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.	)	

ADDENDUM TO CASE MANAGEMENT ORDER NO. 12A

I. SCOPE OF ORDER

Pursuant to PTO 22A this Court has held show cause hearings[1] to address cases in which the discovery periods set forth in CMO 12A have elapsed, yet Product ID Information of the type described in paragraph 6 has not been obtained.[2] During these hearings, certain Plaintiffs have submitted documents outside the parameters of the presumptive evidence contemplated by Case

[1] *See, e.g.*, transcripts for hearings before this Court on April 28, 2022, May 2, 2022, July 12, 2022, and September 13, 2022.

[2] CMO 12A, paragraph 6 identifies the types of Product ID Information that is "presumed sufficient to establish the identity of the manufacturer(s) or labeler of docetaxel in this MDL."

> a. National Drug Code ("NDC") numbers contained in a patient's pharmacy, billing or insurance records; or
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> b. A Statement Regarding Chemotherapy Drug Administered ("Statement") identifying the manufacturer(s) or labelers of the drug administered to Plaintiff and the correct dates of treatment, certified and signed by an authorized person on behalf of the patient's infusion pharmacy, treatment facility, or other authorized health care professional, provider, or insurance carrier.
>
> c. Medical and/or billing records showing that docetaxel was administered prior to March 8, 2011.

CMO 12A, ¶ 6.

Management Order 12A, paragraph 6 as evidence of product identification. This Order provides further guidance regarding these documents.[3]

II. TYPES OF EVIDENCE

The sufficiency of evidence submitted will depend upon the facts of each individual case and the documents presented. The documents described in this section may or may not be sufficient to identify the proper Defendant(s) or avoid dismissal. The evidence the Court will consider for a Plaintiff who seeks to identify the proper Defendant(s) with evidence other than the Product ID Information described in CMO 12A, paragraph 6, after completing the discovery processes described in CMO 12A, is as follows:[4]

1. A signed statement from an authorized person at the Plaintiff's infusion or treatment facility:

    a. Describing the facility's customary purchase and dispensing practices during the relevant months before and during Plaintiff's chemotherapy treatment, including a description of the volume and frequency of docetaxel purchases; the period of time a docetaxel product would typically spend "on the shelf" at a facility between purchase and infusion; and the customary relationship between purchases and infusions, if any (*e.g.*, was product purchased periodically and kept on hand, or purchased upon prescription for a specific patient) ("purchasing and infusion timeframe"); and

    b. Attaching the facility's complete purchasing records showing that within the purchasing and infusion timeframe before one or more of Plaintiff's chemotherapy infusions, only a single manufacturer's medication was purchased; **or**

2. A signed statement from an authorized person at the Plaintiff's infusion or treatment facility:

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[3] Nothing in this Order amends or supersedes the requirements of CMO 12A, including the definition of "presumed sufficient evidence" in paragraph 6. In other words, presenting the type(s) of evidence described in this Order — whether or not sufficient to avoid dismissal — is different than and not equivalent to having presumptive evidence of product identification.

[4] This listing of potential evidence is not necessarily exhaustive; the Court may, under exceptional circumstances or for good cause shown, consider other evidence presented to establish product identification.

a. Describing the facility's customary purchase and dispensing practices during the relevant months before and during Plaintiff's chemotherapy treatment, including the relevant purchasing and infusion timeframe; and

b. Identifying all distributors of docetaxel to the facility within the purchasing and infusion timeframe before one or more of the Plaintiff's chemotherapy infusions; and

c. Attaching complete distribution records showing that within that purchasing and infusion timeframe before one or more of plaintiff's chemotherapy infusions, only a single manufacturer's medication was distributed to the facility; **or**

3. Lot numbers in the Plaintiff's chemotherapy administration medical records reflecting the lot numbers of docetaxel used in Plaintiff's chemotherapy treatments.

III. DEADLINES

IT IS ORDERED that the parties meet and confer as to the Plaintiffs' cases dismissed on the record at any Show Cause Hearing from April 28, 2022 until the September 13, 2022 Show Cause Hearing limited to those where dismissal was obtained despite contested purchase and/or distribution records,[5] and then submit to the Court a motion listing only the cases in which the Parties agree that Plaintiff's case shall be reinstated. If reinstated by agreement, those Plaintiffs shall have thirty (30) days from the Order of reinstatement to accomplish the production of additional evidence described in Section II, above. If there remains a dispute as to whether that Plaintiff's case is subject to reinstatement, the issue of whether those cases will be reinstated shall be heard at the February 7, 2023 show cause hearing. (Rec. Doc. 15285).

IT IS FURTHER ORDERED that any Plaintiff whose case was noticed for the September 13, 2022 Show Cause Hearing but whose matter was continued for a future hearing (*see* Rec. Doc. 14722) as well as the Plaintiffs identified on Defendants' September 21, 2022 Notice of Non-

[5] This conferral should include any Plaintiff who had obtained purchase and/or distribution records in advance of the Show Cause Hearing for which she was noticed but nonetheless agreed on the record at the hearing that prior rulings applied to result in dismissal of her case.

Compliance have thirty (30) days from the date of entry of this Order to (1) produce Product ID Information contemplated by CMO 12A, ¶ 6, or alternatively, (2) produce evidence of the type described in section II above. If the treatment facility is non-responsive, on good cause shown, Plaintiffs may be granted additional time to comply.

This Order will apply to future CMO 12A Notices of Non-Compliance issued pursuant to PTO 22A.

Notwithstanding entry of this Order, both sides reserve all objections to and arguments regarding the sufficiency of evidence to avoid dismissal.

New Orleans, Louisiana this 6th day of December, 2022.

HON. JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE