UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL))	MDL No. 16-2740
PRODUCTS LIABILITY)	
LITIGATION)	SECTION: "H" (5)
)	
This document relates to:)	
Lula Gavin, 18-11232)	
Clare Guilbault, 16-17061)	
Debbie Hubbard, 18-10283)	
Audry Plaisance, 18-8086)	

ORDER AND REASONS

Before the Court is Plaintiffs' Motion for Leave to File Amended Short Form Complaints of Bellwether Pool Plaintiffs (Doc. 10817). For the following reasons, the Motion is **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel, that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second is set for May 24, 2021.²

Before the first bellwether trial, the Court ruled on Defendants' summary judgment motions asserting statute-of-limitations defenses.³ In its

¹ Docetaxel is the generic version of Taxotere.

² The second trial was continued due to the COVID-19 pandemic.

³ Doc. 7571.

rulings, the Court had to decide when Plaintiffs injuries manifested and when the statute of limitations began to run.⁴ The Court looked to Plaintiffs' Master Complaint, which states as follows:

Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate cause Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy.⁵

Based on this, the Court found that generally the statute of limitations begins to run six months after a patient completes chemotherapy.⁶

On October 8, 2019, Plaintiffs filed a Motion to Amend the Master Complaint.⁷ Plaintiffs wished to no longer define their injury as manifesting six months after chemotherapy.⁸ Instead, the proposed amendments alleged that "[t]here 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." On December 11, 2019, the Court denied the motion, noting that the parties and the Court had been operating under Plaintiffs' original definition of their alleged injury for years. ¹⁰

Around the time of this denial, the Court saw an influx of motions to amend short-form complaints.¹¹ Many Plaintiffs sought to amend their responses to Question 12 of their short-form complaints, which prompts Plaintiffs to detail the "[n]ature and extent of alleged injury (including

⁴ See id. at 5 n.12.

⁵ Doc. 4407 at ¶ 181.

⁶ See Doc. 7571 at 5 n.12.

⁷ Doc. 8334.

⁸ Doc. 8702 at 2.

⁹ *Id*.

¹⁰ *Id.* at 3–4.

¹¹ See Doc. 8703; Doc. 10338.

duration, approximate date of onset (if known), and description of alleged injury)."¹² As an example, Plaintiff Alice Hughes had originally answered Question 12 by saying, "Hair Loss and Thinning – August 2012."¹³ She sought to amend her answer to read simply, "Permanent, irreversible and disfiguring alopecia," removing any reference to the date of onset for her injury.¹⁴ The Court denied her motion, along with others, noting that "it is apparent that Plaintiffs seek to revise their allegations to buttress their claims against statute-of-limitations defenses."¹⁵ The Court further wrote that "[t]he proposed amendments would prompt Defendants to conduct additional discovery and prepare a different statute-of-limitations defense."¹⁶ Because of this potential for prejudice, the Court did not allow Plaintiffs to amend their pleadings.¹⁷

On May 11, 2020, to deal with the continuing flurry of motions, the Court issued Pretrial Order 105 ("PTO 105") to establish what kind of amendments are permissible and what kind are not. Accordingly, PTO 105 provides that "Plaintiffs may amend their complaints to add factual allegations regarding particularized facts individual and specific to each Plaintiff's medical care and treatment and/or that Plaintiff's communications with medical professionals." ¹⁸ In the instant Motion, the four Plaintiffs listed in the above caption seek leave to amend their complaints, averring that their amendments are consistent with PTO 105. Defendants Hospira, Inc. and Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc. (together, "Hospira") oppose the Motion.

¹² See Doc. 8703 at 5.

¹³ *Id*.

 $^{^{14}}$ *Id*.

 $^{^{15}}$ *Id*.

 $^{^{16}}$ *Id*.

¹⁷ See *id*.

¹⁸ Doc. 10338.

LEGAL STANDARD

Under Rule 15(a)(2), "[t]he court should freely give leave [to amend a pleading] when justice so requires." However, leave to amend "is by no means automatic." Instead, "decisions concerning motions to amend are 'entrusted to the sound discretion of the district court." While leave should be freely given, "that generous standard is tempered by the necessary power of a district court to manage a case." In deciding whether to grant leave, courts should consider five factors: (1) undue delay, (2) bad faith or dilatory motive, (3) repeated failure to cure deficiencies by previous amendments, (4) undue prejudice to the opposing party, and (5) futility of the amendment. 23

LAW AND ANALYSIS

Hospira first argues that Plaintiff Hubbard should not be permitted to amend her response to Question 12 of her short-form complaint. Question 12 prompts Plaintiff to detail the "[n]ature and extent of alleged injury (including duration, approximate date of onset (if known), and description of alleged injury)."²⁴ Plaintiff Hubbard wishes to allege that she suffered her injury "beginning sometime after treatment with Taxotere (docetaxel)."²⁵ This conflicts with her Plaintiff Fact Sheet ("PFS"), however, which provides that she suffered her injury in January 2015, six months after completing her

¹⁹ FED. R. CIV. P. 15(a)(2).

²⁰ Wimm v. Jack Eckerd Corp., 3 F.3d 137, 139 (5th Cir. 1993).

²¹ Smith v. EMC Corp., 393 F.3d 590, 595 (5th Cir. 2004) (quoting Quintanilla v. Tex. Television, Inc., 139 F.3d 494, 499 (5th Cir. 1998)).

²² Schiller v. Physicians Res. Grp. Inc., 342 F.3d 563, 566 (5th Cir. 2003).

²³ Smith, 139 F.3d at 595 (citing Foman v. Davis, 371 U.S. 178, 182 (1962)).

²⁴ Doc. 10817-5.

 $^{^{25}}$ *Id*.

chemotherapy treatment.²⁶ As this Court has ruled before, Plaintiffs are not allowed to distance themselves from the definition of Permanent Chemotherapy Induced Alopecia provided in the Master Complaint. Accordingly, Plaintiff Hubbard may not amend her response to Question 12.

Next, Hospira argues that Plaintiffs Guilbault and Plaisance are attempting to assert claims that are not permitted by Louisiana law. Regarding Plaintiff Guilbault, Hospira takes issue with two of her claims: Count I, which is "Strict Products Liability – Failure to Warn," and Count II, which is "Strict Products Liability for Misrepresentation." Plaintiff Guilbault adopted these claims from the Master Complaint. Notably, Plaintiff Guilbault concedes that Louisiana law governs her case, and she has agreed to remove Count II from her complaint.

As Hospira notes, this Court has previously ruled that Count I is not viable under Louisiana law.²⁸ The Louisiana Products Liability Act (the "LPLA") establishes "the exclusive theories of liability for manufacturers for damage caused by their products."²⁹ Because the LPLA does not permit any theory of strict liability, a strict liability claim is not "viable as an independent theory of recovery against a manufacturer" in a products liability action under Louisiana law.³⁰ Plaintiff Guilbault acknowledges that her failure to warn claim arises exclusively under the LPLA. The Court, therefore, sees no need to strike Count I but instead interprets it as being subject to the LPLA.

Regarding Plaintiff Plaisance, Hospira objects to the claims she alleges under Illinois law. According to her complaint, Plaisance received treatment in

²⁶ Doc. 10907-3. Plaintiff's PFS states that her injury occurred in 2014 and 2015. Given that Hubbard was still receiving treatment in 2014, the Court interprets her PFS to state that her hair loss became permanent in 2015.

²⁷ Doc. 10817-4 at 5.

²⁸ Doc. 8703.

²⁹ *Id.* (quoting LA. REV. STAT. § 9:2800.52).

³⁰ *Id.* (quoting Jefferson v. Lead Indus. Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997)).

Louisiana and suffered her injury in Louisiana.³¹ Also, she currently lives in Louisiana. Hospira avers that Plaisance's case has no connection to Illinois other than Hospira having its principal place of business there.

The Court will not engage in a choice-of-law analysis at this time, although the Court suspects that Plaintiff's Illinois law claims ultimately will not survive. Plaintiff asks the Court to consider Illinois choice-of-law rules, but even these rules would create a strong presumption that Louisiana law should apply in Plaisance's case.³² The Court doubts that Plaintiff can overcome the presumption. Despite this, the Court will not delve into a thorough choice-of-law analysis at this juncture, as this could lead to a flurry of other Plaintiffs asking the Court to conduct choice-of-law analyses in their cases. For now, Plaintiff may assert claims under Illinois law.

Lastly, Hospira argues that Plaintiffs are attempting to add allegations that run afoul of PTO 105. In the charts below, the Court issues its rulings on the specific amendments Plaintiffs seek to make:

Plaintiff Lula Gavin

Proposed Allegation	Ruling
Plaintiff, prior to undergoing chemotherapy treatment in	Granted
November 10, 2011, discussed potential side effects with	
her prescribing oncologist, Dr. Shannon Penland.	
Plaintiff was instructed by Dr. Penland that although she	Granted
may experience hair loss during the course of her	

³¹ Doc. 10817-6 at 3, 5.

³² Paulsen v. Abbott Labs., Case No. 15-cv-4144, 2018 WL 1508532, at *12 (N.D. Ill. March 27, 2018) ("The place where Plaintiff's injury occurred is Georgia, and therefore there is a strong presumption that Georgia substantive law applies to Plaintiff's personal injury claims.").

chemotherapy treatments, her hair loss would be	
temporary.	
At no time did Plaintiff receive a warning that her use of	Denied –
Taxotere may result in permanent hair loss.	Duplicative of
	Master
	$Complaint^{33}$
At some time after completing chemotherapy, Plaintiff	Granted
noticed that hair was not re-growing as fast or as fully as	
she had anticipated.	
Plaintiff did not suspect she may be suffering from	Denied –
permanent hair loss caused by Taxotere until she saw a TV	Plaintiff may
advertisement in 2016 that stated a chemotherapy drug	simply state
called Taxotere could cause permanent hair loss.	when she saw
	the ad
This was the first time Plaintiff suspected that her lack of	Denied –
full hair regrowth might actually be permanent hair loss	Attempting to
caused by her use of Taxotere.	manipulate
	statute-of-
	limitations
	analysis

Plaintiff Clare Guilbault

Proposed Allegation	Ruling
Plaintiff, prior to undergoing chemotherapy treatment in	Granted
December of 2013, discussed potential side effects with her	

 $^{^{33}}$ See Doc. 4407 at ¶ 5 ("Plaintiffs . . . now suffer from permanent hair loss, a side effect for which they were not warned and were wholly unprepared.").

prescribing oncologist, Dr. Theodossiou and her	
chemotherapy nurses Amanda and Suzzane Murray.	
Plaintiff was instructed by Dr. Theodossiou that although	Granted
she may experience hair loss during the course of her	
chemotherapy treatments, her hair loss would be	
temporary and that any hair lost would re-grow.	
At no time did Plaintiff receive a warning that her use of	Denied –
Taxotere may result in permanent hair loss.	Duplicative of
	Master
	Complaint
Plaintiff believed that she would experience full hair re-	Denied –
growth following completion of her chemotherapy	Duplicative of
treatments based on conversations with her healthcare	Master
providers.	Complaint
Plaintiff also reached out to a friend who was also cancer	Granted
survivor, looking for advice on how to encourage faster hair	
regrowth. Her friend suggested that she take Biotin.	
Plaintiff did not suspect she may be suffering from	Denied –
permanent hair loss caused by Taxotere until she observed	Plaintiff may
a legal advertisement in approximately May of 2016.	simply state
	when she saw
	the ad
This was the first time Plaintiff suspected that her lack of	Denied –
full hair regrowth might actually be permanent hair loss	Attempting to
caused by her use of Taxotere. Plaintiff filed her lawsuit	manipulate
within 7 months of first learning of the connection between	statute-of-
the use of Taxotere and permanent hair loss.	

limitations
analysis

Plaintiff Debbie Hubbard

Proposed Allegation	Ruling
Plaintiff, prior to undergoing chemotherapy treatment on	Granted
February 25, 2014, discussed potential side effects with	
an oncology nurse at her infusion center. The nurse	
indicated that, although she may experience hair loss	
during the course of chemotherapy treatments, her hair	
loss would be temporary. Plaintiff's treating oncologist (Dr.	
Yunus) and a nurse practitioner also indicated that hair	
loss during chemotherapy was "normal" or something to	
that effect.	
Plaintiff did not suspect she may be suffering from	Denied –
permanent hair loss caused by Taxotere/Docetaxel until	Plaintiff may
she saw an advertisement in 2018 that a chemotherapy	simply state
drug called Taxotere could cause permanent hair loss.	when she saw
Plaintiff also believes she saw a Facebook posting about	the ad
Taxotere lawsuits. This was the first time Plaintiff	
suspected her lack of full hair re-growth might actually be	
permanent hair loss caused by her use of	
Taxotere/Docetaxel.	

Plaintiff Audry Plaisance

Proposed Allegation	Ruling
Plaintiff's prescribing physician advised her that her hair	Granted
loss would be temporary, though no indication was given	
as to exactly how long the regrowth would take. Further,	
Plaintiff was placed on other medications, including	
hormonal medications, following her treatment with	
docetaxel. It was her understanding that these	
medications may impact hair regrowth[.] As such, Plaintiff	
did not understand and could not have understood after	
multiple inquires that her hair loss was permanent.	
Liability	Denied –
1. Plaintiff repeats, reiterates, and realleges all	Plaintiff
paragraphs of this Complaint inclusive, with the same	Plaisance filed
force and effect as if fully set forth herein.	her suit in
2. Plaintiff shows that the serious risk of developing	2018. The
disfiguring permanent alopecia and other injuries are the	Court will not
direct and proximate result of breaches of obligations owed	allow these
by Defendants to Plaintiff, including defects in design,	amendments at
marketing, manufacture, distribution, instructions and	this stage in
warnings by Defendants, which breaches and defects are	her case.
listed more particularly, but not exclusively, as follows:	
a. Failing to instruct and/or warn of the risk of developing	
disfiguring permanent alopecia and other injuries;	
b. Failing to adequately instruct and/or warn healthcare	
providers, including those healthcare providers who	

administered docetaxel to Plaintiff of the serious risk of developing disfiguring permanent alopecia and other injuries;

- c. Manufacturing, producing, promotion, formulating, creating, and/or designing docetaxel without adequately testing, accounting for, monitoring, and reporting persistent, permanent, and disfiguring permanent alopecia;
- d. Failing to provide adequate warning of the dangers associated with docetaxel;
- e. Designing, formulating, researching, developing, manufacturing, marketing, promoting and selling docetaxel when it knew or reasonably should have known of its propensity to cause disfiguring permanent alopecia and other injuries;
- f. Defendants' design, development, manufacture, marketing, and sale of docetaxel which drug is defective and unreasonably dangerous for the undisclosed risk of developing disfiguring permanent alopecia and other injuries;
- g. The continued production and sale of docetaxel without adding adequate warnings despite Defendants' knowledge of the association between docetaxel and disfiguring permanent alopecia and other injuries;
- h. Providing inaccurate labeling and inadequate warnings and instructions;

- i. Utilizing inadequate testing methods which were not accurate, sensitive, specific, and/or reproducible to track the actual rate of permanent alopecia;
- j. Other breaches and defects which may be shown through discovery or at trial; and
- k. Failure to act with the required degree of care due and owing to plaintiff and her physician(s).

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Leave to File Amended Short Form Complaints of Bellwether Pool Plaintiffs (Doc. 10817) is **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs may amend their short-form complaints consistent with this opinion.

New Orleans, Louisiana, this 13th day of January, 2021.

JAME TRICHE MILAZZO UNITED STATES DISTRICT JUDGE