

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

DIANE THORNTON,

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC AND SANOFI
US SERVICES, INC.,

Defendants.

Case No. 23-1228-KHV-GEB

MEMORANDUM AND ORDER

This matter comes before the Court on Plaintiff's Motion for Leave to File Amended Complaint (**ECF No. 65**). After careful consideration of the parties' briefing and the argument of counsel, the Court GRANTS Plaintiff's motion.

I. Background¹

This case was originally brought in the United States District Court for the Eastern District of Louisiana ("MDL Court") as part of *In re: Taxotere (Docetaxel) Products Liability Litigation*, MDL No. 2740. Plaintiff alleges she suffered from permanent alopecia or hair loss after using Taxotere; a chemotherapy drug manufactured, labeled, and distributed by Defendants, to treat her breast cancer. In Plaintiff's Amended Short Form Complaint, which incorporates by reference the Master Long Form Complaint, Plaintiff

¹ Unless noted otherwise, the information in this section is taken from the Complaint and Jury Demand (23-2512-KHV-GEB ECF No. 1), Short Form Complaint (23-2512-KHV-GEB ECF No.5), and Amended Transfer Order re: Doc. 16347 (Wave 2 Cases) (23-2512-KHV-GEB ECF No. 8). This background information should not be construed as judicial findings or factual determinations.

brought claims sounding in Strict Products Liability – Failure to Warn, Strict Products Liability for Misrepresentation, Negligence, Negligent Misrepresentation, Fraudulent Misrepresentation, Fraudulent Concealment, Fraud and Deceit, and Breach of Express Warranty.

In the MDL Court the parties worked through a series of Master and Short Form Complaints, Motions to Dismiss pursuant to Fed. R. Civ. P. 12, Amended Complaints, and filing of Answers.² After an extended period of general discovery and the trial of certain bellweather cases, the case was transferred to the District of Kansas on October 25, 2023. The Court set a Status Conference before District Judge Kathryn H. Vratil and the undersigned Magistrate Judge on December 11, 2023.³ Following the Status Conference, a Scheduling Order was entered directing Plaintiff to file a motion for leave to amend as discussed during the conference no later than December 28, 2023.⁴ Plaintiff was also directed to omit allegations regarding other defendants and/or other chemotherapy drugs which were part of the Master Complaint in the MDL Court and to plead her claims in

² MDL Court Pretrial Order No. 15 (Deadlines for Master and Short Form Complaint, Motions to Dismiss and Master Answer), 23-2512-KHV-GEB ECF No. 7-2, pp. 15-17; MDL Court Pretrial Order No. 53 (Amendments to Plaintiffs' Master Long Form Complaint, Exemplar Short Form Complaint and Plaintiffs' Fact Sheet), 23-2512-KHV-GEB ECF No. 7-2, pp. 118-19; MDL Court Pretrial Order No. 61 (Order Dismissing Count Two and Count Eight of the Master Long Form Complaint) 23-2512-KHV-GEB ECF No. 7-2, pp. 120-22; MDL Court Pretrial Order No. 62 (Master Answer Deadline), 23-2512-KHV-GEB ECF No. 7-2, pp. 123-24; MDL Court Pretrial Order No. 37A (Amends and Supersedes Pretrial No. 37 with Procedures for Short Form Complaints and Motions for Leave to Amend Short Form Complaints, 23-2512-KHV-GEB ECF No. 7-2, pp. 140-42, and MDL Court Pretrial Order No. 105 (Short Form Complaint Allegations and Amendments – Statute of Limitations Order) and related Stipulations, 23-2512-KHV-GEB ECF No. 7-2, pp. 167-74.

³ Order, 23-2512-KHV-GEB ECF No. 14.

⁴ Scheduling Order, 23-2512-KHV-GEB ECF No. 38, p. 6.

accordance with Kansas law. Plaintiff timely filed her Motion for Leave to File Amended Complaint⁵ and Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services, Inc. timely filed their response in opposition.⁶

The Court and the parties discussed the then pending Motion for Leave to Amend at the January 11, 2024 Status Conference. The Court found the initial Motion for Leave to Amend as moot due to Plaintiff's failure to follow the Court's guidance from the December conference. The proposed First Amended Complaint still included factual allegations regarding other defendants and chemotherapy drugs. The facts pled were redundant and not case specific, and the proposed complaint included claims which had been dismissed by the MDL Court. The Court ordered Plaintiff to file an amended motion addressing those deficiencies in the proposed amended complaint no later than January 15, 2024.⁷ Plaintiff timely filed the current motion. Defendants filed their response in opposition on January 22, 2024.⁸ The parties again discussed the proposed amended complaint with the Court during the February 12, 2024 Status Conference. The discussion this time was directed at more substantive issues including the separation of claims for clarity, pleading the appropriate definition of injury as ordered by the MDL Court, and pleading fraud claims with sufficient particularity. Plaintiff was permitted to file an amended, proposed First Amended Complaint addressing the issues discussed during the

⁵ Motion for Leave to File Amended Complaint, ECF No. 42.

⁶ Opposition, ECF No. 47.

⁷ Order, ECF No. 55.

⁸ Opposition, ECF No. 69.

conference no later than February 26, 2024.⁹ And Defendants were permitted to file a supplemental response in opposition.¹⁰ Both Plaintiff's amended, proposed First Amended Complaint and Defendants' supplemental response in opposition were timely filed.¹¹ And finally, the parties were given the opportunity to argue the current motion at the March 12, 2024 Status Conference. The motion is ripe and the Court is prepared to rule.

II. Plaintiff's Motion for Leave to File Amended Complaint (ECF No. 65).

A. Legal Standards

The standard for permitting a party to amend her pleadings is well established. A party may amend its pleading as a matter of course under Fed. R. Civ. P. 15(a)(1), either before the responding party answers or within 21 days after service of a responsive pleading. In cases such as this where the time to amend as a matter of course has passed, without the opposing party's consent, a party may amend its pleading only by leave of the court under Rule 15(a)(2). Leave "shall be freely given when justice so requires."¹²

The decision to grant or deny leave to amend is within the sound discretion of the Court.¹³ "If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits."¹⁴ "In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by

⁹ Order, ECF No. 80.

¹⁰ *Id.*

¹¹ Proposed First Amended Complaint, ECF No. 91 and Opposition, ECF No. 96.

¹² Fed. R. Civ. P. 15(a)(2).

¹³ *Foman v. Davis*, 371 U.S. 178, 182 (1962).

¹⁴ *Id.*

amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be ‘freely given.’”¹⁵ However, futility of amendment is adequate justification to deny leave to amend.¹⁶ A court is “justified in denying the motion to amend if the proposed amendment could not have withstood a motion to dismiss or otherwise failed to state a claim.”¹⁷

A complaint must plead sufficient facts to state a claim for relief that is plausible on its face in order to withstand a motion to dismiss.¹⁸ All well-pleaded facts are accepted as true.¹⁹ Additionally, all reasonable inferences derived from such facts are viewed in the light most favorable to Plaintiff.²⁰ However, conclusory allegations without supporting facts are insufficient to state a claim.²¹

1. Futility

Here, Defendants do not allege undue delay, bad faith or dilatory motive, or undue prejudice as a basis to deny Plaintiff’s motion. Therefore, the Court need not address such factors and will focus on the specific arguments raised by Defendants. Through the process set forth in the Procedural Background section, *supra*, discussing certain deficiencies in the briefing and proposed First Amended Complaint and permitting an amended, proposed

¹⁵ *Id.*

¹⁶ *Schepp v. Fremont Cnty., Wyo.*, 900 F.2d 1448, 1451 (10th Cir. 1990) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

¹⁷ *Id.*

¹⁸ *Archuleta v. Wagner*, 523 F.3d 1278, 1283 (10th Cir. 2008).

¹⁹ *Shero v. City of Grove*, 510 F.3d 1196, 1200 (10th Cir. 2007).

²⁰ *Archuleta*, 523 F.3d at 1283.

²¹ *Hall v. Bellmon*, 935 F.2d 1106, 1110 (10th Cir. 1991).

First Amended Complaint be submitted, the parties and Court worked through certain of Defendants' objections to the amendment. Plaintiff, through the process, has substantially revised the claims alleged. She no longer makes any claims based upon fraud. She retains her claims of negligent and strict product liability - failure to warn and retains her allegations the statute of limitations has been tolled by Defendants' alleged fraudulent concealment of the known risk of permanent alopecia from treatment with Taxotere.

Defendants have three remaining objections to Plaintiff's amendment: 1) Plaintiff has not pleaded her fraudulent concealment allegations in support of tolling the statute of limitations with sufficient particularity making the claim for tolling futile; 2) amendment to include any facts which post-date Plaintiff's chemotherapy treatment from October 2012 through May 2013 should be denied as futile; and 3) Plaintiff's proposed First Amended Complaint lacks sufficient factual detail under Fed. R. Civ. P. 8(a) and should be denied as futile. The Court will address each of them in turn.

a. Plaintiff has not pleaded her fraudulent concealment allegations with sufficient particularity.

The pleading standard which applies to fraud claims is procedural, thus federal law applies.²² "To toll the statute of limitations based on fraudulent concealment, plaintiffs must show defendants' use of fraudulent means, successful concealment from plaintiffs, and the fact that plaintiffs did not know or could not have known by due diligence of their cause of action."²³ The fraudulent means "must be pleaded with particularity under Rule

²² *AKH Co., Inc. v. Universal Underwriters Ins. Co.*, No. 13-2003-JAR, 2015 WL 1809157, at *13 (D. Kan. April 21, 2015) (citing *Gasperini v. Ctr. For Humanities, Inc.*, 518 U.S. 415, 427 (1996)).

²³ *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1078 (D. Kan. 2009) (citing *Ballen v.*

9(b).²⁴ Therefore Plaintiff's complaint must "set forth the time, place and contents of the false representations, the identity of the party making the false statements and the consequences thereof."²⁵ Defendants argue Plaintiff's conclusory allegations in support of tolling the statute of limitations lack factual support. Specifically, they allege Plaintiff fails to allege any nexus between the fraudulent concealment allegations and herself.

Plaintiff's amended, proposed First Amended Complaint ("FAC") alleges: 1) the Taxotere label fails to reflect any information regarding the risk of permanent alopecia; 2) in what years Defendants knew some percentage of patients treated with Taxotere suffered from persistent alopecia; and 3) in 2006 Defendants' Global Safety Officer admitted Defendants knew Taxotere caused permanent hair loss. In the FAC, Plaintiff additionally alleges despite Defendants knowing there was a risk of permanent alopecia for some patients treated with Taxotere, in 2006 Defendant Sanofi-Aventis U.S. LLC undertook acts to conceal permanent hair loss as a possible side effect of Taxotere. It is alleged they did so by creating an informational tear sheet provided to chemotherapy nursing staff to give to patients which represented hair loss following the use of Taxotere was temporary. The Court finds Plaintiff's FAC sets forth the time, place and contents of the false representations, as well as the identity of the party making the false statements with sufficient particularity.

Defendants also allege Plaintiff fails to allege with particularity, a nexus between

Prudential Bache Sec., 23 F.3d 335, 337 (10th Cir. 1994)).

²⁴ *Id.*

²⁵ *Id.* (citing *Koch v. Koch Indus.*, 203 F.3d 1202, 1236 (10th Cir. 2000)).

the purported fraudulent concealment and any delay in her learning of the risk of permanent alopecia, i.e., the consequences of the fraudulent concealment. The Court disagrees. In the FAC, Plaintiff alleges: 1) because of Sanofi's fraudulent concealment of the association between Taxotere and permanent alopecia, the medical community, the public, and patients, including herself were deprived of adequate information about the drug and the risk Taxotere permanently prevents hair regrowth; 2) before undergoing chemotherapy treatment with Taxotere her prescribing oncologist told her the hair loss from chemotherapy would be temporary; 3) she was never informed her use of Taxotere might result in permanent hair loss; 4) due to Defendants concealment from Plaintiff and her prescribing oncologist, she agreed to undergo treatment with Taxotere with the misunderstanding her hair loss would be temporary; and 5) Plaintiff did not suspect or have reason to suspect her hair loss was permanent and Defendants conduct caused her injuries until 2017 when she saw an advertisement. The Court finds Plaintiff has pleaded her allegations regarding fraudulent concealment tolling the statute of limitations with sufficient particularity.

b. Amendment to include any facts which post-date Plaintiff's chemotherapy treatment from October 2012 through January 2013 should be denied as futile.

The parties agree Plaintiff received chemotherapy treatments, including Taxotere, from October 2012 through January 2013. The FAC includes allegations regarding Defendants development, approval, and labeling changes regarding Taxotere. These allegations begin with the FDA's approval of Taxotere on May 14, 1996 when the label purportedly reflected no information about the risk of permanent alopecia through October

5, 2015 when the FDA allegedly asked Defendants to amend the Taxotere label to identify permanent alopecia in the “Adverse Reactions” section of the label and beyond to FDA approval of Defendants’ proposed label change on October 5, 2018. The First Amended Complaint additionally includes allegations regarding what Defendants knew or what medical studies had allegedly shown about the incidence of permanent alopecia following treatment with Taxotere. Those allegations begin with the initiation of two trials sponsored by Defendants beginning in 1997 and 1998, set forth alleged known outcomes of permanent alopecia in 2004 and 2005, and continues through a May 12, 2016 European Medicines Agency report, which purportedly finds a causal association between Taxotere and permanent alopecia when patients who were treated with Taxotere. Defendants, without any development of the issue, argue such facts after the time Plaintiff received her chemotherapy treatment are irrelevant to Plaintiff’s claims and therefore futile.

Defendants, as the parties opposing amendment, bear the burden of establishing futility.²⁶ Defendants cite to one District of Oregon case, *Schultz ex rel. Morris v. Wells Fargo Bank, Nat. Ass’n*,²⁷ wherein the court denied amendment to include certain facts which were irrelevant to the plaintiff’s claims. Defendants cite to no Tenth Circuit or District precedent in support of its argument that purportedly irrelevant facts are futile. Even if the *Schultz ex rel. Morris* case set precedent for this Court to follow, the cases are factually different and therefore distinguishable.

The facts which were not permitted through amendment in the *Schultz* case made

²⁶ *Anderson v. PAR Elec. Contractors, Inc.*, 318 F.R.D. 640, 642 (D. Kan. 2017).

²⁷ No. 11-1467, 2013 WL 1826575, at *6 (D. Or. April 30, 2013).

allegations regarding persons who were not a party to the case. They included allegations about the non-party's drug convictions, their taking advantage of Schultz financially, and their prolonged unemployment.²⁸ Although the claims were not relevant, they were not permitted to be included through amendment because they were potentially harmful to those persons who, because they were not parties to the case, were unable to file a motion to strike.²⁹ Here the allegations which post-date Plaintiff's chemotherapy treatment are related to: 1) what and when Defendants knew about the risk of permanent alopecia from treatment with Taxotere; 2) when any changes to the Taxotere labeling occurred; and 3) whether such changes occurred prior to Plaintiff's treatment, thereby providing her with warning regarding the risk of permanent alopecia. Defendants have not met their burden to show the facts which post-date Plaintiff's chemotherapy treatment are futile.

c. Plaintiff's proposed First Amended Complaint lacks sufficient factual detail under Fed. R. Civ. P. 8(a) and should be denied as futile.

Last, Defendants allege Plaintiff's First Amended Complaint lacks sufficient detail pursuant to Fed. R. Civ. P. 8(a)(2). They allege due to Plaintiff's failure to allege details including the type of cancer she was treated for, the identity of her prescribing oncologist, the chemotherapy regimen received, and whether she has been diagnosed with permanent alopecia, she has failed to state a claim for relief. The Court disagrees.

Fed. R. Civ. P. 8(a)(2) requires a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." "[T]he pleading standard in Rule 8

²⁸ *Id.*

²⁹ *Id.*

does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”³⁰ “A pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’”³¹

Both of Plaintiff’s claims are brought pursuant to K.S.A. 60-3302(c) of the Kansas Product Liability Act (“KPLA”) which states as follows:

“Product liability claim” includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any action based on, strict liability in tort, negligence, breach of express or implied warranty, breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent, misrepresentation, concealment or nondisclosure, whether negligent or innocent, or under any other substantive legal theory.

“Kansas law recognizes three ways in which a product may be defective: (1) a manufacturing defect; (2) a warning defect; and (3) a design defect.”³² Plaintiff alleges warning defects. “To establish a prima facie case based on negligence or strict liability in a products liability case, plaintiff must produce evidence to establish three elements: (1) the injury resulted from a condition of the product; (2) the condition was an unreasonable dangerous one; and (3) the condition existed at the time it left defendant’s control.”³³

³⁰ *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

³¹ *Id.*

³² *Messer v. Amway Corp.*, 210 F. Supp. 2d 1217, 1227 (D. Kan. 2002), *aff’d*, 106 F. App’x 678 (10th Cir. 2004) (citing *Savina v. Sterling Drug, Inc.*, 247 Kan. 105, 114, 795 P.2d 915, 923 (1990)).

³³ *Id.* (citing *Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 630, 886 P.2d 869, 886 (1994)).

The Court construes Defendants argument to mean Plaintiff has not sufficiently plead allegations her injury resulted from a condition of the product. The Court has reviewed the FAC. It alleges more than a formulaic recitation of the elements of a claim for negligent or strict product liability - failure to warn and sets forth more than just labels and conclusions. It alleges: 1) Plaintiff underwent treatment for early stage breast cancer; 2) her treatment included Taxotere which she used from October 2012 through January 2013; 3) prior to receiving chemotherapy treatment she was informed by her prescribing oncologist, hair loss from chemotherapy would be temporary; 4) following her treatment her hair did not fully grow back as anticipated; 5) Defendants put Taxotere into interstate commerce unreasonably and without providing proper warning to her and her health care providers of the risk of permanent alopecia; and 6) she was permanently disfigured as the direct and proximate result of her use of Taxotere. Plaintiff additionally goes to great lengths to allege the lack of warning in the label regarding risk of permanent hair loss when Taxotere labeling was first approved by the FDA, to show changes were not made to the labeling until after she underwent treatment with Taxotere, to allege Taxotere was in a defective condition due to these defects in the warnings, and to allege Taxotere's defective condition was unreasonably dangerous. The Court finds the FAC sets forth the short and plain statement of the claim showing that the pleader is entitled to relief required by Fed. R. Civ. P. 8.

IT IS THEREFORE ORDERED Plaintiff's Motion for Leave to File Amended Complaint (**ECF No. 65**) is **GRANTED**. Plaintiff shall file the First Amended Complaint, previously filed as a proposed complaint at ECF No. 91, no later than April 19, 2024.

IT IS FURTHER ORDERED Defendants shall file their answer or other responsive pleading to Plaintiff's First Amended Complaint within 14 days after the service of the amended pleading as provided by Fed. R. Civ. P. 15(1)(3).

IT IS SO ORDERED.

Dated April 12, 2024, at Wichita, Kansas.

s/ Gwynne E. Birzer
GWYNNE E. BIRZER
United States Magistrate Judge