UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

This Document Relates To All Actions

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OPINION & ORDER

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

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Hundreds of plaintiffs have sued three related companies – Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG and Bayer OY ("Bayer" or "Defendants") – alleging that they were injured when Mirena, an intrauterine contraceptive device manufactured by Defendants, perforated, became embedded in or migrated from their uteruses. These diversity cases have been consolidated before this Court as part of a multi-district litigation ("MDL"). (Case Management Order No. 1, (13-MD-2434 Doc. 8).)[1] Plaintiffs have brought claims alleging negligence, strict liability, manufacturing defect, design defect, failure to warn, breach of warranty (implied and express), negligent misrepresentation, fraud, and various state-specific statutory violations, (*see, e.g.*, Shayna S. Cook Decl. Ex. 8),[2] all arising from alleged "secondary perforation" of Mirena. Before the Court is Defendants' Omnibus Motion for Summary

[1] All subsequent docket references are to No. 13-MD-2434, unless otherwise noted.

[2] "Shayna S. Cook Decl." refers to the Declaration of Shayna S. Cook in Support of Defendants' Omnibus Motion for Summary Judgment. (Doc. 3175.)

Judgment. (13-MD-2434 Doc. 3172; 13-MC-2434 Doc. 215.) For the reasons stated below, Defendants' Motion is GRANTED.

I. Background

A. Factual Background

The following facts, which are based on Defendants' Local Rule 56.1 statement and Plaintiffs' responses thereto ("56.1 Stmt. & Resp."), (Doc. 3228), Plaintiffs' Opposition 56.1 statement and Defendants' responses thereto ("Opp. 56.1 Stmt. & Resp."), (Doc. 3246), supporting materials, and the record in this case, are undisputed except where noted.[3]

Mirena is a plastic, intrauterine device ("IUD")[4] that delivers the hormone levonorgestrel ("LNG") into the uterus and is designed to prevent pregnancy for up to five years. (Opp. 56.1 Stmt. & Resp. ¶¶ 8-9; Kekatos Decl. Ex. 3, at 4.)[5] Mirena is inserted by a trained health care provider using an inserter provided by Bayer. (Kekatos Decl. Ex. 2, at 2-3.) Mirena has been sold in the United States since December 2000 when it was approved by the Food and Drug

[3] In their 56.1 Statement, Defendants seem to rely on – or at least refer to – evidence previously deemed inadmissible by the Court, such as deposition testimony of experts proffered by Plaintiffs. *See In re Mirena IUD Prods. Liab. Litig.*, No. 13-MD-2434, 2016 WL 890251, at *61 (S.D.N.Y. Mar. 8, 2016), (Doc. 3073). I am unclear as to why Defendants cited to Plaintiffs' precluded experts rather than their own undisputed experts. A court may rely only on admissible evidence at the summary judgment stage. *See Rubens v. Mason*, 387 F.3d 183, 188 (2d Cir. 2004) ("[I]n deciding a motion for summary judgment, a court may rely only on material that would be admissible at trial."). To the extent such evidence is offered to show positions Plaintiffs have taken, I may take judicial notice of it, *see Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) (court may take judicial notice of prior proceedings "to establish the fact of such litigation and related filings," not for the truth of matters asserted in those proceedings), but otherwise I disregard it. Because this motion primarily relates to legal questions, however, and because the parties' positions are clear from this and previous briefing, Defendants' reliance on some inadmissible evidence in their 56.1 Statement does not prevent adjudication of the motion.

To the extent this decision quotes or discusses information from documents submitted under seal or in redacted form, that information is hereby unsealed because of the presumption in favor of public access to information affecting judicial decisions. *See In re Fosamax Prods. Liab. Litig.*, 807 F. Supp. 2d 168, 173 n.2 (S.D.N.Y. 2011).

[4] Bayer refers to Mirena as an intrauterine system ("IUS"). The Court regards the terms IUD and IUS as interchangeable.

[5] "Kekatos Decl." refers to the Declaration of Diogenes P. Kekatos in Opposition to Defendants' Omnibus Motion for Summary Judgment. (Doc. 3230.)

Administration ("FDA"). (Opp. 56.1 Stmt. & Resp. ¶ 10.) A risk associated with Mirena is uterine perforation, which may include the IUD penetrating into, passing through or becoming embedded in the uterine wall or cervix. (Kekatos Decl. Ex. 2, at 13.)

The meaning of perforation is important to this litigation but somewhat confounding. According to defense expert Jay Goldberg, M.D., M.S.C.P.:

> To perforate means to create a hole in the wall of a structure, usually iatrogenically [inadvertently]. Perforation can be categorized as total (or complete) perforation and partial (or incomplete) perforation. A total uterine perforation signifies an injury completely through the uterine wall, whereas a partial uterine perforation goes only partially through the myometrium [the middle layer of the uterine wall]. (Sometimes the term partial perforation is used to describe an IUD that has breached completely through the myometrium and serosa [the outer layer of the uterine wall], but is at least partially still within the uterine cavity.) When a partially perforated IUD becomes fixed within the myometrium of the uterus, it is often referred to as being embedded. . . . [M]igration is a term sometimes used to describe the movement of an IUD from inside the uterine cavity through a complete perforation and out into the abdominal cavity. As such, migration is a consequence of complete perforation, rather than a distinct phenomenon (just as embedment is a consequence of partial perforation).

(Kekatos *Daubert* Decl. Ex. B, at 12-13.)[6] One of Plaintiffs' experts, Dr. Susan Wray, Ph.D., whose testimony has been excluded but whose definition of perforation is instructive for purposes of understanding the alleged phenomenon of secondary perforation, described uterine perforation as "puncturing" or "penetration" of IUDs and migration as the "movement" of "IUDs within the body." (Declaration of Christopher J. Cook in Support of Defendants' Motion to Exclude the Testimony of Susan Wray, Ph.D., (Doc. 2693), Ex. B, at 21.) The difficulty arises from the fact that the term "perforation," it seems, may refer to both the injury to the uterine wall (which may be a puncture partly or all the way through that wall) and to the penetration of part

[6] "Kekatos *Daubert* Decl." refers to the Declaration of Diogenes P. Kekatos in Support of Plaintiffs' Motion to Exclude Defendants' Experts. (Doc. 2704.)

or all of the IUD device itself either into or through the uterine wall. At issue in this litigation is the timing of such perforations, and whether Mirena's label adequately warned of all risks associated with perforation.

The Mirena label has undergone several changes. In 2000, when Mirena was approved, the label stated: "An IUD may perforate the uterus or cervix, most often during insertion although the perforation may not be detected until some time later." (Christopher J. Cook Decl. Ex. 1, at MIR_INDNDA_00010729.)[7] The perforation portion of the label changed in 2008, 2009, 2013 and 2014. (*Id.* Exs. 2, 25, 27; Kekatos Decl. Ex. 19.) The first three of these labels contained the same sentence regarding the timing of any risk of 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." (Christopher J. Cook Decl. Ex. 2, at MIR_INDNDA_00039752; *id.* Ex. 25, at MIR_FCR_2046; *id.* Ex. 27, at MIR_INDNDA_00319917.) The 2014 label reflected a change. It stated: "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." (Kekatos Decl. Ex. 19, at 13.) The current label, approved in 2015, contains the same sentence. (*Id.* Ex. 2, at 13.)

The parties do not dispute that all iterations of the Mirena label have warned that perforation can occur at the time of, or related to, the insertion procedure. They disagree, however, on the existence of what has been called "secondary perforation," "spontaneous perforation," or "spontaneous migration" throughout this litigation. A secondary perforation is defined as a perforation that occurs subsequent and unrelated to the insertion of a Mirena. (56.1

[7] "Christopher J. Cook Decl." refers to the Declaration of Christopher J. Cook in Support of Defendant's Motion for Summary Judgment in *Danley v. Bayer Healthcare Pharmaceuticals, Inc.* (13-CV-6586). (Doc. 2759.)

Stmt. & Resp. ¶ 1.) Bayer argues that the consensus in the scientific community is that secondary perforation cannot occur, and that any injury to the uterine wall occurs only at the time of insertion, even if detection of the injury or movement of the IUD itself occurs later. (Ds' Mem. at 4, 16.)[8] Such an injury may be caused during insertion by the sound (a device used to measure the uterus before insertion), by the inserter or by the IUD itself. (Kekatos *Daubert* Decl. Ex. B, at 13.) Plaintiffs contend that secondary perforation can occur, which means that Mirena can spontaneously perforate or migrate without any injury at the time of or related to the insertion procedure. (Ps' Mem. at 1-3.)[9] Such a possibility, they argue, was not mentioned in the label warning used from 2008 through 2014, the time frame of Plaintiffs' injuries. (*Id.* at 3.)[10]

B. Procedural Posture

On April 8, 2013, pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation consolidated cases in which Plaintiffs alleged that Mirena "migrate[d] away from its original position, perforate[d] the uterus, and/or cause[d] related injuries," and found there were "common" issues "concerning the alleged risk of perforation and migration." (Shayna S. Cook Decl. Ex. 2, at 1.) Almost 1,300 cases are currently pending before this Court. During the course of the MDL, several cases were selected to be part of an Initial Disposition Pool ("IDP") and went through full discovery. (Docs. 883, 1524.) After a series of strikes by both sides, as well as voluntary dismissals, two cases were left and set to go to trial as early as the spring of

[8] "Ds' Mem." refers to Defendants' Memorandum of Law in Support of Their Omnibus Motion for Summary Judgment. (Doc. 3174.)

[9] "Ps' Mem." refers to Plaintiffs' Memorandum of Law in Opposition to Defendants' Omnibus Motion for Summary Judgment. (Doc. 3227.)

[10] They further argue that such a warning would have made a difference in Plaintiffs' choices, because women who are unaware of the risk of secondary perforation will not monitor their Mirenas as carefully as those who are aware, and others will choose not to use Mirena at all because of the uncertainty involved. (Ps' Mem. at 3.)

2016. (Docs. 2660, 2951.) In connection with the IDP cases, the parties submitted a number of motions to exclude several of each other's experts pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). (*See* Docs. 2679, 2682, 2685, 2688, 2691, 2694, 2697, 2702, 2705, 2724.) On March 8, 2016, the Court excluded all of Plaintiffs' experts who had offered opinions on general causation – in other words, that Mirena is capable of causing secondary perforation. *See Mirena*, 2016 WL 890251, at *61. Familiarity with that decision, which is incorporated herein by reference, is presumed.

Following the *Daubert* rulings, Plaintiffs voluntarily dismissed the two cases that were being prepared for trial. (Docs. 3148, 3149.) Defendants filed the instant omnibus motion on May 4, 2016, (Doc. 3172), requesting that the Court grant summary judgment in all pending cases in this MDL because Plaintiffs are left without any experts to show that Mirena is capable of causing secondary perforation. Plaintiffs opposed on June 8, 2016, (Doc. 3227); Defendants filed reply papers on June 22, 2016, (Doc. 3245); and Plaintiffs filed a sur-reply on July 6, 2016, (Doc. 3262), which I permitted because of the importance of the issue, (Doc. 3249).

The parties agree that proof of general causation – "whether *the type of injury at issue can be caused or exacerbated* by the defendant's product," *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 251 n.1 (2d Cir. 2005) (emphasis in original) – is necessary in a products liability case such as this.[11] The "type of injury at issue" is perforation, embedment or migration absent injury to the uterus upon insertion – the concept Plaintiffs call secondary perforation or spontaneous migration. The parties do not dispute that the Mirena label has always warned of

[11] In a products liability action, plaintiffs must prove both general and specific causation. *See Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377-78 (5th Cir. 2010). "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." *Id.* at 378 (internal quotation marks omitted). The Court need not discuss specific causation to resolve this motion.

the potential risk of perforation upon or related to insertion. Plaintiffs, however, argue that the label is inadequate because it did not warn of perforation unrelated to insertion, which they must show exists as a phenomenon in order to prove general causation and prevail. Thus, "in the context of these cases, evidence of general causation means evidence that secondary perforation can occur." *See Mirena*, 2016 WL 890251, at *23 n.28. Plaintiffs do not dispute that each claim in this case requires such proof. In their opposition papers Plaintiffs note that "on-going failure to warn [of spontaneous perforation] underlies every lawsuit in the Mirena MDL," (Ps' Mem. at 8), and that "Bayer's motion seeks to terminate *every* plaintiff's recovery rights in this MDL," (*id.* at 35). They do not argue that certain claims can survive even without evidence of the existence of secondary perforation. The parties disagree, however, on whether general causation can be proven without expert testimony.

Defendants argue that expert testimony is required, and thus that there is an absence of sufficient evidence for a jury to find that Plaintiffs have proven causation. (Ds' Mem. at 7-12.) Plaintiffs do not dispute that they must prove general causation for all of their claims, but contend that they can meet their burden of introducing sufficient evidence to create a genuine issue of material factual on that issue through certain documents and testimony that they argue amount to admissions by Defendants that secondary perforation exists, and that such admissions are an adequate substitute for expert testimony on the issue of general causation. (Ps' Mem. at 8-11, 17-32.) Defendants respond that the alleged admissions do not suffice to show causation because all fifty states mandate expert testimony, and that the documents and statements to which Plaintiffs point do not admit the existence of secondary perforation in any event. (Ds' Mem. at 12-24.)

II. Discussion

A. Legal Standards

Summary judgment is appropriate when "the movant shows that 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). "[T]he dispute about a material fact is 'genuine' . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is "material" if it "might affect the outcome of the suit under the governing law . . . . Factual disputes that are irrelevant or unnecessary will not be counted." *Id.* On a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. The movant bears the initial burden of demonstrating "the absence of a genuine issue of material fact," and, if satisfied, the burden then shifts to the non-movant to present "evidence sufficient to satisfy every element of the claim." *Holcomb v. Iona Coll.*, 521 F.3d 130, 137 (2d Cir. 2008) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). "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*, 477 U.S. at 252. Moreover, the non-movant "must do more than simply show that there is some metaphysical doubt as to the material facts," *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986), and he "may not rely on conclusory allegations or unsubstantiated speculation," *Fujitsu Ltd. v. Fed. Express Corp.*, 247 F.3d 423, 428 (2d Cir. 2001) (internal quotation marks omitted).

"A party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including

those made for purposes of the motion only), admissions, interrogatory answers, or other materials . . . ." Fed. R. Civ. P. 56(c)(1). In the event that "a party fails . . . to properly address another party's assertion of fact as required by Rule 56(c), the court may," among other things, "consider the fact undisputed for purposes of the motion" or "grant summary judgment if the motion and supporting materials – including the facts considered undisputed – show that the movant is entitled to it." Fed. R. Civ. P. 56(e)(2), (3).

B. Expert Testimony on Causation

As in any products liability or personal injury action, Plaintiffs must prove causation – that the Defendants' conduct (such as a failure to adequately warn) was the proximate cause of Plaintiffs' injuries. *See In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) ("[C]ausation is a required element in every product liability case."), *aff'd sub nom. Fenandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App'x 249 (4th Cir. 2011) (*per curiam*); *see also, e.g., Luttrell v. Novartis Pharm. Corp.*, 894 F. Supp. 2d 1324, 1340 (E.D. Wash. 2012) (proximate cause in products liability has two elements – cause in fact and legal causation – under Washington law), *aff'd*, 555 F. App'x 710 (9th Cir. 2014); *Moran v. Pfizer, Inc.*, 160 F. Supp. 2d 508, 510-11 (S.D.N.Y. 2001) (causation required element under New Jersey law); *Porter v. Pfizer Hosp. Prods. Grp., Inc.*, 783 F. Supp. 1466, 1475 (D. Me. 1992) (proof of causation required element of strict liability claims under Maine law); *Mothershead v. Greenbriar Country Club, Inc.*, 994 S.W.2d 80, 89 (Mo. Ct. App. 1999) (causation required element of failure to warn in products liability case under Missouri law).

Generally, in products liability cases, "to establish causation, [plaintiffs] must offer admissible expert testimony regarding both general causation . . . and specific causation." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002); *see Rutigliano v.*

Valley Bus. Forms, 929 F. Supp. 779, 783 (D.N.J. 1996), *aff'd sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 118 F.3d 1577 (3d Cir. 1997). The parties agree, (Ds' Mem. at 7-8; Ps' Mem. at 34-35), and the substantive law across all relevant jurisdictions holds, (*see* Shayna S. Cook Decl. Ex. 1),[12] that where a causal link is beyond the knowledge or expertise of a lay jury, "expert testimony is required to establish causation." *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004); *see, e.g., Show v. Ford Motor Co.*, 697 F. Supp. 2d 975, 983 (N.D. Ill. 2010) ("[P]roducts liability cases that involve complex products beyond a lay jury's understanding require expert testimony."), *aff'd*, 659 F.3d 584 (7th Cir. 2011); *Brookshire Bros., Inc. v. Smith*, 176 S.W.3d 30, 36 (Tex. App. 2004) ("When a lay person's general experience and common sense will not enable that person to determine causation, expert testimony is required."); *Wilhelm v. State Traffic Safety Comm'n*, 185 A.2d 715, 719 (Md. 1962) ("To allow a jury of laymen, unskilled in medical science, to attempt to answer such a [complex] question would permit the rankest kind of guesswork, speculation and conjecture.").

"[C]ases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person," and thus expert testimony is required. *In re Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004); *see, e.g., Silverstein v. Procter & Gamble Mfg. Co.*, 700 F. Supp. 2d 1312, 1316 (S.D. Ga. 2009) ("[I]f the inference that the defendant's product caused the plaintiff's injury is not a 'natural inference that the juror could make through human experience . . . medical expert testimony [is] essential to prove causation.'") (alterations in original) (quoting *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1320 (11th Cir. 1999)); *Jones v. Ortho Pharm. Corp.*, 209 Cal. Rptr. 456, 460 (Cal. Ct.

[12] The relevant jurisdictions are the fifty states, the District of Columbia, Puerto Rico and the Virgin Islands. (*See* Shayna S. Cook. Decl. Ex. 1.) Because the cases in this MDL are diversity cases, the governing substantive law is that of the relevant state or territory. *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996) ("[F]ederal courts sitting in diversity apply state substantive law and federal procedural law.").

App. 1985) ("The law is well settled that in a personal injury action causation must be proven within a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case.").

Expert testimony is required in cases involving complex causation issues, including medical device cases, because without it the jury is left to speculate on medical issues with which the average person is unfamiliar. *See Hughes v. Stryker Sales Corp.*, No. 08-CV-655, 2010 WL 1961051, at *5 (S.D. Ala. May 13, 2010) ("In the typical case involving a complex medical device, the absence of expert testimony would force a jury to engage in speculation and conjecture on issues of defect and causation . . . . Therefore, courts routinely require expert testimony in such matters."), *aff'd sub nom. Hughes v. Stryker Corp.*, 423 F. App'x 878 (11th Cir. 2011).[13]

Thus, summary judgment is appropriate where required expert testimony is absent from the record. *See C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 838 (7th Cir. 2015) ("With no experts to prove causation . . . the appellants cannot prove their toxic-tort case . . . [and] summary judgment . . . was proper.") (citation omitted); *Hendrix ex rel. G.P. v. Evenflo Co.*, 609

[13] *See also Lewis v. Johnson & Johnson*, 601 F. App'x 205, 210-11 (4th Cir. 2015) ("[P]roof other than expert testimony provides sufficient evidence of causation only when a layperson's general experience and common understanding would enable [him/her] to determine from the evidence, with reasonable probability, the causal relationship between the defect and the injury.") (*per curiam*) (internal quotation marks omitted); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1068 (D. Or. 2013) ("The purpose of the requirement for a showing of reasonable medical probability of causation in cases involving complex medical questions is to prevent jurors from speculating about causation in cases where that determination requires expertise beyond the knowledge and experience of an ordinary lay person.") (internal quotation marks omitted); *Washington v. Wash. Hosp. Ctr.*, 579 A.2d 177, 181 (D.C. 1990) ("The purpose of expert opinion testimony is to avoid jury findings based on mere speculation or conjecture."); *Beckles v. Madden*, 993 A.2d 209, 214 (N.H. 2010) (in medical malpractice case, expert testimony required to show proximate cause so jury will not engage in "idle speculation") (internal quotation marks omitted); *Dellinger v. Pediatrix Med. Grp., P.C.*, 750 S.E.2d 668, 677 (W. Va. 2013) ("[W]e find there is quite simply nothing upon which a jury may make such an inference [of proximate cause] beyond abject speculation. The lack of expert medical testimony as to causation was therefore . . . fatal to petitioner's case . . . .") (footnote omitted); *City of Cedarburg Light & Water Comm'n v. Allis-Chalmers Mfg. Co.*, 149 N.W.2d 661, 662 (Wis. 1967) ("There may be cases where the issue of causation, like the issue of negligence, involves technical, scientific or medical matters which are beyond the common knowledge or experience of jurors and without the aid of expert testimony the jury could only speculate as to what inferences to draw if it were left to determine the issue. The lack of expert testimony in such cases results in an insufficiency of proof.") (*per curiam*).

F.3d 1183, 1203 (11th Cir. 2010) ("[W]ithout this [expert] testimony there is no genuine dispute of material fact regarding causation . . . [and] the district court's grant of summary judgment on [plaintiff's] sole remaining claim was appropriate."); *Ronwin v. Bayer Corp.*, 332 F. App'x 508, 514 (10th Cir. 2009) (affirming district court 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) ("[A]bsent an admissible general causation opinion, Plaintiffs' claims necessarily fail and [defendant's] motion for summary judgment must be granted."); *Kilpatrick v. Breg, Inc.*, No. 08-CV-10052, 2009 WL 2058384, at *11 (S.D. Fla. June 25, 2009) ("In the absence of any reliable expert evidence on causation, summary judgment must be granted in favor of [defendant]."), *aff'd*, 613 F.3d 1329 (11th Cir. 2010).

Here, Defendants argue that expert testimony is required to prove that Mirena can spontaneously perforate the uterus absent any injury at insertion because "[t]hat question necessarily focuses on scientific questions beyond the understanding of lay jurors," (Ds' Mem. at 8), and note that Plaintiffs recognized the complexity of the issue of secondary perforation when they attempted to submit expert testimony on the subject, (*id.* (citing Doc. 2780, at 19, in which Plaintiffs stated in the course of opposing a *Daubert* motion that expert testimony on how the uterus functions involved a "complex area requiring specialized knowledge" that was "necessary to assist the trier of fact.").) Plaintiffs now argue, however – in fleeting fashion – that Mirena cases are "simple soft-tissue cases that do not require experts for general causation." (Ps' Mem. at 34; *see* Ps' Sur-Reply at 4.)[14]

Plaintiffs' argument in this regard is unpersuasive. That one's bone might break if crushed in a car crash is within the ordinary experience of a lay person. That a medical device

[14] "Ps' Sur-Reply" refers to Plaintiffs' Sur-Reply in Opposition to Defendants' Omnibus Motion for Summary Judgment. (Doc. 3262.)

might spontaneously burrow into or burst through the wall of an anatomical cavity is not. For example, it would come as a surprise to most people if a hearing aid could, for no particular reason, wander from its intended placement, work its way through the wall of the ear canal and end up elsewhere in the head, or even that it could work its way into getting stuck part way through the wall of the ear canal. There is no basis on which to conclude that it is within the ordinary experience and understanding of lay people that an IUD could spontaneously travel through or become embedded in an intact uterine wall. And certainly lay people would have no idea *how* such a thing might occur.

Plaintiffs' assertion that a "uterine perforation occurring . . . a year or more after an uneventful insertion" is such a simple phenomenon that no state would require expert testimony for it, (Ps' Mem. at 35 n.17), and that this demonstrates "that Mirena cases are within the understanding of a lay jury," (Ps' Sur-Reply at 4), is not convincing. It might be obvious that the Mirena had traveled from where it belonged to where it ended up, but it is not obvious how that could happen in an undamaged uterus. *See Parker v. Emp'rs Mut. Liab. Ins. Co. of Wis.*, 440 S.W.2d 43, 49 (Tex. 1969) ("[I]n the absence of factual circumstances of probability understandable to a jury there must be some scientific testimony that can be interpreted as an inference of hypothetical probability before we can allow a jury to speculate upon the rights of citizens. . . . If the experts cannot predict probability in these situations, it is difficult to see how courts can expect a jury of laymen to be able to do so."). Especially because both sides' experts opine that not all injuries upon insertion are detected, *see Mirena*, 2016 WL 890251, at *14-15, *19, just because a Mirena is found out of place well after an insertion believed to be uneventful does not answer whether spontaneous migration has occurred.

The concept of secondary perforation as Plaintiffs describe it involves an analysis of the anatomy and physiology of the uterus, the physics of the forces at work in the uterus, the strength of its muscles, the types of injuries that could be caused by the Mirena insertion procedure, and whether and how such injuries can be detected with existing technology. *See, e.g.*, *id.* at *6-15, *17-22, *32-37. The medical complexity of the theory of secondary perforation, as well as most people's unfamiliarity with uterine anatomy and IUDs such as Mirena, puts well beyond the common understanding of lay jurors the question of whether Mirena is capable of moving through the uterine wall absent injury upon insertion. Reference to the Court's *Daubert* decision and the expert reports cited therein demonstrates as much. It simply cannot be said that lay people understand that a Mirena might spontaneously penetrate an intact uterine wall, let alone why or how.

Expert testimony would thus normally be required to prove that secondary perforation can occur with Mirena. *See Fane v. Zimmer, Inc.*, 927 F.2d 124, 131 (2d Cir. 1991) (device implanted in patient "was not one with which an ordinary person would come into contact" and issue of causation in "complicated medical case . . . was one beyond the sphere of the ordinary juryman and required expert testimony"); *Hughes*, 2010 WL 1961051, at *5 ("courts routinely require expert testimony" in "the typical case involving a complex medical device"); *Swallow v. Emergency Med. of Idaho, P.A.*, 67 P.3d 68, 77 (Idaho 2003) (expert testimony required to determine whether drug caused heart attack because that is a "matter of science that is far removed from the usual and ordinary experience of the average person").

Plaintiffs suggest in the alternative that whether the existence of secondary perforation is within the common understanding of the average juror cannot be decided on this omnibus motion, or even as part of this MDL, because "[c]ategorizing the Mirena cases [as complex or

simple] will be a matter of first impression for most if not all states, and it is impossible to predict how each state will treat them." (Ps' Mem. at 34.) Although an analysis of Mirena or secondary perforation may be a matter of first impression, all jurisdictions have a similar rule requiring expert testimony where a matter is outside the ken of an ordinary lay juror. Because Mirena is a medical device and the theory of secondary perforation is a concept requiring a nuanced understanding of IUDs and uterine anatomy, the Court has no serious doubt that all jurisdictions would treat this issue as one requiring expert testimony to prove causation. Plaintiffs certainly have not presented authority suggesting otherwise. Nonetheless, the discussion does not end here.

C. Can "Admissions" Be Sufficient to Establish General Causation?

Plaintiffs argue that despite the absence of expert testimony as to general causation, "*a defendant's admissions can be used to satisfy general causation*," (Ps' Mem. at 12) (emphasis in original), and list alleged admissions that they claim create an issue of material fact that should be determined by a jury, (*id.* at 21-32).

Federal Rule of Evidence ("FRE") 801(d)(2) provides that a statement is not hearsay if:

> [t]he statement is offered against an opposing party and: (A) was made by the party in an individual or representative capacity; [or] (B) is one the party manifested that it adopted or believed to be true; [or] (C) was made by a person whom the party authorized to make a statement on the subject; [or] (D) was made by the party's agent or employee on a matter within the scope of that relationship and while it existed . . . .

"[B]ecause admissions against a party's interests are received into evidence without many of the technical prerequisites of other evidentiary rules – such as, for example, trustworthiness and

personal knowledge – admissibility under the rule should be granted freely." *Pappas v. Middle Earth Condo. Ass'n*, 963 F.2d 534, 537 (2d Cir. 1992).[15]

Plaintiffs argue that statements made by Bayer (or one of its predecessors) fall within this rule, and show that Bayer admitted that secondary perforation can occur with Mirena, thus proving general causation, or at least creating a question of material fact that should be decided by a jury. The parties have cited, and the Court has identified, only a handful of cases that even arguably deal with this question. They do not focus on admissibility under FRE 801, but instead arguably impliedly suggest that admissions might suffice to prove general causation. Likewise, the issue here is not so much whether the alleged admissions are admissible against Bayer as a matter of the law of evidence, but whether as a matter of substantive products liability law admissions can substitute for expert evidence of causation, given the widely held principle that expert testimony is required in cases involving a complex or technical question outside the ken of the average lay juror. *See Lasley v. Georgetown Univ.*, 688 A.2d 1381, 1384 (D.C. 1997) ("Our rule for medically complicated cases is that proof of causation normally requires medical opinion testimony.").[16]

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[15] The 2011 amendments to the Federal Rules of Evidence changed the language of Rule 801(d)(2) from "admissions" of party opponents to "statements" of party opponents. *See* Fed. R. Evid. 801 advisory committee's note. This was a stylistic – not substantive – change to the rule. *Id.*; *see United States v. Adams*, 722 F.3d 788, 810 n.14 (6th Cir. 2013) (noting that 2011 amendments to FRE were "merely stylistic"). For ease of reference, I will refer to "admissions" in discussing Rule 801(d)(2).

[16] Accordingly, *Aliotta v. Nat'l R.R. Passenger Corp.*, 315 F.3d 756 (7th Cir. 2003), which both parties discuss, is of little direct importance. In that case the Seventh Circuit held that the trial court had properly excluded a railroad company employee's deposition testimony that a condition at its station created a dangerous vacuum that could have sucked the plaintiff's decedent under the train. *See id.* at 763. It found that statements of a party-opponent on a scientific or technical subject must not only qualify under Rule 801(d)(2) but must also pass muster under Rules 701 and 702, as interpreted by *Daubert*. *Id.* The Court reasoned: "[I]n this particular case, we see no good reason why unqualified and unreliable scientific knowledge should be exempted from the expert evidence rules simply because the speaker is an employee of a party-opponent." *Id.* This holding has been criticized as "[a] truly disturbing and incorrect statement," 30B Michael H. Graham & Kenneth W. Graham, Jr., Fed. Prac. & Proc. Evid. § 7015 (2014 ed.), and this Court does not adopt it. Rather, I assume that the statements at issue (except for the Progestasert label discussed below) are admissible against Bayer under the rules of evidence as admissions of an opposing party. The evidentiary question addressed in *Aliotta* casts no direct light on the question here: whether (presumably admissible) statements of Defendants suffice to get to the jury on the issue of general causation in the absence of

A review of the cases cited by Plaintiffs – as well as common sense – suggest that if it is conceivable at all that a statement by a party opponent could be used in place of expert testimony to prove causation, the circumstances in which this might occur would be exceedingly rare, especially in the pharmaceutical or medical contexts. The purpose of expert testimony in such cases – to prevent the jury from engaging in speculation in deciding the element of causation[17] – must be borne in mind in considering whether admissions can substitute for expert testimony in a case where the causation question involves complex medical or technical issues. As discussed below, the most that can be wrung from the authority cited by Plaintiffs is that if admissions could ever substitute for expert testimony in a complex case that requires expert testimony as to causation under state law, those admissions would have to be clear, unambiguous, and concrete, rather than an invitation to the jury to speculate as to their meaning.

The case on which Plaintiffs most heavily rely is *In re Meridia Products Liability Litigation*, in which the district court found that a diet drug's product insert constituted an

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expert testimony where the scientific or technical issue is beyond the everyday experience of a layperson. *Aliotta* does cast indirect light on the issue, however. The concern that animated the Seventh Circuit's decision on the evidence-law question – that jurors need reliable scientific testimony from qualified experts to reach conclusions on complex technical questions – applies to the substantive-law question of whether admissions (admissible in evidence) can substitute for expert testimony on issues not within the common knowledge or experience of lay people.

[17] *See, e.g.*, *Schudel v. Gen. Elec. Co.*, 35 F. App'x 481, 484 (9th Cir. 2002) ("Because [plaintiff's] injuries involved obscure medical factors and laypeople could not determine the injuries' cause without resorting to speculation or conjecture, expert testimony was required to establish causation."); *Uribe v. Sofamor, S.N.C.*, No. 95-CV-464, 1999 WL 1129703, at *7 (D. Neb. Aug. 16, 1999) ("[T]he lack of expert testimony on the question of causation results in an insufficiency of proof where the issue involves technical, scientific or medical matters which are beyond the common knowledge or experience of jurors and the jury could only speculate as to what inference to draw.") (internal quotation marks omitted); *Gillikin v. Burbage*, 139 S.E.2d 753, 760 (N.C. 1965) ("Where a layman can have no well-founded knowledge and can do not more than indulge in mere speculation (as to the cause of a physical condition), there is no proper foundation for a finding by the trier without expert medical testimony.") (internal quotation marks omitted); *Baughman v. Pina*, 113 P.3d 459, 460 (Or. Ct. App. 2005) ("When the element of causation involves a complex medical question, as a matter of law, no rational juror can find that a plaintiff has established causation unless the plaintiff has presented expert testimony that there is a reasonable medical probability that the alleged negligence caused the plaintiff's injuries. The rule prevents jurors from speculating about causation in cases where that determination requires expertise beyond the knowledge and experience of an ordinary lay person.") (citations omitted).

admission of causation for a particular injury. 328 F. Supp. 2d 791, 810 (N.D. Ohio 2004) [hereinafter *Meridia 1*], *aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006) [hereinafter *Meridia 2*]. Although the court ultimately granted summary judgment in favor of defendants, it found that plaintiffs had "met their burden of showing a genuine issue of material fact" with respect to causation for high blood pressure, because the product inserts for patient and doctor stated: "MERIDIA SUBSTANTIALLY INCREASES BLOOD PRESSURE IN SOME PATIENTS." *Id.* (internal quotation marks omitted). The court concluded that these statements "constitute[d] admissions of Meridia's potential to cause substantial increases in blood pressure." *Id.*[18] The district court's opinion was affirmed by the Sixth Circuit, which found "no fault with the district court's treatment of the causation factor." *Meridia 2*, 447 F.3d at 866. But the district court had assumed for the sake of argument that no states' laws required expert testimony on the issue of general causation. *See id.* at 865 ("[R]ather 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.'") (alteration in original) (quoting *Meridia 1*, 328 F. Supp. 2d at 802). I do not make the same assumption here, where all jurisdictions have such a requirement. Fatal to Plaintiffs' argument, the district court in *Meridia 1* specifically noted that "in cases originating from states that require expert testimony in mass tort cases, Plaintiffs' claims would fail if the Plaintiffs did not offer admissible expert testimony tending to establish general causation." *Meridia 1*, 328 F. Supp. 2d at 802 (footnote omitted). That is the case here. Because the issue of secondary perforation is outside the realm of common knowledge and experience of a lay juror, which in all jurisdictions means that expert testimony is required, *Meridia 1* and *Meridia 2* are not applicable to this case. Further, the statements that

[18] The court went on to grant summary judgment for the defendants because the same statement constituted an adequate warning. *See Meridia 1*, 328 F. Supp. 2d at 814-15.

Plaintiffs argue are sufficient to raise a question of fact are so different from the statement on Meridia's label that they would not suffice as a substitute for expert testimony. Indeed, the Sixth Circuit highlighted that it was the "specific wording" on the label – "MERIDIA SUBSTANTIALLY INCREASES BLOOD PRESSURE" – that sufficed to show causation. *See Meridia 2*, 447 F.3d at 866. There is no indication that that Court would feel the same way about the far more ambiguous statements at issue here, as will be discussed below.

Plaintiffs cite several other cases that they argue imply that a defendant's statements could possibly substitute for expert testimony in proving general causation. In *Westberry v. Gislaved Gummi AB*, the Fourth Circuit noted that the manufacturer's Material Safety Data Sheet ("MSDS") for talc – the product alleged to have caused injuries – "provided that inhalation of [talc] dust in high concentrations irritates mucous membranes." 178 F.3d 257, 264 (4th Cir. 1999) (alteration and internal quotation marks omitted). This does not strike the Court as a complex medical issue beyond the ken of a lay juror, and therefore requiring expert testimony, but in any event the issue was not whether the MSDS statement could substitute for expert testimony. Rather, the comment regarding the MSDS was made in the context of evaluating whether the plaintiffs' expert had a sufficient basis for his specific causation opinion. The *Westberry* court's discussion shows no more than that an MSDS is properly considered by an expert. Nothing in *Westberry* suggests that a manufacturer's statement suffices to defeat summary judgment in the absence of expert testimony.

In *Howell v. Centric Group, LLC*, the court assumed that an "MSDS alone might be sufficient to raise an issue of fact regarding general causation, *i.e.*, that anise oil, in sufficient quantities, could be capable of causing the types of injur[ies] alleged," No. 09-CV-2299, 2011 WL 4499372, at *5 (D. Colo. Sept. 27, 2011), *aff'd*, 508 F. App'x 834 (10th Cir. 2013) ("[W]e

assume, as the district court did, that anise oil is capable of causing injuries similar to those [Plaintiff] complained of . . . ."), but held that the plaintiff had failed to raise a material fact issue as to specific causation, *id.* at *5-6. The assumption in *Howell* that the MSDS *could* be enough to create an issue of fact on general causation is *dictum*, apparently made for the sake of argument, and does not convince this Court that such a statement would replace the need for expert testimony in a case where it is generally required.[19]

In *Vanderwerf v. SmithKlineBeecham Corp.*, plaintiffs alleged that Paxil, a drug used to treat depression in adults, caused a family member to commit suicide. 529 F. Supp. 2d 1294, 1297-98 (D. Kan. 2008). After plaintiffs' expert was excluded, plaintiffs argued that even without their expert's testimony, the defendant had "admitted general causation" based on testimony of "its corporate representative." *Id.* at 1307. The court held that plaintiffs had misrepresented the corporate representative's testimony, *id.*, and that at most the defendant had admitted that the drug "*may* increase the risk of suicidal behavior and suicide in adult patients between the ages of 18 and 30," which did not suffice to create a genuine issue of material fact because plaintiff's decedent was 36, *id.* at 1308 (emphasis in original). Although one could read the court's discussion as suggesting that had the testimony been more concrete and more applicable to plaintiff's decedent, it might have been enough to create a genuine dispute of material fact, the court never held as much, and never even discussed the issue, apparently

[19] In *Lewis v. Johnson & Johnson*, the Fourth Circuit found no error in the district court directing a verdict for the defendant because no expert testimony on causation had been offered, adding, "[Plaintiff] does not argue that the remaining testimony – by, for instance, employees of the defendant – establishes causation." 601 F. App'x at 212. Its comment could be read as suggesting that a directed verdict might not have been appropriate if statements of employees established causation. But this *dictum* in an unpublished decision that the court designated as non-precedential does not hold that, or even discuss whether, stray statements of employees are sufficient to raise an issue of fact on the causation element in cases where expert testimony is required to prevent a jury from speculating.

preferring to reject plaintiff's argument on a factual basis rather than get into an unnecessary legal issue.[20]

In *Rhodes v. Bayer Healthcare Pharmaceuticals, Inc.*, the court had excluded plaintiff's expert's opinion on general causation and held that "[a]bsent evidence of general causation, there is no valid factual predicate for [the expert's] opinion regarding specific causation." No. 10-CV-1695, 2013 WL 1289050, at *6 (W.D. La. Mar. 26, 2013). It noted in a footnote that plaintiffs had argued that the defendant (Bayer) admitted in its labeling that the drug in question can cause the alleged injury, but found that argument "entirely false," citing the language of the alleged admission to the effect that certain injuries had "been reported." *Id.* at 6 n.3 (internal quotation marks omitted). That the *Rhodes* court chose to dispatch plaintiff's admission argument on

[20] In their sur-reply, Plaintiffs suggest that *In re Accutane Products Liability*, 511 F. Supp. 2d 1288 (M.D. Fla. 2007), also supports their argument. (Ps' Sur-Reply at 2-3.) In *Accutane*, the court found that an expert's reliance on internal company documents and case reports did not have sufficient indicia of reliability. *Id.* at 1296-98. The expert had concluded that the defendants' employees had admitted causation, a conclusion that the court found so baseless that it had already precluded mention of the so-called admissions at trial. *Id.* at 1297-98. In rejecting the expert's conclusion that defendants had admitted that Accutane caused the disease in question, the court stated that if that were the case, it "could have saved a lot of time" and "this opinion would have been unnecessary." *Id.* at 1296. This remark – perhaps rooted in the commonsense notion that a manufacturer that had in fact unequivocally admitted causation in internal documents available to plaintiffs would be hard-pressed to deny causation in litigation – seems plainly designed to highlight how far off the expert was in regarding the documents as admissions of causation. The decision, confined to a *Daubert* analysis of an expert's opinion, contains no analysis of whether the admissions could, as a matter of state substantive law, have substituted for expert testimony had they truly been admissions. Moreover, *Accutane* further bolsters the idea that expert testimony is paramount in complex cases and that reliance on ambiguous documents like case reports that contain "subjective beliefs as to the causes of particular ailments" and "reflect the reporter's opinion as to causality" are insufficient to establish causation. *Id.* at 1297.

Plaintiffs also cite *Lugue v. Hercules, Inc.*, 12 F. Supp. 2d 1351 (S.D. Ga. 1997), in support of their argument that admissions are sufficient to defeat summary judgment even in the absence of expert testimony. (Ps' Sur-Reply at 3 n.4.) The *Lugue* court denied summary judgment because the defendant had "admitted in an interrogatory answer that its trucks were responsible" for contamination. *Id.* at 1358-59. This was a *judicial* admission. Judicial admissions are "formal concessions . . . by a party or counsel that have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact." *Hoodho v. Holder*, 558 F.3d 184, 191 (2d Cir. 2009) (internal quotation marks omitted); *see Banks v. Yokemick*, 214 F. Supp. 2d 401, 405 (S.D.N.Y. 2002) (judicial admission is formal act done in the course of judicial proceedings that concedes for purposes of the litigation that the proposition of fact alleged by the other side is true). Had Bayer admitted as part of this litigation that secondary perforation occurs, *Lugue* would be applicable. As it is, *Lugue* is irrelevant. But the existence of judicial admissions belies Plaintiffs' hyperbolic suggestion that if Bayer's argument here were to be accepted, "no court could ever accept a medical device defendant's admission of general causation when it wanted to try a case solely on specific causation" or "only on damages." (Ps' Mem. at 17-18.) In that situation a simple judicial admission by the defendant would accomplish the desired end.

factual grounds hardly amounts to a holding that a clearer admission would have substituted for expert testimony and sufficed to establish general causation.

Likewise, in a case involving the drug Zoloft, *Smith v. Pfizer, Inc.*, the district court held that a report made by defendant to the Irish Medicines Board could not fairly be understood as an admission of either an association or of general causation. No. 98-CV-4156, 2001 WL 968369, at *11 (D. Kan. Aug. 14, 2001). It did not address whether an actual admission, had there been one, would have sufficed to take the case outside Kansas' rule that expert testimony is necessary when "understanding of the facts is not within the common knowledge or experience of laymen." *Id.*[21]

None of these cases hold what Plaintiffs wish the Court to hold here: that a defendant's admission can substitute for expert testimony on general causation. To the contrary, they either dispose of that suggestion by finding that the statements at issue were not admissions of causation, and/or base their discussions on assumptions made for the sake of argument and not applicable here. A court's statement, in effect, that "Plaintiff loses because he has no expert on general causation, and by the way, he does not have anything else either," is not the same as a statement that "Plaintiff would have won if he had something else" – and it certainly does not suggest that that something else could be something much less reliable than expert testimony. To whatever extent the *dicta* in these cases arguably suggest that clear admissions could create a

[21] *Blaz v. Galen Hospital Illinois, Inc.*, involved a motion for class certification in a case involving radiation exposure. 168 F.R.D. 621 (N.D. Ill. 1996). The court found, in rejecting plaintiff's argument that the need to litigate general causation satisfied the typicality requirement of Federal Rule of Civil Procedure 23(a), that the defendants had "admitted that the treatments administered at [the hospital] during that time period [did] in fact place those treated patients at an increased risk for cancers," and thereby "conceded the general causation issue by admitting that a correlation exist[ed] between these cancers and the radiation treatment." *Id.* at 625. It located this concession in an affidavit submitted by the defendant. (*See id.*; N.D. Ill. Dkt. No. 96-CV-91 Doc. 50.) The *Blaz* Court plainly treated the affidavit as a *judicial* admission – a "formal concession[] . . . [a] factual affirmation[] or stipulation[] of some sort . . . that [removes the factual issue] from dispute." *Banks*, 214 F. Supp. 2d at 405 (internal quotation marks omitted). It said nothing suggesting that non-judicial admissions of the sort at issue here obviate the need for expert testimony.

genuine issue of material fact as to causation at the summary judgment stage, they are not persuasive authority for the proposition that admissions can substitute for expert testimony in cases where a complex medical or technical issue is involved. Not only do they not discuss the issue in any direct way – understandably, because they do not purport to hold what Plaintiffs suggest – but they do not consider the paramount importance of expert testimony on complex technical issues with which jurors are unfamiliar, or the reason for that requirement. The danger of a jury speculating on scientific issues means that, at least absent the clearest and most unambiguous admission that the product or device in question can cause the alleged injury, a jury exposed to admissions but not expert testimony will be without the grounding in science necessary to determine whether, as a scientific matter, the events the plaintiff posits can occur in real life. *See Porter v. Whitehall Labs., Inc.*, 791 F. Supp. 1335, 1352 (S.D. Ind. 1992) ("A jury cannot step blindly where science fears to tread."), *aff'd*, 9 F.3d 607 (7th Cir. 1993); *see also Pro Serv. Auto., L.L.C. v. Lenan Corp.*, 469 F.3d 1210, 1214 (8th Cir. 2006) ("[E]xpert testimony is necessary where the lay jury [does] not possess the experience or knowledge of the subject matter sufficient to enable them to reach an intelligent opinion without help.") (alteration in original) (internal quotation marks omitted); *Click v. Pilot Freight Carriers, Inc.*, 265 S.E.2d 389, 391 (N.C. 1980) ("[W]here the exact nature and probable genesis of a particular type of injury involves complicated medical questions far removed from the ordinary experience and knowledge of laymen, only an expert can give competent opinion evidence as to the cause of the injury.").

Meade v. Parsley, No. 09-CV-388, 2010 WL 4909435 (S.D.W. Va. Nov. 24, 2010), is instructive. There plaintiffs argued that a product's package inserts and warnings acknowledged a causal link between the drug and the alleged injuries. *Id.* at *7. The court noted that the

plaintiffs had not cited any 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," *id.*, and found that plaintiffs' contention was "undermined by the general principle that causation evidence in toxic tort cases must be in the form of expert scientific testimony," *id.* (citing *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002)). The court further held that the "drug['s] label, which merely warns of [its] potential side-effects without explaining the scientific basis for the warning, [was] no substitute for expert testimony that establishes causation in terms of reasonable probability." *Id.*

Not only would it leave the jurors at sea to allow employees' statements, taken out of context, to serve as admissions of general causation in an area that normally requires expert testimony, but as a policy matter it might stifle free discussion of adverse event reports and potential label changes, and discourage pharmaceutical companies and other manufacturers from open discourse, if such discussion might later be held to concede the issue of general causation. This danger is without any compensating benefit, given that comments of corporate employees, unmoored from their context and created in the conduct of daily business rather than through the formal procedures applicable to expert witnesses, are so inherently unlikely to be clear and definite enough to prevent the jury from being left to speculate as to whether a product is capable of causing a particular injury.

In summary, no court has held that admissions can substitute for required expert testimony, and this Court will not be the first. Such a ruling would disregard the purpose of the requirement for expert testimony, leaving jurors to speculate, and would chill free and frank discussion by manufacturers of drugs or devices. But I need not go so far as to say that admissions can *never* substitute for expert testimony, because – as discussed in the next section –

even if such statements could ever suffice, they would have to be much less ambiguous than the ones Plaintiffs offer here.

D. Bayer's Alleged "Admissions"

Even if admissions could conceivably ever substitute for expert testimony in a given case, they would have to be comparable to expert testimony in terms of reliability, not because Rules 701 and 702 or *Daubert* apply to admissions, but because otherwise they would not serve the purpose of expert testimony: providing the jury with a scientific, non-speculative basis to assess general causation. It is hard to imagine a case where Plaintiffs' counsel could not find an expert who could make the point using a reliable methodology, yet a patchwork of snippets of Defendants' employees' statements would do the trick. This, in any event, is not that case. The alleged admissions offered by Plaintiffs here do not suffice, because they are not clear or concrete or detailed enough, either individually or collectively, to permit a jury to consider intelligently the existence, or not, of secondary perforation. To the contrary, to the extent they support Plaintiffs' thesis at all, they are so patently less reliable than admissible expert testimony that they cannot reasonably substitute for such testimony. I will discuss each of the alleged admissions in turn.

1. Adoption of the Progestasert Label

Plaintiffs argue that the label for the IUD Progestasert constitutes an "adoptive admission" by Bayer.[22] (Ps' Mem. at 3-4, 21-23.) Progestasert was a hormone-releasing IUD manufactured by Alza Corporation that provided contraceptive effects for up to one year.

[22] Plaintiffs also discuss the label of another IUD – ParaGard – but only for "context"; they specifically note that Plaintiffs "do ***not*** contend that Bayer's adoption of the ParaGard label is an admission of general causation." (Ps' Mem. at 4 n.4 (emphasis in original).) This is no surprise, because, as Plaintiffs acknowledge, the ParaGard label discusses migration, not perforation. (*Id.*) Further, it purports only to summarize anecdotal reports, not scientific findings. (Kekatos Decl. Exs. 10, 11, 12.)

(Kekatos Decl. Ex. 13, at 2, 5.) The Patient Information section of the 1987 Progestasert label contains the sentence: "Partial or total perforation of the uterus may occur at the time of or after PROGESTASERT system insertion." (*Id.* at 6.) The FDA, in reviewing the Mirena label when it was introduced in 2000, said that its "[r]ecommended warnings [for Mirena] include the warnings that are currently on the USA labels for the other two USA-approved IUDs. These include warnings about . . . perforation . . . ." (*Id.* Ex. 4, at 2.) Plaintiffs argue that this reference to the Progestasert label, along with Bayer's failure to oppose or object to the FDA's recommendation, combined with testimony from Bayer's experts that the risks of other IUDs are similar to those of Mirena, shows that Bayer adopted the Progestasert warning and thereby admitted to the existence of secondary perforation. (Ps' Mem. at 3-4, 21-23.)[23] I disagree.

A person or entity can adopt another's statement "by any appropriate means, such as language, conduct or silence," and a party "may adopt a written statement by using it or taking action in response to or in compliance with it." *Penguin Books U.S.A., Inc., v. New Christian Church of Full Endeavor, Ltd.*, 262 F. Supp. 2d 251, 258 (S.D.N.Y. 2003). If the "statement at issue is a document, the adoptive admission test is whether the surrounding circumstances tie the possessor and the document together in some meaningful way." *In re: Gen. Motors LLC*, No. 14-MD-2543, 2015 WL 8578945, at *2 (S.D.N.Y. Dec. 9, 2015) (internal quotation marks omitted). This generally involves a party accepting and acting upon evidence or a report, such as by firing an employee. *See id.* (collecting cases).

Plaintiffs have not offered any evidence tying Bayer to the Progestasert label or showing that Bayer used or relied upon that label in any meaningful way. Bayer was not responsible for

[23] Bayer argues that the Progestasert label in 2000 stated, "It is generally believed that perforations occur at the time of insertion, although they may not be detected until later." (Opp. 56.1 Stmt. & Resp. ¶ 16; Shayna S. Cook Decl. Ex. 30, at 12.). Although this language would undermine Plaintiffs' argument, I need not resolve the dispute over which warning was in effect in 2000, (*see* Doc. 3259, ¶ 16), in light of my disposition below.

the wording of the Progestasert label or the FDA's suggestion. Nor did Bayer adopt the FDA's position: the Mirena label in fact differed from Progestasert's label, which was supposedly the warning the FDA recommended. Plaintiffs argue that because the FDA and Bayer's experts "agree . . . that Paragard, Progestasert and Mirena all have the same perforation risks," (Ps' Mem. at 3-4), this means that Bayer adopted the Progestasert warning. A defense expert opining that the FDA was aware of perforation as a risk of any IUD, (*see, e.g.*, Kekatos Decl. Ex. 6), or considering the risks of perforation across IUDs to be the same, (*id.* Exs. 5, 7, 8, 9), however, does not show that secondary perforation is one of those risks or that Bayer adopted the stance of the manufacturer of Progestasert or the FDA. Accordingly, Bayer's silence regarding, and implicit rejection of, the FDA's suggestion that it adopt the Progestasert label does not constitute an adoptive admission that secondary perforation occurs with Mirena.

Moreover, the Progestasert label, even if somehow adopted by Bayer, is hardly an admission that secondary perforation exists. It is far from clear that the statement that "[p]artial or total perforation of the uterus may occur at the time of or after PROGESTASERT system insertion" means that perforation may occur without any injury upon insertion. Rather, because it lumps partial and total perforation together, it could mean that a perforation initiated upon insertion might not become total – in other words, the device might not migrate clear through the uterine wall – until later. Or it could mean that when the uterine wall is damaged upon insertion, actual penetration by the device may occur then or later.

This ambiguous statement thus does not suffice to raise a genuine issue of material fact because it was neither adopted by Bayer nor an admission as to secondary perforation that the jury could consider without speculating.

2. Subsequent Mirena Label

Mirena's label changed in 2014.[24] The new label stated, with respect to the risk of 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." (Kekatos Decl. Ex. 19, at 13.) Plaintiffs argue that this statement (like the identical statement in the label for another Bayer IUS, Skyla) admits that secondary perforation occurs with Mirena. (Ps' Mem. at 24.) Unlike the unambiguous label statement in *Meridia 1*, 328 F. Supp. 2d at 810, or the clear statement in the MSDS in *Howell*, 2011 WL 4499372, at *5, however, the Mirena label does not clearly admit the existence of secondary perforation. Its grammar is complex – one might even say opaque – and it, like the Progestasert label, is susceptible to several different interpretations. The label's definition of perforation includes "penetration/embedment of Mirena in the uterine wall," so we know that the term "perforation," as used in the label, comprises more than a hole in or injury to the uterine wall. Thus, when the label says that "perforation" may occur "most often during," and therefore occasionally after, insertion, it cannot logically be regarded as meaning that injury to the uterine wall may occur apart from insertion. The thing that occurs after insertion could be the embedment or penetration of the Mirena, not the initial insult to the uterus. Indeed, if (as apparently intended) "perforation" here means the Mirena device's penetration into or passage through the uterine wall, the label says nothing meaningful about secondary perforation because it does not address whether there was any damage to that wall at the time of insertion. It thus would not make sense to read the label as saying perforation can occur apart from insertion. Further, the label does not distinguish between injury caused upon insertion (whether by the

[24] Defendants do not argue that the 2014 label is inadmissible under FRE 407 as a subsequent remedial measure, and accordingly I do not discuss the issue.

sound, the inserter or the Mirena itself) and injury caused by the Mirena later going into or through the opening created by that injury. It thus conflates in one sentence several different phenomena, and cannot fairly be read as a concession that what occurs "most often during insertion," and therefore occasionally after insertion, is a spontaneous journey of the Mirena out of the uterine cavity in the absence of any damage upon insertion. Indeed, Defendants interpret the warning as simply acknowledging that "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." (Ds' Mem. at 16.) That each side has a plausible reading of the label language that conflicts with the other's reading highlights that the label would leave the jury to speculate as to whether secondary perforation exists.

Plaintiffs argue that it should be up to the jury to assess the meaning of Defendants' statements, (Ps' Mem. at 24, 34; Ps' Sur-Reply at 5), but the problem is that in the absence of expert testimony, the jury would have no scientific basis on which to do so, and would be doing just what the requirement of expert testimony is designed to avoid: speculating about a complex medical process without any specialized information with which to make an intelligent decision as to whether it is capable of causing Plaintiffs' injuries. That there are disputes as to the meaning of Defendants' statements thus does not mean that the jury should – without any scientific basis – simply pick one side's position or the other's, but rather shows that they would be guessing if they undertook that task without expert testimony on the medical and technical issues.

Allowing this ambiguous language to form a basis of the jury's decision, where normally expert testimony on the subject is required, would undermine the principle that it is improper for a jury to speculate on matters that do not fall within the common knowledge or experience of a

lay person. *See Hughes*, 2010 WL 1961051, at *5; *Wilhelm*, 185 A.2d at 719. Further, there may be myriad reasons, including an abundance of caution or the avoidance of lawsuits, why a manufacturer may warn of a possible phenomenon without being convinced that it is a genuine risk, and permitting the label to substitute for expert testimony here would present a wholly conjectural basis for a jury to determine general causation. And allowing a label to substitute for expert testimony would discourage manufacturers from exercising caution, providing potential users with less information rather than more where the science is debatable, a result inimical to the public health.

Accordingly, the 2014 Mirena label does not create an issue of fact sufficient to defeat summary judgment on the issue of general causation. *See Meade*, 2010 WL 4909435, at *7 (label warning of side effect without explaining scientific basis for warning is no substitute for expert testimony that establishes causation in terms of reasonable probability).

3. Skyla Label

Plaintiffs argue that Bayer admitted the existence of secondary perforation through the label for Skyla, another IUS manufactured by Bayer, which is smaller than Mirena and used for up to three years rather than five. (Kekatos Decl. Ex. 16.) Like Mirena, it releases the hormone LNG. (*Id.*) The Skyla label (like the 2014 Mirena label) states: "Perforation (total or partial, including penetration/embedment of Skyla in the uterine wall or cervix) may occur most often during insertion, although the perforation may not be detected until sometime later." (*Id.*, at 14.) Plaintiffs again argue that the "most often" language of the label is an acknowledgement that perforation sometimes occurs after insertion which, along with Bayer's experts' statements opining that the perforation risks for all IUDs are the same, constitutes an admission that secondary perforation can occur with Mirena. (Ps' Mem. at 23.) As discussed with respect to

the Progestasert label, however, Bayer's experts' opinions that the risks of IUDs are the same does not amount to an admission that secondary perforation exists. Moreover, like the Progestasert label, the Skyla label – as already discussed in detail in with respect to the Mirena label – is too grammatically inscrutable to qualify as an admission that secondary perforation is a genuine phenomenon. This is not like the situation in *Meridia 1*, where the label at issue clearly stated that the alleged injury is caused by the drug. *See Meridia 1*, 328 F. Supp. 2d at 810. Further, as discussed above, a manufacturer may have motives, apart from science, for being overinclusive on a warning label.

For these reasons, the Skyla label is insufficient to create a genuine issue of material fact with respect to general causation.

4. Bayer's Health Canada Letter

In June 2010, Bayer sent a Dear Health Care Professional ("DHCP") letter to health care providers in Canada on the "[a]ssociation of MIRENA® . . . with the potential risk of uterine perforation." (Kekatos Decl. Ex. 22.)[25] The letter stated: "Uterine perforation may occur with MIRENA® at the time of insertion or after the insertion with limited clinical symptoms." (*Id.*) Plaintiffs argue that in this sentence Defendants admit that secondary perforation can occur. (Ps' Mem. at 5, 25-27.) Defendants argue that this language does not conflict with its position that damage may have occurred at insertion but is "only manifest[ed] later in perforation." (Ds' Reply at 7.)[26] The statement in the DHCP letter does not admit that secondary perforation – as Plaintiffs define it – occurs. As with the other statements that use the term "perforation," it is

[25] Because I find Bayer's Canadian DHCP letter does not create a genuine issue of material fact, I need not address whether the letter, which Bayer attributes to a Canadian entity, Bayer Inc., (Ds' Mem. at 25 n.7; Shayna S. Cook Decl. Ex. 37), but which was signed by a representative of Bayer Healthcare Pharmaceuticals, (Kekatos Decl. Ex. 22), may be attributed to the Defendants to this action.

[26] Ds' Reply refers to Reply Memorandum in Support of Defendants' Omnibus Motion for Summary Judgment. (Doc. 3245.)

grammatically odd, but it can best be read to say simply that the Mirena device itself may penetrate the uterine wall during or after insertion, but to say nothing about whether penetration after insertion occurs with or without damage to that wall upon insertion.[27] As with the previously discussed statements, the ambiguity in the language of this letter as to what is meant by perforation and as to the timing of perforation does not create a genuine issue of material fact because without an expert to opine on the mechanism of secondary perforation, the jury would have to speculate on what the letter's author meant by perforation in that context, whether the letter meant to say that it can occur without injury upon insertion, and how that might occur. This letter cannot satisfy Plaintiffs' burden to prove general causation in the absence of expert testimony. *See Vanderwerf*, 529 F. Supp. 2d at 1307-08 (DHCP letter disclosing possible risk of increase in suicidal behavior was insufficient to create a genuine issue of material fact as to causation).

4. Statements by Bayer Employees & Internal Documents

Finally, Plaintiffs have compiled emails, a PowerPoint presentation given by a Bayer employee, and deposition testimony that they argue admit the existence of secondary perforation and therefore general causation. (Kekatos Decl. Exs. 23, 24, 28, 29, 31, 34.) These emails "demonstrate that [Bayer] employees raised questions" about the timing of perforations in Mirena users "and discussed possible changes to the product label, generally without reaching conclusive findings." *See In re Zoloft (Sertralinehydrochloride) Prods. Liab. Litig.*, No 12-MD-

[27] Two sentences earlier, the DHCP letter states, in describing "post-market reports of uterine perforation," that "[s]ome cases of uterine perforation were not detected during or immediately after the insertion." (Kekatos Decl. Ex. 22.) This suggests that that the later sentence's reference to "perforation . . . with MIRENA® . . . after the insertion with limited clinical symptoms," (*id.*), may be intended to describe post-insertion *detection* of the device's perforation, not a situation where the device migrates post-insertion in the absence of injury to the uterine wall associated with insertion.

2342, 2016 WL 1320799, at *9 (E.D. Pa. Apr. 5, 2016). They do not amount to admissions that secondary perforation exists.

One example to which Plaintiffs point is a discussion document regarding the U.S. patient insert for Mirena, authored in 2000 by medical advisor Hannele Savonius, which states – in connection with expulsion, not perforation – that "expulsion is not always complete" and that uterine contractions during menstruation may push the IUD out of place or expel it. (Kekatos Decl. Ex. 23, at MIR_JR_00203754.) This communication does not mention perforation, let alone secondary perforation, let alone state that uterine contractions may push the IUD into or through the uterine wall. In short, it does not conflict with Bayer's position that perforation may not be complete upon insertion but is related to the insertion procedure.

In the emails that Plaintiffs argue are admissions of general causation, (*id.* Exs. 24, 28, 29), Bayer employees discuss case reports that they have received regarding perforations, and discuss the potential need for further investigation. These cannot serve as admissions of general causation that secondary perforation occurs, *see Zoloft*, 2016 WL 1320799, at *9 (internal discussion documents insufficient to prove general causation); *Meridia 1*, 328 F. Supp. 2d at 809 (internal company documents that did not represent conclusions were not admissions), and permitting them to do so would have a chilling effect on pharmaceutical employees in discussing adverse event reports and possible label changes.

Further, as with previous statements, these emails are ambiguous because the authors do not seem to apply a uniform definition of the term "perforation." For example, the Jaakkola email, (Kekatos Decl. Ex. 24), seems to contrast situations where the Mirena penetrates the myometrium at insertion with situations where that occurs later, but does not say that in the latter scenario, there had been no injury to the uterus upon insertion. The event that Jaakkola says can

happen "in association with insertion or later" is "the IUS . . . end[ing] up in the abdominal cavity," which he says can happen even if the "IUS was properly in situ first." (*Id.* at MIR_AC_00373529.) But he does not say that that can happen absent any injury to the uterus at the time of insertion. He does say that "in many cases when the IUS is found in [the] abdomen, there has been an [*sic*] uterine perforation," (*id.*), which, he explains, is why Defendants, for internal purposes, code all such events as perforations. The phrase "in many cases" arguably means that not all cases where the Mirena has migrated to the abdomen follow a uterine perforation, but the context suggests that he meant that in many cases there was an *observed* uterine perforation, whereas in some cases no such perforation was reported. In any event, no Plaintiff has claimed that migration could occur absent perforation, or that it occurred that way in her case. And Jaakkola's comment was made in the context of explaining why no separate figures for migrations and perforations exist, not in presenting an opinion as to whether secondary perforation exists.

Likewise, the Sallinen email, (*id.* Ex. 28), focuses on reporting of perforation before and after the introduction of a new inserter. After noting the lack of information regarding which inserter was used when the perforation is reported well after insertion, Sallinen says that some perforations occur "late and not associated to insertion procedure." (*Id.* at MIR_PSEU_00286454). This clearly seems to refer to the reporter of the event not associating a late-discovered perforation with insertion, and does not constitute a statement that Sallinen believes secondary perforation exists.

The Walsh email, (*id.* Ex. 29), discusses reports regarding migrations that occur without any initial uterine injury being noted, and muses on whether to mention these reports on the label with the caveat that they may have involved injury at the time of insertion. This hardly amounts

to a concession that spontaneous migration occurs – in other words, that they did *not* involve injury upon insertion. Case reports are not reliable evidence of causation, *see McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (finding that "reports reflect complaints called in by product consumers without any medical controls or scientific assessment" and that this "[u]ncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation"); *Zoloft*, 2016 WL 1320799, at *9 ("[Adverse event] reports are certainly relevant to the generation of study hypotheses, but are insufficient to create a material question of fact on general causation."); *Accutane*, 511 F. Supp. 2d at 1298 ("[Adverse event] reports are unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes."); *Cloud v. Pfizer Inc.*, 198 F. Supp. 2d 1118, 1138 (D. Ariz. 2001) ("[I]ndividual case reports and retrospective medical articles summarizing individual case reports are not an adequate basis from which a jury could conclude that [the drug] causes [injury]."), and an employee's ruminations about them are little better.

A "Lunch and Learn" PowerPoint presentation given in 2008 by Chuck Walsh, a Bayer employee in the drug safety department, (Opp. 56.1 Stmt. & Resp. ¶ 24; Kekatos Decl. Exs. 26, 31), states in a bullet point on one slide: "Migration into the abdomen (spontaneous perforation unrelated to insertion) can occur." (Kekatos Decl. Ex. 31, at MIR_CW_00636230.) Plaintiffs argue that this statement is an admission that secondary perforation exists. (Ps' Mem. at 31.) But the previous bullet point on the same slide reads: "Uterine or cervical perforation possible during insertion – 'sounding' depth to fundus 6-10 cm," (Kekatos Decl. Ex. 31, at MIR_CW_00636230), which suggests perforation occurs upon insertion, not after. In any event, the statement on which Plaintiffs rely conflates migration and perforation, perhaps reflecting the

reality that in the abbreviated setting of a PowerPoint presentation, for an informal gathering where words are not chosen as carefully as they are during a lawsuit, ambiguity can result.[28] It seems clear that the journey of the Mirena from the uterus to the abdomen is called "spontaneous" because it occurs after insertion, not because Walsh was saying that it occurred in the absence of any injury at the time of insertion. In any event, in the absence of expert testimony, a jury would be required to speculate on the meaning of these words and on whether there is any scientific basis for believing that Plaintiffs' theory of general causation is sound.

Finally, the deposition testimony of Dr. Antonio Costales, (*id.* Ex. 34), Bayer's Global Medical Expert for Therapeutic Area Primary Care in Women's Healthcare in Clinical Development, (Opp. 56.1 Stmt. & Resp. ¶ 26), does not create a genuine issue of material fact. Dr. Costales' testimony ponders the possibility that a perforation unrelated to insertion could occur. (Kekatos Decl. Ex. 34, at 26:22-28:18.) He "acknowledge[s] that [perforation without insertion-related injury] could happen" if "an inanimate object would be . . . like, moving," such as where "Mirena may have been inserted in a woman who has let's say fibroids and fibroids would be growing." (*Id.* at 28:18, 28:13-14, 27:15-17). The gist of his testimony is that anything is possible and he could "imagine" a scenario when something "doesn't happen the way you would expect," but he believed "99 percent" that injury upon insertion would have to occur. (*Id.* at 27:8, 27:7, 27:2-3.) Whatever Dr. Costales meant, it was not that he believes that secondary perforation exists. To the contrary, he seemed to be indicating that he did not believe it existed but could not rule it out because "medicine really is not an exact science. I believe it's

[28] At his deposition, Mr. Walsh explained that the bullet point reference to spontaneous perforation reflected what the reporter had told Bayer: "[T]here are cases where the time frame of perforation is not reported to us and is unknown, and those might be referred to as spontaneous, quote, unquote. . . . [I]n other words, they were not reported as associated with insertion, although that doesn't mean they weren't, it's just that they were not related by the reporter as being occurring at insertion." (Kekatos Decl. Ex. 32, at 116:16-117:4.)

an art." (*Id*. at 27:4-5.) This is not evidence from which a reasonable jury could conclude that it is more likely than not that secondary perforation occurs. *See Mitchell v. Toledo Hosp.*, 964 F.2d 577, 582 (6th Cir. 1992) ("mere possibility" of factual dispute insufficient to defeat summary judgment) (internal quotation marks omitted); *Quinn v. Syracuse Model Neighborhood Corp*., 613 F.2d 438, 445 (2d Cir. 1980) ("mere possibility" of factual dispute insufficient "to overcome a convincing presentation by the moving party").

With all of these alleged admissions, a jury would have to read between the lines to discern the speaker's intended meaning, without any scientific or other basis to sort out the ambiguities. And even if the intended meaning could somehow be divined, the jury would have no basis to determine if the statements rest on a sound scientific footing. Expert testimony that amounts to no more than say-so is insufficient to defeat summary judgment, *see, e.g., Whitfield v. City of Newburgh*, No. 08-CV-8516, 2015 WL 9275695, at *27 (S.D.N.Y. Dec. 17, 2015); *Realtime Data, LLC v. Stanley*, 897 F. Supp. 2d 146, 153 (S.D.N.Y. 2012), and the comments cited by Plaintiffs here do not even rise to the level of say-so. They simply cannot fairly be interpreted as the speaker or author saying that secondary perforation exists. And even if they could, one simply cannot tell what scientific basis the speaker or author would have for such an assertion. The relevant jurisdictions require expert testimony so that juries will have a sound basis for assessing causation, yet absent expert testimony, a lay jury could not reasonably evaluate the meaning or reliability of such statements. They thus cannot serve as a substitute for expert testimony.

For the reasons stated above, the statements, labels and letters that Plaintiffs argue are admissions of the existence of secondary perforation are insufficient, individually or collectively,

to substitute for expert testimony and raise a genuine issue of material fact as to general causation.

III. Conclusion

Accordingly, assuming there could ever be admissions that would suffice to allow a jury to find general causation without speculating, the admissions to which Plaintiffs point here do not fit the bill. They are not sufficiently clear, concrete or detailed. "[A] lay jury could not sort out the fundamental proof issues in [Plaintiff's] favor on this evidentiary showing without engaging in impermissible and improper conjecture as to matters extending well beyond their common knowledge and experience." *Hughes*, 2010 WL 1961051, at *6. In most, if not all, cases – and certainly in this one – allowing admissions to substitute for expert testimony would defeat the salutary purpose of the expert-testimony requirement. In the absence of such expert testimony in cases where state law demands it, a jury would be left to speculate on the issue of causation. Further, allowing ambiguous and often confusing statements made by employees to serve as admissions of causation in a products liability case involving complicated medical injuries would chill open discussion of a product's risks.

Having excluded Plaintiffs' expert opinion on general causation, and having concluded that there are no admissions that can substitute for such opinion, and there being no dispute that all claims rise or fall with that decision, I find that Defendants have shown an absence of genuine dispute, and that no reasonable jury could find in favor of Plaintiffs, because there is no evidence in the record from which a jury could find that secondary perforation exists and is capable of causing Plaintiffs' injuries. The Court reaches this conclusion reluctantly, knowing that it will doom hundreds of cases, but in the Court's view it is compelled by the law.

For the reasons stated above, Defendants' Omnibus Motion for Summary Judgment is GRANTED. The Clerk of Court is respectfully directed to terminate the pending motions, (13-MD-2434 Doc. 3172; 13-MC-2434 Doc. 215), and enter judgment in and close all remaining member cases in this MDL.

SO ORDERED.

Dated: July 28, 2016
White Plains, New York

CATHY SEIBEL, U.S.D.J.