UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: All cases	)	

ORDER AND REASONS

Before the Court is a Motion for Entry of an Order Requiring Proof of Diagnosis filed by Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants") (Rec. Doc. 16607). For the reasons set forth herein, Sanofi's Motion is **GRANTED IN PART**. Accordingly, the Court enters Case Management Order No. 40, attached hereto.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent chemotherapy-induced alopecia ("PCIA"). Plaintiffs bring various claims including failure to warn, negligent misrepresentation, and fraudulent misrepresentation.

[1] Docetaxel is the generic version of Taxotere, although the Court uses the term "generic" loosely.

This litigation, which is in its eighth year, has encountered numerous roadblocks in both the bellwether selection and remand and/or transfer processes. As Sanofi points out, approximately half of the cases selected as bellwethers were removed or disqualified from the pool for, among other things, failure to establish product identification or failure to provide requisite photographs of the alleged hair loss injury.[2] Another four cases were voluntarily dismissed with prejudice by Plaintiffs.[3] Of the 19 bellwether cases to face dispositive motion practice, all but two were dismissed.[4] Thus, even after careful selection, the majority of selected cases could not reach trial.

Similarly, numerous cases that were initially selected to be remanded/and or transferred were subsequently found to be ineligible. The remand/transfer process was divided into multiple "waves": "Wave 1" and "Wave 2." On April 19, 2022, two hundred cases were identified as candidates for the Wave 1 remand.[5] By April 3, 2023, only 93 cases remained in Wave 1.[6] Plaintiffs in the balance of the originally nominated cases dismissed their lawsuits, asked to defer to a later wave, or were ruled or agreed to be ineligible for Wave 1. On May 22, 2023, the Court transferred 82 cases back to their designated venues in the district courts.[7] Since that time, approximately 20 additional Wave 1 cases have resolved, and three have been dismissed on remand to the transferor courts.

On June 23, 2023, this Court identified a list of 1,000 cases selected to comprise Wave 2.[8] After conferral, the parties identified 427 cases that were

[2] Rec. Doc. 16607-1 at 7.
[3] *Id.* at 7.
[4] *Id.*
[5] Case Management Order No. 34 ("CMO 34") (Rec. Doc. 14045) identified 200 cases selected by the Court and parties for the Wave 1 remand process set forth in Case Management Order No. 33 ("CMO 33") (Rec. Doc. 13946).
[6] Rec. Doc. 15761.
[7] Rec. Doc. 15836.
[8] Rec. Doc. 16347.

not amenable to transfer due to questions of product identification, subject matter jurisdiction, applicability of prior fencepost rulings by the Court, and other concerns related to their candidacy for prosecution.[9] After subsequent settlements, less than 400 cases were ultimately remanded.

Sanofi alleges that, based on available data, more than 80% of the cases in this MDL involve Plaintiffs who have never been diagnosed with the alleged injury, PCIA, and/or have never sought treatment for PCIA.[10] Notably, the bellwether Plaintiffs' hair loss expert and dermatologist has opined that she "cannot make [a] diagnosis [of alopecia] from pictures" because hair loss has many causes that cannot easily be distinguished.[11] Hair loss can be caused by estrogen-reducing hormones;[12] it may also be genetic.[13] In fact, one plaintiff was ultimately removed from the trial pool after her expert dermapathologist diagnosed her with androgenic alopecia (female pattern hair loss), rather than her alleged injury, PCIA.[14]

Citing the above issues with proof, Sanofi previously raised the issue of whether this Court should implement measures for medical corroboration of the specific injury alleged in these lawsuits. Sanofi initially filed its Motion for Entry of an Order Requiring Proof of Diagnosis on July 17, 2020.[15] Following a lead and liaison conference in August 2020, the Court deferred ruling on

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[9] Rec. Doc. 16511.
[10] Rec. Doc. 16607-2 at 2. Notably, the PSC does not refute this point.
[11] Rec. Doc. 16696 at 4.
[12] *Id.* Hormone medications like Tamoxifen, which breast-cancer patients may take for a decade following chemotherapy, can cause hair loss and thinning. *Id.* According to Sanofi, nearly 40% of all Plaintiffs report taking these estrogen-reducing hormone medications, e.g., Arimidex, Tamoxifen, and Femara. *Id.* According to Sanofi, nearly 40% of all Plaintiffs report taking these estrogen-reducing hormone medications, e.g., Arimidex, Tamoxifen, and Femara. *Id.*
[13] *Id.*
[14] Rec. Doc. 16607-1 at 8. Further, Sanofi cites to a study supporting that "[r]oughly 40 percent of all women who live past middle age will develop permanent female pattern hair loss in their lifetime as a by-product of their family history." Rec. Doc. 16696 at 4.
[15] Rec. Doc. 10908.

Sanofi's Motion, subject to being re-urged after the third bellwether trial.[16] After the Court dismissed all of the plaintiffs selected for the third bellwether trial, Sanofi re-urged its Motion in February 2022.[17] The Court declined to make an explicit ruling and entered Case Management Order No. 33, which began the Wave 1 remand process.[18]

Finally, the Court has recently been apprised that Sanofi and certain plaintiffs have reached an agreement in principle anticipated to dispose of approximately 2,500 cases pending before this Court and remanded previously from these proceedings. Thus, with nearly 30% of the pending cases reaching settlement, Sanofi filed the instant Re-Urged Motion for Entry of an Order Requiring Proof of Diagnosis. Plaintiffs, via the Plaintiffs' Steering Committee and Lead and Liaison Counsel, (collectively, "the PSC"), oppose.[19]

LAW AND ARGUMENT

Sanofi requests that this Court enter a *Lone Pine* order, the name of which derives from the New York district court decision *Lore v. Lone Pine Corp.*[20] The United States Court of Appeals for the Fifth Circuit has explained that "*Lone Pine* orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation."[21] "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."[22] *Lone Pine* orders

[16] Rec. Doc. 15834 at 21.
[17] *Id.*
[18] *Id.*
[19] Rec. Doc. 16687. The PSC also submitted a competing Proposed Order at the request of the Court. Rec. Doc. 16705.
[20] 1986 WL 637507, No. L–33606–85 (N.J. Super. Ct. 1986).
[21] Acuna v. Brown, 200 F.3d 335, 340 (5th Cir. 2000) (citing FED. R. CIV. P. 16).
[22] *Id.*

generally require plaintiffs to make a prima facie showing of causation—or face dismissal.[23]

The Fifth Circuit has approved the use of *Lone Pine* orders in mass tort litigation.[24] In *Acuna v. Brown & Root, Inc.*, the Fifth Circuit held that the district court was within its discretion to issue a pre-discovery order mandating that all plaintiffs submit expert affidavits specifying the plaintiffs' injury and the cause; the Fifth Circuit noted that the order "essentially required that information which plaintiffs should have had before filing their claims pursuant to Fed. R. Civ. P. 11(b)(3)."[25]

Although *Acuna* concerned a pre-discovery *Lone Pine* order, since *Acuna*, district courts, including this Court, have entered *Lone Pine* orders near the end of litigation.[26] Indeed, district courts implement such orders before remand to ensure either that "transferor courts receive only viable cases,"[27] or that "only plaintiffs with meritorious cases are compensated" if the parties ultimately reach a settlement.[28] Even so, a *Lone Pine* order is not appropriate

[23] *See In re* Vioxx Prods. Liab. Litig., 557 F. Supp. 2d 741, 744 (E.D. La. 2008) (Fallon, J.); *see also In re* Fosamax Prod. Liab. Litig., No. 06 MD 1789, 2012 WL 5877418, at *3 (S.D. N.Y. Nov. 20, 2012) (noting the plaintiffs' "habit of dismissing cases" when called on to prove causation).
[24] *Acuna*, 200 F.3d at 340.
[25] *Id.*
[26] *See* In re *Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d at 744 (entering *Lone Pine* order requiring evidence of specific causation and citing the "advanced stage of the litigation"); *see also In re* Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., 18-md-2848, 2022 WL 952179, at *2 (E.D. Penn. Mar. 30, 2022) (same).
[27] *Id.*
[28] In re *Fosamax,* No. 06 MD 1789, 2012 WL 5877418, at *3.

in every case or suitable at every stage of litigation.[29] "In crafting a *Lone Pine* order, courts should strike a balance between efficiency and equity."[30]

Sanofi requests that the Court enter an order requiring Plaintiffs who are otherwise eligible for remand to do the following:

1. Certify her willingness to proceed,
2. Provide updated authorizations and an updated Plaintiff Fact Sheet,
3. Submit an expert medical declaration by a qualified physician diagnosing the Plaintiff with PCIA caused by Taxotere, and
4. Participate in certain, limited discovery.[31]

In response, the PSC argues that a *Lone Pine* order is an extraordinary procedure to be implemented only where "existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues" of the litigation.[32] The PSC further argues that entering a *Lone Pine* order would be unfair and prejudicial and could potentially undermine settlement negotiations and stall the remand process.[33]

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[29] In re *Vioxx*, 557 F. Supp. 2d at 744. District Courts have likewise cited the furtherance of settlement negotiations and/or ongoing attempts to settle as factors supporting the issuance of a *Lone Pine* order. *In re* Avandia Mktg., Sales Pracs., and Prods. Liab. Litig., No. 2007-MD-1871, 2010 WL 4720335, at *1 (E.D. Penn. Nov. 15, 2010); *see also* Rec. Doc. 16696 at 7 (citing *In re* Yasmin and Yaz (Drospirenone) Mktg. Sales Pracs. and Prods. Liab. Litig., No. 09-md-02100, at 2 (S.D. Ill. Aug. 3, 2015) (noting that "the parties have successfully negotiated the resolution of a large number of the cases")).

[30] In re *Vioxx,* 557 F.Supp.2d at 744.

[31] Rec. Doc. 16607-1; 16607-2. Only cases involving Product Identification identifying Sanofi as the manufacturer are currently eligible for remand due to the pending appeal on preemption as to the 505(b)(2) Defendants. Rec. Doc. 13946 at 17.

[32] Rec. Doc. 16687 at 4 (quoting Nolan v. Exxon Mobil Corp., No. 13-439, 2016 WL 1213231, at *11 (M.D. La. Mar. 23, 2016)).

[33] The PSC's first argument is that this Court previously ruled on Sanofi's Motion and that the standard for reconsideration under Rule 59(e) is not satisfied. Rec. Doc. 16687 at 7–8. However, as explained above, the Court deferred ruling on Sanofi's first Motion until after the third bellwether trial—which never took place. Rec. Doc. 10908. After the third bellwether pool Plaintiffs were dismissed, Sanofi renewed its request. Rec. Doc. 16687-2. Rather than make an explicit ruling, the Court entered CMO 33, which initiated the Wave 1

The Court finds that a *Lone Pine* order is appropriate at this stage, particularly in light of the parties' recent settlements. Any potential inequities outweigh the need for additional case management procedures as to the remaining, unsettled cases before they proceed to remand. Notably, courts in other jurisdictions have imposed *Lone Pine* orders that "require plaintiffs to furnish specific evidence like proof of a medical diagnosis, with the goal of winnowing non-compliant cases from the MDL"—which is exactly what Sanofi is requesting in the present case.[34]

Moreover, it would not be unduly burdensome to mandate that Plaintiffs obtain basic proof of their injuries by way of a diagnosis. Although Sanofi has requested that Plaintiffs produce what appear to be complete expert reports, the Court will not require a Rule 26(f) expert report at this time. Nor will Plaintiffs be required to produce expert testimony that Taxotere caused their PCIA. Rather, Plaintiffs need only show that they actually have PCIA—rather than some other type of hair loss. After years of discovery, two bellwether trials, and initiation of the remand process, it is time for Plaintiffs to come forward with an affirmative diagnosis—which would otherwise be required to prove their injuries. Thus, as reflected in the attached Case Management Order, Plaintiffs who otherwise qualify for remand will be required to, *inter alia*, produce proof of diagnosis via expert affidavit.

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remand process. Rec. Doc. 16696. Thus, there is no prior decision to alter, amend, and/or reconsider under Rules 59(e).

[34] *In re* Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., 18-md-2848, 2022 WL 952179, at *2 (E.D. Penn. Mar. 30, 2022) (quoting Hamer v. LivaNova Deutschland GmbH, 994 F.3d 173 (3d Cir. 2021)). In the *Zostavax* litigation, numerous plaintiffs appealed the dismissal of their cases after they failed to comply with the district court's *Lone Pine* order mandating that the plaintiffs produce laboratory tests linking the Zostavax vaccine to the alleged injury, shingles. *In re Zostavax*, 18-md-2848, 2022 WL 952179, at *2–3. On appeal, plaintiffs contended that, rather than require the reports at issue, the district court could have chosen alternative ways to prove specific causation, including requiring "expert reports opining that specific causation could be established within a reasonable degree of medical certainty." Brief for Appellant at 20, *In re* Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., No. 23-1032 (3d Cir. April 14, 2023), ECF no. 20.

CONCLUSION

Accordingly, for the foregoing reasons, Sanofi's Motion for Entry of an Order Requiring Proof of Diagnosis (Rec. Doc. 16607) is **GRANTED IN PART.** The Court enters Case Management Order 40, attached hereto.

New Orleans, Louisiana, this 16th day of February, 2024.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
THIS DOCUMENT RELATES TO: ALL CASES	)	

CASE MANAGEMENT ORDER NO. 40

Before the Court is a Motion for Entry of an Order Requiring Proof of Diagnosis filed by Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively "Sanofi") (Rec. Doc. 16607). For the reasons set forth in the foregoing Order and Reasons, Sanofi's Motion is **GRANTED IN PART.** Accordingly, the Court enters the following Case Management Order:

I. Wave 3 Plaintiffs

a. Criteria. This Order applies to all "Wave 3 Plaintiffs." Wave 3 Plaintiffs are those whose cases

i. have not been remanded,

ii. have not settled, and

iii. satisfy the eligibility criteria for transfer as set forth in Case Management Order No. 33 ¶ 3(a) (Sanofi-only Product Identification) and the exclusion criteria set forth in ¶ 4(a) (CMO 12A, Single-Manufacturer Product Identification).

b. Identification of non-settling cases. On or before **June 14, 2024**, the Court will identify all cases the court-appointed mediator in this matter indicates were not settled in the agreement dated February 9, 2024.

c. **Dismissals.** After being identified as a non-settling Plaintiff, Wave 3 Plaintiffs may be removed by voluntary dismissal until **September 12, 2024**. All dismissals of Wave 3 cases shall be with prejudice, unless good cause is shown that dismissal without prejudice is warranted. The provisions of Pretrial Order No. 54 (Rec. Doc. 671) governing dismissals without prejudice otherwise remain in effect.

II. Obligations of Wave 3 Plaintiffs

a. **Certificate of Willingness to Proceed.** On or before **June 21, 2024,**[1] counsel for Wave 3 Plaintiffs must upload to MDL Centrality a certificate indicating that the plaintiff is willing to proceed.[2]

b. **Updated Plaintiff Fact Sheet & Updated Authorizations.** Wave 3 Plaintiffs must physically sign updated authorizations by **July 1, 2024.** Wave 3 Plaintiffs also must review and update, if necessary, the Plaintiff Fact Sheet pursuant to Pretrial Order Nos. 55 (Rec. Doc. 688), 38 (Rec. Doc. 326), and Amended 22 (Rec. Doc. 325) by **July 1, 2024.** Wave 3 Plaintiffs must physically sign verification of any update to the Plaintiff Fact Sheet.

c. **Expert Medical Declaration Confirming Permanent Alopecia on Physical Examination and, if Medically Necessary, Scalp Biopsy.** By **July 1, 2024,** Wave 3 Plaintiffs must upload to MDL Centrality a signed expert declaration, authored by a qualified physician in good standing with his or her

[1] The Court recognizes that the timeframe between identification of non-settling cases and the filing of a certificate of willingness to proceed is short. However, the Court contemplates that counsel will have sufficient time to comply with the Order, given the date of its issuance.
[2] A sample certification is attached to this Order as Exhibit A.

state licensing authority.[3] The declaration shall state that, based on the expert's physical examination of Plaintiff, and a review of the pertinent medical records, the expert is prepared to testify that, to a reasonable degree of medical probability, Plaintiff has suffered permanent chemotherapy-induced alopecia ("PCIA") as alleged in her Complaint(s).

i. The expert declaration must include: (i) certification that the physician physically examined the plaintiff, (in person), (not via telemedicine or other remote application), as well as a description of his or her physical findings and (ii) identification of all documents, including lab results, pathology reports, photographs, medical records, or physical examination reviewed.

ii. Where the physician's normal practices would require the same in order to rule out other forms of alopecia, said declaration must also include the gross and microscopic pathological findings, on scalp biopsy, of the plaintiff.

iii. The expert medical declaration must be uploaded to MDL Centrality using the "Proof of Injury – Post-Order Expert Medical Declaration" document-type field within the deadlines set forth in this Order. The medical declaration shall be physically signed by the physician under penalty of perjury.

[3] The expert must meet the requirements of Rule 702. This includes possessing the appropriate specialized qualifications required to diagnose the injury and its cause (such as certain dermatologists, dermatopathologists, or potentially, certain oncologists). A general practitioner, for example, will not suffice.

iv. No expert report pursuant to Federal Rules of Civil Procedure 26(a)(2)(B) is currently required.

III. Deceased Plaintiffs. For Wave 3 cases in which the alleged victim is deceased, counsel for Plaintiff (or succession representative) must file an affidavit from a qualified expert certifying that the expert physically examined the deceased and that, on any occasion prior to death, the deceased was diagnosed with permanent chemotherapy-induced alopecia.

IV. Wave 3 Discovery

a. Written Discovery. The parties cannot serve written discovery in Wave 3 cases at this time and without further leave.

b. Physician Depositions. Up to four depositions in each case shall be allowed: (i) the plaintiff, (ii) the plaintiff's prescribing physician, (iii) the plaintiff's diagnosing expert, and (iv) one (1) sales representative who called on the plaintiff's "Healthcare Provider" as defined in the Defendant Fact Sheet prior to the plaintiff's treatment.

i. Pretrial Order No. 70B (Rec. Doc. 5256) allows for the ex parte scheduling of depositions by non-attorney staff. It remains in effect. All parties' prior objections to said Order and stated in defendants' Motion to Amend (Rec. Doc. 9109) are expressly preserved.

V. Enforcement. Any Wave 3 Plaintiff who fails to comply with the terms of this Order shall be listed for Non-Compliance and Show Cause Order Process following the ordinary procedures of Pretrial Order No. 22A (Rec. Doc. 3493) and her case shall be dismissed with prejudice, absent a compelling reason. Plaintiffs' objections to entry

of this Order are noted and preserved for purposes of appeal of any dismissal pursuant to it.

New Orleans, Louisiana, this 16th day of February, 2024.

HON. JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	))))	**MDL No. 16-2740** **SECTION: "H" (5)**
THIS DOCUMENT RELATES TO: [*insert case name and number*]	))	

EXHIBIT A

DECLARATION OF [*INSERT NAME OF ATTORNEY*]

I, [*attorney's name*], am an attorney with the law firm of [law firm's name]. I represent [*plaintiff's name*] in the above-captioned matter. [*plaintiff's name*] has been personally contacted and has indicated [*his/her*] willingness to proceed in this litigation.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on_____.

Attorney Signature: _____

Attorney Name: _____