UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| IN RE: | **OPINION & ORDER** |
| MIRENA IUD PRODUCTS LIABILITY LITIGATION | 13-MD-2434 (CS)<br>13-MC-2434 (CS) |
| This Document Relates To<br>Danley v. Bayer, 13-CV-6586<br>Hayes v. Bayer, 14-CV-288 | <br>13-CV-6586 (CS)<br>14-CV-288 (CS) |

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Danley v. Bayer, 13-CV-6856, and Hayes v. Bayer, 14-CV-288, are the first two cases selected for trial in the In re Mirena IUD Products Liability Litigation multidistrict litigation ("Mirena MDL"). Plaintiffs have sued three related companies, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG and Bayer OY ("Bayer" or "Defendants"), alleging that Mirena, an intrauterine device ("IUD") perforated Plaintiffs' uteruses and caused them injuries, and that Defendants did not adequately warn Plaintiffs about the risks of Mirena. Plaintiffs Danley and Hayes have also brought claims alleging design defect and negligence, and are seeking punitive damages.[1]

Before the Court is Plaintiffs' Omnibus Motion to Preclude the Expert Testimony of Defendants' Experts Steven Goldstein, M.D., Jay Goldberg, M.D., M.S.C.P., Michael Policar, M.D., M.P.H., Michelle Collins, Ph.D., C.N.M., R.N.-C.E.F.M., Vanessa Dalton, M.D., M.P.H., Geri Hewitt, M.D., and Marcia Javitt, M.D., F.A.C.R., (Doc. 2702). Plaintiffs also move to preclude Defendants' regulatory experts, Dena Hixon, M.D., (Doc. 2705), and David Feigal, Jr., M.D., M.P.H., (Doc. 2724). Also before the Court are Defendants' motions to preclude the testimony of Plaintiffs' causation experts Roger Young, M.D., Ph.D., (Doc. 2694), John Jarrell, Ph.D., P.E., (Doc. 2679), Susan Wray, Ph.D., (Doc. 2691), and Richard Strassberg, M.D., (Doc. 2688). Defendants have also moved to preclude Plaintiffs' regulatory expert Suzanne Parisian, M.D., (Doc. 2685), and Plaintiffs' epidemiological expert April Zambelli-Weiner, Ph.D., (Doc. 2697).

[1] Plaintiffs withdrew their claims for manufacturing defect, breach of warranty, fraud, negligent misrepresentation and violation of state consumer protection statutes. (Docs. 2850 at 2 n.3, 2853 at 32). Unless otherwise noted, all references to docket numbers refer to docket entries in 13-MD-2434.

## I. Background

### A. Background Applicable to Both Cases

The following facts, which are based on the record generated by these motions and Defendants' motions for summary judgment, (Docs. 2756, 2762) – including Defendants' Local Rule 56.1 Statements and Plaintiffs' responses thereto, (Docs. 2851 ("Danley 56.1 Stmt. & Resp."), 2854 ("Hayes 56.1 Stmt. & Resp.")),[2] and supporting materials – are undisputed except where noted.[3]

In 2000 the U.S. Food and Drug Administration ("FDA") approved the Mirena, a plastic T-shaped IUD that measures 1.26 by 1.26 inches, as safe and effective for intrauterine contraception. (Danley 56.1 Stmt. & Resp. ¶¶ 1-2.) Mirena provides contraceptive protection for up to five years, and has a cylinder in its stem that continuously releases a dose of the hormone levonorgestrel ("LNG"), (id. ¶ 3), a synthetic progestin. (Declaration of Diogenes P. Kekatos in Support of Plaintiffs' Omnibus Motion ("Kekatos Omnibus Decl."), (Doc. 2704), Ex. B, General Expert Report of Jay Goldberg, M.D., M.S.C.P. ("Goldberg Report"), at 8.) It must be prescribed and inserted by a healthcare professional. (Danley Stmt. & Resp. ¶ 4.) The Mirena has removal threads that permit the user to check its placement. (Id. ¶ 13.)

The Mirena label has undergone four changes to its warning regarding the risk of perforation since the FDA's initial approval in 2000.[4] (Id. ¶ 6.) The 2009 label, which was in

[2] Defendants submitted separate local Rule 56.1 statements in connection with their summary judgment motions for the Hayes and Danley cases. The Court uses the Rule 56.1 statement from Danley for purposes of this background section, and indicates below where case-specific statements are referenced.

[3] Some of the information was submitted under seal. To the extent this information is quoted or discussed, it is hereby unsealed due to the presumption in favor of public access to information affecting judicial decisions. See In re Fosamax Prods. Liab. Litig., 807 F. Supp. 2d 168, 173 n.2 (S.D.N.Y. 2011).

[4] In 2000 when the FDA reviewed the Mirena label, it struck the sentence, "There are reports of IUD migration after insertion," which was in the initial label submission proposed by Bayer. (Declaration of Christopher J. Cook in Support of Defendants' Opposition to Plaintiffs' Motion to Exclude Proposed Testimony of Dena R. Hixon, M.D.

effect at the time both Ms. Hayes' and Ms. Danley's Mirenas were inserted, included a "Highlights" section on the first page that stated: "Perforation may occur during insertion. Risk is increased in women with fixed retroverted uteri, during lactation, and postpartum." (Id. ¶¶ 8-9; Hayes 56.1 Stmt. & Resp. ¶¶ 8-9.) The 2009 label also included a Warnings section that stated, "Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later . . . Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal obstruction, abscesses and erosion of adjacent viscera." (Danley 56.1 Stmt. & Resp. ¶ 10.) It further warned that surgical removal might be required if perforation occurred. (Id.) The label also instructed healthcare providers to teach patients that they should check the Mirena threads every month, and that a patient should contact her doctor if unable to feel the threads. (Id. ¶ 13.) The label additionally instructed healthcare providers to, prior to insertion, give each patient a copy of the "Patient Information Booklet" that is included with every Mirena, and to discuss potential side effects and how to feel the Mirena threads. (Id. ¶ 14.) The Patient Information Booklet states that "Mirena can cause serious side effects," including embedment and perforation, without reference to the timing of these potential events. (Id. ¶ 15.) Beginning in 2005, the warning label for ParaGard, another IUD, included the sentence: "Spontaneous migration has also been reported." (Id. ¶ 53.)

The parties agree that Defendants warned against the possibility of uterine perforation during insertion. (Id. ¶ 9.) They also agree that Defendants did not warn against the possibility

("Cook Hixon Decl."), (Doc. 2787), Ex. 1, Amended Regulatory Expert Report of Dena R. Hixon, M.D. ("Hixon Report"), at 27; id. Ex. 8, at MIR_INDNDA_00010784.) In addition, in 2008 Bayer proposed another change to the Mirena label, which included language stating that "[p]erforation . . . may occur rarely, most often during insertion although the perforation may not be detected until some time later." (Id. Ex. 10, at MIR_INDNDA_00038079.) The FDA added a comment in a communication to Bayer recommending that Bayer remove the words "rarely" and "most often" from this section of the warning. (Id.)

that perforation could occur after and unrelated to insertion, which Plaintiffs call "secondary perforation" or "spontaneous migration."[5] Whether such a possibility exists is at the heart of their dispute. Plaintiffs and their experts maintain that a properly placed Mirena, with no perforation related to insertion, is capable of later perforating the uterus and migrating out of it. (Id. ¶ 56; Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of Roger C. Young, M.D., Ph.D. ("Cook Young Decl."), (Doc. 2696), Ex. B, General Causation Expert Report of Roger C. Young, M.D., Ph.D. ("Young Report"), at 6; Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of Susan Wray, Ph.D. ("Cook Wray Decl."), (Doc. 2693), Ex. B, General Expert Report of Dr. Susan Wray, Ph.D. ("Wray Report"), at 22.) Defendants and their experts assert that Plaintiffs' theory of secondary perforation has not been proven, and that perforation of the uterus can only occur upon insertion of a Mirena, although detection of perforation or migration can occur later. (Danley 56.1 Stmt. & Resp. ¶ 56; Kekatos Omnibus Decl. Ex. A, General Expert Report of Steven Goldstein, M.D. ("Goldstein Report"), at 23; Kekatos Omnibus Decl. Ex. F, General Expert Report of Geri D. Hewitt, M.D. ("Hewitt Report"), at 24.) The expert reports and proposed expert testimony discussed below deal primarily with these issues.

The parties also dispute the significance and validity of the European Active Surveillance Study on Intrauterine Devices ("EURAS") study. EURAS was a study of 61,448 women using Mirena or copper IUDs in six European countries who were followed between 2006 and 2013 to "identify and compare the incidence of uterine perforation and other medically adverse events associated with levonorgestrel-releasing intrauterine systems . . . and

[5] "Secondary perforation" and "spontaneous migration" will be used interchangeably.

copper intrauterine devices (IUDs) under routine conditions of use in a study population representative of typical users." (Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of April Zambelli-Weiner, Ph.D. ("Cook Zambelli-Weiner Decl."), (Doc. 2699), Ex. E, Klaas Heinemann et al., Risk of Uterine Perforation with Levonorgestrel-Releasing and Copper Intrauterine Devices in the European Active Surveillance Study on Intrauterine Devices, 91 Contraception 274, 274 (2015) (hereinafter "Heinemann 2015").) The study concluded that uterine perforation was rare, and that there were no clinically significant differences in perforation rates between IUDs containing LNG and copper IUDs. (Id. at 274, 278-79.) EURAS was funded by Bayer, (Cook Zambelli-Weiner Decl. Ex. D, at 1), but overseen by an independent Safety Monitoring and Advisory Council consisting of "internationally acknowledged experts in the field," which made "recommendations and final decisions in all scientific matters" and which approved all study materials, (id. at 26).

The parties also dispute the capacity of two-dimensional ("2D") versus three-dimensional ("3D") ultrasound in detecting proper placement of a Mirena and signs of perforation. Defendants claim that "[t]wo-dimensional ultrasound imaging cannot rule out damage to the myometrium or a partial perforation at insertion," while Plaintiffs assert that Mirena's label "tells medical providers that they can confirm proper placement of a Mirena by utilizing 2-D ultrasound." (Danley 56.1 Stmt. & Resp. ¶ 60.)

### B. Background Related to Jennifer Danley

Jennifer Danley used Mirena for contraception on two separate occasions. Her first Mirena was inserted on February 14, 2006 and removed without complication on March 4, 2010. (Danley 56.1 Stmt. & Resp. ¶¶ 16, 17, 26, 27.) Ms. Danley's second Mirena was inserted by

Victoria Roebuck, a nurse practitioner, on June 29, 2011. (Id. ¶ 31.) On that occasion Ms. Danley signed a consent form indicating that she had read Mirena literature and had her questions answered, but Plaintiffs allege that Ms. Danley was not provided the Patient Information Booklet, (id. ¶ 33), although they concede she had gotten it before her first insertion, (id. ¶ 25). Immediately after Ms. Danley's second Mirena was inserted, she underwent a 2D ultrasound, and the ultrasound report said the IUD was seen "HIGH/RT." (Id. ¶¶ 35-36.) The parties dispute whether the ultrasound images show that Ms. Danley's uterus was perforated at insertion. (Id. ¶ 39.)

On January 3, 2013, Ms. Danley went to her healthcare provider after a positive home pregnancy test. (Id. ¶ 41.) Ms. Roebuck could not locate the threads of Ms. Danley's Mirena, and an ultrasound from that date showed no IUD in Ms. Danley's uterus. (Id. ¶ 43.) Ms. Danley's providers suspected that the IUD may have perforated Ms. Danley's uterus and ordered an X-ray. (Id. ¶ 44.) An X-ray from January 8, 2013 showed the IUD was within Ms. Danley's abdominal cavity. (Id. ¶ 45.) Ms. Danley's Mirena was removed on January 23, 2013 via laparoscopic surgery. (Id. ¶ 46.)

**C. Background Related to Christie Hayes**

Ms. Hayes' Mirena was inserted by Dr. Merle Robboy on February 3, 2011. (Hayes 56.1 Stmt. & Resp. ¶ 17.) The parties dispute whether Ms. Hayes was provided with the Patient Information Booklet. (Id. ¶ 14.) Ms. Hayes was under anesthesia and conscious sedation during the insertion of her Mirena. (Id. ¶ 23.) Ms. Hayes presented to Dr. Robboy on September 29, 2011 for removal of her Mirena, and during the removal attempt the threads of Ms. Hayes' Mirena, which were still visible outside her cervix, broke off. (Id. ¶ 24-25.) Dr. Robboy noted that the Mirena was likely embedded in the uterine wall. (Id. ¶ 25.) On October

1, 2011, Ms. Hayes presented to Dr. John McHugh for removal of the IUD via hysteroscopy, which did not locate the Mirena inside Ms. Hayes' uterus. (Id. ¶¶ 26-27.) On October 26, 2011, Ms. Hayes' Mirena was found outside her uterus and removed via laparoscopic surgery. (Id. ¶36.)

## II. Discussion

### A. Legal Standard

The admissibility of expert testimony is governed principally by Rule 702:

> 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 on 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. The party offering the testimony has the burden of establishing its admissibility by a preponderance of the evidence. See Fed. R. Evid. 702 advisory committee's note; Bourjaily v. United States, 483 U.S. 171, 175-76 (1987). The standard for admissibility is the same at the summary judgment stage as it is at trial. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997) ("On a motion for summary judgment, disputed issues of fact are resolved against the moving party . . . . But the question of admissibility of expert testimony is not such an issue of fact.").

Rule 702 represents a liberal standard of admissibility for expert opinions, as compared to the previous and more restrictive standard set out in Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923). See, e.g., Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 588-89 (1993) (Frye test of general acceptance in the scientific community superseded by the Federal Rules; "a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal

Rules and their 'general approach of relaxing the traditional barriers to "opinion" testimony'") (quoting Beech Aircraft Corp. v. Rainey, 488 U.S. 153. 169 (1988)). "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." Id. at 596. Despite the liberal standard, however, the district court still must ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." Id. at 589; see Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999) (Rule 702 requires district courts to fulfill the "gatekeeping" function of "mak[ing] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.").

First, the district court must determine whether an expert is qualified. Qualification "may be based on 'a broad range of knowledge, skills, and training.'" In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 172 (S.D.N.Y. 2009) (quoting In re TMI Litig., 193 F.3d 613, 664 (3d Cir. 1999)). Courts within the Second Circuit have "liberally construed expert qualification requirements." In re Methyl Tertiary B*utyl Ether ("MTBE") Prods. Liab*. Litig., No. 00-CV-1898, 2008 WL 1971538, at *5 (S.D.N.Y. May 7, 2008) (internal quotation marks omitted).

Experts need not conduct studies of their own in order to opine on a topic; a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable. See McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1042-43 (2d Cir. 1995) (rejecting argument that because expert had "no experience performing or interpreting air quality studies" he was not qualified to testify);[6] see also Cedar Petrochemicals, Inc. v. Dongbu

[6] In Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 255 (2d Cir. 2005), the Second Circuit limited its prior holding in McCullock because of the Supreme Court's decision in Joiner. The Ruggiero court disavowed *McCullock's* statement that "'[d]isputes as to the strength of [the expert's] credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.'"

Hannong Chem. Co., 769 F. Supp. 2d 269, 284 (S.D.N.Y. 2011) ("Experts need not have actually collected the data on which they base their conclusions in order to be credible."); In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) ("If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent.") (citing Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 80 (2d Cir. 1997)).

Next, the district court must evaluate the reliability of proposed expert testimony. Daubert enumerated a list of factors that, although not constituting a "definitive checklist or test," a district court might consider in evaluating whether a proffered expert opinion has the required indicia of scientific reliability: whether a theory or technique had been and could be tested, whether it had been subjected to peer review, its error rate, and its degree of acceptance within the relevant scientific community. Daubert, 509 U.S. at 593-94. Rule 702 also requires a sufficiently rigorous analytical connection between the expert's methodology and conclusions. "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002); see Joiner, 522 U.S. at 146 ("[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data

Ruggiero, 424 F.3d at 255 (quoting McCullock, 61 F.3d at 1044) (alteration in original). It did so because the Court in Joiner held that "'[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.'" Id. (quoting Joiner, 522 U.S. at 146) (alteration in original). But Ruggiero did not cast doubt on *McCullock's* comment regarding credentials, and courts in this circuit continue to cite it. See, e.g., Cruz v. Kumho Tire Co., No. 10-CV-219, 2015 WL 2193796, at *5 (N.D.N.Y. May 11, 2015).

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.").

The Daubert factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Kumho Tire Co., 522 U.S. at 150 (internal quotation marks omitted). Indeed, expert testimony may be based on "experience alone—or experience in conjunction with other knowledge, skill, training or education." Fed. R. Evid. 702 advisory committee's note. "In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." Id.; see Kumho Tire Co., 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). In all cases, "the test of reliability is flexible," and a district court has "the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." Kumho Tire Co., 526 U.S. at 141-42 (emphasis in original and internal quotation marks omitted).

After determining that a witness is qualified to testify as an expert as to a particular matter and that the opinion is reliable, Rule 702 requires the district court to determine whether the expert's testimony will "help the trier of fact." Fed. R. Evid. 702. Although expert testimony can be very persuasive, see Nimely v. City of N.Y., 414 F.3d 381, 397 (2d Cir. 2005), the testimony is still admissible if it is relevant and helpful. By definition, expert testimony that "usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it," United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991), does not "aid the jury in making a decision"; rather, it "undertakes to

tell the jury what result to reach," and thus "attempts to substitute the expert's judgment for the jury's," United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994) (emphasis omitted).

Plaintiffs seek to exclude nine of Defendants' experts, and Defendants seek to exclude six of Plaintiffs' experts. Each motion and expert is discussed separately below.[7]

### B. Defendants' Clinical Experts

Plaintiffs move in one omnibus motion, (Doc. 2702), to preclude seven of Defendants' experts from testifying on five subjects: (1) secondary perforation; (2) contractility[8] or weakening of the uterus from exposure to the hormone LNG; (3) 2D ultrasound's ability to detect proper placement of Mirena inside the uterus; (4) Mirena labeling; and (5) epidemiological studies including the EURAS IUD study. (Plaintiffs' Omnibus Memorandum of Law In Support of Their Motion to Exclude Proposed Testimony of Defendants' Experts ("Ps' Omnibus Mem."), (Doc. 2703), 2.) I first summarize the general contours of the issues.

- **Secondary Perforation**

Plaintiffs and their experts contend that secondary perforation is the phenomenon of an IUD perforating (puncturing) a uterus that occurs after, and is unrelated to, its insertion. (Ps' Omnibus Mem. 2-3; Wray Report at 22.) Bayer and its experts opine that perforation can only occur in connection with the insertion of an IUD, although the perforation may be detected at a later time. (See, e.g., Goldstein Report at 27-28; Hewitt Report at 24-25.)

[7] Plaintiffs submitted one omnibus motion seeking to exclude seven of Defendants' experts. (Doc. 2702.) All other motions to exclude were filed separately and will be discussed individually below.

[8] Uterine contractility refers to contractions of uterine muscles. (Goldstein Report at 25-26.)

- **Effect of LNG on the Uterus and Uterine Contractions**

Plaintiffs and their experts allege that exposure to LNG, released by the Mirena as part of its contraceptive effect, causes the endometrium (the inner-most layer of the uterus)[9] to weaken and become more susceptible to perforation by an IUD. They posit that uterine contractions (which occur regularly apart from childbirth) help to propel an IUD through the uterine wall. (Wray Report at 19-20, 25-26; Young Report at 11-13.) Bayer's experts dispute the effects of LNG on the uterus, state that LNG does not have a thinning or weakening effect on the myometrium (the middle, muscular layer of the uterus through which a migrating Mirena would have to pass), and maintain that uterine contractions could not force through that wall an IUD that has not at least partially perforated. (See, e.g., Kekatos Omnibus Decl. Ex. D, General Expert Report of Michelle Collins, Ph.D., C.N.M., R.N.-C.E.F.M. ("Collins Report"), at 23-25.)

- **Ultrasound Imaging**

Bayer's experts have opined that although 2D ultrasound is still a commonly used method to detect whether a Mirena has been properly placed – in other words, to determine whether perforation or damage occurred at insertion – this type of imaging cannot rule out such damage, and 3D ultrasounds produce higher quality images capable of more detailed detection. (See, e.g., Kekatos Omnibus Decl. Ex. G, General Expert Report of Marcia C. Javitt, M.D., F.A.C.R. ("Javitt Report"), at 4.) Plaintiffs argue that Defendants' experts should not be allowed to opine on the superiority of 3D imaging because 2D imaging is capable of detecting proper placement of an IUD; it is frequently used to ensure proper placement; and Bayer has never

[9] The uterus is comprised of three layers: (1) the inner-most lining (endometrium); (2) the middle muscular layer (myometrium); and (3) the thin outer layer (perimetrium or serosa). (Medscape, Uterus Anatomy, http://emedicine.medscape.com/article/1949215-overview (last updated July 22, 2015); Goldberg Report at 3-4; Wray Report at 3-4, 11; Kekatos Omnibus Decl. Ex. E, General Expert Report of Vanessa K. Dalton, M.D., M.P.H. ("Dalton Report"), at 4.) The "stroma," is "the tissue underlying the myometrium," (Young Report at 11), or "cell-rich connective tissue," (Wray Report at 4).

instructed or recommended that physicians use 3D ultrasounds to detect Mirena. (Ps' Omnibus Mem. 3-4.)

- **Mirena Label**

Bayer's medical experts opine that from a clinical perspective, the Mirena label has always been adequate to warn of its risks. (See, e.g., Kekatos Omnibus Decl. Ex. C, General Expert Report of Michael Policar, M.D., M.P.H. ("Policar Report"), at 36.) Plaintiffs argue that Defendants' Obstetrics and Gynecology ("OB/GYN") experts are not qualified to opine on the adequacy of the Mirena label because they have not worked in a regulatory capacity. (Ps' Omnibus Mem. 4.)

- **Epidemiological Studies**

Bayer's experts offer opinions regarding the scope and results of the EURAS IUD study. (See, e.g., Goldberg Report at 17-19.) Plaintiffs argue that Bayer's OB/GYN experts are not qualified to opine on the adequacy of the EURAS IUD study because they are not epidemiologists, biostatisticians or medical scientists. (Ps' Omnibus Mem. 4.)

Defendants' experts' qualifications and opinions are discussed below, followed by an analysis of each opinion that Plaintiffs seek to exclude.

### 1. Experts' Qualifications & Opinions

#### a. Michelle Collins, Ph.D., C.N.M., R.N.-C.E.F.M.

Dr. Collins is an Associate Professor of nursing, specializing in nurse-midwifery, and a director of a nurse-midwifery education program at Vanderbilt University's School of Nursing. (Collins Report at 1; Declaration of Christopher J. Cook in Support of Defendants' Opposition to Plaintiffs' Omnibus Motion ("Cook Omnibus Decl."), (Doc. 2773), Ex. 7, Curriculum Vitae of Michelle Collins ("Collins CV").) She teaches courses that cover IUD content, including IUD

insertion, and practices part-time in the nurse-midwifery clinical faculty practice. (Collins Report at 1.) Dr. Collins has prescribed and inserted "hundreds of IUDs," including ParaGard and Mirena. (Id.) Dr. Collins wrote a doctoral dissertation examining the effect of progestins, and one study she used included women with Mirena IUDs. (Id.) She teaches, writes and makes presentations in her field, including authoring a textbook chapter on hormonal contraception. (Id.; Collins CV.)

Dr. Collins opines on the benefits and risks of various types of contraception, including Mirena. (Collins Report at 3-13.) She concludes that the benefits associated with Mirena use outweigh its risks. (Id. at 26.) Dr. Collins discusses shortcomings associated with 2D ultrasound imaging of IUDs. (Id. at 18-19.) She additionally concludes that there is no evidence supporting Plaintiffs' theory of secondary or delayed perforation, and that perforation can only occur upon insertion of an IUD. (Id. at 22-25.) She dismisses several theories put forth to show that secondary perforation is possible, (id. at 23-25), and concludes that Mirena's label has always adequately outlined the proper risks from a medical perspective, (id. at 25-26).

**b. Vanessa Dalton, M.D., M.P.H.**

Dr. Dalton is a tenured Associate Professor in the Department of Obstetrics and Gynecology, Division of Gynecology, at the University of Michigan. (Dalton Report at 1; Cook Omnibus Decl. Ex. 10, Curriculum Vitae of Vanessa Dalton ("Dalton CV").) She holds undergraduate, medical and public health degrees. (Dalton Report at 1.) Dr. Dalton has researched reproductive health services, including contraception, and she has served on committees for the American Congress of Obstetricians and Gynecologists ("ACOG"). (Id.) Dr. Dalton leads a weekly family planning clinic and consultative service providing counseling and provision of contraception, and she supervises or personally places 5 to 10 IUDs in a typical

month. (Id. at 2.) More than half of her clinical practice is in "family planning related services." (Id.) She has studied and published on LNG-releasing IUDs and the possible complications from IUDs in post-partum women. (Cook Omnibus Decl. Exs. 11, 12.)

In her report, Dr. Dalton describes the effectiveness of different types of contraception. (Dalton Report at 6-18.) She concludes that the EURAS-IUD study provides the best evidence to show rates of IUD-associated perforation and notes that the study found similar rates of perforation between LNG-containing IUDs and copper IUDs. (Id. at 20-22.) Dr. Dalton concludes that Plaintiffs' theory of spontaneous migration is not supported by evidence and dismisses possible mechanisms of non-insertion related perforation, including migration through the fallopian tubes, pressure necrosis, uterine contractions and thinning effects of LNG on the uterine wall. (Id. at 24-27.) In addition, Dr. Dalton opines that the Mirena label has always adequately conveyed the risks associated with Mirena. (Id. at 29-31.) She also opines that 2D ultrasound technology is not always capable of detecting whether a portion of an IUD has extended into the myometrium. (Id. at 23.)

**c. Jay Goldberg, M.D., M.S.C.P., C.E.F.M.**

Dr. Goldberg is a board certified obstetrician/gynecologist and holds leadership positions in obstetrics and gynecology at Einstein Medical Center in Philadelphia. (Goldberg Report at 1.) Dr. Goldberg practices full-time as an OB/GYN and sees many patients for family planning and contraception. (Id.) He personally inserts several Mirena IUDs per month, and sometimes as many as five per week. (Id. at 10; Cook Omnibus Decl. Ex. 20, Deposition of Jay Goldberg ("Goldberg Dep."), at 57:11-18.) He has published dozens of peer-reviewed articles and is a manuscript referee for more than a score of medical journals. (Goldberg Report at 2; Cook Omnibus Decl. Ex. 6, Curriculum Vitae of Jay Goldberg ("Goldberg CV").) Dr. Goldberg

opines generally on the benefits of contraception and IUDs and the mechanisms by which IUDs function. (Goldberg Report at 4-10.)

Dr. Goldberg concludes, based on available evidence and the general consensus in the scientific community, that perforation occurs, or at least initiates, at the time an IUD is inserted. (Id. at 13-14.) Dr. Goldberg opines that IUDs cannot move independently and dismisses potential theories by which spontaneous migration could occur. (Id. at 13-14, 23-30.) He also opines on the limitations of 2D ultrasound in detecting uterine perforation. (Id. at 14-15.) Dr. Goldberg discusses the EURAS-IUD study, and disagrees with some criticisms levied against it. (Id. at 17-19.) In addition, Dr. Goldberg concludes that the Mirena label has always adequately conveyed to prescribing physicians the risks of Mirena. (Id. at 21-23.)

**d. Steven Goldstein, M.D.**

Dr. Goldstein is a tenured professor at New York University School of Medicine in the department of Obstetrics and Gynecology. (Goldstein Report at 1.) Dr. Goldstein is the Director of Gynecologic Ultrasound and Co-Director of Bone Densitometry and Body Composition. (Id.) He has a half-time private practice, seeing patients of all ages as a gynecologist, and counsels and places IUDs. (Id. at 1-2.) Dr. Goldstein has written and edited textbooks on ultrasounds of the female pelvis, and published articles on 2D-versus-3D ultrasound, including specific discussions regarding the detection of IUD placement. (See, e.g., Cook Omnibus Decl. Ex. 44.) Dr. Goldstein opines generally on contraceptive methods, IUDs and the risk of perforation associated with IUDs. (Goldstein Report at 2-14.) Based on the EURAS-IUD study, he finds

no statistically significant difference in the perforation rate of Mirena compared to other IUDs. (Id. at 10-14.)

Dr. Goldstein opines that most perforations are not diagnosed until after insertion, (id. at 14-17), and concludes that Plaintiffs' theory of secondary perforation, and the alleged mechanisms by which it might occur, are "unproven" and "implausible," (id. at 23). Dr. Goldstein opines on the use of 2D and 3D ultrasound in detecting proper Mirena placement, and concludes that 2D ultrasound cannot rule out injury to or perforation of the myometrium. (Id. at 17-18.) Dr. Goldstein also concludes that Mirena's label has always adequately informed clinicians regarding the risks of perforation, and that the label's varying statements have not impacted his decision on whether to prescribe Mirena for a patient. (Id. at 19-23.)

**e. Geri Hewitt, M.D.**

Dr. Hewitt is an associate professor at Ohio State University College of Medicine in the OB/GYN and Pediatrics Departments. (Hewitt Report at 1.) Dr. Hewitt supervises and teaches residents and medical students on the gynecologic and labor and delivery services, and works in a practice providing the "full range of general adult OB/GYN, including well woman care, contraception and family planning, obstetrical services, and gynecologic surgery." (Id.) Dr. Hewitt counsels patients on contraception, and "routinely place[s]" IUDs. (Id. at 1-2.) She serves on committees and boards related to OB/GYN services. (Id. at 3.) Her teaching activities "include both educating trainees about the risks and benefits of IUDs, and training and supervising IUD placement." (Id. at 2.) She is co-author of a 2005 article on progestin-only contraceptives, including Mirena. (Cook Omnibus Decl. Ex. 9.)

Dr. Hewitt opines that spontaneous migration is not possible and that uterine perforation occurs or at least initiates at the time of insertion. (Hewitt Report at 18-20.) Dr. Hewitt

dismisses theories espousing mechanisms by which a Mirena could spontaneously migrate. (Id. at 24-29.) She disagrees with Plaintiffs' epidemiological expert, Dr. Zambelli-Weiner, regarding her criticisms of the EURAS-IUD study. (Id. at 15-16.) Dr. Hewitt also opines that, as a prescribing doctor, the Mirena label "has always adequately and appropriately informed clinicians about the known risk of uterine perforation." (Id. at 30.)

**f. Marcia Javitt, M.D., F.A.C.R.**

Dr. Javitt is the Director of Medical Imaging at the Rambam Health Care Campus in Haifa, Israel, and served as the Section Head of Body MRI and of Genitourinary Radiology at Walter Reed Army Medical Center in Washington from 2002 to 2011. (Javitt Report at 1.) She is trained in Ultrasound, Computed Tomography and MRI, and has over 30 years of experience in radiology. (Id.) She has written textbooks, book chapters and peer-reviewed articles, focusing her research on imaging of the female pelvis. (Id.)

Dr. Javitt opines on the imaging of IUDs and the differences between 2D and 3D ultrasound technology. (Id. at 3-6.) She concludes that 3D ultrasound offers advantages over 2D ultrasound with respect to localizing IUDs within the uterine cavity. (Id. at 4.) Dr. Javitt opines that 2D ultrasound cannot always rule out that any portion of an IUD has entered the myometrium. (Id.) In addition, Dr. Javitt concludes that neither 2D nor 3D ultrasound can rule out injuries to the uterine wall caused by a uterine sound[10] or the instrument used to insert the IUD when the IUD is normally positioned within the uterine cavity. (Id.)

**g. Michael Policar, M.D., M.P.H.**

Dr. Policar is a board certified OB/GYN. (Policar Report at 1.) He also has a Master's degree in Public Health. (Id.) Since October 2014, Dr. Policar has worked part-time training

[10] A uterine sound is the metal or plastic instrument used to measure the depth of the uterus during IUD placement. (Policar Report at 18.)

and supervising OB/GYN residents, mentoring post-residency Family Planning fellows, and serving on committees at San Francisco General Hospital. (Id. at 3.) Dr. Policar has previously held senior positions at the Planned Parenthood Federation of America, and as the national Medical Director was "responsible for creating and updating the clinical Standards and Guidelines that clinicians in every Planned Parenthood affiliate in the United States were expected to follow." (Id. at 1, 3.) He has had an extensive career in OB/GYN, including 34 years of clinical experience in family planning. (Id. at 1-3.) Dr. Policar is also a senior author of "Contraceptive Technology," a textbook on family planning. (Id. at 3.) Dr. Policar has inserted and removed IUDs, including Lippes Loop, Copper 7, Progestasert, ParaGard, Mirena and Skyla during his career, and he has supervised "between 2-4 Mirena insertions per week over the last 13 years." (Id. at 4.)

Dr. Policar opines that all perforations occur at the time of the IUD insertion procedure, although diagnosis may be delayed, and that it is an uncommon but possible scenario that an embedment that occurred at the time of placement progresses over time to form a complete perforation via which the IUD could be propelled into the abdominal cavity. (Id. at 20-21, 24.) Dr. Policar is unaware of any plausible mechanism by which an IUD could spontaneously migrate out of the uterus, and opines that such a concept is not accepted in the family planning community. (Id. at 20-21, 24.) In his report, Dr. Policar discusses the benefits of the EURAS-IUD study and writes that its "clinical import has been widely endorsed within the medical community." (Id. at 27.) Dr. Policar additionally opines on the limitations of 2D ultrasound, noting that 2D ultrasound can fail to diagnose an embedment in some circumstances. (Id. at 32.) Dr. Policar also concludes that the "Mirena label[s] over time have adequately informed

clinicians of the salient clinical information" and that his understanding of the risks of perforation remained constant despite changes to the label. (Id. at 36.)

### 2. Opinions on Secondary Perforation[11]

Bayer's experts' opinions on secondary perforation, contractility of the uterus and weakening of the uterus by LNG are closely related and will be discussed together. Plaintiffs first argue that Bayer's clinical experts lack the medical experience necessary to opine on these issues. A general thrust of Plaintiffs' arguments is that Defendants' experts have not personally studied uterine activity upon exposure to LNG or pointed to studies ruling out the possibility of secondary perforation. Not only is personal study not necessary, see McCullock, 61 F.3d at 1042-43; Cedar Petrochemicals, Inc., 769 F. Supp. 2d at 284; In re Zyprexa, 489 F. Supp. 2d at 282, but Defendants do not dispute that their own experts have not personally conducted such studies. Further, given that Defendants' experts are attempting to prove a negative – that secondary perforation does not exist – pointing to the absence of convincing studies or the weaknesses of studies on which Plaintiffs rely, and evaluating them in light of their clinical experience, training and research, is in these circumstances a logical and valid approach. After all, perforation is, as Defendants point out, a clinical phenomenon. See Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 735 (S.D.W. Va. 2014); Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 480-82 (E.D.N.Y. 2011); DeKeyser v. Thyssenkrupp Waupaca, Inc., 747 F. Supp. 2d 1043, 1050 (E.D. Wis. 2010). With that in mind, I turn to each expert's proposed testimony.

Dr. Collins has both academic and clinical experience related to contraception in general and IUDs in particular. She has the qualifications and expertise in the field of family planning and OB/GYN necessary to allow her to opine on the efficacy of the Mirena IUD and Plaintiffs'

[11] Because Dr. Javitt's report opines only on imaging of IUDs, in this and subsequent sections not related to imaging or radiology, "Bayer's experts" or "Defendants' experts" refer only to the six experts who opine on these topics.

theory of secondary perforation under *Daubert's* admissibility standard. See Daubert, 509 U.S. at 589. Furthermore, Dr. Collins' academic research related to hormones and her dissertation topic indicate that she is qualified to testify regarding the effect of LNG on the uterus and uterine contractility. (See Collins Report 1.) Plaintiffs argue that all of Bayer's experts, including Dr. Collins, "blindly state that there is no evidence that secondary perforation actually occurs," (Ps' Omnibus Mem. 11), but this is not so. Instead, Dr. Collins' opinions on secondary perforation (like those of the other experts) are based on her experience as a clinician who has inserted and instructed others on the insertion of IUDs, and on a review of medical literature.[12] (Collins Report at 21-25.) Although Plaintiffs and their experts may disagree with Dr. Collins' conclusions, these disagreements are best explored on cross-examination.

Plaintiffs additionally argue that Dr. Collins' opinion on secondary perforation is not reliable because she ignored contrary scientific literature and Bayer's own internal and public findings. (Ps' Omnibus Mem. 13.) Potentially conflicting statements by Bayer personnel are irrelevant for purposes of this Daubert motion.[13] Plaintiffs' argument that Dr. Collins ignored contradictory scientific literature is unfounded; she specifically addressed the leading study on which Plaintiffs rely – the Goldstuck study[14] – and found it to suffer "from multiple methodological and analytical flaws that render its conclusions inaccurate." (Collins Report at

[12] Dr. Collins cites seven studies to support her claim that perforation occurs only at insertion of an IUD. (Collins Report at 22.

[13] This issue is discussed in more detail below.

[14] The Goldstuck study refers to a 2014 study by Norman D. Goldstuck & Dirk Wildemeersch, Role of Uterine Forces in Intrauterine Device Embedment, Perforation, and Expulsion, 6 Int'l J. of Women's Health 735 (2014). (Compendium of Authorities, ("Compendium"), (Doc. 2819), Ex. 9.) The study's authors found that measured perforation forces are from "20 N [Newtons] to 54 N" and calculations showed "the uterus is capable of generating up to 50 N of myometrial force depending on internal pressure and surface area." (Id. at 735.) The authors concluded that "[t]he uterine muscle seems capable of generating enough force to cause an IUD to perforate the myometrium provided it is applied asymmetrically" and gave a "physical theory for IUD expulsion and secondary IUD perforation." (Id.)

24.) The Court expresses no opinion on the validity of the Goldstuck study, but because the parties so vehemently disagree on its credibility, it is a suitable topic for cross-examination before a jury. While failure to consider contrary studies may undermine reliability, cf. In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004) (discussing problems of admissibility when expert failed to consider two epidemiological studies addressing topic at hand that reached different conclusions from expert), Dr. Collins in fact analyzed conflicting arguments. Her opinions are also grounded in reliable sources, and because of the complicated medical nature of Mirena and its effects, her testimony is helpful to a trier of fact and is not unduly prejudicial.

Dr. Dalton's medical qualifications are sufficient for her to opine on the effect of LNG on the uterus and Plaintiffs' theory of secondary migration. See In re Zyprexa, 489 F. Supp. 2d at 282. She has experience practicing as an OB/GYN and has had the opportunity to place and supervise the placement of many IUDs throughout her career. (Dalton Report at 2.) Although she has not performed any studies herself, this does not mean she is not qualified to give a medical opinion using her experience as well as a review of relevant scientific literature. See McCullock, 61 F.3d at 1042-43. Plaintiffs criticize Dr. Dalton because, in the section of her report where she concludes that LNG does not cause thinning of the uterine wall, she states only that she has not seen literature to that effect, rather than citing any study showing that such thinning does not occur. (Ps' Omnibus Mem. 17.) But her list of materials considered contains these studies, (Dalton Report app. B),[15] and a lack of specific citation in her report goes to the

[15] For example, Dr. Dalton cites Janina Kaislasuo et al., Intrauterine Contraception: Incidence and Factors Associated with Uterine Perforation—A Population Based Study, 27 Human Reprod. 2658, 2662 (2012) (Cook Omnibus Decl. Ex. 23), and Mira Harrison-Woolrych et al., Insertion of Intrauterine Devices: A Comparison of Experience with Mirena and Multiload Cu 375 During Post-Marketing Monitoring in New Zealand, 116 N.Z. Med. J. 1, 4 (2003) (Cook Omnibus Decl. Ex. 24), which concluded that perforation incidents were similar for LNG-containing and copper IUDs. Throughout their reports, Defendants' experts cite other studies for the proposition that hormonal IUDs containing LNG have similar rates of perforation as copper IUDs in addition to Kaislasuo and

weight of her opinions, not their admissibility. The fact that these studies are listed shows a reliable foundation upon which Dr. Dalton based her opinions. See Amorgianos, 303 F.3d at 269. Dr. Dalton's report regarding spontaneous migration cites scientific literature to support her claim, and she specifically addresses the Goldstuck study on which Plaintiffs rely. Dr. Dalton's opinions are sufficiently reliable to pass muster under Daubert, see Deutsch, 768 F. Supp. 2d at 480-81 (allowing doctors to testify where they based their opinions on their own experiences and review of literature), and her medical testimony would be helpful to the trier of fact.

Plaintiffs move to exclude Dr. Goldberg's testimony, arguing that like Defendants' other experts, he is not qualified because he has not personally conducted studies related to secondary perforation and the effect of LNG on the uterus, and that his opinion on secondary perforation is not based on reliable scientific literature. (Ps' Omnibus Mem. 10.) Dr. Goldberg opines generally on uterine perforation, (Goldberg Report at 12-20), and on theories of spontaneous IUD migration, which he concludes are "just speculative hypotheses, without any sound scientific basis," (id. at 23). Dr. Goldberg's experience as a medical doctor specializing in OB/GYN and his familiarity and experience in placing and teaching how to place IUDs qualify him to opine on the effects of LNG on the uterus and on Plaintiffs' theory of secondary perforation, and are indicative of the reliability of his opinions. See In re Fosamax, 645 F. Supp. 2d at 181 (finding the "clinical experience of the PSC's oral maxillofacial experts" to be "highly indicative of the reliability of their opinions"). As previously discussed, experts need not perform studies themselves to be qualified to testify. McCullock, 61 F.3d at 1042-43. Moreover,

Harrison-Woolrich. (See Cook Omnibus Decl. Exs. 21-22, Heinemann 2015; Abbey B. Berenson et al., Complications and Continuation of Intrauterine Device Use Among Commercially Insured Teenagers, 121 Obstetrics & Gynecology 951 (2013).) If LNG in fact thinned the myometrium (the middle layer of the uterine wall), they reason, LNG-containing IUDs would have increased rates of perforation. Studies that suggest that there is no difference between perforation rates of copper IUDs and IUDs containing LNG support Defendants' experts' views that LNG does not have an effect on the uterus that makes it more susceptible to perforation.

Dr. Goldberg cites to studies to bolster his claims that LNG does not thin the myometrium, and he analyzes and finds fault with several studies Plaintiffs cite. (Goldberg Report at 24-29.) Although Plaintiffs and their experts may take issue with Dr. Goldberg's conclusions, these criticisms go to the weight, not the admissibility, of his testimony and are best addressed on cross-examination. In re Zyprexa, 489 F. Supp. 2d at 285 ("The mere fact that an expert's testimony conflicts with the testimony of another expert or scientific study does not control admissibility.") (citing Fed. R. Evid. 702 advisory committee's note (2000)). In addition, Dr. Goldberg's medical opinions are helpful to the trier of fact.

Dr. Goldberg may not, however, opine on the impact of "lawsuit-generated scientific misinformation." (Goldberg Report at 29-30.)[16] The probative value of this opinion is substantially outweighed by its prejudicial effect. Fed. R. Evid. 403; see Nimely, 414 F.3d at 397 ("[T]he Supreme Court . . . has noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations."). Dr. Goldberg's view on how lawsuits affect women's contraceptive choices – assuming it would pass muster under Daubert (a dubious proposition) – is not relevant to either Plaintiffs' or Defendants' theories of these cases, would waste time, and would unfairly prejudice Plaintiffs.

Dr. Goldstein's opinions related to the effects of LNG on the uterus, uterine contractions and the possibility of secondary migration are sufficiently reliable and pass muster under Rule 702 and Daubert. Dr. Goldstein's clinical and academic experience qualify him to opine on whether LNG can contribute to uterine perforations and whether spontaneous migration can occur. See McCullock, 61 F.3d at 1043. Dr. Goldstein bases his opinions on his decades of

[16] Although Plaintiffs did not raise this issue, it seems important enough for the Court to address sua sponte. See United States v. Clark, 822 F. Supp. 990, 1000 n.6 (W.D.N.Y. 1993).

experiences as a doctor and a review of scientific literature. See Deutsch, 768 F. Supp. 2d at 482. Dr. Goldstein cites several studies for the proposition that uterine perforations occur, or at least initiate, at the time of insertion. (Goldstein Report at 28.) In addition, in his materials list Dr. Goldstein refers to studies that lend support for the proposition that LNG does not have a thinning effect on the myometrium, in that perforation rates do not differ between hormonal and copper IUDs. (See Goldstein Report app. C.) Dr. Goldstein also confronts contradictory studies, including Goldstuck. Plaintiffs can cross-examine to challenge Dr. Goldstein's credibility.

Dr. Hewitt is qualified to opine on the theory of spontaneous migration and potential effects of LNG on the uterus. Her opinion is "based on [her] education, training, experience, and [her] review of the medical literature." (Hewitt Report at 24.) She cites several publications to support her view that spontaneous migration cannot occur. (Id.) This passes muster under Daubert. See Deutsch, 768 F. Supp. 2d at 480-81. She also confronts conflicting reports and explains her reasoning for dismissing their conclusions. (Hewitt Report at 25-26, 28-29.) Cf. In re Rezulin, 309 F. Supp. at 563. In addition, her medical testimony is relevant to this case and helpful to the trier of fact. The appropriate way for Plaintiffs to challenge Dr. Hewitt's opinions is through cross-examination.

Plaintiffs once again miss the mark in arguing that Dr. Policar is not qualified to testify regarding secondary perforation, uterine contractility or weakening of the uterus by LNG. (Ps' Omnibus Mem. 10-13, 15-18.) Like Bayer's other clinical experts, Dr. Policar is a distinguished practitioner with a long career in OB/GYN practice. He has co-authored a textbook on family planning titled "Contraceptive Technology," which is in its twentieth edition. (Policar Report at 3; Cook Omnibus Decl. Ex. 2.) Dr. Policar bases his opinions on his experience and also the "family planning literature over the past 25 years." (Policar Report at 20.) His disagreement

with Plaintiffs' theories regarding perforation unrelated to insertion are grounded in his experience and in the literature, as is appropriate under Daubert. His testimony is also relevant to this case and helpful to the trier of fact. Plaintiffs may challenge Dr. Policar's theories and opinions on cross-examination. See In re Zyprexa, 489 F. Supp. 2d at 285.

For the reasons stated above, Bayer's experts have demonstrated the requisite qualifications, reliability and helpfulness to the trier of fact to pass muster under Rule 702 and Daubert with respect to Plaintiffs' theory of secondary perforation, uterine contractility and the effects of LNG on the uterus. Plaintiffs' motion to exclude these experts from opining on these topics is denied.

**3. Opinions on the Mirena Label**

Bayer's clinical experts all share similar backgrounds as healthcare providers who have experience prescribing and inserting IUDs, and all offer opinions regarding the adequacy of the Mirena label from the perspective of a medical practitioner who is familiar with Mirena and similar products. (See Collins Report at 25-26; Goldstein Report at 19-23; Goldberg Report at 21-23; Policar Report at 34-37; Dalton Report at 29-31; Hewitt Report at 29-30.) Plaintiffs argue that none of Defendants' experts are qualified to offer an opinion on labeling because they lack "any education or training with respect to FDA labeling." (Ps' Omnibus Mem. 19-20.) But none of Defendants' experts opine on FDA regulations or on the adequacy of the Mirena warning from a regulatory perspective. Rather, they only describe how they as clinicians have perceived the label and its wording with respect to perforation, and how, if at all, that wording affects their practices. As Dr. Goldstein said during his deposition:

> I would definitely offer an opinion on the label as it pertains to how I, as a clinician and one who teaches, you know, you graduate seven residents a year times 30 years, 210 now out-in-practice OB/GYNs, how we do or do not utilize

> the label. But as far as from a regulatory point of view, that's not my area of expertise.

(Cook Omnibus Decl. Ex. 19, Deposition of Steven Goldstein ("Goldstein Dep."), at 76:1-10.)[17] Plaintiffs do not cite any cases where a prescribing physician or medical practitioner has been excluded from opining on how a label is perceived from a clinical medical perspective. The cases they cite deal generally with the relevance of expert testimony in specialized fields. In Redman v. John D. Brush Co., 111 F.3d 1174 (4th Cir. 1997), the court found the expert's testimony regarding industry standards for burglar-deterrent safes unreliable because he did not rely on "information of a kind reasonably relied on by experts in the field." Id. at 1179. Barrett v. Atlantic Richfield Co., 95 F.3d 375, 382 (5th Cir. 1996), and Nora Beverages, Inc. v. Perrier Group of America, Inc., 164 F.3d 736, 746 (2d Cir. 1998), are similarly unhelpful for Plaintiffs because although they stand for the general proposition that an expert must be qualified in a field related to his expertise and have relevant experience in order to testify, Bayer's clinical experts in the current case do have such relevant experience and expertise. See Watkins v. Cook Inc., No. 13-CV-20370, 2015 WL 1395773, at *10 (S.D.W. Va. Mar. 25, 2015) (allowing doctor to opine on label based on knowledge and experience with product, but not on FDA regulations); Deutsch, 768 F. Supp. 2d at 440 (doctors were qualified to "opine as to the adequacy of the labels from the perspective of oncologists and prescribing physicians" but not as to whether label complied with FDA regulations).

Plaintiffs argue that Defendants' experts should not be allowed to "testify in the absence of knowledge of the risks of Mirena," and that because Bayer's experts "ignore that secondary

[17] Drs. Collins, Dalton, Goldberg, Hewitt and Policar similarly do not opine on the label from a regulatory perspective, but instead offer opinions based on their knowledge as practicing medical professionals. (Collins Report at 1, 25-26; Dalton Report at 1-2, 29-31; Goldberg Report at 1, 34-37; Hewitt Report at 1-2, 29-30; Policar Report at 3-4, 34-37.)

perforation is real, they are not equipped to offer an opinion on the adequacy of the Mirena labeling." (Plaintiffs' Reply Memorandum in Further Support of their Omnibus Motion ("Ps' Omnibus Reply"), (Doc. 2843), 5.) This argument does not withstand scrutiny. Defendants' experts do not ignore the argument that secondary perforation exists; rather, through their study of the literature and their own clinical experiences, they do not find the argument persuasive. The legitimacy of this claim is obviously hotly contested, and the Court does not offer an opinion on its validity, but it does not mean that Bayer's experts should not be able to opine on whether the label is adequate from a physician's perspective. It is precisely because Defendants' experts believe secondary perforation is not a real phenomenon that they think the label, despite not warning against it, is adequate – in other words, that the label conveys the legitimate risks of the product. Because Bayer's experts have based these opinions on a sound methodology, they have the requisite qualifications, and their testimony is helpful to the trier of fact, their views are admissible under Daubert. 509 U.S. at 590-91. Should the jury be convinced that secondary perforation is possible, it will discount the experts' opinions about the label accordingly.

Bayer's clinical experts all have experience in inserting IUDs, including Mirena, and have familiarity with its label, how it is understood, and how it is discussed with patients. Plaintiffs' motion to exclude Bayer's clinical experts' testimony regarding those aspects of the Mirena label is therefore denied. Defendants' experts may not, however, opine on FDA regulations or whether the Mirena label complied with them, as these doctors are not qualified as experts on that subject.

**4. Opinions on 2D Versus 3D Ultrasound**

Plaintiffs move to preclude all of Bayer's experts' opinions that 2D ultrasound is not capable of always accurately detecting the presence of a Mirena. Plaintiffs argue that Bayer has

never instructed or recommended that 3D rather than 2D ultrasound is the preferred method of locating a Mirena. (Ps' Omnibus Mem. 18-19; Ps' Omnibus Reply 4-5.) In addition, Plaintiffs argue that "[t]here is no peer-reviewed literature to support the position that 2D ultrasound is incapable of detecting the presence of Mirena," and cite Defendants' experts' reports as stating 2D ultrasound is reliable in the IUD/Mirena context. (Ps' Omnibus Mem. 18.) These arguments mischaracterize Defendants' experts' reports and deposition testimony.[18]

Bayer's clinical experts opine generally that 2D ultrasound can show whether an IUD is present in the uterus, but not necessarily whether a portion of an IUD has extended (or has become embedded) into the patient's myometrium. (See Collins Report at 18-19; Dalton Report at 23; Goldberg Report at 14-15; Goldstein Report at 17-18; Hewitt Report at 19-20; Policar Report at 32.) With the exception of Dr. Javitt, Defendants' experts do not offer lengthy opinions on this topic. These experts do not, as Plaintiffs seem to claim, offer opinions that 3D ultrasound is the standard of care or that "2D ultrasound is incapable of ensuring Mirena placement," (Ps' Omnibus Mem. 19); they only opine as to the limitations of 2D ultrasound in detecting perforation of the myometrium. If Plaintiffs disagree with the conclusions of Bayer's experts regarding those limitations, counsel may question them on cross-examination. But in doing so they must bear in mind that saying that 2D ultrasound cannot definitively rule out embedment or perforation is not the same thing as saying 2D ultrasound is unacceptable or 3D ultrasound is routinely required.

[18] To the extent Plaintiffs challenge Defendants' experts' qualifications to opine on these subjects, the challenge is rejected. Defendants' experts, as experienced clinical physicians or medical practitioners, have "educational and experiential qualifications" in a closely related field that qualify the experts to opine on the issue of imaging IUDs. In re Zyprexa, 489 F. Supp. 2d at 282. They all have experience inserting IUDs and locating them via ultrasound, and therefore are familiar with the general practices and limitations of that type of imaging.

In addition, Plaintiffs characterize as "unsupportable" the experts' views that 2D ultrasound is incapable of ruling out uterine perforation, (Ps' Omnibus Reply 4), but this argument is unavailing not only because Defendants' experts set forth reliable bases (including studies) for that opinion, (Javitt Report at 4), but also in light of the fact that several of Plaintiffs' own experts have said the same thing.[19] The fact that Plaintiffs' own experts agree on the limitations of 2D ultrasound show Bayer's experts' opinions concerning imaging are, at the very least, supportable.

Dr. Javitt, whose opinion focuses on 2D versus 3D ultrasound, is an accomplished radiologist and has served in leadership positions for national and international radiology committees that draft practice guidelines. (Javitt Report at 1.) She opines on the differences between 2D and 3D ultrasound technology, and concludes that a 2D ultrasound may not always be able to rule out that a portion of an IUD has entered the myometrium. (Id. at 4.) Dr. Javitt also opines that if the IUD is properly placed in the uterine cavity even 3D ultrasound cannot rule out injuries to the uterine wall caused by other objects, such as a uterine sound or an IUD inserter. (Id.) Dr. Javitt reaches this conclusion by analyzing several studies that lend support to her claims. (Id.) She is sufficiently qualified under Daubert to opine on ultrasound, and her report and proposed testimony are sufficiently reliable because she bases her opinions on her experience as a radiologist and on scientific literature. See Amorgianos, 303 F.3d at 266-67. Again, if Plaintiffs disagree with Dr. Javitt's conclusions, they can take it up on cross-

[19] (See, e.g., Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of Richard Strassberg, M.D., ("Cook Strassberg Decl."), (Doc. 2690), Ex. B, Deposition of Richard Strassberg ("Strassberg Dep."), at 65:11-14 ("[W]ith a 2-D ultrasound, a portion of the Mirena might be embedded in the myometrium and you wouldn't be able to tell; right? [Dr. Strassberg:] Correct."); Cook Young Decl. Ex. A, 8/19/15 Deposition of Roger Young ("8/19/15 Young Dep."), at 163:14-17 ("[W]ith a 2D ultrasound, you can't rule out that one of the arms is embedded in the myometrium, correct? [Dr. Young:] Correct."); Cook Wray Decl. Ex. A, Deposition of Susan Wray ("Wray Dep."), at 261:8-13 ("And you agree that there are limitations in 2-D ultrasound such that sometimes it will miss the existence of perforation, correct? [Dr. Wray:] So to that I would have to say, that is my understanding from the reading, yes.").)

examination. Their criticisms do not undermine her reliability, but rather go to the weight that should be given to her testimony. See id. at 267. In addition, Dr. Javitt's proposed testimony regarding the technical nature of ultrasound imaging would be helpful to assist a lay person in understanding the ways in which placement of the Mirena and possible perforations can be detected.

Plaintiffs also argue that because Bayer has never suggested that 3D ultrasound is necessary to ensure the location of a Mirena, it is "disingenuous" for Bayer's experts to offer testimony that 2D ultrasound may not be able to rule out perforation at insertion. (Ps' Omnibus Reply 4.) Although Plaintiffs are free to make this point during cross-examination, it does not warrant preclusion under Daubert. Plaintiffs do not cite any authority for the proposition that because Defendants never instructed patients or doctors to use one method, experts cannot opine on limitations of another method, or that their testimony should be excluded in such circumstances as "disingenuous." Any discrepancy between Defendants' statements and their experts' views at trial may be fodder for questioning and argument by Plaintiffs, but does not undermine the admissibility of the opinions. Dr. Javitt acknowledges in her report that when properly conducted, "2D US [ultrasound] can reliably assess whether an IUD is located in or near the uterine cavity." (Javitt Report at 3.) She also points out, however, that even though 2D ultrasound can determine whether an IUD is in the uterine cavity, it cannot always rule out that an IUD located in the uterine cavity has also partially entered the myometrium. (Id. at 3-4.) This distinction seems entirely logical and does not undermine the reliability of Dr. Javitt's report or the opinions of other experts regarding 2D versus 3D ultrasound.

Defendants' experts, who are all experienced medical practitioners with academic and clinical expertise, are qualified to opine on the narrow issue of the limitations of 2D ultrasound

in detecting perforation. In addition, they base their opinions on peer-reviewed studies. They thus pass muster under *Daubert's* reliability standard. See Daubert, 509 U.S. at 593. These opinions are also helpful to the trier of fact because they relate to a technical, medical issue that would be beyond the ken of a lay person. For the reasons stated above, Plaintiffs' motion to exclude Defendants' experts' testimony on the subject of 2D versus 3D ultrasound is denied. For the same reasons, Plaintiffs' motion to exclude Dr. Javitt's expert testimony is also denied.

**5. Opinions on Epidemiology**

Plaintiffs move to exclude Bayer's clinical experts' opinions regarding epidemiological studies, including the EURAS IUD study, because they are not epidemiologists and therefore not qualified to testify as to these studies. (Ps' Omnibus Mem. 21-22.) This level of expertise, however is not required under Daubert. See In re Zyprexa, 489 F. Supp. 2d at 282. Moreover, medical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies. See, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig., No. 11-CV-5304, 2013 WL 1558690, at *6 (D.N.J. Apr. 10, 2013) (doctor qualified to opine on clinical trials even though he was not an epidemiologist); Lyman v. Pfizer, Inc., No. 09-CV-262, 2012 WL 2971550, at *3 (D. Vt. July 20, 2012) ("A medical doctor does not have to be an epidemiologist in order to testify about epidemiological studies.").

Bayer's clinical experts' medical qualifications in the field of OB/GYN, their familiarly with IUDs, and their experience evaluating (and in some cases conducting) epidemiological studies as part of their clinical work and research suffice under Daubert and qualify them to opine on epidemiological studies, including the validity and sufficiency of the EURAS study. See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 09-CV-10012, 2011 WL 6740363, at *6 (S.D. Ill. Dec. 22, 2011) (doctor's "extensive experiences

qualife[d] him to give expert opin[ions] about the epidemiological studies that he . . . reviewed"). Accordingly, Plaintiffs' motion to exclude Defendants' experts' opinions as to epidemiological studies is denied.

**6. Conflicting Bayer Statements and Documents**

Plaintiffs next contend that Defendants' experts' testimony should be excluded under Daubert because it arguably contradicts statements made by Bayer employees. (Ps' Omnibus Mem. 14-15.) Plaintiffs do not cite any authority for this proposition. The one case that Plaintiffs cite in this section of their brief, Hilaire v. DeWalt Industrial Tool Co., 54 F. Supp. 3d 223, 234 (E.D.N.Y. 2014), does not support Plaintiffs' argument for exclusion based on alleged contrary statements made by a party. In fact, the court there remarked, echoing Daubert, that once testimony "has been found to be admissible, the adverse party is free to challenge any shaky or unreliable testimony," id. (internal quotation marks omitted), before the jury using "'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof,'" id. at 235 (quoting Daubert, 509 U.S. at 596) (emphasis added).

Plaintiffs further criticize Defendants' experts' testimony as unreliable for failing to consider Bayer's public positions and internal discussions related to secondary perforation. (Ps' Omnibus Reply 3-4.) To support their argument, Plaintiffs cite only Nimely, 414 F.3d at 396-97, which broadly states that when expert opinions are "based on data, a methodology, or studies that are simply inadequate to support the conclusions reached," that testimony should be excluded. Although this is certainly true under Daubert, it does not mean that potentially conflicting statements made by a party necessarily render that party's expert's testimony unreliable. The statements and public positions of Bayer are not scientific literature that an expert would be expected to confront in the exercise of intellectual rigor in the field. See In re

Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (expert testimony unreliable if expert does not acknowledge or account for "relevant scientific literature . . . tending to refute the expert's theory"). Under Daubert and its progeny, it is the role of the district court to analyze the qualifications of experts, the reliability of the methods used by an expert, and whether expert testimony will assist the trier of fact, not to weigh conflicting evidence – let alone conflicting evidence of a non-scientific nature in the form of party admissions. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 162 (E.D.N.Y. 2001) ("In assessing the reliability of a proffered expert's testimony, a district court's inquiry under Daubert must focus, not on the substance of the expert's conclusions, but on whether those conclusions were generated by a reliable methodology."), *aff'd*, 303 F.3d 256.

To whatever extent Defendants' public or internal statements conflict with its experts' opinions or its litigation positions in these cases, that will be a problem for Defendants that Plaintiffs may exploit via cross-examination and argument. But Defendants' experts' failure to confront alleged conflicting statements made by Bayer does not warrant exclusion under Daubert. See Huskey, 29 F. Supp. 3d at 735 ("The plaintiffs also contend that [the expert's] opinion is unreliable because he did not review internal [company] documents that refute his conclusion . . . [the expert's] failure to review particular documents goes to the weight of his opinion, not its admissibility.").

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For the reasons stated above, all seven of Defendants' experts have the necessary qualifications and have utilized reliable methods in their opinions as required by Rule 702 and Daubert, and their testimony will assist the trier of fact. Accordingly, Plaintiffs' omnibus motion to exclude Bayer's clinical experts, (Doc. 2702), is DENIED.

### C. Plaintiffs' Causation Experts

Defendants move to preclude Drs. Young, Jarrell, Wray and Strassberg from offering opinions regarding general and specific causation. Each is discussed separately below.

#### 1. Roger C. Young, M.D., Ph.D.

Defendants move to preclude Dr. Young's expert testimony relating to his theory of how secondary perforation of an IUD can occur – his theory of general causation – on the grounds that the methodology upon which he bases his opinions is unreliable and that he takes impermissible speculative leaps in forming his conclusions. Dr. Young's general causation expert report and proposed testimony are offered by Plaintiffs to show a mechanism by which perforation of an IUD unrelated to insertion – in other words, secondary perforation or spontaneous migration – could occur. Dr. Young also offers a specific causation opinion that secondary perforation did occur in Ms. Danley's case. (Cook Young Decl. Ex. C, Expert Report of Roger C. Young, M.D., Ph.D. ("Young Danley Report").) For the reasons stated below, Defendants' motion is GRANTED with respect to both Dr. Young's general causation opinions and his specific causation opinions.

##### a. General Causation

###### i. Opinions

In his general causation report, Dr. Young opines on "potential mechanisms of secondary perforation of Mirena IUDs." (Young Report at 2.) He sets forth a "[b]iologically plausible mechanism for IUD uterine perforation" that consists of four steps. (Id. at 10-11.) The mechanism assumes (at "Step 0") that the IUD is correctly placed within the uterine cavity. (Id. at 11.) At Step 1 of Dr. Young's mechanism, there is "delayed embedding" of the IUD in the uterine wall, which occurs unrelated to the insertion procedure. (Id.) Dr. Young opines that this

"delayed embedding" is facilitated by "chemical changes of the lining on the uterus caused by locally high concentrations of levonorgestrel [LNG]," which serves to thin the endometrium, exposing the underlying musculature and leading to an enhanced foreign body reaction ("FBR"). (Id. at 12.) According to Dr. Young, this thinning and FBR leads to a "greater likelihood that the Mirena will experience delayed embedding" in the uterine wall. (Id.) Step 2 in Dr. Young's mechanism refers to "penetration of the IUD into the uterine wall to a deeper level than embedding," with one part of the IUD "lead[ing] the way" as the IUD penetrates the uterine wall. (Id. at 13.) Again, at this stage Dr. Young attributes the softening of the connective tissue near the IUD, caused by LNG, as a significant contributing factor to IUD penetration. (Id.) Dr. Young asserts that uterine contractions also contribute to penetration of the uterine wall. (Id.)

Step 3 in Dr. Young's mechanism refers to perforation of the uterus by the IUD, which is the "phase where the IUD actively penetrates the uterine wall until some portion of the IUD protrudes through the wall into the abdominal cavity." (Id. at 14.) Dr. Young opines it is likely that the Mirena penetrates the uterus "by mechanical and chemical mechanisms." (Id. at 15.) The chemical mechanisms relate to the softening of the uterine tissue discussed at Steps 1 and 2, and the mechanical mechanisms refer to uterine contractions and the force required for the Mirena to perforate on its own. (Id.) Dr. Young acknowledges that the Mirena actually tends to reduce contractions, but finds that because it does not eliminate them, they can still contribute to secondary perforation. (Id.) Dr. Young estimates the amount of force created by the effect of uterine contractions on the Mirena using the size of Mirena and the force quantities found in one study examining the uterus and in another examining the heart. (Id. at 15-16.) The final stage in Dr. Young's analysis, Step 4, refers to "[t]ransmigration of IUD into abdominal cavity," which is when the IUD exits the uterus. (Id. at 16.) Dr. Young opines that once the IUD has partially

penetrated, complete penetration is "accomplished when uterine contractions occur in response to the presence of a foreign body." (Id.) Dr. Young's mechanism is thus based upon the effects of LNG on the uterus, which he concludes enhances the risk of secondary perforation, and the forces generated by uterine contractions. (Id.) He additionally concludes that knowledge of "mechanisms of secondary perforation are well-known" in medical literature. (Id.)

**ii. Qualifications**

Dr. Young is an experienced doctor specializing in OB/GYN. Dr. Young completed a residency in OB/GYN in 1986, and has since practiced obstetrics and gynecology in an academic setting. (Young Report at 3.) Dr. Young has served as a professor at the University of Vermont School of Medicine, Dartmouth Medical School, the Medical University of South Carolina and Duke University. (Id.) He is currently a professor at the University of Tennessee Health Sciences Center. (Id.) Dr. Young also has clinical experience in OB/GYN that has included caring for patients, supervising residents and teaching clinical medicine to medical students. (Id. at 4.) Dr. Young has learned, and subsequently taught, "how to place and remove copper 7, copper T, ParaGard and Mirena IUDs." (Id. at 6.) Over the course of his 27 years of clinical practice, Dr. Young has placed or supervised the placement of approximately 300 IUDs. (Id.) When Dr. Young was the Director of the Division of General Obstetrics and Gynecology at the University of Vermont, he "created a didactic, a practicum, and brief written test that each resident was required to complete prior to being able to place an IUD as the primary operator." (Id.) In addition, Dr. Young has researched "subcellular, cellular, tissue-level, and organ-level uterine physiology" with a focus on the "[d]evelopment of function with the hormonal effects of pregnancy, pre-labor changes, and labor." (Id. at 3.) He has "written and published 50 articles or book chapters in peer-reviewed journals, including mathematical simulation computer

programs that describe uterine contractions in pregnancy." (Id.) Dr. Young has also extensively researched the functioning of the uterus. (Id.)

Defendants argue that Dr. Young has "no specialized knowledge or experience concerning Mirena, perforation, or the biomechanics of the non-pregnant uterus." (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of Roger C. Young, M.D., Ph.D. ("Ds' Young Mem.") 3.) Dr. Young's academic and clinical background in obstetrics and gynecology, however, as well as his specific research on the functioning of the uterus, including effects of hormones and uterine contractions, make him qualified to opine on the issue of whether an IUD such as Mirena is capable of perforating a uterus unrelated to insertion. See In re Zyprexa, 489 F. Supp. 2d at 282. The Court must now determine whether Dr. Young's opinion and methodology meet *Daubert's* standards of reliability. See Daubert, 509 U.S. at 589; Amorgianos, 303 F.3d at 266.

**iii. Reliability**

Defendants move to exclude the testimony of Dr. Young on the grounds that it is unreliable. (Ds' Young Mem. 6-9.) Dr. Young's report and proposed testimony – which purport to be scientific, and thus the sort of expert testimony to which the four Daubert reliability factors apply, see Daubert, 509 U.S. at 592-93 – fail to meet any of those four factors. First, Dr. Young's mechanism has never been tested or studied in human patients, nor has it undergone animal or in vitro[20] testing. (8/19/15 Young Dep. at 137:7-10, 137:22-138:2.) Dr. Young acknowledged that it would be very difficult to test his mechanism because one cannot rule out, using standard techniques, disruption to the endometrial layer or trauma to the stroma upon

[20] In vitro testing refers to testing in "an artificial environment." Merriam-Webster Online Dictionary 2015, available at http://www.merriam-webster.com/. This differs from "in vivo" testing, which refers to a situation occurring "in the living body of a plant or animal." Id.

insertion, yet the absence of such injury is assumed at Step 0 of his theory. (Id. at 159:15-160:20.) Second, Dr. Young's mechanism has not been "subjected to peer review and publication," Daubert, 509 U.S. at 593, nor has it been scrutinized by the scientific community, (8/19/15 Young Dep. at 138:3-10). Dr. Young has shared his theory only with lawyers, not with other medical researchers or experts. (8/19/15 Young Dep. at 138:11-17.)Third, Dr. Young's mechanism has produced no "known or potential rate of error," Daubert, 509 U.S. at 594, because it has not been tested, (8/19/15 Young Dep. at 137:7-10, 137:22-138:2). Finally, Plaintiffs have not shown that Dr. Young's proposed mechanism has gained "general acceptance" within the scientific community. Daubert, 509 U.S. at 594. Dr. Young acknowledged that he is unaware of anyone in the scientific community who agrees with his mechanism of perforation, (8/19/15 Young Dep. at 228:16-24), and he only began to investigate his theory in the context of this litigation, (id. at 138:8-10, 163:21-164:6). See In re Pfizer Inc. Sec. Litig., No. 04-CV-9866, 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010) (expert testimony regarding mechanism of causation permitted where "deemed plausible and credible in the relevant medical literature"), as amended (Mar. 29, 2010).

Expert testimony developed solely for litigation can weigh against reliability. See Eghnayem v. Bos. Sci. Corp., 57 F. Supp. 3d 658, 670 (S.D.W. Va. 2014); In re Rezulin, 369 F. Supp. 2d at 420, 424. In addition, although the factors outlined in Daubert are not a "definitive checklist or test," Daubert, 509 U.S. at 593, "when an expert is offering testimony that is presented as a scientific conclusion and the expert's method fails to satisfy any of the factors identified in Daubert, a court should pause and take a hard look before allowing a jury to consider it," In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig., 593 F. Supp. 2d 549, 564 (S.D.N.Y. 2008), on reconsideration in part (June 26, 2008) (emphasis in original).

Because Dr. Young's mechanism does not meet any of the criteria listed in Daubert, the Court carefully scrutinizes Dr. Young's proposed testimony and concludes that it lacks a reliable methodology.

Expert testimony "must be supported by appropriate validation – i.e., good grounds, based on what is known." Daubert, 509 U.S. at 590 (internal quotation marks omitted). Moreover, an expert, "whether basing testimony upon professional studies or personal experience, [must] employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., 526 U.S. at 152. In the scientific community, "[s]cientific methodology . . . is based on generating hypotheses and testing them to see if they can be falsified." Daubert, 509 U.S. at 593. Dr. Young, however, was given a conclusion by lawyers and worked backwards to hypothesize a mechanism by which it might occur. (See Young Report at 2) ("I have been asked to offer an opinion as to the potential mechanisms of secondary perforation of Mirena IUDs."). No testing of the hypothesis was conducted. This exercise does not seem to have involved any scientific methodology, but rather consisted of reverse-engineering a theory to fit the desired outcome. This does not rise to the level of intellectual rigor employed in the medical or scientific field, see Kumho Tire Co., 526 U.S. at 152, and alone would warrant exclusion. See Faulkner v. Arista Records LLC, 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014) ("[M]ethodology . . . aimed at achieving one result . . . is unreliable, and . . . must be excluded."); In re Accutane Prods. Liab., 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007) ("While [the expert's] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation."); Golod v. La Roche, 964 F. Supp. 841, 860-61 (S.D.N.Y. 1997) ("[A]lthough [the expert's] theory may be biologically plausible, it does not constitute 'scientific knowledge' within the meaning of

Daubert. Instead, it is, at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis. Although there may be circumstances in which a scientific hypothesis that is, practically speaking, untestable, would nevertheless be admissible, perhaps because of general acceptance in the scientific community, this is not such a case."). Indeed, "the courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it." Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996). Dr. Young's expert testimony is therefore inadmissible.

Furthermore, apart from the requirement that the opinion constitute "scientific knowledge," as opposed to hypothetical speculation, an expert's analysis must be "reliable at every step." Amorgianos, 303 F.3d at 267. Defendants argue that Dr. Young's mechanism theory is unreliable because each step requires a "[s]peculative [l]eap[]." (Ds' Young Mem. 9-18.) At Steps 1 through 4 of his mechanism, Dr. Young cites studies and publications that he alleges support his theory of the mechanism for secondary perforation. A closer look, however, shows that Dr. Young draws impermissibly speculative conclusions from these studies that "exceed the limitations the authors themselves place[d] on the[se] stud[ies]." In re Accutane Prods. Liab., No. 04-MD-2523, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd*, 378 F. App'x 929 (11th Cir. 2010).

As part of Step 1 of his mechanism, Dr. Young opines that the IUD embeds into the uterine wall – the myometrium – after, and unrelated to, insertion. (Young Report at 11-12.) Dr. Young says this is possible due to the uterus's reaction to the IUD, a foreign body, being inside it, and the effect of LNG on the uterus. (Id.) Dr. Young relies on the Phillips study[21] to bolster his argument that a FBR takes place when an IUD is present in the uterus, (Young Report at 12),

[21] "Phillips" refers to V. Phillips et al., The Effects of the Levonorgestrel Intrauterine System (Mirena Coil) on Endometrial Morphology, 56 J. Clinical Pathology 305 (2003). (Compendium Ex. 17.)

and cites to several studies that discuss the effects of LNG on the endometrium, (id. at 11-12; see Compendium Exs. 4, 6, 17, 18).[22] As Dr. Young conceded at his deposition, however, none of these studies, including Phillips, discusses effects that LNG might have on the myometrium, the layer of muscle beyond the endometrium through which an IUD must puncture for perforation and migration to occur. (See Young Report at 11-12; 8/19/15 Young Dep. at 182:7-21.) The distinction matters because, by his own account, the endometrium and myometrium are distinct anatomical features: the former is a "thin layer," (Young Report at 4), composed of "glandular tissue," (8/19/15 Young Dep. at 112:15-20), whereas the later is a 1.3-2 cm layer made up of muscular tissue, (id. at 112:2-14). Moreover, during his deposition Dr. Young could not point to an article or study that supported the notion that LNG has a foreign body effect on the myometrium as opposed to the endometrium, (id. at 187:4-188:2; 191:22-194:1), and conceded that he was not aware of any evidence that LNG thins the myometrium, (id. at 114:9-11). Dr. Young opines, without explanation or analysis, that "[a]ny inflammation of the endometrium is going to extend into the myometrium," based on the small distance (5 microns) and shared blood supply between the two. (Id. at 182:11-21.) He does not explain why this proximity means that an outer layer, made of muscle, will react the same way as an inner layer, made of a different type of tissue, to the presence of a hormone in the cavity the inner layer surrounds. This type of speculation, whereby the conclusions are linked to studies only by Dr. Young's say-so, is impermissible under Daubert. See Joiner, 522 U.S. at 146 (where opinion "is connected to existing data only by the ipse dixit of the expert," the "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered"); see also McClain v. *Metabolife Int'l, Inc.*, 401 F. 3d 1233, 1244-1245 (11th Cir. 2005) ("The conclusions that [the

[22] Phillips found "stromal inflammatory cell infiltrate" in 59 of 75 cases where individuals were using a LNG intrauterine system. Phillips, supra note 21, at 305.

expert] draws about ephedrine by analogy . . . are very important to his opinions, but he did not show the reliability of each of his steps in deducing Metabolife's toxicity from this analogy. This is a fatal defect under Daubert.").[23]

Additionally, another important piece of Step 1 of Dr. Young's theory is his conclusion that uterine cells grow around the IUD, or "remodel," to attach it to the uterine wall. (8/19/15 Young Dep. at 172:10-173:8; Young Report at 11.) Dr. Young, however, disavowed the one article he cited to support this claim, and said that it does not actually support that proposition, (8/19/11 Young Dep. at 172:7-21, 177:24-178:2), and could not point to another study showing that uterine cells will grow around an IUD like Mirena, (id. at 172:22-173:20.) Dr. Young testified that he relied on two articles mentioned in his CV involving laboratory studies of cell growth on scaffolding. (Id. at 173:21-175:6.) Dr. Young's report does not discuss these studies, and during his deposition he did not explain why the growth of cells in these studies lends support to his theory that presence of an IUD leads to cell growth around it in the uterus. Indeed, he conceded that there are no studies that would support analogizing the two. (Id. at 176:13-22.) Dr. Young's analysis in this regard does not rise to the level of intellectual rigor generally seen in the scientific community, and thus does not meet the requirements of Rule 702 and Daubert.

Step 2 of Dr. Young's theory refers to penetration of the IUD into the uterine wall to a deeper level than embedding, a process helped by a softening in connective tissue due to the increased presence of LNG in the uterus. (Young Report at 13.) Dr. Young primarily relies on G.S. Anthony et al., Forces Required for Surgical Dilatation of the Pregnant and Non-Pregnant

[23] Extrapolation from studies to support an expert's conclusions, as well as the use of in vitro versus in vivo studies, may at times go to the weight and not the admissibility of expert testimony. See In re Ephedra Prods. Liab. Litig., 393 F. Supp. 2d 181, 189 (S.D.N.Y. 2005) ("[A]nalogy, inference and extrapolation can be sufficiently reliable steps to warrant admissibility so long as the gaps between the steps are not too great."). Nonetheless, here, the gaps between Dr. Young's theory and the authorities on which he relies are too great to warrant admissibility. He does not explain why his analogies, inferences and extrapolations are valid in this context.

Human Cervix, 89 British J. Obstetrics & Gynaecology 913 (1982), (Compendium Ex. 2) ("Anthony study"), for the proposition that progestins such as LNG weaken uterine tissue. The authors of this study were analyzing the force required to dilate the cervix. The study specifically found no direct correlation "between circulating levels of [progesterone] and the cervical resistance in non-pregnant or early pregnant subjects." (Id. at 915.) Despite this finding that seemingly contradicts the proposition for which he cites it, Dr. Young believes this study supports his theory because the authors state that the study found "patients receiving Depo-Provera showed a significantly lower level of cervical resistance . . . than did the cycling group." (Id. at 915.) Depo-Provera – a birth control shot that contains a progestin – is a different contraceptive than Mirena. The Anthony study did not attribute the weakening effect of Depo-Provera to progestin, and in fact noted that another progestin-containing contraceptive (the combined oral contraceptive pill) had no such effect. (Id.) To conclude that Mirena would cause the same effect as Depo-Provera because they both contain progestin – particularly when other contraceptives also containing progestin had the opposite effect, the effect of Depo-Provera was not attributed to progestin, and the study found no correlation between progestin levels and that effect – is to impermissibly draw grossly "overreaching conclusions," In re Accutane, 2009 WL 2496444, at *2, which are connected solely to the data by Dr. Young's say-so, see Joiner, 522 U.S. at 146; see also Dunn v. Sandoz Pharm. Corp., 275 F. Supp. 2d 672, 681 (M.D.N.C. 2003) ("[Expert's] assertion that because bromocriptine is an ergot alkaloid and may behave like other ergot alkaloids and cause vasoconstriction simply does not support the proposition that Parlodel causes stroke in postpartum women. Opinions merely expressing 'possibilities' do not suffice to support the admissibility of expert testimony.") (citing Saldana v. Kmart Corp., 260 F.3d 228, 234 (3d Cir. 2001)).

Moreover, at the end of his Step 2 analysis, Dr. Young acknowledges that LNG actually decreases the strength and frequency of uterine contractions, but argues that because they are not eliminated entirely, they still contribute to embedment. (Young Report at 13.) But he does not account for this diminishing effect in his analysis. "[A]ny theory that fails to explain information that would otherwise tend to cast doubt on that theory is inherently suspect." In re Rezulin, 369 F. Supp. 2d at 425. The extrapolations and inferences Dr. Young makes at Step 2 of his analysis are just too speculative to suffice under Daubert.

At Step 3 of his analysis, Dr. Young relies in part on the Goldstuck study, supra note 14, to show that uterine contractions have sufficient force to penetrate the uterine wall. (Young Report at 14-15.) Although Goldstuck presents evidence relating to the force of uterine contractions in connection with an IUD, Dr. Young conceded that there were errors in the study's methods and findings. (8/19/15 Young Dep. at 304:6-307:5.) He said an important value for measuring uterine contractions that the authors of Goldstuck attributed to another article did not actually appear in that other article, and described the Goldstuck authors as being "disingenuous." (Id. at 304:15-305:11.) Nevertheless, Dr. Young continued to rely at least in part on the numbers generated by Goldstuck and said, without further explanation, that the author's errors "made in one way tended to counterbalance other errors that [the author] made." (Id. at 305:19-306:20.) Dr. Young seems to have performed some sort of calculation of his own to mitigate the errors he found in Goldstuck, (see id. at 303:4-8, 306:13-307:5, 318:10-323:5), but these calculations do not appear in his report nor were they apparent during his deposition. When asked to explain where he got some of the figures he used in that calculation, Dr. Young cited "just kind of my experience working with pregnant and nonpregnant tissue and just in terms of contractility of uterine tissue," (id. at 320:23-321:2), and said that he derived these

calculations from his "experience and talking with the people who have done the research, [who] seem to be getting those values," (id. at 324:1-10.)[24] This does not rise to the level of intellectual rigor of medical or scientific study, rendering this opinion unreliable. See Joiner, 522 U.S. at 422; In re Rezulin, 369 F. Supp. 2d at 434.

As in Step 2 of his theory, Dr. Young again does not account for the fact that Mirena actually decreases the strength and frequency of uterine contractions, even though he acknowledged that Goldstuck did not involve uterine contractions in women with Mirena, further underscoring his unreliable methodology. See Rezulin, 369 F. Supp. 2d at 425. Dr. Young ultimately concludes that the contractile force of Mirena is 390 lbs/in², which is sufficient to penetrate uterine tissue "compared to the amount of force required to penetrate heart muscle . . . which is approximately . . . 290 lbs/ in²." (Young Report at 15.) The article that Dr. Young cited for the 290 figure involved a study of pig hearts, which Dr. Young said was an appropriate equivalent because he had "felt a lot of uteruses that ha[d] been taken out at the time of hysterectomy, and it feels remarkably like the pig hearts that my grandmother used to buy when I was a kid. So the softness of these two tissues are very similar." (8/19/15 Young Dep. at 291:15-24.)[25] Such a subjective comparison of muscle of a pig heart to a female uterus creates "simply too great an analytical gap between the data and the opinion proffered" to pass muster under Rule 702 and Daubert. Joiner, 522 U.S. at 146. But beyond that, Dr. Young corrected himself that it was chicken hearts he had felt as a child, and that he had no basis for comparing

[24] In one instance Dr. Young noted that published figures for uterine contractility were based on pregnant tissue, so to account for the fact that such tissue is more contractile than non-pregnant tissue, he reduced the value. (Young Dep. at 321:7-20.) But he provided no explanation for why or how he chose the reduced value, which "appears to have been plucked out of thin air based on vague qualitative notions." LaserDynamics, Inc. v. Quanta Comput., Inc., 694 F.3d 51, 69 (Fed. Cir. 2012).

[25] Although animal studies may be reliable sources, courts must use "caution" "in extrapolating results in tissue culture to effects in live humans." In re Rezulin, 369 F. Supp. 2d at 428-29.

uterine tissue to pig hearts. (8/19/15 Young Dep. at 292:21-293:6.) So that aspect of Dr. Young's testimony is not even connected to the data by ipse dixit. See Joiner, 522 U.S. at 146.

#### iv. Assisting the Trier of Fact

In light of their failure to meet the Daubert factors, absence of methodology, reverse reasoning and analytical gaps, Dr. Young's general causation opinions do not have sufficient indicia of reliability to pass muster under Daubert, and therefore they would not be helpful to a jury.

### b. Causation Opinion in Danley

Dr. Young has also authored a case-specific causation opinion for Plaintiff Jennifer Danley, which Defendants move to exclude as contradictory and unreliable. Defendants also argue that because Dr. Young has not given a general causation opinion, or relied on another expert's general causation opinion, he may not give a specific causation opinion. (Ds' Young Mem. 20-21.) The records show that Ms. Danley's Mirena was inserted on June 29, 2011. (Cook Young Decl. Ex. I.) An ultrasound was performed to check the position of the Mirena immediately following placement, and the technician noted that the IUD was seen "HIGH/RT."[26] (Id. Ex. J.) On January 3, 2013, Ms. Danley went to her healthcare provider after she had a positive home pregnancy test. (Id. Ex. M.) On January 8, 2013, an X-ray was performed that revealed Ms. Danley's IUD was located "overlying the left lilac bone." (Id. Ex. N.) On January 23, 2013, Ms. Danley's Mirena was removed by a "diagnostic laparoscopy." (Id. Ex. O.)

[26] The parties dispute the meaning of "HIGH/RT" and whether this indicates that Ms. Danley's uterus was perforated at the time of insertion.

### i. Opinions

Dr. Young opines that Ms. Danley's second Mirena was inserted on June 29, 2011 without complications and the Mirena was correctly located within the uterine cavity. (Young Danley Report at 2.) He concludes that Ms. Danley did not experience symptoms at the time of or immediately after insertion that would suggest that perforation occurred at that time. (Id.) He also opines that an IUD has little or no contraceptive effect if it is located outside the uterine cavity, and notes Ms. Danley did not become pregnant until 18 months after insertion. (Id.) Dr. Young reasons that had Ms. Danley's uterus been perforated at the time of insertion, resulting in the Mirena's placement directly into the abdominal cavity, it "is unlikely it would have taken 18 months for her to become pregnant." (Id.) Dr. Young thus concludes that the Mirena entered Ms. Danley's abdominal cavity during the fall of 2012 due to secondary perforation, requiring an abdominal laparoscopy to remove the Mirena, which she would not have otherwise needed. (Id.)

### ii. Lack of General Causation

Defendants argue that Dr. Young's specific causation is inadmissible because in his report on Ms. Danley, Dr. Young did not give a general causation opinion or rely on another expert's general causation opinion. (Ds' Young Mem. 20-21.) "'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.'" In re Rezulin, 369 F. Supp. 2d at 402 (quoting In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998)).[27] In the absence of evidence of general causation, evidence of specific causation is

[27] The Rezulin court also cited Mary Sue Henifin, Howard M. Kipen & Susan R. Poulter, Reference Guide on Medical Testimony, in Reference Manual on Scientific Evidence 439, 444 (Fed. Jud. Ctr. ed., 2000)), which states that "[g]eneral causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease (e.g., that smoking cigarettes can cause lung cancer)." In re Rezulin, 369 F. Supp. 2d at 402; see Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 251 n.1 (2d Cir. 2005) ("General causation bears on whether the type of injury at issue can be caused or exacerbated by the defendant's

"irrelevant." In re Rezulin Prods. Liab. Litig., 441 F. Supp. 2d 567, 578 (S.D.N.Y. 2006).[28] "[A] physician must have some reliable basis for believing that a particular substance is capable of causing the injury in question in relevant circumstances before concluding that the substance caused that injury in a particular case*." In re Rezulin*, 369 F. Supp. 2d at 438.[29] Although Dr. Young did not cite his mechanism theory for secondary perforation in his specific causation report, during his deposition he stated that he believed the "transmigration of [Ms. Danley's] IUD occurred through [his] mechanism" and that the four steps of his mechanism occurred in Ms. Danley's case. (Cook Young Decl. Ex. D, 8/20/15 Deposition of Dr. Roger C. Young ("8/20/15 Young Dep."), at 472:17-473:3.)

But because I have found that Dr. Young's general causation opinion is not based on a reliable methodology and is therefore inadmissible, his specific causation must also be excluded. See In re C.R. Bard, Inc., 948 F. Supp. 2d at 605 ("[Expert's] specific causation opinions are

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product. Specific causation bears on whether, in the particular instance, the injury actually was caused or exacerbated by the defendant's product.") (internal quotation marks omitted and emphasis in original).

[28] Plaintiffs have not disputed this proposition. The parties also do not dispute that Ms. Hayes' and Ms. Danley's Mirenas caused her injuries – in both cases the Mirena was located outside their uteruses and had to be removed. Instead, the parties dispute how that injury occurred – i.e., whether the perforation occurred upon insertion (a risk against which Defendants warned) or after insertion. Thus, in the context of these cases, evidence of general causation means evidence that secondary perforation can occur and evidence of specific causation means evidence that it occurred in the cases of Ms. Hayes and Ms. Danley. See In re Rezulin, 369 F. Supp. 2d at 438 (general or specific causation relate to "the injury in question in relevant circumstances").

[29] Put another way, "[a] physician attempting to establish a causal relationship between exposure to a substance and a particular patient's illness must 'demonstrate that the medical and scientific literature provides evidence that in some circumstances the exposure under consideration can cause the outcome under consideration. This step is synonymous with establishment of general causation.'" In re Rezulin, 369 F. Supp. at 436 (quoting Henifin et al., supra note 27, at 469). Although In re Rezulin concerned toxic tort litigation, this concept that a specific causation opinion must be based on a reliable general causation opinion logically applies, and has been applied, in cases involving devices. See, e.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 887 (10th Cir. 2005) ("In concluding that Plaintiff's systemic injuries were a result of her silicone breast implants, Plaintiff's experts attempted to demonstrate specific causation without first demonstrating general causation . . . Plaintiff's experts agree that, at best, silicone-associated connective tissue disease is an untested hypothesis. At worst, the link has been tested and found to be untenable. Therefore, there is no scientific basis for any expert testimony as to its specific presence in Plaintiff."); In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 605 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013) (specific causation opinion in transvaginal mesh case excluded after court found expert's general causation opinion, on which specific causation opinion was based, unreliable).

based on her general causation opinions. In other words, her opinion as to each bellwether plaintiff is that the plaintiff suffered nerve injuries through one or both of the general causation mechanisms . . . Because I found that [the expert's] general causation opinions are not based on reliable methodology and principles, her specific causations opinions – based on her general causation opinions – should also be excluded."); Rezulin, 441 F. Supp. 2d at 578 (excluding experts' specific causation opinions for failing to offer opinions as to general causation). Dr. Young's specific causation opinion is therefore inadmissible on this ground.[30]

**iii. Reliability**

In any event, in addition to being inadmissible because of lack of evidence of general causation, Dr. Young's methodology in reaching his conclusion that Ms. Danley experienced a secondary perforation of her Mirena is not based on a reliable methodology, warranting exclusion under Daubert. Dr. Young relies on the ultrasound that was taken following the insertion of Ms. Danley's Mirena and a lack of any post-insertion symptoms to conclude that the Mirena "was correctly located within the uterine cavity at this time." (Young Danley Report at 6.) That the IUD was in the uterine cavity, however, does not mean there was no injury upon insertion (whether from a sound, the inserter or the IUD). Further, Dr. Young acknowledged that 2D ultrasound cannot rule out the embedment of an arm of the IUD in the myometrium, (8/19/15 Young Dep. at 163:6-17), and that many perforations are asymptomatic, (8/20/15 Young Dep. at 431:13-15). Dr. Young concludes that in Ms. Danley's case it is more likely than not that secondary perforation occurred without explaining why hers is unlikely to be a case where 2D

[30] Dr. Young in his Danley report does not refer to other general causation opinions on which he relied in forming his specific causation opinion. Moreover, even if he had relied on Dr. Jarrell's and Dr. Wray's testimony, because I find that testimony to be inadmissible, see pages 54-85 below, Dr. Young cannot base his opinions on their reports on general causation.

ultrasound missed an injury or where injury occurred without symptoms. This say-so does not rise to the level of reliability required under Rule 702 and Daubert.

Moreover, Dr. Young opines that Ms. Danley became pregnant in late 2012 because the Mirena was in place (producing its contraceptive effects) until it perforated her uterus at that time, but he fails to account for or consider alternative evidence that could explain why Ms. Danley did not become pregnant sooner. For example, Dr. Young admitted that he would not know whether Ms. Danley and her husband were having intercourse while Ms. Danley was ovulating. (Id. at 424:1-9.) Ms. Danley also used condoms as birth control from 2003 to 2013, which would include the time her second Mirena was implanted. (Cook Young Decl. Ex. P, at JDanley-PFS-000080; Cook Young Decl. Ex. L, Deposition of Jennifer Danley ("J. Danley Dep."), at 132:10-12.) Ms. Danley was also breastfeeding her baby for seven months following the insertion of her second Mirena, (J. Danley Dep. at 200:8-15), which Dr. Young acknowledged would have "some contraceptive effect," although Dr. Young said the effect would not be "total," (8/20/15 Young Danley Dep. at 426:10-15). Dr. Young also acknowledges that if an IUD's drug reservoir is still within the myometrium it would have some reduced contraceptive effect, although he claims, without explanation, that this was not the case for Ms. Danley, (id. at 428:21-429:6), even though, according to him, it could take "[d]ays or weeks to years" for an IUD to penetrate into the uterine wall to a deeper level than embedding, (Young Report at 11). Dr. Young's failure to give "reasonable explanation[s]" for discounting or dismissing these alternative possibilities for why Ms. Danley did not become pregnant for 18 months undermines the reliability of his opinions. See Deutsch, 768 F. Supp. 2d at 474 ("[E]ven though 'an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation

for dismissing specific alternative factors identified by the defendant.'" (quoting Israel v. Spring Indus. Inc., 98-CV-5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006)).

Defendants' motion to exclude Dr. Young's proposed testimony regarding secondary perforation in the case of Ms. Danley is thus granted.

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For the reasons stated above, Defendants' motion to exclude the proposed testimony and opinions of Dr. Young in their entirety is GRANTED.

**2. John Jarrell, Ph.D., P.E.**

Defendants move to exclude the expert testimony of John Jarrell, Ph.D., P.E. on the grounds that he is not qualified to opine on the effects of LNG on the uterus, the "sharpness" of Mirena, or IUDs in general. (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of John Jarrell, Ph.D., P.E. ("Ds' Jarrell Mem."), (Doc. 2680), 3-7.) Defendants also move to exclude Dr. Jarrell's testimony on the grounds that it is unreliable and irrelevant. (Id. at 2-3.)[31] For the reasons stated below, Defendants' motion to exclude Dr. Jarrell's testimony is GRANTED.

[31] In their Opposition, (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude the Testimony of John Jarrell, Ph.D., P.E. ("Ps' Jarrell Opp."), (Doc. 2774)), Plaintiffs do not oppose Defendants' argument that Dr. Jarrell should not be allowed to opine on a safer alternative design, and therefore the Court deems this argument abandoned. Cf. Cowan v. City of Mount Vernon, 95 F. Supp. 3d 624, 645 (S.D.N.Y. 2015) ("Federal courts may deem a claim abandoned when a party moves for summary judgment on one ground and the party opposing summary judgment fails to address the argument in any way.") (internal quotation marks and citation omitted). In addition, Dr. Jarrell stated at his deposition that he did not propose any safer alternative design in his expert report, indicating he does not intend to offer an opinion on an alternative safer design. (Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of John Jarrell, Ph.D., P.E. ("Cook Jarrell Decl."), (Doc. 2681), Ex. A, Deposition of John Jarrell ("Jarrell Dep."), at 99:12-15) ("Do you disclose anywhere in your expert report in which you propose a supposedly safer alternative design of an IUD? [Dr. Jarrell:] No, I don't address that."). Accordingly, the motion is granted insofar as it relates to any opinion of Dr. Jarrell's regarding a safer alternative design of the Mirena.

**a. Opinions**

Dr. Jarrell offers five opinions in his expert report. (Cook Jarrell Decl. Ex. B, General Expert Report of John D. Jarrell, Ph.D., P.E. ("Jarrell Report"), at 3-4.) First, Dr. Jarrell opines that the hormone that Mirena releases into the uterine cavity, LNG, causes a thinning of the endometrium, the inner layer of the uterine wall. Second, Dr. Jarrell says the tips of the arms of the Mirena (the ends of the top of the "T" shape of the plastic device) are relatively sharp when compared to the smoother, adjacent surfaces of the Mirena. Third, he opines that although the Mirena generally has flexible arms, these arms become stiff and rigid when loaded in "constrained conditions," causing the device to transfer pressures to the uterus in response to contractions, leading to necrosis (or dead tissue), embedment, and sometimes perforation. Fourth, Dr. Jarrell states that pressure on uterine tissue, generated by uterine contractions, and the presence of a rigid Mirena, create sufficient force to lead to the rapid development of pressure wounds and injury to cells. Finally, Dr. Jarrell opines that an inflammatory response and FBR occurs when polyethylene and silicone polymers (synthetic materials found in Mirena) come in contact with "compromised tissues," enhancing damage and accelerating erosion in the uterus, and thus increasing the potential for migration. (Id. at 3-4.) In addition, during his deposition Dr. Jarrell opined that he found a manufacturing defect in the Mirena that he tested. (Jarrell Dep. at 190:18-191:12, 196:24-197:3.)

**b. Qualifications**

Dr. Jarrell is a "multi-discipline engineer specializing in the analysis of complex designs and failures involving materials, mechanical and biological systems." (Jarrell Report at 1.) Dr. Jarrell is "actively involved in engineering analysis, design, product development and research." (Id.) Dr. Jarrell has Bachelor's and Master's of Science degrees in Materials Science and

Engineering, as well as a Doctorate in Biology, Medical Science and Engineering from Brown University. (Declaration of Diogenes P. Kekatos in Opposition to Defendants' Motion to Exclude the Testimony of John Jarrell, Ph.D., P.E. ("Kekatos Jarrell Decl."), (Doc. 2775), Ex. A, Jarrell Report app. B ("Jarrell CV"), at 1.) He has authored "multiple peer-reviewed publications and abstracts on materials, toxicity, cell interactions with materials, biomaterials, implants and coatings and a guide book on materials selection, friction and wear for medical device designers." (Jarrell Report at 2.) In addition, Dr. Jarrell has U.S. and foreign patents covering "active biomaterials, siloxane and metal oxide composites, active delivery and medical applications." (Id.)

Although Dr. Jarrell seems to be an accomplished and experienced biomedical engineer – he has experience in certain biomaterials and implants – he has no previous experience with IUDs or hormonal contraception like Mirena. (Jarrell Dep. at 84:7-85:8.)[32] Nor does he have any particular familiarity with the anatomy of the uterus. (Id. at 75:16-77:11 (Dr. Jarrell's "training in uterine anatomy" occurred in connection with Mirena and mesh litigation).) Dr. Jarrell's experience in engineering and biomaterials perhaps qualifies him to opine on a mechanism by which a Mirena might perforate a uterus, see In re Zyprexa, 489 F. Supp. 2d at 282, but he is not qualified to opine on the effects of LNG on the uterus because he is not a medical doctor nor does he have relevant experience or expertise in hormonal contraception or the effects of hormones on uterine tissue. Dr. Jarrell's only experience with LNG comes from reviewing a number of articles supplied to him by Plaintiffs' counsel, which Dr. Jarrell

[32] Dr. Jarrell said he was familiar with "drug delivery devices for contraception" before becoming involved in this litigation because he took a course on drug delivery, which included a topic on contraception, at Brown University. (Jarrell Dep. at 79:22-80:8.) One class in which contraception was a topic would not give a student "expertise" in that field, and certainly not enough to be able to opine as an expert even under *Daubert's* liberal admissibility standards.

subsequently copied and pasted into his expert report. (Jarrell Report at 14-18.)[33] This is not the level of rigor an expert in the field would apply and does not pass muster under Daubert. See Mancuso v. Consol. Edison Co. of N.Y., 967 F. Supp. 1437, 1443 (S.D.N.Y. 1997) (finding expert unqualified because he relied on counsel to supply him with relevant scientific literature and "subsequently attempted, with dubious success, to qualify himself as [an expert] by a selective review of the relevant literature"); see also Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (criticizing "litigation-driven expertise" where expert "relied upon the plaintiff's attorney to provide him with the relevant scientific literature"); cf. Arista Records LLC v. Lime Grp., LLC, No. 06-CV-5936, 2011 WL 1674796, at *17 (S.D.N.Y. May 2, 2011) (allowing expert where conclusions were "not based on a selective review of a limited universe of sources strictly for the purposes of preparing to testify").

**c. Reliability**

Although Dr. Jarrell is not qualified to opine on alleged thinning effects of LNG on the endometrium, see Amorgianos, 303 F.3d at 267 (expert testimony inadmissible if any step in the analysis is unreliable), assuming he would rely on Plaintiffs' other experts for that proposition or that he does not intend to opine on this issue at trial,[34] the Court assesses the reliability of the subsequent steps of his analysis, and concludes that they do not have sufficient indicia of reliability under Daubert. See Joiner, 522 U.S. at 146 ("[N]othing 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.").

[33] At his deposition, Dr. Jarrell said before this litigation he had never considered the effect of LNG on the endometrium. (Jarrell Dep. at 169:24-170:2.)

[34] Dr. Jarrell stated at his deposition that he did not believe he would be opining at trial that a supposed thin, fragile endometrium resulting from LNG is part of the mechanism by which an IUD perforates the uterus. (Jarrell Dep. at 170:10-17.)

### i. Relative Sharpness of Mirena

Dr. Jarrell opines that the "tips of the Mirena arms contain relatively sharp edges compared to the smoother adjacent surfaces, based on [his] inspection under microscopy and with metrology." (Jarrell Report at 18.) The substance of Dr. Jarrell's "experiment" seems to have consisted of him squeezing a Mirena with a gloved hand and determining, based on his own tactile senses, that the tips are "relatively sharp" "compared to the smoother surfaces that are adjacent to the tips." (Jarrell Dep. at 185:20-187:5.) Dr. Jarrell based this opinion on his "inspection and handling of the exemplar Mirena" during which time he observed "relatively sharp edges." (Jarrell Report at 18.) Dr. Jarrell relied primarily upon his own senses to determine the Mirena was "sharp" and compared it to itself, not to other IUDs (or even to other Mirenas to potentially argue that one Mirena in particular was sharper than others). This is not scientific and does not amount to reliable expert testimony. See In re C.R. Bard, Inc., 948 F. Supp. 2d at 604-05 (general causation opinion precluded when it was "based on nothing more than [the expert's] personal, unscientific observation and opinion that 'it's obvious' that mesh arms are sharp and can serrate or tear nerves" and finding such testimony to be "the type of subjective, conclusory approach that cannot reasonably be assessed for reliability and that Rule 702 is designed to exclude") (internal quotation marks omitted); In re Rezulin, 309 F. Supp. 2d at 544 (finding that allowing experts "to tender purely subjective views in the guise of expert opinions" would "border on the absurd"). Dr. Jarrell admitted at his deposition that individuals' opinions as to whether the Mirena feels sharp could differ. (Jarrell Dep. at 188:12-20.) Dr. Jarrell was also unable to cite support, peer-reviewed or otherwise, that backs his theory that the Mirena IUD is sharp. (Jarrell Dep. at 184:22-185:2.) Dr. Jarrell's methodology is devoid of objective standards that can be tested by others. Dr. Jarrell's experiment has not been peer-

reviewed or recreated in any other testing. See Daubert, 509 U.S. at 593-94. It cannot be recreated or reviewed because he provides no standards by which he measured sharpness. Further, it was prepared solely for litigation, which by itself does not warrant exclusion, but weighs against reliability of an expert's testimony. See In re Rezulin, 369 F. Supp. 2d at 420 (courts may consider "whether an expert's opinion was developed for litigation," in addition to the four Daubert factors).

Plaintiffs try to salvage Dr. Jarrell's opinions by pointing out that Dr. Jarrell performed "tactile analysis and evaluation" and "direct observation," which they argue are "generally accepted methods used by experts in [Dr. Jarrell's] field." (Ps' Jarrell Opp. 13-14.) The quoted language apparently refers to Dr. Jarrell touching and looking at the Mirena, something the jury is capable of doing itself.[35] See Andrews v. Metro N. Commuter R.R. Co., 882 F.2d 705, 708 (2d Cir. 1989) (expert testimony inadmissible if directed to "lay matter which a jury is capable of understanding and deciding without the expert's help"). To support their argument that feeling an item is a reliable methodology, Plaintiffs cite a 1901 article with advice on how a surgeon should sharpen instruments. (Allen DeVilbiss, Care & Use of Instruments, 36 J. Am. Med. Ass'n 1099 (1901), Cook Jarrell Decl. Ex. F). While this article does advise that the surgeon feel his instruments to see if they are sharp, the article nowhere suggests that doing so is a scientific exercise or otherwise indicates that touching an item would provide sufficient scientific rigor for expert testimony or is otherwise generally accepted as a method for engineers. Plaintiffs also cite the Mirena specifications as well as a long report on a copper IUD, neither of which assist them in addressing the entirely subjective and non-scientific nature of Dr. Jarrell's "squeeze

[35] Although Dr. Jarrell utilized microscopes to get a closer look at the Mirena and take photographs, such images cannot demonstrate the relative sharpness of an item, and in any event the jury can look at the same photographs.

test."[36] Because it does not bear indicia of reliability under Daubert, Dr. Jarrell will not be allowed to opine about the relative sharpness of the Mirena.

**ii. In Vitro Mechanical Testing of Mirena**

Dr. Jarrell also gives an opinion that the "Mirena design has generally flexible arms" but that they "become very stiff when loaded in constrained conditions," which "causes the device to become very rigid at the tips, allowing the device to transfer high forces and pressures to the tissues in response to uterine contractions leading to tissue necrosis, embedment and in some instances, perforation and migration." (Jarrell Report at 22.) Dr. Jarrell described a "constrained condition" as corresponding to the top of the Mirena arms contacting the top of the fundus (the top portion of the uterus opposite the cervix) and the tips of the arms contacting the adjacent uterine surface. (Id.) Although Dr. Jarrell says the Mirena has "generally flexible arms," he says that in a constrained position the arms are unable to flex and became much stiffer. (Id.) To measure the forces they transfer to uterine tissue in that position, he tested a Mirena in laboratory equipment apparently intended to mimic the uterus. (Id. at 10-11, 22.) Dr. Jarrell used double-sided tape to affix the tips of the Mirena's arms to an "abutting block" across the top of the arms to apply pressure to the Mirena and hold it in place. (Id. at 11; Jarrell Dep. at 234: 2-14.)

[36] The two cases Plaintiffs cite in support of their arguments regarding Dr. Jarrell's methodology, Figueroa v. Boston Scientific Corp., 254 F. Supp. 2d 361, 368-69 (S.D.N.Y. 2003), and Lappe v. American Honda Motor Co., 857 F. Supp. 222, 228 (N.D.N.Y. 1994), *aff'd*, 101 F.3d 682 (2d Cir. 1996), stand for the proposition that an expert need not perform all relevant tests or examine all relevant reports or documents in order for his or her testimony to be sufficiently reliable and therefore admissible. Figueroa relied on McCullock, which has since been discredited, see Ruggiero, 424 F.3d at 255, and Lappe found that although the expert "may have neglected to perform some essential tests or measurements," this goes "to the weight of his testimony, not its admissibility." 857 F. Supp. at 228 (internal quotation marks omitted). Lappe does not help Plaintiffs because – unlike Dr. Jarrell's opinion regarding "sharpness" here – the expert there had relied on facts, investigation and traditional technical expertise. Id. Moreover, the Lappe court rejected the application of Daubert (then newly decided) to the proffered engineering testimony. See id. Lappe and Figueroa do not undermine my conclusions that I would not be fulfilling my gatekeeping function if Dr. Jarrell were allowed to testify regarding his "squeeze test" in front of a jury.

Dr. Jarrell's constrained testing conditions do not reliably replicate the conditions inside a woman's uterus, and therefore render his methodology and the conclusions he draws from it unreliable. Dr. Jarrell admitted at his deposition that he did not have any basis to suggest that the way the Mirena became rigid in his experiment occurs in vivo (inside a human being). (Jarrell Dep. at 228:23-229:2, 318:10-14.)[37] Obviously, no tape is used to affix the tips of the Mirena to the sides of the uterus – indeed, they are not affixed at all – and obviously the top of the arms does not meet the soft fundus the way it was pressed against the metal abutting block. This creates "too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146; see Winebarger v. Bos. Sci. Corp., No. 13-CV-28892, 2015 WL 1887222, at *17 (S.D.W. Va. Apr. 24, 2015) (testing that produced certain results at very high temperatures that could not be replicated in human body, "without [expert] providing any explanation or support for his opinion," did not fit facts of case and was therefore irrelevant and unhelpful). It seems apparent that without affixing the tips of the arms to the pressure plates of his apparatus and pressing down on the tops of the arms with a hard surface, Dr. Jarrell could not obtain the force numbers he needed for his theory, so he used that method despite an absence of correlation to any real-life conditions. This strikes the Court as exactly the sort of unreliable "science" the Daubert test was intended to weed out. See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig., No. 14-MN-2502, 2015 WL 7422613, at *12 (D.S.C. Nov. 20, 2015) (excluding testimony where expert "played around" with various scenarios until desired result was reached).

Similarly, Dr. Jarrell's manual pressure plate testing, which he utilized to get a "numerical value" for the forces that the Mirena's arms could resist, (Jarrell Dep. at 223:20-

[37] Dr. Jarrell did not have an opinion on a clinical scenario in which the Mirena arms would be constrained in a uterus. (Jarrell Dep. at 141:8-10.)

224:19), also does not satisfactorily replicate conditions inside a uterus as it appears Dr. Jarrell held the Mirena and pushed it against the pressure plate.[38] Dr. Jarrell does not provide a convincing explanation for why his in vitro experiment is a suitable replica for a uterus, and therefore there is too great of an analytical gap between his mechanical testing and the environment inside a woman's uterus, making his testimony both unreliable and unhelpful to a jury. See Joiner, 522 U.S. at 146.

Defendants also criticize Dr. Jarrell's report and proposed testimony because his mechanical test has not been tested by others, let alone peer reviewed, and he does not cite other support for his methodology or conclusions. (Ds' Jarrell Mem. 13-14.) Although peer-review and studies supporting a methodology are not always necessary, see Kumho Tire Co., 526 U.S. at 156, here these factors, when added to the unreliability of Dr. Jarrell's in vitro mechanical testing, further weaken the reliability of Dr. Jarrell's experiment. See Daubert, 509 U.S. at 593. Plaintiffs' broad claims that engineers are qualified to opine generally on mechanisms and their citation to the Reference Manual on Scientific Evidence are unavailing. See McClain, 401 F.3d at 1244 (finding expert testimony speculative and inadmissible when based upon "broad principles of pharmacology"); Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998) ("The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.").[39] Moreover, although Dr. Jarrell's experiment may be reproducible, this does not

[38] Dr. Jarrell apparently first described these manual tests done on a pressure plate during his deposition, (Jarrell Dep. at 223:5-7), and photographs of the testing are attached as Exhibit H to the Kekatos Jarrell Declaration. These photos show Dr. Jarrell "pressing the Mirena against the pressure plate and measuring the forces that the Mirena sustained under different loading angles, loading conditions" to see "the maximum force it would support." (Jarrell Dep. at 338:8-16.)

[39] Walker v. Soo Line Railroad Co., 208 F.3d 581, 589-90 (7th Cir. 2000), which Plaintiffs cite, (Ps' Jarrell Opp. 19-20), to support their argument that Dr. Jarrell should be allowed to testify based on his broad engineering experience, stands for the proposition that a jury should be able to hear alternative explanations for an event. In that case, however, the court noted that the expert had "scientifically valid testimony," something that is lacking here. Id. at 590. In re Scrap Metal Antitrust Litigation, 527 F.3d 517, 529-30 (6th Cir. 2008), states that it is not the role

alleviate the unreliability caused by the fact that the testing conditions were unlike those present in a uterus.

In addition, Defendants argue that Dr. Jarrell's report and testimony are unreliable because his mechanical testing amounted to an ad hoc test with no written protocol. (Ds' Jarrell Mem. 14-15.) Although not necessarily dispositive, the fact that Dr. Jarrell did not have a written protocol prior to testing the Mirena, (Jarrell Dep. at 56:13-17) – he apparently created it after the fact, a short time before his deposition, (id. at 133:25-134:22) – again weighs against admissibility. See Hall v. Bos. Sci. Corp., No. 12-CV-8186, 2015 WL 868907, at *12 (S.D.W. Va. Feb. 27, 2015) (noting expert's "failure to adhere to testing standards or a written protocol" in finding methodology unreliable). Dr. Jarrell's mechanical testing of the Mirena is not sufficiently reliable to withstand Daubert scrutiny, and he may not opine on this topic.

**iii. Pressure Wound Theory**

Without his force calculations, Dr. Jarrell cannot opine that Mirena transfers enough force to cause pressure wounds. Putting that aside, however, there are other problems with his proposed pressure-wound testimony.

Dr. Jarrell opines that "[s]ustained pressures between human tissues and rigid objects can lead to the rapid development of pressure wounds" and that "[t]he rigidity and geometry at the tips of the Mirena and pressures generated by uterine contractions are sufficient to cause rapid degradation to soft tissues." (Jarrell Report at 24.) He also finds that "[a]n inflammatory response and foreign body reaction occurs when polyethylene (and silicone polymers) come in contact with compromised tissues and during embedment and migration," which "enhances

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of the district court to choose one version of facts over another, but to "determine whether [the expert testimony] rests upon a reliable foundation." Id. This proposition does not help Plaintiffs because Dr. Jarrell's report and proposed testimony do not rest upon a reliable foundation.

damage and breakdown of surrounding tissues and accelerates erosion and perforation of tissues, enhancing the potential for migration." (Id. at 29.) Dr. Jarrell, albeit a qualified and impressive engineer, is not qualified to opine on pressure wounds in the uterus based on studies and patent filings he has read. (Id. at 29-32). In his report, to support his pressure wound opinion, Dr. Jarrell quotes portions of a study "evaluat[ing] uterine and serum concentrations of LNG," (id. at 29), a patent filing by Bayer stating the shape of an IUD should have "**blunt surfaces and gentle curves**," (id. at 31) (emphasis in original), and two articles that relate to a foreign body response and host reactions, (id. at 31-32). Dr. Jarrell does not offer any analysis as to why these sources support his pressure wound theory or tie them to Mirena, nor has he the relevant expertise to undertake such an analysis. See Ellis v. YMCA Camp Mohawk, Inc., 615 F. App'x 697, 698 (2d Cir. 2015) ("Federal Rule of Evidence 702 requires expertise based on specialized knowledge and experience, not a mere understanding derived from others' publications."). Dr. Jarrell is not a physician nor does he claim to have clinical experience with IUDs. (Jarrell Dep. at 75:3-6, 75:16-18, 82:23-83:5, 84:7-24.) His Ph.D. in biology, medical science and engineering and his research in biomaterials do not suffice to render him an expert in how the uterus responds to the presence of Mirena.

Furthermore, because Dr. Jarrell had never heard of perforation before being contacted about this case, it is safe to say his theory of IUD perforation was created for purposes of this litigation. (Jarrell Dep. at 85:5-8.) Although a methodology or experiment that is created for litigation does not automatically require exclusion, such an origin is a factor in assessing reliability. See In re Rezulin, 369 F. Supp. 2d at 420 (listing whether an expert's opinion was developed for litigation as factor for consideration in Daubert analysis); see also Amorgianos, 137 F. Supp. 2d at 190-91 (excluding experts after finding that they had not "tested [the]

hypothesis in any way or subjected it to peer review. Instead, plaintiff's experts have aired their hypothesis only in the courtroom and have elected not to share their ideas on this subject with their peers in the medical and industrial hygienic communities."). Here, Dr. Jarrell had very limited experience and exposure to IUDs prior to this litigation, and drafted his report based upon at least one important study (Goldstuck, see supra note 14) that he received from Plaintiffs' counsel and of which he had not heard before being retained. (Jarrell Dep. at 266:1-11.) This is not the level of academic rigor that would be expected of an engineer or doctor in the field. In addition, Dr. Jarrell's pressure wound hypothesis has not been tested or peer reviewed, (Id. at 295:19-296:3), and Dr. Jarrell does not point to any convincing evidence of acceptance within the scientific community. See Golod, 964 F. Supp. at 860 (excluding an expert because his theory did "not constitute 'scientific knowledge' within the meaning of Daubert. Instead, it is, at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis.").[40]

Plaintiffs argue in their Opposition that the Zakin study[41] shows that Dr. Jarrell's pressure-wound theory is supported within the scientific community. (Ps' Jarrell Opp. 21.) That study, however, appears to discuss pressure necrosis from an already-embedded IUD, not secondary perforation as Plaintiffs posit in this case. More fundamentally, even assuming the Zakin study could lend some support to Dr. Jarrell's theory, Dr. Jarrell does not cite this study in his report, nor is it on his list of documents on which he relied. (Kekatos Jarrell Decl. Ex. A app. A.) It is not the district court's purview to analyze the validity of the expert's conclusions based on the universe of scientific knowledge, but rather to determine whether the expert's

[40] The court in Golod noted that there might be instances where an untested or untestable theory may be admissible, but that they would be where there was general acceptance in the scientific community. See 964 F. Supp. at 860-61.

[41] "Zakin" refers to David Zakin et al., Complete and Partial Uterine Perforation & Embedding following Insertion of Intrauterine Devices. I. Classification, Complications, Mechanism, Incidence, and Missing String, 36 Obstetrical & Gynecological Survey 335 (1981). (Kekatos Jarrell Decl. Ex. J.)

methodology was reliable and stands up to the intellectual rigor of the expert's field. See Kumho Tire, 526 U.S. at 152. That, unbeknownst to the expert, a study exists that may support his conclusions does not render his methodology any stronger.

Defendants also argue that Dr. Jarrell's opinion is unreliable because he based his opinion on uterine contractions on studies of women not using Mirena or a similar progestin-releasing IUD. (Ds' Jarrell Mem. 17-19.) Although this by itself might not warrant exclusion if there were a scientific basis for applying these studies to women using Mirena, fatal to Dr. Jarrell's opinion is his inability to even explain why these studies would be applicable to Mirena users. When asked where he got the baseline number measuring force of uterine contractions, Dr. Jarrell stated, "I had to look at the existing literature to get from an engineering standpoint the ranges of pressures that I could use for calculations, so these were the numbers that were available in the published literature." (Jarrell Dep. at 268:12-23). Dr. Jarrell acknowledged that those figures arose from a study of women not using Mirena, (id. at 268:8-11), and that he did not know how use of a Mirena would affect them, (id. at 269:9-11 ("How a Mirena influences those [numbers], I didn't see the literature giving me numbers of that."); see id. at 269:14-15 ("If I had those numbers, I would have used them."); id. at 292:18-19 ("I don't know what the pressures are under Mirena.")). His lack of access to reliable data does not justify use of unreliable data, and militates against admission under Daubert. See In re Rezulin, 369 F. Supp. 2d at 426 ("A crucial consideration in evaluating the admissibility of expert testimony is whether the conclusions flow reliably from the premises."). Indeed, Dr. Jarrell acknowledged in his deposition that the LNG in Mirena reduces the force of uterine contractions, (Jarrell Dep. at 256:12-19), but in his analysis he ignored this inconvenient truth. A legitimate scientist or engineer in the field, knowing he did not have reliable numbers for a stage of his analysis, would

decline to reach a conclusion. Dr. Jarrell's proceeding when he knew he did not have the proper basis suggests that his "methodology was aimed at achieving one result," Faulkner, 46 F. Supp. 3d at 381, which is the sort of science Daubert does not allow.

Dr. Jarrell's reliance on animal studies, without a sound basis for extrapolating these studies to human uteruses, is another example where his conclusions do not "flow reliably from the premises." In re Rezulin, 369 F. Supp. 2d at 426. Although animal studies can be reliable bases for expert opinions on humans if there is a scientific basis for such extrapolations, see In re Fosamax, 645 F. Supp. 2d at 186-87, in this instance Dr. Jarrell could not articulate why these studies were the appropriate foundation for his pressure wound opinion, (Jarrell Dep. at 294:7-12). In fact, Dr. Jarrell copied and pasted portions of studies to support his opinion without any analysis, except that he put certain sections in bold font. (Jarrell Report at 27-29.) Further, the animal studies involved sustained pressure for hours, (Jarrell Dep. at 263:14-9, 297:13-16), contrary to uterine contractions, which are measured in seconds, (id. at 263:9-13, 297:17-22). There are just too many gaps between Dr. Jarrell's analysis and the conclusions he draws to permit him to testify under Daubert. See Joiner, 522 U.S. at 144-45. Dr. Jarrell may not offer opinions on the relative sharpness of Mirena, his mechanical testing hypothesis or his pressure wound and necrosis theories.

**iv. Manufacturing Defect**

Defendants seek to exclude any opinions Dr. Jarrell might offer regarding alleged manufacturing defects. (Ds' Jarrell Mem. 24-25.) At his deposition, Dr. Jarrell offered an opinion that he found a 70 micron misalignment in the Mirena he tested, which he claimed exceeded the manufacturing specification of 50 microns. (Jarrell Dep. at 190:18-191:12, 196:24-197:3.) Dr. Jarrell was referring to the part of the product where two portions of a mold meet.

(Id. at 190:2-17.) Dr. Jarrell did not offer this opinion in his expert report, but Plaintiffs argue he should be allowed to testify on this subject because it would be justified and harmless, and Defendants had the opportunity to question Dr. Jarrell during his deposition. (Ps' Jarrell Opp. 23-25.) I need not analyze whether there was harm or whether it was justified because Dr. Jarrell's deposition testimony shows that he cannot reliably link any alleged misalignment with perforation, let alone perforation in the Hayes or Danley cases, because Dr. Jarrell did not do any testing on the specific Mirenas that allegedly caused the injuries in this litigation. Further, Dr. Jarrell admitted that he did not know of any clinical relevance of the misalignment he identified in the sample Mirena, nor could he identify support for the proposition that a parting line mismatch in an IUD was connected to a risk of perforation. (Jarrell Dep. at 194:6-10, 200:6-10, 201:19-24.) Dr. Jarrell's statements show that his opinion regarding a manufacturing defect is ultimately irrelevant under Rule 401 because it is not connected to the facts or issues in this case. See In re Rezulin, 309 F. Supp. 2d at 554 (finding expert testimony not relevant under Rules 401 and 702).

**d. Assisting the Trier of Fact**

Because, as discussed above, Dr. Jarrell is unqualified to testify about his opinion regarding the effects of LNG on the uterus, and the rest of his opinions are unreliable, his testimony would not be helpful to a jury.

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Accordingly, Defendants' motion to exclude the testimony of Dr. Jarrell is GRANTED.

**3. Susan Wray, Ph.D.**

Defendants move to exclude the expert testimony of Susan Wray, Ph.D. on the ground that Dr. Wray lacks the qualifications to opine on whether a Mirena can perforate a uterus

unrelated to insertion, on the mechanism by which this could occur, and on the adequacy of the Mirena label. (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of Susan Wray, Ph.D. ("Ds' Wray Mem."), (Doc. 2692), 1-2.) Defendants argue that Dr. Wray's general causation opinion should be excluded because it is unreliable, in that it contains analytical gaps and is grounded on insufficient data, and that her mechanism opinion should be excluded because it is based only on her own say-so and lacks an objective basis. (Id. at 2.) For the reasons stated below, Defendants' motion is GRANTED.

**a. Opinions**

Dr. Wray opines, based on her expertise and a review of scientific literature, that "contractions of the myometrium [the muscular middle layer of the uterus] can cause the transport of the Mirena device through the uterine wall into the peritoneal cavity and beyond (e.g. bladder, bowel)." (Wray Report at 3.) In addition, Dr. Wray opines that these contractions of the myometrium are able to transport a Mirena through the uterine wall without there having been any injury to the uterine wall during insertion. (Id.) It is Dr. Wray's view that the force of contractions alone are sufficient to cause a Mirena to migrate out of the uterus. (Id.) As part of her mechanism opinions, Dr. Wray also opines that "[i]n women with smaller than average width of their uterine cavity, adolescents and/or the nulliparous [those who have never had children] . . . disproportion between their uterus and the device size (32mm) . . . will lead to pressure on the uterine lining" that may not cause immediate damage but over months will cause erosion of the uterine lining. (Id. at 25). Dr. Wray also opines that decreased estrogen availability in the myometrium can lead to more perforations, despite proper insertion of the Mirena, (id. at 25-26), and that the effects of Mirena on the endometrium and myometrium "will build up over months and years," (id. at 19).

**b. Qualifications**

Dr. Wray is a professor of physiology at the University of Liverpool, where she served as departmental chair from 2004 to 2008. (Wray Report at 1.) From 2008 to 2013, Dr. Wray was the Director of the Centre for Better Births at Liverpool Women's Hospital, and since 2015 she has served as the co-Director of the Harris-Wellbeing of Women Centre for Preterm Birth Research. (Id.) As a scientist, Dr. Wray has focused her research on women, neonatal health and physiology, and she has worked with clinicians on issues related to uterine contractions. (Id.) Defendants argue that Dr. Wray is not qualified to opine on general causation or the mechanism by which a Mirena can perforate a uterus unrelated to insertion because she is not a medical doctor and has no expertise in contraception or IUDs. (Ds' Wray Mem. 4-5.) At her deposition, Dr. Wray admitted to not having conducted any research on contraception, (Wray Dep. at 37:9-11), authored publications on contraceptives, (id. at 37:12-14), or personally examined, tested or even handled a Mirena, (id. at 43:9-11, 44:9-11).

While it is a close question, given her lack of familiarity with contraceptives in general, Mirena in particular, the effect of LNG on the uterus or clinical evaluation of patient symptoms, Dr. Wray is an expert on uterine physiology, particularly the myometrium and uterine contractions, (id. at 29:22-30:8; Declaration of Diogenes P. Kekatos in Opposition to Defendants' Motion to Exclude the Testimony of Susan Wray, Ph.D. ("Kekatos Wray Decl."), (Doc. 2781), Ex. B, Wray Report app. A, Curriculum Vitae of Susan Wray ("Wray CV"), at 19), which gives her sufficient qualification to opine on a mechanism by which uterine contractions might cause a Mirena IUD to migrate outside the uterus after proper placement at insertion. See Hilaire, 54 F. Supp. 3d at 236 ("An expert need not be precluded 'from testifying merely because he or she does not possess experience tailored to the precise product or process that is

the subject matter of the dispute.'") (quoting Yaccarino v. Motor Coach Indus., Inc., No. 03-CV-4527, 2006 WL 5230033, at *9 (E.D.N.Y. Sept. 29, 2006)); In re Zyprexa, 489 F. Supp. 2d at 282 ("If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent.") (citing Stagl, 117 F.3d at 80); Lappe, 857 F. Supp. at 226 ("In a product liability action, an expert witness is not strictly confined to his area of practice, but may testify concerning related applications; a lack of specialization affects the weight of the opinion, not its admissibility."). Dr. Wray's expertise in uterine anatomy, especially the myometrium, is a closely related topic to migration of IUDs, and therefore qualifies her to give a mechanism opinion.[42] Her lack of specific experience in contraceptives, including IUDs, does not warrant exclusion.

Defendants also claim that Dr. Wray is unqualified to use case reports[43] as the basis for her secondary perforation opinion because such a method requires her to analyze specific patient cases, which she is unqualified to do because she is not a medical doctor. Defendants' argument imposes too high a burden upon experts in medical cases. See Corrigan v. Methodist Hosp., 874 F. Supp. 657, 660 (E.D. Pa. 1995) ("[N]on-medical doctors can testify as to causation of illness if they have an expertise in that area."); Hutchison v. Am. Family Mut. Ins. Co., 514 N.W.2d 882, 887-88 (Iowa 1994) ("[W]e refuse to impose barriers to expert testimony other than the basic requirements of Iowa rule of evidence 702 and those described by the Supreme Court in Daubert. The criteria for qualifications under rule 702 – knowledge, skill, experience, training,

[42] Defendants cite Mancuso, 967 F. Supp. at 1443, to argue that Dr. Wray became an expert after she was hired by Plaintiffs. Although this factor goes to Dr. Wray's reliability, discussed below, Dr. Wray's background and experience show that she has been an expert on the uterus for a number of years and that this expertise was not acquired for this litigation.

[43] A case report is a "type of information used by physicians and medical researchers . . . which is a description of a particular patient's clinical history and symptoms." In re Rezulin, 369 F. Supp. 2d at 406.

or education – are too broad to allow distinctions based on whether or not a proposed expert belongs to a particular profession or has a particular degree."); Baroldy v. Ortho Pharm. Corp., 760 P.2d 574, 588 (Ariz. Ct. App. 1988) ("A non-medical doctor . . . is not precluded from testifying as to diagnosis and causation solely because he is not a medical doctor."). Dr. Wray is therefore qualified to opine on a mechanism of secondary perforation.

Defendants additionally argue that Dr. Wray is not qualified to opine on the adequacy of Mirena's label because this is not within her area of expertise. Dr. Wray's experience as a physiologist and as an expert on the myometrium do not enable to her opine on the adequacy of the Mirena label; Dr. Wray even admitted that she is not qualified to offer an opinion on pharmaceutical labeling in the United States. (Wray Dep. at 66:10-17.) Plaintiffs do not argue otherwise. She will thus be precluded from testifying on the adequacy of the Mirena label.

**c. Reliability**

**i. Daubert Factors**

In order to satisfy the admissibility standards set forth in Rule 702 and Daubert, the expert must not only be qualified, but his or her testimony must also be reliable. See Fed. R. Evid. 702 (testimony must be based on "sufficient facts or data" and "the product of reliable principles and methods"); Daubert, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation – i.e., good grounds, based on what is known. In short, the requirement that an expert's testimony pertain to scientific knowledge establishes a standard of evidentiary reliability.") (internal quotation marks omitted). Dr. Wray's testimony does not satisfy any of the four factors listed in Daubert to assist district courts in considering whether a proffered opinion has sufficient indicia of reliability. Daubert, 509 U.S. at 593-94. Her theory of secondary perforation has not been tested, and therefore has no known error rate. (Wray Dep. at

368:1-12.) Her conclusions have not been subject to peer review; there is no evidence that she has published her work in journals or elsewhere, or that she even gave any thought to secondary perforation of IUDs before being retained in this case. (Id. at 49:17-50:13.) Her theory has not been generally accepted in the scientific community. Textbooks on gynecology and leading organizations such as the World Health Organization ("WHO") and ACOG do not support her opinions regarding secondary perforation.[44] Even if there are some members of the medical and scientific community who agree that secondary perforation is a plausible way by which an IUD can perforate a uterus, Plaintiffs have not established general acceptance. See Mancuso, 967 F. Supp. at 1447 ("[A]lthough we decline to rule on whether the literature supports all of plaintiff's ailments at this time, we do note that based upon the record before this Court, plaintiffs certainly have not established that it is generally accepted that PCB exposure could have caused their symptoms."). Although the Daubert factors are not a "definitive checklist" for reliability, Daubert, 509 U.S. at 593, "when an expert is offering testimony that is presented as a scientific conclusion and the expert's method fails to satisfy any of the factors identified in Daubert, a court should pause and take a hard look before allowing a jury to consider it." In re MTBE, 593 F. Supp. 2d at 564 (emphasis in original). The Court must, therefore, carefully scrutinize the facts and data upon which Dr. Wray relies and the way she has applied principles and methods to the facts in order to evaluate the reliability of her opinions.

[44] (See, e.g., Cook Wray Decl. Ex. I, WHO, Family Planning and Population, Intrauterine Devices: What Health Workers need to know (1997), at 14-15 ("Perforation of the uterus can occur during the IUD insertion procedure if the IUD or the inserter tube accidentally pierces the uterine wall."); id. Ex. J, American College of Obstetricians & Gynecologists, Long-Acting Reversible Contraception (LARC): IUD and Implant, Frequently Asked Questions, at 184 (2014) ("The IUD can perforate (or pierce) the wall of the uterus during insertion."); id. Ex. L. Gretchen M. Lentz et al., Comprehensive Gynecology 261 (6th ed. 2012) ("Perforation always occurs at the time of insertion . . . IUDs correctly inserted entirely within the endometrial cavity do not migrate or wander through the uterine muscle into the peritoneal cavity.").)

### ii. Scientific Methodology

Dr. Wray's contention that it is "undisputed" that secondary perforation occurs, without confronting scientific literature that refutes this notion, casts doubt upon the reliability of her opinions. See In re Rezulin, 369 F. Supp. 2d at 425 ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable."). An expert who "discusse[s] only the evidence that [she] believed would advance the plaintiffs' position," does not exhibit "'the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" Id. at 426 (quoting Kumho Tire Co., 526 U.S. at 152). Dr. Wray does not discuss any contradictory evidence, and instead took the occurrence of secondary perforation – the existence of which is the major dispute of this litigation – as a given.[45] (Wray Report at 22.) By assuming, without any apparent basis, that secondary perforation is an "undisputed" phenomenon, and then positing a mechanism by which she believes it may occur, Dr. Wray's indulges in "at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis." Golod, 964 F. Supp. at 860.

Like Dr. Young, Dr. Wray came up with a plausible hypothetical mechanism by which secondary perforation could occur. (See Wray Report at 2 ("I have been asked to consider the

[45] Plaintiffs point to a portion of Dr. Wray's deposition to argue that she did confront contradictory evidence:

> [O]f course there are going to be a mixture of explanations put forward by authors, those of them that are trying to find or speak to mechanism. Some of that is best explained by secondary perforations. So I'm not arguing that they [sic] cannot, and is not, primary perforation. But I'm saying all these things taken together, along with the penetration into other smooth muscle organs . . . is pointing us in a direction that is entirely consistent with uterine contractility moving Mirena through the uterus perforation, and that is what I'm calling secondary perforation.

(Wray Dep. at 287:22-288:10.) This does not show that Dr. Wray confronted or distinguished contradictory evidence regarding the existence of secondary perforation. Instead it seems to indicate that she merely acknowledged the existence of primary perforation. Moreover, Dr. Wray also stated during her deposition that although "[you] look[] at both sides when you're forming your opinion," "I wasn't spending a lot of time trying to think of reasons why my opinion might not be reasonable once I've reached my opinion." (Id. at 101:9-13.)

mechanisms whereby the Mirena IUS perforates the uterus."); Wray Dep. at 50:8-13 ("[W]ith regard to IUDs specifically . . . you first heard the term secondary perforation in the course of your – you said preparation for your report in this case? [Dr. Wray:] Yes."); id. at 109:12-22 (Dr. Wray has not conducted testing to validate her mechanism opinion); id. at 200:10-13 ("plausible" that strong uterine activity will move IUD through uterine wall); id. at 370:14-16 (secondary perforation is "plausible mechanism for what occurred there").)[46] As noted earlier, however, "[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified." Daubert, 509 U.S. at 593. It does not meet the "same standards of intellectual rigor that are demanded in [her] professional work," Rosen, 78 F.3d at 318-19, to come up with a theory by which a phenomenon could occur, and leave it at that, which is apparently what Dr. Wray has done here. See Anderson v. Bristol Myers Squibb Co., No. 95-CV-03, 1998 WL 35178199, at *12 (S.D. Tex. Apr. 20, 1998) ("[A]n opinion that is 'an insightful, or even an inspired, hunch' is not admissible if it lacks scientific rigor; 'the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.'") (quoting Rosen, 78 F.3d at 319). As the court in Anderson explained, it is not that experts "are insincere in their opinions or that their opinions may not some day be validated through scientific research and experiment; it is simply that the law cannot wait for such a confirmation." Id.; see In re Accutane, 511 F. Supp. 2d at 1303 ("This Court's gate-keeping function is to ensure that opinions based on mere theory do not reach the jury. . . [An expert's] opinion may very well be correct. His conclusions may be proven true. But at this point there is a gap between the data and the opinions he proffers."); Dunn, 275 F. Supp. 2d at 684 ("While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom

[46] Dr. Wray acknowledged during her deposition that she was not aware of any "medical or scientific organization that uses the term secondary perforation with regard to IUDs." (Wray Dep. at 50:16-21.)

cannot aid the fact finder in making a determination of whether liability exists. Ultimately, speculation is unreliable evidence and is inadmissible.") (footnote omitted). Like Dr. Young's, Dr. Wray's proposed mechanism of how an IUD might perforate a uterus unrelated to insertion, which has not been proven and which Dr. Wray created in the context of this case, "is merely a hypothesis; it may be a very good hypothesis begging for testing and further study, but it is only an untested hypothesis." Anderson, 1998 WL 35178199, at *12. It falls into the category of unreliable speculation that is inadmissible under Daubert, which by itself warrants exclusion of her testimony. See In re Accutane, 511 F. Supp. 2d at 1296 ("While [the expert's] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation. [The expert's] theory does not show the reliability of each step necessary to make the testimony admissible under Daubert.").

Dr. Wray also does not explain in her deposition or report why Mirena's effects on the endometrium would necessarily impact the risk of perforation of the myometrium, nor could she identify a theory to support her claim. (Wray Report at 13; Wray Dep. at 328:23-330:15.) In addition, Dr. Wray takes an immense analytical leap, without adequately explaining the reasoning or methodology behind it, when she points to uterine activity ushering menstrual flow down to the cervix or sperm up to the fallopian tube as support for the notion that a Mirena could be transported through the uterine wall. (Wray Report at 13-14.) While these are examples of "myometrial activity transporting things beyond the uterus," (id.), she provides no reason to think that the movement of bodily fluids through anatomical pathways toward anatomical openings would shed any light on whether a plastic object could penetrate the muscular myometrium in the absence of any preexisting damage to that wall. This obvious analytical gap undermines the reliability of Dr. Wray's opinions. See Joiner, 522 U.S. at 146.

### iii. Dr. Wray's Sources

Apart from the issues identified above, Defendants also challenge Dr. Wray's use of the sources on which she purports to rely. In addition to relying upon her experience and expertise related to the myometrium and the uterus, Dr. Wray cites articles and multiple case reports to support her conclusion that a Mirena IUD is capable of secondary perforation. Case reports are generally disfavored by courts as evidence of causation because they merely describe "'reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; [they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.'" Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1361 (N.D. Ga. 2001) (quoting Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995)), *aff'd sub nom.* Rider v. Sandoz Pharm. Corp., 295 F.3d 1194 (11th Cir. 2002); see In re Rezulin, 369 F. Supp. 2d at 406 ("The difficulty with case reports . . . is distinguishing between association and causation. Simply because a patient exposed to a particular substance exhibited a set of symptoms does not mean that it was the substance that caused the symptoms.").

Although some courts have found case reports to be sufficiently reliable indicators of causation when they exist in large quantities, see Bee v. Novartis Pharm. Corp., 18 F. Supp. 3d 268, 304-05 (E.D.N.Y. 2014); In re Fosamax, 645 F. Supp. 2d at 184-85, that is not the case here. Unlike In re Fosamax, in which the court noted there were "hundreds of published case reports," 645 F. Supp. 2d at 184, Dr. Wray cites a total of 95 supporting authorities, a fraction of which are case reports. (Kekatos Wray Decl. Ex. B app. B.) Moreover, unlike the situations in Bee and In re Fosamax, where the case reports found an association between a particular disease and a particular drug, several of the case reports Dr. Wray cites acknowledge the possibility that

perforation occurred at insertion but was only detected later when the Mirena had more fully embedded or migrated out of the uterus. The parties, and Dr. Wray, do not dispute that perforation can occur at insertion, (Wray Dep. at 287:8-10), and an injury at insertion through which the Mirena later migrates constitutes primary (not secondary) perforation. (Wray Report at 21.) It appears that these case reports might be construed to support the theory of secondary perforation only in that they reveal a temporal lag between insertion and detection of the migration of the Mirena. Without something more to show that these studies actually involve secondary perforation, as opposed to a primary perforation that was detected later, Dr. Wray appears to be relying upon her ipse dixit, which is not a reliable ground for a scientific opinion. See Joiner, 522 U.S. at 146.

An example of this gap appears in the Chen article,[47] cited by Dr. Wray and by Plaintiffs in their Opposition, (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude the Testimony of Susan Wray, Ph.D. ("Ps' Wray Opp."), (Doc. 2780), 14 n.3), which does not seem to involve secondary perforation. The point of the Chen article is that it documents "the shortest interval between insertion and proven bowel injury by an IUD." (Chen Report at 295.) It describes a copper IUD that was found in the bowel four weeks after insertion. It describes a painful insertion procedure and post-insertion pain and spotting, all suggesting that "the uterine perforation most likely occurred during insertion and perforation [sic]." (Id. at 297.) It thus acknowledges that discovery of migration post-insertion does not mean that perforation must also have occurred post-insertion. And to read into the author's use of "most likely" the conclusion that the author believes that perforation can occur post-insertion, when the article does not purport to examine the subject, is to place on "one anecdotal case report," Soldo v.

[47] "Chen" refers to Chih-Ping Chen et al., Ileal Penetration by a Multiload-Cu 375 Intrauterine Contraceptive Device: A Case Report With Review of the Literature, 58 Contraception 295 (1998). (Compendium Ex. 3.)

Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 541 (W.D. Pa. 2003), far more weight than it can reasonably bear. See McClain, 401 F.3d at 1244 (expert's "inclination to draw overreaching conclusions from self-limiting medical articles," among other things, showed "speculative nature of his opinions").

Indeed, some of the other publications, including controlled studies, on which Dr. Wray relies undermine her theory. See In re Accutane, 2009 WL 2496444, at *2 ("[W]hen an expert relies on studies of others, he must not exceed the limitations the authors themselves place on the study. That is, he must not draw overreaching conclusions."). Dr. Wray cites the Boortz article[48] after stating, "As discussed in the literature by many experts, perforations of the uterus may occur at the time of insertion or subsequently." (Wray Report at 21.) But the Boortz article's discussion of uterine perforation does not mention primary or secondary perforation. As Dr. Wray acknowledged at her deposition, this article relates to radiologic imaging of IUDs that have migrated out of the uterus, but does not address whether perforation occurred upon insertion or later. (Wray Dep. at 225:19-227:14.) The Anderson article[49] has nothing to do with IUDs or perforation, and instead, as Dr. Wray acknowledged, (id. at 227:19-228:15), deals generally with "foreign body reaction to biomaterials" implanted within tissue (not cavities). (Anderson at 86.) A connection could possibly be made between this article and the uterus' reaction to an IUD, but Dr. Wray does not make such a connection in her report or in her deposition. The authors of the Kaislasuo article,[50] as Dr. Wray admits, (Wray Dep. at 228:18-

[48] "Boortz" refers to Hillary E. Boortz et al., Migration of Intrauterine Devices: Radiologic Findings & Implications for Patient Care, 32 RadioGraphics 335 (2012). (Cook Wray Decl. Ex. C.)

[49] "Anderson" refers to James M. Anderson et al., Foreign Body Reaction to Biomaterials, 20 Seminars in Immunology 86 (2008). (Cook Wray Decl. Ex. D.)

[50] "Kaislasuo" refers to Janina Kaislasuo et al., Uterine Perforation Caused by Intrauterine Devices: Clinical Course and Treatment, 28 Hum. Reprod. 1546 (2013). (Cook Wray Decl. Ex. E.)

229:2), do not state that secondary perforation is a proven phenomenon. Finally, the authors of the Zakin article discuss the concept of gradual erosion or secondary perforation, and say that there is a "difference in opinion regarding the concept of immediate perforation, partial or incomplete, versus that of a kind of slow erosion," but concludes that "the consensus favors the former." (Zakin, supra note 41, at 344.)

Dr. Wray's reliance on the 1991 Tang study[51] for her opinion that a properly placed Mirena stimulates uterine contractions, (Wray Dep. at 133:3-19, 143:19-24, 358:8-23), is similarly misplaced. That study compared the effects of four types of IUDs (including a LNG-releasing IUD like Mirena) in rabbits, and actually found that the LNG-containing IUD had the lowest level of contractions of the four – even lower than a control group with no IUD. (Tang at 29.) Dr. Wray acknowledged this study did not support her conclusion, but did not offer an explanation or alternative source for her opinion that Mirena users experience enhanced contractions. (Wray Dep. at 170:8-21.) She could not locate any other studies involving Mirena, so fell back to relying upon her "expertise on uterine contractility," which amounts to ipse dixit. (Id. at 170:17-171:3.)[52]

Similarly, Dr. Wray's citations for the proposition that "uterine peristalsis"[53] is "more chaotic in the presence of an IUD," and "may be even more so with Mirena use, due to its

[51] "Tang" refers to D.C. Tang & X.R. Wu, Dynamic Changes of Myometrial Activity, Levels of $PGF_{2\alpha}$ and $E_2$ in Rabbits After Insertion of Four Types of IUDs, 7 Advances in Contraception 29 (1991). (Cook Wray Decl. Ex. N.)

[52] Dr. Wray's report cites H.O.D. Critchley et al., Progestin Rreceptor Isoforms and Prostaglandin Dehydrogenase in the Endometrium of Women Using a Levonorgestrel-Releasing Intrauterine System, 13 Hum. Reprod. 1210 (1998), (Compendium Ex. 4), and other articles to support her opinion that "levels of several inflammatory cytokines have been reported to be increased" in the presence of LNG and that cytokines "are known to stimulate uterine contractions," (Wray Report at 10). Although Dr. Wray may be correct that studies show that LNG can increase inflammatory cytokines, which can "stimulate uterine contractions," Dr. Wray fails to reconcile this theory with the results of the Tang study, which more directly involved an LNG-containing IUD like Mirena and came to a contrary conclusion regarding uterine contractions.

[53] Uterine peristalsis refers to "wave-like uterine contractions that are thought to help move sperm towards the fallopian tube." (Wray Dep. at 345:1-7.) Uterine peristalsis is also known as uterine contractility. (Cook Wray

hormonal effects," (Wray Report at 25), do not hold up under scrutiny. As already discussed, the Tang study, which is the only study she cites for this proposition that involves a Mirena, did not find an increase in uterine contractility. (Wray Dep. at 345:16-22.) Another study Dr. Wray cites for the theory that there is increased chaos of uterine peristalsis with the presence of a Mirena, Kido 2008, not only did not involve a Mirena but actually found that peristaltic frequency in IUD users was lower than in the control group, (Kido 2008, supra note 53, at 56-57), and that "in the presence of an IUD, uterine peristalsis [is] inhibited."[54] (Id. at 57; Wray Dep. at 346:17-347:12.) Dr. Wray also cited three other studies that did not involve Mirena IUDs in support of her opinion. (Wray Dep. at 353:10-354:5, 355:1-12, 357:16-358:7.) Dr. Wray also cited one study that does not mention IUDs, let alone a Mirena IUD, but only refers to prostaglandins. (Id. at 354:11-22.) Dr. Wray was unable to explain her reliance on these studies during her deposition. (Id. at 359:24-361:7.) The absence of Mirena IUDs, or LNG-containing IUDs, in these studies, and the fact that the Tang and Kido studies seem to contradict Dr. Wray's opinions, indicate that Dr. Wray's conclusions do not "flow reliably from the premises," which is a "crucial consideration in evaluating the admissibility of expert testimony." In re Rezulin, 369

Decl. Ex. O, Aki Kido et al., Intrauterine Devices and Uterine Peristalsis: Evaluation with MRI," 26 Magnetic Resonance Imaging 54, 54 (2008) ("Kido 2008").)

[54] The study itself noted that one of its limitations was that "the kind of IUD used was not the same, and distinction of IUDs with or without copper was not considered." (Kido 2008, supra note 53, at 57.) The authors also noted that they did not consider hormonal measurements, (id. at 58), which Dr. Wray specifically mentioned as having an effect because Mirena releases hormones, (Wray Report at 25). See In re Accutane, 2009 WL 2496444, at *2 (expert must not exceed the limitations of a study or draw "overreaching conclusions"). Dr. Wray said at her deposition that Kido 2008 "says that actually the contractions with this IUD are stronger" and also involved a "change in direction," (Wray Dep. at 358:12-23), without explaining the study's language stating uterine peristalsis was actually lower in the women with IUDs. Further, the study's authors wrote that "the direction of peristaltic waves" in IUD users could be "supportive of an attempt to expel the IUD from the uterine cavity," (Kido 2008, supra note 53, at 57), which would be through an anatomical opening and not through the uterine wall.

F. Supp. 2d at 426. Dr. Wray takes too great of an analytical leap from these studies to form her opinion, which therefore warrants exclusion.[55] Joiner, 522 U.S. at 146.

Several other of Dr. Wray's opinions are not grounded in any scientific literature. For example, Dr. Wray could not identify a study for the proposition that inserting a Mirena into women with smaller uterine cavities, adolescents and/or nulliparous women leads to pressure on the uterine lining and erosion of it over time. (Wray Report at 25; Wray Dep. at 342:13-24, 344:4-20.) Dr. Wray seems to imply in her report (and Plaintiffs argue in their Opposition) that because the FDA has approved another IUD, the Skyla, which is 4 mm smaller than Mirena, the Mirena must be too large or more likely to perforate in such women. (Wray Report at 25.) Without an explanation or reasoning, however, that is merely speculation. That a different product with different specifications is on the market does not tell us anything about what happens with Mirena. See Kakeh v. United Planning Org., Inc., 587 F. Supp. 2d 125, 130 (D.D.C. Cir. 2008) ("When an expert's testimony is based on 'guesswork, speculation or conjecture,' it should be excluded.") (quoting Joy v. Bell Helicopter Textron, Inc., 999 F.2d 549, 568 (D.C. Cir. 1993)). Further, not only does Dr. Wray provide no basis for her pressure/erosion

[55] Plaintiffs are correct that the court in In re Ephedra found that a controlled study was not necessary for an expert's general causation opinion to be reliable. See In re Ephedra, 393 F. Supp. 2d at 187-88. That case, however, is distinguishable from this one. There the court highlighted that "differential etiology" or "differential diagnosis" – where an expert eliminates all plausible causes but one – can be a sufficiently reliable methodology to opine on causation. Id. at 187. (Other courts have found that differential diagnosis can only be used to establish specific causation, not general causation. See In re Rezulin, 369 F. Supp. 2d at 436-37.) Dr. Wray, however, does not purport to have performed a differential diagnosis or to have used any particular methodology. Further, the Ephedra court also only allowed the experts to testify that the substance could cause the injury, not that it has been proven that it does cause the injury. 393 F. Supp. 2d at 186-87. If Dr. Wray were allowed to offer her theory with such a caveat, it would greatly diminish the helpfulness of her testimony. Finally, the Ephedra court found that in that case the experts' inferences were "based on the kind of plausible and suggestive, even if inconclusive, scientific data generally relied upon by physicians and epidemiologists when they must make a decision of importance in the absence of conclusive proof." Id. at 194. There is no showing here that Dr. Wray's opinion has the sort of basis accepted in her field, and "there is simply too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146; see Accutane, 511 F. Supp. 2d at 1296 (finding "biological theory" that is "merely plausible" inadmissible under Daubert).

theory – it is set forth with no citation – but she does not even attempt to quantify the pressure or show that it would amount to anything that would have physiological consequences.

Dr. Wray similarly lacks support for the proposition that because of decreased estrogen availability in the myometrium, Mirena "may produce a myometrium that is contractile but less extensive and hence weakened and more prone to perforations, despite initial correct and non-damaging insertion of the device." (Wray Report at 25-26.) Dr. Wray could not identify any studies or other objective support for this opinion. (Wray Dep. at 362:17-363:19.) Dr. Wray based her conclusion on what she would expect to happen, but although she is an expert on the myometrium, she is not an expert on contraceptives, let along LNG-releasing IUDs, or their effects. (Id. at 37:9-18, 42:20-22, 45:5-7, 45:16-46:6.) This does not pass muster under Daubert. See McClain, 401 F.3d at 1244. Dr. Wray also lacks support for her assertion that Mirena's effects on the endometrium and myometrium "build up over months and years." (Wray Report at 19.) She does not cite any sources in her report, and at her deposition she could not point to a study. (Wray Dep. at 203:1-10, 206:1-8.) This speculation does not have sufficient indicia of reliability.

Furthermore, Dr. Wray was asked at her deposition to identify specific published case reports that ruled out damage to the uterine wall during insertion, as well as peer-reviewed publications stating that changes in the endometrium influence the risk of perforation of the myometrium. (Wray Dep. at 391:4-392:16.) Dr. Wray could not give examples during her deposition, and Plaintiffs did not mention any in their papers.

Plaintiffs respond to Defendants' arguments relating to lack of citation and adequate support for Dr. Wray's opinions by pointing to the 95 sources Dr. Wray cites in her report. (Ps' Wray Opp. 11, 13, 15-16.) Quantity does not equal reliability. Plaintiffs fail to show how these

articles reliably substantiate Dr. Wray's views. Apart from the case reports and studies discussed above, which do not reliably bolster Dr. Wray's opinions, Plaintiffs do not offer other reliable sources on which Dr. Wray based her conclusions. Plaintiffs cite some articles that are not helpful, and do not address the substantive arguments put forth by Defendants regarding certain publications.[56] Plaintiffs argue that Defendants' attacks on the studies and reports on which Dr. Wray relies are subjects for cross-examination and do not warrant exclusion. (Id. at 16-17.) Plaintiffs additionally contend that an expert can rely upon a combination of studies to support a conclusion, quoting Goebel v. Denver & Rio Grande Western Railroad Co., 346 F.3d 987, 993 (10th Cir. 2003). The full quotation from Joiner that the Goebel court cites is that it is "within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions." Joiner, 522 U.S. at 146-47. Ultimately it is up to the district court to determine if too great an analytical gap exists between the sources and the expert's proposed testimony. Too great a gap exists here, even when looking at the cited studies and case reports in combination. Moreover, it is Plaintiffs' burden to prove the reliability of their experts' opinions, which in Dr. Wray's case they have failed to do. See Fed. R. Evid. 702 advisory committee's note to 2000 amendment; Bourjaily, 483 U.S. at 175-76.

**iv. Created for Litigation**

Finally, Dr. Wray had not heard of secondary perforation prior to being consulted in connection with this litigation, another indication that her opinions lack the reliability to be

[56] Plaintiffs cite Anh Dinh et al., A review of the Endometrial Histologic Effects of Progestins and Progesterone Receptor Modulators in Reproductive Age Women, 91 Contraception 360 (2015), (Compendium Ex. 6), to support Dr. Wray's opinions related to the effects of LNG. (Ps' Opp. to Exclude Wray 12 n.1.) There is no evidence, however, that there is a connection between this study, which discusses effects on the endometrium and not the myometrium, and uterine perforation – a gap that Dr. Wray has left unexplained, as further discussed below.

admissible. See Eghnayem, 57 F. Supp. 3d at 670 (concern that testimony is litigation-driven has "a role in applying Daubert"); In re Rezulin, 369 F. Supp. 2d at 420 (courts have considered "whether an expert's opinion was developed for litigation," in addition to the four Daubert factors, in assessing reliability); Awad v. Merck & Co., 99 F. Supp 2d 301, 304 (S.D.N.Y. 1999) ("[A] significant consideration is whether research was conducted independently or for the sole purpose of litigation."), *aff'd sub nom.* Washburn v. Merck & Co., 213 F.3d 627 (2d Cir. 2000). Dr. Wray acknowledged at her deposition that the first time she heard of secondary perforation was after being retained as an expert in this litigation. (Wray Dep. at 50:8-13.) This is but another factor that demonstrates Dr. Wray's opinion is not sufficiently reliable under Daubert and would not stand up in a scientific setting.

**d. Assisting the Trier of Fact**

Because Dr. Wray's opinions do not have sufficient indicia of reliability to pass muster under Daubert, they would not be helpful to a jury.

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For the reasons stated above, Defendants' motion to exclude the testimony of Susan Wray, Ph.D. is GRANTED.

**4. Richard Strassberg, M.D.**

Defendants move to exclude the opinion of Dr. Strassberg, who has offered a specific causation opinion for Hayes. Defendants argue that Dr. Strassberg's opinions are not reliable because they do not have a reliable foundation and are not based on sufficient facts and data. (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of Richard Strassberg, M.D. ("Ds' Strassberg Mem."), (Doc. 2689), 3-4.) For the reasons stated below, the

Court finds Dr. Strassberg's opinion lacking the indicia of reliability required under Daubert, and therefore Defendants' motion to preclude him from testifying is GRANTED.

**a. Opinions**

Dr. Strassberg offers five opinions in this three page report. First, Dr. Strassberg opines that Ms. Hayes was an appropriate candidate for Mirena. Second, he states that the insertion of Ms. Hayes' Mirena was done within accepted medical standards and in compliance with the product's label and instructions for use. Third, Dr. Strassberg opines that there is no reason to believe that perforation occurred at the time Ms. Hayes' Mirena was inserted. Fourth, Dr. Strassberg states there is no reason to believe that the care and treatment provided to Ms. Hayes by the healthcare professionals involved in the insertion or removal of her Mirena deviated from accepted medical standards. Fifth, Dr. Strassberg concludes that after being properly placed, the Mirena subsequently perforated Ms. Hayes' uterus. (Cook Strassberg Decl. Ex. A, Case Specific Expert Report of Richard Strassberg ("Strassberg Report"), at 1-2.) Defendants move to preclude Dr. Strassberg's testimony in its entirety, but their arguments address only his third and fifth opinions, so the Court will do the same.

**b. Qualifications**

Dr. Strassberg is an Assistant Professor in the Department of Obstetrics and Gynecology at the University of Miami School of Medicine. (Strassberg Report at 2.) He has also practiced as a clinician at several hospitals. (Id.) Dr. Strassberg has served as Chairman of the OB/GYN Department and of OB Complications at South Miami Hospital. (Id.) He has practiced as a clinical instructor and has served as President of the Miami Obstetrical-Gynecological Society. (Id.) Because of his clinical experience related to obstetrics, gynecology and family planning, Dr. Strassberg is qualified to give an opinion as to whether Ms. Hayes' Mirena perforated her

uterus at the time of insertion or later. Nonetheless, Rule 702 and Daubert require that in addition to an expert being qualified, the expert's testimony must also be reliable. Daubert, 509 U.S. at 590.

**c. Lack of a General Causation Opinion**

Defendants argue that Dr. Strassberg's expert testimony should be excluded because it lacks a required foundational predicate – a general causation opinion. (Ds' Strassberg Mem. 4-6.) As discussed in connection with Dr. Young, in the absence of evidence of general causation, evidence of specific causation is "irrelevant." In re Rezulin, 441 F. Supp. 2d at 578. The court in In re Rezulin in 2005 held that "a physician must have some reliable basis for believing that a particular substance is capable of causing the injury in question in relevant circumstances before concluding that the substance caused that injury in a particular case." 369 F. Supp. 2d at 438. Plaintiffs attempt to challenge this proposition by distinguishing the procedural posture of a different In re Rezulin decision, 441 F. Supp. 2d 567, from 2006, but they do not address the 2005 decision that contained the language quoted above, nor do they seem to seriously quarrel with the proposition that a specific causation expert must show general causation or rely on a reliable general causation opinion. (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude the Testimony of Richard Strassberg, M.D. ("Ps' Strassberg Opp."), (Doc. 2778), 5-6.) Rather, they point out that Ms. Hayes intends to rely on other experts for a general causation opinion. (Id. at 6.) But the problem is that Dr. Strassberg has not relied on those experts in forming his opinion that the Mirena caused Ms. Hayes' injuries subsequent and unrelated to insertion, (Strassberg Dep. at 41:20-42:14), nor has he offered a general causation opinion himself, (id. at 41:6-13, 42:15-18), creating a gap in the causal chain of his analysis. See In re Accutane Prods. Liab. Litig., No. 04-MD-2523, 2007 WL 4404176, at *1

(M.D. Fla. Aug. 15, 2007) (permitting specific causation expert to testify based on general causation opinion of another doctor "if doctors in his profession normally rely upon the opinions of other experts . . . and if in fact he did rely upon such opinion"); Adams v. Cooper Indus., Inc., No. 03-CV-476, 2007 WL 2219212, at *8 (E.D. Ky. July 30, 2007) (excluding opinion where specific causation expert did not fill gap in analysis or rely on another expert who did); Colon v. Abbott Labs., 397 F. Supp. 2d 405, 416 (E.D.N.Y. 2005) (specific causation expert excluded in part because opinion contained a "significant analytic gap . . . between the possibility that infant formula may cause [a disease] and [the expert's] conclusion that [certain formula] was actually a substantial factor in causing [plaintiff's] diabetes"). Dr. Strassberg's failure to offer or rely upon a general causation opinion renders his specific causation opinions without foundation and therefore inadmissible.

**d. Reliability**

Apart from lacking a general causation predicate for his specific causation opinion, Dr. Strassberg's report and proposed testimony do not have sufficient indicia of reliability. Dr. Strassberg's expert report consists of one page listing his opinions, one page listing his qualifications, and one page describing Ms. Hayes' medical records followed by a restatement of the same opinions listed on the first page. (Strassberg Report at 1-3.) Although Dr. Strassberg is a qualified OB/GYN, his expert opinion in this instance consists of nothing more than conclusory statements, which fails under Rule 702 or Daubert. See Hilaire, 54 F. Supp. 3d at 244 (finding expert report lacking sufficient detail for court to consider reliability and "consist[ing] primarily of conclusory statements").

Dr. Strassberg's report does not cite any publications or medical literature in support of his opinions, and he acknowledged at his deposition that he did not review any medical literature

in reaching them. (Strassberg Dep. at 164:24-165:2.) Moreover, based on his report, the court cannot determine what caused Dr. Strassberg to formulate his opinions.[57] He provides literally no analysis, explanation or basis for his opinions, which not only violates Federal Rule of Civil Procedure 26(a)(2)(B)(i) (requiring that expert report contain complete statement of all opinions and the basis and reasons for them), but which seems to be a classic case of "opinion evidence that is connected to existing data only by the ipse dixit of the expert," Joiner, 522 U.S. at 146. Rule 702 and Daubert "mandate the exclusion" of expert opinion "based on data, a methodology, or studies that are simply inadequate to support the conclusions reached." Amorgianos, 303 F.3d at 266. They must surely also mandate exclusion where there is no data, methodology or study underlying the opinion at all. For this reason alone, Dr. Strassberg's opinions must be excluded.

Dr. Strassberg fared little better during his deposition. He attempted to explain his analysis by saying that he based his opinion that perforation did not occur at insertion on the inserting doctor's experience, a note from the doctor describing the procedure as uncomplicated, the threads of the Mirena being visible after insertion, and post-insertion examination and a September 29, 2011 ultrasound. (Strassberg Dep. at 222:5-18, 228:8-229:4.) Nonetheless, when asked specifically how he determined the perforation occurred after insertion, Dr. Strassberg merely said: "My opinion, just what I said there, that the IUD was properly placed and subsequently became a perforation. I don't know how that happened or when it happened, but . . . my opinion is that the perforation wasn't caused by the provider at the time of insertion."

[57] Plaintiffs argue that Dr. Strassberg relied on "differential diagnosis" to opine on the cause and timing of the perforation of Ms. Hayes' uterus. (Ps' Strassberg Opp. 8.) Dr. Strassberg stated no such thing in either his report or deposition testimony. The cases Plaintiffs cite regarding the validity of differential diagnosis as a methodology are irrelevant where, as here, the only suggestions that such a methodology was used comes from counsel's say-so in a brief. Differential diagnosis involves "'ruling in' all scientifically plausible causes of the plaintiff's injury" and "then 'rul[ing] out' the least plausible causes of injury until the most likely cause remains." Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 989 (8th Cir. 2001); see Ruggiero, 424 F.3d at 254. There is not the slightest indication that Dr. Strassberg undertook either prong of such an analysis.

(Id. at 224:24-225:6.) Dr. Strassberg is to be commended for his candor in admitting that he does not know when or how the perforation occurred, but that admission shows his report and testimony to be unreliable. See R.F.M.A.S., Inc. v. So, 748 F. Supp. 2d 244, 248-49 (S.D.N.Y. 2010) ("Expert testimony that is merely 'subjective belief or unsupported speculation' should be excluded.") (quoting Daubert, 509 U.S. at 590).

In addition, there are flaws with each of the bases on which Dr. Strassberg rests his opinion that perforation did not occur at insertion. First, Dr. Strassberg's reliance on the years of experience of the inserting physician amounts to speculation. He cites nothing to support his implication that experienced doctors never inadvertently perforate the uterus upon insertion, and common sense suggests the opposite, even if perhaps the likelihood of such an event occurring may be higher with a newer practitioner. The conclusion that Dr. Robboy did not perforate Ms. Hayes' uterus because he is experienced is speculation based solely on Dr. Strassberg's ipse dixit. See Joiner, 522 U.S. at 146.

Second, that no complications were noted is, by Dr. Strassberg's own account, unsurprising, given that Ms. Hayes was under sedation during the insertion of her Mirena and would not have felt any pain if a perforation occurred. (Strassberg Dep. at 179:2-12.) Likewise, the inserting doctor's belief that the Mirena was properly placed is not a reliable basis for concluding that no perforation occurred upon insertion. No responsible professional would conclude the insertion procedure in the belief that the Mirena was in the wrong position, and yet nobody disputes that it sometimes is. Accordingly Dr. Strassberg's reliance on the fact that the insertion procedure seemed to be uneventful to indicate that perforation did not occur at insertion is flawed.

Third, Dr. Strassberg's reliance on the threads of the Mirena being visible after insertion does not, by his own account, support his conclusions. Although visible threads can be an indicator of proper placement, Dr. Strassberg admitted that the visibility of the threads does not mean that a perforation did not occur and that he could not rely on the visibility of the threads in September 2011 to conclude that the Mirena was properly placed in February. (Strassberg Dep. at 191:5-21, 230:11-15.)[58] Fourth, by his own account, Dr. Strassberg was unable to determine from the September 29, 2011 ultrasound "how much of the IUD [was] in the uterus or 100 percent that it [was in the uterus]," (id. at 196:19-21), and that he could not tell "where the IUD was," (id. at 198:1-3), or whether it had perforated. Because each of the facts on which Dr. Strassberg relied in formulating his opinion that the perforation of Ms. Hayes' uterus did not occur at insertion does not reliably support that conclusion, his opinion does not reliably flow from the data and there is "too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146.

Finally, while not conclusive, the unreliability of Dr. Strassberg's opinion is underscored by the fact that he did not consider alternative factors that may have caused perforation. Although an expert need not rule out every alternative in forming an opinion, "[a] factor that courts have considered in Daubert analyses is whether an expert has accounted adequately for obvious alternative explanations," which is "appropriate because any theory that fails to explain information that otherwise would tend to cast doubt on that theory is inherently suspect." In re Rezulin, 369 F. Supp. 2d at 425; see In re Fosamax Prods. Liab. Litig., 924 F. Supp. 2d 477, 493

[58] Moreover, as Defendants point out in their brief and as Dr. Strassberg acknowledged at his deposition, (Strassberg Dep. at 217:22-218:9), because the threads of Ms. Hayes' Mirena were still visible on September 29, 2011 when an ultrasound was performed, (Cook Strassberg Decl. Ex. F, at 2), just two days before a hysteroscopy procedure showed that the Mirena was not in her uterus, (id. Ex. G at 3), the position of the Mirena could not have changed substantially after the threads were trimmed upon insertion.

(S.D.N.Y. 2013) ("'While an expert need not rule out every potential cause in order to satisfy Daubert [sic], the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant.'") (quoting Israel, 2006 WL 3196956, at *5).

Dr. Strassberg, however, did not rule out obvious possible alternatives. Ms. Hayes had a separate procedure immediately before her Mirena was inserted during which the physician inserted a cannula (tube) and a sharp object (a curette) into her uterus. (Strassberg Dep. at 174:2-22, 176:14-20.) By his own account this procedure could have perforated the uterus or damaged the myometrium, (id. at 177:1-5; see id. at 62:1-3), yet Dr. Strassberg did not even consider or offer an explanation for dismissing this potential alternative cause of perforation, (id. at 217:17-19).[59] In addition, Dr. Strassberg did not address the fact that a metal sound (a probing instrument) was inserted into Ms. Hayes's uterus twice – before and after insertion – which Dr. Strassberg acknowledged carried a risk of perforation each time. (Id. at 62:1-3, 63:19-64:3.)[60] Dr. Strassberg also conceded that it was possible that a partial perforation (where an IUD is partially inside and partially outside the uterus) or embedment (where a portion of an IUD is located in the uterus and another portion is in the myometrium) occurred at the time of insertion,

[59] Plaintiffs claim that Dr. Strassberg said there is no increased risk of perforation after the procedure at issue, an opinion he "[b]ased on literature." (Strassberg Dep. at 87:4-12.) Plaintiffs ignore, however, that Defendants are not saying that the procedure increases the risk of perforation from insertion of the Mirena, but rather that the procedure itself, which involves instruments entering the uterus, poses, as Dr. Strassberg acknowledged, (id. at 87:13-15), a risk of perforation. Plaintiffs also point to testimony of Dr. Policar, one of Defendants' experts, to the effect that no studies have shown that the procedure in question, and sounding (measuring) of the uterus before insertion, increase the risk of perforation during insertion. (Ps' Strassberg Opp. 12-14.) Plaintiffs miss the mark, however, because Defendants' point is that Dr. Strassberg did not consider the risk from the procedure and sounding themselves.

[60] Plaintiffs point out that Dr. Policar testified that there were no studies showing increased perforation risk in women whose uteruses were resounded after IUD insertion. (Declaration of Diogenes P. Kekatos in Opposition to Defendants' Motion to Exclude the Testimony of Richard Strassberg, M.D. ("Kekatos Strassberg Decl."), (Doc. 2779), Ex. D, Deposition of Michael Policar, M.D., M.P.H. ("Policar Dep."), at 20:13-21:15.) This fact does nothing to salvage Dr. Strassberg's opinions, because Dr. Strassberg testified that sounding does cause a risk of uterine perforation, (Strassberg Dep. at 62:1-3), and yet he did not consider whether that might have occurred in Ms. Hayes' case.

(id. at 211:14-20, 220:1-15, 225:12-18), but he did not reconcile these possibilities with his opinions that perforation did not occur upon insertion and that the Mirena was properly placed at that time. Dr. Strassberg's failure to at least confront these obvious alternatives render his opinions unreliable, and reinforce the conclusion that his testimony should be excluded.

#### e. Assisting the Trier of Fact

Dr. Strassberg's opinions do not have a reliable foundation because they are not based on any theory of general causation and are unreliable, and would therefore not be useful to a jury.[61]

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For the reasons stated above, Defendants' motion to exclude the testimony of Dr. Strassberg is GRANTED as to his opinions: (1) that there is no reason to believe that perforation occurred at the time Ms. Hayes' Mirena was inserted; and (2) that after being properly placed, the Mirena subsequently perforated Ms. Hayes' uterus. The Court expresses no view on whether the remainder of Dr. Strassberg's opinions would be relevant or admissible in the absence of the excluded opinions.

### D. Defendants' Regulatory Experts

Plaintiffs move to exclude the proposed testimony of Defendants' regulatory experts, Dr. David Feigal, M.D., M.P.H. and Dr. Dena Hixon, M.D.

#### 1. David Feigal, M.D., M.P.H.

Plaintiffs move to exclude the proposed expert testimony of David Feigal, M.D., M.P.H. Plaintiffs argue that Dr. Feigal's opinions are duplicative of those put forth by Dr. Hixon. In addition, Plaintiffs argue that Dr. Feigal is not qualified to give an opinion on the adequacy of the Mirena label, has an insufficient basis to opine on the FDA's willingness to accept different

[61] Because the Court finds Dr. Strassberg's report and testimony unreliable on several other bases, I need not decide whether Dr. Strassberg lacked key data necessary (such as 3D ultrasound) to verify his conclusions.

perforation warnings for Mirena, should not be allowed to opine on Bayer's compliance with standards, including FDA regulations, and should not be allowed to opine on the FDA's state of mind. For the reasons stated below, Plaintiffs' motion to preclude Dr. Feigal's testimony is GRANTED in part and DENIED in part.

**a. Opinions**

In his expert report, Dr. Feigal opines on the adequacy of the Mirena label. He concludes that the Mirena label's warnings were "scientifically accurate, concise and adequate to alert physicians" to the risk of perforation. (Declaration of Diogenes P. Kekatos in Support of Plaintiffs' Motion to Exclude Expert Opinion of Dr. David Feigal ("Kekatos Feigal Decl."), (Doc. 2726), Ex. 5, Regulatory Expert Report of David W. Feigal, Jr., M.D., M.P.H. ("Feigal Report"), at 34.) He finds that the essential risk information regarding perforation has always been present in the label, and that perforation is "clearly associated with insertion." (Id.) Dr. Feigal further opines that the FDA in 2000 would not have accepted a warning that there were reports of migration after insertion, because the FDA, before it approved the Mirena label, struck language to that effect. (Id.) He concludes that despite variations in the wording, each Mirena label contained essential information to adequately warn of Mirena's risks, that Bayer performed its post-marketing surveillance adequately, and that clinical trials show that Mirena is a very effective form of birth control, the risks of which are well documented and properly described in the label. (Id. at 34-35.)

**b. Duplicative Testimony of Dr. Feigal**

Plaintiffs argue that Dr. Feigal's testimony should be excluded because it is duplicative of Dr. Hixon's. I need not decide whether admitting Dr. Feigal's testimony would be "needlessly . . . cumulative" pursuant to Rule 403 because Defendants have said they will only

be introducing evidence from one of their regulatory experts at any given trial. (Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Proposed Testimony of David Feigal, Jr., M.D., M.P.H. ("Ds' Feigal Opp."), (Doc. 2797), 7-8.) Plaintiffs' motion with respect to the cumulative nature of Dr. Feigal's testimony is therefore denied as moot.

**c. Qualifications**

Dr. Feigal is board certified in Internal Medicine and has a Master's Degree in Public Health in epidemiology and biostatistics. (Feigal Report at 1.) From 1992 to 2004, Dr. Feigal held senior positions at the FDA. (Id. at 2.) From 1992 to 1997, he held positions in the FDA's Center for Drug Evaluation and Research ("CDER"), where he had authority to "approve investigational studies of new drugs," halt studies for safety reasons, approve "new indications for approved drugs," approve manufacturing methods, and take compliance actions – all with respect to anti-viral or anti-infective drugs. (Id.) In these positions, Dr. Feigal was "responsible for the evaluation of safety and efficacy of new drugs, including the approval process and continuing oversight of the safety and effectiveness of those drugs after approval." (Id. at 3.) From 1997 to 1999, Dr. Feigal served as the Medical Deputy Director of the Center for Biologics Evaluation and Research, where he was responsible for medical issues associated with blood, vaccines and therapeutic proteins. (Id. at 2.) From 1999 to 2004, Dr. Feigal was the Director of the Center for Devices and Radiological Health ("CDRH"), which is responsible for the approval of new medical devices, (id.), including contraceptive devices, (Declaration of Christopher J. Cook in Support of Defendants' Opposition to Plaintiffs' Motion to Exclude Proposed Testimony of David W. Feigal, M.D., M.P.H. ("Cook Feigal Decl."), (Doc. 2798), Ex. 2, Deposition of David Feigal ("Feigal Dep."), at 37:2-4). He was also a member of the WHO Task Force on Contraceptive Methods. (Id. at 36:19-37:1.) Dr. Feigal is familiar with "the process

and criteria utilized by FDA in assessing safety and efficacy, pharmaceutical product labeling and pharmaceutical manufacturing quality," and he "participated directly in that process for years." (Feigal Report at 3.) Dr. Feigal was also responsible for reviewing and approving changes to product labels, although none involving IUDs. (Feigal Dep. at 66:5-67:5.)

After his tenure at the FDA, Dr. Feigal taught and participated in research grants at Arizona State University, where he is currently an adjunct professor in the School of Law. (Feigal Report at 3.) Dr. Feigal has also held senior positions in two biotech companies, and has been a consultant in legal cases for the past eleven years, where he has provided expert opinions and testimony for both plaintiffs and defendants. (Id.)

Plaintiffs do not dispute that Dr. Feigal is qualified to offer opinions regarding the regulatory workings of the FDA. (Memorandum of Law in Support of Plaintiffs' Motion to Exclude the Testimony of Dr. David Feigal ("Ps' Feigal Mem."), (Doc. 2725), 4.) They do argue, however, that because he has never prescribed, inserted, or otherwise worked closely with Mirenas or other IUDs, he is not qualified to opine on the adequacy of the Mirena label. (Id. at 12-14.) Plaintiffs also argue that Dr. Feigal acquired any relevant expertise related to IUDs solely in connection with this litigation. (Id. at 12.) Defendants argue that Dr. Feigal does have relevant experience in contraception and counseling patients about the risks and benefits of IUDs, and that his experience at the FDA, including reviewing and evaluating regulatory requirements, makes him qualified to opine on the adequacy of the Mirena label. (Ds' Feigal Opp. 8-12.)

Plaintiffs' arguments for precluding Dr. Feigal's testimony fail in the context of a regulatory expert opining on the adequacy of a label. Although Dr. Feigal is not an OB/GYN, nor has he prescribed or inserted IUDs, he has had some experience with contraception over the

course of his career. (Feigal Dep. at 17:20-18:8, 19:11-20:13, 40:1-15.) In addition, Dr. Feigal is opining on the adequacy of the Mirena label from a regulatory perspective – a field in which he is qualified – which means he does not need to have equally specialized knowledge in a particular medical field. See In re Depakote, No. 14-CV-847, 2015 WL 4775868, at *7 (S.D. Ill. Feb. 13, 2015) ("[Expert's] opinions as to the adequacy of the warning fall within her expertise since she has been involved with the reviewing, drafting, and interpretation of drug safety data, and regulation or approval of product labeling for prescription drugs."); Hilaire, 54 F. Supp. 3d at 236 ("An expert need not be precluded 'from testifying merely because he or she does not possess experience tailored to the precise product or process that is the subject matter of the dispute.'") (quoting Yaccarino, 2006 WL 5230033, at *9); In re Zyprexa, 489 F. Supp. 2d at 282 (expert with education and experience in closely related field permitted to testify). Critiques of Dr. Feigal's expertise in this regard go to the weight of his testimony, not its admissibility. See Lemmon v. Wyeth, LLC, No. 04-CV-1302, 2012 WL 2848161, at *10 (E.D. Mo. July 11, 2012) ("These witnesses have specialized knowledge of the regulatory procedures, pharmaceutical labeling, FDA standards and practice, governmental statutes and regulations, pharmaceutical industry customs and practices, administrative rules, internal policies, and other factors that can assist the trier of fact in determining the adequacy of Defendants' label warnings. Defendants' challenge to the testimony of these experts goes more to the weight, rather than the admissibility, of the evidence."); Lappe, 857 F. Supp. at 226 (expert may testify as to related applications and lack of specialization goes to weight, not admissibility).

The Depakote decision is helpful. There the court found that an expert who was not a medical doctor, and therefore could not prescribe drugs, was qualified to opine on the adequacy of a drug label because her opinions did not "necessarily center on the prescribing physician's

subjective interpretation of the . . . label." In re Depakote, 2015 WL 4775868, at *7 (finding that the expert's "opinions [were] based on her knowledge of the federal regulations governing pharmaceutical drug labels and experience in reviewing, evaluating and communicating safety information to physicians, including that contained in drug labels"). Dr. Feigal is more qualified than the expert in Depakote because he is a physician who has practiced and taught internal medicine. (Feigal Report at 1.)

In re Celexa & Lexapro Prods. Liab. Litig., MDL No. 1736, 2013 WL 791784, at *4 (E.D. Mo. Mar. 4, 2013), is also illuminating. In that case, the defendants argued that one of plaintiffs' experts was not qualified to offer an expert opinion "because his job at the FDA did not include drafting warning labels or statistics, and he ha[d] no specific experience with antidepressants or suicidality." Id. The court found these arguments "meritless" because "the combination of [the expert's] qualifications and his extensive experience and training in both the public and private sectors regarding regulatory compliance and safety issues provide[d] him with specialized knowledge that [would] assist a jury at trial." Id. Although the defendants, like Plaintiffs here, "ma[de] much out of the fact that [the expert did] not have any prior experience with antidepressants and suicidality specifically," this did not prevent the court from admitting the expert's opinions. Id. The court noted that the expert relied on another expert's report regarding background information, but the second expert was also not a medical doctor. Id. Dr. Feigal was able to rely upon his medical training, some familiarity with contraception, and extensive experience in connection with FDA regulations, in order to opine on the adequacy of the Mirena label from a regulatory perspective.[62] I find these factors in combination sufficient to

[62] The cases that Plaintiffs cite to support their argument that testimony should be excluded where "the expert lacks any meaningful involvement with the product at issue," (Ps' Feigal Mem. 14), did not involve FDA or other regulatory experts. Opining on regulatory issues in connection with a drug's label requires expertise in the regulatory field, unlike, for example, an engineer with no specialized knowledge or training related to laundry

show that Dr. Feigal has adequate expertise and will allow him to so opine. See Argonaut Ins. Co. v. Samsung Heavy Indus. Co., 929 F. Supp. 2d 159, 168 (N.D.N.Y. 2013) (in connection with expert testimony "[a] court should look at the totality of the witness' qualifications in making [the] assessment") (internal quotation marks omitted).[63] As long as he does not stray from his expertise in the regulatory arena into the area of how other physicians might interpret the label, he will be permitted to testify on the adequacy of the label. Plaintiff's argument that Dr. Feigal's expertise was established solely for this litigation is rejected because Dr. Feigal has many years of experience as both a doctor and working for the FDA, making him qualified to opine on the adequacy of the Mirena label under FDA standards, and he is not purporting to have expertise in contraception in general or IUDs in particular.

Dr. Feigal is not, however, qualified to testify on the existence (or not) of the phenomenon of secondary perforation, nor is he qualified to opine that mentioning post-insertion migration in the Mirena warning would not have given healthcare providers useful information.[64] Despite having general knowledge about contraception, Dr. Feigal has never prescribed or inserted an IUD, (Feigal Dep. at 19:8-10, 38:4-8, 20:21-24), nor does he have specialized

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equipment seeking to opine on an alternative design for a laundry press. See Barban v. Rheem Textile Sys. Inc., No. 01-CV-8475, 2005 WL 387660, at *3-4 (E.D.N.Y. Feb. 11, 2005), *aff'd*, 147 F. App'x 222 (2d Cir. 2005).

[63] Plaintiffs' reliance on the Alloderm decision, in which Dr. Feigal's testimony was excluded, does not preclude admission of his testimony here. See In re Alloderm Litig., Nos. 5972-11, 507-12, 1469-12, 2015 WL 5022600 (N.J. Super. Ct. Law Div. Aug. 14, 2015). Although that court found that Dr. Feigal lacked the particular experience "necessary to opine as to what kind of product risks and patient morbidities a surgeon would want to know to conduct a proper risk-utility analysis of the appropriateness of a particular hernia repair product for a particular patient" and that "logically, Dr. Feigal cannot opine as to what information a surgeon would need with respect to performing hernia repair," id. at *6 (emphasis in original), in that case his testimony regarding the FDA had already been excluded as irrelevant and he was opining only on the information needed by surgeons in performing a specialized surgery, id. at *4. In other words, what was left of his testimony was untethered to his expertise regarding FDA requirements. Here, however, Dr. Feigal's opinions concern the adequacy of the Mirena label from a regulatory perspective. (Feigal Report at 34.) He is not opining about adequacy from the perspective of a physician or other provider.

[64] Dr. Feigal opines that "the comment in the . . . proposed labeling regarding 'reports of migration after insertion,' adds no additional information to the perforation Warning for healthcare professionals." (Feigal Report at 23.)

training or expertise involving the uterus or how it is affected by hormones such as LNG, (id. at 30:13-31:5, 36:3-9). Although Dr. Feigal describes himself as an expert in IUDs, (id. at 36:11-15), his lack of clinical experience with IUDs indicates otherwise. Dr. Feigal is not qualified to opine on the existence of secondary perforation or on the adequacy of Mirena's label from a clinical perspective. See Dura Auto Sys. of Ind., Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty."); In re Diet Drugs, MDL No. 1203, 2001 WL 454586, at *7 (E.D. Pa. Feb. 1, 2001) ("[A] party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue."). Dr. Feigal can review the FDA record with respect to Mirena and explain it to the jury, including what the FDA and Bayer said and did, what their discussions were, what the record before the FDA consisted of, what is required by the FDA and – using the methodology he used at the FDA (reviewing regulatory requirements, data, pharmacovigilance, post-marketing surveillance, etc.) – whether Defendants met those requirements. He may not, however, opine on whether secondary perforation exists or what a clinician would have made of an additional warning regarding it.

**d. Reliability**

**i. FDA's Interpretation of the Mirena Label**

Plaintiffs argue that Dr. Feigal should not be allowed to offer opinions related to the FDA's willingness to accept different perforation warnings for Mirena, because he failed to consider or analyze the label for Progestasert, another progestin-releasing IUD on the market before Mirena, (Kekatos Feigal Decl. Ex. 8), to which the FDA referred in recommending warnings for Mirena, (id. Ex. 7), and because he is speculating that the FDA would not have accepted a stronger label. (Ps' Feigal Mem. 14-17.)

Dr. Feigal's failure to analyze the Progestasert label goes to the weight, not the admissibility, of his testimony. The FDA's Medical Review for Mirena does contain the sentence, "Recommended warnings include the warnings that are currently on the USA labels for the other two USA-approved IUDs," (Kekatos Feigal Decl. Ex. 7, at 6), and the product information for Progestasert does contain the sentence, "Partial or total perforation of the uterus may occur at the time of or after PROGESTASERT system insertion," (id. Ex. 8 at 618). But the FDA Medical Review states, in the sentence immediately following that quoted above, that recommended warnings "include warnings about pelvic infection, ectopic pregnancy, congenital anomalies, septic abortion, perforation, embedment, and breast cancer." (id. 7 at 6.) There is no specific reference to post-insertion perforation. While the fact that the FDA had approved the Progestasert warning is fair game for cross-examination of Dr. Feigal, and seems to undermine his conclusion that the FDA would not have permitted such a warning for Mirena (which opinion I exclude below in any event), in these circumstances his failure to discuss it in his report is not so glaring as to render his opinion unreliable or inadmissible. See Daubert, 509 U.S. at 596 ("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."); Pfizer Inc. v. Teva Pharm. USA, Inc., 461 F. Supp. 2d 271, 279 (D.N.J. 2006) (finding an expert's failure to consider some documents "an issue best addressed by cross-examination").

In connection with Dr. Feigal's opinion that the FDA would not have approved a Mirena label with wording that Plaintiffs believe should have been included, Dr. Feigal will not be permitted to testify as to what type of label the FDA would or would not have ultimately accepted or rejected. This is impermissible speculation as to the state of mind of the FDA. See

Kruszka v. Novartis Pharm. Corp., 28 F. Supp. 3d 920, 931 (D. Minn. 2014) ("[The experts] may not proffer an opinion relating to what individuals . . . with the FDA thought with respect to certain documents or about their motivations."); Deutsch, 768 F. Supp. 2d at 442 (testimony on "intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise") (internal quotation marks omitted). Nonetheless, he may testify as to what the FDA did, and what it said, based on the documents he reviewed. Dr. Feigal based his opinion on documents that reflect communications between Bayer and the FDA, exchanged during multiple label approval processes spanning several years. (Feigal Report at 20-27.) Dr. Feigal may opine on these documents, including what they mean, and on commentary provided by the FDA in connection with added and stricken language in the label. See Kruszka, 28 F. Supp. 3d at 931 (finding that expert testimony on what the FDA and pharmaceutical company "actually did, rather than thought, [is] properly within the scope of admissible testimony," and allowing expert testimony on the reasonableness of defendant's interactions with FDA and compliance with FDA regulations); see also In re Levaquin Prods. Liab. Litig., No. 08-CV-5742, 2011 WL 6888533, at *2 (D. Minn. Dec. 29, 2011) (expert permitted to testify as to FDA's intent only in instances where intent was "clearly indicated in public documents").[65] Dr. Feigal may not testify as to whether the FDA would have rejected or accepted a specific warning, and Plaintiffs' motion is thus granted with respect to such testimony.

[65] Plaintiffs broadly assert that Dr. Feigal opines on Bayer's and the FDA's motives in his Report. (Ps' Feigal Mem. 10, 17.) Apart from Dr. Feigal's testimony regarding whether the FDA would have rejected or accepted alternative labels, which I have already said is impermissible testimony, Dr. Feigal does not appear to offer any other testimony on the state of mind of Bayer or the FDA. Plaintiffs should object as they see fit at trial if Dr. Feigal strays into impermissible testimony.

### ii. Compliance with FDA Regulations

Although experts cannot "supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence," In re Rezulin, 309 F. Supp. 2d at 541, and while generally "an expert's testimony on issues of law is inadmissible," Bilzerian, 926 F.2d at 1294, courts admit expert testimony regarding companies' compliance with FDA regulations, see, e.g., Wells v. Allergan, Inc., No. 12-CV-973, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) (finding expert testimony about FDA regulations would not "usurp" the role of the trial judge); In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 09-MD-2100, 2011 WL 6302287, at *25 (S.D. Ill. Dec. 16, 2011) (discussing FDA regulations and finding that "[t]o the extent [the expert] does offer legal conclusions, the Court finds that [the expert's] testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. [The expert's] testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not [the expert] nor any other witness, will instruct the jury on the law in this case."); In re Fosamax, 645 F. Supp. 2d at 191 (denying motion to preclude expert from "testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith"); Pfizer, 461 F. Supp. 2d at 278-79 (finding admissible expert testimony regarding pharmaceutical company's "compli[ance] with the FDA's statutory and regulatory requirements").

Admitting expert testimony in this context makes sense given the complicated nature of FDA regulations, and it would be helpful to the jury to have an expert explain this complex regulatory process. See In re Fosamax, 645 F. Supp. 2d at 191 ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the

pharmaceutical industry. [The expert's] assessment of the reasonableness of [the pharmaceutical company's] conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury."). Moreover, as was the case in the Fosamax MDL, this case is "not governed by federal regulations but by state law theories of negligence and strict liability." Id. at 191 n.16. Expert testimony regarding Bayer's compliance with FDA regulations therefore will not usurp the Court's role in explaining the law to the jury, but will assist the jury in determining whether Bayer "acted as a reasonably prudent pharmaceutical manufacturer." Id. The parties' should propose an instruction making clear that the jury must determine the outcome based on the law as I give it to them, not on the legal views of a witness. See id. Furthermore, "[c]ross-examination and competing expert testimony . . . will ensure that the jury carefully weighs [this expert's] testimony." Id. at 191. Plaintiffs' motion with respect to Dr. Feigal's opinions in connection with Bayer's compliance with FDA regulatory standards is thus denied.[66]

**e. Assisting the Trier of Fact**

Dr. Feigal's opinions concerning the complicated regulatory framework of the FDA, the process by which the FDA approves a pharmaceutical product's label, and the adequacy of the Mirena label, would be helpful to a jury in this case. See In re Depakote, 2015 WL 4775868, at *8 ("[T]his [expert] testimony should be permissible due to the complex nature of the drug labeling process and procedures, and the jury will need assistance in understanding it."); In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig., No. 09-MD-2096, 2011 WL 798898, at *22 (D. Ariz. Feb. 24, 2011) ("Industry practice and the regulatory framework governing both prescription and over-the-counter drugs . . . are complex . . . . Expert testimony could help a jury understand agency rules and procedures. The same is true of industry standards

[66] As discussed below, Defendants' motion to preclude the testimony of Dr. Parisian on this subject is also denied.

regarding a company's responsibilities when it learns of consumer health complaints. Because the concept and practices of pharmacovigilance are intricate and technical, expert testimony may assist a jury in understanding the process of detecting and responding to safety signals."). Dr. Feigal's proposed testimony is relevant to the adequacy of the Mirena label and to Bayer's interactions with the FDA regarding Mirena (which in turn relate to the issues of duty, defect and reasonable care), and a jury would find Dr. Feigal's regulatory knowledge and expertise helpful. For those reasons, with the limitations on Dr. Feigal's testimony related to the existence and clinical significance of secondary perforation as well as the FDA's ultimate rejection of alternative labels for Mirena discussed above, Dr. Feigal's testimony is otherwise admissible.

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For the reasons stated above, Plaintiffs' motion to exclude the testimony of Dr. Feigal is therefore GRANTED in part and DENIED in part.

**2. Dena Hixon, M.D.**

Plaintiffs move to exclude the proposed testimony of Defendants' regulatory expert, Dr. Dena Hixon. Plaintiffs argue that Dr. Hixon did not properly disclose the basis of her opinions or the facts she considered as required by Federal Rule of Civil Procedure 26(a)(2)(B)(i), and should therefore be excluded from testifying pursuant to Federal Rule of Civil Procedure 37(c)(1). (Memorandum of Law in Support of Plaintiffs' Motion to Exclude Proposed Testimony of Dena R. Hixon, M.D. ("Ps' Hixon Mem."), (Doc. 2706), 13-16.) Plaintiffs additionally argue that Dr. Hixon's testimony should be excluded under Federal Rule of Evidence 403,[67] and that pursuant to Rule 702 and Daubert, Dr. Hixon should not be allowed to

[67] Plaintiffs also argue that Dr. Hixon should not be permitted to testify because her testimony is unnecessarily duplicative of Dr. Feigal's. As discussed with respect to Dr. Feigal, because Defendants will not be offering both Dr. Feigal's and Dr. Hixon's testimony at any given trial, (Defendants' Memorandum of Law in Opposition to

opine on the FDA's willingness to accept different perforation warnings for Mirena, Bayer's compliance with duties, standards or FDA regulations, or any entity's motives, intent or state of mind. For the reasons stated below, Plaintiffs motion to preclude the testimony of Dr. Hixon is GRANTED in part and DENIED in part.

**a. Opinions**

Dr. Hixon opines generally on the role of the FDA and the regulatory framework in connection with approving new drugs and labeling. (Hixon Report at 4-12.) Dr. Hixon concludes, based on her experience as an OB/GYN and as an officer at the FDA, that Bayer met or exceeded its regulatory responsibilities with respect to Mirena, and that Bayer acted reasonably in accepting an FDA edit that removed certain language related to the risk of perforation from the Mirena label in 2000. (Id. at 40-41.)[68] Dr. Hixon also opines that the FDA would not have accepted the words "most often" in the Mirena label in 2008,[69] and that the Mirena warning has at all times been adequate. (Id. at 41.) She concludes that Bayer acted responsibly in its post-marketing surveillance of Mirena, that the benefits of Mirena outweigh its risks, and the risk of perforation is well-known to healthcare providers. (Id.)

Plaintiffs' Motion to Exclude Proposed Testimony of Dena R. Hixon, M.D. ("Ds' Hixon Opp."), (Doc. 2786), 17), Plaintiffs' motion to exclude Dr. Hixon's testimony as cumulative and duplicative is denied as moot.

[68] During its review of the Mirena label in 2000, the FDA struck the sentence "There are reports of IUD migration after insertion" from the label proposal that Bayer submitted. (Cook Hixon Decl. Ex. 8, at MIR_INDNDA_00010784.)

[69] In 2008, Bayer proposed a change to the Mirena label, and included language stating that "[p]erforation . . . may occur rarely, most often during insertion although the perforation may not be detected until some time later." (Cook Hixon Decl. Ex. 10, at MIR_INDNDA_00038079.) The FDA recommended "against using nonspecific terms" and suggested that Bayer remove the words "rarely" and "most often" from this section of the warning. (Id.) The FDA directed Bayer to "[c]onsider either no frequency qualifier or a frequency range, derived from studies designed with follow-up examinations and data collection that would allow an estimate of perforation rate." (Id.)

**b. Qualifications**

Dr. Hixon is a licensed medical doctor who completed residencies in Family Practice and in Obstetrics and Gynecology and is board-certified by the American Board of Obstetrics and Gynecology. (Hixon Report at 1.) Dr. Hixon has 13 years of clinical OB/GYN experience, which included inserting a small number of IUDs. (Id.; Cook Hixon Decl. Ex. 2, Deposition of Dena Hixon ("Hixon Dep."), at 23:5-14.) For almost 13 years after her clinical practice, Dr. Hixon was a Medical Officer in the FDA's Center for Drug Evaluation and Research, during which time she served as a primary reviewer and team leader in the Division of Reproductive and Urologic Drug Products at the Office of New Drugs. (Hixon Report at 1.) Dr. Hixon reviewed and evaluated information regarding the safety and efficacy of women's reproductive health products, including IUDs with a drug releasing component, and other contraceptives. (Id.) In addition, Dr. Hixon reviewed "postmarketing labeling proposals, safety reports, and supplemental applications for new indications and/or for labeling changes." (Id.) Dr. Hixon was also involved with the regulatory review of Mirena for a period of months in 2000 when its initial labeling was considered. (Hixon Dep. at 59:18-60:16.) Dr. Hixon's work as an OB/GYN and her experience and training as an officer at the FDA qualify her to opine on the regulatory implications surrounding Mirena and its original and subsequent labels. Plaintiffs do not argue that Dr. Hixon is unqualified to offer her opinions, except in connection with her opinion regarding the FDA's willingness to accept different perforation warnings.

Plaintiffs argue that Dr. Hixon is not qualified to opine on the FDA's willingness to accept alternative warning labels for Mirena because she was not aware of certain discussions that took place between the Defendants and the FDA about the perforation warning, she was not "in the driver's seat" in connection with "Changes Being Effected" (the term used to describe the

situation where manufacturers add or strengthen warnings), she had little knowledge about perforation warnings for other IUDs, and she did not know the FDA's position regarding the perforation warning in several hypothetical contexts. (Ps' Hixon Mem. 17-18.) While I agree, for reasons discussed earlier and below, that testimony regarding what the FDA would or would not have done is impermissible, the basis for my view is not Plaintiffs' challenge to Dr. Hixon's qualifications. Dr. Hixon does have experience related to "Changes Being Effected" label changes, (Hixon Dep. at 82:20-83:2), and even if she did not, if an "expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent," In re Zyprexa, 489 F. Supp. 2d at 282 (citing Stagl, 117 F.3d at 80). Dr. Hixon's knowledge (or lack thereof) about perforation warnings for other IUDs, although perhaps a suitable topic for cross-examination, is not grounds for preclusion of a regulatory expert opining on the adequacy of Mirena's label and the actions of Bayer based on the documentary record. That Dr. Hixon was unwilling to offer speculative testimony on the state of mind of the FDA in hypothetical situations does not disqualify her because such testimony would be improper in any event.

**c. Dr. Hixon's Rule 26 Disclosures**

Plaintiffs argue that Dr. Hixon's testimony should be excluded in its entirety because she has not adequately disclosed the bases for her opinions or the facts that she considered in forming her opinions, in violation of Federal Rule of Civil Procedure 26(a)(2)(B)(i). (Ps' Hixon Mem. 13-14.) Plaintiffs argue that because Dr. Hixon refused to discuss conversations that took place at the FDA regarding Mirena, including her own conversations in connection with the pre-marketing regulatory review of Mirena, and because Dr. Hixon failed to name individuals who

were involved in these discussions, Defendants have violated Rule 26, and therefore Dr. Hixon's testimony should be excluded as a sanction pursuant to Federal Rule of Civil Procedure 37(c)(1).

Rule 26(a)(2)(B) requires that an expert's report contain, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming" his or her opinions. "[T]he courts have embraced an objective test that defines 'considered' [in Rule 26(a)(2)(B)(ii)] as anything received, reviewed, read, or authored by the expert, before or in connection with the forming of his opinion, if the subject matter relates to the facts or opinions expressed." Euclid Chem. Co. v. Vector Corrosion Techs., Inc., No. 05-CV-80, 2007 WL 1560277, at *4 (N.D. Ohio May 29, 2007) (footnotes omitted). Under Rule 37(c)(1), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) . . . the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." "Rule 37 is self-executing" and "the non-disclosing party has the burden to demonstrate that the failure to disclose was substantially justified or that the failure was harmless." Atkins v. Cty. of Orange, 372 F. Supp. 2d 377, 395-96 (S.D.N.Y. 2005), *aff'd on other* grounds sub nom. Bellotto v. Cty. of Orange, 248 F. App'x 232 (2d Cir. 2007). The Court has "wide discretion to impose sanctions, including severe sanctions, under [Rule 37]." Design Strategy, Inc. v. Davis, 469 F.3d 284, 294 (2d Cir. 2006).[70] Rule 37 does not require a showing of bad faith in order for sanctions to be imposed, and preclusion is not

[70] The four factors set forth by the Second Circuit in Softel, Inc. v. Dragon Medical & Scientific Communications, Inc., to determine whether excluding testimony as a sanction is appropriate are not directly applicable here because they concern a late disclosure. 118 F.3d 955, 961 (2d Cir. 1997). For example, the third factor is "the prejudice suffered by the opposing party as a result of having to prepare to meet the new testimony," id., which does not apply here where Dr. Hixon repeatedly in her deposition refused to disclose certain aspects of her tenure at the FDA, and Defendants in their Opposition have not offered to disclose the bases of Dr. Hixon's opinions that she deems protected by her duty of confidentiality to the FDA.

mandatory even where the district court finds no substantial justification and the failure to disclose is not harmless. Id. at 296-97.

According to her report, Dr. Hixon based her opinions on her "knowledge of the FDA regulations, policies and procedures, as well as [her] own training and clinical experience as an obstetrician gynecologist providing women's health care and [her] experience at FDA as a medical officer and regulatory reviewer of Mirena, other IUDs, and other contraceptive products." (Hixon Report at 42.) Throughout her report she cites to a number of documents, including communications between Bayer and the FDA from the time of the initial review of Mirena and after, to support her opinions regarding the adequacy of Mirena's label and Bayer's post-marketing actions. The only relevant bases of her opinions that Dr. Hixon could possibly be withholding relate to the time period when she was actively a member of the team reviewing the Mirena label; she refused to name individuals or disclose specific conversations related to this particular review. (Hixon Dep. at 58:6-15.) I find no ground, therefore, to exclude under Rule 37(c) any of Dr. Hixon's testimony relating to the regulatory framework of the FDA or to Bayer's actions and the label change that occurred after Dr. Hixon was no longer a part of the team working on Mirena. I will only consider whether proposed testimony by Dr. Hixon that could be based on her work as a regulatory reviewer of Mirena should be precluded under Rule 37(c) for the alleged Rule 26 violation.

Although Defendants argue that Dr. Hixon is not basing her testimony on her personal recollections regarding the Mirena labeling process, Plaintiffs are correct that (as Dr. Hixon conceded, (Hixon Dep. at 134:23-135:2)) it would be impossible for a witness to divorce herself from her memories about what occurred during a project in which she was an active participant and segregate that information from the documentary record in forming her opinions. Moreover,

Dr. Hixon states in her report that she based her opinions, at least in part, on her experience as a "regulatory reviewer of Mirena." (Hixon Report at 42.) In addition, she conceded that "there are some details of [her] involvement with Mirena at FDA that [she was] aware of but [could not] testify to," (Hixon Dep. at 53:8-12), and while she maintains that her opinions were based on the records, she admitted that she "remember[ed] what [she] remember[ed]" and that her "experiences at FDA with the product" would likely "bleed into" her opinions, (id. at 54:3-5, 15-20). Further, "even if the expert avers under oath that he did not actually consider certain materials in forming his opinion, that will not control," and instead courts apply an "objective test" that defines "considered" as any facts or data on the subject matter learned by the expert at any time before rendering her opinion. Euclid Chem. Co., 2007 WL 1560277, at *3-4. Although in her report Dr. Hixon does not cite to specific conversations or incidents that occurred as part of the FDA's review of Mirena, she was part of that review (which must have considered whether Bayer met its regulatory responsibilities and whether the Mirena label adequately warned of the relevant risks) and therefore she was obligated, if she was to serve as an expert, to disclose the things "considered," regardless of whether she says she stuck to the documentary record. See United States v. Dish Network, L.L.C., 297 F.R.D. 589, 596 (C.D. Ill. 2013) ("A court should not solely credit the subjective representations of the expert when determining what the expert 'considered.'"). Dr. Hixon personally participated in determining whether Bayer complied with regulations, acted reasonably or effectively warned, but because she cannot segregate that experience from her expert opinions on these subjects, and because she will not fully disclose many facts underlying her personal participation, such as the contents of conversations, she will not be allowed to testify as to the FDA's actions in connection with the Mirena label during the time she was involved – specifically, from submission of its New Drug

Application ("NDA") on January 31, 2000 through December 5, 2000 when the final label edits were sent from the FDA to Bayer. (See Hixon Report at 20-22; Hixon Dep. at 59:18-63:14; Cook Hixon Decl. Ex. 4 (NDA 21-225 for Mirena); Cook Hixon Decl. Ex. 8 (NDA 21-225 Final Label Edits for Mirena).)

Allowing Dr. Hixon to testify without having fully disclosed the bases for her opinions is harmful to Plaintiffs because they cannot effectively cross-examine her. *See Fid. Nat'l* Title Ins. *Co. of N.Y. v. Intercounty Nat'l* Title Ins. Co., 412 F.3d 745, 751 (7th Cir. 2005) (expert must disclose materials reviewed "even if in the end he does not rely on them in formulating his expert opinion, because such materials often contain effective ammunition for cross-examination"). During her deposition, Dr. Hixon refused to discuss "who said what or who did what" during the FDA review process, (Hixon Dep. at 134:4-6), yet she stated that she "remember[ed] discussions that the remainder of the information in the label [apart from the stricken language regarding reports of IUD migration after insertion] includ[ed] not only the perforation warning but throughout the label was adequate to warn about the risk of perforation," and that "the term 'migration' was not well-defined and it was not felt to add to the inserter's understanding of perforation and how to manage it," (Hixon Dep. at 138:1-19). Plaintiffs' inability to cross-examine Dr. Hixon regarding, or find other witnesses to, these discussions is not harmless. Moreover, a jury would likely afford Dr. Hixon's testimony added credence because she was present during the FDA's Mirena review and would be perceived as having inside information. Allowing her to testify without allowing Plaintiffs an effective cross-examination would be harmful because Plaintiffs would not be able to undermine this added credibility.

Nor have Defendants shown the failure to disclose to be substantially justified. Dr. Hixon's personal unwillingness to divulge names of individuals involved in the regulatory

review of Mirena or specific discussions that took place may be justified in light of her duty of confidentiality to the FDA.[71] Nonetheless, it is Bayer's burden to show that its failure to disclose its expert's basis is substantially justified in the context of this case, and it has failed to do so. See Wright v. Aargo Sec. Servs., Inc., No. 99-CV-9115, 2001 WL 1035139, at *2 (S.D.N.Y. Sept. 7, 2001). Defendants have not offered a reason why they chose Dr. Hixon as a regulatory expert when they knew she could not fully disclose the bases of her opinions. Plaintiffs should not be unfairly prejudiced because Defendants chose to retain an expert who participated directly in some of the events at issue but cannot discuss them.

Further, I find that the probative value of Dr. Hixon's testimony about events involving the FDA when she was reviewing Mirena is substantially outweighed by a danger of unfair prejudice." See Fed. R. Evid. 403. "'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it,'" *Price v. Fox Entm't Grp., Inc.*, 499 F. Supp. 2d 382, 387 (S.D.N.Y. 2007) (quoting Daubert, 509 U.S. at 595), and in connection with Dr. Hixon's testimony, Plaintiffs cannot (as discussed above) effectively cross-examine her or dissipate the aura of credibility from her "insider" testimony. See United States v. Deutsch, 987 F.2d 878, 884 (2d Cir. 1993) ("[T]he probative value of this evidence is lessened by the inability of the other party to cross-examine."); Gill v. Arab Bank, PLC, 893 F. Supp. 2d 523, 541-42 (E.D.N.Y. 2012) (expert testimony excluded where "[m]uch, if not all, of [the expert's] testimony [was] based on facts developed through confidential . . . investigations" and the opposing party was unable to adequately cross-examine).

[71] The FDA's staff manual directs employees not to disclose "nonpublic information," which includes information not available under the Freedom of Information Act. (Cook Hixon Decl. Ex. 17.) Information related to individuals in the "predecisional" phase of an agency's regulatory review is protected by the deliberative process privilege, which seeks to "assure that subordinates within [a government] agency will feel free to provide the decisionmaker with their uninhibited opinions and recommendations without fear of later being subject to public ridicule or criticism." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980).

Dr. Hixon's testimony relating to the FDA's review of Mirena's NDA in 2000 is thus excluded pursuant to Rule 37(c)(1) and in any event is also inadmissible under Rule 403.

**d. Reliability**

Plaintiffs additionally argue that Dr. Hixon's testimony should also be excluded under Rule 702 and Daubert because her testimony is not sufficiently reliable.

**i. FDA's Willingness to Accept a Different Perforation Warning and State of Mind Testimony**

As discussed in greater detail in connection with Dr. Feigal, expert testimony related to a company's or agency's state of mind, motives or intent is impermissible. See In re Rezulin, 309 F. Supp. 2d at 546. Dr. Hixon is not allowed to opine on an entity's intent or state of mind that is not "clearly indicated in public documents." In re Levaquin, 2011 WL 6888533, at *2. Dr. Hixon will be permitted to testify to the same extent as Dr. Feigal. She may explain and opine on documents or communications between Bayer and the FDA and on public filings relating to Mirena (except to the extent I have already limited her admissible testimony under Rule 37(c) and Rule 403).

In her report, Dr. Hixon wrote that the "FDA would not accept the words 'most often' in the Mirena perforation warning" in 2008. (Hixon Report at 41). Dr. Hixon may describe what language the FDA struck, what it said regarding why it struck that language, and what recommendations it made for Defendants to consider, but it will go too far (and is unnecessary) to say the FDA at that time "would not accept" that language under any circumstances. That the FDA "recommend[ed]" against using non-specific terms and suggested that Defendants "[c]onsider either no frequency qualifier or a frequency range," (Cook Hixon Decl. Ex. 10, at MIR_INDNDA_00038079), does not mean that it necessarily would have refused "most often" had Defendants pushed back or provided more information. Dr. Hixon may not opine on what

type of label the FDA would have hypothetically accepted or rejected, as this is impermissible state of mind testimony. See Kruszka, 28 F. Supp. 3d at 931; Deutsch, 768 F. Supp. 2d at 442. Defense counsel may argue to the jury that the FDA's conduct in 2008 shows that it would not have accepted a warning regarding perforation after insertion, and Plaintiffs' counsel may argue to the contrary, and the jurors will decide what inference is justified. But experts will not draw that inference for them.

**ii. Compliance with FDA Regulations**

Dr. Hixon opines that Bayer's conduct comported with FDA rules and regulations. Dr. Hixon's thirteen years of experience working at the FDA qualify her to opine on the FDA's regulatory framework and Bayer's compliance therewith. As previously discussed in connection with Dr. Feigal, courts have consistently found that expert testimony regarding FDA regulations and a company's compliance under that regulatory scheme is admissible. See, e.g., Wells, 2013 WL 7208221, at *1; In re Yasmin & YAZ, 2011 WL 6302287, at *25; In re Fosamax, 645 F. Supp. 2d at 191; Pfizer, 461 F. Supp. 2d at 278-79. Furthermore, in this case, as in Fosamax, the ultimate issues a jury will decide relate to state law claims of strict liability and negligence, not FDA regulatory violations. See In re Fosamax, 645 F. Supp. 2d at 191 n.16. For these reasons, the Court will (as discussed below) permit Plaintiffs' expert to offer opinions that Defendants did not comply with FDA requirements, and Dr. Hixon's testimony regarding Bayer's compliance with FDA regulations is likewise admissible.

**e. Helpfulness to the Trier of Fact**

Like that of Dr. Feigal (and Plaintiffs' expert Dr. Parisian), Dr. Hixon's testimony – to the extent that it is otherwise admissible – is helpful to the trier of fact because of the complex nature of the FDA framework. Expert testimony from a regulatory expert on complicated

schemes like the FDA's statutory framework, as well as opinions on the adequacy of a drug's label and the reasonableness of a pharmaceutical company's conduct, are useful in assisting the trier of fact. See In re Depakote, 2015 WL 4775868, at *8; In re Zicam, 2011 WL 798898, at *22.

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For the reasons stated above, Plaintiffs' motion to preclude Dr. Hixon's testimony is GRANTED in part and DENIED in part.

**E. Plaintiffs' Regulatory Expert – Suzanne Parisian, M.D.**

Defendants move to exclude the proposed testimony of Suzanne Parisian, M.D. Defendants argue that Dr. Parisian is not qualified to opine on causation and other scientific issues related to Mirena, foreign regulatory issues, and potential alternative designs. (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of Suzanne Parisian, M.D. ("Ds' Parisian Mem."), (Doc. 2686), 5-11.) Defendants also argue that Dr. Parisian's narrative of the regulatory history involving Mirena is not a proper subject of expert testimony, that Dr. Parisian offers improper legal conclusions that Bayer violated the Food, Drug, and Cosmetic Act ("FDCA") and related regulations, and that Dr. Parisian improperly speculates about Bayer's and the FDA's knowledge, motives and state of mind. (Id. at 11-15.) In addition, Defendants argue that Dr. Parisian's labeling and pharmacovigilance opinions are unreliable. (Id. at 15-24.) For the reasons stated below, Defendants motion is GRANTED in part and DENIED and in part.

**1. Opinions**

Dr. Parisian provides four opinions: (1) that the manufacturer of a drug, not the FDA, is responsible for ensuring the drug's safety and the adequacy of the drug's label and warnings,

(Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of Suzanne Parisian, M.D. ("Cook Parisian Decl."), (Doc. 2687), Ex. B, Expert Report of Suzanne Parisian, M.D. ("Parisian Report"), at 14-28); (2) that Defendants had access to information to support a label change reflecting the risk of migration as a result of perforation unrelated to insertion, (id. at 28-62); (3) that Defendants' pharmacovigilance techniques for monitoring the safety of Mirena were flawed and failed to adequately address the reported post-market risks, (id. at 62-75); and (4) that Bayer failed to consider and implement safer alternative designs for Mirena, (id. at 75-78).

**2. Qualifications**

Dr. Parisian has previously practiced medicine as a general practitioner, emergency physician and pathologist, and is currently licensed to practice medicine in Arizona and Virginia, although she has not treated a live patient since 1988 and has not practiced pathology since the 1990s. (Parisian Report at 6; Cook Parisian Decl. Ex. A, Deposition of Suzanne Parisian ("Parisian Dep."), at 49:5-15.) From 1991 to 1995, Dr. Parisian was a Commissioned Officer in the United States Public Health Service, and was assigned to the Center for Devices and Radiological Health at the FDA, where she served as a medical officer in the Office of Health Affairs from 1991 to 1993 and Chief Medical Officer in the Office of Device Evaluation from 1993 to 1995. (Parisian Report at 6-7.) Dr. Parisian "helped broadly cover both pre-market evaluation and post-market compliance issues, with an emphasis on post-market issues for products sold in the United States." (Id. at 7.)

Dr. Parisian was responsible for reviewing adverse event reports ("AERs") submitted by manufacturers, product recalls, labeling, and communications from manufacturers to physicians and the public regarding the performance of FDA-regulated products. (Id.) She also assisted in

authoring FDA-issued Safety Alerts and was responsible for publicity in connection with causes of injury, issues with the performance of devices, and risks to public health. (Id.) After leaving the FDA in 1995, Dr. Parisian founded a consulting firm specializing in matters involving the FDA, the regulation of medical products, and public health. (Id. at 10.) As president of the company, Dr. Parisian helps, among other things, to design and market new medical products, "present marketing applications to FDA," and "draft product labeling." (Id.) She has authored a graduate-level textbook and lectured to the industry on the FDA, and she has served as an expert, primarily for plaintiffs. (Id.; Parisian Dep. at 23:7-29:5.)

Defendants argue that Dr. Parisian lacks the expertise to opine on medical causation related to Plaintiffs' theory of secondary perforation – that a Mirena can migrate out of the uterus unrelated to insertion – and other scientific issues related to the Mirena IUD. (Ds' Parisian Mem. 6-10.) Dr. Parisian is a medical doctor, but she has no expertise or special skills related to the uterus or IUDs, nor is she a gynecologist. (Parisian Dep. at 49:21-50:9, 103:24-104:23.) Because she does not have specialized expertise in this area, she will not be permitted to testify or give an opinion that a Mirena can perforate the uterus unrelated to insertion – which she asserted implicitly in her report and which she discussed during her deposition. See Dura Auto. Sys., 285 F.3d at 614 ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science.").[72]

[72] Dr. Parisian has been barred from testifying on general causation in a number of other cases. See, e.g., Bartoli v. Novartis Pharm. Corp., No. 13-CV-724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014); Rowland v. Novartis Pharm. Corp., 9 F. Supp. 3d 553, 562 (W.D. Pa. 2014); Deutsch, 768 F. Supp. 2d at 469; Oakberg v. Zimmer, Inc., No. 03-CV-47, 2004 WL 5503779, at *2 (D. Mont. Nov. 23, 2004); Linsley v. C.R. Bard, Inc., No. 98-CV-2007, 2000 WL 343358, at *5 (E.D. La. Mar. 30, 2000).

Dr. Parisian's relevant experience and expertise are in the field of FDA regulations, and her testimony will thus be limited to that field.[73]

Although seemingly more regulatory in nature, Dr. Parisian's testimony related to "causal association" – as this term is used pursuant to 21 C.F.R. § 201.57(c)(6)(i)[74] – is also inadmissible because Plaintiffs have not "sufficiently differentiate[d]" testimony related to causal association from general medical causation. Rowland, 9 F. Supp. 3d at 562 (excluding Dr. Parisian from offering "causation testimony of any kind"); see Dopson-Troutt v. Novartis Pharm. Corp., No. 06-CV-1708, 2013 WL 1344755, at *3 (M.D. Fla. Apr. 2, 2013) (excluding Dr. Parisian from offering opinions regarding "causal association" because Plaintiffs did not "meaningfully distinguish" it from medical causation).[75] Defendants' motion with respect to testimony relating to medical causation or regulatory causation is granted.[76]

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[73] Plaintiffs argue that Dr. Parisian "will not give opinion testimony on the issue of medical causation." (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude the Testimony of Suzanne Parisian, M.D. ("Ps' Parisian Opp."), (Doc. 2776), 9.) Dr. Parisian's report and deposition, however, seem to suggest in several instances that she may give such testimony, at least implicitly. Moreover, Plaintiffs cite cases and attempt to distinguish Defendants' cases to counter Defendants' argument that Dr. Parisian's testimony on causation is inadmissible, (id. at 9-10), an effort that would seem to be unnecessary if she were not being offered to opine on medical causation. In any event, should Dr. Parisian attempt to give testimony on medical causation, such testimony is inadmissible.

[74] 21 C.F.R. § 201.57(c)(6)(i) provides that a drug's "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established."

[75] Plaintiffs cite one New Jersey Superior Court case where Dr. Parisian was permitted to testify on regulatory causation. (Ps' Parisian Opp. 17.) The court in Meng v. Novartis Pharmaceuticals Corp., (Declaration of Diogenes P. Kekatos in Opposition to Defendants' Motion to Exclude the Testimony of Suzanne Parisian, M.D. ("Kekatos Parisian Decl."), (Doc. 2777), Ex. 6), broadly permitted Dr. Parisian to testify as to any FDA regulations. In this case, however, I find Dr. Parisian's medical knowledge and experience with respect to contraception and IUDs insufficient to qualify her to testify on causation.

[76] This means Dr. Parisian will not be permitted to testify that the Mirena label should have been changed to warn of secondary perforation, because she is not qualified to say either that that risk was clinically significant or that there was reasonable evidence of causal association. Although she could in theory have relied on the opinions of other experts in that regard, and gone on to explain what Defendants should have done when confronted with reasonable evidence of causal association between the device and a clinically significant risk, she did not do so here; indeed, she did not read the reports of any of the other experts prior to writing her report. (Parisian Dep. at 60:7-15, 92:17-93:3.) Dr. Parisian included Dr. Zambelli-Weiner's report in her list of documents considered, but she acknowledged that she had not actually seen the report. (Id. at 60:20-61:6.) Accordingly, Dr. Parisian may testify

Defendants also argue that Dr. Parisian is not qualified to testify on the implications of epidemiological studies, including the EURAS study. (Ds' Parisian Mem. 8-9.) While she was at the FDA, Dr. Parisian helped design and issue an epidemiological study, she received training from an epidemiologist, and her work involved analyzing research pharmaceutical companies conducted. (Parisian Report at 7-9.) At her deposition, Dr. Parisian acknowledged that she is not an epidemiologist, but that she has been involved with epidemiological studies. (Parisian Dep. at 126:9-12.) This experience is sufficient to allow her to analyze studies and reports and rely on them in forming her opinions. See In re Zyprexa, 489 F. Supp. 2d at 282 ("If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent.") (citing Stagl, 117 F.3d at 80); see also In re NuvaRing Prods. Liab. Litig., No. 08-MD-1964, 2013 WL 791835, at *3 (E.D. Mo. Mar. 4, 2013) ("Dr. Parisian [is] qualified within the field of epidemiology and to analyze conclusions of other scientific experts and rely on them when forming her own opinions."); In re Yasmin & YAZ, 2011 WL 6302287, at *20 ("[B]ased upon Dr. Parisian's education and experience, including training in epidemiology while at the FDA, it would appear reasonable for Dr. Parisian to rely on epidemiological . . . experts to support her opinions."). Because of Dr. Parisian's experience with epidemiology, Defendants' motion with respect to her testifying about or relying upon epidemiological studies, including the EURAS study, is denied.

Dr. Parisian will not be allowed to opine on foreign regulatory issues. Dr. Parisian is admittedly not an expert in the laws of foreign jurisdictions, and therefore is not qualified to

as to what Defendants should have done in terms of investigation based on the post-marketing information available to them, but may not opine that that information amounted to evidence of causal association sufficient to warrant a label change.

testify on those subjects. (Parisian Dep. at 124:23-126:8.) There is no reason to believe that the regulatory framework of Canada or Germany is similar to the FDA's system. Moreover, Dr. Parisian's report and proposed testimony in this area is a recitation of reports and regulatory actions, with little or no analysis, which is not proper expert testimony because it is not helpful to the trier of fact. See In re Trasylol Prods. Liab. Litig., 709 F. Supp. 2d 1323, 1336 (S.D. Fla. 2010) (finding Dr. Parisian's testimony on "foreign regulatory matters" inadmissible); In re Rezulin, 309 F. Supp. 2d at 553 (finding that plaintiffs' experts are not "appropriate vehicles" for introduction of evidence related to foreign regulatory actions because subject of that testimony is a lay matter). If Plaintiffs wish to submit evidence to show that Bayer was on notice of adverse events they may do so, if the evidence proves to be otherwise admissible, but not through Dr. Parisian. And if Dr. Parisian wants to refer to the fact of a particular foreign regulatory action as evidence of information available to Defendants on the basis of which a regulatory obligation in the U.S. was triggered, she may do so. But she may neither summarize foreign regulatory history nor imply that an action required abroad was necessarily required in the U.S. Defendants' motion to preclude opinions on foreign regulatory issues is granted.

Dr. Parisian is also not qualified to opine on potential alternative, safer designs for Mirena, including the Skyla IUD or an IUD described in a patent application.[77] Opinion Four in Dr. Parisian's report is therefore wholly inadmissible. Dr. Parisian is not an engineer, nor has she ever designed IUDs, nor does she have any particular expertise in IUDs. (Parisian Dep. at 53:7-11.) Dr. Parisian is an expert in the field of FDA regulations, and her testimony will be

[77] In any event, Plaintiffs state that Dr. Parisian is not going to testify that "any particular product or design was safer than Mirena." (Ps' Parisian Opp. 22.) To the extent Plaintiffs plan to have Dr. Parisian testify "that Bayer had the ability to look at alternative designs," (id.), that point seems too obvious for expert testimony to be necessary or helpful.

thus limited to that field. Defendants' motion with respect to proposed testimony by Dr. Parisian regarding safer alternatives to Mirena is granted.

**3. Narrative Testimony**

Defendants argue that Dr. Parisian's testimony of Mirena's regulatory history is an impermissible narrative or regurgitation of facts. In her report, Dr. Parisian writes at length about the regulatory history of Mirena and internal communications among Bayer personnel and between Bayer and the FDA. (See, e.g., Parisian Report at 32-33, 35, 43-44.) To the extent Dr. Parisian "is simply rehashing otherwise admissible evidence about which [she] has no personal knowledge, such evidence – taken on its own – is inadmissible." Highland Capital Mgmt., L.P. v. Schneider, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005); see In re Rezulin, 309 F. Supp. 2d at 551 (excluding expert testimony on historical and regulatory background of drug that is just as easily understood by jury if submitted through percipient witness). Dr. Parisian may rely upon the regulatory history of Mirena, as well as documents reflecting communications between Bayer and the FDA and internal Bayer communications, in forming her regulatory opinions, but she may not present these documents to the jury with no analysis or merely "read, selectively quote from, or 'regurgitate' the evidence." In re Fosamax, 645 F. Supp. 2d at 192 (quoting In re Prempro Prods. Liab. Litig., 554 F. Supp. 2d 871, 880, 886 (E.D. Ark. 2008), *aff'd in rel*evant part, 586 F.3d 547 (8th Cir. 2009)). Defendants' motion with respect to Dr. Parisian's narrative testimony is granted insofar as she merely repeats facts, as opposed to using documents and background to opine on the FDA, the adequacy of Mirena's label and the reasonableness of Bayer's conduct pursuant to FDA regulations.

### 4. Reasonableness of Bayer's Conduct Under FDA Regulations

Dr. Parisian's experience as an officer at the FDA qualifies her to opine on the background of the FDA, its functions, and the FDA's regulatory framework. See Lemons v. Novartis Pharm. Corp., 849 F. Supp. 2d 608, 614 (W.D.N.C. 2012) (allowing Dr. Parisian to testify on "the role, process, and function of FDA and the responsibilities of pharmaceutical drug sponsors"). As is the case with Defendants' regulatory experts Drs. Feigal and Hixon, this type of expert testimony on the complex FDA framework is helpful to a jury. Defendants argue, however, that Dr. Parisian should be excluded from testifying that Bayer violated the FDCA and related regulations. (Ds' Parisian Mem. 12-13.) The Court finds Defendants' arguments unpersuasive.

As discussed in more detail with respect to Dr. Feigal, although generally experts cannot offer opinions on legal matters, see United States v. Lumpkin, 192 F.3d 280, 289 (2d Cir. 1999) (expert testimony inadmissible if it "usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it") (internal quotation marks and alteration omitted), the testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury. See In re Fosamax, 645 F. Supp. 2d at 191 (denying motion to "preclude Dr. Parisian from testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith"). The Fosamax court found that "Dr. Parisian's assessment of the reasonableness of [the pharmaceutical company's] conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury." Id. (citing several cases allowing Dr. Parisian to testify in this vein). Moreover, because this case involves state law claims of negligence and strict

liability, Dr. Parisian's testimony regarding compliance with FDA regulations does not usurp the role of the jury, but rather merely helps them understand a complicated statutory framework. See id. at 191 n.16.[78] To the extent Bayer seeks to preclude Dr. Parisian from testifying about Bayer's compliance with FDA regulations, the motion is denied.

**5. State of Mind Testimony**

Defendants also seek to preclude Dr. Parisian from testifying as to the state of mind, knowledge or motives of Bayer and the FDA. (Ds' Parisian Mem. 13-15.) Defendants are correct that an expert's testimony on the "intent, motives or states of mind of corporations, regulatory agencies and others" is inadmissible. In re Rezulin, 309 F. Supp. 3d at 546. Plaintiffs contend, however, that Dr. Parisian will not offer opinions regarding Bayer's motive, intent or state of mind and that she simply relies on internal company documents in forming her opinion that Bayer did not comply with its duties in accordance with regulatory requirements. (Ps' Parisian Opp. 12-14.) In her report, however, Dr. Parisian seems to impermissibly speculate on Bayer's or the FDA's state of mind or intent. For example, on page 33 of her report, Dr. Parisian writes, "[T]he 'project lead' seemed concerned about maintaining timelines rather than taking the time necessary for addressing the safety of the United States Mirena user and providing an adequate label." Dr. Parisian has no expertise in divining the concerns or motives of others, and may not opine on such topics. See In re Trasylol, 709 F. Supp. 2d at 1346. To the extent Plaintiffs want the jury to draw inferences about intent or motive from Defendants' statements, that is a matter for argument. Nonetheless, Dr. Parisian may opine on what documents in Bayer's possession said – in other words, on what Bayer "knew" in the sense of what

[78] The Court will instruct the jury, if applicable under relevant state law, that evidence of violation of FDA standards may be evidence of, but does not necessarily establish, negligence. In addition, if there is any dispute as to what FDA regulations are applicable to Mirena, the issue can be raised with the Court, and the Court will outline the relevant statutes and regulations for the jury.

information was in its possession – or on the FDA's or Bayer's intent to the extent it is "clearly indicated in public documents." In re Levaquin, 2011 WL 6888533, at *2. She may also opine on what the FDA would have done in a typical situation when presented with a set of facts.[79] Defendants' motion with respect to state of mind testimony is therefore granted to the extent Dr. Parisian opines on the motives, intent or state of mind of an entity that is not set forth in documents or grounded in specific, objectively knowable facts.

**6. Reliability**

Defendants argue that Dr. Parisian did not use a reliable methodology to reach her opinions regarding the adequacy of the Mirena label and Bayer's pharmacovigilance policies. (Ds' Parisian Mem. 15-24.) Defendants, however, attempt to force Dr. Parisian's opinions into the four-factor mold set forth by Daubert that governs scientific expert opinions but is not applicable to a non-scientific regulatory expert. See Kumho Tire Co., 526 U.S. at 150 ("[F]actors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.") (internal quotation marks omitted); id. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."); In re Fosamax, 645 F. Supp. 2d at 190 ("An expert is permitted to draw a conclusion from a set of observations based on extensive and specialized experience."). None of the four factors listed in Daubert apply to Dr. Parisian, which makes sense because she is not purporting to be a scientist giving a scientific opinion. See Pritchett v. I-Flow Corp., No. 09-CV-2433, 2012 WL 1059948, at *8 (D.

[79] With respect to the ParaGard label, Dr. Parisian can opine on the type of information that the FDA normally would require in order to accept or reject a label change and on what triggers a company's obligation to seek a label change, but she cannot testify as to whether the FDA would have approved language in the Mirena label simply because the ParaGard label has similar language, given that she has no knowledge regarding what prompted ParaGard's label change. (Parisian Dep. at 222:23-224:4.)

Colo. Mar. 28, 2012) (finding that Dr. Parisian's opinions were not "manifestly scientific in nature"). Her regulatory opinions are based upon her training and experience, as well as a review of "pertinent portions of the regulatory filings," In re Fosamax, 645 F. Supp. 2d at 190-91, and Bayer's internal documents, which is the same methodology she would have employed as an officer at the FDA, see Forman v. Novartis Pharm. Corp., 794 F. Supp. 2d 382, 384 (E.D.N.Y. 2011) (finding Dr. Parisian's reliance on regulatory filings, internal documents and medical literature sufficiently reliable to opine on the reasonableness of the pharmaceutical company's conduct with respect to the FDA). This is permitted under Daubert.[80] I will discuss Dr. Parisian's opinions on the adequacy of the Mirena label and Bayer's pharmacovigilance in turn.

**7. Adequacy of Mirena Label**

Defendants argue that Dr. Parisian used an unreliable methodology to reach her conclusions about Mirena's labeling and that her opinions are based on unreliable and speculative data. (Ds' Parisian Mem. 16-23.) As discussed above, Dr. Parisian has relied on her training and experience at the FDA to form her opinions regarding the adequacy of the Mirena label, which is a reliable methodology. See In re Fosamax, 645 F. Supp. 2d at 190-91; see also Pritchett, 2012 WL 1059948, at *8 ("Dr. Parisian's opinions . . . are primarily based on her public-sector work experience in applying federal statutes and regulations to medical devices . . . . Contrary to Defendant's assertion, Dr. Parisian does not fail to use any methodology; her methodology is her training and experience in applying applicable regulations to medical devices."). Dr. Parisian will be permitted to opine on the adequacy of the Mirena

[80] The Fosamax court found admissible Dr. Parisian's "conclusions about [a pharmaceutical company's] conduct based on her review of pertinent portions of the regulatory filings for [a drug] and [the pharmaceutical company's] internal company documents," which was "the methodology [Dr. Parisian] applied as a Medical Officer, and [which was applied by the pharmaceutical company's] regulatory experts." In re Fosamax, 645 F. Supp. 2d at 190-91.

label from a regulatory, not a medical, perspective, which is squarely within her area of expertise. Although Defendants argue that Dr. Parisian is not qualified to rely upon adverse event reports, this issue does not require exclusion of her testimony. Dr. Parisian may rely on adverse event reports or other submissions from Bayer to the FDA to show the extent of Bayer's knowledge of certain events and what this might have required it to do from a regulatory perspective. Defendants may cross-examine Dr. Parisian on her qualifications and whether she drew proper inferences from these adverse event reports, but her opinions on the adequacy of the Mirena label are sufficiently reliable that they do not warrant exclusion.[81] Defendants' motion to exclude Dr. Parisian's testimony on the adequacy of the Mirena label is denied.

**8. Pharmacovigilance Opinion**

Defendants also argue that Dr. Parisian's third opinion on pharmacovigilance[82] is unreliable and should be excluded. (Ds' Parisian Mem. 23-24.) Dr. Parisian may opine on the reasonableness of Bayer's conduct in monitoring and evaluating adverse events associated with Mirena based upon her experience at the FDA, how companies typically react to post-marketing adverse events, and relevant FDA regulations. This third opinion in her report, however, largely consists of copied and pasted statements from internal Bayer documents. (Parisian Report at 62-75.) As previously discussed, Dr. Parisian will not be permitted to offer narrative testimony that merely relays the contents of documents without any expert analysis. Such testimony, if

[81] Other courts have permitted Dr. Parisian to opine on the adequacy of a drug's label in similar situations. See, e.g., Rowland, 9 F. Supp. 3d at 562 (finding that courts involved in the Zometa litigation uniformly allowed Dr. Parisian to testify on the "adequacy of Zometa warnings and labels"); Taylor v. Novartis Pharm. Corp., No. 06-CV-61337, 2013 WL 5118945, at *8 (S.D. Fla. Apr. 22, 2013) (limiting Dr. Parisian's testimony to "FDA labeling"); NuvaRing, 2013 WL 791835, at *3 (finding Dr. Parisian qualified "to offer testimony concerning FDA regulatory and labeling issues").

[82] Merriam-Webster defines pharmacovigilance as "the monitoring, evaluation, and prevention of adverse effects associated with the administration of medicines." Merriam-Webster Online Dictionary 2015, available at http://www.merriam-webster.com/

otherwise admissible, is best presented through fact witnesses. Dr. Parisian, therefore, will be allowed to opine on the reasonableness of Bayer's pharmacovigilance policies under the FDA's regulatory framework, but she will not be permitted to simply recite or regurgitate documents and speculate on Bayer's motives based on these documents. Dr. Parisian must also limit her testimony to implications involving the FDA, as she is not qualified to testify generally about medical standards. Defendants' motion with respect to Dr. Parisian's pharmacovigilance opinion is thus granted in part and denied in part.

**9. Assisting the Trier of Fact**

As discussed above and in the discussion relating to Drs. Feigal and Hixon, Dr. Parisian's testimony regarding the complex FDA regulatory framework, Bayer's compliance with FDA regulations, and the adequacy of the Mirena label are relevant to this case and would be helpful to a jury. Therefore, except for the limitations on Dr. Parisian's testimony already outlined, Dr. Parisian will be allowed to opine on the FDA regime generally, Bayer's conduct in complying with regulatory standards, and the adequacy of the Mirena label.

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For the reasons stated above, Defendants' motion to exclude the testimony of Dr. Parisian is GRANTED in part and DENIED in part.

**F. Plaintiffs' Epidemiological Expert – April Zambelli-Weiner, Ph.D.**

Defendants move to exclude the proposed testimony of Plaintiffs' epidemiological expert, April Zambelli-Weiner. As a threshold matter, Defendants contend that the EURAS[83]

[83] EURAS is the short form for the European Active Surveillance Study for Intrauterine Devices (EURAS-IUD), which was a prospective cohort study that followed 61,448 women in six European countries between 2006 and 2013. (Heinemann 2015 at 275.) The objectives of the study were to identify and compare uterine perforation and adverse events associated with LNG-releasing IUDs and copper IUDs. (Id.) The study was funded by Bayer, (Cook Zambelli-Weiner Decl. Ex. D, at 1), and overseen by an independent Safety Monitoring and Advisory Council made up of experts in the field who approved all study materials, (id. at 26).

study on which she opines is not relevant to Plaintiffs' claims in this litigation. Defendants further argue that Dr. Zambelli-Weiner is not qualified to offer opinions on general causation related to secondary perforation, the efficacy of diagnostic imaging in uterine perforation detection, pharmacovigilance, Mirena's label, or Bayer's interactions with foreign regulatory authorities. Defendants also argue that her opinions are based on unreliable methodologies. Defendants additionally argue that Dr. Zambelli-Weiner's opinions regarding Bayer's "ethical" obligations and state of mind should be precluded. For the reasons stated below, Defendants' motion to preclude the testimony of Dr. Zambelli-Weiner is GRANTED in part and DENIED in part.

**1. Opinions**

Dr. Zambelli-Weiner gives six opinions in her expert report, all related to the EURAS study: (1) information was available to Bayer before the design and implementation of the EURAS study that secondary perforation was a serious safety signal warranting further investigation; (2) the EURAS study suffered from methodological limitations that compromised the internal and external validity of the study and limits the inferences that can be drawn from it, including perforation rates; (3) the EURAS study was not properly designed to detect perforations over the lifecycle of Mirena with a high degree of sensitivity or to discriminate between primary and secondary perforation; (4) the EURAS study was not designed to advance the understanding of mechanisms of insertion-related and non-insertion-related perforation; (5) the EURAS extension was underpowered from its inception to test perforation rates of Mirena compared to copper IUDs within a reasonable margin; and (6) despite its methodological limitations, the EURAS study provides evidence that Mirena use is associated with a significantly increased risk of perforation compared to copper IUDs. (Cook Zambelli-Weiner

Decl. Ex. A, General Expert Report of Dr. April Zambelli-Weiner, Ph.D. ("Zambelli-Weiner Report"), at 2.)

**2. Qualifications**

Dr. Zambelli-Weiner has a Bachelor's degree in Chemistry and English, a Master's of Public Health degree in Epidemiology and Community Health, and a Ph.D. in Epidemiology and Human Genetics. (Zambelli-Weiner Report at 3.) She has more than 15 years of experience in epidemiologic research, including reading, mentoring, publishing and applied work. (Id.) Dr. Zambelli-Weiner has "participated in the design and implementation of large clinical, population and family-based studies, including the collection of primary data in clinical settings and in the field," and she has performed reviews and conducted research for both public and private clients. (Id.) Defendants do not move to exclude Dr. Zambelli-Weiner "from offering certain of her criticisms of EURAS that arguably fall within her background as an epidemiologist." (Memorandum of Law in Support of Defendants' Motion to Exclude the Testimony of April Zambelli-Weiner, Ph.D. ("Ds' Zambelli-Weiner Mem."), (Doc. 2698), 1.) In light of Defendants' position and Dr. Zambelli-Weiner's qualifications in epidemiology, her opinions criticizing the methodology and design of the EURAS study, and describing the shortcomings in the study's findings, are admissible under Rule 702 and Daubert. Defendants' arguments to preclude other opinions of Dr. Zambelli-Weiner are discussed below.

**3. Relevance**

Defendants argue as a threshold matter that all of Dr. Zambelli-Weiner's opinions regarding the EURAS study are irrelevant pursuant to Federal Rule of Evidence 401 because the opinions do not advance Plaintiffs' claims in this litigation. (Ds' Zambelli-Weiner Mem. 1 n.1.) Defendants are correct that expert testimony must be relevant to be admissible, United States v.

Khan, 787 F.2d 28, 34 (2d Cir. 1986), but in this case both parties mention and seem to be relying, to some extent, on the results of the EURAS study. If neither Plaintiffs nor Defendants choose to rely upon the EURAS study, Dr. Zambelli-Weiner's testimony will be moot. To the extent it is mentioned, however, Dr. Zambelli-Weiner will be allowed to opine on the study, with the limitations on her proposed testimony discussed below.

**4. General Causation and Secondary Perforation**

Dr. Zambelli-Weiner is not qualified to opine on general causation or a mechanism for secondary perforation. During her deposition, Dr. Zambelli-Weiner stated both that she is not qualified to opine on a mechanism of secondary perforation and that she does not intend to offer an opinion on general causation. (Cook Zambelli-Weiner Decl. Ex. B, Deposition of April Zambelli-Weiner ("Zambelli-Weiner Dep."), at 90:10-14; 333:22-334:9.) Plaintiffs argue that Dr. Zambelli-Weiner is not offering such opinions, but that she is opining, "based upon a review of case reports, adverse event data and relevant scientific and medical literature," that there was information available to indicate that a number of IUD users experience perforations unrelated to insertion. (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude the Testimony of April Zambelli-Weiner, Ph.D. ("Ps' Zambelli-Weiner Opp."), (Doc. 2784), 5.)

Dr. Zambelli-Weiner is not permitted to opine on how, why or whether secondary perforation occurs, which Dr. Zambelli-Weiner concedes are not opinions she intends to offer. (Zambelli-Weiner Dep. at 90:10-14.) Nonetheless, Dr. Zambelli-Weiner is qualified and will be permitted to opine from an epidemiological perspective, based on information available when the EURAS study was being designed and implemented, that a well-designed study should have taken the possibility of secondary perforation into account. "Epidemiology is the study of the relationship between exposures and diseases in large populations." In re Fosamax, 645 F. Supp.

2d at 187. The "disease" in question here is secondary perforation. Dr. Zambelli-Weiner does not attempt to prove it actually occurs, but rather she opines that there was evidence, in case reports and case series, that "established a safety signal for secondary IUD uterine-perforation beginning more than 20 years prior to the design of the EURAS study." (Zambelli-Weiner Report at 7.) Based on this available evidence in case reports and literature, which was sufficiently suggestive of the possibility of secondary perforation, Dr. Zambelli-Weiner concluded that a study purporting to examine perforation should not have been constructed in a way that did not distinguish between insertion-related and non-insertion-related events. Evaluating the design of studies falls squarely within the wheelhouse of an epidemiologist. See Deutsch, 768 F. Supp. 2d at 455 ("As a pharmacoepidemiologist, designing, executing, analyzing, and evaluating studies on [the relationship between a pharmaceutical drug and a disease] is precisely [the expert's] area of expertise."); In re Seroquel Prods. Liab. Litig., No. 06-MD-1769, 2009 WL 3806436, at *6-7 (M.D. Fla. July 20, 2009) (allowing epidemiologist to opine on design and execution of defendants' studies). Thus, although Dr. Zambelli-Weiner will not be permitted to testify as to whether secondary perforation exists or how it occurs, she will be allowed to opine that there was evidence (such as case reports and other literature) that were sufficiently suggestive of it that it should have been taken into account in the design of the EURAS study.

Defendants further argue that Dr. Zambelli-Weiner's opinion that the time from insertion to the detection of perforation is a "surrogate measure of secondary perforation" is inadmissible. (Ds' Zambelli-Weiner Mem. 7-9.) The Court agrees that Dr. Zambelli-Weiner does not base this opinion on a reliable methodology. She bases what she described as this "logical concept" on nothing more than her conjecture that the temporal lag between insertion and detection suggests

that the perforation occurs later. (Zambelli-Weiner Dep. at 144:11-145:8.) This type of speculative testimony based only on Dr. Zambelli-Weiner's say-so is impermissible. See Joiner, 522 U.S. at 146 ("[N]othing 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."). Plaintiffs are correct that an expert is often qualified to opine in a related field, and an epidemiologist does not need to be an expert in a particular field to analyze the data or studies showing a relationship between a drug and a disease. See Deutsch, 768 F. Supp. 2d at 455. In this instance, however, Dr. Zambelli-Weiner is not basing her opinions on an analysis of data or studies, but rather on what she describes as a "logical concept," which does not pass muster under Rule 702 or Daubert. If her opinion is based on simple common sense, it is not helpful; the jury does not need expert opinion because its common sense will suffice. And if the jury needs expert opinion because common sense will not suffice, it must come from an expert who is applying her expertise. Dr. Zambelli-Weiner is not doing so where she attributes her opinion to simple logic rather than any application of principles of epidemiology.

**5. Diagnostic Imaging Opinions**

Defendants move to exclude Dr. Zambelli-Weiner's opinions on the efficacy of diagnostic imaging in detecting uterine perforation. (Ds' Zambelli-Weiner Mem. 9-13.) Dr. Zambelli-Weiner criticized the EURAS study for not utilizing diagnostic imaging post-insertion and again twelve months later. (See, e.g., Zambelli-Weiner Report at 22-23.) Despite Defendants' arguments that Dr. Zambelli-Weiner is not qualified to discuss diagnostic imaging because she is not a doctor or clinician, in the context of critiquing an epidemiological study it is within her expertise to discuss basic methods used in studies to evaluate results. (Zambelli-Weiner Dep. at 187:10-20) ("What is true is that I'm not a clinician. I certainly can evaluate and

recommend and design studies that use diagnostic criteria, which are used in regular practice by Bayer's own experts."). Opining that diagnostic imaging could have improved a study, for example, seems to fall squarely within an epidemiologist's area of expertise, even if the epidemiologist is not an expert in ultrasound. See Deutsch, 768 F. Supp. 2d at 455. If one were to accept Defendants' arguments, an epidemiologist would have to be an expert in every area of medical testing used in a study in order to opine on that study.[84]

Moreover, Bayer's argument that Dr. Zambelli-Weiner fails to meet the four Daubert factors is not persuasive. Dr. Zambelli-Weiner is not offering a scientific opinion; she is opining that had diagnostic imaging – a general method used to evaluate patients in studies – been used in EURAS, the study would have produced more "robust, actionable results." (Zambelli-Weiner Report at 18.) The Daubert factors are not appropriate in every context. See Kumho Tire Co., 526 U.S. at 150 ("[F]actors identified in Daubert may or may not be pertinent in assessing reliability . . . ."); UMG Recordings, Inc. v. Lindor, 531 F. Supp. 2d 453, 457 (E.D.N.Y. 2007) ("The Daubert factors . . . were intended as suggestions, and are not appropriate for every type of expert testimony.") (citing Daubert, 509 U.S. at 593). Dr. Zambelli-Weiner may not, however, opine that including an imaging protocol in EURAS would have shown a specific value of perforation rates, in this case "~2/1000 insertions." (Zambelli-Weiner Report at 18.) Dr. Zambelli-Weiner does not adequately explain why the results of one study that she cites in her report, (id.), would necessarily be the results had there been more imaging in EURAS, and during her deposition she declined to "wed[] [herself] to a particular number," (Zambelli-Weiner Dep. at 268:12-17). Dr. Zambelli-Weiner thus can opine generally on how imaging might affect

[84] Dr. Zambelli-Weiner may opine on whether imaging would have improved the study, but she may not opine on what kinds of imaging can or cannot rule out injury to the uterus upon insertion. If the jury concludes, based on other evidence, that no imaging can rule out such an injury, it will discount Dr. Zambelli-Weiner's testimony accordingly.

a study like EURAS, but she may not opine on a particular statistic that would have resulted because she has provided no basis, other than her own say-so, as for why that specific number would result (and also backed away from that number). See Golod, 964 F. Supp. at 861 ("'[T]he courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it.'") (quoting Rosen, 78 F.3d at 319) (alteration in original).

**6. Pharmacovigilance Opinions**

Defendants argue that Dr. Zambelli-Weiner is not qualified to render pharmacovigilance opinions and that those opinions are not reliable. (Ds' Zambelli-Weiner Mem. 13-18.) Plaintiffs concede that Dr. Zambelli-Weiner is "not a pharmacovigilance expert and will offer no opinions related to such processes," but argue that she is an "expert on the collection, analysis and interpretation of data" and should therefore be allowed to opine on data derived from Bayer's pharmacovigilance processes. (Ps' Zambelli-Weiner Opp. 13.) Dr. Zambelli-Weiner will not be permitted to opine on whether Bayer's pharmacovigilance practices were adequate because this is outside the scope of her expertise. It falls within her area of expertise, however, to testify on whether, from an epidemiological point of view and given the information that existed at the time, the EURAS study was properly designed. See In re Silicone Gel Breasts Implants Prods. Liab. Litig., 318 F. Supp. 2d 879, 895-96 (C.D. Cal. 2004) (epidemiologist "with extensive experience in designing, conducting and analyzing epidemiological studies" had credentials "specific to an inquiry about the methodological soundness of Defendants' epidemiological data," and was "qualified to evaluate and explain the available epidemiological evidence concerning breast implants," and thus his "analysis of the existing epidemiological evidence [was] admissible"). Dr. Zambelli-Weiner cannot opine on whether Bayer's pharmacovigilance

was good or bad, but she can testify whether the information collected via that pharmacovigilance was properly evaluated.

In addition to being outside the scope of her expertise, Dr. Zambelli-Weiner's opinions relating to the adequacy of Bayer's pharmacovigilance efforts are not based on a sound methodology. Much of her opinions consist of her interpretations of internal Bayer documents, including emails, which in her view reflect confusion over internal coding. (Zambelli-Weiner Report at 8-14; Zambelli-Weiner Dep. at 219:8-20.) Dr. Zambelli-Weiner does not have any special expertise that gives her particular insight into these emails or what was going on at Bayer at the time, nor can she "read minds." In re Fosamax, 645 F. Supp. 2d at 192. It is impermissible for experts to opine on the state of mind or motives of corporations or regulatory bodies. In re Rezulin, 309 F. Supp. 2d at 546. Dr. Zambelli-Weiner admitted that she did not know how Bayer analyzed perforation events it received in connection with Mirena, (Zambelli-Weiner Dep. at 206:11-207:7), which makes her testimony on this point speculative and unhelpful to a jury. See In re Fosamax, 645 F. Supp. 2d at 194 (excluding opinion by expert as lacking foundation "because he d[id] not know what types of animal testing [the pharmaceutical company] conducted with Fosamax"). Defendants' motion with respect to an opinion on the adequacy of Bayer's pharmacovigilance by Dr. Zambelli-Weiner is granted, but she can testify as to what an epidemiologist trying to design a good study would do with the information that Bayer had. She may not evaluate Bayer's internal coding system or its pharmacovigilance but can explain what, epidemiologically speaking, one should do when one has data like what Bayer had in its possession at the time.

### 7. Bayer's "Ethical" Obligations

Dr. Zambelli-Weiner may not opine on broad, undefined obligations that she believes Bayer failed to follow. (See, e.g., Zambelli-Weiner Report at 10 ("Bayer had an obligation to monitor potential safety issues and to investigate them further."); id. ("[S]afety signals should have spurred further investigation in well-designed studies even in the absence of regulatory involvement.").) Dr. Zambelli-Weiner does not seem to be basing her opinions of Bayer's obligations on any objective factors. She is not qualified to opine on – nor does she purport to use – FDA or any other objective standards, and we are left with a vague notion that in her personal opinion Bayer's conduct was inadequate. This is impermissible expert testimony. See In re Rezulin, 309 F. Supp. 2d at 543 (experts' opinions "concerning purported ethical standards [were] based on their personal, subjective views" and were therefore mere speculation and inadmissible under Rule 702); Pantaleo v. Hayes, No. 08-CV-6419, 2013 WL 5213690, at *4 (N.D. Ill. Sept. 17, 2013) (finding inadmissible expert testimony "based only on her personal opinion of what she believes defendants should have done as opposed to what they were required to do"); Johnson v. Wyeth LLC, No. 10-CV-2690, 2012 WL 1204081, at *2 (D. Ariz. Apr. 11, 2012) (because plaintiff could not "point to any objective standard" relied upon by experts, their opinions amounted to nothing more than "'subjective belief or unsupported speculation'") (quoting Daubert, 509 U.S. at 590). Defendants' motion with respect to Dr. Zambelli-Weiner's opinions on the adequacy of Bayer's conduct in light of amorphous ethical standards is granted.[85]

[85] Dr. Zambelli-Weiner may opine on what a good epidemiologist should have done to construct an effective study or to properly analyze data, to the extent these opinions are tied to specific professional standards, but she may not opine generally about what Bayer should have done beyond what applicable regulatory or particular professional standards require.

### 8. Mirena Label

Dr. Zambelli-Weiner will not be allowed to opine on the adequacy of the Mirena label. Plaintiffs state that Dr. Zambelli-Weiner will not be offering any such opinion, but argue she should be permitted to testify on the content of the label as it "relates to the correlation between the Mirena label and design of the EURAS study." (Ps' Zambelli-Weiner Opp. 16.) It is not clear what testimony Plaintiffs are attempting to describe. In her report, in any event, Dr. Zambelli-Weiner writes that "[c]ertain aspects of the MIRENA® label appear to be questioned by case reports in the literature," which seems to be an opinion on the inadequacy of the label. (Zambelli-Weiner Report at 7.) Dr. Zambelli-Weiner is not qualified to offer an opinion on Mirena's label as she is not a medical doctor, clinician or regulatory expert, and acknowledged that she is not an expert on labeling. (Zambelli-Weiner Dep. at 38:16-18, 162:14-24, 164:1-8.) Defendants' motion with respect to opinions on labeling is granted.

### 9. Foreign Regulatory Action

Defendants argue that Dr. Zambelli-Weiner's proposed testimony regarding the German regulatory equivalent of the FDA, the Federal Institute for Drugs and Medical Devices ("BfArM"), and Bayer's interactions with BfArM, should be excluded. (Ds' Zambelli-Weiner Mem. 21-24.) For example, in her report, Dr. Zambelli-Weiner mentions that "BfArM also sought some insight into the mechanism of IUD related uterine perforations" and referred to "BfArM concerns" that "Bayer did not investigate." (Zambelli-Weiner Report at 7.) As discussed in connection with Dr. Parisian, experts are not the "appropriate vehicles" to introduce evidence regarding foreign regulatory actions, In re Rezulin, 309 F. Supp. 3d at 553, unless perhaps the expert has specialized expertise in a foreign regulatory body and its requirements. Dr. Zambelli-Weiner has no such expertise. She admitted that she is not a regulatory expert.

(Zambelli-Weiner Dep. at 377:23-24.) Moreover, Dr. Zambelli-Weiner cannot opine on the state of mind of BfArM, because any such testimony would be purely speculative and is impermissible. See In re Rezulin, 309 F. Supp. 3d at 546; In re Fosamax, 645 F. Supp. 2d at 192.[86] To the extent Bayer's interactions with BfArM cast light on what Bayer knew and when it knew it, direct evidence of those interactions may be introduced to the extent relevant, but not under the guise of expert opinion and not via an epidemiologist – except to the extent (if at all) that BfArM provided data to Bayer that it took into account in designing the study, or should have.

In addition, Dr. Zambelli-Weiner's testimony regarding foreign regulators is excluded under Federal Rule of Evidence 403 because its probative value is substantially outweighed by its likelihood of confusing the jury.[87] Because this litigation is based on U.S. law, and because evidence regarding the FDA will be admitted, the actions taken by foreign regulatory agencies are not particularly probative and likely will be confusing. Except as just described, Dr. Zambelli-Weiner will not be allowed to opine on the actions of BfArM, and Defendants' motion to exclude her testimony on this issue is granted.

[86] To the extent BfArM said what its state of mind was, testimony about it would not be speculative, but to the same extent expert testimony would not be needed.

[87] Courts have found that evidence of foreign regulatory actions in products liability litigation is properly excluded as irrelevant and/or confusing. See, e.g., Deviner v. Electrolux Motor, AB, 844 F.2d 769, 773 (11th Cir. 1988) ("The District Court's desire to avoid confusing the jury with Swedish law and statistics cannot rightly be described as abuse of discretion . . . ."); In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 950, 965 (D. Minn. 2009) ("[A]ny discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded."); In re Seroquel Prods. Liab. Litig., No. 06-MD-1769, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009) ("[W]hatever minimal relevance the foreign regulatory actions might have is clearly overwhelmed by the likelihood of jury confusion."), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009); In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) ("[A]llowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion.").

### 10. Helpfulness to Trier of Fact

Despite the limitations set forth above, Dr. Zambelli-Weiner's testimony regarding the EURAS study, including her description of what it did and did not test and her criticisms of it, based on her training and experience as an epidemiologist, would be helpful to a jury. Dr. Zambelli-Weiner may therefore offer opinions regarding the breadth and scope of the EURAS study, and what she believes are shortcomings of the study and its findings. She is qualified to render these opinions, which are both reliable and relevant, if the parties discuss the EURAS study. If Defendants disagree with Dr. Zambelli-Weiner's conclusions regarding the study, they can cross-examine her or offer contradictory testimony.

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For the reasons stated above, Defendants' motion to preclude the testimony of Dr. Zambelli-Weiner is GRANTED in part and DENIED in part.

## III. Conclusion

For the foregoing reasons, Defendants' and Plaintiffs' motions are granted to the extent set forth above and otherwise denied. Specifically:

- Plaintiffs' Omnibus Motion to Exclude Defendants' Experts is DENIED.
- Defendants' Motion to Exclude the Testimony of Dr. Young is GRANTED.
- Defendants' Motion to Exclude the Testimony of Dr. Jarrell is GRANTED.
- Defendants' Motion to Exclude the Testimony of Dr. Wray is GRANTED.
- Defendants' Motion to Exclude the Testimony of Dr. Strassberg is GRANTED.
- Plaintiffs' Motion to Exclude the Testimony of Dr. Feigal is GRANTED IN PART and DENIED IN PART.

- Plaintiffs' Motion to Exclude the Testimony of Dr. Hixon is GRANTED IN PART and DENIED IN PART.
- Defendants' Motion to Exclude the Testimony of Dr. Parisian is GRANTED IN PART and DENIED IN PART.
- Defendants' Motion to Exclude the Testimony of Dr. Zambelli-Weiner is GRANTED IN PART and DENIED IN PART.

The Clerk of Court is respectfully requested to terminate the pending motions (13-MD-2434 Docs. 2679, 2685, 2688, 2691, 2694, 2697, 2702, 2705 and 2724 and 13-MC-2434 Docs. 134, 140, 143, 146, 149 and 152).

**SO ORDERED**.

Dated: March 8, 2016
White Plains, New York

Cathy Seibel
CATHY SEIBEL, U.S.D.J.