UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
Wanda Stewart, Case No. 17-cv-10817;
Dora Sanford, Case No. 17-cv-09417;
Alice Hughes, Case No. 17-cv-11769.

MOTION OF PSC FOR LEAVE TO FILE AMENDED SHORT FORM COMPLAINTS FOR THIRD BELLWETHER TRIAL PLAINTIFFS

NOW INTO COURT, through the Plaintiffs' Steering Committee ("PSC"), come trial plaintiffs, Wanda Stewart, Dora Sanford, and Alice Hughes, identified in Case Management Order No. 21 (Rec. Doc. 8430), who, pursuant to the attached Memorandum in Support, respectfully request leave to file the attached proposed, redacted, Amended Short Form Complaints (Exhibits 1-3), using the revised Exemplar Short Form Complaint in Pretrial Order No. 73 (Rec. Doc. 1463). Plaintiffs' Liaison Counsel has conferred with Liaison Counsel for the Sandoz, Hospira and Accord Defendants and understands these Defendants oppose Plaintiffs' requests.

The proposed, redacted, Amended Short Form Complaints and proposed Order are attached hereto.[1] The PSC intends to file an *Ex Parte* Motion for Leave to File Unredacted Amended Short Form Complaint for Third Bellwether Trial Plaintiffs Under Seal.

WHEREFORE, Plaintiffs pray that the attached proposed Order be entered and, accordingly, that they be granted leave to file the attached proposed, redacted, Amended Short Form Complaints.

[1] The pleadings are redacted pursuant to the Court's Protective Order, PTO 50.

Dated: November 14, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2019, I electronically filed the foregoing with the Clerk of 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.

/s/ M. Palmer Lambert
M. PALMER LAMBERT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
Wanda Stewart, Case No. 17-cv-10817;
Dora Sanford, Case No. 17-cv-09417;
Alice Hughes, Case No. 17-cv-11769.

MEMORANDUM IN SUPPORT OF MOTION OF PSC FOR LEAVE TO FILE AMENDED SHORT FORM COMPLAINTS FOR THIRD BELLWETHER TRIAL PLAINTIFFS

MAY IT PLEASE THE COURT:

Plaintiffs, through the Plaintiff's Steering Committee ("PSC"), respectfully request leave of Court to file redacted Amended Short Form Complaints for the Third Bellwether Trial Plaintiffs, Wanda Stewart (Sandoz), Dora Sanford (Hospira), and Alice Hughes (Accord), identified in Case Management Order No. 21 (Rec. Doc. 8430).

Pursuant to Case Management Order No. 14D (Doc. 7416), as amended by agreement of the parties, Plaintiffs' deadline to amend their pleadings is the date of the instant filing. Despite agreement that the instant filing is made timely within the agreed deadline, undersigned counsel has been unable to obtain consent to this motion for leave to file from the Sandoz, Hospira and Accord Defendants. The PSC understands that Defendants object to the request for leave to file the attached proposed amending complaints on the basis that they disagree with the supplemental and amending allegations. Respectfully, the amendments are both consistent with prior trial

plaintiffs' amendments to their complaints and made to conform to the PSC's proposed third amended master long form complaint.[1]

Unless the opposing party can show prejudice, bad faith, or undue delay, the Court should grant leave to file an amended pleading. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Leave to amend should be freely given when justice so requires. Fed. R. Civ. P. 15(a)(2); *Foman*, 371 U.S. at 182. In the context of this MDL, plaintiffs are required to use the master complaint structure pursuant to Pretrial Order No. 15 (Doc. 230). Accordingly, interests of fairness, equity and justice support allowing the above referenced Plaintiffs leave to amend their pleadings to conform to the LPLA and to adopt later amendments, including proposed amendments, to the master long form complaint. Plaintiffs also should be granted leave to file their amended pleadings to clarify their allegations regarding application of certain factual allegations made in previous versions of the master complaint to the specific context of liberative prescription and contra non valentem under Louisiana law.[2]

Because the trial scheduling order deadlines allow for amendment of pleadings to date, and considering the bellwether plaintiffs' recent selection to proceed with phase II discovery in accordance with the bellwether trial structure adopted by the Court in this MDL, Plaintiffs respectfully request that the Court grant their instant motion for leave to amend their short form complaints. *See* CMO 14-14D, 19, 20, 21. Defendants will have the opportunity, pursuant to the trial scheduling order CMO 14D (as amended by party agreement), to challenge these allegations

[1] As the Court is aware, the PSC has filed a motion for leave to amend their master long form complaint (Doc. 8334), which is currently set for oral argument on December 5, 2019. Doc. 8389.

[2] As the Court likewise is aware, Plaintiffs Deborah Johnson and Tanya Francis have presented a motion for reconsideration, or in the alternative clarification, (Doc. 7857) concerning the Court's Order and Reasons (Doc. 7571) applying master allegations to the analysis of liberative prescription and contra non valentem under Louisiana law.

through phase II discovery and with motion practice brought in accordance with the scheduling order deadlines.

Dated: November 14, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2019, I electronically filed the foregoing with the Clerk of 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.

/s/ M. Palmer Lambert
M. PALMER LAMBERT

EXHIBIT 1

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: ***Wanda Jean Stewart v. Accord Healthcare, Inc., et al.*** **Case No. 2:17-cv-10817**	**COMPLAINT & JURY DEMAND**

SECOND AMENDED SHORT FORM COMPLAINT[1]

Plaintiff incorporates by reference the Second Amended Master Long Form Complaint and Jury Demand filed in the above referenced case on September 27, 2018 (MDL Doc. 4407), subject to the amendments set forth in paragraph 13 of this Amended Short Form Complaint.[2] Pursuant to Pretrial Order No. 15, this Short Form Complaint adopts allegations and encompasses claims as set forth in the Second Amended Master Long Form Complaint against Defendant(s).

Plaintiff(s) further allege as follows:

1. Plaintiff:

   Wanda Jean Stewart

2. Spousal Plaintiff or other party making loss of independent/secondary claim (i.e., loss of consortium):

   N/A

3. Other type of Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

   N/A

4. Current State of Residence: Louisiana

[1] (Effective as of January 4, 2019) This version of the Short Form Complaint supersedes all prior versions of the form pursuant to Pretrial Order No. 73. This Court-approved version of the Short Form Complaint is available on the Court's Taxotere webpage and through MDL Centrality.

[2] Because the PSC has sought leave to file a third amended master long form complaint, Plaintiff has incorporated the proposed amending allegations herein.

5. State in which Plaintiff(s) allege(s) injury: Louisiana

6. Defendants (check all Defendants against whom a Complaint is made):

a. Taxotere Brand Name Defendants

- ☐ A. Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc.
- ☐ B. Sanofi-Aventis U.S. LLC

b. Other Brand Name Drug Sponsors, Manufacturers, Distributors

- ☑ A. Sandoz Inc.
- ☐ B. Accord Healthcare, Inc.
- ☐ C. McKesson Corporation d/b/a McKesson Packaging
- ☐ D. Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.
- ☐ E. Hospira, Inc.
- ☐ F. Sun Pharma Global FZE
- ☐ G. Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories Ltd.
- ☐ H. Pfizer Inc.
- ☐ I. Actavis LLC f/k/a Actavis Inc.
- ☐ J. Actavis Pharma, Inc.
- ☐ K. Other:

7. Basis for Jurisdiction:

- ☑ Diversity of Citizenship
- ☐ Other (any additional basis for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure:

8. Venue:

District Court and Division in which remand and trial is proper and where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court:

USDC Middle District of Louisiana

9. Brand Product(s) used by Plaintiff (check applicable):

- ☐ A. Taxotere
- ☐ B. Docefrez
- ☑ C. Docetaxel Injection
- ☑ D. Docetaxel Injection Concentrate
- ☐ E. Unknown
- ☐ F. Other:

10. First date and last date of use (or approximate date range, if specific dates are unknown) for Products identified in question 9:

June 2014 through October 2014

11. State in which Product(s) identified in question 9 was/were administered:

Louisiana

12. Nature and extent of alleged injury (including duration, approximate date of onset (if known), and description of alleged injury:

Permanent, irreversible and disfiguring alopecia.

13. Counts in Master Complaint brought by Plaintiff(s):

☑ Count I – Strict Products Liability – Failure to Warn

☐ Count III – Negligence

☐ Count IV – Negligent Misrepresentation

☐ Count V – Fraudulent Misrepresentation

☐ Count VI – Fraudulent Concealment

☐ Count VII – Fraud and Deceit

☑ Other: Plaintiff(s) may assert the additional theories and/or State Causes of Action against Defendant(s) identified by selecting "Other" and setting forth such claims below. If Plaintiff(s) include additional theories of recovery, for example, Redhibition under Louisiana law or state consumer protection claims, the specific facts and allegations supporting additional theories must be pleaded by Plaintiff in sufficient detail as required by the applicable Federal Rules of Civil Procedure.

Plaintiff amends the below identified paragraphs in the Second Amended Master Complaint as follows:

Replace paragraph 10 with the following:

10. Plaintiffs could not, by the exercise of reasonable diligence, have discovered that their usage of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez resulted in their injuries. In fact, Defendants have yet to acknowledge that these drugs permanently prevent hair regrowth, and Plaintiffs did not suspect, nor did they have reason to suspect that these drugs prevented hair regrowth or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

After paragraph 124, add the following:

124a. The label approved for Taxotere for this indication reflected the medical community's understanding that temporary hair loss is commonly associated with

chemotherapy drugs and provided no information about the risk of permanent alopecia.

124b. In fact, the clinical trial sponsored by Sanofi to support initial approval did not evaluate alopecia as a long-term side-effect of Taxotere.

Replace paragraph 136 with the following:

136. Sanofi obtained FDA approval in May 2010 to add language related to pediatric safety and efficacy, including: "The overall safety profile of TAXOTERE in pediatric patients receiving monotherapy or TCF was consistent with the known safety profile for adults." Additional changes to this label included a number of edits described by Sanofi as "housekeeping" that, among other things, deleted the phrase "hair generally grows back" and added "most common side effects of TAXOTERE include: […] hair loss" to the "Patient Information" section of the label. As with previous labels, the May 2010 label provides no information about irreversible or permanent hair loss.

136a. [redacted]

136b. [redacted]

136c. [redacted]

[redacted]

136d. [redacted]

[redacted] Sanofi then submitted a CBE sNDA on November 24, 2015 adding the language "cases of permanent alopecia have been reported" to the "Adverse Reactions" and "Patient Counseling Information" sections of the label. Sanofi also made changes to the "Patient Information" section of the label adding that the most common side effects of TAXOTERE include "hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The FDA approved Sanofi's sNDA on December 11, 2015.

136e. On April 11, 2018, Sanofi submitted a Prior Approval sNDA, request that the Taxotere label be updated to identify adverse events occurring at the conclusion of the follow-up period in TAX 316 in 2010. Among the adverse events identified by Sanofi included 29 patients who had alopecia ongoing at a median follow-up of 10-years. FDA approved Sanofi's proposed label change on October 5, 2018.[3]

After header "III. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia."

148a. In 1997, Sanofi initiated TAX 316, a self-sponsored clinical trial comparing the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with operable node-positive breast cancer. A total of 1040 patients from 112 centers participated in TAX 316 with 744 patients receiving TAC and 736 receiving

[3] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020449Orig1s079ltr.pdf

FAC. In 2004, an interim analysis of TAX 316's 55-month median follow-up data demonstrated that 3.2% of patients who took Taxotere had persistent alopecia.

After paragraph 149, add the following:

149a. In March 2006, Sanofi's pharmacovigilance department received an inquiry from a physician about the reversibility of alopecia following Taxotere treatment, noting that a patient had been experiencing alopecia since 2004. In response, Sanofi's Global Safety Officer for Taxotere internally acknowledged that cases of irreversible alopecia had occurred during Sanofi's clinical trials for Taxotere and that the medical literature might contain additional reports of irreversible alopecia. Despite this, Sanofi's Global Safety Officer advised against doing a literature search on the topic of irreversible alopecia and Taxotere. In addition, Sanofi withheld this information from the Taxotere label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 152, add the following:

152a. By early 2010, Sanofi had received reports from hundreds of women describing their permanent hair loss following treatment with Taxotere. Despite this fact, Sanofi withheld this information from the label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 157, add the following:

157a. Later in 2010, Sanofi completed its analysis of the ten-year follow-up results for TAX 316, the clinical trial used to support the adjuvant breast cancer indication. This analysis found that the number of women reporting persisting hair loss had increased from the 22 patients reported in 2004 to 29 patients out of the 687

patients tracked into follow-up. This represented an increase in the incidence of persistent alopecia from approximately 3% to 4.2%. Sanofi had previously decided in 2009 not to update the U.S. label with the follow-up data from TAX 316. Instead, Sanofi submitted to the FDA only the Final Clinical Study Report for TAX 316, which is over a thousand pages long, without submitting a labeling change. In addition, Sanofi continued to conceal this information from the medical community and consumers, including Plaintiffs.

157b. [redacted]

157c. [redacted]

157d. [redacted] Instead, Sanofi continued to conceal this information from the medical community and consumers in the United States,

including Plaintiffs.

Replace paragraph 181 with the following:

181. There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed "persistent" six months beyond the completion of chemotherapy.

181a. Sanofi has stated in court filings that "persistent" alopecia generally describes hair loss for some duration of time following chemotherapy (e.g., 3 days, 30 days, 3 months, 6 months, etc.) and carries with it the potential for hair regrowth to occur.

181b. Sanofi has also stated in court filings that "irreversible" or "permanent" alopecia, at a basic level means that an individual's hair will never regrow.

181c. Before this litigation and after, Sanofi has described Permanent Chemotherapy Induced Alopecia in a number of different ways. Employees of Sanofi have testified that permanent hair loss does not necessarily mean hair loss of six months. [redacted]

[redacted]

181d. Upon information and belief, the varying definitions of Permanent Chemotherapy Induced Alopecia, as described above, were not reasonably knowable to prescribers or consumers of Taxotere, including Plaintiffs.

After paragraph 213, add the following:

A. Sanofi Actively Sought to Hide that Taxotere Could Cause Permanent Hair Loss

213a. Sanofi's marketing efforts also affirmatively sought to minimize any association between Taxotere and permanent alopecia.

213b. According to Sanofi's Global Safety Officer for Taxotere, Sanofi knew that Taxotere could cause permanent hair loss in 2006. Despite this, Sanofi created and published in 2006 an information brochure for oncology nurses that described alopecia as "a common, yet temporary, side effect of some cancer medicines" and provided no information regarding the risk of permanent alopecia associated with Taxotere.

213c. [redacted]

213d. [redacted]

[redacted]

213e. [redacted]

213f. [redacted]

213g. [redacted]

213h. [redacted]

[redacted]

213i. [redacted]

213j. As a result of Sanofi's fraudulent concealment of the association between Taxotere and Permanent Chemotherapy Induced Alopecia, the medical community and patients, including Plaintiffs, were deprived of adequate information about the drug. Consequently, Plaintiffs were unaware of the connection between their use of Taxotere and their injury of permanent hair loss.

Plaintiff adds the following additional "Other" Counts:

Inadequate Warning Under LSA-RS 9:2800.57

1. Plaintiff repeats, reiterates, and re-alleges all paragraphs of the Master Long Form Complaint, with the same force and effect as if fully set forth herein.

2. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced TAXOTERE® into the stream of commerce, and in the course of same, directly advertised or marketed TAXOTERE® to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and her physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.

3. Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of TAXOTERE® and/or are associated with the use of TAXOTERE®.

4. The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of TAXOTERE®. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia.

5. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff's physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, although Defendants aggressively and fraudulently promoted the product to physicians.

6. Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, TAXOTERE® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

7. Defendants' failure to adequately warn Plaintiff and her prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Plaintiff's prescribing physicians and Plaintiff herself from correctly and fully evaluating the risks and benefits of TAXOTERE®.

8. Had Plaintiff been adequately warned of the serious risk of disfiguring

permanent alopecia associated with TAXOTERE®, Plaintiff would not have taken TAXOTERE®.

9. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff's physicians would have discussed the risks of disfiguring permanent alopecia with Plaintiff and/or would not have prescribed it.

10. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of TAXOTERE®, Plaintiff suffered disfiguring permanent alopecia.

11. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

14. Name of Attorney(s), Bar Number(s), Law Firm(s), Phone Number(s), Email Address(es) and Mailing Address(es) representing Plaintiff(s):

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Attorneys for Plaintiff

EXHIBIT 2

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: ***Dora Sanford v. Hospira, Inc. and Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.*** **Case No. 2:17-cv-09417**	**COMPLAINT & JURY DEMAND**

SECOND AMENDED SHORT FORM COMPLAINT[1]

Plaintiff incorporates by reference the Second Amended Master Long Form Complaint and Jury Demand filed in the above referenced case on September 27, 2018 (MDL Doc. 4407), subject to the amendments set forth in paragraph 13 of this Amended Short Form Complaint.[2] Pursuant to Pretrial Order No. 15, this Short Form Complaint adopts allegations and encompasses claims as set forth in the Second Amended Master Long Form Complaint against Defendant(s).

Plaintiff(s) further allege as follows:

1. Plaintiff:

   Dora Sanford

2. Spousal Plaintiff or other party making loss of independent/secondary claim (i.e., loss of consortium):

   N/A

[1] (Effective as of January 4, 2019) This version of the Short Form Complaint supersedes all prior versions of the form pursuant to Pretrial Order No. 73. This Court-approved version of the Short Form Complaint is available on the Court's Taxotere webpage and through MDL Centrality.

[2] Because the PSC has sought leave to file a third amended master long form complaint, Plaintiff has incorporated the proposed amending allegations herein.

3. Other type of Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

N/A

4. Current State of Residence: Louisiana

5. State in which Plaintiff(s) allege(s) injury: Louisiana

6. Defendants (check all Defendants against whom a Complaint is made):

a. Taxotere Brand Name Defendants

- ☐ A. Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc.
- ☐ B. Sanofi-Aventis U.S. LLC

b. Other Brand Name Drug Sponsors, Manufacturers, Distributors

- ☐ A. Sandoz Inc.
- ☐ B. Accord Healthcare, Inc.
- ☐ C. McKesson Corporation d/b/a McKesson Packaging
- ☑ D. Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.
- ☑ E. Hospira, Inc.
- ☐ F. Sun Pharma Global FZE
- ☐ G. Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories Ltd.
- ☐ H. Pfizer Inc.
- ☐ I. Actavis LLC f/k/a Actavis Inc.
- ☐ J. Actavis Pharma, Inc.
- ☐ K. Other:

7. Basis for Jurisdiction:

- ☑ Diversity of Citizenship
- ☐ Other (any additional basis for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure:

8. Venue:

District Court and Division in which remand and trial is proper and where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court:

USDC Middle District of Louisiana

9. Brand Product(s) used by Plaintiff (check applicable):

- ☐ A. Taxotere
- ☐ B. Docefrez
- ☑ C. Docetaxel Injection
- ☑ D. Docetaxel Injection Concentrate
- ☐ E. Unknown
- ☐ F. Other:

10. First date and last date of use (or approximate date range, if specific dates are unknown) for Products identified in question 9:

October 8, 2013 through January 21, 2014

11. State in which Product(s) identified in question 9 was/were administered:

Louisiana

12. Nature and extent of alleged injury (including duration, approximate date of onset (if known), and description of alleged injury:

Permanent, irreversible and disfiguring alopecia.

13. Counts in Master Complaint brought by Plaintiff(s):

☑ Count I – Strict Products Liability – Failure to Warn

☐ Count III – Negligence

☐ Count IV – Negligent Misrepresentation

☐ Count V – Fraudulent Misrepresentation

☐ Count VI – Fraudulent Concealment

☐ Count VII – Fraud and Deceit

☑ Other: Plaintiff(s) may assert the additional theories and/or State Causes of Action against Defendant(s) identified by selecting "Other" and setting forth such claims below. If Plaintiff(s) include additional theories of recovery, for example, Redhibition under Louisiana law or state consumer protection claims, the specific facts and allegations supporting additional theories must be pleaded by Plaintiff in sufficient detail as required by the applicable Federal Rules of Civil Procedure.

Plaintiff amends the below identified paragraphs in the Second Amended Master Complaint as follows:

Replace paragraph 10 with the following:

10. Plaintiffs could not, by the exercise of reasonable diligence, have discovered that their usage of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez resulted in their injuries. In fact, Defendants have yet to acknowledge that these drugs permanently prevent hair regrowth, and Plaintiffs did not suspect, nor did they have reason to suspect that these drugs prevented hair regrowth or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

After paragraph 124, add the following:

124a. The label approved for Taxotere for this indication reflected the medical community's understanding that temporary hair loss is commonly associated with

chemotherapy drugs and provided no information about the risk of permanent alopecia.

124b. In fact, the clinical trial sponsored by Sanofi to support initial approval did not evaluate alopecia as a long-term side-effect of Taxotere.

Replace paragraph 136 with the following:

136. Sanofi obtained FDA approval in May 2010 to add language related to pediatric safety and efficacy, including: "The overall safety profile of TAXOTERE in pediatric patients receiving monotherapy or TCF was consistent with the known safety profile for adults." Additional changes to this label included a number of edits described by Sanofi as "housekeeping" that, among other things, deleted the phrase "hair generally grows back" and added "most common side effects of TAXOTERE include: […] hair loss" to the "Patient Information" section of the label. As with previous labels, the May 2010 label provides no information about irreversible or permanent hair loss.

136a. [redacted]

136b. [redacted]

136c. [redacted]

[redacted]

136d. [redacted]

[redacted] Sanofi then submitted a CBE sNDA on November 24, 2015 adding the language "cases of permanent alopecia have been reported" to the "Adverse Reactions" and "Patient Counseling Information" sections of the label. Sanofi also made changes to the "Patient Information" section of the label adding that the most common side effects of TAXOTERE include "hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The FDA approved Sanofi's sNDA on December 11, 2015.

136e. On April 11, 2018, Sanofi submitted a Prior Approval sNDA, request that the Taxotere label be updated to identify adverse events occurring at the conclusion of the follow-up period in TAX 316 in 2010. Among the adverse events identified by Sanofi included 29 patients who had alopecia ongoing at a median follow-up of 10-years. FDA approved Sanofi's proposed label change on October 5, 2018.[3]

After header "III. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia."

148a. In 1997, Sanofi initiated TAX 316, a self-sponsored clinical trial comparing the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with operable node-positive breast cancer. A total of 1040 patients from 112 centers participated in TAX 316 with 744 patients receiving TAC and 736 receiving

[3] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020449Orig1s079ltr.pdf

FAC. In 2004, an interim analysis of TAX 316's 55-month median follow-up data demonstrated that 3.2% of patients who took Taxotere had persistent alopecia.

After paragraph 149, add the following:

149a. In March 2006, Sanofi's pharmacovigilance department received an inquiry from a physician about the reversibility of alopecia following Taxotere treatment, noting that a patient had been experiencing alopecia since 2004. In response, Sanofi's Global Safety Officer for Taxotere internally acknowledged that cases of irreversible alopecia had occurred during Sanofi's clinical trials for Taxotere and that the medical literature might contain additional reports of irreversible alopecia. Despite this, Sanofi's Global Safety Officer advised against doing a literature search on the topic of irreversible alopecia and Taxotere. In addition, Sanofi withheld this information from the Taxotere label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 152, add the following:

152a. By early 2010, Sanofi had received reports from hundreds of women describing their permanent hair loss following treatment with Taxotere. Despite this fact, Sanofi withheld this information from the label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 157, add the following:

157a. Later in 2010, Sanofi completed its analysis of the ten-year follow-up results for TAX 316, the clinical trial used to support the adjuvant breast cancer indication. This analysis found that the number of women reporting persisting hair loss had increased from the 22 patients reported in 2004 to 29 patients out of the 687

patients tracked into follow-up. This represented an increase in the incidence of persistent alopecia from approximately 3% to 4.2%. Sanofi had previously decided in 2009 not to update the U.S. label with the follow-up data from TAX 316. Instead, Sanofi submitted to the FDA only the Final Clinical Study Report for TAX 316, which is over a thousand pages long, without submitting a labeling change. In addition, Sanofi continued to conceal this information from the medical community and consumers, including Plaintiffs.

157b. [redacted]

157c. [redacted]

157d. [redacted] Instead, Sanofi continued to conceal this information from the medical community and consumers in the United States,

including Plaintiffs.

Replace paragraph 181 with the following:

181. There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed "persistent" six months beyond the completion of chemotherapy.

181a. Sanofi has stated in court filings that "persistent" alopecia generally describes hair loss for some duration of time following chemotherapy (e.g., 3 days, 30 days, 3 months, 6 months, etc.) and carries with it the potential for hair regrowth to occur.

181b. Sanofi has also stated in court filings that "irreversible" or "permanent" alopecia, at a basic level means that an individual's hair will never regrow.

181c. Before this litigation and after, Sanofi has described Permanent Chemotherapy Induced Alopecia in a number of different ways. Employees of Sanofi have testified that permanent hair loss does not necessarily mean hair loss of six months. [redacted]

[redacted]

181d. Upon information and belief, the varying definitions of Permanent Chemotherapy Induced Alopecia, as described above, were not reasonably knowable to prescribers or consumers of Taxotere, including Plaintiffs.

After paragraph 213, add the following:

A. Sanofi Actively Sought to Hide that Taxotere Could Cause Permanent Hair Loss

213a. Sanofi's marketing efforts also affirmatively sought to minimize any association between Taxotere and permanent alopecia.

213b. According to Sanofi's Global Safety Officer for Taxotere, Sanofi knew that Taxotere could cause permanent hair loss in 2006. Despite this, Sanofi created and published in 2006 an information brochure for oncology nurses that described alopecia as "a common, yet temporary, side effect of some cancer medicines" and provided no information regarding the risk of permanent alopecia associated with Taxotere.

213c. [redacted]

213d. [redacted]

[redacted]

213e. [redacted]

213f. [redacted]

213g. [redacted]

213h. [redacted]

[redacted]

213i. [redacted]

213j. As a result of Sanofi's fraudulent concealment of the association between Taxotere and Permanent Chemotherapy Induced Alopecia, the medical community and patients, including Plaintiffs, were deprived of adequate information about the drug. Consequently, Plaintiffs were unaware of the connection between their use of Taxotere and their injury of permanent hair loss.

Plaintiff adds the following additional "Other" Counts:

Inadequate Warning Under LSA-RS 9:2800.57

1. Plaintiff repeats, reiterates, and re-alleges all paragraphs of the Master Long Form Complaint, with the same force and effect as if fully set forth herein.

2. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced TAXOTERE® into the stream of commerce, and in the course of same, directly advertised or marketed TAXOTERE® to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and her physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.

3. Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of TAXOTERE® and/or are associated with the use of TAXOTERE®.

4. The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of TAXOTERE®. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia.

5. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff's physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, although Defendants aggressively and fraudulently promoted the product to physicians.

6. Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, TAXOTERE® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

7. Defendants' failure to adequately warn Plaintiff and her prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Plaintiff's prescribing physicians and Plaintiff herself from correctly and fully evaluating the risks and benefits of TAXOTERE®.

8. Had Plaintiff been adequately warned of the serious risk of disfiguring

permanent alopecia associated with TAXOTERE®, Plaintiff would not have taken TAXOTERE®.

9. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff's physicians would have discussed the risks of disfiguring permanent alopecia with Plaintiff and/or would not have prescribed it.

10. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of TAXOTERE®, Plaintiff suffered disfiguring permanent alopecia.

11. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

14. Name of Attorney(s), Bar Number(s), Law Firm(s), Phone Number(s), Email Address(es) and Mailing Address(es) representing Plaintiff(s):

By: */s/Michael P. McGartland*
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Attorneys for Plaintiff

EXHIBIT 3

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: ***Alice D. Hughes v. Accord Healthcare, Inc.*** **Case No. 2:17-cv-11769**	**COMPLAINT & JURY DEMAND**

SECOND AMENDED SHORT FORM COMPLAINT[1]

Plaintiff incorporates by reference the Second Amended Master Long Form Complaint and Jury Demand filed in the above referenced case on September 27, 2018 (MDL Doc. 4407), subject to the amendments set forth in paragraph 13 of this Amended Short Form Complaint.[2] Pursuant to Pretrial Order No. 15, this Short Form Complaint adopts allegations and encompasses claims as set forth in the Second Amended Master Long Form Complaint against Defendant(s).

Plaintiff(s) further allege as follows:

1. Plaintiff:

   Alice D. Hughes

2. Spousal Plaintiff or other party making loss of independent/secondary claim (i.e., loss of consortium):

   N/A

3. Other type of Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

   N/A

[1] (Effective as of January 4, 2019) This version of the Short Form Complaint supersedes all prior versions of the form pursuant to Pretrial Order No. 73. This Court-approved version of the Short Form Complaint is available on the Court's Taxotere webpage and through MDL Centrality.

[2] Because the PSC has sought leave to file a third amended master long form complaint, Plaintiff has incorporated the proposed amending allegations herein.

4. Current State of Residence: Louisiana

5. State in which Plaintiff(s) allege(s) injury: Louisiana

6. Defendants (check all Defendants against whom a Complaint is made):

a. Taxotere Brand Name Defendants

- ☐ A. Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc.
- ☐ B. Sanofi-Aventis U.S. LLC

b. Other Brand Name Drug Sponsors, Manufacturers, Distributors

- ☐ A. Sandoz Inc.
- ☑ B. Accord Healthcare, Inc.
- ☐ C. McKesson Corporation d/b/a McKesson Packaging
- ☐ D. Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.
- ☐ E. Hospira, Inc.
- ☐ F. Sun Pharma Global FZE
- ☐ G. Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories Ltd.
- ☐ H. Pfizer Inc.
- ☐ I. Actavis LLC f/k/a Actavis Inc.
- ☐ J. Actavis Pharma, Inc.
- ☐ K. Other:

7. Basis for Jurisdiction:

- ☑ Diversity of Citizenship
- ☐ Other (any additional basis for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure:

8. Venue:

District Court and Division in which remand and trial is proper and where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court:

USDC Eastern District of Louisiana

9. Brand Product(s) used by Plaintiff (check applicable):

- ☐ A. Taxotere
- ☐ B. Docefrez
- ☑ C. Docetaxel Injection
- ☑ D. Docetaxel Injection Concentrate
- ☐ E. Unknown
- ☐ F. Other:

10. First date and last date of use (or approximate date range, if specific dates are unknown) for Products identified in question 9:

November 2011 through February 2012

11. State in which Product(s) identified in question 9 was/were administered:

Louisiana

12. Nature and extent of alleged injury (including duration, approximate date of onset (if known), and description of alleged injury:

Permanent, irreversible and disfiguring alopecia.

13. Counts in Master Complaint brought by Plaintiff(s):

☑ Count I – Strict Products Liability – Failure to Warn

☐ Count III – Negligence

☐ Count IV – Negligent Misrepresentation

☐ Count V – Fraudulent Misrepresentation

☐ Count VI – Fraudulent Concealment

☐ Count VII – Fraud and Deceit

☑ Other: Plaintiff(s) may assert the additional theories and/or State Causes of Action against Defendant(s) identified by selecting "Other" and setting forth such claims below. If Plaintiff(s) include additional theories of recovery, for example, Redhibition under Louisiana law or state consumer protection claims, the specific facts and allegations supporting additional theories must be pleaded by Plaintiff in sufficient detail as required by the applicable Federal Rules of Civil Procedure.

Plaintiff amends the below identified paragraphs in the Second Amended Master Complaint as follows:

Replace paragraph 10 with the following:

10. Plaintiffs could not, by the exercise of reasonable diligence, have discovered that their usage of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez resulted in their injuries. In fact, Defendants have yet to acknowledge that these drugs permanently prevent hair regrowth, and Plaintiffs did not suspect, nor did they have reason to suspect that these drugs prevented hair regrowth or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

After paragraph 124, add the following:

124a. The label approved for Taxotere for this indication reflected the medical community's understanding that temporary hair loss is commonly associated with

chemotherapy drugs and provided no information about the risk of permanent alopecia.

124b. In fact, the clinical trial sponsored by Sanofi to support initial approval did not evaluate alopecia as a long-term side-effect of Taxotere.

Replace paragraph 136 with the following:

136. Sanofi obtained FDA approval in May 2010 to add language related to pediatric safety and efficacy, including: "The overall safety profile of TAXOTERE in pediatric patients receiving monotherapy or TCF was consistent with the known safety profile for adults." Additional changes to this label included a number of edits described by Sanofi as "housekeeping" that, among other things, deleted the phrase "hair generally grows back" and added "most common side effects of TAXOTERE include: […] hair loss" to the "Patient Information" section of the label. As with previous labels, the May 2010 label provides no information about irreversible or permanent hair loss.

136a. [redacted]

136b. [redacted]

136c. [redacted]

[redacted]

136d. [redacted]

[redacted] Sanofi then submitted a CBE sNDA on November 24, 2015 adding the language "cases of permanent alopecia have been reported" to the "Adverse Reactions" and "Patient Counseling Information" sections of the label. Sanofi also made changes to the "Patient Information" section of the label adding that the most common side effects of TAXOTERE include "hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The FDA approved Sanofi's sNDA on December 11, 2015.

136e. On April 11, 2018, Sanofi submitted a Prior Approval sNDA, request that the Taxotere label be updated to identify adverse events occurring at the conclusion of the follow-up period in TAX 316 in 2010. Among the adverse events identified by Sanofi included 29 patients who had alopecia ongoing at a median follow-up of 10-years. FDA approved Sanofi's proposed label change on October 5, 2018.[3]

After header "III. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia."

148a. In 1997, Sanofi initiated TAX 316, a self-sponsored clinical trial comparing the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with operable node-positive breast cancer. A total of 1040 patients from 112 centers participated in TAX 316 with 744 patients receiving TAC and 736 receiving

[3] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/020449Orig1s079ltr.pdf

FAC. In 2004, an interim analysis of TAX 316's 55-month median follow-up data demonstrated that 3.2% of patients who took Taxotere had persistent alopecia.

After paragraph 149, add the following:

149a. In March 2006, Sanofi's pharmacovigilance department received an inquiry from a physician about the reversibility of alopecia following Taxotere treatment, noting that a patient had been experiencing alopecia since 2004. In response, Sanofi's Global Safety Officer for Taxotere internally acknowledged that cases of irreversible alopecia had occurred during Sanofi's clinical trials for Taxotere and that the medical literature might contain additional reports of irreversible alopecia. Despite this, Sanofi's Global Safety Officer advised against doing a literature search on the topic of irreversible alopecia and Taxotere. In addition, Sanofi withheld this information from the Taxotere label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 152, add the following:

152a. By early 2010, Sanofi had received reports from hundreds of women describing their permanent hair loss following treatment with Taxotere. Despite this fact, Sanofi withheld this information from the label and concealed it from the medical community and consumers, including Plaintiffs.

After paragraph 157, add the following:

157a. Later in 2010, Sanofi completed its analysis of the ten-year follow-up results for TAX 316, the clinical trial used to support the adjuvant breast cancer indication. This analysis found that the number of women reporting persisting hair loss had increased from the 22 patients reported in 2004 to 29 patients out of the 687

patients tracked into follow-up. This represented an increase in the incidence of persistent alopecia from approximately 3% to 4.2%. Sanofi had previously decided in 2009 not to update the U.S. label with the follow-up data from TAX 316. Instead, Sanofi submitted to the FDA only the Final Clinical Study Report for TAX 316, which is over a thousand pages long, without submitting a labeling change. In addition, Sanofi continued to conceal this information from the medical community and consumers, including Plaintiffs.

157b. [redacted]

157c. [redacted]

157d. [redacted] Instead, Sanofi continued to conceal this information from the medical community and consumers in the United States,

including Plaintiffs.

Replace paragraph 181 with the following:

181. There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between twelve to twenty-four months following chemotherapy treatment. Some literature has indicated that hair loss can be deemed "persistent" six months beyond the completion of chemotherapy.

181a. Sanofi has stated in court filings that "persistent" alopecia generally describes hair loss for some duration of time following chemotherapy (e.g., 3 days, 30 days, 3 months, 6 months, etc.) and carries with it the potential for hair regrowth to occur.

181b. Sanofi has also stated in court filings that "irreversible" or "permanent" alopecia, at a basic level means that an individual's hair will never regrow.

181c. Before this litigation and after, Sanofi has described Permanent Chemotherapy Induced Alopecia in a number of different ways. Employees of Sanofi have testified that permanent hair loss does not necessarily mean hair loss of six months. [redacted]

[redacted]

181d. Upon information and belief, the varying definitions of Permanent Chemotherapy Induced Alopecia, as described above, were not reasonably knowable to prescribers or consumers of Taxotere, including Plaintiffs.

After paragraph 213, add the following:

A. Sanofi Actively Sought to Hide that Taxotere Could Cause Permanent Hair Loss

213a. Sanofi's marketing efforts also affirmatively sought to minimize any association between Taxotere and permanent alopecia.

213b. According to Sanofi's Global Safety Officer for Taxotere, Sanofi knew that Taxotere could cause permanent hair loss in 2006. Despite this, Sanofi created and published in 2006 an information brochure for oncology nurses that described alopecia as "a common, yet temporary, side effect of some cancer medicines" and provided no information regarding the risk of permanent alopecia associated with Taxotere.

213c. [redacted]

213d. [redacted]

[redacted]

213e. [redacted]

213f. [redacted]

213g. [redacted]

213h. [redacted]

[redacted]

213i. [redacted]

213j. As a result of Sanofi's fraudulent concealment of the association between Taxotere and Permanent Chemotherapy Induced Alopecia, the medical community and patients, including Plaintiffs, were deprived of adequate information about the drug. Consequently, Plaintiffs were unaware of the connection between their use of Taxotere and their injury of permanent hair loss.

Plaintiff adds the following additional "Other" Counts:

Inadequate Warning Under LSA-RS 9:2800.57

1. Plaintiff repeats, reiterates, and re-alleges all paragraphs of the Master Long Form Complaint, with the same force and effect as if fully set forth herein.

2. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced TAXOTERE® into the stream of commerce, and in the course of same, directly advertised or marketed TAXOTERE® to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and her physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.

3. Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of TAXOTERE® and/or are associated with the use of TAXOTERE®.

4. The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of TAXOTERE®. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia.

5. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff's physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, although Defendants aggressively and fraudulently promoted the product to physicians.

6. Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, TAXOTERE® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

7. Defendants' failure to adequately warn Plaintiff and her prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Plaintiff's prescribing physicians and Plaintiff herself from correctly and fully evaluating the risks and benefits of TAXOTERE®.

8. Had Plaintiff been adequately warned of the serious risk of disfiguring

permanent alopecia associated with TAXOTERE®, Plaintiff would not have taken TAXOTERE®.

9. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff's physicians would have discussed the risks of disfiguring permanent alopecia with Plaintiff and/or would not have prescribed it.

10. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of TAXOTERE®, Plaintiff suffered disfiguring permanent alopecia.

11. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

14. Name of Attorney(s), Bar Number(s), Law Firm(s), Phone Number(s), Email Address(es) and Mailing Address(es) representing Plaintiff(s):

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
Wanda Stewart, Case No. 17-cv-10817;
Dora Sanford, Case No. 17-cv-09417;
Alice Hughes, Case No. 17-cv-11769.

NOTICE OF SUBMISSION

TO: ALL COUNSEL OF RECORD

PLEASE TAKE NOTICE that the Motion of PSC for Leave to File Amended Short Form Complaints for Third Bellwether Trial Plaintiffs will come before the Court for submission on the 4th day of December 2019, at 9:30 a.m.

Dated: November 14, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2019, I electronically filed the foregoing with the Clerk of 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.

/s/ M. Palmer Lambert
M. PALMER LAMBERT