UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL)

PRODUCTS LIABILITY

LITIGATION

SECTION "N" (5)

MDL NO. 2740

THIS DOCUMENT RELATES TO ALL CASES

<u>AMENDED PRETRIAL ORDER NO. 22</u> [Service of Plaintiff Fact Sheets and Defendant Fact Sheets]

This Order amends and supersedes this Court's previous Pretrial Order No. 22 (Rec. Doc.

279) that was issued on March 10, 2017.¹

In accordance with Pretrial Order No. 18, this Order governs the form and schedule for service

of Plaintiff Fact Sheets ("PFS"), Record Document 236-1, and Defendant Fact Sheets ("DFS"),

Record Document 236-2, in cases that were: (1) transferred to this Court by the Judicial Panel on

Multidistrict Litigation, pursuant to its Order of October 4, 2016; (2) subsequently transferred to

this Court by the Judicial Panel on Multidistrict Litigation pursuant to Rule 7.4 of the Rules of

Procedure of that Panel; and (3) originally filed in this Court or transferred or removed to this

Court.

1. Considering the nature of the case and the difficulty of identifying the exact manufacturer,

each side shall be given reasonable flexibility with the timeframes set forth herein.

Accordingly, the Parties may agree to extensions of the below deadlines for the completion

and service of PFSs, executed Authorizations, and DFSs. If the Parties cannot agree on an

For simplicity purposes, this Order completely supersedes Pretrial Order No. 22 and contains all information relevant to form and schedule for service of the fact sheets.

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extension of time after meeting and conferring, the requesting Party may apply to the Court for such relief upon a showing of good cause.

PLAINTIFF FACT SHEETS:

- 2. Plaintiffs shall each complete and serve upon Defendants a PFS and Authorizations for Release of Records of all healthcare providers and other sources of information and records (*e.g.* pharmacies, employers, etc.) using MDL Centrality in the form set forth in PFS. R. Doc. 236-1. In addition, any plaintiff asserting a claim for lost wages must complete an authorization for release of employment records. Those Plaintiffs shall also produce with their PFS all documents responsive to the document requests contained therein.
- 3. A complete and verified² PFS, signed and dated Authorizations, and all responsive documents in Plaintiff's possession shall be submitted to the Defendants using MDL Centrality on the following schedule: (a) within seventy-five (75) days from the date of this Order for any Plaintiff whose case has been docketed in this MDL on or before the date of this Order; (b) within seventy-five (75) days of the date the case is docketed in this MDL for any Plaintiff whose case is docketed in the MDL after the date of this Order. The Authorizations are set forth in PFS Attachment A.
- 4. In the event any single law firm has more than twenty-five (25) PFSs due on the same date in accordance with the schedule set forth above, that firm shall submit to Defendants at least twenty-five (25) PFSs in accordance with the above schedule, an additional twenty-five (25) PFSs within sixty (60) days of those submissions; and any additional PFSs within sixty (60) days of those submissions.

² Plaintiffs may verify a PFS by their handwritten signature or through the use of an electronic signature using an application such as DocuSign, and all subsequent amendments or supplements to the PFS may be verified by signature of the plaintiff's attorney.

- 5. Plaintiffs who fail to provide a complete and verified PFS, signed and dated Authorizations, and all responsive documents requested in the PFS within the time periods set forth herein shall be given notice of deficiency³ via MDL Centrality within forty-five (45) days of service of the PFS,⁴ and shall be given thirty (30) additional days from the date the notice of deficiency is submitted through MDL Centrality to cure such deficiency. Afterwards, Defendants may add the name and case number of any Plaintiff who fails to cure deficiencies within the thirty-day cure period to the Agenda for the next Status Conference. No briefing is required. Any Plaintiff who remains deficient at the time of that Status Conference will be subject to an Order to Show Cause, returnable at the following Status Conference, which will require Plaintiff to show cause why her Complaint should not be dismissed with prejudice. Failure to timely comply may result in a dismissal of Plaintiff's claim.
- 6. Authorizations shall be dated and signed. Defendants may use the Authorizations for all healthcare providers and other sources of information and records (e.g., pharmacies, employers, etc.) identified in the PFS, without further notice to Plaintiff's counsel. Within twenty (20) days of receipt of records by Defendants, Defendants' Liaison Counsel ("DLC") shall make said records received pursuant to the Authorizations available to Plaintiffs' Liaison Counsel ("PLC") and Plaintiff's counsel by uploading a copy to MDL

³ Each party shall bring any and all deficiencies to the attention of the opposing counsel in one letter, and shall be barred from raising any additional deficiencies that were apparent at the time, absent good cause shown, except those arising from the response to/cure of the deficiency.

⁴ Service of a completed Fact Sheet and Records Authorizations shall be deemed to occur when the submitting party has performed each of the steps required by the MDL Centrality System to execute the online submission of the materials, and the submitting party has received confirmation on screen that the materials have been successfully submitted, and the receiving party has received notification of the submission via the MDL Centrality System.

- Centrality at a reasonable cost to the requesting Plaintiff of electronically reproducing records received by defendants.
- 7. If Defendants wish to use an Authorization to obtain medical records from a source that is not identified in the PFS, Defendants shall provide the Plaintiff's counsel for that particular case with fourteen (14) days written notice (email) of the intent to use an authorization to obtain records from that source. If Plaintiff's counsel fails to object to the request within fourteen (14) days, Defendants may use the authorization to request the medical records from the source identified in the notice. If Plaintiff's counsel objects to the use of the authorization to obtain records from the source identified in the notice within said fourteen (14) day period, Plaintiff's counsel and Defendants' counsel shall meet and confer in an attempt to resolve the objection. If counsel are unable to resolve the objection, Plaintiff shall file a motion for a protective order within thirty (30) days of the Defendants' notice of intent to use the authorization.
- 8. Plaintiffs' responses to the PFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and responses to requests for production of documents under Fed. R. Civ. P. 34 and shall be supplemented in accordance with Fed. R. Civ. P. 26.
- 9. Defendants' use of the PFS and Authorizations shall be without prejudice to Defendants' right to serve additional discovery, if authorized in further Orders of the Court.

DEFENDANT FACT SHEETS:

10. Because of the naming of multiple defendants in individual cases and questions of product identification, the following limitations shall apply to which Defendant(s) serve DFSs, in the form set forth in DFS, Record Document 236-2, in which cases:

a. *Before 2011 – Sanofi Defendants only:* If the first treatment date and last treatment date identified by a Plaintiff in PFS Section V(12)(c-d) is before 2011 and the PFS is submitted with the documentation required by PFS Section III and VI, only Defendants Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S., LLC, and Winthrop US (collectively "sanofi Defendants") must complete and serve a corresponding DFS. Sanofi Defendants need not complete and serve a DFS in any case where it has not been properly served either with process and summons consistent with the Federal Rules of Civil Procedure or consistent with Pretrial Order No. 9 (R. Doc. 160).

b. 2011 or Later with Product Identification – That Defendant Only:

- i. If the first treatment date and last treatment date the Plaintiff identified in PFS Section V(12)(c-d) is 2011 or later; Plaintiff has provided the information request by PFS Section VI(12-14); and the PFS is submitted with the documentation required by PFS Section III and VI;
- ii. Only the Defendant(s) whose product the Plaintiff identified in PFS Section III(2-3) and for whom documentation required by PFS Section VI was provided must complete and serve a DFS. No Defendant must complete and serve a DFS in any case where it has not been properly served either with process and summons consistent with the Federal Rules of Civil Procedure or by service through procedures for streamlined service as approved by Orders in this MDL.
- c. 2011 or Later without Product Identification Named, Served Defendants But Limited DFS Only:

- If the first treatment date and last treatment date the Plaintiff identified in PFS Section V(12)(c-d) is 2011 or later; Plaintiff has provided the information request by PFS Section VI(12-14); and the PFS is submitted with the documentation required by PFS Sections III and VI; and
- ii. If the Plaintiff selects "unknown" or does not identify the product allegedly taken in PFS Section III(2-3) and certifies in PFS Section III(4) that reasonable, good faith efforts were made to identify the manufacturer of Docetaxel; then
- iii. Each Defendant named by Plaintiff in her lawsuit Complaint and properly served either with process and summons consistent with the Federal Rules of Civil Procedure or by service through procedures for streamlined service as approved by Orders in this MDL must complete and serve a DFS, but only DFS Sections I II.
- iv. Notwithstanding the requirements of this Paragraph, no Defendant must complete and serve any DFS, including DFS Sections I II, if their Docetaxel product was not FDA approved until after the last treatment date identified by the Plaintiff in PFS Section V(12)(c-d).
- v. Defendants subject to the provisions of this paragraph need not complete any remaining DFS sections unless and until the product used in the Plaintiff's care is identified by supplementation of PFS Section III(2-3); Plaintiff has provided the information requested by PFS Section VI(12-14); and the PFS is submitted with the documentation required by PFS Section III and VI. However, once the above-stated conditions are met, Defendant

must complete and submit a DFS in accordance with the time period and requirements set forth herein.

- 11. Subject to the limitations set forth in Paragraph 10, Defendants shall submit a DFS to the Plaintiff using MDL Centrality within seventy-five (75) days of the date the Defendants receive a substantially completed PFS from a Plaintiff. Solely for the purpose of triggering the DFS submission deadline, the term "substantially completed" in this Order and in the DFS (R. Doc. 236-2) is defined as service on Defendants of the PFS with Plaintiff's signed verification and the documentation required by PFS Sections III and VI, i.e., prescription and/or pharmacy records demonstrating use of Taxotere (or Docetaxel), as well as medical records in Plaintiff's possession demonstrating alleged injury or photographs showing Plaintiff's hair before and after treatment with Taxotere (Docetaxel) along with the dates the photographs were taken.
- 12. In the event any single Defendant has more than twenty-five (25) DFSs due on the same date in accordance with the schedule set forth above, that Defendant shall submit to Plaintiffs at least twenty-five (25) DFSs in accordance with the above schedule, an additional twenty-five (25) PFSs within sixty (60) days of those submissions; and any additional DFSs within sixty (60) days of those submissions.
- 13. If Defendants fail to provide a complete and verified DFS within the time period set forth hereinabove, Defendants shall be given notice of the deficiency⁵ via MDL Centrality within forty-five (45) days of service of the DFS and shall be given thirty (30) additional days from the date the notice of deficiency is received through MDL Centrality to cure

⁵ Each party shall bring any and all deficiencies to the attention of the opposing counsel in one letter, and shall be barred from raising any additional deficiencies that were apparent at the time, absent good cause shown, except those arising from the response to/cure of the deficiency.

such deficiency. Afterwards, Plaintiffs may add the name and case number of any cases in

which Defendants failed to cure deficiencies within the thirty-day cure period to the

Agenda for the next Status Conference. No briefing is required. Any Defendant who

remains deficient at the time of that Status Conference will be subject to an Order to Show

Cause, returnable at the following Status Conference, which will require Defendant to

show cause why its defenses should not be stricken in that case. Failure to timely comply

may result in a dismissal of defenses.

14. Defendants' responses on a DFS shall be treated as answers to interrogatories under Fed.

R. Civ. P. 33 and responses to requests for production of documents under Fed. R. Civ. P.

34 and shall be supplemented in accordance with Fed. R. Civ. P. 26.

15. It will be the responsibility of the counsel for the particular plaintiffs or defendants

involved, as well as in coordination with Liaison Counsel for plaintiffs and defendants, to

attempt to cure deficiencies and get a PFS/DFS served prior to raising the issue with the

Court.

16. Plaintiffs' use of the DFS shall be without prejudice to the right of the Plaintiffs in a specific

case to serve additional discovery, if authorized in further Orders of the Court.

New Orleans, Louisiana this 12th day of April, 2017.

KURT D. ENGELHARDT

UNITED STATES DISTRICT JUDGE