UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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

CASE MANAGEMENT ORDER NO. 12
(PRODUCT IDENTIFICATION ORDER)

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 has both 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. Within fifteen (15) days of the entry of this Order, or within thirty (30) days after filing a Short Form Complaint, each Plaintiff must make a diligent, good faith, and documented effort to: (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,

[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).

pharmacy, billing (*i.e.*, a patient itemized statement), and/or insurance billing records from such infusion facility containing the National Drug Code ("NDC") number(s) for the docetaxel Plaintiff received, or other proof of the identity of the manufacturer 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 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.[2] 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 of this Order, within seven (7) days of entry of 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.

3. If Plaintiff has not received Product ID Information within thirty (30) days of the Plaintiff's initial written request, or if Plaintiff receives written notice from the infusion facility that it does not possess or will not disclose Product ID Information to Plaintiff, Plaintiff shall notify the named Defendant(s) in writing within seven (7) days, through Defense Liaison Counsel (John

[2] 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.

Olinde – 505b2liaison@chaffe.com and Douglas Moore – dmoore@irwinllc.com) and the contact person for the Defendant(s) named and served in the lawsuit,[3] 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) an executed certification by Plaintiff or Plaintiff's counsel certifying that Plaintiff has made a diligent, good faith, and documented effort to obtain Product ID Information.

4. Within fourteen (14) 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, identifying themselves as manufacturers of docetaxel and requesting Product ID Information to be produced within fourteen (14) days of receipt of the letter. 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. Should the infusion facility fail to provide the Defendants with Product ID Information within thirty (30) days of Defendants' letter to the

[3] The name and email address of the contact person for each Defendant are listed in Exhibit A attached hereto.

infusion facility, Defendants shall provide counsel for Plaintiff a copy of the request letter to, and any responses from, the infusion facility.

5. Within seven (7) 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 requiring the infusion facility to release Product ID Information within fourteen (14) days. Plaintiff shall provide a copy of the subpoena pursuant to FRCP 45, through Defense Liaison Counsel (John Olinde – 505b2liaison@chaffe.com and Douglas Moore – dmoore@irwinllc.com) and the contact person for the Defendant(s) named and served in the lawsuit.[4] If the infusion facility fails to comply with the subpoena, the Court shall take appropriate action.

6. The following information is presumed sufficient evidence 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 medical, pharmacy, billing or insurance records; or

b. A Certificate of Authenticity of Product Identification Administered ("Certification") identifying the manufacturer(s) or labeler for Plaintiff and the correct dates of treatment, signed by an authorized person on behalf of the patient's infusion pharmacy, treatment facility, or other authorized health care professional. Such Certification need not be notarized and can be in the form of the Certification attached hereto as Exhibit B.

[4] The name and email address of the contact person for each Defendant are listed in Exhibit A attached hereto.

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 Plaintiff obtains Product ID Information, Plaintiff shall upload such evidence to MDL Centrality within seven (7) days of receipt of such evidence. Plaintiff shall submit such evidence under the "Product Identification" document type field.

8. Where Product ID Information exists, 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, it shall notify counsel for all named parties of the existence of such evidence within seven (7) days of its discovery. If such evidence is not produced by the close of discovery once a case is identified in a trial scheduling order, 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.

9. Within fourteen (14) days of the date Plaintiff uploads the Product ID Information to MDL Centrality, Plaintiff shall voluntarily dismiss any and all named Defendants not identified by the Product ID Information.

10. If Plaintiff fails to voluntarily dismiss any Defendant not identified by the Product ID Information within fourteen (14) days of the date Plaintiff uploads such evidence to MDL Centrality, such Defendant may place the issue on the Agenda for the next Status Conference. No briefing is required. Twenty-one (21) days prior to the next Status Conference, Defense Liaison Counsel shall identify to Plaintiffs' Liaison Counsel the cases Defendants intend to place on the Agenda for the next Status Conference pursuant to this Order. Any case naming Defendants without proper Product ID Information 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 claims against said Defendant (s) should not be dismissed.

11. Any Plaintiff who has served a PFS as of the date of this Order and fails to comply with the requirements of Paragraphs 1-3 within forty-five (45) days of this Order, or fails to comply with the requirements of Paragraph 5, shall be subject to dismissal upon motion by Defendants, absent good cause shown. For all other Plaintiffs, failure to comply with Paragraphs 1-3 of this Order within the time permitted to serve a PFS under Amended Pretrial Order No. 22 (Rec. Doc. 325), or failure to comply with the requirements of Paragraph 5 of this Order, shall subject such Plaintiff to dismissal upon motion by Defendants, absent good cause shown.

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 seventy-five (75) days from the issuance date on the subpoena issued pursuant to Paragraph 5 of this Order, regardless of whether a response is provided by the infusion facility. If Product ID Information is not determined following the 75-day period set forth above, Plaintiff's case may be subject to dismissal upon motion by any named Defendant.

New Orleans, Louisiana, this 12th day of January 2018.

KURT D. ENGELHARDT
UNITED STATES DISTRICT JUDGE

EXHIBIT A

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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
- □ 0075-8003-01
- □ 0075-8004-04

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

HOSPIRA, INC.
- □ 0409-0201-02
- □ 0409-0201-10
- □ 0409-0201-20
- □ 0409-0201-25
- □ 0409-0201-26
- □ 0409-0201-27

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
- □ 16729-267-63
- □ 16729-267-64
- □ 16729-267-65

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

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

ACTAVIS PHARMA, INC.
- □ 45963-734-54
- □ 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 REPRESENATIVE OF PRACTICE/INFUSION CENTER

_____ NAME OF PRACTICE/INFUSION CENTER

_____ PRINTED NAME & TITLE OF REPRESENTATIVE

_____ ADDRESS

_____ DATE

_____ CITY, STATE, ZIP