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 All Actions

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OMNIBUS MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

INTRODUCTION

This Court excluded Plaintiffs' causation experts because they could not link Mirena to secondary perforation through any scientifically reliable methodology. Without experts who can reliably connect Mirena to secondary perforation, this litigation cannot proceed. Every jurisdiction implicated in this MDL requires that plaintiffs must come forward with admissible expert testimony to meet their burden on such complex, scientific questions. Not surprisingly, courts – including in MDLs overseeing thousands of cases – consistently grant summary judgment when a party cannot introduce scientifically reliable expert evidence on causation. *See, e.g.*, *Meade v. Parsley* No. 2:09-CV-00388, 2010 WL 4909435, at *7-8 (S.D.W. Va. Nov. 24, 2010); *In re Zoloft (Sertralinehydrochloride) Products Liab. Litig.*, No. 12-MD-2342, 2016 WL 1320799, at *10 (E.D. Pa. Apr. 5, 2016); *In re Bausch & Lomb Inc. Contacts Lens Sol. Products Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010).

Plaintiffs have fully recognized this requirement, earlier arguing to the Court that their experts should be allowed to testify because this litigation involved a "complex area requiring specialized knowledge" and thus expert testimony would be "necessary." In an unprecedented about-face, they now contend that they do not require expert evidence of causation at all. In the place of reliable expert testimony, Plaintiffs seek leave to prove their causation claims on these complex medical issues with a hodgepodge of materials – adverse event reports, labeling, foreign regulatory actions, and snippets from company documents and depositions – that neither individually nor collectively can meet their evidentiary burden.

No court has blessed such an approach. Indeed, it is entirely illogical that Plaintiffs could prove complex medical causation through a lawyer's assemblage of documents when experts in the field that the Court otherwise deemed qualified could not establish a reliable causation methodology. For this reason, the Court need not even engage in the exercise of evaluating

Plaintiffs' documents, as every jurisdiction to consider the issue has required expert testimony on scientific causation issues that are beyond the understanding of laypeople. But even taken on the merits, the documents Plaintiffs now point to cannot meet their fundamental evidentiary threshold on general causation.

Unable to prove general causation, or even that secondary perforation occurs, Plaintiffs cannot prove specific causation. Attempting to convert factual testimony from treating physicians into an expert opinion that rules out primary perforation would be improper, and subsequent specific causation experts will not be able to overcome the foundational defects in the specific causation experts this Court has already excluded.

For these reasons, no Plaintiff in this litigation can create a genuine issue of material fact on either general or specific causation. Bayer is therefore entitled to summary judgment.

FACTUAL AND PROCEDURAL BACKGROUND

On April 8, 2013, the Judicial Panel on Multidistrict Litigation centralized Mirena actions alleging secondary perforation here in the Southern District of New York pursuant to 28 U.S.C. § 1407. In doing so, the JPML found that the actions involved common questions of law and fact, including a common issue of general causation. *See* Ex. 2, 4/8/13 JPML Order at 1 (common questions include "the alleged risks of perforation and/or migration").

After the parties engaged in thorough (and extremely expensive) generic fact discovery, they worked up an initial wave of cases through case-specific discovery (the Initial Disposition Pool, or IDP). The parties then participated in extensive generic expert discovery, as well as case-specific expert discovery in the two cases selected for the IDP trial pool: *Danley v. Bayer HealthCare Pharmaceuticals Inc.* (Case No. 13-cv-6586-CS) and *Hayes v. Bayer Healthcare Pharmaceuticals Inc.* (Case No. 14-cv-0288-CS).

Plaintiffs designated a total of seven experts. Two of those experts, Dr. Richard Luciani and Dr. Susan Wray, offered opinions on general causation – that Mirena is capable of causing secondary perforation at the general population level. Two other experts, Dr. Roger Young and Dr. Richard Strassberg, offered case-specific causation opinions in *Danley* and *Hayes*, respectively.

The parties and the Court set up a single wave of generic expert discovery that would apply to the IDP and any subsequent discovery pools. Indeed, the Case Management Order governing the Second Disposition Pool (SDP) explained that "[g]eneric expert reports are governed by CMO 9A," and only provided for permission to file new ***case-specific*** reports in SDP cases. *See* CMO 24A (Doc. No. 2401), ¶¶ 19-20; CMO 9A (Doc. No. 1391), ¶ 9 (all generic expert reports due May 18, 2015). As this Court has recognized, the schedule "doesn't contemplate a second round of generic discovery or expert discovery." *See* Ex. 3, 6/25/14 Conf. Tr. at 10:23-11:3.

On October 22, 2015, Bayer moved to exclude most of Plaintiffs' experts' opinions, including all of their general and specific causation opinions. In response, Plaintiffs emphasized the critical role of their experts' testimony in proving general causation to the jury. Although Plaintiffs withdrew the general causation opinions of Dr. Richard Luciani rather than oppose Bayer's motion to exclude, Plaintiffs emphasized the essential need for expert testimony in defending the opinions of their general causation expert Dr. Wray:

> It is undeniable that understanding how the uterus functions will be critical to the men and women of the jury deciding this case. ***This is a complex area requiring specialized knowledge.*** Dr. Wray, who has spent twenty-five (25) years studying and teaching this subject, will certainly help in this regard. ***Her testimony***, subject to Defendants' cross-examination, ***is paramount in deciding causation***. Therefore, ***Dr. Wray's opinion on the mechanisms of how Mirena perforates the uterus is necessary to assist the trier of fact in their understanding of the evidence and facts at issue***.

Pls.' Opp. to Defs.' Mtn. to Exclude Wray (MD-2434, Doc. No. 2780), at 19 (emphases added). In addition to Defendants' motions to exclude, Plaintiffs also moved to exclude testimony of nine Bayer experts.

On March 8, 2016, the Court issued an Opinion and Order ruling on all pending motions to exclude. *See* 3/8/16 Opinion and Order (MD-2434, Doc. No. 3073) ("*Daubert* Order"). The Court excluded all of Plaintiffs' generic clinical and scientific experts in their entirety, noting that although they were generally qualified, there was no scientifically reliable basis for their opinions. For instance, in excluding the entire testimony of Dr. Wray – Plaintiffs' ***only*** expert remaining in the litigation who offered a general causation opinion – the Court found that she "does not discuss any contradictory evidence, and instead took the occurrence of secondary perforation – the existence of which is the major dispute of this litigation – as a given." *Daubert* Order at 74.

As the Court recognized, the occurrence of secondary perforation is ***not*** a given. To the contrary, the consensus in the medical community, as reflected by leading medical organizations and textbooks, is that perforation happens only at the time of or related to insertion. *See, e.g.*, Ex. 5, Robert A. Hatcher et al., *Contraceptive Technology* 151 (20th ed. 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. 6, Gretchen Lentz et al., *Comprehensive Gynecology* 261 (6th ed. 2012) ("Perforation always occurs at the time of insertion.").

In addition to excluding Dr. Wray, the Court excluded the specific causation opinions of Plaintiff experts Dr. Young and Dr. Strassberg. As a result, Plaintiffs have no admissible expert causation testimony to present at trial.

After the *Daubert* ruling, the Court invited the parties' views on the course forward for this MDL in light of the exclusion of Plaintiffs' causation experts. The Court's comprehensive *Daubert* decision prompted Plaintiffs to reverse course. Abandoning their earlier acknowledgement that expert testimony would be "paramount in deciding causation," Plaintiffs now dismissively characterize scientific experts as "not essential" to prove scientific causation. Ex. 7, Pls.' 3/22/16 Ltr. at 2. Ignoring the uniform national law requiring an expert to sponsor opinions on complex medical questions, Plaintiffs would replace expert testimony on general causation with a hodgepodge of materials sponsored only by the lawyers. At the same time, they now suggest that they can meet their specific causation burden for future plaintiffs through unreliable testimony from their healthcare providers or through additional specific causation experts. *Id.* at 7-8.

Given the absence of any admissible expert opinion on the core questions of medical causation, Defendants requested leave to file an Omnibus Motion for Summary Judgment on causation. The Court granted Defendants' request, and also requested that Defendants produce a survey of the law as to the necessity of expert testimony to establish causation in complex medical cases. That survey is appended here, and confirms that every jurisdiction implicated here requires that a plaintiff come forward with admissible expert testimony to prove causation.

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 N.Y.*, 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).

Where the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial[,] . . . there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322-23. Thus, if "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof," the moving party is entitled to a judgment as a matter of law. *Id.* at 323.

ARGUMENT

Causation is a required element in every personal injury action. *See In re Bausch & Lomb*, 693 F. Supp. 2d at 520. To establish causation in a pharmaceutical product liability case, plaintiffs "must offer admissible expert testimony regarding both general causation . . . and specific causation." *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002). "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 378 (5th Cir. 2010). Notably, "a plaintiff must establish general causation before moving to specific causation." *Id; see also Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005).

In these cases, the Court has determined that Plaintiffs have failed to introduce any reliable expert evidence on general causation. This failure by itself should end the litigation, supporting entry of summary judgment on Plaintiffs' claims. The Court's *Daubert* Order also forecloses the possibility that Plaintiffs can proffer reliable specific causation expert evidence. Defendants are therefore also entitled to summary judgment on that ground as well.

I. SUMMARY JUDGMENT IS REQUIRED WHEN PLAINTIFFS LACK EXPERT TESTIMONY ON GENERAL CAUSATION

In cases involving complex medical issues, plaintiffs must demonstrate general causation through expert testimony. As set forth in the attached Appendix prepared at the Court's request, the nationwide law is uniform that expert testimony is an essential element to satisfy a plaintiff's burden of proof in cases involving complex issues of medical causation,. *See* Ex. 1, Appendix summarizing the law on medical causation for 53 jurisdictions in the United States. This case, which involves allegations of an "unproven" injury and "complicated" mechanism of injury, is no exception. *See Daubert* Order at 19.

As a general matter, "expert testimony is required to establish causation" in personal injury cases where the question of causation is "beyond the knowledge of the lay juror." *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004); *see also Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1214 (10th Cir. 2004); *Green v. Ensign-Brickford Co.*, 595 A.2d 1383, 1388 (Conn. 1991); *Waller v. Indus. Comm'n*, 406 P.2d 197, 200 (Ariz. 1965); *Stephen v. Ford Motor Co.*, 37 Cal. Rptr. 3d 9, 17 (Cal. Ct. App. 2005). The need for expert testimony applies not only to toxic tort cases, but to all "[p]ersonal injury cases involving pharmaceuticals, toxins or medical devices [that] involve complex questions of medical causation beyond the understanding of a lay person." *In re Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004); *see, e.g.*, *Fane v. Zimmer, Inc.*, 927 F.2d 124, 131 (2d Cir. 1991) ("[The] device implanted in

[plaintiff] was not one with which an ordinary person would come in contact. The issue of causation in such a complicated medical case, therefore, was one beyond the sphere of the ordinary juryman and required expert testimony."); *Disher v. Synthes (U.S.A.)*, 371 F. Supp. 2d 764 (D.S.C. 2005) (medical expert testimony needed to prove causation in action arising out of fracture of implanted device).

This case does not represent some special exception to this general and broadly applicable rule. Because any claim of primary perforation during insertion would run headlong into Bayer's indisputably clear warning, Plaintiffs by necessity have focused their claims exclusively on the notion of "secondary perforation." *See, e.g.*, Ex. 8, Heather Keller Am. Compl. at 5. The Court has accordingly recognized that the question of whether Mirena causes secondary perforation "is at the heart of [the] dispute." *See Daubert* Order at 6. That question necessarily focuses on scientific questions beyond the understanding of lay jurors, as was amply demonstrated in the lead up to the Court's *Daubert* ruling.

Before their experts were excluded, Plaintiffs' actions reflected the recognition that this dispute involved "a matter of science that is far removed from the usual and ordinary experience of the average person." *Swallow v. Emergency Medicine of Idaho, P.A.*, 67 P.3d 68, 77 (Idaho 2003) (affirming summary judgment absent expert testimony establishing general causation). Plaintiffs hired a range of experts to meet their burden of proof on general causation, and their own *Daubert* briefs emphasized the scientific nature of the case and the importance of expert testimony to causation. *See, e.g.*, Pls.' Opp. to Defs.' Mtn. to Exclude Wray (MD-2434, Doc. No. 2780), at 19 (emphasizing that case involved ***"a complex area requiring specialized knowledge***" making expert testimony "***paramount in deciding causation***" and "***necessary to assist the trier of fact***") (emphases added).

Plaintiffs' candid recognition of the complex nature of the causation question in this case is hardly surprising, as causation here is far from "a matter of common sense or everyday experience." *Hendrian v. Safety-Kleen Systems, Inc.*, 2015 WL 4770966, at *4 (E.D. Mich. 2015). Setting aside their clear methodological failures, the reports by Plaintiffs' experts demonstrate that proof of secondary perforation requires an understanding of anatomy and physics, including the makeup of the various layers of the uterine wall, how uterine muscles work, and the way Mirena affects the uterus. Indeed, Plaintiffs' experts relied on complex biochemical and physical properties in their failed attempts to postulate how Mirena might perforate the uterus independent of an external force at insertion causing some damage. For example, Dr. Wray proposed numerous mechanism theories addressing the "contractile forces of the uterus," the effects of the hormone levonorgestrel on the endometrium, and the "elevation of prostaglandins and cytokines as a consequence of hormonal changes and inflammation reactions in response to Mirena." Ex. 9, Wray Expert Report, at 25-28. Similarly, Dr. Young's mechanism theory for secondary perforation alleged "chemical changes of the lining on the uterus" due to levonorgestrel and involved mathematical calculations of the claimed forces exerted by a Mirena during uterine contractions. Ex. 10, Young Expert Report, at 11-16. To measure such forces, Plaintiffs even retained an expert to conduct experiments with laboratory equipment intended to mimic the uterus. Ex. 11, Jarrell Expert Report, at 10-11, 22.

The fact that expert testimony is necessary here is reinforced by Plaintiffs' definition of secondary perforation, which involves no injury to the uterus at the time of insertion – an admittedly theoretical phenomenon. Ex. 12, Wray Dep. at 55:24-56:19 (confirming that a "small nick to the endometrium that leads to perforation would be a primary perforation"). Plaintiffs' proffered experts admitted that even sophisticated imaging may not rule out uterine damage at

insertion. *See* Ex. 13, Young Dep. at 163:6-9 ("Q. So with a 2D ultrasound you can't detect whether the arm is embedded in the myometrium, correct? A. Yes."); *see also* Ex. 14, Luciani 9/2/15 Dep., at 37:17-38:3 ("I would defy any physician in the world to rule that out since there is no available modality that you could rule out that there was some slight damage to the endometrium during the insertion of any foreign body into the uterus"). And as the Court recognized, uterine perforations are often asymptomatic. *See Daubert* Order at 52; *see also* Ex. 12, Wray Dep. at 230:16-22 ("A lack of clinical symptoms does not rule out a perforation, yes.").

Expert testimony is required in this context because, even if the mechanical act of one object perforating another may be understandable by laypersons, whether uterine perforation can occur "spontaneously" (independent of insertion) is not. *See Howerton v. Pfaff*, 425 P.2d 533, 537 (Or. 1967) ("We agree that 'ordinary hernia' is within the common knowledge of laymen, but there is a wide difference between determining whether an injury 'actually exists,' and its cause.") (citation omitted). Indeed, the Court has acknowledged "the complicated medical nature of Mirena and its effects" and admitted the testimony of Bayer's medical experts as "helpful to the trier of fact" precisely because "they relate to a technical, medical issue that would be beyond the ken of a lay person." *Daubert* Order at 24, 34.

Because the general causation issue in this litigation necessarily involves expert opinion on the mechanism and timing of uterine perforations, which a layperson cannot determine based on her own experience, Plaintiffs cannot evade their expert testimony obligation by insisting that their unproven secondary perforation theory is more akin to a "mechanical injur[y]" from a car crash than a "biochemical injury" from a pharmaceutical product.[1] Ex. 4, Pls.' 3/30/16 Ltr.

[1] And even if Plaintiffs' car crash analogy were apt here, a car accident case that "does not involve a sudden onset, visible injury, or an injury that as a matter of common knowledge follows the act" requires expert medical testimony to establish causation. *Harris v. Washington*,

(Doc. No. 3106) at 3; *see also* Ex. 15, 4/5/16 Conf. Tr. at 9:20-21. As the Court itself intuitively recognized, this case is "not like [causation questions in] a car crash." Ex. 15, 4/5/16 Conf. Tr. at 24:20. Instead, the causation inquiry here is complicated because the injuries themselves are often not immediately obvious, and how the injury occurred – the central causation question in this litigation – is certainly not within a layperson's understanding. *See Hamil v. Bashline*, 392 A.2d 1280, 1285 (Pa. 1978) ("[I]t is generally acknowledged that the complexities of the human body place questions as to the cause of pain or injury beyond the knowledge of the average layperson.").

It is thus wholly unsurprising that courts proceed in exactly the opposite way that Plaintiffs urge the Court to proceed here, routinely holding that summary judgment is appropriate when plaintiffs fail to offer reliable expert testimony.[2] This includes cases where entire classes of MDL plaintiffs have been appropriately dismissed when they were unable to proffer experts on general causation.

For example, plaintiffs' inability to proffer the required expert testimony on causation between a contact lens solution and certain bacterial eye infections in *Bausch & Lomb* brought most arms of the MDL litigation to a swift end. *In re Bausch & Lomb Inc.*, 693 F. Supp. 2d at

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654 S.W.2d 303, 306 (Mo. Ct. App. 1983); *see also Roache v. Charney*, 38 A.3d 281, 286 (Del. 2012) (citations omitted) (noting that expert testimony is required to prove causation in a personal injury action relating to a car accident).

[2] *See Rutigliano v. Valley Business Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996) (holding that defendant manufacturers were entitled to summary judgment based on lack of admissible general causation expert testimony); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1485 (D.V.I.), *aff'd*, 46 F.3d 1120 (3d Cir. 1994) (granting summary judgment for manufacturer in part because "Plaintiff's expert opinion evidence regarding general causation is insufficient"); *Ronwin v. Bayer Corp.*, 332 F. App'x 508, 514 (10th Cir. 2009) (affirming district court's conclusion that "absent expert testimony on causation, summary judgment was appropriate"); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009) (granting summary judgment for defendant manufacturer because "absent an admissible general causation opinion, Plaintiffs' claims necessarily fail").

518-19. Following the "well-established rule requiring proof of general causation," the court granted summary judgment against all but one class of plaintiffs upon determining that its *Daubert* ruling excluded their only general causation expert. *Id.* The court's in-depth review of law from more than forty jurisdictions left no doubt that "the concept of general causation" is a "necessary precursor to proving specific causation . . . in all jurisdictions." *Id.* at 518. Consequently, plaintiffs were foreclosed from offering specific causation expert testimony as an "end-run around the general causation requirement." *Id.* at 520; *see also In re Zoloft*, 2016 WL 1320799, at *10 (entering summary judgment against hundreds of plaintiffs after excluding their general causation experts under *Daubert*).

In the aftermath of the Court's *Daubert* ruling, Plaintiffs have no experts who can reliably testify as to general causation. Without the required expert testimony demonstrating that Mirena is capable of causing secondary perforation, Plaintiffs' claims fail as a matter of law and this litigation should come to an end.

II. PLAINTIFFS CANNOT CURE THEIR EXPERTS' LACK OF RELIABLE METHODOLOGY WITH EVEN LESS RELIABLE EVIDENCE

Left with no admissible expert testimony on general causation, Plaintiffs propose an unprecedented course: abandon expert testimony altogether and in its place substitute a lawyer proffer of an assortment of internal documents, adverse event reports, regulatory materials, and snippets from company depositions that they mischaracterize as "admissions." As a threshold matter, no court has ever sanctioned such an approach, which would effectively swap out the unreliable methodology of an expert with even less reliable lawyer advocacy. The law is clear that the Court need not even engage on this tactic, as the absence of expert testimony is the beginning and end of the inquiry.

Indeed, it would turn *Daubert* on its head if Plaintiffs could avoid the import of this Court's ruling by simply replacing their inadmissible scientists with little more than a lawyer's compilation of snippets and sound bites. The Court found that Plaintiffs' experts were qualified, but it found that they had not used a reliable methodology to find secondary perforation. It would be profoundly nonsensical to hold that qualified experts cannot construct a reliable methodology for linking Mirena to secondary perforation, but lawyers can instead ask a jury to infer causation from an assortment of loosely strung together statements in documents and depositions untethered to any witness and unexplained by any qualified expert.

This outcome would be particularly perverse when Plaintiffs' core "admission" materials hinge on spontaneous adverse event reports: these reports – and the uncertainty inherent in interpreting such uncontrolled data – were the subject of the internal emails, the interaction with regulatory bodies, and the selected testimony cited by Plaintiffs. If, for example, Dr. Wray (whom the Court otherwise deemed qualified) cannot reliably discern causation from adverse event reports or peer-reviewed published case reports – which the Court properly rejected – then labeling, regulatory correspondence, and employee depositions arising from these reports cannot somehow be melded together through some unexplained lawyer alchemy to prove causation.

In short, Plaintiffs' request that they be allowed to present to the jury an *even less scientifically sound* presentation than the one the Court rejected as unreliable simply cannot be squared with this Court's *Daubert* ruling. The Court excluded Plaintiffs' experts from opining on causation because their methodologies were "not sufficiently reliable under *Daubert* and would not stand up in a scientific setting." *Daubert* Order, at 85. Plaintiffs' attempt to move forward with a subset of alleged "admissions" – without any veneer of the expert analysis

Plaintiffs previously deemed "paramount" – is fundamentally at odds with the Court's *Daubert* ruling and the Federal Rules.

III. PLAINTIFFS MISCHARACTERIZE THE EVIDENCE THEY CITE, AND IT IS INADMISSIBLE

Even if Plaintiffs could persuade the Court to ignore the uniform law requiring a causation expert, and even if they could persuade the Court to ignore the implications of its own *Daubert* ruling, their "admissions" argument fails on its face: (1) Plaintiffs mischaracterize the evidence they cite as Bayer "admissions" of secondary perforation; and (2) the documents and testimony they rely on are inadmissible and cannot be considered on a motion for summary judgment.

A. Plaintiffs Have Presented No Evidence Of General Causation

None of the non-expert "evidence" Plaintiffs cited in their March 22, 2016 letter creates a genuine issue of material fact. First, the four IUD labels cited by Plaintiffs are not evidence of general causation, because the FDA standard for prescription drug labeling is far different (and lower) than the Plaintiffs' burden on general causation and because the labels do not concede causation. Second, Plaintiffs cite multiple documents that do nothing more than summarize adverse event reports, which under case law and the FDA's own guidelines are not evidence of general causation (as both this Court and Plaintiffs' experts must and have acknowledged). Finally, Plaintiffs' remaining evidence – much of which they grossly misinterpret – does not create a genuine issue of material fact as to general causation.

1. Labels are not evidence of general causation

Plaintiffs argue that four drug labels – the 2014 Mirena label, the 1997 and 2005 ParaGard IUD labels, and the 1987 Progestasert IUD label – are evidence that secondary perforation exists.

At the outset, Plaintiffs ignore a critical distinction recognized by courts across the country: "the FDA often uses a different standard than a court does to evaluate evidence of causation in a products liability action." *In re Neurontin Mktg., Sales Practices, & Products Liab. Litig.*, 612 F. Supp. 2d 116, 136 (D. Mass. 2009); *see also* 21 C.F.R. 201.57(c)(6)(i) (requiring "reasonable evidence of a causal association" to provide warning); *Daubert* Order at 119 & n.74 (recognizing FDA standard); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) ("The FDA evaluates pharmaceutical drugs using a different standard than the causation standard at issue in the present case."); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1370 (N.D. Ga. 2001) ("The standard by which the FDA deems a drug harmful is much lower than is required in a court of law. The FDA's lesser standard is necessitated by its prophylactic role in reducing the public's exposure to potentially harmful substances."), *aff'd sub nom. Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 513 (W.D. Pa. 2003) ("[T]he decisions made in the regulation of pharmaceutical companies do not necessarily reflect methodologies or conclusions considered acceptable in the scientific arena and are not necessarily based on the scientific method. . . . Plaintiff's experts have themselves admitted that FDA decision-making is based on a different standard than tort law-based scientific proof of causation."). As even Plaintiffs' proffered expert admits, FDA regulations set a fundamentally different (and lower) bar for when a warning must be included in a drug's label than the burden Plaintiffs bear to prove general causation here. *See* Ex. 16, Parisian Dep. at 88:1-89:4 ("***Causation isn't the standard for updating your label***; it's an association. . . . ***it's not scientific causation; it's basically an association that you can't show that your drug is not involved***.") (emphasis added).

The sole case that Plaintiffs cite for the proposition that prescription drug labels may serve as an "admission" sufficient to prove general causation is an outlier and actually reinforces that the labels in this case are not admissions. *See* Ex. 7, Pls.' 3/22/16 Ltr. at 3-4 (citing *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004)). While the district court in *Meridia* suggested that a clear admission in labeling *might* be sufficient to prove general causation, the warning language at issue in that case stands in stark contrast to the Mirena warning in this case. The *Meridia* warning was explicit: "MERIDIA SUBSTANTIALLY INCREASES BLOOD PRESSURE IN SOME PATIENTS." *In re Meridia*, 328 F. Supp. 2d at 810. As the Court of Appeals noted, this stark language was unique because it differed from more common regulatory language expressing some uncertainty about causation. *See Meridia Products Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 866 (6th Cir. 2006) ("The [trial] court contrasted the strong language of 'substantially increases' with milder warning language such as 'is associated with.'").

Unlike in *Meridia*, the 2014 Mirena label does not explicitly state that Mirena causes secondary perforation. It merely states: "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." Ex. 28, 2014 Mirena Label, at 13. The language of the Mirena label reflects an acknowledgement of a proposition with which all the experts in this case agree: a partial perforation of the uterine wall may occur at insertion, but may not become a complete perforation (*i.e.*, go through all three layers of the uterus) until after insertion, and that does not constitute a secondary perforation. *See, e.g.*, Ex. 12, Wray Dep. at 262:15-263:2; Ex. 13, Young Dep. at 159:15-21. Indeed, Plaintiffs admit that the so-called "admission" in the label is only "veiled and indirect"; *i.e.*, ***not***

an admission. Ex. 7, Pls.' 3/22/16 Ltr. at 3-4. Plaintiffs' suggestion that the 2014 Mirena label can help lay jurors determine general causation – without the aid of any scientific expert – lacks any support.

In addition to the obvious factual difference between this case and *Meridia*, it bears noting that the *Meridia* court's reliance on labeling to prove causation had no precedent under state law, as the *Meridia* court itself recognized: "that the Meridia label and internal company documents reveal [d]efendants' recognition that Meridia has the capacity to cause injury . . . is a novel argument, and it creates an issue of first impression for this Court." *In re Meridia*, 328 F. Supp. 2d at 808. The Court could entertain this "novel argument" only through the unusual and counter-factual assumption that no state law imposed a requirement for expert testimony. *Id.*; *see also In re Meridia*, 447 F.3d at 865 (noting that district court had assumed the most favorable view of the law for the plaintiffs, including that "rather than inquire into whether any state requires expert testimony as to causation, the court 'assume[d] *arguendo* that no states' laws erect such a requirement"). As demonstrated above and in the survey of jurisdictions attached hereto, that is simply not the law. *See* Ex. 1, Appendix. Unsurprisingly, no court has come close to adopting such an expansive reading of *Meridia* that Plaintiffs advocate here. To the contrary, cases addressing the issue demonstrate that Plaintiffs' interpretation of *Meridia* is unsupported. *See, e.g.*, *Meade v. Parsley*, No. 2:09-CV-00388, 2010 WL 4909435, at *7 (S.D.W. Va. Nov. 24, 2010) (noting that "Plaintiffs cite no authority for the proposition that a plaintiff in a pharmaceutical products liability case can satisfy his burden of proving general causation by relying on the defendant manufacturer's drug label warnings [and that] this contention is undermined by the general principle that causation evidence in toxic tort cases must be in the form of expert scientific testimony.").

Lewis v. Johnson & Johnson, which the Court brought to the parties' attention during the April 5, 2016 hearing, also fails to support Plaintiffs' contention that non-expert evidence can establish general causation. 601 F. App'x 205 (4th Cir. 2015). In affirming summary judgment due to plaintiff's failure to present expert testimony on causation, the court in *Lewis* did not hold that testimony from defendant's employees could prove causation; it only noted in dicta that plaintiff had not presented such evidence. *Id.* at 212. The court emphasized that "[i]n a products liability case, proof other than expert testimony provides sufficient evidence of causation only when a layperson's general experience and common understanding would enable the layperson to determine from the evidence, with reasonable probability, the causal relationship between the defect and the injury." *Id.* at 210-11. As Plaintiffs and the Court have acknowledged, the theory of secondary perforation is beyond the common understanding of a layperson, so this hypothetical discussion in dicta is not applicable to this MDL.

The ParaGard and Progestasert IUD labels are even further afield from any causation admission. Bayer does not manufacture these products and has no role in their labeling. Therefore, their labels cannot constitute admissions by Bayer. Furthermore, these other IUD labels are the result of data and regulatory interactions not before this Court and would require expert testimony to link them to Mirena. These labels thus do nothing to meet Plaintiffs' burden to survive summary judgment on general causation.

2. Adverse event reports are not evidence of general causation

Several of Plaintiffs' proposed general causation exhibits are internal company documents discussing individual adverse event reports, which cannot serve as evidence of causation in this action. Indeed, the FDA itself has stated that in adverse event reports, "there is no certainty that the reported event (adverse event or medication error) was actually due to the product" because the "FDA does not require that a causal relationship between a product and

event be proven, and reports do not always contain enough detail to properly evaluate an event." *See* Ex. 29, Questions and Answers on FDA's Adverse Event Reporting System (FAERS), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ (last visited May 4, 2016). Adverse event reports "reflect complaints called in by product consumers without any medical controls or scientific assessment." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005). "Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation." *Id.* Bayer company employees routinely review such reports to evaluate the safety of Bayer medicines. Communications generated in the course of this process, summarizing adverse event reports received from third parties and raising questions, represent responsible discourse among pharmaceutical company employees, but cannot meet Plaintiffs' burden of proof on general causation.

For this reason, Judge Rufe recently held in the *Zoloft* MDL that while adverse event reports "are certainly relevant to the generation of study hypotheses, [they] are insufficient to create a material question of fact on general causation." *In re Zoloft*, 2016 WL 1320799, at *9. Even in the *Meridia* case on which Plaintiffs so heavily rely, the court rejected the argument that adverse event reports (and the company's apparent causality assessments related to those reports) created an issue of material fact as to general causation. *See In re Meridia*, 328 F. Supp. 2d at 809-10 (recognizing that "internal [company] documents do not represent conclusions").

Indeed, as made clear by the FDA, Plaintiffs' own experts must agree that adverse event reports cannot prove causation. Plaintiffs' regulatory expert Dr. Parisian admits that "[a]n 'adverse event' is defined as any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of a medicinal product, ***whether or not considered related to***

a product. ***Proof of causality is not necessary for reporting adverse events***." Ex. 17, Parisian Report at 20 (emphasis added). Plaintiffs' epidemiology expert Dr. April Zambelli-Weiner similarly admits that "spontaneous adverse event reports do not establish causation between an exposure and an adverse event" and specifically that "the case reports and the spontaneous adverse event reports with Mirena do not establish that Mirena causes secondary perforation." Ex. 18, Zambelli-Weiner Dep. at 86:9-23.[3]

This case law and these facts are fatal to much of Plaintiffs' so-called admissions. [redacted] The emails ***do not*** give any opinions or admissions regarding secondary perforation. [redacted] At most, these documents "demonstrate that [Bayer] employees raised questions about associations between [Mirena] and [secondary perforation] and

[3] This Court reached a similar conclusion in its *Daubert* Order, rightly pointing out the inherent unreliability of individual case reports – which are merely reviewed and published accounts of individual adverse events like those relied on by Plaintiffs here – in rejecting Plaintiffs' expert Dr. Wray's opinion, which was based on these types of materials. *See Daubert* Order at 77-78 ("Case reports are generally disfavored by courts as evidence of causation because . . . '[they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.'") (citation omitted). As this Court held, "[w]ithout something more to show that these studies actually involve secondary perforation, as opposed to a primary perforation that was detected later, Dr. Wray appears to be relying upon her *ipse dixit*, which is not a reliable ground for a scientific opinion." *Id.*

discussed possible changes to the product label, generally without reaching conclusive findings.[4] The documents may be relevant to questions of [Bayer]'s knowledge and actions if [Mirena] were found to cause [secondary perforation], but do not raise a genuine issue of material fact as to causation." *In re Zoloft*, 2016 WL 1320799, at *9.

When Dr. Wray relied on published case reports that she asserted establish "secondary perforation, as opposed to a primary perforation that was detected later," this Court held that she connected the data to her conclusions by "relying upon her *ipse dixit*." *Daubert* Order at 78. Plaintiffs now seek permission to have jurors do what Dr. Wray was not permitted to do – use unreliable data to speculate baselessly on general causation. If experts that the Court deemed qualified cannot rely on peer-reviewed, published case reports to opine on causation, lay jurors certainly cannot be charged with interpreting emails discussing spontaneously reported cases to find causation. The summaries of adverse event reports that Plaintiffs proffer do not provide evidence that secondary perforation exists and do not create a genuine issue of material fact as to general causation.

3. Plaintiffs misinterpret evidence they claim is sufficient to show general causation

The remainder of Plaintiffs' proffered evidence is also insufficient to create a genuine issue of material fact on general causation.

[redacted]

[4] The same limitations of case reports provides an additional reason why the Paragard labels are far from "compelling evidence" of secondary perforation: those labels only vaguely state that "***[t]here are reports*** of IUD migration after insertion" and "[s]pontaneous migration ***has also been reported***." *See* Ex. 7, Pls.' 3/22/16 Ltr. at 6-7 (citing Ex. 21, 1997 ParaGard Label and Ex. 22, 2005 ParaGard Label) (emphasis added).

[redacted] Plaintiffs' misinterpretation of this document, which discusses complex medical concepts, demonstrates the peril of presenting internal company documents addressing scientific issues to lay jurors and inviting them to speculate on their import. This Court already rejected this precise type of speculation from Plaintiffs' expert Dr. Wray. *See Daubert* Order at 76 ("While these are examples of 'myometrial activity transporting things beyond the uterus,' she provides no reason to think that the movement of bodily fluids through anatomical pathways toward anatomical openings would shed any light on whether a plastic object could penetrate the muscular myometrium in the absence of any preexisting damage to that wall.") (citation omitted). Where experts the Court deemed qualified were not permitted to make this unsupported scientific leap, it would be improper for Plaintiffs to invite lay jurors through the use of these documents to make a similar scientifically unreliable conclusion.

Plaintiffs also misinterpret [redacted]

[redacted] Plaintiffs must prove that secondary perforation exists ***more likely than not***. Evidence that casts general causation in terms of possibility, rather than probability, cannot create an issue of material fact. *See Jund v. Town of Hempstead*, 941 F.2d 1271, 1286 (2d Cir. 1991) ("A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant.") (citation omitted); *see also ExxonMobil Oil Corp. v. Amex Const. Co.*, 702 F. Supp. 2d 942, 965 (N.D. Ill. 2010) ("'mere speculation cannot create questions of fact' and '[o]pinions expressing a mere possibility with regard to a hypothetical situation are insufficient to establish a genuine issue of material fact'") (quoting *Beatty v. LaFountaine*, 896 N.E.2d 16, 20 (Ind. Ct. App. 2008)).

Similarly, Plaintiffs seek to offer snippets of deposition testimony of [redacted] Once again, "[a] mere possibility of such causation is not

enough." *See Jund*, 941 F.2d at 1286. This Court carefully evaluated and rejected a detailed but untested articulation of the secondary perforation theory when it was offered by Plaintiffs' experts. *See, e.g.*, *Daubert* Order at 74 (recognizing that Dr. Wray engaged in "at most, scientifically-grounded speculation"). Plaintiffs can fare no better by relying on a company witness's passing acknowledgement of a "possibility."[5]

Finally, none of the remaining documents that Plaintiffs cite touch upon the ultimate general causation issue in this litigation – ***whether Mirena can perforate the uterus when there is no injury to the uterine lining at the time of insertion***. *See* Ex. 10, Young Expert Report, at 11 (describing as a prerequisite for secondary perforation that the "IUD is correctly placed within the uterine cavity, with no disruption of the endometrial layer"); Ex. 12, Wray Dep. at 55:24-56:19 (confirming that a "small nick to the endometrium that leads to perforation would be a primary perforation").

By characterizing these documents as "proof" that Mirena caused secondary perforation, Plaintiffs ask this Court, and intend to eventually ask lay jurors, to go beyond the four corners of these documents and infer without any evidence that the authors intended them to describe an admittedly unproven and probably unprovable theory of secondary perforation. In the face of unrebutted expert testimony by Bayer's experts, there is simply not enough evidence for a rational juror to find that secondary perforation – as Plaintiffs define it – exists.

B. Plaintiffs' Purported Evidence Of General Causation Is Inadmissible

Much of the evidence Plaintiffs rely on in support of general causation is inadmissible under the Federal Rules of Evidence. Plaintiffs cannot rely on these documents to survive summary judgment, since "[i]t is well settled that the evidence considered in connection with a

[5] It would be particularly inappropriate to allow reasonable scientific discourse to be falsely construed as an "admission."

summary judgment motion must be admissible at trial." *Dabney v. Christmas Tree Shops*, 958 F. Supp. 2d 439, 451 (S.D.N.Y. 2013) (Seibel, J.), *aff'd sub nom. Dabney v. Bed Bath & Beyond*, 588 F. App'x 15 (2d Cir. 2014).

1. Most of Plaintiffs' evidence is inadmissible hearsay

The majority of Plaintiffs' purported evidence is inadmissible hearsay. The most straightforward examples are the ParaGard and Progestasert IUD labels, the 2006 BfArM Letter, and the 2010 Health Canada Letter. All of these documents are out-of-court statements from third parties[6] that Plaintiffs offer to prove the truth of the matters asserted therein. *See* Fed. R. Evid. 801-802. Plaintiffs, as the proponents of the evidence, have the burden to show either that the statements were "made by a person whom [a] party authorized to make a statement on the subject" or were "made by [a] party's agent or employee on a matter within the scope of that relationship and while it existed." Fed. R. Evid. 801(d)(2)(C)-(D).[7] They cannot do this.

In addition, Plaintiffs offer several documents that describe and summarize adverse event reports, which, as discussed above, "reflect complaints called in by product consumers without any medical controls or scientific assessment." *McClain*, 401 F.3d at 1250. But "AERs [adverse event reports] are inadmissible hearsay when offered to prove the truth of the matter asserted: in this case, that a particular drug product is associated with the adverse event the report describes."

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[6] Neither ParaGard nor Progestasert is manufactured by Bayer. BfArM is the German regulatory authority. The 2010 Health Canada Letter was not written by a party to these actions, but rather by Canadian entity Bayer Inc.

[7] To the extent Plaintiffs argue the 2010 Health Canada Letter falls under one of these exceptions, they would have to establish that Bayer Inc. was acting as an agent of one of the parties when it sent the letter to Canadian healthcare providers: "the proponent of the evidence must establish the existence of an agency relationship between the parent and the subsidiary under the applicable principles of agency law." *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 505 F. Supp. 1190, 1247 (E.D. Pa. 1980) *aff'd in part, rev'd in part on other grounds sub nom. In re Japanese Elec. Products Antitrust Litig.*, 723 F.2d 238 (3d Cir. 1983). Plaintiffs have adduced no evidence to make such a showing here. The 2010 Health Canada Letter is therefore inadmissible hearsay.

Wolfe v. McNeil-PPC, Inc., No. CIV.A. 07-348, 2012 WL 38694, at *2 (E.D. Pa. Jan. 9, 2012). The ParaGard IUD labels, [redacted] do nothing more than describe the contents of adverse event reports. *See supra* at 18-21. As a result, any portion of these documents that describes or summarizes the contents of adverse event reports is inadmissible hearsay and cannot be considered on this motion for summary judgment.

2. Documents related to foreign regulatory issues are inadmissible under Federal Rule of Evidence 403

As this Court already held, "[b]ecause this litigation is based on U.S. law, and because evidence regarding the FDA will be admitted, the actions taken by foreign regulatory agencies are not particularly probative and likely will be confusing." *Daubert* Order at 139. Here, the 2006 BfArM Letter and the 2010 Health Canada Letter are the product of German and Canadian regulatory actions and are inadmissible under Federal Rule of Evidence 403 as more prejudicial than probative and likely to cause juror confusion. *See Daubert* Order at 121 ("There is no reason to believe that the regulatory framework of Canada or Germany is similar to the FDA's system.").

"Courts have found that evidence of foreign regulatory actions in products liability litigation is properly excluded as irrelevant and/or confusing." *Daubert* Order at 139 n.87 (citing *Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 773 (11th Cir. 1988) ("The District Court's desire to avoid confusing the jury with Swedish law and statistics cannot rightly be described as abuse of discretion . . . ."); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d at 965 ("[A]ny discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded."); *In re Seroquel Prods. Liab. Litig.*, No. 06-MD-1769, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009) ("[W]hatever minimal relevance the foreign regulatory actions might

have is clearly overwhelmed by the likelihood of jury confusion."), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) ("[A]llowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion.")). Permitting plaintiffs to introduce evidence of interactions with foreign regulatory agencies "without providing context concerning the regulatory schemes and decision-making processes involved would strip the jury of any framework within which to evaluate the meaning of that evidence." *In re Seroquel*, 601 F. Supp. 2d at 1318.

The Court already prohibited Plaintiff's FDA regulatory expert, Dr. Parisian, from "opin[ing] on foreign regulatory issues" related to the 2006 BfArM Letter and the 2010 Health Canada Letter in part because "[t]here is no reason to believe that the regulatory framework of Canada or Germany is similar to the FDA's system." *Daubert* Order at 120-21. As evidenced by the significant difference between FDA's standard for labeling and Plaintiffs' general causation burden in these cases (*see supra* at 14-18), this context is important and potentially dispositive of how the documents are interpreted.

The extensive involvement of Health Canada (the Canadian equivalent to the FDA) in the content of the letter is clear from the produced documents. [redacted] It is possible that, as is true of the FDA in the United States, the Canadian regulatory scheme requires Health Canada to "'err on the side of caution,' and take regulatory action . . . 'upon a lesser showing of harm to the public than the

preponderance-of-the-evidence or more-like-than-not standard used to assess tort liability.'" *In re Neurontin*, 612 F. Supp. 2d at 136 (citations omitted). No witness in this litigation can testify to that foreign regulatory scheme or provide the context for the language Plaintiffs focus on in the 2010 Health Canada Letter. Thus, for the same reasons that the Court excluded proposed foreign regulatory testimony in its *Daubert* Order, the products of foreign regulatory actions should be excluded under Federal Rule of Evidence 403 and cannot be considered on this Motion for Summary Judgment. *See Daubert* Order at 120-21, 138-39.

3. Documents and testimony purporting to give scientific opinions are inadmissible under Federal Rules of Evidence 701 and 702

As explained in detail above, Plaintiffs misinterpret multiple statements by Bayer employees and others as supposed admissions or evidence that secondary perforation exists. In reality, the documents proffered by Plaintiffs variously discuss the contents of adverse event reports, the risk of expulsion, and the fact that a perforation may not complete (*i.e.*, go through all three layers of the uterus) until after insertion (*see supra* at 18-24). However, to the extent that Plaintiffs or this Court interpret the evidence as stating that secondary perforation exists, it is barred as improper expert testimony under Federal Rules of Evidence 701 and 702.

"If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is . . . not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. When a witness giving expert testimony is disclosed pursuant to the Federal Rules, the Court is given the opportunity to perform a *Daubert* analysis, evaluating the witness's qualifications and the reliability of the methodology underpinning the witness's scientific opinions. Here, the Court has had no such opportunity to evaluate the authors of the documents and testimony cited by Plaintiffs to determine whether the statements Plaintiffs focus on were based on a reliable methodology.

The Seventh Circuit has excluded testimony of a defendant's employee who admitted to general causation on this very basis. *See Aliotta v. Nat'l R.R. Passenger Corp.*, 315 F.3d 756, 763 (7th Cir. 2003). In *Aliotta*, plaintiff claimed that her husband was standing on a train platform and was "sucked under" a passing train due to a vacuum allegedly created underneath the train. *Id.* at 758-60. Defendant argued that this was not possible, submitting an expert report stating that any "vacuum effect" created by a passing train would be minimal and incapable of pulling a bystander underneath the train. *Id.* at 760. In his deposition however, one of defendant's employees testified to the opposite, claiming that "the train is so large, it creates a vacuum . . . [that] will pull a person towards the train who is standing too close. . . . If you were standing within a few feet of a passenger train going 79 miles an hour, there's a very good chance that you would be killed." *Id.* at 759-60. The Court excluded this testimony, holding that even though it was a statement of a party opponent, it is not "free from the requirements of Rule 701(c), Rule 702 and *Daubert*." *Id.* at 763. The fact that the evidence was from defendant's own employee "does not protect [his] unreliable scientific testimony from exclusion under Rule 701(c) and 702, and his statements, as offered for the truth of the matter contained in them (i.e., the existence of a dangerous 'vacuum effect'), were properly excluded." *Id.*

The same should hold true here. Having failed once to proffer any admissible expert testimony, Plaintiffs now intend to offer expert opinions by bypassing the rigors of a Rule 702 and *Daubert* analysis. Plaintiffs cannot show that the snippets of emails and deposition testimony were the conclusion of a scientific methodology.

IV. THERE IS NO GENUINE ISSUE OF MATERIAL FACT ON SPECIFIC CAUSATION

Even if Plaintiffs could establish general causation – which they cannot do – expert testimony is also necessary to prove specific causation in any individual case. Plaintiffs

incorrectly claim that these cases are akin to a car accident case, and that secondary perforation can be proven by individual Plaintiffs through the testimony of their healthcare providers. At best, this proposed testimony does nothing more than invite the jury to speculate about which of two competing possibilities occurred to Plaintiffs. As a result, each Plaintiff will inevitably fail to prove by a preponderance of the evidence that she experienced a secondary perforation.

Furthermore, even if Plaintiffs designate new experts to give specific causation opinions in future cases, those experts will be excluded for the same reasons that this Court excluded the specific causation opinions for Plaintiffs Danley and Hayes in its *Daubert* Order. Because Plaintiffs are incapable of producing admissible evidence to create a genuine issue of material fact on specific causation, Defendants are entitled to summary judgment on all Plaintiffs' claims.

A. Treater Testimony Alone Is Insufficient To Create A Genuine Issue Of Material Fact On Specific Causation

As a straightforward matter of law, expert testimony is required to show specific causation in complex pharmaceutical cases like these, where causation is not a natural inference that a lay juror can make. *See supra* at 7-12 & Ex. 1, Appendix.

Disregarding this law, Plaintiffs argue that they can satisfy their burden on specific causation by introducing testimony from healthcare providers that they do not believe the uterus was perforated during insertion:

> If a plaintiff's inserting medical provider testifies to a reasonable degree of medical certainty, based on the factors typically evaluated by practitioners in his or her field (feel, patient reaction, string check, ultrasound, etc.), that the uterus was *not* perforated during the Mirena's insertion, the plaintiff will have provided admissible specific causation testimony. Bayer will have the right to challenge the treater's opinion and try to convince the jury that perforation occurred at insertion, but if the jury believes the treating provider, there is only one remaining alternative: perforation occurred *after* insertion.

Ex. 7, Pls.' 3/22/16 Letter at 8. This strategy is flawed for several reasons.

First, it is undisputed that the multi-factor methodology Plaintiffs describe in their letter (evaluating "feel, patient reaction, string check, ultrasound, etc.") is not capable of excluding perforation at insertion, let alone whether the insertion damaged a Plaintiff's endometrium. As the Court itself recognized, "the inserting doctor's belief that the Mirena was properly placed is not a reliable basis for concluding that no perforation occurred upon insertion. No responsible professional would conclude the insertion procedure in the belief that the Mirena was in the wrong position, and yet nobody disputes that it sometimes is." *Daubert* Order at 90. Plaintiffs' experts themselves have admitted that every single element on their list of "factors" is consistent with either perforation or uterine damage at the time of insertion. For instance, they all agree that perforation at insertion can be asymptomatic. *See, e.g.*, Ex. 13, Young Dep., at 151:16-152:1; Ex. 12, Wray Dep. at 230:16-22; Ex. 27, Luciani 9/1/15 Dep. at 157:3-9. And they also agree that that visible threads and ultrasound "confirmation" of position cannot rule out uterine injury at insertion. *See, e.g.*, Ex. 12, Wray Dep. at 260:23-262:3; Ex. 27, Luciani 9/1/15 Dep. at 215:10-15, 220:3-9, 221:12-16; Ex. 13, Young Dep. at 159:15-160:20. Indeed, one of Plaintiffs' experts, Dr. Luciani, opined that it would be ***impossible to ever detect whether a Mirena insertion disrupted a user's endometrium***. Ex. 14, Luciani 9/2/15 Dep. at 37:17-38:3 ("I would defy any physician in the world to rule that out since there is no available modality that you could rule out that there was some slight damage to the endometrium during the insertion of any foreign body into the uterus"). Plaintiffs' treating physicians would have no basis but speculation to say that, to a reasonable degree of medical certainty, a Plaintiff's perforation was unrelated to insertion.

Second, because no technique exists to rule out perforation or damage to the uterus at the time of insertion (a prerequisite for secondary perforation), jurors will be left to speculate about

whether each Plaintiff experienced a primary or secondary perforation. When Plaintiffs have provided no evidence that secondary perforation exists at all, much less that a secondary perforation is more likely than an asymptomatic primary perforation, their attempt to have the jury speculate on this point is improper. *See Jund*, 941 F.2d at 1286 ("A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant.") (citation omitted); *Sakaria v. Trans World Airlines*, 8 F.3d 164, 172-73 (4th Cir. 1993) ("In a long line of decisions in this circuit, we have emphasized that proof of causation must be such as to suggest 'probability' rather than mere 'possibility,' precisely to guard against raw speculation by the fact-finder."); *Calhoun v. Honda Motor Co.*, 738 F.2d 126, 130 (6th Cir. 1984) ("if a party seeks to establish causation by circumstantial evidence 'the evidence must be sufficient to tilt the balance from possibility to probability'") (citation omitted); *Quam v. Mobil Oil Corp.*, 496 F. Supp. 986, 988 (S.D.N.Y. 1978) ("The evidence here presents no more than a choice of probabilities upon which the jury would be speculating. Such speculation will not be permitted.") *aff'd*, 599 F.2d 42 (2d Cir. 1979).

Finally, Plaintiffs may not use percipient witnesses to offer belated, thinly-veiled specific causation opinions that are not subject to the requirements of Federal Rule of Evidence 702, *Daubert*, and this Court's scheduling orders. Under Plaintiffs' strategy, the healthcare provider would testify that, knowing an individual Plaintiff eventually experienced a perforation, he or she still believes to a reasonable degree of medical certainty that the perforation did not occur at insertion. Such an opinion would be an expert opinion on specific causation in disguise, complete with an implicit opinion on general causation (*i.e.*, that secondary perforation is possible – a necessary foundation to any specific causation opinion). This gambit would

contravene the Court's deadlines for the disclosure of expert opinions, which have long passed. It would also fundamentally prejudice Defendants, who have not had an opportunity to cross examine these healthcare providers on whether their purported opinions meet the standards set by the Federal Rules and *Daubert* – or to challenge their opinions under those standards.

Testimony by Plaintiffs' healthcare providers is therefore insufficient to create a genuine issue of material fact on specific causation, and Defendants are entitled to summary judgment.

B. Plaintiffs Will Be Unable To Produce Reliable Expert Testimony On Specific Causation

Plaintiffs have left open the possibility of presenting specific causation expert testimony in future cases. *See* Ex. 7, Pls.' 3/22/16 Letter at 8. However, for the reasons explained in this Court's *Daubert* Order, and for many of the same reasons explained above, Plaintiffs will be unable to produce an admissible expert specific causation opinion.

As this Court recognized, "a specific causation opinion must be based on a reliable general causation opinion." *Daubert* Order, at 51 n.29. Thus, an expert purporting to provide a specific causation opinion "must demonstrate that the medical and scientific literature provides evidence that in some circumstances the exposure under consideration can cause the outcome under consideration." *Id.* (citing *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 436 (S.D.N.Y. 2005)) (quotation marks omitted); *see also Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) ("Where an expert employs differential diagnosis to 'rule out' other potential causes for the injury at issue, he must also 'rule in' the suspected cause, and do so using scientifically valid methodology.") (internal quotation marks and citation omitted). With the exclusion of Plaintiffs' general causation experts, no such scientific evidence exists. As a result, no Plaintiff in this litigation will be able to provide reliable expert evidence of specific causation.

In addition, any future specific causation expert will be unable to conclude that a Plaintiff's perforation was more likely than not unrelated to insertion. For the reasons explained above, perforation or damage to the uterus at the time of Mirena insertion cannot be ruled out through any of the diagnostic criteria described by Plaintiffs; indeed, according to Plaintiffs' expert, it cannot be ruled out by any diagnostic criteria at all. *See* Ex. 14, Luciani 9/2/15 Dep., at 37:17-38:3. Because Plaintiffs have not adduced any expert evidence of general causation (which is the foundational predicate for an expert to find specific causation), Plaintiffs will also be incapable of producing expert evidence of specific causation, as confirmed by this Court's *Daubert* Order. As a result, Defendants are entitled to summary judgment.

CONCLUSION

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

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Respectfully submitted,

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