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

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IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION **13-MD-2434 (CS)**
13-MC-2434 (CS)

This Document Relates To

JENNIFER DANLEY v. BAYER HEALTHCARE PHARMACEUTICALS INC. **13-CV-6586 (CS)**

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

(REDACTED: CONFIDENTIAL INFORMATION)

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I. INTRODUCTION

Plaintiff Jennifer Danley has no evidence that the injury she is claiming in this lawsuit exists at all; that she actually suffered from it; that Bayer's warning was inadequate; or that any inadequate warning caused her injury. She simply cannot survive summary judgment on her claim that Bayer failed to warn that Mirena can perforate the uterus unrelated to the insertion procedure (what she calls "secondary perforation").

Plaintiff's failure to warn claim fails for four independent reasons, each of which alone would be fatal to her claim. First, Plaintiff has no admissible expert testimony that secondary perforation is even physiologically capable of happening with Mirena. Indeed, even her experts concede secondary perforation is "a theory" that has "not been proven" and is still "in its infancy." Second, even if this unproven "theory" could happen in some cases, Plaintiff has no evidence that it happened to her – to the contrary, an ultrasound showed her Mirena had perforated at the time of insertion. Third, Bayer's Mirena label adequately warned Plaintiff's healthcare providers of all clinically relevant information related to the risk of uterine perforation, including that the perforation may not be detected until later, may lead to migration outside the uterine cavity and other consequences, and may require surgical removal. And finally, even assuming *arguendo* that Bayer's warning was somehow inadequate, it did not proximately cause Plaintiff's injury: the nurse who prescribed Plaintiff's Mirena took into account that there was "always" a risk that Mirena could perforate the uterus and migrate outside the uterine cavity and decided to prescribe Mirena anyway. Since Plaintiff's healthcare provider took the risk into account in her prescribing decision, nothing Bayer could have said about that risk would have affected the prescribing decision or prevented Plaintiff's injury.

As with Plaintiff's failure to warn claim, there is no evidence to support Plaintiff's remaining claims – design defect, manufacturing defect, breach of warranty, negligence, fraud

and misrepresentation. Finally, Plaintiff cannot put forth any evidence that Bayer's conduct comes anywhere close to the conscious indifference necessary to support her punitive damages claim. There is no dispute that Mirena's benefits outweigh its risks, and Bayer stands with the scientific community that believes the unproven theory of secondary perforation is "implausible" and "unsubstantiated." Defendants are entitled to summary judgment on all claims.

II. FACTUAL BACKGROUND

A. General Background

1. Mirena Is A Safe And Effective FDA-Approved Contraceptive

Mirena is a T-shaped intrauterine device (IUD) that is small (1.26 by 1.26 inches) and made of soft, flexible plastic. Mirena has a hormone cylinder that continuously releases a small dose of levonorgestrel, a progestin hormone that is used in many other FDA-approved contraceptives. Mirena provides contraceptive protection for up to 5 years. Mirena requires a prescription and is inserted by a healthcare provider during an office visit.

The FDA approved Mirena in 2000 as safe and effective for intrauterine contraception. Ex. 1, 2000 Mirena Label. At that time, Mirena had been on the market abroad for a decade. In 2009, FDA approved a new indication for Mirena for treatment of heavy menstrual bleeding. Ex. 2, 2009 Mirena Label. Mirena is still on the market today.

Unintended pregnancy is a significant public health concern in the United States. Nearly half of all pregnancies in the United States are unintended, with nearly half of those due to contraceptive failures.[1] Unintended pregnancy can have significant negative effects (physical,

[1] Ex. 3, *Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy*, Committee Opinion No. 642 (Am. Coll. Obstet. & Gynecol., Wash. D.C.), Oct. 2015 ("ACOG 2015"), at 1; Ex. 4, Brooke Winner et al., *Effectiveness of Long-Acting Reversible Contraception*, 366 New Eng. J. Med. 1998, 1998-99 (2012) ("Winner 2012").

psychological, emotional, and social) on women and offspring, as well as substantial financial consequences for families and society. *See* Ex. 4, Winner 2012, at 1999.

Mirena is one of the most highly effective contraceptives available.[2] The American Congress of Obstetricians and Gynecologists ("ACOG") recommends that its members encourage IUDs for all appropriate patients because of their safety and effectiveness. Ex. 3, ACOG 2015, at 3; Ex. 6, ACOG 2011, at 3. Mirena is also well tolerated by patients, and studies have shown it to have high continuation and satisfaction rates.[3]

2. Uterine Perforation Is A Rare, Known Risk Of All IUDs

Like all medicines, Mirena is not 100% risk-free. One potential risk of all IUDs (indeed, all intrauterine procedures) is uterine perforation. Uterine perforation refers to inadvertently poking a hole through both the endometrium (the thin inner lining of the uterus) and the myometrium (the thick muscular layer of the uterus). A hole that goes only partway through the myometrium is sometimes referred to as embedment or partial perforation.[4]

A perforated IUD is typically removed via same-day laparoscopic surgery (using small abdominal incisions) if the IUD is in the abdominal cavity.[5] A partially perforated IUD may be

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[2] Ex. 5, Robert A. Hatcher et al., *Contraceptive Technology* 151 (20th ed. 2011) ("Hatcher 2011"); Ex. 6, *Long-Acting Reversible Contraception: Implants and Intrauterine Devices*, Practice Bulletin No. 121 (Am. Coll. Obstet. & Gynecol., Wash. D.C.) Jul. 2011 ("ACOG 2011"), at 2; Ex. 7, Klaas Heinemann, et al., *Comparative contraceptive effectiveness of levonorgestrel-releasing and copper intrauterine devices: the European Active Surveillance Study of Intrauterine Devices*, 91 Contraception 280, 280 (2015).

[3] Ex. 8, Jeffery F. Peipert et al., *Continuation and Satisfaction of Reversible Contraception*, 117(5) Obstet. Gynecol. 1105, 1105 (2011); Ex. 9, Michaela O'Neil-Callahan et al., *Twenty-Four-Month Continuation of Reversible Contraception*, 122(5) Obstet. Gynecol. 1083, 1083 (2013); Ex. 10, Justin T. Diedrich et al., *Three-year continuation of reversible contraception*, Am. J. Obstet. Gynecol. (forthcoming 2015).

[4] Sometimes the term "partial perforation" is used to refer to an IUD that has breached the entire myometrium but is still at least partially in the uterus.

[5] See Ex. 11, Gillian Dean et al., *Management of problems related to intrauterine contraception*, UpToDate (2013) ("Dean 2013"), at 4-5.

removed by pulling on the threads or via a hysteroscopic procedure (inserting a scope and instruments through the cervix into the uterus). *See* Ex. 11, Dean 2013 at 4-5.

The risk of uterine perforation with IUDs is rare – approximately 1 per 1,000 IUD insertions.[6] The recently completed EURAS study, which followed over 60,000 IUD users, re-affirmed this rate of IUD perforation as well as the benign clinical course of perforations.[7]

Healthcare providers who insert IUDs are well aware of the potential risk of perforation from their medical training.[8] They consider this potential risk in their risk-benefit analysis when recommending Mirena to their patients, and they explain it to patients during the informed consent process. Other known potential side effects of Mirena include expulsion (where the IUD comes out through the cervix) and diminished menstrual bleeding. Ex. 6, ACOG 2011 at 2.

3. Perforation Occurs During Insertion But May Not Be Detected Until Later

The only known mechanism of uterine perforation is mechanical trauma to the uterus due to instrumentation. IUD perforations all initiate from damage to the uterine wall during sounding or the insertion process. Some uterine perforations are diagnosed at the time of IUD insertion, but many perforations are asymptomatic and remain undiagnosed at the time of insertion.[9] *See* Ex. 16, Young Case-Specific Dep. at 431:13-19 ("many perforations are asymptomatic"). A perforation may be detected because the patient presents with symptoms of

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[6] Ex. 12, WHO, Family Planning and Population, *Intrauterine Devices: What Health Workers Need to Know* (1997), at 14-15; Ex. 6, ACOG 2011 at 2; Ex. 5, Hatcher 2011 at 157.

[7] Ex. 13, 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, 279 (2015) ("From a public health perspective, the most important finding may be the rarity of perforation and the absence of serious sequelae if perforation occurred.").

[8] *See* Ex. 14, Antoinette A. Danvers et al., *Lawsuits against Mirena: Potential impact on public health*, 89 Contraception 489, 490 (2014) ("Danvers 2014") (describing perforation as one of the "known side effects and complications of IUC use").

[9] *See* Ex. 15, Kerstin Andersson, *Perforations With Intrauterine Devices: Report from a Swedish Survey*, 57 Contraception 251, 251-52 (1998) ("Andersson 1998") (36 out of 50 perforations were diagnosed more than a month after insertion).

perforation like pain or bleeding, but many other perforations remain asymptomatic even at the time of diagnosis and are detected only incidentally when a patient's IUD threads are not seen or when a patient becomes pregnant.[10] Because perforations may be and often are asymptomatic, the time when a perforation is ***detected*** is not necessarily the time it ***occurred***.

The consensus in the medical community is that perforation occurs or at least initiates at the time of insertion. Leading gynecology textbooks teach that perforation occurs at the time of insertion and that no evidence supports the theory of perforation unrelated to insertion (Plaintiffs' so-called "secondary perforation" theory).[11] Review articles commonly used by healthcare providers also reject the secondary perforation theory.[12] A partial perforation at the time of insertion may, over time, become a complete perforation.[13] In this regard, a ***completed*** perforation may not occur until after insertion, but even then the perforation is caused by injury to the uterine wall at the time of insertion.

Perforation, especially a partial perforation or embedment, is sometimes difficult to diagnose. As Plaintiff's own experts admit, perforation is often asymptomatic. *See* Ex. 18, Young Dep., at 151:16-152:1 (agreeing that "given that many perforations are asymptomatic, [] the time when you detect a perforation is not necessarily the time it occurred"); Ex. 19, Wray

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[10] *See* Ex. 15, Andersson 1998, at 252 (35 out of 50 perforations diagnosed due to pregnancy or missing threads).

[11] *See* Ex. 5, Hatcher 2011, at 157 ("Perforation of the uterus can occur at the time of IUC placement; no evidence supports the notion that IUCs can migrate outside the uterus thereafter."); Ex. 17, Gretchen Lentz et al., Comprehensive Gynecology 261 (6th ed. 2012) ("Lentz 2012") ("Perforation always occurs at the time of insertion.").

[12] Ex. 11, Dean 2013 at 4 ("Uterine perforation occurs during IUD insertion and complicates about 1 in 1000 insertion procedures. . . . Perforations diagnosed after the insertion procedure have been attributed to spontaneous IUD migration; although difficult to disprove, we think this explanation is implausible."); *see also* Ex. 14, Danvers 2014 at 490 (calling spontaneous migration theory "unfounded").

[13] Ex. 17, Lentz 2012 at 261 ("Sometimes only the distal portion of the IUD penetrates the uterine muscle at insertion. Then uterine contractions over the next few months force the IUD into the peritoneal cavity.").

Dep. at 230:16-22 ("A lack of clinical symptoms does not rule out a perforation, yes."); Ex. 20, Luciani Dep. at 157:3-9 (agreeing that "an embedment upon insertion with a complete perforation some weeks, months, or years later can be asymptomatic while it's occurring").

The absence of IUD threads may be a sign of perforation; however, as Plaintiff's experts concede, the presence of the threads cannot exclude a portion of the Mirena being embedded in the myometrium (since the threads are cut ***after*** insertion). *See, e.g.*, Ex. 21, Strassberg Dep. at 191:5-21 ("Just because you then look and see strings doesn't mean you haven't perforated the uterus."); Ex. 18, Young Dep. at 139:17-140:17 ("The thread offers no evidence one way or the other" about partial perforation.); Ex. 19, Wray Dep. at 237:3-7 (agreeing that "the presence of strings does not rule out embedment or even complete perforation").

And ultrasound imaging may detect a perforation, particularly when the IUD is completely outside of the uterus. But as Plaintiff's experts agree, two-dimensional ultrasound cannot rule out damage to the myometrium or a partial perforation. *See* Ex. 18, Young Dep. at 163:6-17 (agreeing that "with a 2D ultrasound you can't detect whether the [IUD] arm is embedded in the myometrium"); Ex. 21, Strassberg Dep. at 65:2-14 (with 2D ultrasound, "you don't know exactly where [the IUD] is, whether it's embedded"); Ex. 19, Wray Dep. at 261:8-13 (agreeing that "there are limitations in 2-D ultrasound such that sometimes it will miss the existence of perforation"); Ex. 20, Luciani Dep. at 221:12-16 (agreeing that "2D ultrasound certainly cannot rule out an embedment of an IUD in the myometrium").

There are no published studies providing clinical support for Plaintiff's secondary perforation theory. The single-patient case reports Plaintiff relies on to support her secondary perforation theory merely describe the lack of symptoms and seemingly normal ultrasound or

thread checks.[14] But as noted above, Plaintiffs' own experts admit that perforation cannot be ruled out by the absence of symptoms, the presence of threads, or 2D ultrasound imaging, so these case reports do not provide actual evidence of secondary perforation.

4. The Mirena Label Warns Of The Risk Of Perforation

The Mirena label has warned of the risk of perforation since its initial FDA approval in December 2000 and in each of its revised labels since that time. The FDA has approved multiple changes to the Mirena perforation warning over the years.[15] The FDA has never asked Bayer to add a warning about so-called "secondary perforation."

The initial, FDA-approved Mirena label included the following in the Warnings section:

7. Perforation

An IUD may perforate the uterus or cervix, most often during insertion although the perforation may not be detected until some time later. If perforation occurs, the IUD must be removed and surgery may be required. Adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera have been reported with IUDs.

It is recommended that postpartum **MIRENA®** insertion be delayed until uterine involution is complete to decrease perforation risk. There is an increased risk of perforation in women who are lactating. Inserting **MIRENA®** immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete.

Ex. 1, 2000 Mirena Label, at MIR_INDNDA_00010729.

[redacted]

[14] *See* Ex. 22, Mark Erian et al., *The Wandering Mirena: Laparoscopic Retrieval*, 15 J. Soc. Laparo. Surg. 127, 129 (2011) ("Erian 2011") (relying on presence of threads); Ex. 23, Jeffrey Levsky & Mark Herskovits, *Incidental detection of a transmigrated intrauterine device*, 11 Emerg. Radiology 312 (2005) ("Levsky 2005") (asymptomatic perforation detected as incidental finding). In their Motion to Exclude Bayer's Experts, Plaintiffs cited Erian 2011 and Levsky 2005 as "well-supported scientific literature" supporting secondary perforation. *See* Mem. of Law in Support of Their Motion to Exclude Expert Testimony (Doc. No. 2703), at 13.

[15] The Mirena label has undergone four relevant label changes since approval, including in July 2008, October 2009, February 2013, and May 2014.

In July 2008, FDA approved a revised Mirena label that changed, *inter alia*, the perforation warning language. Ex. 25, 2008 Mirena Label. The revised warning stated:

> **7. Perforation**
>
> Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later. If perforation occurs, pregnancy may result (see **WARNINGS, Ectopic Pregnancy** and **Intrauterine Pregnancy**). Mirena must be located and removed; surgery may be required. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.
>
> The risk of perforation may be increased in lactating women, in women with fixed retroverted uteri, and during the postpartum period. To decrease the risk of perforation postpartum, Mirena insertion should be delayed a minimum of 6 weeks after delivery or until uterine involution is complete. If involution is substantially delayed, consider waiting until 12 weeks postpartum. Inserting Mirena immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete.

Ex. 25, 2008 Mirena Label at MIR_FCR_2046. [redacted]

In October 2009, FDA approved Mirena to treat heavy menstrual bleeding. While the perforation warning remained unchanged, the label added a "Highlights" section on the front page that also warned of perforation. Ex. 2, 2009 Mirena Label at MIR_INDNDA_0039741. This label was in place at the time of Plaintiff Danley's Mirena insertion.

In February 2013, Bayer amended the perforation warning again to incorporate interim results from the EURAS study that showed an increased risk in perforation among lactating women. The new language read, "Clinical trials with Mirena excluded breast-feeding women. An interim analysis from a large postmarketing safety study shows an increased risk of perforation in lactating women." Ex. 27, 2013 Mirena Label, at MIR_INDNDA_00319918.

In May 2014, FDA approved a modified inserter for Mirena. Along with new insertion instructions, the label included other modifications, including to the perforation warning:

5.6 Perforation

Perforation (total or partial, including penetration/embedment of Mirena in the uterine wall or cervix) may occur most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy and result in pregnancy. The incidence of perforation during clinical trials, which excluded breast-feeding women, was < 0.1%.

If perforation occurs, locate and remove Mirena. Surgery may be required. Delayed detection or removal of Mirena in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.

An interim analysis from a large postmarketing safety study shows an increased risk of perforation in lactating women. The risk of perforation may be increased if Mirena is inserted when the uterus is fixed retroverted or not completely involuted during the postpartum period. Delay Mirena insertion a minimum of six weeks or until involution is complete following a delivery or a second trimester abortion.

Ex. 28, 2014 Mirena Label, at MIR_INDNDA_322217, section 5.6.

FDA recently approved two additional levonorgestrel-releasing IUDs – Skyla (approved in 2013) and Liletta (approved in 2015). *See* Ex. 29, Skyla NDA Approval Letter; Ex. 30, Liletta NDA Approval Letter. In doing so, FDA approved substantially the same perforation warning language as the Mirena label.

B. Case-Specific Facts

1. Ms. Danley's First Mirena

[redacted]

Ms. Miller testified that in 2006, it was her practice to provide the Mirena Patient Information Booklet to a patient to read prior to the insertion of Mirena. Ex. 33, Miller Dep. at 81:2-13; Ex. 34, Patient Information Booklet (Miller Dep. Ex. 13). The Patient Information Booklet contained the following warning about the risk of perforation:

> • Perforation. **MIRENA®** may go through the uterus. This is called perforation. If your uterus is perforated, you may need surgery to remove **MIRENA®**. Perforation can cause internal scarring, infection, or damage to other organs.

Ex. 34, Patient Information Booklet (Miller Dep. Ex. 13), at 4. As Ms. Miller testified, the perforation warning in the Patient Information Booklet does not give any time limitation regarding when the IUD might perforate through the uterus, and in counseling her patients, Ms. Miller does not provide any such time limitation herself. Ex. 33, Miller Dep. at 84:12-17. On the date of insertion, Ms. Danley and Ms. Miller signed a consent form from the last page of the Patient Information Booklet indicating that Ms. Danley had "read the patient information booklet and [] had [her] questions about Mirena answered." Ex. 35, 2/14/06 Signed Consent Form (Miller Dep. Ex. 20); Ex. 33, Miller Dep. at 112:12-113:9.

[redacted]

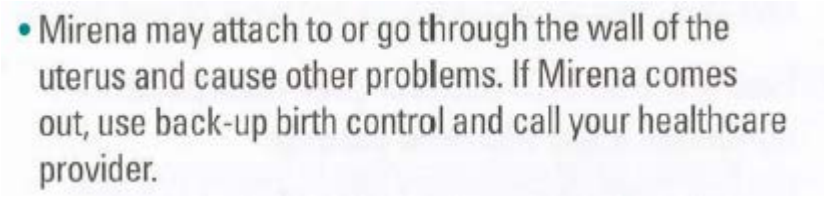
2. Ms. Danley's Second Mirena

[redacted]

Much like the medical community at large, Ms. Roebuck considers Mirena to be one of the most effective methods of contraception available to patients, with a continuation rate greater than other common contraceptive products like the birth control pill. Ex. 38, Roebuck Dep. at 34:21-35:7, 37:24-38:2, 39:3-21; *see supra* at 2-3.

When Ms. Roebuck discusses the risk of perforation with her patients, she informs them that "there is a chance that the IUD will go through the wall of the uterus and end up out here in the abdomen." Ex. 38, Roebuck Dep. at 48:23-49:6. She does not limit when perforation can occur in relation to insertion. *Id.* at 49:7-10. With respect to the risk that Mirena can migrate (she calls it "travel") through the uterus, Ms. Roebuck tells her patients that "it's ***always*** a risk." *Id.* at 49:11-17 (emphasis added); *see also id.* at 74:6-14 (testifying that she believes she discussed risks of perforation and "traveling" with Ms. Danley). In the risk-benefit analysis that Ms. Roebuck performed before deciding whether Mirena was right for Ms. Danley, she considered the risks of perforation and "traveling" before deciding that the benefits of Mirena outweighed the risks. *Id.* at 75:7-24.

As with her first Mirena, Ms. Danley signed a consent form indicating that she had read Mirena literature and had all her questions answered. *See* Ex. 39, 6/29/11 Signed Consent Form (Roebuck Dep. Ex. 9); Ex. 40, Mirena Pamphlet (Miller Dep. Ex. 5); Ex. 38, Roebuck Dep. at 56:24-58:5, 78:15-79:15. And as with the literature that she read in advance of her first Mirena insertion, the brochure that Ms. Danley read prior to her second insertion warned of the risk of perforation without any time limitation:


• Mirena may attach to or go through the wall of the uterus and cause other problems. If Mirena comes out, use back-up birth control and call your healthcare provider.

See Ex. 40, Mirena Pamphlet, at 2, 9; Ex. 38, Roebuck Dep. at 56:24-58:5, 78:15-79:15.

[redacted]

[redacted]

Ms. Roebuck, who inserted Ms. Danley's second Mirena and participated in her care and perforation diagnosis in January 2013, knew the risk of the complication that Ms. Danley experienced and took it into account before inserting Mirena. Ex. 38, Roebuck Dep. at 104:4-8.

III. ARGUMENT

There is no genuine issue of material fact with respect to any of Plaintiff's claims. Defendant is therefore entitled to judgment as a matter of law.

First, Plaintiff did not even experience the injury she claims to have experienced – a natural prerequisite to recover on any of her claims. ***Second***, Plaintiff's failure to warn claim – the core of this lawsuit – is fatally flawed. Not only is Mirena's label adequate, warning of the

risk of uterine perforation and all clinically relevant information pertaining thereto, but any alleged inadequacy in the label was not the proximate cause of Plaintiff's injury. ***Third***, there is no genuine issue of material fact with respect to Plaintiff's remaining claims of design defect, manufacturing defect, negligence, warranty, fraud, and punitive damages; as a result, those claims should be dismissed.

A. Summary Judgment Standard

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "In moving for summary judgment against a party who will bear the ultimate burden of proof at trial, the movant may satisfy this burden by pointing to an absence of evidence to support an essential element of the nonmoving party's claim." *Gummo v. Village of Depew*, 75 F.3d 98, 107 (2d Cir. 1996) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)). The burden then shifts to the party opposing summary judgment to present evidence sufficient to satisfy every element of the claim. The non-moving party is required to "designate specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324 (internal quotation marks omitted). "The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

B. Georgia Law Applies To Plaintiff's Claims

"When an action involving state law claims is transferred pursuant to the MDL provision of 28 U.S.C. § 1407 (2000), 'a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed.'" *In re WorldCom, Inc. Sec. Litig.*, 03 CIV 4498, 2005 WL 2403856, at *2 (S.D.N.Y. Sept. 30, 2005) citing *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir.1993)). Plaintiff's action was filed in the United States District

Court for the Northern District of Georgia. Therefore, the state law and choice of law rules of Georgia apply to the instant action.

Georgia applies the substantive law of the place where the tort or wrong was committed or where the injury was incurred. *Ferguson v. TWA*, 135 F. Supp. 2d 1304, 1308 (N.D. Ga. 2000); *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413, 419 (Ga. 2005) ("The rule of lex loci delicti remains the law of Georgia . . . ."). Ms. Danley resided in Georgia throughout the relevant events; her Mirena was inserted in Georgia; and her perforation was detected and treated there. Accordingly, Georgia law applies to Ms. Danley's case.

C. Plaintiff Danley Did Not Experience The Injury She Claims

"It is elementary that, in order to recover, a plaintiff must show that [a drug] actually caused the injuries of which she complains." *Jack v. Glaxo Wellcome, Inc.*, 239 F. Supp. 2d 1308, 1321 (N.D. Ga. 2002). To make this showing, Plaintiff must establish two elements: "general causation" and "specific causation." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1357 (N.D. Ga. 1999). "General causation is the capacity of a product to cause injury; specific causation is proof that the product in question caused the injury of which the plaintiff complains." *Id.*; *see also Jack*, 239 F. Supp. 2d at 1321.

Here, Plaintiff alleges that she experienced "secondary perforation," a term Plaintiff uses to describe an alleged phenomenon of perforation unrelated to the insertion procedure. However, she cannot show a genuine issue of material fact with respect to either general causation – that secondary perforation happens at all – or specific causation – that secondary perforation happened to her. She therefore cannot recover on her claims.

1. Plaintiff Has Adduced No Reliable Evidence That Secondary Perforation Occurs

Under Georgia law, a plaintiff in a product liability action must put forth admissible medical expert testimony on causation to survive summary judgment. *See Butler v. Union Carbide Corp.*, 712 S.E.2d 537, 544 (Ga. Ct. App. 2011) ("Absent reliable expert testimony . . . there is insufficient evidence to create a jury issue as to causation."); *Wheeler v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 1344, 1352 (S.D. Ga. 2013). Here, none of Plaintiff's proffered experts provide admissible expert testimony to support her secondary perforation theory. Plaintiff cannot satisfy the element of general causation and her claims should be dismissed.

As an initial matter, Plaintiff disclosed only two experts that purport to give general causation opinions – Dr. Richard Luciani and Dr. Susan Wray. *See* Ex. 45, Luciani Generic Expert Report, at 1, 6-9, 11; Ex. 46, Wray Generic Expert Report, at 3, 25-28.[16] However, for the reasons detailed in Defendants' Motions to Exclude Drs. Luciani and Wray, neither expert gives reliable testimony on general causation and both experts' causation testimony should be excluded. *See* Motions to Exclude the Testimony of Dr. Luciani (MDL-2434, Doc. Nos. 2682-84), and Dr. Susan Wray (Doc. Nos. 2691-93). Plaintiff's failure to provide reliable expert testimony on general causation alone is enough reason to dismiss her claims.

Furthermore, there is no reliable way to adduce evidence of secondary perforation. All experts agree that perforation can occur at the time of, or related to injury caused by, the insertion procedure. Plaintiff calls this "primary perforation." *See* Ex. 46, Wray Generic Expert Report, at 21, 24 (perforation after any insertion-related injury, including even a "small nick," is primary perforation); Ex. 47, Young Generic Expert Report, at 10 (describing as a prerequisite

[16] As explained in the *Daubert* motions filed as to each, Plaintiff experts Drs. Jarrell, Zambelli-Weiner, Parisian, and Young do not purport to offer opinions on general causation.

for his secondary perforation mechanism theory that the "IUD is correctly placed within the uterine cavity, with no disruption of the endometrial layer").

On the other hand, "secondary perforation is a theory" that has "not been proven" generally, nor can it be proven in any individual case. Ex. 18, Young Dep. at 136:6-10. Plaintiff's experts rely on certain facts to support the proposition that secondary perforation exists, but each fact is equally consistent with primary perforation. For example, Plaintiff's experts suggest that they can distinguish primary perforation from secondary perforation in any given case due to (1) the absence of pain and other symptoms at insertion; (2) the time lapse between insertion and detection of perforation; (3) the visibility of IUD threads outside the cervix; or (4) an ultrasound appearing to show the IUD in the uterus. Yet Plaintiff's experts also admit that each of these facts is consistent with primary perforation. Accordingly, this evidence is irrelevant because it does not have "any tendency to make [secondary perforation] more or less probable than it would be without the evidence." Fed. R. Evid. 401.

All experts agree that primary perforation can be asymptomatic and that, as a result, the time that a perforation is ***detected*** is not necessarily the time that the perforation ***occurred***. *See, e.g.*, Ex. 18, Young Dep., at 151:16-152:1 (agreeing that "given that many perforations are asymptomatic, [] the time when you detect a perforation is not necessarily the time it occurred"); Ex. 19, Wray Dep. at 230:16-22 ("A lack of clinical symptoms does not rule out a perforation, yes."); Ex. 20, Luciani Dep. at 157:3-9 (agreeing that "an embedment upon insertion with a complete perforation some weeks, months, or years later can be asymptomatic while it's occurring"). Indeed, the Mirena label has always warned that detection of perforation can be delayed. Ex. 1, 2000 Mirena Label at MIR_INDNDA_00010729 ("An IUD may perforate the uterus or cervix, most often during insertion ***although the perforation may not be detected until***

some time later.") (emphasis added). Given the universal acknowledgment that primary perforation can be asymptomatic and that its detection can be delayed, facts (1) and (2) above (lack of symptoms and time lapse to detection) are insufficient to distinguish the known mechanism of primary perforation from the hypothetical and unproven mechanism of secondary perforation.

Facts (3) and (4) provide equally unreliable evidence of the timing of perforation. Plaintiff's experts acknowledge that visible threads and ultrasound "confirmation" of position cannot actually rule out uterine injury. *See, e.g.*, Ex. 19, Wray Dep. at 260:23-262:3 (ultrasounds and visible threads cannot rule out perforation and it is impossible to rule out injury at insertion in any individual case); Ex. 20, Luciani Dep. at 215:10-15 (it is impossible to rule out endometrial injury at time of insertion), 220:3-9 (agreeing that "[e]ven with 3D ultrasound, you could not determine with a hundred percent certainty that there's been no damage to the myometrium"), 221:12-16 (agreeing that "2D ultrasound certainly cannot rule out an embedment of an IUD in the myometrium"); Ex. 18, Young Dep. at 159:15-160:20 (agreeing that you cannot rule out trauma to the uterus using any standard technique, including thread check or ultrasound).

Plaintiff's causation experts offer no evidence of secondary perforation that is not equally as consistent with delayed detection of primary perforation, nor could they. Because she cannot produce evidence to support a material element of her claims, there is no genuine issue of material fact and Plaintiff's claims should be dismissed.

2. Plaintiff Has Adduced No Admissible Evidence That She Experienced A Secondary Perforation

As with general causation, Plaintiff must put forth admissible medical expert testimony on specific causation to survive summary judgment. *See Wheeler*, 944 F. Supp. 2d at 1352 ("in order to survive summary judgment, Plaintiff must have presented a competent expert who could

testify 'to a reasonable degree of medical certainty' that Zometa caused Mrs. Wheeler's injuries"); *Lawson v. Smith & Nephew Richards, Inc.*, No. CIV.A.4:96-CV0297RWS, 1999 WL 1129677, at *2 (N.D. Ga. Sept. 30, 1999).

Plaintiff designated only one expert to testify as to specific causation – Dr. Roger Young. However, for the reasons detailed in Defendants' Motion to Exclude Dr. Young, his testimony on specific causation is unreliable and should be excluded. *See* Motion to Exclude the Testimony of Dr. Young (MDL-2434, Doc. Nos. 2694-96).

Under Federal Rule of Evidence 702, an expert is not permitted to opine on specific causation, as Dr. Young does, without first establishing general causation by a scientifically valid methodology. *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 436 (S.D.N.Y. 2005). Here, Dr. Young admits that he is not giving a general causation opinion, is not relying on any other Plaintiff expert for his conclusions in Ms. Danley's case, and is simply assuming that secondary perforation happens for purposes of this case. Ex. 18, Young Generic Dep. at 67:23-68:24, 313:9-22; Ex. 16, Young Case-Specific Dep. at 370:10-20, 404:16-406:5. Thus, Dr. Young "rules in" the possibility of secondary perforation in Ms. Danley's case without any reliable evidence that secondary perforation can happen at all. For this reason, and for other reasons outlined in Defendants' Motion to Exclude Dr. Young, his specific causation opinion is unreliable and should be excluded. Plaintiff's claims should therefore be dismissed for failure to provide reliable expert testimony on specific causation.

[redacted]

[redacted]. Her injury occurred at the time of insertion and therefore she did not experience secondary perforation. Defendant is entitled to judgment as a matter of law on all of Plaintiff's claims.

[17] Plaintiff did not seek to exclude these opinions by Defendant's experts in her *Daubert*/Federal Rule of Evidence 702 motion, filed on October 22, 2015.

D. There Is No Genuine Issue Of Material Fact With Respect To Plaintiff's Failure To Warn Claim

Plaintiff claims Bayer failed to warn of the risk of secondary perforation. "To establish a claim for failure to warn, the plaintiff must show the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." *Wheat*, 46 F. Supp. 2d at 1362-63 (citation omitted). As an initial matter, "[t]he duty to warn an end user of a risk associated with product use arises when the manufacturer knows or reasonably should know of a danger arising from product use." *Id.* (citing *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)). As laid out in detail above, Plaintiff cannot present reliable evidence that secondary perforation is a potential risk of Mirena at all. *See supra* at 15-17.

Assuming *arguendo* that secondary perforation is an actual risk of Mirena, Plaintiff's failure to warn claim fails for two additional reasons. First, the Mirena label adequately warns of the risk of perforation. Second, the alleged inadequate warning was not the proximate cause of Plaintiff's injury because Plaintiff's inserting healthcare provider considered the risk of the injury Plaintiff claims to have experienced in her prescribing decision. Plaintiff's failure to warn claim (Count IV) should therefore be dismissed.

1. The Mirena Label Adequately Warns Of The Risk Of Perforation

At the time of Plaintiff's second Mirena insertion, the Mirena label adequately warned her healthcare providers of all clinically relevant risks of perforation. As a result, Defendant did not breach its duty to warn and Plaintiff's failure to warn claim should be dismissed.

In Georgia, "[u]nder the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003). "For a warning to be adequate, it must provide a 'complete

disclosure of the existence and extent of the risk involved.'" *Thornton v. E.I. Du Pont De Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994) (applying Georgia law) (citation omitted).

The 2009 Mirena label in effect at the time of Plaintiff's insertion provides a complete disclosure of the existence and extent of the perforation risk – *i.e.*, that perforation is a risk of Mirena use that may not be detected until after insertion and that monitoring for perforation should continue throughout Mirena use. The label contains a two-paragraph Perforation warning in the Warnings section emphasizing that perforation may be detected after insertion, may result in migration outside the uterine cavity, and may require surgical removal:

5.7 Perforation

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later. If perforation occurs, pregnancy may result *[see Warnings and Precautions (5.1 and 5.2)]*. Mirena must be located and removed; surgery may be required. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.

The risk of perforation may be increased in lactating women, in women with fixed retroverted uteri, and during the postpartum period. To decrease the risk of perforation postpartum, Mirena insertion should be delayed a minimum of 6 weeks after delivery or until uterine involution is complete. If involution is substantially delayed, consider waiting until 12 weeks postpartum. Inserting Mirena immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete.

Ex. 2, 2009 Mirena Label at MIR_INDNDA_00039572-53.

The 2009 Mirena label describes the perforation risk in multiple other places as well:

> If there is a clinical concern and/or exceptional pain or bleeding during ***or after*** insertion, appropriate and timely measures and assessments, for example ultrasound, should be performed to exclude perforation.
>
> * * *
>
> ***Reexamine and evaluate patients 4 to 12 weeks after insertion and once a year thereafter***, or more frequently if clinically indicated.
>
> ***If the threads are not visible,*** they may have retracted into the uterus or broken, or ***Mirena may have broken, perforated the uterus***, or been expelled *[see Warnings and Precautions (5.7 and 5.8)]*. If the length of the threads has changed from the length at time of insertion, the system may have become displaced. Pregnancy must be excluded and the location of Mirena verified, for example, by sonography, X-ray, or by gentle exploration of the uterine cavity with a probe.

Ex. 2, 2009 Mirena Label at MIR_INDNDA_00039750, -754 (emphasis added).

The 2009 Patient Information Booklet – part of the FDA-approved labeling for Mirena and intended to be given to the patient and discussed between the patient and healthcare provider – warns of the perforation risk without any time limitation whatsoever:

> ***Mirena may go through the uterus. This is called perforation.*** If your uterus is perforated, Mirena may no longer prevent pregnancy. It may move outside the uterus and can cause internal scarring, infection, or damage to other organs, and you may need surgery to have Mirena removed.

Id. at MIR_INDNDA_00039766 (emphasis added); MIR_INDNDA_00039761 (instructing provider to give patient the Patient Information Booklet and discuss it prior to insertion).

Finally, the Mirena label instructs healthcare providers to teach patients that the Mirena threads should be checked every month, and that a patient should contact her healthcare provider if she cannot feel the Mirena threads to check if the Mirena is still in the correct location:

> **Should I check that Mirena is in the proper position?** Yes, you should check that Mirena is in proper position by feeling the removal threads. You should do this after each menstrual period. . . . If you cannot feel the threads at all, ask your healthcare provider to check that Mirena is still in the right place.

Id. at MIR_INDNDA_00039765 (emphasis in original); *see also id.* at -761, -767.

Plaintiff's proposed regulatory expert Dr. Suzanne Parisian claims that even with these warnings and instructions, the Mirena label implies that perforation happens only at insertion and does not warn healthcare providers to consider the possibility of perforation months or years after insertion. *See* Ex. 50, Parisian Dep. at 106:9-107:7, 111:14-25, 189:24-190:11, 352:13-353:3. Her labeling opinion is based not on the clinical difference between the injuries that might be caused by differently timed perforations, but rather on "why it's important in the label that a physician be aware that there could be potential injury later, and why they need to be following the woman up." *Id.* at 132:7-20. But Mirena's label has always warned that perforation can be detected subsequent to insertion and that healthcare providers must be

following up with their patients and monitoring for perforation. And it has never suggested that the risk of delayed detection was no longer present after a certain event or period of time.

Indeed, the facts of this very case call Dr. Parisian's "expert" opinion into question. At Ms. Roebuck's deposition, Plaintiff's counsel asked her to compare the original Mirena label from 2000 – which said "[a]n IUD may perforate the uterus or cervix, ***most often during insertion***" – with the 2009 label – which said "[p]erforation or penetration of the uterine wall or cervix ***may occur during insertion***." Ex. 38, Roebuck Dep. at 127:20-128:8; Ex. 1, 2000 Mirena Label, at MIR_INDNDA_00010729; Ex. 2, 2009 Mirena Label, at MIR_INDNDA_0039752. Plaintiff's counsel asked whether "anybody from Bayer [told her] that they had changed the information in the warnings section to say that perforation can only occur at insertion." *Id.* at 128:9-13.[18] Ms. Roebuck rejected the premise of the question, saying that "[n]either one of these say that it can only occur at insertion." *Id.* Despite the changed label language, Ms. Roebuck testified that her understanding of the perforation risk of Mirena has not changed in the 15 years that she has inserted Mirenas since it came on the market. *Id.* at 63:24-64:16.

[redacted] Thus the very actions of Ms. Danley's healthcare providers belie the central assumption underlying Plaintiff's claim – that her healthcare providers were unaware that perforation could manifest remote from insertion.

[18] Plaintiffs have conceded that they think the "most often" language warns of secondary perforation. *See* Plaintiffs' Memorandum of Law in Support of Their Motion to Exclude Expert Testimony (Doc. No. 2703), at 13 (claiming that language "most often during insertion" "acknowledges that secondary perforation can indeed occur after insertion").

The 2009 Mirena label adequately warned about the clinically relevant risks of perforation. This is borne out not only by the label language itself, but by the testimony and actions of Ms. Danley's healthcare providers. As a result, Ms. Danley's failure to warn claim should be dismissed. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) ("If the warning was adequate, the inquiry ends, and the plaintiff cannot recover.").

2. Bayer's Alleged Failure To Warn Was Not The Proximate Cause Of Plaintiff's Injury

Even assuming that the Mirena perforation warning is inadequate, the inadequate warning did not proximately cause Plaintiff's injury because her prescribing healthcare provider considered the potential risk of Plaintiff's claimed injury before making the decision to prescribe Mirena to her. Therefore, her failure to warn claim should be dismissed.

"[A] plaintiff in a products liability action premised on a failure to warn is required under Georgia law to show that the absent or defective warning proximately caused the plaintiff's injury." *Eberhart v. Novartis Pharm. Corp.*, 867 F. Supp. 2d 1241, 1253-54 (N.D. Ga. 2011). "If a plaintiff's treating physician would have taken the same course of action even with a proper warning from the drug manufacturer, then the causal link is broken and the plaintiff is unable to recover." *Id.*; *see also Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002).

Here, Plaintiff can present no evidence that a different warning would have changed Ms. Roebuck's prescribing decision. Indeed, Ms. Roebuck believed at the time that she prescribed Ms. Danley's Mirena that perforation and migration was "***always a risk.***" Ex. 38, Roebuck Dep. at 48:23-49:17 (emphasis added).

Furthermore, Ms. Roebuck, who also participated in the treatment of Ms. Danley after her perforation, acknowledged that at the time of insertion, she knew the risk of ***the very complication that Ms. Danley experienced*** and made her prescribing decision with that

knowledge in mind. *Id.* at 104:4-13. Because Ms. Roebuck had actual knowledge of the injury Plaintiff claims and decided to go forward with the Mirena insertion anyway, Plaintiff cannot recover. *See Wheeler*, 944 F. Supp. 2d at 1353 (Plaintiff cannot recover when "a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided"); *Wheat*, 46 F. Supp. 2d at 1363 (same).

Proximate causation is also called into question by Nurse Roebuck's understanding of the comparative perforation risk between Mirena and ParaGard (the only other IUD on the market in the United States at the time of Ms. Danley's insertion). Beginning in 2005, ParaGard's perforation warning included the sentence, "Spontaneous migration has also been reported."[19] *See* Ex. 51, 2005 ParaGard Label, at 7. In fact, Dr. Parisian claims that the absence of the same warning in Mirena's label makes it inadequate. *See* Ex. 52, Parisian Expert Report at 42-43. Despite this supposed warning of secondary perforation in ParaGard's label for the past 10 years, Ms. Roebuck testified that she believes that the perforation risks of Mirena are the same as those of ParaGard (which she also prescribes). *See* Ex. 38, Roebuck Dep. at 31:7-10, 35:12-36:18.

In light of Ms. Roebuck's testimony, a jury could not reasonably find that a different warning would have changed her prescribing decision. There is no genuine issue of material fact with respect to proximate causation, and as a result, Defendant is entitled to judgment as a matter of law on Plaintiff's failure to warn claim.

E. Defendant Is Entitled To Judgment As A Matter Of Law On Plaintiff's Remaining Claims

Plaintiff cannot present evidence to create a genuine issue of material fact on essential elements of her remaining claims. Those claims should therefore be dismissed.

[19] Plaintiff has used the terms "secondary perforation" and "spontaneous migration" interchangeably.

1. Plaintiff's Design Defect Claim Should Be Dismissed As A Matter Of Law

"In order to prevail on a claim for defective product design, a plaintiff must prove both that the product is defective and that the defect was the proximate cause of the alleged injury." *Folsom v. Kawasaki Motors Corp. U.S.A.*, 509 F. Supp. 2d 1364, 1374 (M.D. Ga. 2007). To determine whether a product has a design defect, Georgia applies the "risk-utility test," wherein the court considers, *inter alia*, "the availability of an alternative safer design" and technological and commercial feasibility of that alternative design. *Wheat*, 46 F. Supp. 2d at 1361. "The burden is on the plaintiff to present evidence that the manufacturer acted negligently by showing the risks inherent in the product's design outweigh the utility or benefit from the product." *Id.* Here, Plaintiff can offer no evidence in support of her design defect claim. There is no evidence that Mirena's risks outweigh its benefits; that a safer alternative design exists; or that Mirena's allegedly defective design proximately caused Plaintiff's injury.

First, every single one of Plaintiff's OB/GYN experts in this litigation acknowledges that the benefits of Mirena outweigh its risks. *See* Ex. 20, Luciani Dep. at 245:20-247:3 (agreeing that he "would be willing to recommend an IUD to a patient even with the belief that secondary perforation of an IUD is possible"); Ex. 21, Strassberg Dep. at 50:19-51:12; Ex. 18, Young Dep. at 95:14-98:7. On this point at least, they are in agreement with the rest of the medical community. *See supra* at 2-3. Plaintiff cannot meet her burden to show that "the risks inherent in the product's design outweigh the utility or benefit from the product" when every one of her OB/GYN experts believes that the benefits outweigh the risks of Mirena. *See Wheat*, 46 F. Supp. 2d at 1361.

Second, Dr. Parisian is the only one of Plaintiff's proposed experts who purported to offer an opinion on safer alternative design. *See, e.g.*, Ex. 52, Parisian Expert Report, at 6.

However, at her deposition, Dr. Parisian refused to stand by the opinion in her expert report, explaining, "I'm just saying that the company could always look for safer alternative design. So I'm not saying that something is." Ex. 50, Parisian Dep. at 341:18-342:2. Even if she were still proposing to opine on a safer alternative design, Dr. Parisian is woefully unqualified to do so. *See* Defs.' Motion to Exclude the Testimony of Dr. Parisian (Doc. Nos. 2685-87), at 10-11. Plaintiff has no evidence that a safer alternative design exists, or that it was technologically or commercially feasible at the time of Ms. Danley's Mirena insertion.

Finally, Plaintiff cannot show that Mirena's alleged defect – whatever it is – proximately caused her injury. Plaintiff's general causation expert claims that secondary perforation is not just a risk of Mirena – it is a risk of ***all IUDs***. *See* Ex. 20, Luciani Dep. at 236:14-237:10. Therefore, Plaintiff cannot credibly claim that if Mirena had an alternative design she would not have experienced the secondary perforation she claims to have experienced with Mirena.

As Plaintiff cannot present evidence supporting any element of her design defect claim, Count II of her Complaint should be dismissed.

2. Plaintiff's Manufacturing Defect Claim Should Be Dismissed As A Matter Of Law

Plaintiff can present no evidence in support of her manufacturing defect claim. In Georgia, "a manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Jones v. Amazing Products, Inc.*, 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002). There is no evidence in the record that Plaintiff's Mirena deviated from manufacturers' specifications, and that that deviation proximately caused her injury. As a result, Plaintiff's manufacturing defect claim (Count III) should be dismissed.

3. Plaintiff's Negligence Claim Should Be Dismissed As A Matter Of Law

Plaintiff's negligence claim (Count I) avers that Bayer is liable for at least 16 boilerplate (and mostly duplicative) types of negligent conduct. *See* Complaint at ¶ 53. In reality, all of Plaintiff's allegations of negligence fall into four categories: failure to test, design defect, manufacturing defect, and failure to warn.

With respect to failure to test, "Georgia does not recognize a cause of action for negligent testing." *Grieco v. Tecumseh Products Co.*, No. 4:12-cv-195, 2013 WL 5755436, at *5 (S.D. Ga. Oct. 23, 2013) (citing *Villegas v. Deer & Co.*, 135 Fed. App'x 279, 281 (11th Cir. 2005)). To the extent that Plaintiff's negligence claim is based on failure to test, it should be dismissed.

With respect to design defect and manufacturing defect, "there is no difference between liability based on strict product liability and liability based on negligence." *Wheat*, 46 F. Supp. 2d at 1365. Therefore, to the extent that Plaintiff's negligence claim is based on design defect or manufacturing defect theories, it should be dismissed for the same reasons described above.

With respect to failure to warn, Plaintiff's claim fails for the same three reasons as her strict liability failure to warn claim: (1) there is no duty to warn, because there is no genuine issue of material fact regarding whether secondary perforation is even a risk of Mirena; (2) there was no breach of that duty, because Mirena's label adequately warned of all clinically relevant risks; and (3) the allegedly inadequate warning did not proximately cause Plaintiff's injuries. *See supra* at 15-17, 20-25; *Mascarenas v. Cooper Tire & Rubber Co.*, 643 F. Supp. 2d 1363, 1375 (S.D. Ga. 2009); *Grieco*, 2013 WL 5755436, at *5. Therefore, to the extent that Plaintiff's negligence claim is based on failure to warn, it should be dismissed.

To the extent Plaintiff argues that her negligence claim is based on any other action or inaction by Bayer, there is no evidence that Bayer breached any duty it had to Plaintiff or her

healthcare providers and there is no evidence that such a breach proximately caused Plaintiff's injuries. As a result, Plaintiff's negligence claim (Count I) should be dismissed in its entirety.

4. Plaintiff's Warranty Claims Should Be Dismissed As A Matter Of Law

Plaintiff pleads causes of action for breach of express warranty (Count V) and breach of implied warranties (Count VI). Setting aside the fact that Plaintiff cannot present any evidence in support of her warranty claims, they fail for two more basic reasons.

First, "[u]nder Georgia law, to recover for a breach of warranty, a plaintiff must show privity between himself and the defendant." *Wheeler v. Novartis*, 944 F. Supp. 2d at 1354 (citation omitted); *see also Gowen v. Cady*, 376 S.E.2d 390, 393 (Ga. Ct. App. 1988) ("'if a defendant is not the seller to the plaintiff-purchaser, the plaintiff as the ultimate purchaser cannot recover on the implied or express warranty, if any, arising out of the prior sale by the defendant to the original purchaser'") (citation omitted). Plaintiff cannot allege that she purchased her Mirena directly from Bayer. Her warranty claims therefore fail for lack of privity.

Second, under the learned intermediary doctrine, Plaintiff is "legally deemed to have relied on [hear healthcare provider's] advice, and not on the package labeling." *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 75 (Ga. Ct. App. 1997). As a result, she "cannot show any breach of warranty caused by inadequate package labeling proximately caused the injury claimed." *Id.* Therefore, Plaintiff cannot show that a warranty, if any existed, proximately caused her injury.

Plaintiff's breach of warranty claims (Counts V & VI) should therefore be dismissed.

5. Plaintiff's Fraud and Misrepresentation Claims Should Be Dismissed As A Matter Of Law

Plaintiff pleads four fraud-based causes of action: fraudulent misrepresentation (Count VII); fraudulent concealment (Count VIII); negligent misrepresentation (Count IX); and fraud

and deceit (Count X). There is no genuine issue of material fact as to any of these claims and they should all be dismissed.

As an initial matter, Plaintiff's fraud claims were not pled with particularity as required by Federal Rule of Civil Procedure 9(b). *See In re Mirena IUD Products Liab. Litig.*, 29 F. Supp. 3d 345, 362 (S.D.N.Y. 2014) (finding similarly-pled fraud claims did not meet the federal pleading standard). Thus, Defendant is not even on notice of what specific conduct Plaintiff alleges to be fraudulent. *See* Complaint at ¶¶ 126-190 (alleging fraud in conclusory fashion).

Nevertheless, whatever Plaintiff's theory of fraud is, she cannot satisfy the elements of her various fraud claims. For example, to the extent that Plaintiff's fraud claims are based on misrepresentations or omissions directed toward her, those claims are foreclosed by the learned intermediary doctrine. "The learned intermediary doctrine bars any claim based upon an alleged failure to warn the patient. . . . It encompasses any claim based upon the failure of the manufacturer to provide the patient with correct or necessary information concerning the use of the product." *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1324 (M.D. Ga. 2011). Among other claims, the learned intermediary doctrine bars fraud, fraudulent concealment, and misrepresentation claims to the extent they are based on representations or omissions directed at a patient. *Id.* (citing *Catlett v. Wyeth, Inc.*, 379 F. Supp. 2d 1374, 1381 (M.D. Ga. 2004)).

In addition, Plaintiff can present no evidence that Bayer made a false representation of material fact (required for fraudulent misrepresentation, negligent misrepresentation, and fraud and deceit) or that Bayer omitted a material fact with intent to defraud (required for fraudulent concealment).[20]

[20] *See Wheat*, 46 F. Supp. 2d at 1364 (describing elements of fraudulent misrepresentation); *Rampura, LLC v. Main & 75 Ctr., LLC*, No. CIVA1:06CV515CAP, 2008 WL 3861203, at *9 (N.D. Ga. Feb. 13, 2008) (fraudulent concealment); *Arch Ins. Co. v. Clements, Purvis & Stewart*,

Finally, Plaintiff cannot establish that she or her healthcare provider relied on any false representation or omission by Bayer. Plaintiff admits that the reason that she had a second Mirena inserted was because "[t]he first one had worked well." Ex. 32, Danley Dep. at 190:11-17. The only thing she claimed to have relied on was her healthcare provider. *See id.* at 155:6-8, 163:18-21. Even if Plaintiff's fraud theory were based on misrepresentations to her healthcare provider, Ms. Roebuck, Plaintiff cannot establish proximate causation because Ms. Roebuck already assumed that secondary perforation is possible and took that risk into account in her prescribing decision. *See* Ex. 38, Roebuck Dep. at 48:23-49:17, 104:4-13. Therefore, there is no genuine issue of material fact with respect to the reliance prong in any of Plaintiff's fraud claims.

Plaintiff's inability to establish the elements in her various fraud claims is not limited to those described above. Plaintiff cannot present any evidence to show that Defendant knew any alleged misrepresentation was false (required for fraudulent misrepresentation, fraudulent concealment, and fraud and deceit); that Defendant intended to induce reliance (required for fraudulent misrepresentation, fraudulent concealment, and fraud and deceit); or that reliance was justifiable or reasonable (required for all claims). There is no genuine issue of material fact with respect to Plaintiff's fraud-based claims (Counts VII-X). As a result, they should be dismissed.

6. Plaintiff's Punitive Damages Claim Should Be Dismissed As A Matter Of Law

Count XI of Plaintiff's Complaint alleges that Defendant is liable for punitive damages. However, punitive damages are "only a form of recovery for certain other claims and cannot stand as a separate cause of action." *Nationwide Capital Corp. v. ADP, Inc.*, No. 1:06-cv-1967-RLV, 2007 WL 2479292, at *4 (N.D. Ga. Aug. 24, 2007); *Fuller v. Home Depot Servs., LLC*,

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P.C., 850 F. Supp. 2d 1371, 1373 (S.D. Ga.) *aff'd*, 434 F. App'x 826 (11th Cir. 2011) (negligent misrepresentation); *Paulk v. Thomasville Ford Lincoln Mercury*, 732 S.E.2d 297, 301 (Ga. Ct. App. 2012) (fraud and deceit).

No. 1:07-cv-1268 RLV, 2007 WL 2345257, at *9 (N.D. Ga. Aug. 14, 2007). Therefore, Plaintiff's punitive damages claim (Count XI) should be dismissed.

In addition, Defendant is entitled to judgment as a matter of law that punitive damages cannot be recovered in this action. Under Georgia law, "'[p]unitive damages may not be recovered where there is no entitlement to compensatory damages.'" *S. Gen. Ins. Co. v. Holt*, 416 S.E.2d 274, 276-77 (Ga. 1992). As explained above, all of Plaintiff's claims for compensatory damages should be dismissed. With no valid claim for actual damages to which Plaintiff's request for punitive damages could attach, that request should be denied as well.

Furthermore, in Georgia, punitive damages "may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to the consequences." O.C.G.A. § 51-12-5.1(b). Even if one or more of Plaintiff's other claims survive, there is no genuine issue of material fact that would allow her to meet this standard.

First, Mirena is one of the safest and most efficacious contraceptive products on the market, and all of Plaintiff's OB/GYN experts agree that its risks outweigh its benefits. *See supra* at 2-3, 26; Ex. 5, Hatcher 2011, at 151-52; Ex. 6, ACOG 2011, at 2. In fact, physicians have criticized Mirena lawsuits as harmful to women's health. *See* Ex. 14, Danvers 2014 at 491.

Second, Plaintiff's experts admit that even as of today, "[s]econdary perforation is a theory" that has "not been proven." Ex. 18, Young Dep. at 136:3-10. Dr. Luciani admits that the theory of secondary perforation is still "in its infancy." Ex. 20, Luciani Dep. at 464:23-465:24. He knows of no evidence, whether it be in "articles, position statements, practice guides, training bulletins, textbooks, abstracts, medical conferences, [or] the whole gamut of scientific thought,"

to support the idea that secondary perforation is generally accepted in the medical community. *Id.* at 463:8-466:8. Plaintiff cannot credibly claim that Defendants engaged in "conscious indifference" when her own experts concede that secondary perforation still has not been established – more than four years after Plaintiff's Mirena insertion.

Third, Plaintiff's unproven theory goes against the teachings of the great majority of the medical and scientific community, with which Bayer stands. *See, e.g.*, Ex. 11, Dean 2013 at 4 ("Perforations diagnosed after the insertion procedure have been attributed to spontaneous IUD migration; although difficult to disprove, we think this explanation is implausible."); Ex. 14, Danvers 2014 (claims of "tearing of the uterus after proper insertion" is "unsubstantiated by science"). Well-regarded textbooks in gynecology state that perforation only occurs at the time of insertion. *See* Ex. 17, Lentz 2012, at 261 ("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."); Ex. 5, Hatcher 2011, at 157 ("Perforation of the uterus can occur at the time of IUC placement; no evidence supports the notion that IUCs can migrate outside the uterus thereafter.").

Finally, even if the risk of secondary perforation exists, it is clinically insignificant in light of the Mirena label's warning that perforation may be detected after insertion. *See supra* at 20-24. Given the undisputed benefit that Mirena provides to society and the hypothetical nature of Plaintiff's secondary perforation theory, Plaintiff cannot conceivably argue that Defendant's conduct rose to a level of "willful misconduct, malice, fraud, wantonness, oppression," or "conscious indifference to the consequences" of its actions. O.C.G.A. § 51-12-5.1(b).

Other MDL courts interpreting a "clear and convincing evidence" standard for punitive damages have granted summary judgment on records with more evidence than exists here. In *In*

re Conagra Peanut Butter Products Liability Litigation, plaintiff sought punitive damages after becoming infected with *Salmonella* due to eating contaminated peanut butter. No. 1:07-MD-1845-TWT, 2014 WL 3767793, at *1 (N.D. Ga. July 30, 2014) In that case, plaintiff claimed she could show at trial that the defendant's peanut roaster was defective and insufficiently sterilized the peanuts, and that defendant was aware that the faulty roaster posed safety hazards. *Id.* at 1. The Court held, under Georgia law, that while plaintiff's evidence might be sufficient to show gross negligence, it was not enough to support punitive damages. Here, Plaintiff cannot even show that Mirena was defective, much less that Bayer knew of and disregarded the defect.

In *In re Fosamax*, like here, plaintiff engaged Dr. Parisian to amass a collection of what she interpreted to be company bad acts. 647 F. Supp. 2d 265, 284-85 (S.D.N.Y. 2009). Plaintiff's primary evidence in support of punitive damages was adverse event reports that Dr. Parisian felt were particularly incriminating. *Id.* The *Fosamax* Court dismissed plaintiffs' punitive damages request, finding that "[t]he adverse event reports upon which Plaintiff relies so heavily do not discuss ONJ, but instead address patients with symptoms and conditions that could possibly, but not necessarily, indicate ONJ." *Id.* at 284. That is exactly the case here. The adverse event reports for Mirena that Dr. Parisian relies on to infer company knowledge of secondary perforation do not, as she asserts, indicate the existence of secondary perforation. Instead, they are nothing more than descriptions of perforation with positive thread checks, purported ultrasound "confirmation" of position, an absence of symptoms at insertion, or merely a long time lapse since insertion – facts that Plaintiff's own experts concede are equally consistent with perforation related to insertion. *See supra* at 15-17; *see also* Defs.' Motion to Exclude the Testimony of Dr. Parisian (Doc. Nos. 2685-87), at 19-22.

Dr. Parisian concedes that Bayer informed the FDA of these reports and about the theoretical possibility of perforation unrelated to insertion in a Benefit-Risk Summary Bayer submitted to the FDA in 2000: [redacted] *See* Ex. 52, Parisian Expert Report at 31-32 (citing Ex. 53, Benefit-Risk Summary, at MIR_INDNDA_00044744). Even Dr. Parisian is not claiming that Bayer failed to provide information to the FDA. *See* Ex. 50, Parisian Dep. at 162:19-163:16. Rather, she claims that Bayer should have, *inter alia*, fought harder to keep language in the label that the FDA crossed out during negotiations. *See* Ex. 52, Parisian Expert Report, at 34-36, 47-50.

Bayer stands with the bulk of the scientific community in finding no reliable evidence that secondary perforation exists and Bayer has not withheld any information from the FDA. If secondary perforation exists, it poses no increased clinical danger to women using Mirena and the theory is by Plaintiff's expert's own admission "in its infancy." There is no "clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to the consequences." O.C.G.A. § 51-12-5.1(b). Because there is no genuine issue of material fact with respect to Plaintiff's request for punitive damages, Defendant is entitled to judgment as a matter of law that punitive damages are not available in this case.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment should be granted, and Plaintiff's claims dismissed in their entirety.

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Respectfully submitted,

/s/ *Shayna S. Cook*

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