited Discovery discussed above shall not prejudice or otherwise foreclose the opportunity for the Parties to file later, non-duplicative summary judgment and *Daubert* motions after completing full fact and expert discovery. The Court's use of the term "non-duplicative" is intended to express the Court's intention not to permit later summary judgment motions concerning topics addressed in summary judgment motions filed at the conclusion of the expedited discovery period or *Daubert* motions concerning witnesses addressed in *Daubert* motions filed at the conclusion of the expedited discovery period.

IT IS SO ORDERED.

All Citations

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