UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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

CASE MANAGEMENT ORDER NO. 12A
(AMENDED PRODUCT IDENTIFICATION ORDER)

Case Management Order No. 12 ("CMO 12") (Rec. Doc. 1506) was entered on January 12, 2018. An amendment to CMO 12 is necessary to clarify the parties' obligations and the procedures governing the discovery of Product ID Information and subsequent dismissal of defendants whose product was not used. This Order applies to all present and future cases docketed in MDL 2740 as well as all parties in the litigation and supersedes CMO 12. Each party must discharge the obligations of this Order in a diligent, good faith, and documented manner.

Amended Pretrial Order No. 22 (Rec. Doc. 325) requires each Plaintiff to submit to the Defendants a complete and verified Plaintiff Fact Sheet ("PFS") to be accompanied by all responsive documents in Plaintiff's possession within seventy-five (75) days of the date the case is docketed in this MDL. The PFS contains questions related to the identification of the Taxotere/docetaxel/docefrez ("docetaxel") infused and to the production of records to identify the manufacturer of the docetaxel infused. *See* Pretrial Order 18, Attachment 1 (Rec. Doc. 236-1).[1]

Recognizing the importance of determining product identification in MDL 2740, **IT IS ORDERED** that:

[1] Pretrial Order No. 18 (Rec. Doc. 236) requires each Plaintiff's PFS to be accompanied by any "records demonstrating use of Taxotere® or other docetaxel" in the Plaintiff's possession. If the manufacturer of such docetaxel is unknown, the Plaintiff must certify to have made "reasonable, good faith efforts to identify the manufacturer of the Docetaxel used in my treatment, including requesting records from my infusion pharmacy." See Pretrial Order No. 18, Attachment 1 at Part III (Rec. Doc. 236-1).

1. Within sixty (60) days after filing a Short Form Complaint, each Plaintiff must: (a) determine the facility, center, hospital, or clinic (hereinafter "infusion facility") in which the Plaintiff was infused with docetaxel; (b) determine the time frame Plaintiff was treated with docetaxel at such infusion facility; and (c) request, order, and ultimately pay for medical, pharmacy, billing (*i.e.*, a patient itemized statement), insurance billing records from such infusion facility containing the National Drug Code ("NDC") number(s) for the docetaxel Plaintiff received, and/or completion of the attached Exhibit B form entitled "Statement Regarding Chemotherapy Drug Administered",[2] or other proof of the identity of the manufacturer or labeler of the docetaxel Plaintiff received as provided in Paragraph 6 of this Order ("Product ID Information"). All initial requests for records containing Product ID Information shall be in writing and accompanied by a valid medical authorization signed by the Plaintiff. Plaintiff is strongly encouraged to contact the infusion facility by telephone before sending such written request to determine where and/or to whom such written request(s) should be sent.[3] The written request shall request production of such Product ID Information no more than thirty (30) days after the written request. If Plaintiffs have substantially complied with these obligations prior to the entry of this Order, they shall notify Defendants in accordance with Paragraph 3 or Paragraph 7 of this Order, within twenty-one (21) days of entry of this Order, unless Plaintiff has already done so in connection with the original CMO 12.

If a Plaintiff has already obtained Product ID Information, uploaded it in accordance with this Order, and dismissed any defendant named which, according to the Product ID Information

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[2] The Plaintiff's Letter shall request that the form (1) identify the Plaintiff and the correct dates of treatment, (2) is signed by an authorized person on behalf of the patient's infusion pharmacy, treatment facility, or other authorized health care professional, as defined in Paragraph 6 of this Order, and (3) need not be notarized.

[3] Plaintiffs should recognize that infusion facilities may maintain and/or store patient records in different departments and/or locations. For instance, medical records may be maintained in the records department while billing records may be maintained in the billing department.

received did not manufacture or label the product Plaintiff received, in accordance with the presumption in Paragraph 6 of this Order, the Plaintiff has no further obligations under this Order. If all of Plaintiff's infusions of docetaxel occurred prior to March 8, 2011, the Plaintiff shall have no obligations under this Order.

2. If records are not received within thirty (30) days of the issuance of the written request, Plaintiff shall make a diligent, good faith, and documented effort to follow-up with the infusion facility in writing and/or by phone to obtain (i) Product ID Information; or (ii) written notice that the infusion facility either does not possess Product ID Information or will not provide Product ID Information to Plaintiff. In particular, if Plaintiff receives written notice from the infusion facility that Plaintiff has requested Product ID Information from the incorrect entity and identifies the appropriate facility(y/ies), Plaintiff shall request Product ID Information from the other facilities/record holders identified by the infusion facility pursuant to Paragraph 1.

3. If Plaintiff has not received Product ID Information within sixty (60) days of the Plaintiff's initial written request, Plaintiff shall notify the named Defendant(s) in writing within seven (7) days, through Defense Liaison Counsel (John Olinde – 505b2liaison@chaffe.com and Douglas Moore – noproductid@shb.com) and the contact person for the Defendant(s) named[4] and served in the lawsuit, that Product ID Information has not been received and shall provide Defendant(s) with the following information: (i) Plaintiff's name; (ii) Plaintiff's MDL case number; (iii) copies of all written requests for Product ID Information sent by Plaintiff to the infusion facility; (iv) copies of all documented responses from the infusion facility to Plaintiff; and (v) unless provided as an attachment to Plaintiff's PFS in the form authorized by Rec. Doc. 236-1, a valid authorization for the release of Plaintiff's medical records, which contains Plaintiff's

[4] Exhibit A provides the contact e-mail addresses for each Defendant in this litigation.

name, date of birth, social security number, and Plaintiff's signature.

4. Within sixty (60) days of receiving notice from Plaintiff that Plaintiff has not obtained Product ID Information, each named and served Defendant shall determine whether it possesses Product ID Information for Plaintiff. If the named and served Defendant possesses Product ID Information, it shall provide all parties to the action with such Product ID Information within the fourteen (14) day period. If a named and served Defendant does not possess Product ID Information, within twenty-one (21) days of notification to the Defendants that Plaintiff has taken all the steps described above, the named and served Defendants shall collectively send one letter to the infusion facility at the facility and address of Plaintiff's Paragraph 1 and 2 requests, identifying themselves as manufacturers or labelers of docetaxel and requesting Product ID Information only and/or completion of the attached Exhibit B form entitled "Statement Regarding Chemotherapy Drug Administered" to be produced within fourteen (14) days of receipt of the letter. The letter will advise the infusion pharmacy the Product ID information is to be provided to the Defendant submitting the request and that Defendants' request is not intended to duplicate prior records responses from the facility and, if it would, to advise Defendants of the same. If the infusion facility provides Product ID Information, Defendants shall provide counsel for Plaintiff and Plaintiffs' Liaison Counsel a copy of the response from the infusion facility within seven (7) days of receipt of the Product ID Information. If such evidence satisfies the showing set forth in Paragraph 6 of this Order, Plaintiff shall comply with Paragraphs 7 and 9.

a. If the infusion facility requires payment either before or after the production of such records, Defendants shall promptly notify the Plaintiffs and

Plaintiffs shall bear the cost of such payment.[5] The parties shall coordinate with each other and the infusion facility to effectuate such payment.

b. Defendants shall use the authorization provided as an attachment to Plaintiff's PFS in the form authorized by Rec. Doc. 236-1 and if an authorization has not been uploaded, Defendant shall so notify Plaintiff and Plaintiff shall promptly provide a valid authorization. If Defendants' request for Product ID Information is rejected by the infusion facility due to a deficient or invalid authorization, Defendants shall notify Plaintiff of the rejection by providing Plaintiff with a copy of the rejection notice; Plaintiff shall then promptly provide Defendants with an updated authorization that addresses each identified deficiency. Once Plaintiff provides an updated authorization to Defendants, Defendants shall re-submit their request for Product ID Information using the updated authorization.

c. If the infusion facility directs Defendants to a different facility, department, or location ("Different Facility") to obtain Product ID Information, Defendants shall notify Plaintiff within fourteen (14) days of receiving such notice by providing Plaintiff with a copy of such notice. If Plaintiff did not request Product ID Information from such Different Facility, Plaintiff shall re-issue her request to such Different Facility by taking the steps outlined in paragraphs 1 and 2 above within fourteen (14) days of receipt of notice

[5] Plaintiffs are not required to satisfy prepayment requests from a facility for records that are duplicative of previously obtained records or records that do not contain Product ID information, but the onus will be on Plaintiffs to investigate and demonstrate that such conditions are met if refusing to pay.

of the Different Facility. If Plaintiff did request Product ID Information from such Different Facility, Defendants shall re-issue their request to such Different Facility by taking the steps outlined in Paragraph 4 within fourteen (14) days of receipt of notice of the Different Facility.

d. Should the infusion facility fail to provide the Defendants with Product ID Information within thirty (30) days of Defendants' letter to the infusion facility,[6] Defendants shall provide counsel for Plaintiff a copy of the request letter to, and any responses from, the infusion facility within fourteen (14) days.

5. Within thirty (30) days of Plaintiff receiving notice that named Defendant(s) do not possess Product ID Information after Defendants have taken the steps set forth in the preceding paragraph, Plaintiff shall issue a subpoena[7] requiring the infusion facility to release Product ID Information.[8] Plaintiff shall provide a copy of the subpoena pursuant to FRCP 45, through Defense Liaison Counsel (John Olinde –505b2liaison@chaffe.com and Douglas Moore – noproductid@shb.com) and the contact person[9] for the Defendant(s) named and served in the lawsuit. If the infusion facility fails to comply with the subpoena, the Court shall take appropriate action including a Show Cause Order and/or setting a hearing on a motion to compel.

6. The following information is presumed sufficient evidence to establish the identity

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6 Or within thirty (30) days of Defendants' letter to the Different Facility, if triggered by the preceding paragraph (c), whichever is later.

7 Without waiver of any protections afforded third parties under FRCP 45 and upon prior confirmation from the facility of consent to alternate service, the subpoena may be served via both Express Courier which has tracking information (i.e., FedEx or UPS) or and certified mail, as a satisfaction of in lieu of personal service.

8 Without waiver of any protections afforded third parties under FRCP 45 and in an effort to reduce the costs of this process, the infusion facility may be encouraged by the Plaintiff to produce responsive documents via electronic production to Plaintiffs' counsel, rather than physical production within 100 miles of the infusion facility.

9 *See* Exhibit A.

of the manufacturer(s) or labeler of docetaxel in this MDL:

a. National Drug Code ("NDC") numbers contained in a patient's medical, pharmacy, billing or insurance records; or

b. A Statement Regarding Chemotherapy Drug Administered ("Statement") identifying the manufacturer(s) or labeler 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. Such Statement need not be notarized and can be in the form of the Statement attached hereto as Exhibit B. An "authorized person" must be an infusion pharmacist or other person who regularly keeps or reviews records of patient treatment in the course of employment by the Plaintiff's infusion facility, medical facility or health insurance company.

c. Medical and/or billing records showing that docetaxel was administered prior to March 8, 2011, is evidence that the docetaxel was manufactured by sanofi.

7. If any party obtains Product ID Information at any time during this MDL proceeding, that party shall notify all other named parties within thirty (30) days of receipt of obtaining the Product ID Information. Within thirty (30) days of obtaining Product ID Information, Plaintiff shall upload such evidence to MDL Centrality under the "Product Identification" document type field of MDL Centrality.

8. Where Plaintiff has submitted Product ID Information as defined in Paragraph 6, Defendants in MDL 2740 will not dispute such evidence without offering testimonial or

documentary evidence to rebut the presumption. If any party obtains contrary testimonial or documentary evidence regarding Product ID Information ("contrary evidence"), it shall notify counsel for all named parties of the existence of such evidence within seven (7) days of its discovery. In all cases subject to a trial scheduling order, any contrary evidence obtained must be produced by the close of Phase I discovery. Otherwise, once a case is identified in a trial scheduling order and after the close of Phase I discovery, the existing Product ID Information will be deemed affirmative evidence of the identity of the manufacturer or labeler of a plaintiff's docetaxel, absent good cause shown.[10]

9. Within thirty (30) days of the date Plaintiff uploads the Product ID Information for all docetaxel infusions to MDL Centrality, Plaintiff shall voluntarily dismiss any and all named Defendants not identified by the Product ID Information.

a. The Form Dismissal to be used by Plaintiffs is attached as Exhibit C. This form, which requires a signature by plaintiffs' counsel only, shall be used to effectuate dismissals pursuant to this Order, notwithstanding the requirements of FRCP 41, and PTOs 15 (Rec. Doc. 230) and 54 (Rec. Doc. 671), which may require additional signatures by parties who have been served to effectuate dismissals pursuant to those provisions.

b. Plaintiffs should also submit an Amended PFS to update Section III.1, 2, and 3 to reflect the correct defendant(s) and remove the defendants that are dismissed in connection with this Order.

c. Defendants previously named and/or served on Plaintiff's Short Form Complaint hereby reserve any and all defenses that existed up to the time of

[10] For all cases identified under CMO 14, Paragraph 3, contrary evidence must be produced prior to the close of Phase II discovery.

filing such dismissal.

d. Plaintiffs acknowledge that Defendants have not confirmed the sufficiency of any product identification obtained and agree that Defendants retain their right to timely dispute product identification pursuant to Paragraph 8 above. Defendants acknowledge that if a Defendant disputes Product ID Information pursuant to Paragraph 8 above, the Plaintiff retains the right to reinstate her claims against any dismissed Defendant pursuant to Federal Rule of Civil Procedure 60(b)(6).

e. To the extent Plaintiffs need to contact Defendants in connection with the procedure provided in Paragraph 9 specifically, plaintiff should use the contact information provided for each Defendant in Exhibit A.

10. If Plaintiff fails to seek voluntary dismissal of any Defendant not identified by the Product ID Information within thirty (30) days of the date Plaintiff uploads such evidence for all docetaxel infusions to MDL Centrality, such Plaintiff's claims against said Defendants not identified by the Product ID information may be subject to dismissal pursuant to PTO No. 22A after the procedural steps set forth in PTO No. 22A are satisfied.

11. Any Plaintiff who has served or will serve a PFS and failed or fails to comply with the requirements of Paragraphs 1-3 or Paragraph 5, shall be subject to dismissal pursuant to PTO No. 22A after the procedural steps set forth in PTO No. 22A are satisfied.

12 Any Plaintiff who lacks Product ID Information after complying with Paragraphs 1-5 of this Order shall be authorized to conduct discovery to the relevant infusion facility, distributor, and healthcare providers, limited in scope solely to determine Product ID Information, for a period of no more than one-hundred and twenty (120) days from the issuance date on the

subpoena issued pursuant to Paragraph 5 of this Order, or, in cases where such subpoenas have already been issued, within 120 days of entry of this Order, whichever is later, regardless of whether a response is provided by the infusion facility. If any firm needs to conduct discovery pursuant to this provision for more than 25 Plaintiffs, it shall identify to Defendants sets of 25 Plaintiffs whose deadlines shall be extended by successive 30-day periods so that no firm is required to take more than 25 deposition pursuant to this Order in a calendar month. If Product ID Information is not determined following the 120-day (or staggered, if applicable) period set forth above, the issue may be brought to the attention of the Court for appropriate adjudication.

New Orleans, Louisiana, this 24th day of July, 2018.

JANE T. MILAZZO
UNITED STATES DISTRICT JUDGE

EXHIBIT A

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EXHIBIT B

STATEMENT REGARDING CHEMOTHERAPY DRUG ADMINISTERED

PATIENT NAME: _____

DATE OF BIRTH:_____/_____/_____ SSN:_____/_____/ _____

TO BE COMPLETED BY REPRESENTATIVE OF ONCOLOGIST/INFUSION CENTER

*****PLEASE MARK THE NDC FOR THE TAXOTERE/DOCETAXEL ADMINISTERED** ***

SANOFI AVENTIS US LLC
- □ 0075-8001-80
- □ 0075-8001-20
- □ 0075-8003-01
- □ 0075-8004-04

SANOFI AVENTIS US LLC d/b/a WINTHROP US
- □ 0955-1020-01
- □ 0955-1021-04
- □ 0955-1022-08

HOSPIRA, INC.
- □ 0409-0201-02
- □ 0409-0201-10
- □ 0409-0201-20
- □ 0409-0201-25
- □ 0409-0201-26
- □ 0409-0201-27
- □ 0409-0366-01
- □ 0409-0367-01
- □ 0409-0368-01
- □ 0409-0369-01

McKESSON PACKAGING SERVICES
- □ 63739-932-11
- □ 63739-971-17

SANDOZ INC.
- □ 66758-050-01
- □ 66758-050-02
- □ 66758-050-03
- □ 66758-950-02
- □ 66758-950-03
- □ 66758-950-04

ACCORD HEALTHCARE, INC.
- □ 16729-120-49 KIT
- □ 16729-228-50 KIT
- □ 16729-231-63
- □ 16729-231-64
- □ 16729-231-65
- □ 16729-267-63
- □ 16729-267-64
- □ 16729-267-65

SAGENT PHARMACEUTICALS
- □ 25021-222-01
- □ 25021-222-04
- □ 25021-222-07
- □ 25021-245-01
- □ 25021-245-04

PFIZER LABORATORIES
- □ 0069-9141-11
- □ 0069-9141-22
- □ 0069-9141-33
- □ 0069-9142-11
- □ 0069-9142-22
- □ 0069-9142-33
- □ 0069-9143-22
- □ 0069-9143-33
- □ 0069-9144-11
- □ 0069-9144-22
- □ 0069-9144-33

ACTAVIS PHARMA, INC.
- □ 45963-734-52
- □ 45963-734-54
- □ 45963-734-74
- □ 45963-765-52
- □ 45963-781-74
- □ 45963-790-56

DR REDDYS LAB LTD.
- □ 43598-258-11
- □ 43598-259-40

TEVA PHARMS USA
- □ 0703-5720-01
- □ 0703-5730-01

NORTHSTAR RX LLC
- □ 16714-465-01
- □ 16714-500-01

EAGLE PHARMACEUTICALS
- □ 42367-121-25
- □ 42367-121-29

SUN PHARMACEUTICAL INDUSTRIES, INC.
- □ 47335-285-41
- □ 47335-286-41

□ PATIENT WAS NOT ADMINISTERED TAXOTERE/DOCETAXEL

PATIENT □ WAS / □ WAS NOT ADMINISTERED TAXOL/PACLITAXEL

_____/_____/_____ _____/_____/_____ _____

DATE OF FIRST TREATMENT | DATE OF LAST TREATMENT | # OF DOSES

_____ _____

SIGNATURE OF REPRESENTATIVE OF PRACTICE/INFUSION CENTER | NAME OF PRACTICE/INFUSION CENTER

_____ _____

PRINTED NAME & TITLE OF REPRESENTATIVE | ADDRESS

_____ _____

DATE | CITY, STATE, ZIP

EXHIBIT C

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL NO. 2740 SECTION "H" (5) JUDGE MILAZZO MAG. JUDGE NORTH
THIS DOCUMENT RELATES TO:	**NOTICE OF PARTIAL DISMISSAL WITH PREJUDICE AS TO ALL EXCEPT [Defendant(s) for whom Plaintiffs have obtained product identification]** Civil Action No.: 2:XX-cv-XXXXX

Pursuant to CMO 12A, Plaintiff dismisses with prejudice all previously named defendants in this matter except [defendant(s) for whom plaintiffs have obtained product identification], each party to bear its own costs. Plaintiff seeks this partial dismissal pursuant to paragraph 9 of Case Management Order No. 12 (Rec. Doc. 1506). Plaintiff's claims against the remaining defendants are not dismissed, or otherwise affected, by this Notice of Partial Dismissal with Prejudice. If warranted under the circumstances, Plaintiff may seek relief from this dismissal of claims pursuant to Federal Rule of Civil Procedure 60(b)(6).

Dated this _____ day of _____, 2018

[Plaintiff's counsel's signature block]

CERTIFICATE OF SERVICE

I hereby certify that on _____, ___, 2018, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record who are CM/ECF participants.

DATED: _____, ___, 2018 /s/_____