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MEMORANDUM

TO: FDCC 5 Things You Need to Know

FROM: Kelly Strange Crawford

DATE: October 14, 2024

SUBJECT: Drug, Device and Biotechnology

The MDL Court gives the good guys a win in *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, 2024 WL 4362982 (E.D. La. Oct. 1, 2024).

Lone Pine Orders are a helpful tool for defendants in mass tort litigation. If you perform an internet search regarding Lone Pine orders, contributors on the topic suggest that these orders are actually common, but simply infrequently published, thus making research regarding such orders difficult. My experience has been that it often takes an awful lot to finally convince the overseeing court of the utility of such orders in helping to curb the ubiquitous phenomenon of plaintiffs' layers being able to park junk cases in large MDLs or consolidated state court litigations.

For those who are not familiar, Lone Pine Orders are case management orders issued in large, usually consolidated, tort cases that require claimants to come forward with *prima facie* injury, exposure or product identification, and causation evidence by a date certain—or else face dismissal. The name comes from a case in my home state of New Jersey: Lore v. Lone Pine Corp., No. L33606- 85 (N.J. Super.Ct. Law Div., Monmouth Co., Jan. 1, 1986).

The Lone Pine case was a toxic tort matter relating to a landfill. The court required the claimants very early on in the litigation to provide proofs of each claimant's alleged exposure to toxic substances, reports of medical care providers or experts that support causation, and details regarding injury or damage supported by experts. The plan was to ensure that the plaintiffs had adequate evidence to support claims in what was sure to be a very expensive and difficult litigation. Even after

having been granted many extensions, the plaintiffs were not able to produce sufficient objective evidence to demonstrate that they would be able to meet their prima facie claims. The court thus dismissed the case.

The success of the Lone Pine Order led to other courts adopting similar requirements. From the defense perspective, these orders should be required in all such litigation. These orders require plaintiffs to actually do some of the substantive work on their case at the outset of the litigation, rather than waiting for years taking the chance that their case will never be picked for discovery work up and require the expenditure of real money, such as expert fees.

On October 1, 2024, the defense bar received more good news regarding the success of Lone Pine Orders in *In re: Taxotere (Docetaxel) Prods. Liab. Litig.*, 2024 WL 4362982 (E.D. La. Oct. 1, 2024). Taxotere is an MDL in the Eastern District of Louisiana involving a breast cancer chemotherapy drug that allegedly caused permanent, rather than temporary hair loss. In February of 2024, the Court entered an Order granting defendant Sanofi's motion requiring plaintiffs to, among other things, obtain proof of their alleged injury via expert declaration, update their plaintiff fact sheet, and submit a Certificate of Willingness to Proceed. The plaintiffs fought the whole process, filing motions for reconsideration, arguing against the imposition of the Lone Pine requirements. The most recent motion was to reconsider the enforcement of the order as to deceased plaintiffs.

The plaintiffs argued that the Order was unfairly burdensome on the families and representatives of deceased plaintiffs, claiming that it had the effect of dismissing claims of deceased plaintiffs because it required in-person examination and pre-death diagnosis of the qualifying condition. Plaintiffs claimed that the families and representatives did not have sufficient time to comply because they were not yet parties. They also argued that the order subverts the protections of F.R.C.P. 56 because product liability law did not require such an evaluation.

Defendants made some procedural objections to plaintiffs not having raised this argument initially, but the Court addressed the substance head on. And the Court was having none of the plaintiffs' arguments. The Court denied the Plaintiffs' motion, finding that the reconsideration standard was not met and that the plaintiffs' arguments were unpersuasive on their merits. The Court also did not miss the opportunity to comment on the quality of the cases before it (*vel non*), noting that there was no dispute in the litigation that 80 percent of the plaintiffs had not obtained a diagnosis of the qualifying condition. Further, the Court noted that when called upon to prove causation, many plaintiffs dismissed their claims in lieu of proceeding.

A great win for the good guys and a written opinion that Defendants can point to when trying to convince a reluctant court to implement a useful Lone Pine order.

4886-5916-6704, v. 1

In re Taxotere (Docetaxel) Prods. Liab. Litig.

United States District Court for the Eastern District of Louisiana

October 1, 2024, Decided; October 1, 2024, Filed

MDL No. 16-2740 SECTION: "H" (5)

Reporter
2024 U.S. Dist. LEXIS 178426 *

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION; This document relates to: All cases

Prior History: *In re Taxotere (Docetaxel) Prods. Liab. Litig., 2022 U.S. Dist. LEXIS 132200, 2022 WL 2952964 (E.D. La., July 26, 2022)*

Counsel: **[*1]** For Special Master, Special Master: Kenneth Warren DeJean, LEAD ATTORNEY, Kenneth W. DeJean, Attorney at Law, Lafayette, LA.

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For Defendant, Defendant: Douglas J. Moore, LEAD ATTORNEY, Irwin Fritchie Urquhart & Moore, LLC (New Orleans), New Orleans, LA; John Francis Olinde, LEAD ATTORNEY, Chaffe McCall LLP (New Orleans), Energy Centre, New Orleans, LA.

For Jake Woody, MDL Centrality, Interested Party: Jacob S. Woody, LEAD ATTORNEY, BrownGreer PLC (Richmond), Richmond, VA.

Judges: JANE TRICHE MILAZZO, UNITED STATES DISTRICT JUDGE.

Opinion by: JANE TRICHE MILAZZO

Opinion

ORDER AND REASONS

Before the Court is the Motion for Reconsideration of the Court's Order Granting in Part Sanofi's Motion for Entry of an Order Requiring Proof of Diagnosis (Rec. Doc. 16778) as to Deceased Plaintiffs filed by Plaintiffs (Rec. Doc. 17265). For the reasons set forth herein, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, **[*2]** Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of cancer. Among these companies are Defendants Sanofi US Services Inc. and sanofi-aventis U.S. LLC (collectively, "Sanofi). Plaintiffs allege that the drug caused permanent chemotherapy-induced alopecia ("PCIA"). Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more.

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

On February 21, 2024, this Court granted in part Sanofi's Motion for Entry of an Order Requiring Proof of Diagnosis and issued Case Management Order No. 40 ("CMO 40")—a type of order known as a *Lone Pine* order.[2] CMO 40 requires, among other things, that Plaintiffs (1) obtain proof of the alleged injury, PCIA, via expert declaration; (2) update their Plaintiff Fact Sheet; and (3) submit a Certificate of Willingness to Proceed.[3] The particulars differ slightly as between living plaintiffs and deceased plaintiffs proceeding under the name of a personal representative; however, Plaintiffs must all produce an expert affidavit confirming a diagnosis. As to deceased plaintiffs, the Order provides:

> **Deceased Plaintiffs**. For Wave 3 cases in which the alleged victim is deceased, counsel for Plaintiff (or **[*3]** 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.[4]

On March 21, 2024, Plaintiffs filed their first Motion for Reconsideration requesting that the Court vacate or reconsider CMO 40.[5] On May 21, 2024, the Court granted in part Plaintiffs' first Motion for Reconsideration and entered CMO 40A, extending the deadlines for compliance with CMO 40.[6] On July 29, 2024, at the request of the parties and magistrate judge, the Court again extended the deadlines to comply.[7]

On September 4, 2024, pursuant to CMO 40A, the Court issued an Order identifying 54 Plaintiffs whose cases did not settle in recent settlement agreements between Sanofi and other plaintiffs and who are therefore subject to the obligations in CMO 40A.[8] On September 27, 2024, the Court issued CMO 40B, which clarified that the current deadline to comply with CMO 40A applied only to the first group of 54 Plaintiffs ("Group 1 Plaintiffs").[9]

CMO 40B further provides that the Court will identify two additional groups of Plaintiffs who are subject **[*4]** to the obligations set forth in CMO 40A: "Group 2 Plaintiffs" and "Group 3 Plaintiffs." CMO 40B also clarifies that plaintiffs may be added or removed from the lists as the status of their cases evolve.

On August 30, 2024, Plaintiffs filed the instant Motion for Reconsideration, requesting that this Court reconsider and/or amend CMO 40, this time as to deceased plaintiffs.[10] Sanofi opposes.[11]

LEGAL STANDARD

Federal Rule of Civil Procedure 54(b) states that: "[A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." "Under *Rule 54(b)*, 'the trial court is free to reconsider and reverse

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[2] Rec. Doc. 16778. A comprehensive summary of the events leading up to Sanofi's Motion may be found in the Court's February 21, 2024 Order (Rec. Doc. 16778) and Order granting in part Sanofi's first Motion for Reconsideration (Rec. Doc. 16968-1).

[3] *Id.*

[4] *Id.* at 12.

[5] Rec. Doc. 16861.

[6] Rec. Doc. 16968-1.

[7] Rec. Doc. 17194.

[8] Rec. Doc. 17267.

[9] Rec. Doc. 17286.

[10] Rec. Doc. 17265.

[11] Rec. Doc. 17277.

its decision for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of the substantive law.'"[12] "[T]he power to reconsider or modify interlocutory rulings 'is committed to the discretion of the district court,' and that discretion is not cabined by the 'heightened standards for reconsideration' governing final **[*5]** orders."[13]

LAW & ANALYSIS

Plaintiffs argue that CMO 40 is improper because it imposes an unfair burden on the families and representatives of deceased plaintiffs. Specifically, Plaintiffs aver that CMO 40 "basically has the effect of dismissing the claims of deceased plaintiffs" because it requires an in-person examination and pre-death diagnosis of PCIA. Plaintiffs note that families and representatives will not have sufficient time to comply with the Order because they are not yet parties to the case.

Plaintiffs finally argue that this Court's Order subverts the protections of the Federal Rules of Civil Procedure, including *Rule 56*, because product liability law does not *per se* require such an evaluation. Rather, it requires a plaintiff to show, by a preponderance of the evidence, that she suffered an injury as a proximate cause of the defective or unreasonably dangerous product.

In response, Defendants first argue that Plaintiffs' Motion is procedurally improper because the Plaintiffs failed to raise the issue in their first Motion for Reconsideration. Defendants argue that the Court's Order regarding deceased plaintiffs is necessary to ensure that only viable cases proceed to remand. Defendants **[*6]** also point out that Plaintiffs fail to present a viable alternative to the existing Order.

At the outset, the Court notes that Plaintiffs did not raise arguments as to the deceased plaintiffs in their first Motion for Reconsideration. But even assuming that Plaintiffs' arguments are properly raised in the instant Motion, this Court finds such arguments unpersuasive.

First, this Court disagrees that CMO 40 imposes an unfair burden on the representatives of the deceased plaintiffs. *Lone Pine* Orders such as CMO 40 "are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation."[14] "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*."[15]

In issuing its Order, this Court, in striving to "strike a balance between efficiency and equity," considered the advanced stage of this litigation, ongoing settlement negotiations, the burden on Plaintiffs, and the "numerous roadblocks in both the bellwether selection and remand and/or transfer processes."[16] Critically, as stated above, no party disputes that 80 percent of Plaintiffs have not obtained a diagnosis of PCIA **[*7]** (or that Plaintiffs may suffer from a different type of hair loss, rather than PCIA). Additionally, many plaintiffs, when called upon to prove causation, have dismissed their claims in lieu of proceeding.[17] Notably, as this Court previously recognized, one

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[12] *Austin v. Kroger Tex., L.P., No. 16-10502, 864 F.3d 326, 2017 WL 1379453, at *9 (5th Cir. 2017)* (quoting *Lavespere v. Niagara Mach. & Tool Works, Inc., 910 F.2d 167, 185 (5th Cir. 1990)*).

[13] *Saint Annes Dev. Co. v. Trabich, 443 F. App'x 829, 831-32 (4th Cir. 2011)* (quoting *Am. Canoe Assoc. v. Murphy Farms, Inc., 326 F.3d 505, 514-15 (4th Cir. 2003)*).

[14] *Acuna v. Brown, 200 F.3d 335, 340 (5th Cir. 2000)* (citing *FED. R. CIV. P. 16*).

[15] *Id.*

[16] Rec. Doc. 16778.

[17] Rec. Doc. 16873 at 2.

Plaintiff was dismissed from the bellwether pool after she was diagnosed with androgenic alopecia (female pattern hair loss), rather than PCIA.[18]

Thus, after carefully considering the unique circumstances of this litigation and Plaintiffs' issues of proof, this Court—rather than require proof of specific causation by way of a *Rule 26* expert report, as Sanofi initially requested—issued CMO 40, which requires only a limited declaration as to diagnosis. As to deceased plaintiffs, the Order simply requires that representatives for the deceased plaintiffs show that the deceased plaintiff was, at some point, diagnosed with the injury that she alleged in her complaint.

Plaintiffs argue that they have insufficient time to comply with the Order and suggest that additional time may be necessary for counsel to locate heirs and/or file motions to substitute, if they have not yet done so. Notably, the Court entered CMO 40 on February 21, 2024. Plaintiffs **[*8]** have failed to present any credible argument as to why additional time is needed.[19]

Thus, this Court finds the requirements CMO 40 to be reasonable under the circumstances and comport with the "[t]he basic purpose of a *Lone Pine* order," which is "to identify and cull potentially meritless claims and streamline litigation in complex cases."[20]

Second, Plaintiffs argue that the Order is improper and violates the protections of *Federal Rule of Civil Procedure 56* because the expert affidavit would not necessarily be required to prove causation on a motion for summary judgment and/or at trial once a plaintiff's case is ultimately remanded. Plaintiffs also argue that compliance is "nearly impossible" because the in-person examination and diagnosis requirement was imposed after the deceased plaintiffs' deaths. This Court finds Plaintiffs' arguments without merit.

Critically, Plaintiffs do not argue that expert/medical testimony will not be required to prove a diagnosis of PCIA. Rather, Plaintiffs state that

> there is likely sufficient anecdotal, circumstantial evidence that may be sufficient to satisfy the *Daubert* gatekeeping test for deceased plaintiffs' physicians or experts to opine on proximate and specific causation through photographs **[*9]** or based on independent recollection, or family members' recollections, of what the deceased plaintiffs' hair looked like prior to their untimely death.[21]

But as this Court previously recognized, Plaintiffs' own expert has opined that a diagnosis of PCIA requires a physical examination and cannot be made through photos.[22] Indeed, as Defendants point out, Plaintiffs' expert opined that in order to diagnose PCIA, she would need to conduct a differential diagnosis (in order to rule out other

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[18] Rec. Doc. 16778 at 3.

[19] Moreover, this Court, at the request of the parties and the magistrate judge, has extended the deadline for compliance with CMO 40 on several occasions, including through the issuance of CMO 40A. Notably, this MDL has been plagued with issues related to extensive delays in filing and serving suggestions of death and motions to substitute pursuant to *Federal Rule of Civil Procedure 25*, and many cases have proceeded for years without a plaintiff. As such, on February 23, 2024, in response to Sanofi's Motion to Dismiss Pursuant to *Rule 25*, this Court ordered counsel for certain deceased plaintiffs to serve suggestions of death and file proof same into the record. Rec. Doc. 16813. Nevertheless, should counsel and/or a representative for a deceased plaintiff have good cause to request additional time to comply, such a request may be filed with the Court.

[20] *In re Vioxx Prods. Liab. Litig., 557 F. Supp. 2d 741, 744 (E.D. La. 2008)* (citing *Baker v. Chevron USA, Inc., No. 1:05-CV-227, 2007 WL 315346, *1 (S.D. Ohio Jan.30, 2007)*).

[21] Rec. Doc. 17265-1.

[22] Rec. Doc. 16968-1 at 7 (citing Rec. Doc. 16696 at 4); *see also* Rec. Doc. 17277 at 4-5.

types of hair loss), as well as see the patient and talk to the patient.[23] Plaintiffs offer nothing to meaningfully refute this point; nor do they offer an alternative to the existing Order.

In *In re: Zostavax (Zoster Vaccine Live) Products Liability Litigation*, the U.S. Court of Appeals for the Third Circuit, after considering arguments analogous to those which Plaintiffs present here, affirmed the order of the district court dismissing several plaintiffs who failed to comply with the court's *Lone Pine* order.[24] In the *Zostavax* MDL, the plaintiffs alleged that the Zostavax vaccine, which contains "live-attenuated" strain of the varicellazoster virus ("VSV"), caused them to develop shingles, among other **[*10]** things.[25]

VSV causes chickenpox in childhood and shingles in adulthood. After exposure to VSV, a person carries the so-called "wild-type strain" for life; the wild-type strain remains dormant in a person's system and can potentially reactivate, resulting in shingles. Thus, to prove specific causation, plaintiffs alleging that Zostavax caused them to develop shingles would be required to rule out the "obvious alternative cause" that the wild-type virus reactivated.[26]

In light of the above, the district court entered a *Lone Pine* order requiring plaintiffs to produce a polymerase chain reaction assay (a "PCR test"), which can reliably discern between the live-attenuated and wild-type strains.[27] In support of its order, the court noted that no bellwether plaintiffs had obtained such a test and that, during the workup of the bellwether plaintiffs' cases for trial, the plaintiffs' expert was excluded after he failed to perform a differential diagnosis ruling out the reactivation of the wild-type virus as an alternative cause.[28]

After dismissal of their cases for failure to comply with the court's order, several plaintiffs appealed, arguing that the district court abused its discretion **[*11]** because (1) PCR testing was not the only way to establish specific causation; (2) the court's order mandated production of evidence that never existed because none of the plaintiffs had ever received a PCR test; and (3) such evidence could not be created after-the-fact because PCR testing could only be done on existing rashes, and most of the plaintiffs' rashes had already healed.[29]

The Third Circuit affirmed the dismissals, reasoning that "[i]t would have been pointless to allow the Group A cases to proceed to summary judgment because plaintiffs had failed to explain how they could prove specific causation without PCR tests."[30] The court noted that the plaintiffs "offered no more than a conclusory claim that 'expert evidence [would] differ from what was introduced in the Group A Bellwether process,'" and that plaintiffs failed to specifically identify an expert or explain how such evidence would differ.[31]

Here too, Plaintiffs' conclusory claims that "there is likely sufficient anecdotal or circumstantial evidence" for deceased plaintiffs' physicians or experts to satisfy the *Daubert* gatekeeping test are insufficient considering Plaintiffs' own experts' testimony. Plaintiffs have **[*12]** not offered any viable alternatives to an in-person diagnosis

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[23] Rec. Doc. 17277.

[24] *No. 23-1032, 2024 U.S. App. LEXIS 17369, 2024 WL 3423709, at *5 (3d Cir. July 16, 2024)*.

[25] Plaintiffs were grouped into three categories: Group A, Group B, and Group C. *Id.* at *2. The relevant *Lone Pine* order only applied to Group A plaintiffs, or those that alleged shingles or shingles-related injuries. *Id.* at *1.

[26] *Id.* at *1.

[27] *Id.* at *2.

[28] *Id.* at *3.

[29] *Id.* at *2.

[30] *Id.* at *4.

[31] *Id.*

of PCIA; nor have they identified specific experts in support of their arguments.[32] Absent specific evidence for the Court to consider, the Court finds that Plaintiffs have not shown that reconsideration is warranted at this time.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Reconsideration (Rec. Doc. 17265) is **DENIED**.

New Orleans, Louisiana, this 1st day of October, 2024.

/s/ Jane Triche Milazzo

JANE TRICHE MILAZZO

UNITED STATES DISTRICT JUDGE

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[32] Plaintiffs further argue that proof that Taxotere was a proximate cause of a plaintiff's hair loss "in and of itself, does not require a contemporaneous treater to diagnose a condition to the exclusion of other conditions or via differential contemporaneous diagnosis, because the standard is a preponderance of the evidence, not medical certainty . . . ." Rec. Doc. 17265-1 at 3. This Court previously addressed a similar argument in its Order granting in part Plaintiffs' first Motion for Reconsideration, noting that "the medical probability [or certainty] standard" generally equates to a "preponderance of the evidence standard." Rec. Doc. 16968 at 7 n. 25.