UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
WHITE PLAINS DIVISION

----------x

IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

13-MD-2434 (CS)
13-MC-2434 (CS)

----------x

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF JOHN JARRELL, PH.D., P.E.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

Other Authorities

I. INTRODUCTION

Plaintiffs designated Dr. John Jarrell, an engineer who has no expertise in uterine physiology and has zero professional experience with IUDs, to come up with a supposed plausible mechanism of how a Mirena could perforate a uterus outside of the insertion process. In his report, Dr. Jarrell hypothesizes a four-part mechanism theory of perforation. Importantly, Dr. Jarrell does not purport to opine that the four steps he speculates about in his report relate to the actual perforation risk with Mirena. Instead, he candidly admits that he has no idea whether his "plausible" mechanism theory has anything to do with how IUDs like Mirena, in fact, perforate the uterus. Dr. Jarrell does not even claim to opine that the Plaintiffs' alleged injury in this litigation – the supposed "secondary perforation" of Mirena − in fact occurs.

The fatal flaw to Dr. Jarrell's theory is that it simply is made-up for litigation purposes and has no reliable support outside Dr. Jarrell's unqualified *ipse dixit* and a contrived "experiment" Dr. Jarrell commissioned. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 190 (E.D.N.Y. 2001) (finding experts' opinions unreliable where, among other reasons, their hypotheses were first developed in the course of the litigation). Dr. Jarrell's theory is not articulated in the peer reviewed scientific literature; it has not been described outside the litigation as a legitimate scientific hypothesis; and it has not been subjected to reliable scientific testing. The following testimony illustrates how little support Dr. Jarrell has for his theory:

> Q: Well, Doctor, you've posited a theory by which IUDs perforate the uterus by this pressure wound theory that you've come up with, right?
>
> A: Correct.
>
> Q: And you're the only one in the world who has ever come up with that theory, as far as you know, right?
>
> A: For this application, yes.

Deposition Transcript of Dr. John Jarrell ("Jarrell Dep."), Exhibit A, at 302:12-20. But the Federal Rules do not allow a witness to invent a new scientific theory that is totally devoid of any indicia of reliability and present it to the trier of fact. Consequently, this Court should exclude Dr. Jarrell's testimony in its entirety because (1) he has no "specialized knowledge [that] will help the trier of fact;" (2) his testimony is not "based on sufficient facts or data;" (3) his testimony is not "the product of reliable principles and methods;" and (4) he has not "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

II. FACTUAL BACKGROUND

Dr. Jarrell is an engineer; he did not attend medical school and has never been involved in any aspect of patient care. Ex. A, Jarrell Dep. at 74:14-23, 75:3-6, 75:16-18. He has been retained by plaintiff lawyers in a wide variety of cases ranging from automobiles to massage chairs. *See Dodson v. Ford Motor Co.*, 2006 WL 2405868, at *15-18 (R.I. Super. Aug. 17, 2006) (excluding Jarrell's fire causation opinion as unreliable); Ex. A, Jarrell Dep. at 69:18-22. But importantly for the issues in this case, Dr. Jarrell had no prior experience with IUDs before agreeing to serve as Plaintiffs' expert in this case. *Id.* at 84:7-18, 84:20-85:4, 85:20-24.

III. ARGUMENT

Dr. Jarrell's purported mechanism theory rests on four different steps, each of which is a necessary part of his opinions. According to the first step in his analysis, levonorgestrel-releasing intrauterine systems ("LNG-IUS"), like Mirena, cause a thin, fragile endometrium with fragile vascularity. *See* General Expert Report of Dr. John Jarrell ("Jarrell Report"), Exhibit B, at 13-18. Second, he opines that Mirena's arms have "sharp" tips, which can create a concentration of forces and increased pressures on the tissues in contact. *See id*. at 18-22. Third, when tested in a highly contrived *in vitro* experiment, Mirena's arms become stiff and rigid. *See id.* at 22-24. The final step in Dr. Jarrell's mechanism theory provides that the contact created by

Mirena's arms in the constrained loading condition combined with uterine contractions leads to a pressure wound in the uterine wall. Dr. Jarrell speculates that through this four-step process, it is plausible that a Mirena can perforate. But nowhere in his report does he offer the opinion that Mirena in fact causes secondary perforation. In fact, Dr. Jarrell does not purport to opine that his hypothesized mechanism has anything to do with the actual perforation risk with Mirena. In that regard, as is explained in Section III.E *infra*, his opinions ultimately are irrelevant and would not aid the jury. The Second Circuit has made clear that when determining whether an expert's opinion is reliable, the failure of any individual step renders the entire analysis void. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) ("'[*A*]*ny* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*.'") (citation omitted, emphasis in original). Here, ***every*** step of Dr. Jarrell's proposed theory falters and requires exclusion for a variety of reasons, rendering his made-up-for-litigation mechanism hypothesis unable to pass muster under *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993).

A. Dr. Jarrell's Opinions About The Purported Effects Of Levonorgestrel Should Be Excluded

Dr. Jarrell's mechanism theory begins with his assertion that "LNG-IUS causes a thin fragile endometrium with fragile vascularity based on the published scientific literature." Ex. B, Jarrell Report at 13. Dr. Jarrell's proffered opinions about the supposed effects of Mirena on the endometrium should be excluded because: (a) he has no qualifications to offer such opinions; and (b) the opinions are unreliable.

1. Dr. Jarrell Is Unqualified To Opine On The Purported Effects Of Levonorgestrel

Federal Rule of Evidence 702 governs the admissibility of expert testimony and "requires that expert testimony come from someone who is 'qualified as an expert by knowledge, skill,

experience, training, or education….'" *Zaremba v. General Motors Corp.*, 360 F.3d 355, 359-60 (2d Cir. 2004) (quoting Fed. R. Evid. 702).

Dr. Jarrell is not remotely qualified to opine on the effects of the levonorgestrel in Mirena on the endometrium. He has never published or lectured on IUDs, levonorgestrel, or any other form of hormonal contraception. Ex. A, Jarrell Dep. at 84:20-85:4, 85:20-24. Dr. Jarrell freely admitted that prior to being retained as an expert in this litigation (which occurred in August 2014) he had no expertise in levonorgestrel:

> Q: You've never, before being hired in this case, considered the effect of levonorgestrel on the endometrium, true?
>
> A: Correct.
>
> * * *
>
> Q: So if we would have stopped you in August of 2014 and said "Doctor, are you an expert on the effect of levonorgestrel on the endometrium," you would had to have said no, you are not, correct?
>
> A: Correct.[1]

Ex. A, Jarrell Dep at 169:24-170:2, 148:18-148:23. Rather than relying on his education, training, or experience to qualify him as an expert in this area, Dr. Jarrell claims that his expertise derives from reading scientific articles after his retention by the Plaintiffs. But a witness cannot manufacture expertise by reading a handful of scientific articles solely as part of his work in litigation. *See Mancuso v. Consolidated Edison Co. of New York*, 967 F. Supp.1437, 1443 (S.D.N.Y. 1997) ("We cannot help but conclude that [the plaintiffs' expert] was not in fact an expert…when he was hired by the plaintiffs, but that he subsequently attempted, with dubious

[1] At one point in his deposition, Dr. Jarrell suggested that he had pre-litigation knowledge of levonorgestrel by virtue of the fact that "I have children. It's a birth control item, I've been exposed to products because of that." Ex. A, Jarrell Dep. at 146:5-16. Needless to say, general exposure to birth control methods in one's family life does not imbue a witness with sufficient expertise to testify as an expert in this litigation.

success, to qualify himself as such by a selective review of the relevant literature."); *see also Devito v. Smithkline Beecham Corp.*, 2004 WL 3691343, at *7 (N.D.N.Y. Nov. 29, 2004) (deeming proffered expert unqualified because he had previously conducted no research on the drug at issue and his first time reviewing relevant scientific literature was for his work as an expert in the litigation); Ex. A, Jarrell Dep. at 148:18-149:19. Like the excluded expert in *Mancuso*, Dr. Jarrell's purported qualifications in this area derive solely from relying upon articles supplied by plaintiffs' counsel. *See Mancuso*, 967 F. Supp. at 1445 (excluding expert based on, among other reasons, "his reliance upon plaintiffs' attorney to provide him with the scientific literature he relied upon to support his opinion"); Ex. A, Jarrell Dep. at 156:4-10. Dr. Jarrell's testimony should be excluded because he simply "cannot rely on the knowledge and expertise he gains in litigation to qualify himself as an expert." *U.S. ex rel. Gudur v. Deloitte Consulting LLP*, 2007 WL 4322433, at *12 (S.D. Tex. Mar. 5, 2007).

2. Dr. Jarrell's Opinions About The Purported Effects Of Levonorgestrel On The Endometrium Are Unreliable

Putting aside Dr. Jarrell's lack of expertise, his opinion that LNG causes a fragile endometrium should be barred because it is unreliable. A review of Dr. Jarrell's report reveals an absolute dearth of expert analysis. Instead of educating the jury in any meaningful way, he copied and pasted entire passages from articles provided to him by Plaintiffs' counsel. Ex. B, Jarrell Report at 14-16; Ex. A, Jarrell Dep. at 156:4-10, 168:9-19. What little analysis he did present is patently unreliable. For example, he blindly cites a rhesus monkey study for the proposition that LNG causes necrosis (*i.e.*, cell death) of the endometrium but could not articulate how deep or widespread the observed necrosis was or its clinical significance. *See In re Accutane Products Liab.*, 511 F. Supp. 2d 1288, 1297 (M.D. Fla. 2007) ("Dr. Fogel's

willingness to reach conclusions based on documents that he does not understand indicates a bias of wanting to reach a particular conclusion."); Ex. A, Jarrell Dep. at 154:25-155:15, 157:6-12.[2]

Further, Dr. Jarrell cannot connect his speculation about the effect of levonorgestrel on the endometrium (the thin inner lining of the uterus – not the thick muscle layer, the myometrium) to any issue of relevance in this case:

> Q: And you can't identify any peer-reviewed publication, ever been published, to suggest that levonorgestrel's effect for necrosis of the endometrial layer has any relation to the perforation risk with Mirena, true?
>
> A: Any literature? True, I believe so.

Ex. A, Jarrell Dep. at 162:25-163:6, 174:12-24. Because Dr. Jarrell does not (and cannot) explain how this supposed observation relates to the issue in the case, any opinions he attempts to offer on the supposed effect of LNG on the endometrium would not aid the jury.

B. Dr. Jarrell's Opinion That Mirena's Arms Are "Relatively Sharp" Should Be Excluded

Dr. Jarrell states in his report: "During my inspection and handling of the exemplar Mirena, I observed the relatively sharp edges located at the tips of the arms." Ex. B, Jarrell Report at 18. Dr. Jarrell offered this opinion by visually inspecting a Mirena and by "applying manual pressure to the arms using a thumb and forefinger." *Id.* at 18-19. When asked about that testing methodology, Dr. Jarrell testified:

> Q: Does that mean you took the tips of the Mirena arm and squeezed it between your thumb and forefinger?
>
> A: In a gloved hand, yes.

[2] Further, Dr. Jarrell's opinion is clearly litigation-driven since he never studied any purported effects of LNG on the endometrium before being hired. *See In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 424 (S.D.N.Y. 2005) (determining that an opinion was developed solely for litigation where the witness had never proposed his theory in any other context before being retained); Ex. A, Jarrell Dep. at 149:15-19, 169:24-170:2.

Q: Can you demonstrate for the camera what you did to assess the tips of the Mirena arm?

A: I don't have a Mirena with me, but essentially as I squeezed it I could feel tactically that the tips were relatively sharp.

Ex. A, Jarrell Dep. at 185:20-186:4. Because Dr. Jarrell is not qualified to assess the relative "sharpness" of an IUD and because this opinion is based solely on his subjective say-so without any objective support, this opinion should be excluded.

1. Dr. Jarrell Lacks The Requisite Experience To Opine On Mirena's Purported "Sharpness"

Dr. Jarrell is not qualified to opine on the alleged "sharpness" of Mirena's arms because he does not possess any relevant experience or training. Before being hired, Dr. Jarrell had never tested, handled, or inspected any IUD, let alone a Mirena. *Id.* at 82:23-83:5, 83:14-17, 84:7-18. The first IUDs Dr. Jarrell ever handled were Mirenas provided to him by Plaintiffs' counsel in the course of this litigation. *Id.* at 84:7-18. Thus, he clearly lacks any previous exposure that could serve as a baseline to compare the purported "sharpness" of Mirena to any other IUD. Indeed, he never even conducted his subjective "sharpness" test on other IUDs to try and establish a reference point for his commentary about Mirena. Accordingly, Dr. Jarrell should be deemed unqualified to opine on Mirena's alleged "sharpness." *See Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (excluding a challenged expert who lacked "both practical and formal training, experience, and knowledge" in the areas in which he was opining due to his "dearth of knowledge").

2. Dr. Jarrell's Opinion That Mirena's Arms Are "Sharp" Is Unreliable

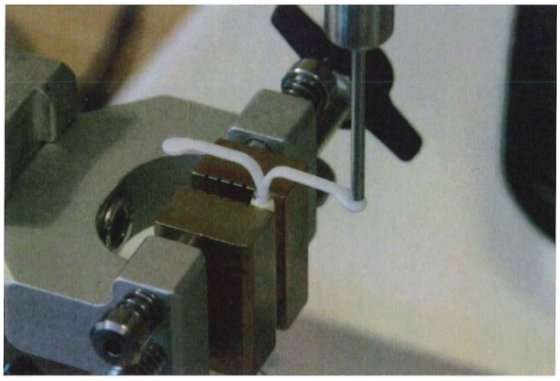
Dr. Jarrell's methodology underlying his "sharpness" opinion fails to meet any recognized measure of reliability. His "squeeze test" and visual inspection are precisely the types of "junk science" *Daubert* sought to address. *See* Ex. A, Jarrell Dep. at 185:11-187:16.

Jarrell's methodology is entirely devoid of any objective standard that can be tested by others. Instead, his opinion "is connected to existing data only by [his] *ipse dixit*." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Dr. Jarrell repeatedly conceded that there is no objective test to measure the "sharpness" of Mirena's arms. Ex. A, Jarrell Dep. at 179:8-10, 179:20-25, 184:18-21. His opinion is nothing more than a personal, qualitative assessment, which has previously been deemed unreliable by this Court. *See In re Rezulin*, 309 F. Supp. 2d at 544 ("[P]ermitting 'experts' to tender purely subjective views in the guise of expert opinions…would border on the absurd."); Ex. A, Jarrell Dep. at 180:3-6. Dr. Jarrell also failed to record quantitative measurements of the force he used in his "squeeze test" and, instead, described the pressure he applied to the Mirena as "gentle." *Id.* at 186:11-16, 187:2-5. The pervasive subjectivity of Dr. Jarrell's methodology forecloses the possibility of calculating an error rate. Dr. Jarrell even acknowledged that perceived "sharpness" may differ from person to person; what one person considers "sharp," another may not. *Id.* at 188:12-20.

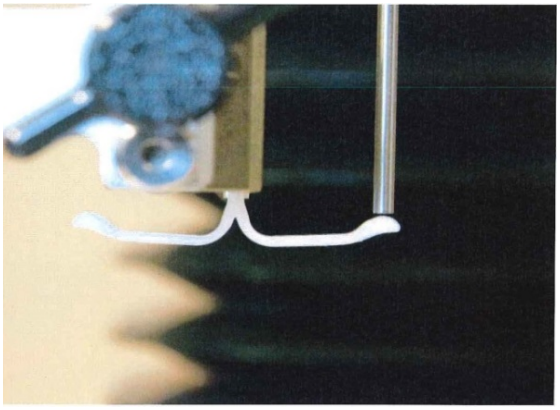
Neither his methodology nor his "sharpness" opinion has been published or subjected to peer review. Dr. Jarrell could not identify a single publication that considers testing an IUD's sharpness by squeezing it with your fingers appropriate nor could he cite any support bolstering his opinion that Mirena has "sharp" arms. *Id.* at 184:22-185:2, 187:12-16. His opinion has not garnered general acceptance in any community. In fact, no regulatory body, medical organization, or anyone else in the world has adopted Dr. Jarrell's opinion that Mirena's arms are "sharp." *Id.* at 181:11-182:2, 184:22-185:2. Dr. Jarrell's "sharpness" opinion fails to meet the threshold of reliability and necessitates exclusion. *See R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 248 (S.D.N.Y. 2010) ("Expert testimony that is merely subjective belief or unsupported speculation should be excluded.") (quotations omitted).

C. Dr. Jarrell's *In Vitro* Mechanical Testing Should Be Excluded

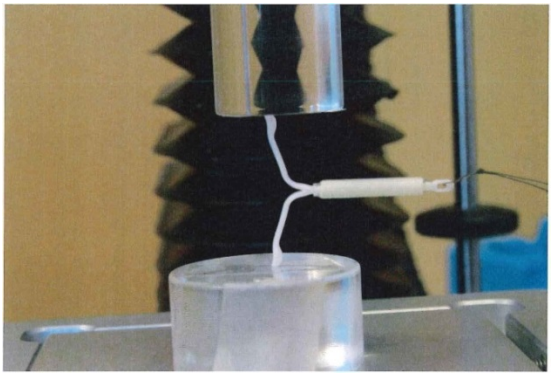
Dr. Jarrell opines that "the Mirena arms become very stiff when loaded in constrained conditions." Ex. B, Jarrell Report at 22. This opinion is based solely on highly contrived *in vitro* mechanical testing that Dr. Jarrell commissioned. Specifically, Dr. Jarrell was provided two "exemplar" Mirenas which he tested under four different conditions to purportedly calculate the amount of force Mirena can withstand before bending. He claims that this experiment captures the amount of pressure concentrated by Mirena's arms against the uterine lining. *Id.* at 22; Ex. A, Jarrell Dep. 232:19-234:14. Dr. Jarrell recognizes that, under normal conditions, Mirena's arms are flexible and bend freely in the uterus in an upward and downward direction. Ex. B, Jarrell Report at 22; Ex. A, Jarrell Dep. at 226:3-11; *see* Jarrell Figures 28 and 29. Dr. Jarrell does not claim that under these normal loading conditions a Mirena can transfer sufficient pressure to the uterine lining to cause a perforation. However, he opines that in one constrained condition Mirena's arms become rigid, purportedly mimicking the transfer of high forces and pressures to the uterine lining. Ex. B, Jarrell Report at 22; *see infra* Jarrell Figure 31. As will be



Jarrell Figure 28: First test condition

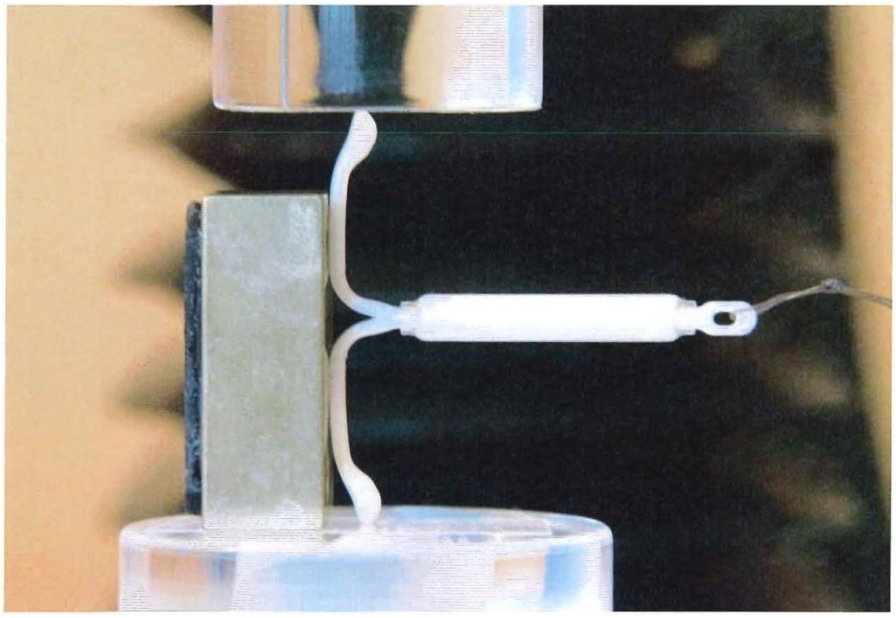


Jarrell Figure 29: Second test condition



Jarrell Figure 30: Third test condition for "compression, elongation"

explained below, Dr. Jarrell went in search of a loading condition he could create *in vitro*, that even he does not claim actually occurs in the body, solely for the purpose of creating higher pressure values in his mechanical testing. Dr. Jarrell's testimony regarding the third step of his analysis should be excluded because (1) an irreconcilable analytical gap exists between his laboratory conditions, in vivo conditions in patients, and his paid conclusions in his report; (2) his opinions do not meet any indicia of reliability; and (3) his methodology does not adhere to an objective protocol.



Jarrell Figure 31: Fourth test condition for "compression, constrained"

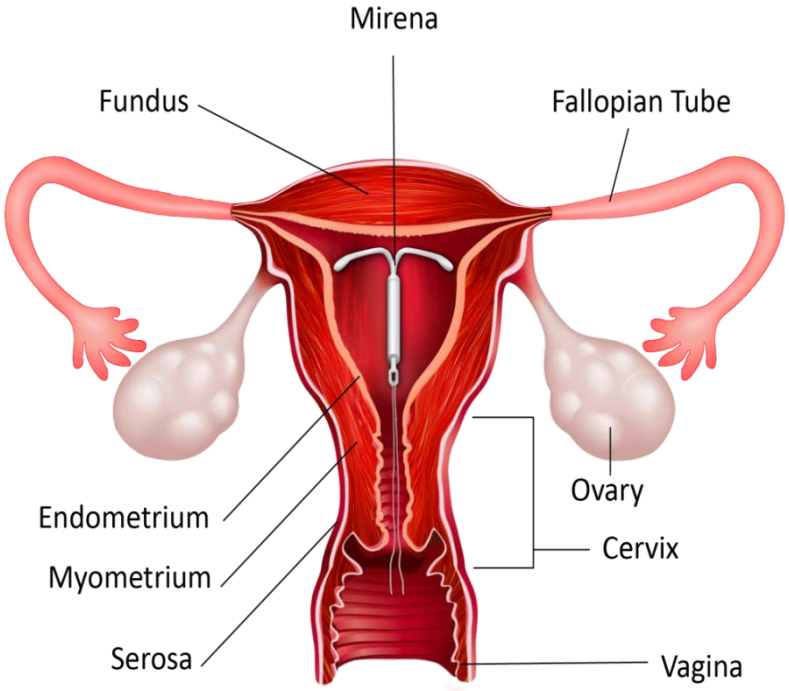


Diagram 1: Mirena properly placed *in vivo*

In Dr. Jarrell's constrained testing condition at issue, the Mirena was initially loaded horizontally. *See supra* Jarrell Figure 31. The tips of the Mirena's arms contacting the top and bottom pressure plates were artificially affixed to the surfaces with double-sided tape. Ex. A, Jarrell Dep. at 234:2-10. An abutting block was then positioned along the top of the Mirena's T-shaped arms to prevent the Mirena from moving and lock it in place. *Id.* at 234:11-14. Dr. Jarrell claims that this manipulated laboratory condition "corresponds with the top of the Mirena arms contacting the top of the fundus and the tips of the arms contacting the adjacent uterine surfaces." Ex. B, Jarrell Report at 22. *Compare* Diagram 1 of a Mirena properly placed *in vivo* *with* Jarrell Figure 31 of his *in vitro* testing condition. The pressure plates, per Dr. Jarrell's logic, represent the uterine lining, while the abutting block is said to represent the fundus. Ex. A, Jarrell Dep. at 236:6-8. Dr. Jarrell subsequently leaps to the conclusion that Mirena can support 88.6 grams of force before bending in the uterus when placed in his constrained condition. Ex. B, Jarrell Report at 22-23. This configuration serves as the basis for step four of his analysis – the "uterine pressure wound" theory.

1. Dr. Jarrell's Testing Conditions Are Untethered From Clinical Reality

Dr. Jarrell's contrived test parameters are in stark contrast to realistic clinical conditions, creating "too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. 136 at 146; *In re Rezulin*, 369 F. Supp. 2d at 420. Where a purported expert's testing methodology fails to replicate an *in vivo* environment, courts have deemed the resulting opinion unreliable. *See Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *13 (S.D.W.V. Feb. 27, 2015); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 547 (S.D.W.V. 2014).

The *Winebarger* court's findings are instructive. There, Defendants argued that Plaintiffs' expert's opinions should be excluded because the tests he conducted on the synthetic vaginal mesh at issue did not replicate the *in vivo* environment. *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *17 (S.D.W.V. Apr. 24, 2015). Specifically, the expert conducted tests at temperatures over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius. *Id.* The court excluded the expert's testimony in full, noting that he "produced certain results while testing polypropylene at very high temperatures…then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion." *Id.*

The similarities between the challenged expert's methodology in *Winebarger* and Dr. Jarrell's testing conditions are striking. Dr. Jarrell's method is also completely unhinged from any clinical reality and should also be excluded. Dr. Jarrell has no basis whatsoever to suggest that his manipulated conditions occur *in vivo*. Ex. A, Jarrell Dep. at 228:23-229:2 ("Q: Do you have any basis whatsoever to suggest that the way in which a Mirena becomes rigid that you've manipulated in your mechanical testing ever occurs in vivo? A: No, I don't know that I do."), 318:10-14 ("Q: Your hypothesized mechanism of IUD perforation is based on a testing condition that you don't know whether it actually happens in vivo, true? A: That's true.").

Dr. Jarrell's admissions regarding the relevance of his mechanical testing are not surprising. His mechanical test required affixing Mirena in the testing apparatus using double-sided tape. That was because Dr. Jarrell's own testing demonstrated that without the tape the loads experienced by a Mirena were far lower. But Mirena does not adhere to the lining of the uterus. Rather it floats in the fluid within the uterus in a condition not remotely similar to double-sided tape. Dr. Jarrell himself admitted the endometrium is a low-friction surface in

which a Mirena is free to move. *Id.* at 234:2-10, 318:15-19. Artificially adhering a Mirena to a testing apparatus just to get higher numbers does not tell a jury anything about the loading conditions of a Mirena in a woman's uterus. Moreover, Dr. Jarrell used a *hard* abutting block to represent the fundus yet he admitted that the fundus is *soft* tissue that has give. *Id.* at 234:2-14, 235:11-24.

The isolation between Dr. Jarrell's methodology and clinical reality is particularly disconcerting because his blatant disregard of the facts significantly altered the resulting data. The introduction of the abutting block drastically manipulated the amount of force Mirena could withstand without bending. When Mirena's arms remain unconstrained, which by Dr. Jarrell's own admission best reflects Mirena's placement in the body, the peak force values Mirena could bear before bending remained low (11.2-11.8 g). Ex. B, Jarrell Report at 12-13 (Table 2), 23 (Table 4); *see supra* Diagram 1; *see supra* Jarrell Figures 28 and 29. But, when Dr. Jarrell added the hard abutting block, the constrained condition "was measured to be approximately 35-40 times higher" than the unconstrained, realistic conditions (88.6 g). Ex. B, Jarrell Report at 22-23 (Table 4); *see supra* Jarrell Figure 31. Due to these fictional testing conditions, Dr. Jarrell's opinion that this method replicates *in vivo* conditions is not reliable. *See In re Denture Cream Products Liab. Litig.*, 2011 WL 9375632, at *12 (S.D. Fla. July 22, 2011) ("Dr. Brewer's conclusion is not reliable because it is based on an inaccurate factual premise.").

2. Dr. Jarrell's Manufactured Test Condition Does Not Meet *Daubert*'s Reliability Standards

In addition to these irreconcilable analytical gaps, Dr. Jarrell's constrained testing condition and all resulting opinions fail *Daubert*'s indicia of reliability. Neither Dr. Jarrell's methodology nor his ultimate opinion has been subjected to the crucible of peer-reviewed publication. Ex. A, Jarrell Dep. at 232:14-18. He could cite no support suggesting that it is an

appropriate methodology to use double-sided tape and a hard abutting block to represent *in vivo* uterine conditions. *Id.* at 237:2-11. No one has ever given credence to his hypothesis regarding Mirena's potential for rigidity, foreclosing any evidence of general acceptance. *Id.* at 232:14-18. The error rate is unknown since Dr. Jarrell is apparently the first person to ever adopt this position. Given these inadequacies, Dr. Jarrell should not be permitted to shield his opinions from *Daubert* scrutiny by claiming he based them in ephemeral "principles of engineering." *See* Ex. A, Jarrell Dep. at 348:23-349:14; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1244 (11th Cir. 2005) ("[O]n the speculative nature of his testimony, O'Donnell attempts to anoint his opinions by claiming that he based them on the 'broad principles of pharmacology.' In the *Daubert* context, such phrases have little value. They are not shibboleths that distinguish those experts that offer reliable science from those who foist junk science on the court.").

3. Dr. Jarrell's Methodology Is An Ad Hoc Endeavor That Did Not Adhere To A Written Protocol

Lastly, courts have questioned a test's reliability where, as here, the witness "fail[ed] to adhere to testing standards or a written protocol." *Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *12 (S.D.W.V. Feb. 27, 2015); *Tyree v. Boston Scientific Corp.*, 2014 WL 5486694, at *42 (S.D.W.V. Oct. 29, 2014). Dr. Jarrell failed to draft a written testing protocol before testing Mirena for purposes of this litigation. Ex. A, Jarrell Dep. at 56:13-17. More troubling is his admission that he first created a protocol not only after he conducted the test, but also *after* he submitted his expert report. *Id.* at 133:25-134:22. In fact, the first time he produced a written testing standard to Defendants was at his deposition. *Id.* at 133:25-134:22. Accordingly, Dr. Jarrell's makeshift testing methodology amounts to inadmissible "guesswork." *See Golod v. La Roche*, 964 F. Supp. 841, 861 (S.D.N.Y. 1997) ("'[T]he court room is not the place for scientific

guesswork, even of the most inspired sort. Law lags behind science; it does not lead it.'") (*quoting Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996)).

D. Dr. Jarrell's Uterine Pressure Wound Theory Is Unsound And Requires Exclusion

The final step of Dr. Jarrell's conjectural house of cards is his uterine pressure wound theory, created anew for this case. Ex. B, Jarrell Report at 24. Dr. Jarrell surmises that the force of uterine contractions combined with Mirena's rigidity (artificially created in step three of his analysis) result in forces sufficient to create pressure wounds in the uterus. Ex. A, Jarrell Dep. at162:6-17; Ex. B, Jarrell Report at 24; *see infra* Jarrell Figure 31. Even if the Court finds Dr. Jarrell's opinions regarding the purported effects of LNG on the endometrium, the alleged "sharpness" of Mirena arms, and his constrained testing condition reliable (they are not), the final step of his analysis does not pass muster. His hypothesis fails to meet any indicia of reliability and can best be characterized as "a series of empirically unbridgeable analytical gaps." *See Zaremba*, 360 F.3d 355 at 359; *In re Rezulin*, 369 F. Supp. 2d at 438. Dr. Jarrell's testimony should be excluded because he bases his newfound hypothesis on insufficient data, a suspect methodology, and incompatible studies. *See Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 255 (2d Cir. 2005) ("[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.") (internal quotation marks omitted).

1. Dr. Jarrell's Uterine Pressure Wound Theory Ventures Far Beyond The Scope Of His Expertise

Dr. Jarrell lacks the necessary relevant expertise to present his "pressure wound" hypothesis to a jury. His ability to read articles written by others is not sufficient. The Second Circuit recently rejected similar grounds for expert qualifications, concluding that expertise must

be "based on specialized knowledge and experience, not a mere understanding derived from others' publications." *Ellis v. YMCA Camp Mohawk, Inc.*, 2015 WL 5254913, at *2 (2d Cir. Sept. 10, 2015). Dr. Jarrell has no experience whatsoever with IUDs or clinical experience of any kind. Ex. A, Jarrell Dep. at 75:3-6, 75:16-18, 82:23-83:5, 84:7-18. There is nothing in Dr. Jarrell's education, training, or experience that qualifies him to opine about the development of pressure wounds in uterine tissue. On that basis alone, his opinion should be excluded.

2. Dr. Jarrell's Theory Does Not Satisfy Any Measure Of Reliability

Dr. Jarrell's uterine pressure wound theory was developed for the express purpose of this litigation. *See Amorgianos*, 137 F. Supp. 2d at 190 (finding experts' opinions unreliable where, among other reasons, their hypotheses were first developed in the course of the litigation). He had never even heard of IUD uterine perforation before being retained, much less secondary perforation. Ex. A, Jarrell Dep. at 85:5-8. His uterine pressure wound theory was shaped with studies selected by counsel, weighing against its reliability. *See Mancuso*, 967 F. Supp. at 1443; Ex. A, Jarrell Dep. at 266:1-11. It has never been peer-reviewed or published. *Id.* at 295:19-296:3. He admitted to being the first person in the world to opine that IUDs can perforate the uterus through pressure wounds created by supposedly "rigid" arms. *Id.* at 283:4-9, 302:12-20. Clearly, his hypothesis has "no acceptance outside this litigation, let alone widespread acceptance." *In re Rezulin*, 369 F. Supp. 2d at 423.

Further, Dr. Jarrell's theory has not been subjected to testing, which makes an error rate incalculable. For instance, Dr. Jarrell does not know how much force is necessary to cause a pressure wound in the myometrium, which is a necessary predicate of perforation. Ex. A, Jarrell Dep. at 282:13-16. This theory "is, at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis." *Golod*, 964 F. Supp. 841 at 860-61 (excluding expert's "novel" theory where the hypothesis had not been published, peer reviewed, or tested, and had

not gained general acceptance because while "biologically plausible, it does not constitute 'scientific knowledge' within the meaning of *Daubert*").

Dr. Jarrell completely ignores and altogether fails to take into account data that contradict his opinions. *See In re Denture Cream*, 2011 WL 9375632, at *12 (finding challenged expert's "conclusion is not reliable because it is based on an inaccurate factual premise"); *In re Rezulin*, 309 F. Supp. 2d at 563 ("[A]n expert may not pick and choose from the scientific landscape and present the Court with what he believes the final picture looks like.") (citation and quotation marks omitted). Dr. Jarrell evidently first developed an opinion for this litigation and then worked backwards, searching for support he could contort to fit the preconceived theory. *In re Rezulin*, 309 F. Supp. 2d at 550 ("[A]n expert may not reach his conclusion first and do the research later."). This approach does not comport with scientific principles. *See Claar v. Burlington Northern RR. Co.*, 29 F.3d 499, 502-503 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method.").

3. Dr. Jarrell's Theory Is Plagued By Unexplained Analytical Gaps

An intractable analytical gap persists between Dr. Jarrell's paid opinions in this litigation and the data on which he relies. *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."). A proposed opinion should be precluded as unreliable where "there is too great an 'analytical gap' between the conclusions reached by the authors of [a challenged expert's] cited articles and the conclusions that []he draws from their work." *Amorgianos*, 137 F. Supp. 2d at 185.

For example, Dr. Jarrell predicates his opinion on an assumed level of baseline uterine contractions in the range from 100 to 300 mmHg. Ex. B, Jarrell Report at 24-25. But even Dr.

Jarrell acknowledged this data is not applicable to patients using a Mirena. Dr. Jarrell relied on studies measuring uterine contractions in non-Mirena users during their menstrual cycles.[3] However, Dr. Jarrell admitted being fully aware that Mirena ***reduces*** contractions during the menstrual cycle. Ex. A, Jarrell Dep. at 256:12-19. Nevertheless, he omitted this confounder from his report and did not account for this reduction in his calculations. *Id.* at 255:23-256:19. Dr. Jarrell used data from another article for the maximum figure in his range, which relied on a study of uterine contractions in one non-Mirena user suffering from dysmenorrhea (painful menstrual cramps). *See* Ex. B, Jarrell Report at 24-25. Again, Dr. Jarrell could not explain how contractile forces measured in a patient without a Mirena bear any relationship to contractile forces in a patient with a Mirena.[4] That means that Dr. Jarrell knowingly used as a basis for calculations contractile pressure data measured in a patient without a Mirena though he was fully aware that Mirena reduces contractions. Importantly for purposes of admissibility, Dr. Jarrell could not explain why that leap was a reliable methodology. Instead, when questioned about the application of these numbers to Mirena users, Dr. Jarrell replied: "I had to look at the existing literature to get…the range of pressures that I could use for calculations, so these were the numbers that were available in the published literature…. ***I don't know what the pressures are under Mirena***." Ex. A, Jarrell Dep. at 268:17-21, 292:13-19 (emphasis added). But not knowing what the correct values are is no excuse for using values he knows to be incorrect.

[3] *See* Ex. C, Carlo Bulletti, et al., *Uterine contractility during the menstrual cycle*, 15 (Suppl. 1) Human Reproduction 81 (2000).

[4] See Ex. D, Norman D. Goldstuck and Dirk Wildemeersh, *Role of uterine forces in intrauterine device embedment, perforation, and expulsion*, 6 Int'l J. of Women's Health 735 (2014). It should be noted that Dr. Jarrell admitted that the maximum contractile pressure cited in the Goldstuck publication is, in fact, wrong due to an erroneous citation in that article. Ex. A, Jarrell Dep. at 278:11-23.

An approach like Dr. Jarrell's was the source of criticism and ultimate exclusion in the *Bextra* MDL. *See In re Bextra and Celebrex Marketing Sales Practices and Product Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007). There, the court excluded a cardiology expert who "reache[d] his opinion by first identifying his conclusion…and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion." *Id.* Jarrell's methodological transgressions are far worse than the expert at issue in *Bextra* because Dr. Jarrell knows that the cherry-picked data in fact does not accurately describe patients using the product at issue. Similarly, this Court should exclude Dr. Jarrell's uterine pressure wound theory because it "does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science.'" *Id.*

4. Dr. Jarrell's Extrapolations Exceed The Bounds Of His Cited Support

Dr. Jarrell has evinced a pattern of taking the cited authors' conclusions much further than the researchers themselves were willing in an effort to bridge the analytical gaps between his support and his paid opinions. He subsequently made no efforts to connect the dots between his leaps of logic using reliable data. Dr. Jarrell's overreaching extrapolations exceed the bounds of permissible expert testimony and require exclusion. *See In re Accutane Products Liab.*, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009) *aff'd*, 378 F. App'x 929 (11th Cir. 2010) ("[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study. That is, he must not draw overreaching conclusions… Without some scientific data to close the gap between hypothesis and opinion, [an expert] cannot do more.").

Specifically, Dr. Jarrell cited articles addressing the ulcerative effects of constantly applied pressure to the legs, pelvic bones, or femoral bones of rats, rabbits, dogs, and pigs. *See*

Ex. B, Jarrell Report at 26-28. He then, somehow, arrives at the conclusion that these studies are directly applicable to pressures generated by Mirena inside of a human uterus.

Irreconcilable fallacies exist in Dr. Jarrell's extrapolation of this animal data, connected by nothing more than his *ipse dixit*. First, these studies analyzed rats, rabbits, dogs, or pigs. *See* Ex. B, Jarrell Report at 26-28. Whenever a scientist purports to rely on animal studies to draw conclusions about human clinical outcomes, there must be some scientific reason why the animal studies at issue can be expected to provide any insight to clinical experience. *See Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 546 (W.D. Pa. 2003) ("To ensure that the expert's conclusion based on animal studies is reliable, there must be 'a scientifically valid link'-such as supporting human data-'between the sources or studies consulted and the conclusion reached.'") (internal citation omitted); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1367 (N.D. Ga. 2001) ("Extrapolations from animal studies to human beings generally are not considered reliable in the absence of a credible scientific explanation of why such extrapolation is warranted."). Here, however, Dr. Jarrell cites animal studies which themselves do not purport to say anything about uterine tissue at all, let alone the effects of an IUD. Instead, the animal models were studying the development of pressure sores that might develop in the soft tissue of a bed-ridden patient. Yet, Dr. Jarrell extends these findings to uterine tissue and failed to articulate a reliable basis for doing so at his deposition. Ex. A, Jarrell Dep. at 294:7-12 ("Q: There's nothing in the Peirce article that would suggest that it's appropriate to take their skin rat model and apply it to the myometrium of a woman, right? A: I don't know if I can answer that question."). Second, the articles Dr. Jarrell cites in support of his pressure wound theory involved the application of *constant pressure for 1 – 18 hours*. Ex. B, Jarrell Report at 27-28. Yet, Dr. Jarrell extrapolates these results to uterine contractions, which last mere seconds and

never longer than a minute. Ex. A, Jarrell Dep. at 263:1-19, 297:17-22. But Dr. Jarrell cannot cite any support for the notion that clinically relevant intrauterine pressure can lead to pressure wounds. *Id.* at 264:25-265:11 ("Q: have you identified any literature for the suggestion that intermittent pressures lasting just a few seconds can cause pressure wounds in any tissue? A: I don't recall anything at that short of a time period. Q: Can you identify any literature for the suggestion that pressures lasting less than an hour can cause pressure wounds? A: I don't know what the shortest time period listed inside of the literature that I quoted is."). In the absence of relevant scientific support, Dr. Jarrell has impermissibly drawn overreaching conclusions from inapplicable animal studies. *See Joiner*, 522 U.S. at 144-45 (1997) (holding that "[t]he [expert's] studies were so dissimilar to the facts present in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them").

5. Dr. Jarrell's Theory Does Not "Fit" The Facts Of This Case

Dr. Jarrell's uterine pressure wound theory does not "fit" the facts of this case and is of no assistance to the jury. *See In re Zyprexa Products Liab. Litig.*, 2009 WL 1357236, at *3 (E.D.N.Y. May 12, 2009) (excluding an expert's opinions due to "extensive factual discrepancies in his analyses" and a "pattern of disregard of the facts"); *In re Rezulin Products Liab. Litig.*, 441 F. Supp. 2d 567, 576 (S.D.N.Y. 2006) ("[T]o meet Rule 702's requirements, the proffered testimony must 'fit' the factual dispute at issue – in other words, it must be 'sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.'") (quoting *Daubert*, 509 U.S. at 591); *In re Rezulin*, 309 F. Supp. 2d at 540 ("This helpful requirement…requires expert testimony to have a valid connection to the pertinent inquiry.") (internal citation omitted). The Second Circuit has recognized that district courts have broad discretion to evaluate "the fit between the experts' opinions and the scientific literature on which they relied." *Amorgianos*, 303 F.3d at 266. Here, the articles upon which Dr. Jarrell relies do not "'fit' the facts of this

case, either in terms of the type and duration of exposure….'" *In re Rezulin*, 369 F. Supp. 2d at 421 (*quoting Amorgianos*, 137 F. Supp. 2d at 188). As discussed, none of Dr. Jarrell's cited literature involved uterine tissue, but he seeks to opine that animal studies measuring skin ulcers are indicative. Ex. A, Jarrell Dep. at 244:10-21. Moreover, these studies involved constant pressure lasting up to 18 hours, in stark contrast to the intermittent pressures within the uterus. Ex. B, Jarrell Report at 27-28; Ex. A, Jarrell Dep. at 263:1-19, 297:17-22. Dr. Jarrell "repeatedly and impermissibly stretched the truth to support [his] findings" requiring the exclusion of his testimony. *In re Zyprexa*, 2009 WL 1357236, at *3.

E. Dr. Jarrell's Held Opinions Are Ultimately Irrelevant

Dr. Jarrell's testimony should be excluded in full because it does not satisfy the relevance requirements of Federal Rule of Evidence 401. *See United States v. Khan*, 787 F.2d 28, 34 (2d Cir. 1986) ("[E]xpert evidence is not immune from the relevance requirement of Fed. Rule Evid. 401 and must be excluded if irrelevant.") (citations and alterations omitted). To garner relevance, Dr. Jarrell's plausible mechanism opinion must be shown to have some nexus to causation. *See In re Bausch & Lomb, Inc. Contact Lens Solution Products Liab. Litig.*, 2009 WL 2750462, at *12 (D.S.C. Aug. 26, 2009) ("[B]iological possibility is insufficient to demonstrate causation.…"); *In re Accutane*, 511 F. Supp. 2d at 1296 ("[B]iological possibility is not proof of causation.").

Dr. Jarrell's testimony is on an island in this litigation. Dr. Jarrell himself does not suggest that any of his held opinions are relevant to Plaintiffs' secondary perforation theory. He did not even include the term "secondary perforation" in his report. Ex. A, Jarrell Dep. at 100:10-13. Although he opines that levonorgestrel causes a thin, fragile endometrium, he is not relating it to any increased risk of perforation. *Id.* at 159:13-16, 167:15-21, 170:10-17. Nor is he opining that Mirena has any effect on the myometrium (the muscular layer of the uterus). *Id.* at

150:12-13, 161:15-17, 162:19-24, 208:4-7. Although he opines that Mirena's arms are "sharp," he does not assert that this has any clinical effect on uterine perforation. *Id.* at 193:23-194:10. He has no idea whether the mechanical testing reflected in the third step of his analysis has any clinical relevance to the risk of perforation. *Id.* at 317:3-11. Dr. Jarrell is also unable to tie his pressure wound theory to any clinical data, conceding that he isn't aware of a single reported incident of IUD perforation by way of pressure wounding. *Id.* at 301:14-18, 304:3-305:4. In fact, none of Plaintiffs' proposed general causation experts (Susan Wray, Richard Luciani, Roger Young) even reference his opinions. Simply put, Dr. Jarrell's purported mechanism opinion is irrelevant to proving causation in this litigation. Accordingly, his opinions should be excluded in their entirety.

F. Dr. Jarrell Cannot Opine On A Safer Alternative Design

In his report, Dr. Jarrell quotes extensively from an application filed by certain Bayer scientists for an IUD design patent. It is not entirely clear what opinions Dr. Jarrell intended to advance by his citation to the patent application. The patent is cited in the section of the report dealing with relative "sharpness". But Dr. Jarrell admitted that the patent application "does not identify an objective measure of what is and is not a sharp feature of an IUD." Ex. A, Jarrell Dep. at 203:3:5. Nor could Dr. Jarrell compare Mirena to the patent application he cites. *Id.* at 203:15-19 ("Q: So you can't assess whether a particular IUD is contrary to the teaching of this patent that you've identified, other than some subjective assessment, correct? A: At this point, correct."). Further, Dr. Jarrell admitted that he has no idea whether anyone has attempted to commercialize the claimed invention or whether it is a feasible design. *Id.* at 204:9-16 ("Q: You don't know whether the claimed invention in this Bayer patent is a commercially feasible product, correct? A: Correct. Q: You don't know whether the invention claimed in the Bayer patent is even suitable for clinical use, correct? A: No, I didn't make that assessment").

Given all his admissions, it is not surprising that at his deposition Dr. Jarrell conceded that he does not offer any opinion on a supposedly safer alternative design of any IUD. *Id.* at 99:12-15. Accordingly, Dr. Jarrell should be precluded at trial from offering any opinion about any alternative design of an IUD.[5]

G. Dr. Jarrell Should Not Be Allowed To Opine About Alleged Manufacturing Defects

Finally, Dr. Jarrell offered at his deposition an opinion not previously disclosed in his expert report. Namely, Dr. Jarrell opined that one of the exemplar Mirenas he inspected exhibited manufacturing "misalignment" that supposedly exceeds the manufacturing specifications for the product.[6] While Dr. Jarrell in his report commented on the appearance of the misalignment and took photographs, he did not offer any opinions that the misalignment exceeded specification. At his deposition, Dr. Jarrell offered for the first time the opinion that the misalignment at some locations exceeded specifications by 20 microns (which is far less the width of a human hair). *Id.* at 193:2-21, 196:24-197:8.

Putting aside the fact that Dr. Jarrell never properly disclosed this opinion under Rule 26, he should not be allowed to comment about any supposed manufacturing defect. Dr. Jarrell conceded that there literally is no support in the scientific literature to suggest any degree of IUD misalignment is at all relevant to IUD perforation:

> Q: Can you identify any support anywhere in the world where anyone else has connected the parting line mismatch of an IUD to perforation risk?
>
> A: None that I'm aware of, no.

[5] Bayer recognizes that it is perhaps unnecessary to move to exclude an opinion that an expert disclaimed offering in his deposition. However, given the potential inferences throughout Dr. Jarrell's report on this issue the argument is included here out of an abundance of caution.
[6] "Misalignment" occurs when using molds in manufacturing.

Id. at 200:6-10. Dr. Jarrell further admitted that even he cannot claim that the supposed manufacturing misalignment has any clinical relevance. *Id.* at 194:6-10 ("Q: So you have no opinion on the – whether there's any clinical relevance to the parting line misalignment that you say you have identified with Mirena, true? A: True."), 201:19-24 ("Q: But you can't suggest the manufacturing defect that you say you've identified has anything to do with the perforation risk clinically? A: No, I don't know the clinical implication."). Even if there were any clinical relevance, he cannot link the exemplar Mirena he obtained from Plaintiffs' lawyers in this litigation to any individual plaintiff's Mirena.

As discussed above, a proffered expert opinion must be relevant in addition to satisfying the requirements of Rule 702. *See Khan*, 787 F.2d at 34. Here, whether or not Dr. Jarrell can correctly measure the manufacturing misalignment is entirely beside the point because neither he nor anyone else in the litigation even purports to link that misalignment to any injury claimed in the litigation. Without that basic connection Dr. Jarrell's observation would not aid the trier of fact and should be excluded.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude the Testimony of John Jarrell, Ph.D., P.E. should be granted, and his opinions should be excluded in their entirety.

Dated: October 22, 2015

Respectfully submitted,

/s/ *Shayna S. Cook*

Shayna S. Cook
Brian P. O'Donoghue
Christopher J. Cook
GOLDMAN ISMAIL TOMASELLI
BRENNAN & BAUM LLP
564 West Randolph St., Suite 400
Chicago, IL 60661

P: (312) 681-6000
F: (312) 881-5191
scook@goldmanismail.com

Lead Counsel for Defendants

E. James Shepherd
SHOOK HARDY & BACON LLP
600 Travis St., Suite 3400
Houston, TX 77002
P: (713) 227-8008
F: (713) 2279508
eshepherd@shb.com

William P. Harrington
BLEAKLEY PLATT & SCHMIDT LLP
One North Lexington Avenue
White Plains, NY 10601
P: (914) 949-2700
F: (914) 683-6956
wpharrington@bpslaw.com

Counsel for Defendants