IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ANNE S. TSAO, M.D.,	§	
Plaintiff,	§	
	§	
vs.	§	CIVIL ACTION NO. 4:16-CV-01724
	§	
FERRING PHARMACEUTICALS, INC.	§	
Defendant.	§	

MEMORANDUM AND ORDER ON DEFENDANT'S MOTIONS TO EXCLUDE EXPERT OPINIONS OF PLAINTIFF AND LAURA M. PLUNKETT, PH.D.

This case was referred by District Judge Vanessa Gilmore pursuant to 28 U.S.C. § 636(b)(1)(A) for the determination of all non-dispositive pretrial matters. (Dkt. 61). Pending before the court are Defendant Ferring Pharmaceuticals, Inc.'s ("Defendant's" or "Ferring's") motions to exclude the expert testimony of Plaintiff Anne Tsao ("Plaintiff" or "Tsao") and Dr. Laura M. Plunkett ("Dr. Plunkett"). (Dkt. 42 and 45). Plaintiff has responded to each motion and Defendant has replied. (Dkt. 58, 59, 62, 63).

A ruling on a motion to exclude the testimony of an expert witness is non-dispositive and may be reversed if the factual findings are clearly erroneous or the legal conclusions are contrary to law. *See Garcia v. BRK Brands, Inc.*, 266 F.Supp.2d 566, 569 (S.D. Tex. 2003) (citing 28 U.S.C. § 636(b)(1)(A)). After considering the pleadings, the record, and the applicable law, it is **ORDERED** that Defendant's motion to exclude the expert testimony of Plaintiff is **GRANTED,** and Defendant's motion to exclude the expert testimony of Laura M. Plunkett is **GRANTED**, in part, and **DENIED**, in part.

I. Background

A. Nature of Plaintiff's claims

Plaintiff has sued Ferring for breach of express warranty, breach of implied warranty, and violations of the Texas Deceptive Trade Practices Act ("DTPA") resulting from her purchase and use of allegedly "defective, adulterated, and misbranded Bravelle," a medication prescribed as part of *in vitro* fertilization ("IVF") treatment. (Dkt. 34 at ¶¶ 1,3). Ferring voluntarily recalled various lots of the medication in October of 2015 because routine stability testing indicated that certain batches of Bravelle "did not meet potency specifications through the entire shelf life and were out of specification ("OOS") at the time of testing (twelve months or more into their shelf life)." (Dkt. 44 at 5).

Plaintiff seeks recovery of economic damages including costs incurred to purchase the Bravelle, the costs of the medications used in conjunction with Bravelle as part of her IVF treatment, and the cost of all IVF treatments that were "associated with administration of the defective, adulterated, and misbranded Bravelle." (Dkt. 34 at ¶ 2). She complains that Ferring failed to inform her that the Bravelle she purchased lacked the potency described in the drug's "Prescribing Information," and that she would not have purchased and used Bravelle had she known it did not meet those product specifications. (Dkt. 34 at ¶¶ 56, 61).

B. Use of Bravelle in connection with an *in vitro* fertilization cycle

In vitro fertilization is a procedure in which eggs, or oocytes, are extracted from an ovary, artificially inseminated, and implanted in a woman. (Expert Report of Eve Feinberg, M.D., Dkt 42-3 at 6). Before a woman begins IVF she undergoes various diagnostic tests designed to assess the "ovarian reserve" or functional capacity of the ovaries. (Dkt. 42-3 at 4). Ovarian reserve testing attempts to measure the number of eggs that can be harvested in a single month as

well as the overall egg supply within the ovary. (*Id.*). One of the diagnostic tests performed as part of the ovarian reserve testing is an Antral Follicle Count ("AFC"). (*Id.*). The AFC is "one of the most important tools a [r]eproductive [e]ndocrinologist can use to predict how many eggs can potentially be retrieved in a single month with the use of fertility drugs." (*Id.* at 4-5).

Oocytes or eggs grow inside the antral follicles and every month a woman has a group of antral follicles that she "uses or loses." (*Id.* at 5). During a normal menstrual cycle, a woman's hormones cause only one follicle to become the dominant follicle in a cohort and each month at ovulation, a single egg is released from that dominant follicle and the other follicles are unused or lost. (*Id.* at 6). During an ovarian stimulation cycle for IVF, the combination of follicle stimulating hormone ("FSH") and other hormones allows many antral follicles, rather than just the dominant follicle, to grow and develop in a single month, which allows multiple eggs to be retrieved from the woman's body. (*Id.* at 6). Bravelle, which contains FSH, is one of the drugs used during the ovarian stimulation phase of IVF to induce the development of more than one follicle and, ultimately, the harvesting of multiple oocytes or eggs. (*Id.*).

The goal of the stimulation phase, which comprises only one part of the total IVF cycle, is the development of multiple follicles rather than a single dominant follicle. Bravelle is medically indicated only for the stimulation of multiple follicles and is used only in the stimulation phase. Additional IVF stages follow stimulation, with the ultimate goal being implantation and development of a chromosomally normal embryo that develops into a sustained pregnancy and live birth.

Following the stimulation and retrieval stages, the harvested eggs are given time to mature prior to fertilization. (*Id*. at 8). Once fertilization is complete, the egg is considered a zygote, which is one cell with two sets of DNA. (*Id*. at 9). Ideally, over a period of five to six

days, the zygote will develop into a blastocyst, which can then be screened for chromosomal abnormalities. (*Id*. at 9-10). It is generally accepted that only chromosomally normal blastocysts will be transferred and implanted into the patient. (*Id*. at 11).

The number of follicles developed and oocytes retrieved after stimulation generally decreases with a woman's age. For example, the mean number of oocytes retrieved in an IVF cycle for a 41 year old woman is 8.6 plus/minus 6.3, compared to 14.75 plus/minus 6.8 for a woman under 30. (*Id*. at 20). In addition, egg quality, which refers to several factors including the incidence of chromosomal abnormalities, decreases markedly with the age. (Dkt. 63-1 at 19). The potential for successful implantation of an embryo and a pregnancy that results in a live birth is highest when the egg has not sustained damage due to aging and does not possess any chromosomal abnormalities. (Dkt. 47-14 at 20).

C. FDA's New Drug Application process and potency specifications for biologic drugs

A manufacturer seeking approval of a new drug such as Bravelle must submit a detailed New Drug Application ("NDA") in accordance with the requirements of The United States Federal Food, Drug, and Cosmetic Act ("FDCA") and other regulations promulgated by the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). As part of the NDA, the manufacturer must submit scientific expert reports and other data evaluating the effectiveness of the drug. *Id*. at § 355(b)(1). The effectiveness, or potency, of a product containing biologically active ingredients, such as Bravelle, is measured by biological activity, which is defined as "the effect or response generated by a given agent upon a living organism." (Dkt. 65-1 at 11). The biological activity of FSH is measured in International Units ("IUs"). The FDA approved two FSH potency specifications for Bravelle, one potency specification for the release of the product and another potency specification for stability testing to be conducted after release. (Dkt. 65-1 at

6; Dkt. 70 at 10, 11). Each of these specifications permits a range of potency defined as a percentage of 82.5 IUs. Upon release, Bravelle must contain 85% to 125% of the label claim of 82.5 IUs to meet the FDA approved potency specification, and during its post-release shelf life, Bravelle must contain 80% to 125% of 82.5IUs. (Dkt. 65-1 at 6; Dkt. 70 at 10, 11). In other words, the FDA permits an FSH bioactivity level anywhere between 70.1 and 103.1 IUs at the release of the product, and 66 to 103.1 IUs throughout the drug's shelf life. (Dkt. 65-1 at 6; Dkt. 70 at 10, 11). FDA regulations require that the potency of a drug comply with the specification range approved in the NDA, not the precise label claim. (Dkt. 65-1 at 10) (citing U.S. Dept. of Health & Human Services, Food and Drug Administration, ICH, Guidance for Industry, Q1A(R2) Stability Testing of New Drug Substances and Products, Rev. 2 (Nov. 2003), *available at* https://www.fda.gov/downloads/drugs/guidances/ucm073369.pdf, (last visited March 20, 2018). In addition, the Code of Federal Regulations defines potency for biologic products as "…the specific ability or capacity of the product, [as measured by appropriate laboratory tests or clinical data]…to effect a given result." 21 C.F.R. §600.3(s).

As part of the NDA approval process, the manufacturer must submit examples of the proposed drug labeling, including text of the proposed label, as well as references to the technical portions of the NDA that support the inclusion of each statement in the label. 21 U.S.C. §§ 355(b)(1), 314.50 (c)(2)(i). After review of all material facts, the FDA must determine that the proposed label is not "false or misleading in any particular [way]." *Id*. at § 355 (d)(7). If the FDA finds that the drug meets this standard, it sends an "approvable" letter to the drug manufacturer, which includes the product specific labeling requirements. *Id*. at § 314.110(a). Approval of the NDA is "conditioned upon the applicant . . . submitting to the FDA a copy of the final printed labeling prior to marketing." *Id*. at § 314.105(b).

D. Opinions from Plaintiff Ann Tsao

Plaintiff is an oncologist and Director of the Mesothelioma and Thoracic Chemo-Radiation Programs at MD Anderson Cancer Center. Her designation of expert witnesses includes herself as a testifying expert. (Dkt. 25 at 13-17). Plaintiff's expert designation states that she intends to testify to the following facts and opinions, which are outside her personal knowledge of treatment she received as an IVF patient:

- the Bravelle she purchased and used was sub-potent;[1]
- her IVF treatment was likely to fail due to the sub-potency of the Bravelle used and/or using sub-potent Bravelle was sub-optimal therapy;
- the charges for her fertility treatments were fair and reasonable in the locale in which they were made;
- it is well established that a prolonged period of ovarian stimulation adversely affects the quality of the eggs when they are exposed to gonadotropins for a prolonged period;
- the ovarian stimulation period is usually 10-12 days and is defined as the period that you are injected daily with ovarian stimulation drugs;
- ovarian follicles need to be 18-20 mm by ultrasound in order to be deemed mature and ready to harvest, which is the surgery to remove them, and taken for embryo creation;
- she was using the maximum amount of Bravelle and Menopur and it was taking her 14-16 days (longer than the usual 10-12 days) to make ovarian follicles large enough in size to harvest;
- the prolonged period of ovarian stimulation was likely due to receiving inadequate doses of ovarian stimulation drugs given that the Bravelle was sub-potent.

(Dkt. 25 at 13-17). In addition to these opinions identified in her expert designation, Plaintiff also testified in deposition that:

- "*in vitro* fertilization [requires] a very fine balance . . . [of] FSH and LH" to stimulate ovarian follicles (Dkt. 42-2 at 33:18-20);
- just like chemotherapy drugs, Bravelle and Menopur work in synergy and their combination results in a successful stimulation with "good quality eggs" (Dkt. 42-2 at 33:22-24);
- a physician would never give a suboptimal drug "and expect that the doublet would actually overcome [the other drug's lack of potency]" (Dkt. 42-2 at 33:25-34:2);
- "suboptimal" Bravelle did not help her stimulate follicles (Dkt. 42-2 at 34:10-12);

[1] Plaintiff's deposition testimony indicates that by "sub-potent" she means less than the 82.5 IUs (75 IUs after diluent is added) of FSH as listed on the Bravelle labeling. (Dkt. 42-2 at 35:2-15). For purposes of the motion to exclude Plaintiff's expert testimony, the court need not distinguish between definition of sub-potent as falling below 82.5 IUs and falling below the stability range allowed by the FDA.

- the average number of follicles during IVF stimulation is 15-20; (Dkt. 42-2 at 30:9-17);
- if she had been given fully potent Bravelle, she would have had a better stimulation with better egg quality (Dkt. 42-2 at 41:11-19, 67:20-22);
- prolonged stimulation negatively impacts the quality of the eggs that are produced (Dkt. 42-2 at 42:7-25, 67:18-20);
- Ferring intentionally sold subpotent Bravelle and knew Bravelle was subpotent at the time she purchased it (Dkt. 42-2 at 73:20–74:15).

Defendant contends that Plaintiff is not qualified to testify on these matters because she lacks expertise in the field of reproductive endocrinology. (Dkt. 42 at 11-14). Plaintiff, however, argues that as a medical doctor, she is qualified to give this opinion testimony. (Dkt. 59 at 5-9).

E. Opinions from Dr. Laura Plunkett

Plaintiff designated Dr. Plunkett as a specially retained expert to testify on numerous issues relating to causation, as well as Defendant's alleged lack of compliance with FDA regulations regarding drug recall and misbranded or adulterated drugs. (Dkt. 25 at 20-21). Dr. Plunkett issued a written report in this case (Dkt. 45-1) and her opinions, which appear in paragraphs 21 through 25 of the report, include the following:

- less potent Bravelle necessitated administration of a higher dose of the medication to achieve sufficient follicle maturation (*Id*. at ¶ 23);
- dosing of Bravelle is a key factor that affects oocyte quality and developmental competency (*Id*.);
- use of Bravelle at higher doses to correct for decreased potency could have important effects on the outcome of the fertility cycle that relate to the quality of the oocytes and the likelihood of a successful outcome (*Id*.);
- Dr. Tsao received Bravelle that would not have produced an optimal response in terms of follicle maturation (*Id*.);
- the Bravelle label was not accurate, and was false and misleading (*Id*. at ¶ 24);
- the Bravelle was misbranded (*Id*.);
- the Bravelle was adulterated (*Id*.).

Plunkett offered the following additional opinions in a supplemental report (Dkt. 57-15):

- the lack of potency stability of Bravelle resulted in Plaintiff being administered a less potent, and thus defective, fertility product that reduced its efficacy as a fertility treatment (¶ 28);

- stability testing of Bravelle was unlikely to reveal intra-batch potency variability, and so the Bravelle vials that Plaintiff used may have contained significantly lower FSH levels than the vials tested (*Id*. at ¶ 31).

II. Analysis

A. Admissibility of expert testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides:

> 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: (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; (b) the testimony is based upon sufficient facts or data; (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.

FED. R. EVID. 702. Thus, the court may admit expert testimony only if the proponent demonstrates that (1) the expert is qualified, (2) the evidence is relevant to the suit, and (3) the evidence is reliable. *Nunn v. State Farm Mut. Auto. Ins. Co.*, No. 3:08-CV-1486-D, 2010 WL 2540754, at *2 (N.D. Tex. June 22, 2010). "The party offering the expert opinion bears the burden of establishing its admissibility by a preponderance of the evidence." *Texokan Operating, Inc. v. Hess Corp.*, 89 F.Supp.3d 903, 909 (S.D. Tex. 2015).

The United States Supreme Court's decision in *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993) provides the analytical framework for determining whether expert testimony meets admissibility requirements. In *Daubert*, the Supreme Court instructed district courts to serve as gatekeepers to ensure that only reliable and relevant expert testimony is presented to the jury. *Johnson v. Arkema, Inc*., 685 F.3d 452, 459 (5th Cir. 2012) (*per curiam*). Expert witness testimony should be excluded if the court "finds that the witness is not qualified to testify in a particular field or on a given subject." *Carlson v. Bioremedi Therapeutic Systems, Inc.*, 822 F.3d 194, 199 (5th Cir. 2016). Rule 702 does not require an expert to be highly qualified to testify,

however, the court will evaluate the witness's knowledge, skill, experience, training, or education with respect to the subject matter of the testimony. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). "[A] party may testify as an expert in his own case, provided that the relevant qualifying criteria … are met." *Rodriguez v. Pacificare of Texas, Inc.*, 980 F.2d 1014, 1019 (5th Cir. 1993).

If a witness possesses the "knowledge, skill, experience, training, or education" to qualify as an expert and give opinion testimony, the court must then assess the reliability and relevance of the proffered opinion testimony. Reliability is determined by assessing "whether the reasoning or methodology underlying the testimony is scientifically valid." *Knight v. Kirby Inland Marine, Inc*., 482 F.3d 347, 352 (5th Cir. 2007). Reliable expert testimony is "grounded in the methods and procedures of science" and must be more than "unsupported speculation or subjective belief." *Arkema*, 685 F.3d at 459. The expert must furnish some objective independent validation of the methodology used to reach her conclusions. *Brown v. Ill. Cent. R.R. Co*., 705 F.3d 531, 536 (5th Cir. 2013). Ultimately, it is the court's responsibility "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In assessing reliability, a district court should consider (1) whether the theory can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the theory's known or potential rate of error; (4) the existence and maintenance of standards and controls; and (5) whether the theory is generally accepted. *Daubert*, 509 U.S. at 593-94. It is important to note that the first step in this "flexible" test is often determining whether the factors mentioned in *Daubert* are appropriate. *Kumho*, 526 U.S. at 150-52.

B. Expert qualifications and reliability of opinion testimony from Plaintiff and Plunkett

1. Plaintiff Ann Tsao's opinion testimony

Defendant has moved to strike Plaintiff's opinion testimony and challenges her ability to testify as an expert in four broad categories: (1) IVF treatments, (2) the stimulation period and its impact on egg and embryo quality, (3) oocyte retrieval rates and live birth rates, and (4) the Bravelle recall. As the basis for its challenge to Tsao's opinion testimony, Defendant contends that Plaintiff is not qualified as a reproductive endocrinologist and that her opinions are not reliable because: they contradict the evidence and testimony from qualified reproductive endocrinologists; her lack of qualifications results in consistent deference to physicians trained in reproductive endocrinology; and her opinions lack the indicia of reliability required for medical expert testimony. (Dkt. 42 at 14-19). The court finds that Plaintiff is not qualified to testify on these matters, and if she were qualified, her testimony is not reliable under *Daubert* and other case law.

1.1. Plaintiff is not qualified to testify as an expert in this case

A medical doctor who is an expert in a particular field of medicine is not necessarily an expert in all areas of medicine. *Kallassy v. Cirruss Design Corp*., No. 3:04-CV-0727N, 2006 WL 1489248, at *7 (N.D. Tex. May 20, 2006). As part of its gatekeeping role, the district court must evaluate whether proffered expert testimony from a clinical physician is "soundly grounded in the principles and methodology of [her] field of clinical medicine." *Anderson v. Bristol Myers Squibb Co*., No. H-95-0003, 1998 WL 35178199, at *6 (S.D. Tex. Apr. 20, 1998); *see also*, *Washington v. United States*, No. 99-50143, 1999 WL 1093659, at *1 (5th Cir. Oct. 27, 1999) (finding no error in district court's exclusion of expert testimony from physician who was not of "same school of practice" as physicians whose care was at issue).

Dr. Tsao is a medical doctor currently employed as an Associate Professor at the University of Texas and the Director of the Mesothelioma and Thoracic Chemo-Radiation Programs at MD Anderson Cancer Center. (Dkt. 42-5 at ¶ 4; Dkt. 34 at ¶ 4). Although Plaintiff is an extremely well-pedigreed physician with specialized training in oncology, she has failed to demonstrate "knowledge, skill, experience, training, or education" with respect to reproductive endocrinology and drug recalls, topics on which she intends to give opinion testimony.

Plaintiff has no training or formal education in the field of reproductive endocrinology: she is not an obstetrician, gynecologist or embryologist; she has never completed the training to become an OB/GYN or completed a post-residency fellowship in reproductive endocrinology; she has never been employed as a reproductive endocrinologist, nor has she written an article on reproductive endocrinology. (Dkt. 42-2 at 75:17-76:21). Her only experience with reproductive endocrinology is as an IVF patient.

Plaintiff's deposition testimony demonstrates that many of her opinions regarding Bravelle and reproductive endocrinology are based on internet research that she conducted using Google and Wikipedia. (Dkt. 42-2 at 38:19, 62:1-25, 95:21-97:4). She also testified that she consulted the websites of different fertility clinics, as well as online patient forums, to research the average stimulation period for women undergoing gonadotropic therapy. (*Id*. at 62:1-25, 143:13-144:4). The fact that Dr. Tsao's opinions rest either on her experience as a patient, or on information she has gathered from the internet, underscores the reality that her opinions are not based on her medical expertise, and that she does not possess the type of knowledge that would qualify her to opine as a physician on the topics for which she has been designated.

Plaintiff cites *Holbrook v. Lykes Bros. Steamship Co., Inc*., 80 F.3d 777 (3rd Cir. 1996) as support for her position that her medical degree qualifies her as an expert in this case and that she

need not be trained in the same sub-specialty as a reproductive endocrinologist.[2] (Dkt. 59 at 11). *Holbrook* and other cases cited by Plaintiff do not present analogous qualification issues. In *Holbrook*, the district court excluded the treating physician's testimony regarding his diagnosis of mesothelioma and the pathology report analyzing lung tissue on which he relied for his diagnosis, because the treating physician practiced internal medicine and "was not an oncologist or specialist in . . . 'definitive cancer diagnosis.'" In its opinion reversing the district court and citing Rule 703 of the Federal Rules of Evidence, the Third Circuit found that the treating physician in that case routinely relied on pathology reports in his medical practice to diagnose conditions and such reliance was a standard medical practice. *Id*. at 781-82. In this case, Dr. Tsao likened the "very fine balance" of FSH and LH levels required for follicle stimulation during IVF to the balancing of medications she performs when prescribing chemotherapy. (Dkt. 42-2 at 33:18-34:2). However, in response to the motion to strike, she fails to put forth any basis for why her expertise with chemotherapy drugs translates to expertise regarding the drugs used for follicle stimulation. Unlike the treating physician in *Holbrook*, whose excluded testimony formed a routine part of his own medical practice, Dr. Tsao has failed to demonstrate that her work as a clinical and academic oncologist involves, in any way, the treatment, diagnosis, or assessment of the issues for which she has designated herself as an expert.

Additionally, with respect to her testimony regarding the Bravelle recall, Plaintiff has not demonstrated any knowledge, skill, experience, education or training that would qualify her as a

[2] Plaintiff also cites *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867 (5th Cir. 2013) and *Huss v. Gayden*, 571 F.3d 442 (5th Cir. 2009) to substantiate her position, but those cases are distinguishable as well. In *Wellogix*, the court did not discuss the expert's credentials, so there is no relevant baseline for the comparison of Tsao's qualifications. In *Huss*, the physician's testimony was limited to rebutting the opposing expert's opinion by demonstrating that the expert's opinion was not supported by medical literature. 571 F.3d at 454. In fact, the *Huss* court counseled against allowing testimony on specific causation where the expert had no personal experience to validate her theory, as is the case here. *Id*. at 455.

drug recall expert. The only evidence in the record regarding her qualifications to give opinions about the timing or propriety of the Bravelle recall is her testimony that her opinions are based on her "general understanding of how pharmaceutical companies work." (*See* Dkt. 42-2 at 70:17-74:19). General knowledge of "how pharmaceutical companies work" fails to qualify Plaintiff as an expert on the Bravelle recall.

The court finds that Plaintiff has not met her burden to demonstrate that she is qualified to give the opinion testimony for which she has been designated as an expert and to which she testified in her deposition, including opinions within the four broad categories to which Defendant has objected: (1) IVF treatments, (2) the stimulation period of IVF and its impact on egg and embryo quality, (3) oocyte retrieval rates and live birth rates and (4) the Bravelle recall. *See Vantz Singletary v. Atrium Finance II, LP D/B/A, Marriott Houston South-Hobby Airport*, 4:16-cv-00496, 2017 WL 1400810, at *4 (S.D. Tex. Mar. 8, 2017) (excluding expert testimony because party offering opinion failed to show witness was qualified to testify on subject matter).

1.2. Plaintiff's opinion testimony is not reliable

The court's finding that Plaintiff has not met her burden to demonstrate she is qualified to give expert opinion testimony is sufficient to end the Rule 702 analysis and exclude her opinion testimony. *See Carlson*, 822 F.3d at 199 ("An expert witness's testimony should be excluded if the district court finds that the witness is not qualified to testify in a particular field or on a given subject.") (internal quotations omitted). However, the court also finds that Plaintiff's opinion testimony should be excluded because it does not meet the standards for reliability: for example, her opinions are not the "product of reliable principles and methods" that have been applied "reliably to the facts of the case." *See id.* at 199, 201 ("An expert's testimony must be reliable at each and every step or else it is inadmissible.").

1.2.a. Plaintiff's opinions do not "fit" with the scientific literature, the data contained in the medical record or her treating physicians' testimony

"While acting as a gatekeeper for expert evidence, [the district court] must evaluate whether there is an adequate 'fit' between the data and the opinion proffered." *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276-77 (5th Cir. 1998) (quoting *Gen. Elec. Co. v. Joiner*, 118 S.Ct. 512, 519 (1997)). Even though *Daubert* focuses on methodology as opposed to the conclusion reached by the expert,

> nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Gen. Elec. Co., 522 U.S. at 146. In this case, Dr. Tsao's opinion that she would have produced more and better quality oocytes in each IVF cycle had the Bravelle she used been fully potent does not "fit" with the scientific data, the information in her medical records, or her treating physicians' testimony.

Plaintiff herself admits that Bravelle is not marketed or represented as affecting the *quality* of oocytes. (Dkt. 42-2 at 67:23-68:7; *see also* Dkt. 42-1). Additionally, Defendant submitted a report by Dr. Eve Feinberg which cites a scientific study demonstrating that gonadotropins, like Bravelle, do not influence the odds of chromosomal abnormality of an egg. (Dkt. 45-14 at 23). Dr. Feinberg's report also states that "[b]ased on our current understanding and research, there is . . . no plausible biologic mechanism for how Bravelle would have an effect on egg quality." (*Id.*) Plaintiff has presented no "objective independent validation of the methodology used to reach her conclusions." *See Brown v. Ill Cent. R.R. Co.*, 705 F.3d 531, 536 (5th Cir. 2013).

Plaintiff's opinion that Bravelle caused her IVF process to result in lower quality eggs rests on her personal belief that Bravelle caused her to have a prolonged stimulation cycle, which in turn affected her egg quality. (Dkt. 42-2 at 42:2-43:1). However, she has offered no scientific basis for this opinion. In fact, her belief that Bravelle resulted in a longer stimulation cycle and a decrease in egg quality, contradicts the testimony of her treating physicians. For example, Dr. Williams testified that Plaintiff responded successfully to Bravelle in various IVF cycles. (Dkt. 42-4 at 54:8-16, 86:5-8, 106:9-22). He also testified that there was nothing unusual about a thirteen day stimulation period for a 40 year old. (*Id*. at 74:14-21). Dr. Hickman, another treating reproductive endocrinologist, testified that while longer stimulation periods are *associated with* poorer egg quality, he would have to speculate as to whether a longer stimulation period would *cause* a decrease in egg quality, and that he had not seen a study establishing a causal correlation between the length of the stimulation cycle and egg quality. (Dkt. 65-7 at 49:15-50:15). Dr. Hickman also testified that when using Bravelle, Plaintiff produced a higher number of oocytes than the average for her age. (Dkt. 65-7 at 45:5-7). In short, Plaintiff's causation opinions are unreliable because she provides no scientific basis for the opinions, and the opinions do not fit with the scientific data, her documented response to Bravelle, or the testimony of three reproductive endocrinologists.

1.2.b. Plaintiff's opinions lack the indicia of reliability required for clinical medical testimony

When functioning as the gatekeeper for clinical medical testimony, the trial court should determine whether the doctor's proposed testimony is soundly based on principles and methods used in her field of clinical medicine. *Lindquist v. Union Pac. R.R. Co*., No. 9:07-CV-27-TH, 2008 WL 4560603, *2 (E.D. Tex. Oct. 7, 2008).

> *Daubert's* object, with respect to the 'reliability' prong, is 'to make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work. .... If they do not, their evidence is inadmissible no matter how imposing their credentials.'

Anderson, 1998 WL 35178199, at *4 (citations omitted). Dr. Tsao's proffered opinion testimony does not meet the same standards of intellectual rigor demanded by her professional work as a medical doctor and oncologist.

Dr. Tsao admits that no peer reviewed articles support her theory that a prolonged stimulation period has adverse effects on the quality of an IVF patient's eggs. (Dkt. 42-2 at 144:5-12). In addition, and perhaps because she has no training as a reproductive endocrinologist, Dr. Tsao used Wikipedia as a source for at least some research and support of her opinions on reproductive technology. (Dkt. 42-2 at 96:1-5, 96:25-97:4). Courts in this circuit have held that Wikipedia is "an unreliable source of information" and have warned against reliance on it and other similarly unreliable internet sources. *Bing Shun Li v. Holder*, 400 F.App'x 854, 857-58 (5th Cir. 2010); *Smartphone Techs. LLC v. Research in Motion Corp*., No. 6:10-cv-74, 2012 WL 489112, at *5 n.3 (E.D. Tex. Feb. 13, 2012) (noting that the information on Wikipedia is not only unreliable, but subject to change on a day-to-day basis).

The court does not believe Dr. Tsao would base her opinions regarding treatment of an oncology patient on Wikipedia research, nor would she make a judgment about the dosage, combination, or effectiveness of chemotherapy drugs for one of her patients based on the dosage, combination, or effectiveness of medications used in fertility treatments. Without some evidence that Plaintiff's opinions are soundly based on the principles and methods used in her field of clinical medicine, her opinions amount to nothing more than unsubstantiated speculation, are unreliable, and should be excluded. *See Wells v. SmithKline Beecham Corp*., 601 F.3d 375, 380-81 (5th Cir. 2010) (excluding expert opinion because the theory had not been subjected to peer

review and publication, nor had it been generally accepted in the scientific community); *Rowan Companies Inc. v. Acadian Ambulance Service, Inc.*, No. H-05-3400, 2008 WL 1989791, at *11-12 (S.D. Tex. May 2, 2008) (excluding expert opinion because it "lack[ed] the necessary indicia of 'intellectual rigor that characterizes the practice of an expert'" in the field of medicine).

1.2.c. Plaintiff's repeated deference to her treating physicians confirms her lack of expertise in reproductive endocrinology

While deference to another expert's opinion does not, by itself, dictate that an expert's opinions are unreliable, in this case, Dr. Tsao's continual deference to her treating endocrinologists highlights Dr. Tsao's lack of knowledge, experience, education, and training in reproductive endocrinology. (S*ee* Dkt. 42 at 17). This lack of expertise is a relevant factor in assessing the reliability of Plaintiff's opinion testimony. *Crappell v. Boh Bros. Construction Co., LLC,* No. 06-1315, 2011 WL 13213835, at *4 (E.D. La. Jan 7, 2011) (finding that proffered expert opinion testimony was unreliable because expert recommended that an individual with greater expertise offer his opinion on the cause of a construction pile failure); *see also IEX Corp. v. Blue Pumpkin Software, Inc.*, No. 4:01-CV-16, 2005 WL 6426934, at * 7 (E.D. Tex. Dec. 14, 2005) (court considered lack of financial expertise in determining that opinions regarding a reasonable royalty were unreliable).

In sum, the court finds that Plaintiff has not met her burden to show that she is qualified to give the opinion testimony for which she has been designated as an expert. In addition, even if she were qualified to testify as an expert, her opinions are not reliable and should be excluded. FED. R. EVID. 702 (c), (d). Of course, Plaintiff may testify as to facts within her personal

knowledge, including, but not limited to, the facts surrounding her purchase of Bravelle and her IVF treatment.[3]

2. Dr. Laura Plunkett's opinion testimony

Defendant challenges the admissibility of Dr. Plunkett's opinion testimony on three topics: (1) the potency of the Bravelle purchased and used by Plaintiff, (2) FDA labeling regulations, and (3) the Bravelle recall.[4] (Dkt. 45 at 11-12). In support of its position, Defendant claims that Plunkett is not qualified to testify on the potency of Bravelle or the propriety of the Bravelle recall, that her opinions are unreliable because they conflict with FDA regulations and other evidence in the record, and that her testimony is not helpful because it does not establish that the Bravelle Plaintiff purchased was out of specification at the time of use. (*Id*. at 15-18, 19-20, 21). The court finds that Plunkett is qualified to testify regarding general pharmacology and toxicology, FDA labeling regulations and recalls in general, and the fact of Ferring's voluntary recall of Bravelle. The court further finds that her opinions that Bravelle purchased and used by Plaintiff (1) was misleading, adulterated and misbranded, (2) out of specification at the time of release or use, and (3) impacted the quality of her oocytes, all should be excluded as unreliable.

[3] This Memorandum and Order does not impact Plaintiff's ability to testify to facts within her personal knowledge. Plaintiff's argument, that excluding her medical opinions will "unfairly limit her ability to testify regarding the facts of her treatment..," is unfounded. (Dkt. 59 at 10).

[4] Plunkett expressly testified that she was not performing a causation analysis concerning Plaintiff's failed IVF treatment and presumably that is why Defendant did not move to exclude a category of opinions delineated as causation opinions. However, some of Plunkett's opinions in her report and testimony bear on the issue of whether Bravelle was a cause in fact of Plaintiff's damages, specifically damages for the cost of her unsuccessful IVF treatments. Those opinions attempting to implicate "subpotent" or "misbranded" or "adulterated" Bravelle as the cause of Plaintiff's economic damages should be excluded whether or not they are identified by Plunkett as a causation opinion. (Dkt. 45-2 at 94:9-25). As discussed further in 2.b.2-2.b.3, Plunkett did not provide reliable testimony regarding whether Bravelle was out of FDA specification at the time Plaintiff purchased and used it, and whether Bravelle impacted the quality of Plaintiff's oocytes, and therefore the success of her IVF treatments.

2.a. Dr. Plunkett is generally qualified to testify as an expert

Dr. Plunkett obtained a Doctor of Philosophy in pharmacology. (Dkt. 45-1 at 12). She has over thirty years of experience in the field of pharmacology. Her extensive research and publication in the field demonstrate that she possesses the expertise to testify on pharmacological matters. Her abstract "Evaluating qualitative and quantitative dose-response data in complete data sets for comparative dose response assessment" appears to be relevant to the issue of dosing and dose-response. (Dkt. 45-1 at 9, 19). She is the principal of a consulting company that works with clients in the pharmacology and toxicology fields to provide risk assessment and regulatory strategy guidance. (*Id*. at 2, 12). Dr. Plunkett has written almost one hundred publications concerning toxicology, pharmacology, and FDA regulations and has given dozens of presentations on those topics. (*Id*. at 14-26). As such, the court finds that, at this stage of the proceeding, Plaintiff has provided sufficient evidence to show that she has the requisite "knowledge, skill, experience, or education" to testify about pharmacology and toxicology and how those principles affect various drugs generally. *See In re Varelto (Rivoxaban) Products Liability Litigation*, MDL No. 2592, 2017 WL 1352860, at *2 (E.D. La. Apr. 13, 2017) (finding Dr. Plunkett qualified to testify on issues related to pharmacological field).

Dr. Plunkett has presented qualifications demonstrating some expertise regarding the FDA regulatory process, including labeling and recall requirements. She has been a consultant for the majority of her career and primarily works with products that are subject to FDA regulation. (*Id.* at 12). Although she has never worked as a regulatory agent for the FDA, Dr. Plunkett possesses knowledge of the regulatory process based on her experience with "projects related to [the] regulation of human drug products," as well as consulting work performed for clients concerning compliance with FDA manufacturing and potency stability regulations. (Dkt.

45-1 at ¶ 7). She has also given lectures to graduate, law, and pharmacy students covering FDA regulations as they apply to the approval, labeling, and post-market reporting requirements for human drugs. (*Id.*). Plaintiff has demonstrated that Plunkett is qualified to provide testimony on FDA regulations and FDA recalls, including the information in paragraphs 1-20 of her report.

2.b. Reliability of Dr. Plunkett's opinion testimony

Having made a threshold determination concerning Dr. Plunkett's general qualifications as an expert on pharmacology, toxicology and FDA regulations, the court must determine whether her expert testimony is relevant and reliable. The relevance of her opinions is not contested. However, the court finds certain opinions--that Bravelle was misbranded and adulterated or in violation of FDA regulations (contained in paragraphs 24 and 26 of her report)--should be excluded as unreliable and/or as inadmissible legal conclusions. The court also finds that Dr. Plunkett's opinions regarding the Bravelle's potency (and specifically its potency at the time it was purchased by and administered to Plaintiff) and Bravelle's effect on Plaintiff's egg quality (contained in paragraphs 23-24, 26, 28, 30 and 32 of her reports) should be excluded as unreliable.

2.b.1. Plunkett's opinions that Bravelle was out of specification, "misbranded" and "adulterated" are unreliable because they are contrary to the FDA regulations or they constitute an inadmissible legal conclusion

Dr. Plunkett issued a report containing the opinion that the Bravelle purchased by and administered to Tsao failed to meet the FDA approved quality specifications because the drug's potency was "reduced below the level . . . indicated on the product labeling." (Dkt. 45-1 at 9, ¶ 21). To the extent this opinion is based on her assumption that Bravelle was required to contain at least 82.5 IUs of FSH, that opinion directly contradicts both the FDA approved labeling and

potency specifications for Bravelle, as well as Dr. Plunkett's own testimony. The opinion testimony is unreliable and should be excluded.

In approving Defendant's NDA for Bravelle, the FDA permitted Defendant to market the drug as long as the FSH levels remained within the FDA approved potency range. (Dkt. 70 at 10, 11). The agency simultaneously approved a label and Prescribing Information for the drug that states "Bravelle contains 82.5 IUs of FSH/vial." (Dkt 45-3, Dkt. 45-5 at 3). Dr. Plunkett's opinion that the Bravelle is subpotent, adulterated, misbranded, or false and misleading, simply because it falls below 82.5 IUs, by any amount, is contrary to established FDA industry guidelines. (*See* 45-9, Expert Report of Peter J. Lisi at 9-10). Dr. Plunkett admitted, and Plaintiff does not dispute, that the FDA approval for Bravelle allowed for a potency range for the life of the product from 80% to 125% of the labeled 82.5 IUs. (Dkt. 45-2 at 133:25-134:24; Dkt. 57 at 6). Thus, in order to avoid being adulterated under the FDA regulations, Bravelle was required to meet the potency range set by the FDA, which is stated as a percentage of 82.5 IUs.

The Food Drug and Cosmetic Act defines a drug as "adulterated" if its strength differs from the standard set forth in an official compendium. 21 U.S.C. §§ 351(b), 352. The U.S. Pharmacopeia (USP) is an official compendium that covers follicle stimulating hormones like Bravelle. USP Monographs Menotropins, U.S. Pharmacopeia, *available at* http://www.pharmacopeia.cn/v29240/usp29nf24s0_m48470.html, (last visited March 23, 2018). USP requirements provide a potency range for follicle stimulating hormones of 80% to 125% of the potency stated on the label claim. *Id*. Therefore, as long as Bravelle met the USP potency range of 85%-125% of 82.5 IUs at release and 80%-125% of 82.5 IUs when used by Plaintiff, it was not out of specification and did not fall within the definition of adulterated.

A drug is "misbranded" if the FDA finds that the labeling proposed in a New Drug Application (NDA) is false or misleading in any particular. 21 U.S.C at § 352(a). Further, a drug is misbranded with respect to the contents of the package label:

> …unless it bears a label containing… (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph *reasonable variations shall be permitted*, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

21 U.S.C. § 352(b)(emphasis added). The Secretary has defined potency for biologic products as "…the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result." 21 C.F.R. § 600.3(s). In other words, the FDA regulations define potency as the ability of the product to effect a given result. *Id*. In addition, the Secretary approved the Bravelle label based on the specification range provided in the NDA. (Dkt. 47 at 5; Dkt. 57 at 6). The Secretary's regulations regarding the meaning of potency and the approval of the Bravelle labeling, which includes the statement that each vial of Bravelle contains 82.5 IUs of FSH, belies Dr. Plunkett's assertion that Bravelle was misbranded under FDA regulations. Dr. Plunkett's opinion that the Bravelle was misbranded completely ignores the fact that the label approved by the FDA incorporates the potency range for biologic drugs established in the USP Monographs Menotropins, U.S. Pharmacopeia. However, at her deposition, she conceded that the FDA approved a wide specification range for FSH potency due to the inherent variability in the bioassay tests used to measure Bravelle's potency. (Dkt. 65-1 at 12; *see* Dkt. 45-2 at 121:15-124:21).

Dr. Plunkett agreed in her deposition that only the FDA has the authority to determine whether, pursuant to its regulations, a drug is misbranded or adulterated, and that the FDA never

determined Bravelle was adulterated or misbranded, and never seized the supply of Bravelle, as it is entitled to do when a drug is misbranded or adulterated:

> Q: Isn't it true that it's only the FDA that has the authority to determine if a product is misbranded or adulterated?
> A: If you're asking me are they the ones that had the authority to write the warning letter to the company, absolutely. However, . . . individuals that understand the regulations [have the ability] to make the judgment that what is being done is inconsistent with the regulations and would meet that definition.

(Dkt. 45-2 at 195: 4-14)

> Q: And I think we already established that you had no evidence that FDA ever told Ferring that it thought Bravelle was misbranded or adulterated?
> A: Based on the documents that I have seen, I said I have not seen that.

(*Id*. at 196: 14-19). Dr. Plunkett has provided no reasonable basis for her opinion that Bravelle was misbranded and adulterated according to FDA regulations. The FDA approved the label, including the dosage information of 82.5 IUs, which with respect to FDA regulations, including the definition of potency for biologic drugs, must be interpreted to incorporate the recognized potency range that applies to biologic drugs.

Finally, Plunkett's opinions that the Bravelle label was "misbranded" or "adulterated" are inadmissible legal conclusions. (Dkt. 45-1 at 10, ¶ 24); *see Gil Ramirez Group, LLC v. Houston Independent School District*, 4:10-cv-04872, 2016 WL 4775688, at *3 (S.D. Tex. Sept. 13, 2016) (expert opinion that defendant's conduct amounted to violations of federal statutes was inadmissible legal conclusion); *Floyd v. Hefner*, 556 F.Supp.2d 617, 640 (S.D. Tex. 2008) (excluding expert opinions that directors violated fiduciary duties as legal conclusions). The Federal Rules of Evidence do not permit an expert to render conclusions of law, because such testimony cannot properly assist the jury in understanding the evidence or determining a fact in issue. *Gil Ramirez*, 2016 WL 4775688, at *3 (citations omitted). Rather, expert testimony couched as legal conclusion "merely tell[s] the jury which result to reach[.]" *United States v.*

Thomas, 847 F.3d 193, 206 (5th Cir. 2017) (citations omitted). The court must remain vigilant against the admission of legal conclusions to uphold its own function in charging the jury regarding the applicable law. *U.S. v. Milton*, 555 F.2d 1198, 1203 (5th Cir. 1977).

Because they are inconsistent with the FDA regulations on which she purports to rely, Dr. Plunkett's opinions that Bravelle was out of specification, adulterated and misbranded are unreliable and should be excluded. In addition and alternatively, her opinions that Bravelle was adulterated, misbranded, or false and misleading under the FDA regulations should be excluded as inadmissible legal conclusions.

2.b.2. Plunkett's conclusion that the Bravelle Plaintiff used was out of specification at the time of purchase and use is speculative, contrary to the evidence, and inadmissible *ipse dixit*

Dr. Plunkett's opinions that Bravelle used by Plaintiff did not meet potency specifications for FSH are unreliable, contradicted by her own deposition testimony, and should be excluded. *Guillory v. Domtar Industries Inc*., 95 F.3d 1320, 1331 (5th Cir. 1996) (expert opinion testimony based on facts that are "indisputably wrong" excluded as unreliable and irrelevant). Under *Daubert*, a finding of reliability and validity do not require certainty, but must be demonstrated by evidence that the expert's opinion is more than speculation. *U.S. v. John Stapp, Inc.*, 448 F.Supp.2d 819, 826 (S.D. Tex. 2006) (citing *Daubert*, 509 U.S. at 590). Here, Dr. Plunkett provides no support for her conclusion that "the Bravelle that was administered to. . . Tsao was less potent than claimed." (Dkt. 45-1 at 9, ¶ 22).

As already established, Dr. Plunkett admitted in her deposition that the label amount of 82.5 IUs allowed for a range of between 66 and 103 IUs. (Dkt. 45-2 at 238:7-10). She also agreed that certain drugs lose potency over time and therefore the FDA approves a drug for a potency range over its shelf life. (Dkt. 45-2 at 51:24-52:8). And, she admitted that although the

potency of the drug may change over the course of a drug's lifecycle due to degradation, as long as it stays within the potency range, it is within specification as approved by the FDA. (*Id*. at 52:20-53:13).

At the time of release of the Bravelle lots that Plaintiff was administered, stability testing of those lots showed that each was within the FDA approved release specifications. (Dkt. 65-1 at 16, Dkt. 47-13 at FERRING-TSAO 000001, 000025, 000044, 000054, 000060). Stability testing of Bravelle at three-month intervals showed that the recalled batches of the drug first fell below the approved potency range at twelve months post-manufacture. (Dkt. 65-1 at 18, Dkt. 47-13 at FERRING-TSAO 000024, 000043). No testing shows that any Bravelle ever tested out of specification within nine months of manufacture. (Dkt. 65-1 at 17). Dr. Plunkett's supplemental report and her testimony demonstrate that "all of the Bravelle that was administered to Dr. Tsao was between six to eight months old" at the time of injection. (Dkt. 57-15 at 33 ¶29; Dkt. 45-2 at 211:19-24). Thus, none of the evidence shows that any lots of Bravelle used by Tsao fell out of specification prior to the time she used them.

Yet, Dr. Plunkett has opined that some of Plaintiff's Bravelle *may have* fallen below the labeled dose and FDA potency range before she used it and before the 12 month stability tests first returned levels below the FDA approved potency range. (*See* Dkt. # 45-1 at ¶ 28). These opinions are speculative and qualify as *ipse dixit* that should be excluded. For example, when Dr. Plunkett was asked about the testing at three, six, and nine months that showed the batches of Bravelle that Plaintiff used were all within the FDA approved potency range for at least nine months, she responded that she could not be certain that those test results would have been the same for the particular vials that were used by Plaintiff with the nine month period. (Dkt. 45-2 at

216:7-15). Further, when Plunkett was asked whether she had seen any out of specification results for batches tested at nine months or less, she responded:

> A: Well I haven't seen data on every batch and every vial, but I –I don't—as I sit here, I don't think I can point you to one, no.
> Q: Okay.
> A: Other than to tell you that I believe that there could be data if you really look at—if they would really dig into each of these issues on an intra-batch variability area.

(Dkt. 45-2 at 247:13-23). In addition, when discussing a particular lot of Bravelle for which the stability testing showed that it met FDA approved specifications at release, but fell below those specifications at fifteen months, Dr. Plunkett was asked whether she could identify when, between zero and fifteen months, the Bravelle fell out of specification. She responded that she could

> only extrapolate from the information provided in the analysis they did inter-batch to indicate that it – it would not be consistent with how they expect it to behave. But other than that, no, I can't tell you exactly when….

(Dkt. 45-2 at 247:1-8). Dr. Plunkett appears to opine, without any reliable or scientific basis, that the data demonstrating that specific Bravelle *batches* did not fall out of specification prior to the nine month mark, does not apply to the individual *vials* from within those batches and which Plaintiff used prior to the nine month mark. (Dkt. 45-2 at 214:8-218:24). Without any scientific evidence to support her opinion, she testified that stability testing on different vials, within a single batch of Bravelle, would have demonstrated different FSH potency and that this "intra-batch" variability supports her opinion that "to a reasonable degree of scientific certainty…some if not all of the Bravelle administered to Dr. Tsao would have been below the labeled FSH dose…" (Dkt. 45-2 at 266:25-269:12). Dr. Plunkett's conclusion rests on little more than her own *ipse dixit* and should be excluded. *Bell v. Foster Wheeler Energy Corp*., No. 15-6394, 2016

WL 5847124, at *3 (E.D. La. Oct. 6, 2016) (excluding opinion testimony as *ipse dixit* because expert provided no testable methodology to support conclusion). A court may appropriately exclude expert testimony if an expert has extrapolated data and there is simply too great an analytical gap between the data and the opinion proffered. *Id.*; *Burleson v. Texas Dept. of Criminal Justice*, 393 F.3d 577, 587 (5th Cir. 2004). In fact, the Fifth Circuit has held that "if an opinion is fundamentally unsupported, then it offers no expert assistance to the jury." *Guile v. U.S.*, 422 F.3d 221, 227 (5th Cir. 2005).

2.b.3. Plunkett's conclusion that Bravelle affects egg quality is unsupported by any evidence in the record

To the extent Plaintiff intends to have Dr. Plunkett testify to her conclusion in her report that "Bravelle's potency . . . is a key issue affecting oocyte quality," that testimony should be excluded as unreliable. (Dkt. 45-1 at 10, ¶ 23). Plunkett's opinion that Bravelle affected Plaintiff's oocyte quality is contrary to the labeled indications for Bravelle, her own deposition testimony, and the testimony of Plaintiff's treating physicians. *Guillory*, 95 F.3d at 1331 (expert opinion testimony based on facts that are "indisputably wrong" excluded as unreliable and irrelevant). As discussed above, a finding of reliability must be supported by evidence that the expert's opinion is more than speculation. *John Stapp, Inc.*, 448 F.Supp.2d at 826 (citations omitted).

Dr. Plunkett admitted in her deposition that Bravelle is not indicated to affect egg quality:

> Q: Okay. Is Bravelle indicated to impact egg quality?
> A: Not – not per the FDA-approved indications.

(Dkt. 45-2 at 110:8-11). She also conceded that she had not formed an opinion regarding Bravelle's effect on egg quality and deferred to the opinions of Plaintiff's physicians on that issue:

> Q: . . . And do you . . . have an opinion as to whether Bravelle . . . does impact egg quality?
> A: No I have not formed that opinion . . . [and] would defer to the physicians in the case.

(*Id*. at 110:16-22). One of the components of egg quality is whether the egg is chromosomally normal or abnormal. Dr. Williams, Plaintiff's treating physician who prescribed Bravelle for her, testified that no medication can change the egg quality with respect to chromosomal abnormality. (Dkt. 45-15 at 62:7-63:12). Another of Plaintiff's treating physicians, Dr. Hickman, testified that no evidence-based treatment can affect the chromosomal abnormality of an egg. (Dkt. 45-16 at 47:19-22). Defendant's expert, Dr. Eve Feinberg, reported that Bravelle cannot impact egg quality and that there is no scientific research establishing that causal link. (Dkt. 47-14 at 22, 23). Because Dr. Plunkett's opinion that Bravelle has an impact on egg quality is unsupported, contradicted by her own testimony, and contradicted by other evidence in the record, it should be excluded as unreliable. *Guile*, 422 F.3d at 227 ("[A]n opinion [that] is fundamentally unsupported . . . offers no expert assistance to the jury.").

III. Conclusion

In sum, Plaintiff has not met her burden to show that Plaintiff's and Dr. Plunkett's testimony is reliable and this Court finds that the unreliable testimony should be excluded. *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998)("The proponent need not prove to the judge that the expert's testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable."). Defendant's motion to exclude Plaintiff's expert testimony is granted in full because she is not qualified to testify as an expert on the subject of reproductive endocrinology and her opinions are unreliable. Defendant's motion to exclude Dr. Plunkett as an expert is granted in part, and denied in part. While Dr. Plunkett is qualified to give expert testimony regarding FDA regulations (including new drug approval and recalls), she

may not give expert testimony that Bravelle was misbranded or adulterated or mislabeled according to the FDA regulations. Dr. Plunkett is also qualified to testify regarding basic pharmacology, but she may not give expert testimony that Bravelle was "subpotent" according to FDA regulations at the time of purchase or use, or that Bravelle affected the quality of Plaintiff's oocytes.

For the reasons stated above, it is ordered that Defendant's Motion to Exclude Expert Opinions of Plaintiff is **GRANTED**, and Defendant's Motion to Exclude the Expert Opinions and Testimony of Plaintiff's Expert Witness, Laura M. Plunkett, PH.D. is **GRANTED**, in part, and **DENIED**, in part.

Signed at Houston, Texas on March 26, 2018.

Christina A. Bryan
United States Magistrate Judge