

IN RE TAXOTERE LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION – MIDDLESEX COUNTY

CASE TYPE: MCL NO. 628

MASTER DOCKET NO.:

MID-L-4998-18-CM

FILED

AUG 07 2019

Judge James F. Hyland

**CIVIL ACTION
IN RE TAXOTERE LITIGATION**

**CASE MANAGEMENT ORDER
REGARDING DEFENDANT FACT SHEET**

THIS MATTER having been presented to the Court on letter briefs submitted by the parties, and for good cause shown;

IT IS on the 7 day of ~~July~~^{Aug.}, 2019,

ORDERED that the Defendant Fact Sheet attached hereto as Exhibit A will be adopted and the operable Defendant Fact Sheet in this matter.

Honorable James F. Hyland, J.S.C.

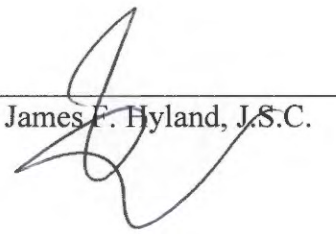


EXHIBIT A

IN RE TAXOTERE LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
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CASE TYPE: MCL NO. 628
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**CIVIL ACTION
IN RE TAXOTERE LITIGATION**

DEFENDANT FACT SHEET – PRODUCT IDENTIFICATION

Within seventy-five (75) days of receiving a substantially completed Plaintiff Fact Sheet (“PFS”), each Defendant named in the Plaintiff’s Complaint (collectively referred to as “Defendants”) must complete and serve this Defendant Fact Sheet (“DFS”) and identify or provide DOCUMENTS and/or data responsive to the questions set forth below for each such Plaintiff. Defendants must supplement their responses to the extent that additional information is provided by Plaintiff in a supplemental PFS, within sixty (60) days of receiving the supplemental information. In the event the DFS does not provide a Defendant with enough space to complete the Defendant’s responses or answers, please attach additional sheets if necessary. Please identify any DOCUMENTS that YOU, the Defendant, are producing as responsive to a question or request by bates number.

DEFINITIONS & INSTRUCTIONS

As used herein, “YOU,” “YOUR,” or “YOURS” means the responding DEFENDANTS.

“DEFENDANTS” shall mean and refer to those companies involved in the development, manufacture and distribution of the drugs known as Taxotere (Docetaxel) including each Defendant named in Plaintiff’s Complaint shall each answer each document request and question that not only calls for YOUR knowledge, but also for all knowledge that is available to YOU by reasonable inquiry, including inquiry of YOUR "officers," "directors," "agents," "employees," and attorneys.

As used herein, the phrase “HEALTHCARE PROVIDER” means: any physician or other individual healthcare provider, health care facility, clinic, hospital or hospital pharmacy identified by full name and address in PFS Section Sections V.13 and V.14 who administered, prescribed, and/or dispensed Taxotere (Docetaxel) to the Plaintiff.

“REMUNERATION” means anything of value, directly or indirectly, overtly or covertly, in cash or in kind, including but not limited to monetary payment, compensation, incentives,

preceptorship fees, gifts, entertainment, sports and/or concert tickets, speaker fees, grants, SAMPLES, reimbursement assistance, beneficiary inducements, wellness programs, patience assistance programs, transportation and/or lodging assistance, adherence to treatment regimen programs, incentives or inducements to remain in network, navigator/care coordination programs, end of life and/or palliative care programs, third party payments of premiums, or any other inducements or programs.

As used herein, the term "DOCUMENT" shall, consistent with New Jersey Rule 4:18-1, refer to any "designated documents (including writings, drawings, graphs, charts, photographs, sound recordings, images, electronically stored information, and any other data or data compilations stored in any medium from which information can be obtained and translated, if necessary, by the respondent into reasonably usable form)" If YOU are aware that any DOCUMENT that was, or might have been, responsive to any sections of this DFS which concern or relate to Plaintiff or Plaintiff's Named Facilities was destroyed, erased, surrendered or otherwise removed from YOUR possession, custody or control, at any time, provide, to the maximum extent possible, the following information: (a) the nature of the DOCUMENT (e.g., letter, memorandum, contract, etc.) and a description of its subject matter; (b) the author or sender of the DOCUMENT; (c) the recipient(s) of the DOCUMENT; (d) the date that the DOCUMENT was authored, sent and received; (e) the circumstances surrounding the removal of the DOCUMENT from YOUR custody, possession or control; and (f) the identity of the person(s) having knowledge of such removal from YOUR custody, possession or control.

As used herein, "KEY OPINION LEADER" or "THOUGHT LEADER" shall mean and refer to physicians, often academic researchers, who are believed by DEFENDANTS to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

The phrase "SAMPLES" refers to any medication or unit of a prescription drug not intended to be sold, which is given to promote the drug's sales. This includes any vouchers or coupons that provide for the HEALTHCARE PROVIDERS or patients access to the medication for a specified period of time.

"PATIENT ASSISTANCE PROGRAM" means programs created by drug companies to offer free or low cost drugs to individuals who are unable to pay for their medication. These Programs may also be called indigent drug programs, charitable drug programs or medication assistance programs.

The phrase "SALES REPRESENTATIVE" means any person presently or formerly engaged or employed by YOU whose job duties include calling on physicians or other health care professionals, healthcare facilities, hospitals, and/or physician practice groups; promoting drugs manufactured or licensed by YOU to physicians or other HEALTH CARE PROVIDERS; distributing drug SAMPLES to physicians or other HEALTH CARE PROVIDERS. "SALES

REPRESENTATIVE” also includes those who occupy positions titled “Professional Sales Representative,” “Sales Professional,” “Specialty Sales Representative,” “Senior Sales Representative,” “Senior Health Care Representative,” “Professional Representative,” “Health Care Representative,” “Institutional” or “Managed Care” sales representative, “Oncology Sales Representative,” “Medical Service Representative,” and “Medical Sales Representative” or any other titles used by Defendants and any of its divisions SALES REPRESENTATIVE also includes any contract employees or SALES REPRESENTATIVES from other companies involved in the promotion or co-promotion of Taxotere (Docetaxel).

The phrase “SALES MANAGER” means any person presently or formerly engaged or employed by YOU whose job duties include managing SALES REPRESENTATIVES and/or the promotion or marketing of pharmaceutical products in a specific geographic region. “SALES MANAGER” includes those who occupy positions titled “District Sales Manager,” “Senior Regional Sales Manager,” “Regional Sales Manager,” “Area Business Manager,” “Business Manager,” or any other titles YOU use or have used in the past for managers involved in the promotion or marketing of Taxotere (Docetaxel).

The phrase “MEDICAL SCIENCE LIAISON(S)” means any person presently or formerly engaged or employed by YOU for the purpose of sales support and direct field communication with physicians or other HEALTH CARE PROVIDERS about medical and science information related to Taxotere (Docetaxel), and opinion leader management. This includes employees with the titles of “Medical Science Liaison (MSL),” “Clinical Education Consultant (CEC)” or any other titles YOU use or have used in the past for these employees.

The phrase “MARKETING ORGANIZATION REPRESENTATIVE,” means any person presently or formerly engaged or employed by YOU for the purpose of generating interest in Taxotere (Docetaxel) by creating and implementing a marketing campaign(s) to reach physicians or other HEALTHCARE PROVIDERS. This includes employees with the title of “Marketing Representative” or any other titles YOU use or have used in the past for these employees.

The phrase “CALL NOTES” means any and all writings, notations, electronically stored information, memoranda, DOCUMENTS, emails, database entries and reports or records, internal communications and any other information reflecting any contact with HEALTHCARE PROVIDERS, and/or information about or referring to HEALTHCARE PROVIDERS related to Taxotere (Docetaxel), oncology, or the treatment of cancer and chemotherapy.

The phrase “TARGETING INFORMATION” means any information the company uses to identify a particular person, group of people, type of health care provider or demographic within a larger audience regarding the promotion of Taxotere (Docetaxel). This includes documentation, including electronically stored information, designating particular campaigns, PROMOTIONAL MATERIAL and/or other promotional efforts directed toward particular types or specialties of healthcare providers (e.g., oncologists) and/or specifically identified healthcare providers.

I. CASE INFORMATION

This DFS pertains to the following case:

Case caption: _____

Civil Action No. _____

Court in which action was originally filed: _____

Date this DFS was completed: _____

**II. SALE OF TAXOTERE (DOCETAXEL) TO DISPENSER
(HOSPITAL/PHARMACY) DIRECTLY AND/OR THROUGH GROUP
PURCHASING ORGANIZATIONS**

A. Did YOU sell, distribute, deliver or otherwise provide Taxotere (Docetaxel) to, any HEALTHCARE PROVIDER, either directly, or pursuant to a Group Purchasing Organization (“GPO”), identified by the Plaintiff in Sections V.13 and V.14 of the PFS, during the time period of twenty-four (24) months preceding Plaintiff’s first administration of Taxotere through the Plaintiff’s last administration of Taxotere (Docetaxel)?

Yes _____ No _____

B. If YOUR answer is “Yes” to Question A. above, please provide a list of all deliveries or shipments of Taxotere (Docetaxel) sold, distributed or otherwise provided to each of the HEALTHCARE PROVIDERS, as identified by the Plaintiff in Sections V.13 and V.14 of the PFS, for the time period spanning from twenty-four (24) months prior to Plaintiff’s first administration of Taxotere (Docetaxel) through Plaintiff’s last administration of Taxotere (Docetaxel). Please include the name of each HEALTHCARE PROVIDER, the date of shipment/distribution of Taxotere (Docetaxel), and the amount of Taxotere (Docetaxel) distributed on said date.

Name of Healthcare Provider	Date of Shipment Distribution	Amount of Taxotere Distributed

C. Please provide all DOCUMENTS reflecting sale or purchase agreements regarding Taxotere (Docetaxel) between DEFENDANTS and the HEALTHCARE PROVIDERS identified by Plaintiff in Sections V.13 and V.14 of the PFS in effect during the time period spanning from twenty-four (24) months prior to Plaintiff’s first administration of Taxotere (Docetaxel) through Plaintiff’s last administration of Taxotere (Docetaxel).

D. Please provide all DOCUMENTS, including product labels, patient information packets, order forms, purchase orders, billing records, invoices, and other DOCUMENTS related to the shipments of Taxotere (Docetaxel) shipped to the

HEALTHCARE PROVIDERS identified by Plaintiff in Sections V.13 and V.14 of the PFS for the time period spanning from twenty-four (24) months prior to Plaintiff's first administration of Taxotere (Docetaxel) through to Plaintiff's last administration of Taxotere (Docetaxel), and associate each label with the code numbers to which they are applicable. With regard to product labels, identification of the labels that applied to applicable lot numbers or dates is acceptable.

III. COMMUNICATIONS AND CONTACTS WITH PLAINTIFF'S HEALTHCARE PROVIDERS

A. For each HEALTHCARE PROVIDER identified in Sections V.13 and V.14 of the PFS:

1. Identify by name all of Defendants' SALES REPRESENTATIVES, MARKETING ORGANIZATIONS REPRESENTATIVES, MEDICAL SCIENCE LIAISONS, and/or any other detail persons ("Representative") who came in contact with any of Plaintiff's HEALTHCARE PROVIDER(S) in connection with Taxotere (Docetaxel) during the timeframe for which such records are available, namely 1996 to present.

Name of Representative	Title

2. Identify the time period, and specifically the dates, during which the Representative had any such contact with the HEALTHCARE PROVIDER.

Name of Representative	Healthcare Provider	Dates of Contact

3. If the Representative is no longer an employee, Defendants will provide the dates of employment for the employee and will also provide the last known address, telephone number, and email address for the Representative.

Name of Representative	Dates of Employment	Last Known Address	Telephone Number	Email Address

4. For each Representative, provide the names of the Representative's Supervising/ District SALES MANAGER. If the Representative's Supervising

District SALES MANAGER is no longer an employee, Defendants will provide the dates of employment for the employee and will also provide the last known address, telephone number, and email address for the former employee.

Supervising/ District SALES MANAGER	Current or Former Employee	Dates of Employment	Last Known Address	Telephone Number	Email Address

B. For each Defendants' Sale Representatives, MARKETING ORGANIZATION REPRESENTATIVES, MEDICAL SCIENCE LIAISONS, and/or any other detail persons ("Representative"), previously identified in Section III.A of this DFS please produce the following:

1. His/her complete CALL NOTES for each such contact that relates to (a) Taxotere (Docetaxel); and/or (b) hair loss; and/or (c) permanent hair loss and/or alopecia.
2. Produce all emails or other written correspondence with the HEALTHCARE PROVIDER(S) that relates to (a) Taxotere (Docetaxel); and/or (b) hair loss; and/or (c) permanent hair loss and/or alopecia.
3. Produce any and all TARGETING INFORMATION related to the HEALTHCARE PROVIDER(S) identified by Plaintiff in Sections V.13 and V.14 of the PFS.

C. For the HEALTHCARE PROVIDERS identified by Plaintiff in Sections V.13 and V.14 of the PFS, please provide the following information related to SAMPLES of Taxotere (Docetaxel):

1. The date(s) on which such SAMPLES of Taxotere (Docetaxel) were provided;
2. The date(s) on which the Taxotere (Docetaxel) was provided through a PATIENT ASSISTANCE PROGRAM;
3. The amount, dosage, and lot numbers of such SAMPLES and/or Taxotere (Docetaxel) provided through a PATIENT ASSISTANCE PROGRAM;
4. The name(s) of the DEFENDANT representative(s) and/or department who provided such SAMPLES Taxotere (Docetaxel);
5. The name(s) of the DEFENDANT representative(s) and/or department who provided Taxotere (Docetaxel) through a PATIENT ASSISTANCE PROGRAM.

HEALTHCARE PROVIDER	Date(s) Shipped and/or Provided	Amount and Dosage	Lot Number	Representative Who Provided

IV. CONSULTING WITH PLAINTIFF’S HEALTHCARE PROVIDER

For each HEALTHCARE PROVIDER identified in Plaintiff’s PFS, please answer the following:

- A. If the HEALTHCARE PROVIDER has been consulted, retained, or compensated by Defendants as a “KEY OPINION LEADER,” “THOUGHT LEADER,” member of a “speaker’s bureau,” “clinical investigator,” “consultant,” advisory board member or in a similar capacity or otherwise has or had a financial relationship with or has been provided REMUNERATION by DEFENDANTS, please state the following for each:
1. Identify the HEALTHCARE PROVIDER.
 2. Identify the date(s) that the HEALTHCARE PROVIDER was consulted, retained, or compensated.
 3. State the nature of the affiliation.
 4. State the type amount of REMUNERATION provided to the HEALTHCARE PROVIDER.

HEALTHCARE PROVIDER	Date(s) Consulted, Retained, or Compensated	Nature of Affiliation	REMUNERATION

5. Please identify and produce any and all consulting agreements/contracts and/or retainer agreements/contracts entered into by DEFENDANTS with the HEALTHCARE PROVIDERS identified in Sections V.13 and V.14 of the PFS.

V. PLAINTIFF'S HEALTHCARE PROVIDER'S PRACTICES

- A. Provide all chemotherapy related prescriber-level data designed to track prescribing or treating practices that YOU obtained on Plaintiff's HEALTHCARE PROVIDERS identified in Sections V.13 and V.14 of the PFS.
- B. Was the HEALTHCARE PROVIDER(S) identified in Sections V.13 and V.14 of the PFS involved in any clinical trial sponsored by DEFENDANTS related to the treatment of cancer? Yes No

If yes, provide the final Investigator Protocol related to any such trial(s).

- C. Did the Plaintiff's HEALTHCARE PROVIDER ever report any adverse events to DEFENDANTS as they pertain to Taxotere (Docetaxel)?
 Yes No

If yes, provide all DOCUMENTS related to the adverse event report/MedWatch form.

CERTIFICATION

I am employed by _____, one of the DEFENDANTS in this litigation. I am authorized by _____ [name of other DEFENDANTS] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individual, including counsel for DEFENDANTS, upon whose advice and information I relied. I hereby certify that the foregoing answers and information are true and that I have supplied all requested DOCUMENTS to the extent that such DOCUMENTS are in my possession, custody and control (including the custody and control of my lawyers). I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Signature

Print Name

Date