IN RE TAXOTERE LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY
FILED AUG 14 2019 Judge James F. Hyland	CASE TYPE: MCL NO. 628 MASTER DOCKET NO. MID-L-4998-18-CM
	CIVIL ACTION **IN RE TAXOTERE LITIGATION**
	PRODUCT IDENTIFICATION ORDER #3

THIS MATTER having come before the Court by way of submissions by the parties; and the Court having considered all papers and submission; and finding that it is necessary to clarify the parties' obligations and the procedures governing the discovery of Product ID Information and in accordance with the same obligations and procedures governing plaintiffs in the MDL Litigation No. 2740 in the interest of state and federal coordination; and that each party must discharge the obligations of this Order in a diligent, good faith, and documented matter; and for good cause shown,

IT IS on the 14th day of August, 2019,

1. Each Plaintiff is to submit a complete and verified Plaintiff Fact Sheet ("PFS") to be accompanied by all responsive documents in Plaintiff's possession with seventy-five (75) days of the date of the Court's Implementation Order Regarding the PFS and DFS. 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.

2. Within sixty (60) days after this Order is entered for cases already on file and after service of the Plaintiff Fact Sheet as well as service of the 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") or lot number for the docetaxel Plaintiff received, and/or completion of the attached **Exhibit A** form entitled "Statement Regarding Chemotherapy Drug Administered",[1] or other documentary evidence of the identity of the manufacturer or labeler of the docetaxel infusion Plaintiff received as provided in Paragraph 5 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.[2] The written request shall request production of such Product ID Information no more than thirty (30) days after the written request.

3. 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 received did not manufacture or label the product Plaintiff received, in accordance with the presumption in Paragraph 5 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

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1 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 5 of this Order, and (3) need not be notarized.

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.

shall have no obligations under this Order.

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.

Nothing in this Order alters defendants' obligation to provide IMS data regarding the plaintiff's facility, as required by the DFS.

4. Nothing in this Order shall prevent a Plaintiff or Plaintiff's Counsel from issuing a subpoena requiring the infusion facility to release Product ID Information. Plaintiff shall provide a copy of the subpoena pursuant to Rule 1:9, through Defense Liaison Counsel and the contact person 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.

5. The following information is presumed sufficient evidence to satisfy a Plaintiff's obligation with respect to the identity of the manufacturer(s) or labeler(s) of his/her docetaxel in this MCL, but may be challenged by countervailing evidence obtained by Defendants during discovery.

a. National Drug Code ("NDC") or lot 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 A**. 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; or

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.

6. If any party obtains Product ID Information at any time during this MCL 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.

7. Within thirty (30) days of the date Plaintiff obtains Product ID Information for docetaxel after service of the Plaintiff Fact Sheet, Plaintiff shall voluntarily dismiss with prejudice any and all named Defendants not identified by the Product ID Information and not disputed by Defendants pursuant to Paragraph 5. If a Defendant disputes Product ID Information that is not provided pursuant to Paragraph 5 above, the Plaintiff retains the right to reinstate her claims against any dismissed Defendant pursuant to Rule 4:50-1, Rule 4:26-4, and Rule 4:26-5.

8. If a Plaintiff does not produce sufficient evidence of proof of manufacturing or labeling as defined by Paragraph 5 for each docetaxel infusion pursuant to the deadlines set forth

in this Order, her case will be put on a list for dismissal to be discussed at the next scheduled Case Management Conference. Any Plaintiff who believes she possesses evidence of product identification that differs from the type of evidence described in Paragraph 5 of this Order will be heard to show cause why her case should not be dismissed at that time.

Honorable James F. Hyland, J.S.C

EXHIBIT A

STATEMENT REGARDING CHEMOTHERAPY DRUG ADMINISTERED

PATIENT NAME: _____

DATE OF BIRTH: ___/___/___ SSN: [redacted]-____
Last 4 #'s

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