UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Barbara Earnest, 16-17144	)	

ORDER AND REASONS

Before the Court are three Motions filed by Defendants Sanofi-Aventis U.S. LLC and Sanofi U.S. Services, Inc. (collectively, "Sanofi" or "Defendants"). The Motions are a Motion to Exclude Expert Testimony on General Causation (Doc. 6163); a Motion to Exclude Expert Testimony of David Madigan, PhD (Doc. 6144); and a Motion to Exclude Expert Testimony of Ellen Feigal, M.D. (Doc. 6149). On July 25, 2019, the Court heard oral argument on two of these Motions—the Motion to Exclude Expert Testimony on General Causation and the Motion to Exclude Expert Testimony of David Madigan. For the following reasons, the Motion to Exclude Expert Testimony on General Causation (Doc. 6163) and the Motion to Exclude Expert Testimony of David Madigan, PhD (Doc. 6144) are **DENIED**. The Motion to Exclude Expert Testimony of Ellen Feigal, M.D. (Doc. 6149) 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,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege

[1] Docetaxel is the generic version of Taxotere.

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 of Plaintiff Barbara Earnest ("Plaintiff") is set to begin September 16, 2019.[2]

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> > (b) the testimony is based on sufficient facts or data;
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> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.[3]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[4] and *Kumho Tire Co. v. Carmichael*.[5] The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.[6] After defining the permissible scope of the expert's testimony,

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[2] To the extent Defendants' Motions relate to Plaintiff Tanya Francis, the Motions are moot, given the Court's dismissal of her case. To the extent the Motions relate to Plaintiff Antoinette Durden, the Court denies the Motions but will permit them to be renewed at a later date.

[3] FED. R. EVID. 702.

[4] 509 U.S. 579 (1993).

[5] 526 U.S. 137 (1999).

[6] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 799 (E.D. La. 2011); *see also* Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert

a court next assesses whether the opinions are reliable and relevant.[7] As the "gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[8]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[9] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[10] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[11] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[12] "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[13] After assessing reliability, a court evaluates relevance.[14] In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.[15]

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony's probative value substantially outweighs its prejudicial effect.[16]

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witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").
[7] *See* United States v. Valencia, 600 F.3d 389, 424 (5th Cir. 2010). *See also* Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881–82 (5th Cir. 2013).
[8] *Wellogix*, 716 F.3d at 881.
[9] *See Daubert*, 509 U.S. at 592–93.
[10] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).
[11] *See Daubert*, 509 U.S. at 590.
[12] *See id.* at 596.
[13] *Id.*
[14] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).
[15] *Id.*
[16] FED. R. EVID. 703.

LAW AND ANALYSIS

The three Motions before the Court are related. In the Motion to Exclude Expert Testimony on General Causation, Sanofi argues that Plaintiff fails to put forward one expert who conducts both parts of the required two-part test for demonstrating causation. Sanofi argues that instead Plaintiff improperly pieces together testimony from two experts—Dr. Madigan and Dr. Feigal. In this Motion, Sanofi also disputes that these experts are qualified to opine on causation, and Sanofi further avers that the experts did not use reliable methodologies in forming their opinions.

In the Motion to Exclude Expert Testimony of David Madigan, Defendants argue that the three analyses upon which Dr. Madigan bases his opinions are unreliable. In the Motion to Exclude Expert Testimony of Ellen Feigal, Defendants argue that Dr. Feigal is unqualified to render her opinions and that her opinions are irrelevant and unreliable.

I. General Causation

Defendants argue that Plaintiff is unable to prove general causation with relevant and reliable expert testimony. The crux of Sanofi's argument is that Plaintiff failed to task one expert with addressing both prongs of the general causation analysis. Sanofi further argues that these experts' causation opinions were not adequately disclosed. According to Sanofi, the experts did not properly articulate their causation opinions in their reports. Sanofi argues that Dr. Madigan, a statistician, failed to state in his report that Taxotere in fact causes permanent alopecia. Regarding Dr. Feigal, Sanofi similarly argues that she failed to state that Taxotere causes permanent alopecia. Lastly, Sanofi argues that the opinions of each expert are independently unreliable. Because these arguments overlap with the arguments Sanofi brings in the individual

motions against these experts, the Court will address these in the following sections regarding the individual experts.

To prevail in a pharmaceutical products liability case, a plaintiff must establish both general and specific causation through reliable expert testimony.[17] "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury."[18] To assess whether general causation exists between an agent and a disease, the case law recognizes a two-prong test.[19] First, there must be evidence showing a "statistically significant association" between the agent and the disease.[20] Second, once an association is found, researchers assess whether a true causal relationship underlies the association.[21] Typically, an expert applies the Bradford Hill criteria to evaluate this second prong.[22] The Bradford Hill criteria are: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge.[23]

Plaintiff relied on Dr. Madigan to identify a statistically significant association. Plaintiff relied on Dr. Feigal to then analyze the association using

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[17] *See* Burst v. Shell Oil Co., No. 14-109, 2015 WL 3755953, at *3 (E.D. La. June 16, 2015); In re Abilify (Aripiprazole) Prods. Liab. Litig., 299 F. Supp. 3d 1291, 1306 (N.D. Fla. 2018).
[18] Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351 (5th Cir.2007).
[19] *See Burst*, 2015 WL 3755953, at *5 (E.D. La. June 16, 2015); *Wagoner*, 813 F. Supp. 2d at 803–04.
[20] *See Wagoner*, 813 F. Supp. at 803–04; *Burst*, 2015 WL 3755953, at *5.
[21] *See Wagoner*, 813 F. Supp. at 803–04; *Burst*, 2015 WL 3755953, at *5.
[22] *See Wagoner*, 813 F. Supp. at 803–04; *Burst*, 2015 WL 3755953, at *5. The Bradford Hill criteria derive from a 1965 lecture by a British epidemiologist and statistician, Sir Austin Bradford Hill. In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II), 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018). In the lecture, he identified nine criteria that can aid researchers in deciding whether a reported association in an epidemiological study is causal. *Id.*
[23] *Burst*, 2015 WL 3755953, at *5.

the Bradford Hill criteria. Plaintiff, therefore, provides evidence on both prongs of the causation analysis. Sanofi fails to cite any law stating that the same expert who identifies the association must also be the one who applies the Bradford Hill criteria. Accordingly, the Court rejects the notion that the law requires one expert to conduct the entire causation inquiry.[24]

The Court further rejects Sanofi's argument that Dr. Madigan is not qualified to testify regarding the second prong. He does not purport to be an epidemiologist, nor does he purport to be qualified to testify on the second prong. Instead, he appropriately limits his opinion to statistics and does not opine on medical causation. He provides only the statistical analysis, which serves as a foundation for Dr. Feigal to testify on the second prong. Insofar as Sanofi argues that Dr. Madigan's opinions are unreliable because they do not show causation, the Court rejects the premise that his opinions had to show causation, as opposed to only a statistically significant association, to be reliable. The law does not require this.[25] For similar reasons, the Court rejects Sanofi's argument that Dr. Feigal is not qualified to testify on the first prong of the analysis. Dr. Feigal does not purport to be a statistician, and she does not purport to be qualified to testify on the first prong of the causation analysis.

The Court further finds that the opinions of these experts were adequately disclosed. The Court sees no issues with Dr. Madigan's report, which plainly demonstrates that he conducted the first prong of the general causation test. He explains the statistical analysis he conducted and expressly states that he agrees with Sanofi's 2015 conclusion that the evidence supports a causal association between docetaxel and permanent alopecia. Further,

[24] *See Abilify*, 299 F. Supp. 3d at 1312–30, 1361–68 (finding Madigan "amply qualified to offer biostatistical analysis" of study serving as basis for statistically significant association while at the same time finding him unqualified to offer opinion on medical causation).
[25] *See id.* (treating analysis of statistical significance as independent from analysis of medical causation).

deposition testimony shows that Defendants explored Dr. Madigan's work and understood his opinion:

> Q: What I want to know is, have you independently done the work necessary to form an independent opinion that [T]axotere causes irreversible alopecia?
>
> A: Sure. I believe it does. I believe there is a causal effect established here.
>
> Q: And the work that you did to establish that [T]axotere causes irreversible alopecia includes what elements?
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> A: So the analysis from the randomized trials. So the meta-analysis of the randomized trials and the analysis of the individual trials, the analysis of the FAERS database and my analysis of the internal database.

Dr. Madigan's report, supplemented by his deposition testimony, leaves no guesswork for Defendants. The Court therefore rejects Sanofi's argument that Dr. Madigan's opinions were not adequately disclosed.

The Court similarly finds that Dr. Feigal adequately disclosed her causation opinion. In the "Conclusions" section of her report, six conclusions are prominently listed.[26] One of these is:

> Permanent chemotherapy-induced alopecia is a known adverse event of Taxotere-containing regimens in the adjuvant treatment of women with early stage operable breast cancer (Stages I, IIA, IIB, IIIA), as evidenced in the company-sponsored randomized controlled clinical trials and in postmarketing surveillance and multiple case studies from 2001 to present.[27]

Another conclusion states that the "Company's own analysis of the data led them to the conclusion that permanent chemotherapy-induced alopecia is causally related to Taxotere."[28]

[26] Doc. 6163-20 at 46–47.
[27] *Id.* at 46.
[28] *Id.*

While her report was less than clear on the analysis underlying her general causation opinion, Sanofi deposed Dr. Feigal for multiple days and explored this underlying analysis. Dr. Feigal testified that she based her causation opinion on her review of the TAX 316 and GEICAM 9805 clinical studies, the pharmacovigilance referenced in Sanofi's 2015 Clinical Overview, and case study reports.[29] Dr. Feigal explained how she applied the Bradford Hill factors in her analysis, further illuminating for Sanofi that her opinion addressed the second prong of the general causation analysis.[30] Accordingly, as Plaintiff writes, "there are no surprises here," and the Court will not find Dr. Feigal's testimony inadmissible for what Defendants call an inadequate disclosure.

II. Dr. David Madigan

Regarding Dr. Madigan, Sanofi first takes issue with his analysis of the FDA's adverse event report database ("FAERS") and his analysis of Sanofi's internal databases. Sanofi argues that the key words Dr. Madigan used to search the databases returned irrelevant results and that Dr. Madigan failed to evaluate the results to ensure their relevancy. As Sanofi explains in its briefing, Dr. Madigan searched the FAERS database for case reports that included all three of the following: (1) "alopecia" as a listed adverse event; (2) "Taxotere" or "docetaxel" as one of the listed drugs; and (3) "disability or permanent damage" listed as an outcome. At oral argument, defense counsel explained that Dr. Madigan had to be creative in choosing these terms. In other

[29] Doc. 7513-2 at 28–30, 60.
[30] *Id.* at 91 (pointing to the increased risk in the randomized controlled clinical trials as support for "dose-response" factor); *id.* at 93 (explaining what sources she considered for the "alternative explanations" factor); *id.* at 95–96 (showing that she considered the "temporality" factor in observing that her sources were "treatment emergent" and occurred after treatment); *id.* at 98 (showing consideration of "replication of findings" factor).

cases, a search could be run for a specific medical condition. However, because "permanent alopecia" was not provided as an option on the case reports, Dr. Madigan could not search for "permanent alopecia" but had to select other terms that would locate pertinent results. Sanofi raises similar arguments regarding Dr. Madigan's search of Sanofi's internal database, averring that his search terms were overbroad.

The Court finds that Dr. Madigan's methodology passes muster.[31] In his report, Dr. Madigan makes clear that the statistical analysis he conducted is accepted in the industry. It is used by drug companies and the FDA.[32] The limitations Sanofi identifies are not weaknesses in Dr. Madigan's methodology; they are limitations beyond his control that he deliberately worked around. Accordingly, Sanofi's concerns relate to the weight of Dr. Madigan's testimony, not its admissibility, and on cross-examination, Defendants can highlight these limitations for the jury.

Regarding Dr. Madigan's search of Sanofi's database, Sanofi further argues that this search was unreliable because Dr. Madigan relied upon another expert, Dr. Antonella Tosti, to decide the search terms. Sanofi emphasizes that Dr. Tosti is a dermatologist and not an expert in statistical analyses. Under Rule 703, however, an expert can rely on the work of another expert provided that the reliance is reasonable.[33] Sanofi has made no showing that Dr. Madigan's collaboration with Dr. Tosti runs afoul of Rule 703.

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[31] *See* In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig., No. 3:09-md-2100, 2011 WL 6302573, at *17 (S.D. Ill. Dec. 16, 2011) (finding Madigan amply qualified to testify about his examination of FAERS database and the detection of safety signals; finding other experts similarly qualified, including one epidemiologist who considered data "on an aggregate scale, not on an individual scale").

[32] *See* Doc. 6144-1 at 6–7.

[33] *See* Tajonera v. Black Elk Energy Offshore Operations, LLC, No. 13-366, 2016 WL 3180776, at *10 (E.D. La. June 7, 2016) ("Federal Rule of Evidence 703 allows experts to base their opinions on facts or data that the expert has been made aware of or personally observed, which includes the efforts of other experts, provided that experts in the particular field would

Sanofi next takes issue with Dr. Madigan's statistical analysis of Sanofi's clinical studies, TAX 316 and GEICAM 9805. Sanofi avers that Dr. Madigan's analysis of the studies is irrelevant because the studies evaluated "ongoing alopecia" not "permanent alopecia." Sanofi suggests that some of the patients who were reported as having "ongoing alopecia" during the follow-up period of the study may have since had their hair regrow. The Court finds that this distinction does not make Dr. Madigan's analysis irrelevant but instead only less persuasive. Accordingly, this is a criticism that Sanofi can highlight for the jury on cross-examination.

Sanofi further argues that Dr. Madigan relied on a flawed methodology in analyzing the two studies. Sanofi emphasizes that the results of each study individually produced no statistically significant results. Sanofi argues that Dr. Madigan cannot now combine the results of the studies to achieve statistical significance. The Court rejects Sanofi's argument and finds that Sanofi's concern goes to the weight of Dr. Madigan's testimony, not to its admissibility.[34]

Finally, Sanofi takes issue with Dr. Madigan's opinion that a safety signal emerged "several years earlier" than 2015. As Sanofi explains, a "safety signal" is "a concern about an excess of adverse events compared to what would be expected to be associated with a product's use."[35] Sanofi argues that Dr. Madigan's opinion is vague and unhelpful to the jury. The Court disagrees. Dr. Madigan's report shows that he was more precise in his analysis than Sanofi

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reasonably rely on those kinds of facts or data in forming an opinion on the subject.") (internal citations omitted).

[34] *See* Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 17–22 (1st Cir. 2011) (reversing district court ruling and allowing expert to draw conclusions based on combination of studies, finding that alleged flaws identified by district court go to weight of testimony not admissibility).

[35] Doc. 6144 at 4 (quoting FDA materials).

admits. He pointed to safety signals that emerged in 2000 and 2008.[36] He need not pinpoint the exact date by which Sanofi should have identified a safety signal for his opinion to be helpful to the jury.

III. Dr. Ellen Feigal

In its Motion to Exclude Expert Testimony on General Causation, Sanofi argues that Dr. Feigal improperly relied on Sanofi's "2015 Clinical Overview," cherry-picked literature, and Sanofi's clinical studies. The Court will address each argument in turn.

The "2015 Clinical Overview" was a report Sanofi created for the FDA in which Sanofi assessed the adverse event reports it had accumulated in its pharmacovigilance database. The Court does not find Dr. Feigal's reliance on the 2015 Clinical Overview improper. This was not the main foundation of Dr. Feigal's opinions as Sanofi suggests. This informed her analysis and provided insight—given that the report included information that was only available to Sanofi—but Sanofi fails to show that she placed undue reliance on the report. Sanofi further avers that Dr. Feigal's analysis of the report was only her "personal interpretation" of it, suggesting that understanding the report requires context. Given Dr. Feigal's experience and her consideration of numerous sources in forming her opinions about Taxotere, the Court sees no issues with Dr. Feigal's consideration the Sanofi's "2015 Clinical Overview." If the document makes more sense with context, Defendants can ensure that the jury has this context when Defendants cross-examine Dr. Feigal.

Regarding the argument that Dr. Feigal cherry-picked her sources, Sanofi states that Dr. Feigal testified that she used her personal judgment in deciding what articles to review and include in her analysis. The Court

[36] *See* Doc. 7469 at 12.

disagrees with Sanofi's characterization of this as cherry-picking. Dr. Feigal appropriately focused her research, using relevant search terms and carefully considering the results of her searches. To support their argument, Defendants rely on *Konrick v. Exxon Mobil Corporation*,[37] and the Court finds this reliance misplaced. In *Konrick*, the court held that the experts mischaracterized the studies they cited.[38] The *Konrick* court wrote that a certain expert "cherry-picked data from studies that do not otherwise support his conclusion, reached conclusions that the authors of the study did not make, and failed to explain contrary results."[39] That is not what happened here. Defendants make no showing that Dr. Feigal mischaracterized the contents of her sources. Instead, what Defendants attack is simply Dr. Feigal's effort to reasonably limit the scope of her research.

Regarding Sanofi's clinical studies, Sanofi raises the same argument against Dr. Feigal that it did against Dr. Madigan—that the studies evaluated "ongoing alopecia" not "permanent alopecia." For the same reasons the Court rejected this argument as to Dr. Madigan, the Court rejects it as to Dr. Feigal.

Sanofi further argues that Dr. Feigal's report "makes no mention" of the Bradford Hill criteria.[40] Sanofi also specifically avers that her assessment is not tied to the question of whether Taxotere, as opposed to another chemotherapy agent, can cause permanent alopecia. First, the Court rejects the notion that an expert must follow "a checklist analysis of the Bradford Hill factors."[41] Instead, as epidemiologists and courts have recognized, the factors

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[37] No. 14-524, 2016 WL 439361 (E.D. La. Feb. 4, 2016).
[38] *See id.* at *7, *13.
[39] *Id.* at *7.
[40] Doc. 6163 at 28.
[41] *See* In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings, No. 14-C-1748, 2017 WL 1833173, at *9 (N.D. Ill. May 8, 2017) (accepting plaintiffs' argument that causation opinion need not follow "checklist analysis of the Bradford Hill factors").

are guidelines.[42] A causation opinion, therefore, need not address each one.[43] To the extent an expert cannot articulate support for a particular factor, this goes to the weight of the expert's opinion, not its admissibility.[44]

Dr. Feigal sufficiently addresses the Bradford Hill factors in her report. For example, she addresses the "temporal relationship" factor throughout her report. As one court explained, this factor can be summarized as followed: "A cause must precede its effect. Strength in temporality, such as when a cause immediately precedes its effect, supports an inference of causation."[45] In her report, Dr. Feigal discusses case studies that reported persistent hair loss occurring after a cancer patient's treatment with Taxotere. In discussing the Sedlacek study, she writes as follows: "Persistent significant alopecia, defined as <50% hair regrowth at least one year after chemotherapy, developed in 7/112 (6.3%) women with localized breast cancer treated with a Taxotere/docetaxel containing regimen."[46] In discussing the Masidonski and Mahon study, she writes as follows: "Over the past 10 years, 13 women treated for breast cancer at their institution have been identified with permanent alopecia, and 11/13 had been treated with a Taxotere/docetaxel-based regimen with an anthracycline and cyclophosphamide, and the other 2 with an anthracycline and cyclophosphamide." [47] Dr. Feigal's discussion of these

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[42] *See Wagoner*, 813 F. Supp. 2d at 803–04; *Testosterone Replacement Therapy*, 2017 WL 1833173, at *11.
[43] *Wagoner*, 813 F. Supp. 2d at 803–04 ("[E]pidemiologists have recognized that . . . 'each factor need not be fulfilled in order for a researcher to proclaim causation.' . . . Unsurprisingly, then, courts have held that an expert's 'failure to satisfy the Bradford Hill criteria does not necessarily compel exclusion of an opinion as unreliable.'") (quoting In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig., 612 F. Supp. 116, 133 (D. Mass. 2009) and In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 936, 946 (D. Minn. 2009)); *Testosterone Replacement Therapy*, 2017 WL 1833173, at *11 (finding that causation opinion need not address each Bradford Hill factor).
[44] *See Wagoner*, 813 F. Supp. 2d at 804.
[45] Davis v. McKesson Corp., No. 18-1157, 2019 WL 3532179, at *32 (D. Ariz. Aug. 2, 2019).
[46] Doc. 6163-20 at 42.
[47] *Id.*

studies shows the cause (Taxotere treatment) preceding the effect (permanent hair loss). This supports an inference of causation under this factor.

As Dr. Feigal suggests in her deposition, however, this factor is somewhat amorphous in this case. She testified as follow:

> There may also be some variability in the timing of recognition of the permanent hair loss and I think you can find, you know, probably from our -- certainly from my reading, everybody has got a different definition for permanency.
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> Some it's six months. Some it's two years. Obviously, that affects the denominator of the people you are calling have permanent alopecia.[48]

Accordingly, the "effect" in this case is more difficult to identify than in cases involving an easily recognizable injury. Especially given this limitation, Dr. Feigal's consideration of this factor suffices.

Dr. Feigal also addresses the "biological plausibility" factor. As courts have explained, "[t]he concept of biological plausibility . . . asks whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent."[49] In her report, Dr. Feigal writes as follows:

> Permanent, irreversible hair loss due to chemotherapy (PCIA) is thought to be likely a result of the hair follicle being permanently damaged, and the hair density is markedly reduced. This is thought to be likely due to irreversible damage of the stem cells.[50]

Dr. Feigal further explains her consideration of this factor in her deposition:

> Q: Do you have an opinion as to how Taxotere causes permanent alopecia?
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> A: Well, I think it's well-known that Taxotere is a cytotoxic chemotherapy agent that can attack the hair in two different

[48] Doc. 7513-2 at 24.
[49] *Milward*, 639 F.3d at 25; *Testosterone Replacement Therapy*, 2017 WL 1833173, at *11.
[50] Doc. 6163-20 at 37.

ways. It's a systemic drug, so it circulates all throughout the body.

Because you have blood vessels in the scalp, the scalp gets exposed. The hair follicles get exposed to the drug. It is known there's two ways that this chemotherapy can lead to hair loss.

It can attack during the growth phase of the hair, but it can also cause thinning of the hair shaft during the telogen phase and so it breaks off and you only get these little baby hairs. That is what's thought in terms of permanent alopecia.

And I have experience with stem cells in another part of the type of work I do, is that cells in your body have what's called stem cells that can renew and replicate. The thought is that it may be poisoning the stem cells so that once that hair is lost, it's lost. You don't have a renewal capability.

So that's -- would be one of the proposed mechanisms of how it could lead to permanent hair loss. The mechanism of reversible alopecia is very well-known.

Q: Okay. The mechanism of what you call irreversible alopecia would you agree is not well-known?

A: I could say it's -- I'm probably not the right expert to comment on the causation of alopecia, I think. You asked me what I think in terms of the mechanism of action and I proposed what people are evaluating it.

Q: But do you have an opinion as to the mechanism of action as to how Taxotere causes permanent hair loss?

. . . .

A: I have an opinion based on my knowledge of how stem cells work and based on my knowledge of how stem cells work in the human body and I have an opinion based on the fact that this is a systemic chemotherapy that is circulating to the scalp.

So my opinion is that it's probably somehow attacking the stem cell and irreversibly either damaging it, destroying it or perhaps interfering with its signaling pathway so that it can't do what it needs to do.

Q: Has that mechanism of action been scientifically proven?

A: Not to my knowledge.

Q: So you would agree that the mechanism of action that supports your opinion is theoretical?

A: I think there's very strong biologic plausibility based on Taxotere's ability to kill hair follicles that it wouldn't take -- it does not take a stretch to think that there might be an ability to attack the stem cell and somehow interfere with signaling or kill it.

Is it proven? No.[51]

Dr. Feigal's report, bolstered by her deposition testimony, sufficiently shows her consideration of the "biological plausibility" factor.

Dr. Feigal also considers the "dose-response relationship" factor. As one court explained, this factor can be summarized as follows: "Causation is more likely if greater amounts of the putative cause are associate with corresponding increases in the occurrence of disease or harm."[52] In her report, in discussing the Martin study, Dr. Feigal notes that "PCIA occurred in 36 (10%) of 358 patients with Taxotere/docetaxel regimens reaching cumulative doses of $\geq$ 400 mg/m² but not in 59 patients receiving lower cumulative doses (300 mg/m²) of Taxotere/docetaxel (e.g., dose response)."[53] In her deposition, Dr. Feigal further commented on dose response. In reviewing a certain study, she said, "I think this was a dose about 75 milligrams per meter squared is what my

[51] Doc. 7513-2 at 20–22.
[52] *Davis*, 2019 WL 3532179, at *32.
[53] Doc. 6163-20 at 45.

memory is serving me and at 100 milligrams per meter squared, they got more exposure, more alopecia."[54] She further stated, "I'm not going to give you the definitive dose because the studies are different and that can happen. You know, not every study is identical with when the observations are seen what dose. I think the pertinent point is that there was a dose response."[55] This shows Dr. Feigal's consideration of the "dose-response relationship" factor.

Finally, Dr. Feigal also considers the "alternative explanations" factor. In discussing the Sedlacek study, for example, Dr. Feigal notes that while 7 of 112 women who were treated with a Taxotere/docetaxel-containing regimen suffered persistent significant alopecia, none of the 126 patients treated with a Taxol/paclitaxel-containing regimen, nor any of the 285 patients treated with doxorubicin without a taxane, suffered persistent alopecia.[56] Dr. Feigal makes similar observations in discussing the Palamaras study and the Martin study.[57] The Court therefore rejects Sanofi's argument that Dr. Feigal failed to consider whether another chemotherapy agent causes permanent alopecia.

Sanofi raises additional arguments in its Motion to Exclude Expert Testimony of Ellen Feigal. Sanofi first argues that Dr. Feigal is not qualified to opine on the "informed consent" discussion between an oncologist and his or her patient. Sanofi avers that Dr. Feigal has not treated a breast cancer patient in 28 years, and she has never counseled a breast cancer patient on the risks and benefits of Taxotere. The Court rejects the notion that Dr. Feigal is unqualified. Dr. Feigal has worked for pharmaceutical companies, and she has worked for the National Cancer Institute. She has given presentations and

[54] Doc. 7513-2 at 14.
[55] *Id.* at 15.
[56] Doc. 6163-20 at 42.
[57] *Id.* at 43, 45.

taught college courses that cover the topic of "informed consent." Dr. Feigal has more than enough experience to render her qualified.

Sanofi next argues that Dr. Feigal's general "informed consent" opinions are irrelevant and will be unhelpful to the jury. This argument is grounded in the learned intermediary doctrine, which provides that a manufacturer has no duty to warn a plaintiff but instead only a duty to warn the treating physician. Defendants assert that the learned intermediary doctrine turns on the testimony of a plaintiff's prescribing physician, not the testimony of a retained expert speculating about the decision-making process. Defendants argue that the jury, therefore, must hear from the prescribing physician and the patient. Based on such testimony, the jury can make inferences about whether an inadequate label caused Plaintiff's injury or whether she would have taken Taxotere regardless of whether Defendants warned of the risk of permanent hair loss associated with the drug. In response, Plaintiff avers that Dr. Feigal's opinions provide insight on how a reasonable physician should have navigated the decision-making process with her patient. Plaintiff argues that under the learned intermediary doctrine, subjective or objective evidence is appropriate.

Because Plaintiff's treating physician, Dr. James Carinder, is available to testify, Dr. Feigal will not be allowed to opine on the facts of Earnest's case. Dr. Carinder can testify about how he would have responded to an adequate warning from Defendants.[58] Dr. Feigal, therefore, can testify about the standard of care for physicians for informing patients through the decision-making process; she cannot, however, testify about the application of these principles to Earnest's case. Similarly, Dr. Feigal can offer general opinions on how pharmaceutical companies disseminate risk information and what

[58] The Court makes no finding as to the admissibility of this evidence in a case where the treating physician is unavailable.

alternative treatments exist for Taxotere patients, but Dr. Feigal cannot offer specific opinions on these topics as they relate to Plaintiff Earnest's case.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Sanofi's Motion to Exclude Expert Testimony on General Causation (Doc. 6163) and Motion to Exclude Expert Testimony of David Madigan, PhD (Doc. 6144) are **DENIED**. Sanofi's Motion to Exclude Expert Testimony of Ellen Feigal, M.D. (Doc. 6149) is **GRANTED IN PART** and **DENIED IN PART**.

New Orleans, Louisiana this 23rd day of August, 2019.

JAY E TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE