UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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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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PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' OMNIBUS MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Litigation looks deceptively easy when a party avoids the difficult issues and carefully frames the lesser aspects of a dispute to suggest it has the upper hand; but superficial treatment bears a price. Bayer's summary judgment motion avoids the important questions entirely – both those asked by the Court and those necessarily implicated by this motion – and distorts the lesser questions to the point where even those were answered incorrectly.

Plaintiffs are taking a different approach. The Court defined the relevant issues for this motion near the end of the April 5, 2016 status conference:

> THE COURT: … So, look. I think we'll tee up this motion. It's the defendants' burden. If I find that in the absence of specific facts I can't really decide, then I'll deny it. But if it's really going to be about **the pure legal issue of whether a plaintiff can ever succeed where the plaintiff doesn't have an expert under the laws of the 50 states,** I probably don't need a specific factual context for that….
>
> **What about the situation where there are, arguably, admissions?** And we know what they all are. So if I found it in cases where it's not common knowledge or a natural inference that admissions could substitute for expert testimony, then **I could look at what the admissions are and say they are or are not fact issues as to what these statements mean.**
>
> So you know, I think the way to get the ball rolling the most quickly is for me to entertain the motion.

Ex. 1 (Apr. 5, 2016 Stat. Conf. Tr.), 25:7-25 (emphasis added).[1] Plaintiffs will answer those questions as clearly and directly as they can; but will first address Bayer's overreaching, correct the unusual number of legal errors contained in its brief, and explain why its arguments are meritless. For years, Bayer[2] has admitted – everywhere but in the courtroom – that Mirena can

[1] "Ex. __" refers to exhibits annexed to the accompanying Declaration of Diogenes P. Kekatos.

[2] For the sake of convenience and simplicity, the Bayer Defendants will be referred to in the singular throughout this Memorandum, and references to "Bayer" or "Defendant" will include reference to predecessor Bayer entities Berlex, Leiras, and Schering AG.

perforate the uterus after being properly inserted.[3/4] Bayer's novel argument that admissions are not allowed with respect to causation issues in medical device cases is plainly incorrect. A party's admissions are admissible evidence, and when such evidence shows that a defendant has admitted general causation (that is, admitted that the complained-of injury *can* occur) no expert testimony on that subject is required.

Bayer has cited neither facts nor law sufficient to meet its burden on summary judgment in *any* state, much less all 50. Its motion should therefore be denied.

II. SUMMARY OF MATERIAL FACTS

The following summary of material facts is drawn from Plaintiffs' Local Rule 56.1(b) Opposing Statement of Material Facts (hereafter "OSMF"), filed contemporaneously with this motion response.

A. GENERAL OVERVIEW OF MIRENA AND PLAINTIFFS' CLAIMS

Mirena is an intrauterine device (IUD) used primarily for birth control, though it can also be prescribed for heavy menstrual bleeding. It is sometimes referred to as a "hormonal IUD" or an "intrauterine system" (IUS) because it incorporates a birth control hormone, levonorgestrel, which is slowly released in the uterus. When Mirena is properly inserted and remains correctly positioned in the uterus, it can provide effective birth control protection for up to five years. Mirena is manufactured by Defendant Bayer and has been sold in the United States since it was approved by the Food and Drug Administration (FDA) in December 2000. More than two million women in the United States use Mirena. OSMF ¶¶ 8-11.

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[3] The parties sometimes use "secondary perforation" as a shorthand reference for uterine perforations that occur after the proper insertion of the Mirena IUD.

[4] Most MDLs involve a dispute about general causation both *inside* and *outside* the courtroom.

Plaintiffs allege that Mirena's warnings are inadequate regarding the risk that Mirena can migrate and perforate the uterus. Specifically, while the Mirena label has always warned of the risk of uterine perforation occurring in connection with *insertion*, until the label was revised in 2014 there was no meaningful indication that Mirena can also perforate the uterus months or years *after* it has been properly inserted. Bayer's failure to adequately warn of the secondary perforation risk has serious implications. Women who are not aware of the risk that perforation can occur long after their Mirena IUD was properly inserted are not going to monitor their IUDs as closely as women who know and understand that risk. Other women will find the uncertainty of the on-going risk of perforation after a proper, uneventful insertion to be unacceptable, and would not use Mirena at all if they were aware of that risk.

B. ADOPTIVE ADMISSIONS: THE PARAGARD AND PROGESTASERT LABELS

1. FDA And Bayer Agree That Mirena's Perforation Risks Are The Same As Those Of Its Competitor IUDs

At the time of Mirena's approval, there were only two other IUDs approved by FDA and sold in the United States:

[redacted]

Ex. 4 (FDA Medical Review for Mirena, NDA 21-225, p. 11) (emphasis added); OSMF ¶ 12. While ParaGard and Progestasert are not identical to Mirena, FDA understood that both of those IUDs were very similar to Mirena, and recommended that their warnings – whether for migration, perforation or other risks – be included in the Mirena label:

[redacted]

Ex. 4 (FDA Medical Review for Mirena, NDA 21-225, p. 6) (emphasis added); OSMF ¶ 13. Bayer's regulatory and other experts agree with FDA that ParaGard, Progestasert and Mirena all

have the same perforation risks. *See* SUMF ¶ 14 and Ex. 5-9 (reports for Bayer's regulatory experts Dr. Hixon and Dr. Feigal, and additional Bayer experts Adena Bargad, Ph.D., Dr. Courtney Schreiber, and Dr. Geri Hewitt). Bayer did not oppose or object to FDA's recommendation that the ParaGard and Progestasert warnings be used for Mirena.

2. The ParaGard "Migration" Warning

At the time of Mirena's approval in 2000, the ParaGard label had an FDA-approved warning for migration: **"There are reports of IUD migration after insertion."** Ex. 10 (1997 ParaGard label) (emphasis added); OSMF ¶ 15. FDA approved a modification of that warning in 2005, changing it to: **"Spontaneous migration has also been reported."** Ex. 11 (2005 ParaGard label) (emphasis added); OSMF ¶ 15. ParaGard's spontaneous migration warning remains unchanged today. Ex. 12 (2013 ParaGard label); OSMF ¶ 15.[5]

3. The Progestasert "Partial Or Total Perforation" Warning

When Mirena was approved, the Progestasert label carried FDA-approved language in the Patient Information section, informing women that **"Partial or total perforation of the uterus may occur *at the time of or after* PROGESTASERT system insertion."** Ex. 13 (1987 Progestasert label) (emphasis added); OSMF ¶ 16. Progestasert had been approved by FDA in 1976 and was discontinued in the U.S. market in 2001. *Id*.

C. **DIRECT ADMISSION: BAYER'S "SKYLA" IUD LABEL (2013)**

In January 2013, Bayer received FDA approval for Skyla, a slightly smaller version of the Mirena IUD. Skyla is said to provide contraceptive protection for up to three years. The "Perforation" section of the original Skyla label contained the following language:

[5] Although the ParaGard label is one of Bayer's adoptive admissions, the relevant label language for ParaGard addresses *notice of migration*, not *causation*. Accordingly, while ParaGard is referenced here to provide context for Bayer's other label admissions, Plaintiffs do ***not*** contend that Bayer's adoption of the ParaGard label is an admission of general causation.

> 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.

Ex. 16 (Skyla label, January 2013) (emphasis added); OSMF ¶ 17. This perforation language remains unchanged in the Skyla label today. Ex. 17 (Skyla label, Sept. 2013). Bayer's experts again agree that the perforation risks for Skyla and Mirena are the same. *See* OSMF ¶¶ 14, 17 and Exs. 5-9.

D. DIRECT ADMISSION: REVISED PERFORATION WARNINGS FOR MIRENA (2014)

The perforation language referenced immediately above for Skyla was approved by FDA for use in the Mirena label in May 2014. The language is identical to that used for Skyla, save for inserting "Mirena" in place of "Skyla":

> 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. 19 (Mirena label, May 2014) (emphasis added); OSMF ¶ 18. This perforation language remains unchanged in Mirena's current label. Ex. 20 (Mirena label, Oct. 2015).

E. DIRECT AND/OR ADOPTIVE ADMISSIONS: BAYER'S HEALTH CANADA LETTERS

The seriousness of Mirena's perforation risk was underscored by action taken by Bayer in Canada in collaboration with Health Canada, the Canadian regulatory equivalent of the FDA. In 2010, Bayer issued a Public Communication and a Dear Health Care Professional letter directed to these issues. The documents specifically noted that "uterine perforation may occur with Mirena at the time of insertion *or after the insertion* with limited clinical symptoms."[6] (Emphasis added.) Bayer has not provided similar information for doctors and patients in the United States.

[6] *See* Ex. 21 (Public Communication); Ex. 22 (Dear Health Care Professional). OSMF ¶ 19.

F. **DIRECT ADMISSIONS: BAYER'S INTERNAL DOCUMENTS**

Bayer has been aware of the risk of secondary perforation and potential mechanisms for causing it since at least 2000, when Mirena entered the U.S. market. In a June 2000 email, [redacted]; OSMF ¶ 20. Another email sent over a decade ago was even more explicit:

[redacted]

Ex. 24 ([redacted]) (emphasis added); OSMF ¶ 21.

Later in 2004, [redacted]:

[redacted]

Ex. 28 ( ) (emphasis added); OSMF ¶ 22.

Two years later in 2006, :

Ex. 29 ( ) (emphasis added); OSMF ¶ 23, 25. :

Id. This suggested label change was shelved by Bayer and never implemented. OSMF ¶ 23, 25.

Finally, in May 2008,), p.1; OSMF ¶ 24 Ex. 31, p.16 (emphasis added); OSMF ¶ 24-25.

G. **DIRECT ADMISSION: SWORN TESTIMONY OF**

An admission of general causation was also made during the discovery deposition of

[redacted] (emphasis added); OSMF ¶ 26-27.

Q. [redacted] (emphasis added); OSMF ¶ 26-27.

To this day, the risk of spontaneous perforation unrelated to insertion – well understood by Bayer – has never been clearly communicated to the millions of women using Mirena, or the physicians who prescribe it. OSMF ¶ 23. This on-going failure to warn underlies every lawsuit in the Mirena MDL.

III. LEGAL STANDARDS

A. SUMMARY JUDGMENT

The burden is on Bayer to establish that "the pleadings, depositions, answers to interrogatories, and **admissions on file**, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (emphasis added); Fed. R. Civ. P. 56(a). The Court must view all evidence in the light most favorable to Plaintiffs, and

resolve all reasonable doubts against Bayer – the party seeking summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

When the non-moving party produces significant relevant evidence that tends to contradict the moving party's allegations, and thereby creates a material question of fact, a motion for summary judgment must be denied. *Id*. at 256-57. "The court cannot try issues of fact" on a summary judgment motion; rather, "it can only determine whether there are issues to be tried." *Schering Corp. v. Home Ins. Co.*, 712 F.2d 4, 9 (2d Cir. 1983) (citations omitted). Summary judgment is a "drastic device." *Id*. at 6. It cannot be granted when "the party opposing summary judgment propounds a reasonable conflicting interpretation of a material disputed fact." *Id*. at 9-10.

B. ADMISSIONS

Under the Federal Rules of Evidence, an opposing party's statement is not hearsay when it is offered against the party and:

> (A) was made by the party in an individual or representative capacity;
>
> (B) is one the party manifested that it adopted or believed to be true;
>
> (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 while it existed[.]

Fed. R. Evid. 801(d)(2).[7] Statements made by employees in the course of their employment concerning any aspect of their involvement in a project are admissible as admissions of the

[7] The language of Rule 801(d)(2) was revised in 2011, changing what used to be called an "admission" to "an opposing party's statement." The Court and parties have continued to use the admissions terminology, since Rule 801(d)(2) is still commonly referred to as the admissions rule and the case law addresses such statements as admissions. The substance of Rule 801(d)(2)

employer under Rule 801(d)(2)(D). *See In re A.H. Robins Co., Inc.*, 575 F. Supp. 718, 724 (D. Kan. 1983) (citing 4 Weinstein's Evidence ¶ 801(d)(2)(D)[01]).[8] Once it is shown that an agency relationship exists between a corporate defendant and an employee, and that statements were made in conjunction with the agent's employment, the burden shifts to the defendant to "substantially controvert the status of [those statements] as admissions." *Id*. at 728.

Similarly, in the Second Circuit, once it is shown that an agency or employee relationship existed; that a statement was made during that relationship; that the statement related to a matter within the scope of the agency; and that the declarant was an advisor or other significant participant with respect to the subject matter of the statement; the requirements for a "vicarious admission" under Rule 801(d)(2)(D) have been met. *JAV Auto Ctr., Inc. v. Behrens*, No. 05 Civ. 6503 (CS), 2008 WL 9392107, at *3 (S.D.N.Y. Oct. 8, 2008) (Seibel, J.; citations omitted), *aff'd*, 360 F. App'x 176 (2d Cir. 2009).

"Adoptive admissions" arise under Rule 801(d)(2)(B) when the opposing party adopts the statement of another or otherwise indicates that it believes in its truth. *See Penguin Books USA, Inc. v. New Christian Church*, 262 F. Supp. 2d 251, 258 (S.D.N.Y. 2003). When statements are offered as adoptive admissions, it must be shown that the party against whom the statement is offered adopted or acquiesced to it. This can be manifested "by any appropriate means, such as language, conduct or silence." *Id*. (citing Weinstein's Federal Evidence, § 801.31 at 801.54-57; *Schering v. Pfizer, Inc.*, 189 F.3d 218, 239 (2d Cir. 1999).

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did not change with the 2011 revisions. *See* Fed. R. Evid. 801(d) advisory committee's note to 2011 amendment (noting that change was intended to be "stylistic only").

[8] The *A.H. Robins* case was an early MDL – now over 30 years ago – that addressed problems with another IUD, the Dalkon Shield.

"Adoption by use" involves the use of another's document, "such as where a party forwards a document to another in response to some request for information contained in the document." *Penguin Books*, 262 F. Supp. 2d at 259 (citations omitted). "[E]ven if the document is not expressly 'vouched for' by the party it must only be shown by implication that business was conducted in a fashion that the statement was adopted." *Id.*(citing *Pekelis v. Transcon. & W. Air, Inc.*, 187 F.2d 122, 128 (2d Cir. 1951)).

All types of Rule 801(d)(2) admissions, whether made directly by employees or adopted from others, are to be freely admitted into evidence:

> The [Rule 801] Advisory Committee Notes observe that because admissions against a party's interest are received into evidence without many of the technical prerequisites of other evidentiary rules – such as, for example trustworthiness and personal knowledge – admissibility under this rule should be granted freely. Liberal admissibility of this sort of proof is grounded on certain premises. One is that an employee is usually the person best informed about certain acts committed in the course of his employment, and another is that while still employed, an employee is unlikely to make damaging statements about his employer, unless those statements are true.

Pappas v. Middle Earth Condo. Ass'n, 963 F.2d 534, 537 (2d Cir. 1992). After an initial evidentiary determination by the judge, "any ambiguities and questions surrounding a party's actions and silences with regard to adoptive admissions should be left to the jury to assess." *Penguin Books*, 262 F. Supp. 2d at 259 (citing *United States v. Tocco*, 135 F.3d 115, 119 (2d Cir. 1998)).

IV. ARGUMENT

Plaintiffs will first address the significant overreaching and legal inaccuracies in Bayer's Memorandum. Bayer's main arguments, based on its mistakes of law, will also be debunked. Plaintiffs will then explain why Bayer's admissions are admissible evidence of general

causation. This Memorandum will conclude by providing, in summary fashion, fair and accurate answers to the questions the Court had asked Bayer to address in this motion.

A. BAYER'S MEMORANDUM RELIES ON IRRELEVANT ARGUMENTS, UNSUPPORTED LEGAL ASSERTIONS, AND LEGAL ERRORS

Bayer's central argument boils down to a lament that, in its view, this MDL should be disbanded because Plaintiffs' experts were excluded under *Daubert*. That does not end the inquiry, and does not justify Bayer's endless rehashing of the *Daubert* ruling or the myriad unsupported legal assertions and legal errors contained in its Memorandum.

1. Bayer's Repetitive Arguments About The Court's *Daubert* Order Are Irrelevant

The vast majority of Bayer's Memorandum is dedicated to rote repetition of the same argument it has made since the Court's *Daubert* Opinion (ECF No. 3073) was entered in March. Bayer argues that because Plaintiffs originally sought to present their case to the jury with general causation experts, and those experts have been excluded, Plaintiffs cannot prove general causation and the case should be done. That simplistic argument fails for two reasons.

First, Plaintiffs pointed out in their March 22, 2016 letter to the Court (ECF No. 3088) that while they would have preferred to use general causation experts, such experts are not needed because Bayer has admitted general causation many times over. There is sound legal authority – including authority from mass-tort MDLs and federal circuit courts – for the proposition that *a defendant's admissions can be used to satisfy general causation*.

Second, the parties and the Court recognize that the "need" for expert testimony on general causation issues is dependent on how the underlying issue is characterized. If an issue is described as complex, and there are no admissions to rely on, expert testimony will likely be required. If an issue is instead described as one a typical juror would understand, experts are not likely to be required. These issues were discussed at the April 5, 2016 status conference, where

Bayer described Mirena perforations as complex; Plaintiffs described them as simple; and the Court suggested they were somewhere in between the two. *See* Ex. 1 (Apr. 5, 2016 Stat. Conf. Tr.) 19:12-13.

In its Memorandum, Bayer devoted almost no attention to its admissions, treating them more like a problem it wished would go away than a serious legal issue. What little analysis Bayer did regarding admissions was so grossly flawed as to be meaningless. *See* Parts IV(A)(2)-(8).[9] Likewise, although Bayer insists that Mirena cases should be called complex, Plaintiffs correctly note that these are actually soft tissue cases. From Plaintiffs' perspective, this debate does not move the ball forward, and is not what the Court asked Bayer to address in its motion. In any event, reiterating that the Court's *Daubert* ruling excluded Plaintiffs' general causation experts does not answer the questions now at issue.

2. Bayer's Unsupported Legal Assertions Should Be Ignored

Bayer's brief is rife with legal assertions for which it cites no supporting authority, and for which – to the best of Plaintiffs' knowledge – none exists. Examples include:

- **"[N]o court has ever sanctioned such an approach."** (Bayer's Mem., p.12, discussing the use of admissions to establish general causation.)
    - This assertion is untrue. The *In re Meridia* cases (Northern District of Ohio and Sixth Circuit) clearly sanction this approach, as do all of the other cases cited in Part IV(A)(7) that took a serious look at this issue.
- **"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."** (Bayer's Mem., p. 12, again discussing admissions and general causation.)
    - This assertion is also inaccurate. There is no exception in Rule 801(d)(2) that frees medical device and pharmaceutical companies from the effects of their admissions. *See also In re Meridia Prod. Liab. Litig.*, 328

[9] *See also* Bayer's Ex. 1 (53-Jurisdiction Survey), which did not even address whether any jurisdiction would take the extraordinary step of refusing to accept admissions of causation.

F.Supp.2d 791, 799 (N.D. Ohio, 2004), and the other cases cited in Part IV(A)(7), where courts have addressed these issues.

- **"[I]t would turn *Daubert* on its head if Plaintiffs could [establish general causation through Bayer's admissions]."** (Bayer's Mem., p.13.)

    - This assertion is absurd. *Daubert* has nothing to do with an admissions analysis. *See*, *e.g.*, 30B Fed. Prac. & Proc. Evid. § 7015 (2014 ed.) ("Admissions of a party-opponent are not admitted because the person making the statement possesses expertise in the particular area. Whether the person possesses or does not possess expertise is itself completely irrelevant to whether a statement qualifies as an admission of a party-opponent."); *see also* Part IV(A)(5).

- **"[T]o 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."** (Bayer's Mem., p.28.)

    - This assertion is also inaccurate. The expertise or lack thereof of the person making an admission is irrelevant. *See* discussion in the bullet point immediately above. Also, the Seventh Circuit opinion on which Bayer relied for this and other similar statements, *Aliotta v. Nat'l R.R. Passenger Corp.*, 315 F.3d 756 (7th Cir. 2003), is acknowledged to have been wrongly decided and it should not be followed. *See* Part IV(A)(5).

- **"[N]o technique exists to rule out perforation or damage to the uterus at the time of insertion[.]"** (Bayer's Mem., p.31.)

    - This assertion is either false or misleading, depending on what Bayer means by "rule out." There are many techniques treating providers use to determine whether damage to the uterus was likely during IUD insertion (e.g., feel, patient reaction, string check, excessive bleeding, ultrasound). Those techniques can "rule out" injury to a reasonable degree of medical certainty, which is all the law requires. *See*, *e.g.*, *DeRienzo v. Metro. Transp. Auth.*, 694 F. Supp. 2d 229, 236-37 (S.D.N.Y. 2010) ("reasonable explanation" is sufficient for ruling out). Bayer's implication that "ruling out" requires *absolute certainty* is incorrect.

Plaintiffs understand why Bayer *wishes* the above propositions were true, but they strongly take issue with Bayer *representing them as true* when they are not. Bayer's unsupported assertions should be disregarded.

3. Bayer Misrepresents The District Court's *Meridia* Holding And Ignores The Sixth Circuit's *Meridia* Decision

Though it will be a challenging task, Bayer has every right to argue, as it appears to do, that *In re Meridia* supports its case. Bayer does not, however, have the right to misrepresent the court's holding. Bayer claims that "the district court in *Meridia* suggested that a clear admission in labeling *might* be sufficient to prove general causation[.]" Bayer's Mem., p.16 (italics in original). What the court actually said is far stronger:

> Reading the product inserts to both physicians and patients in the light most favorable to the Plaintiffs, as the Court must at this stage, **the Court concludes that the inserts constitute admissions of Meridia's potential to cause substantial increases in blood pressure *in some patients.***

In re Meridia, 328 F. Supp. 2d at 801 (bolding added; italics in original). Based on the label's contents, the district court denied defendants' motion for summary judgment on the issue of general causation with respect to the matters covered by the label. *Id*. at 810.

Bayer's Memorandum is completely silent on this point, but on appeal, the Sixth Circuit also addressed this issue, noting that "Plaintiffs argued on summary judgment, *inter alia*, that Meridia's warning label constitutes an admission that Meridia can cause injury." *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 866 (6th Cir. 2006). The Circuit Court then affirmed the district court's holding: **"we find no fault with the district court's treatment of the causation factor[.]"** *Id*. (bolding added).

4. Bayer Misrepresents The Reach Of *Meade v. Parsley*

Bayer again takes liberties when discussing *Meade v. Parsley*, 2010 WL 4909435 (S.D. W. Va. Nov. 24, 2010). First, Bayer claims that *Meade* is one of multiple "cases" demonstrating that "Plaintiffs' interpretation of *Meridia* is unsupported." Bayer's Mem., p.17. Yet Bayer cites no other similar case and Plaintiffs are aware of none. Second, even the quote Bayer used in its

brief makes it clear that in *Meade*, the "Plaintiffs cite[d] no authority" for the use of admissions to establish general causation. Review of the *Meade* decision shows that Fed. R. Evid. 801(d)(2) was neither cited nor discussed; nor was *In re Meridia*. It is telling that *Meade* is the best case Bayer can muster, particularly in light of the other cases endorsing the approach taken by *In re Meridia*. See Part IV(A)(7) below.

5. The *Aliotta* Case Should Not Have Been Cited And Should Not Be Followed

Bayer argues that its many admissions of general causation are unreliable "scientific opinions" barred by Rules 701 and 702, and *Daubert*. See Bayer Mem., p.28-29. Bayer relies exclusively on *Aliotta*, 315 F.3d 756, which held that party-opponent admissions are "[not] always free from the requirements of Rule 701(c), Rule 702, and *Daubert*." *Id*. at 763. Bayer's reliance on *Aliotta* is simply wrong, as is *Aliotta's* assertion that admissions can be excluded as improper expert testimony.

First, "it is well settled that the opinion rule does not apply to a party's admissions." 30B Fed. Prac. & Proc. Evid. § 7015 (2014 ed.) (quoting *Owen v. Atchison, T. & S. F. Ry. Co.*, 393 F.2d 77, 79 (5th Cir. 1968)); *see also* Fed. R. Evid. 801(d)(2) advisory committee's note ("the restrictive influences of the opinion rule" do not apply to admissions).

Second, *Aliotta* is not consistent with Rule 801(d)(2) and is not even followed in the Seventh Circuit where it was decided. *See, e.g.*, *Jordan v. Binns*, 712 F.3d 1123, 1128 (7th Cir. 2013) ("Because trustworthiness is not the touchstone for admissibility of party admissions, they are not subject to the personal-knowledge requirement of FRE 602 or the restrictions of the opinion rule of FRE 701.") (internal citations omitted).

Third, *Aliotta* is one of the most heavily castigated rulings on party admissions in modern history. The following excerpts from the leading treatise Federal Practice and Procedure regarding the *Aliotta* decision are instructive:

> **A truly disturbing and incorrect statement was made in *Aliotta*** *v. National R.R. Passenger Corp.*, 315 F.3d 756, 763 (7th Cir. 2003) that all admissions of a party-opponent are not "always" "free from the requirements of Rule 701(c), Rule 702 and *Daubert*[.]"
>
> Consider the simple admission of a truck driver that "I could have stopped in time if I were only going slower." Under *Aliotta*, the defendant trucking company could assert the opinion is not admissible because it involves an area of scientific knowledge and that clearly the truck driver, under the circumstances, is not an expert in the area[.]
>
> **The adversary theory supports introduction as substantive evidence of admissions of a party-opponent. You said it-the jury will hear it…. Whether the person possesses or does not possess expertise is itself completely irrelevant to whether a statement qualifies as an admission of a party-opponent[.]**
>
> **Appending the potentially totally disruptive and theoretically unjustifiable requirements that "Rule 701(c), Rule 702 and *Daubert*" must be complied with, for at least a vicarious admission of a party-opponent to be admissible, was a truly bad decision that should not be followed.**

30B Fed. Prac. & Proc. Evid. § 7015 (2014 ed.) (bolding and underlining added).

The *Aliotta* decision should not be invoked to impede Plaintiffs' use of Bayer's admissions. *Aliotta* has been severely discredited.

6. Bayer's Argument That Admissions Cannot Be Applied To Causation Is Unsupported And Should Be Rejected

Bayer's principal argument is that admissions, whether adoptive or otherwise, can never be used to establish causation because – according to Bayer – causation always requires expert testimony. *See, e.g.*, Bayer's Mem., p.12 ("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."). No supporting citation was provided by Bayer, and its argument makes no sense.

Under Bayer's novel theory, 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. According to Bayer, the Court would have to say something akin to the following: "No. I'm sorry, I can't do that. You need to bring in your experts, and we'll set aside several days to try the general causation issue. Then we'll move on to specific cause." Similarly, trying a case only on damages would be prohibited, since that would necessarily require admissions of both general and specific cause, and again – per Bayer – those issues would have to be addressed by experts.

There are no exceptions in Fed. R. Evid. 801(d)(2) that prevent the use of admissions for causation, or that offer special protections for medical device or pharmaceutical defendants generally, or Bayer specifically. Admissions can, and regularly do, suffice as proof of causation. They should serve that purpose here as well.

7. Bayer's Argument That Case Law Does Not Support The Use Of Admissions To Establish General Causation Is Simply Wrong

Bayer referred to only four cases that had considered the use of a defendant's admissions to satisfy general causation: *Meade v. Parsley*, discussed above in Part IV(A)(4); *Lewis v. Johnson & Johnson*, 601 F. App'x 205 (4th Cir. 2015), referenced by the Court at the April 5, 2016 status conference; and the *In re Meridia* district court and Sixth Circuit opinions, discussed above in Part IV(A)(3). Plaintiffs have located several additional cases addressing these issues: *Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294 (D. Kan. 2008); *Rhodes v. Bayer Healthcare Pharmaceuticals, Inc*, 2013 WL 12289050 (W.D. La. Mar. 26, 2013); and *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999).

Of the four cases cited by Bayer, *Meade v. Parsley* noted that the plaintiff had not provided any authority for using label information to establish general causation. The issue does not appear to have been researched by court or counsel, because *Meade* makes no reference to

Rule 801(d)(2), or to either of the *In re Meridia* cases, both of which had been decided years earlier. See *Meade*, 2010 WL 4909435. In *Lewis v. Johnson & Johnson*, the court suggested that admissions by defendant's employees could prove general causation, but no such evidence was offered. 601 F. App'x at 212. The *Meridia* courts both found that label inserts are proper admissions regarding general causation. *See* 328 F. Supp. 2d at 801; and 447 F.3d at 866.

In the *Vanderwerf* case, plaintiff's husband had committed suicide at the age of 36 while taking Paxil. Plaintiff tried to use admissions to establish general causation in two ways. First, she cited the deposition testimony of defendant's corporate representative, Dr. Kraus. The court analyzed Dr. Kraus' testimony in detail, but found that it amounted, at most, to an admission that Paxil may increase the risk of suicide "in adult patients between the ages of 18 and 30." 529 F. Supp. 2d at 1308. This was insufficient for the 36-year-old decedent. Second, plaintiff cited FDA findings of a statistically-significant increase in risk for suicidal behavior in adults. However, "FDA specifically rejected any association between suicidality or suicidal behavior in adults age 25 or older" (*id*.), which again excluded causation for a 36-year-old decedent. Although plaintiff was not able to secure admissions for adults the age of her deceased husband, the *Vanderwerf* court, like the courts in the *Meridia* cases and in *Lewis*, appeared to fully accept that admissions could be used to establish general causation.

In *Rhodes v. Bayer*, plaintiff sought to do what was done in the *Miredia* litigation and what Plaintiffs have done here: use Bayer's labeling information as an admission of general causation. The plaintiff in *Rhodes v. Bayer* was unsuccessful because Bayer's label addressed only *reporting*, not *causation*. *See* 2013 WL 1289050 at *6, n.3 ("rare cases … have been reported"). However, it is noteworthy that Bayer failed to disclose *Rhodes v. Bayer* – its own case – in these proceedings. Again, as with the *Meridia* cases, the court in *Rhodes v. Bayer* was

willing to accept admissions of general causation if they had appeared on the product's label. Further, as with *Lewis* and *Vanderwerf*, the court raised no objections to the use of admissions to satisfy general causation, whether those admissions appeared on the label or elsewhere.

In the *Westberry* case, plaintiff alleged injury to his sinuses from the inhalation of talcum powder lubricant used on rubber gaskets. The case went to trial and the jury entered a verdict for plaintiff. Defendant argued on appeal that there was no scientific literature on which plaintiff's expert could rely to satisfy general causation, i.e., to "rule in" talc as a possible cause of plaintiff's injury. 178 F.3d at 262-63. The trial court had allowed plaintiff's expert to satisfy general causation by citing the defendant's MSDS (Material Safety Data Sheet), which admitted that "[i]nhalation of talc dust in high concentrations irritates mucous membranes." *Id*. The Fourth Circuit affirmed the jury's verdict, finding that the admission contained in defendant's MSDS was admissible evidence that the alleged injury could occur. *Id*. at 264-65.

Finally, as described above in Part IV(A)(3), the Sixth Circuit affirmed the lower court's ruling in the *Meridia* litigation, finding that defendant's product label properly admitted general causation. *See Meridia*, 447 F.3d at 866 ("[W]e find no fault with the district court's treatment of the causation factor").

From the above tally, every court that has taken a serious look at this issue, including two federal circuit courts, has found that general causation can be established by admissions.[10] Bayer's protests to the contrary have no substance and should be rejected.

8. Bayer's Argument That "FDA Standards" Preclude The Use Of Labels As Admissions Is Meritless

Bayer argues at page 15 of its Memorandum that the standards for an FDA warning differ

[10] Because the *Meade* court did not find even the well-known *Meridia* cases, it seems fair to say that *Meade* did not involve a serious examination.

from the standards for general causation, and that this precludes the use of labels as admissions of general causation. The same argument was made before the Sixth Circuit in the *Meridia* appeal and soundly rejected. The court phrased the manufacturer's argument as follows:

> Abbott Labs invites this Court on appeal to hold that an FDA-required warning label can never create a triable issue of fact with respect to causation. This is so, Abbott Labs argues, because a regulatory agency's threshold of proof is lower than that appropriate in tort law, *see Allen v. Pa. Eng'g Corp.,* 102 F.3d 194, 198 (5th Cir.1996) (explaining that agencies employ a "weight of evidence" standard, whereas plaintiffs must prove causation by a preponderance), and because the FDA's own rules do not require a proven causal relationship before requiring a warning, *see* 21 C.F.R. § 201.57(e) (2005).

Meridia, 447 F.3d at 866. The court then explained why the defendant's argument failed in the context of a label being used as an admission:

> [T]hese arguments assume that the district court relied on *the fact of* the warning to find causation. The district court relied instead on the specific wording, *see In re Meridia,* 328 F.Supp.2d at 810, which was, according to several record depositions, the product of discussion between the FDA and the regulated party. Thus, we are unwilling to hold that an FDA mandated warning label can never constitute evidence of causation sufficient to create an issue of triable fact.

Id. (emphasis in original). Plaintiffs' situation in the instant case is the same as *Meridia*. They do not argue that Bayer's Mirena labels – whether the Progestasert label adopted by Bayer, or the 2013 Skyla label and 2014 Mirena label written by Bayer – constitute scientific proof of general causation. Rather, the words contained in those labels say ("admit") that the injury at issue in this MDL can occur, and that satisfies general causation. Bayer's argument regarding FDA standards should be rejected here just as it was in the *Meridia* MDL.

B. GENERAL CAUSATION IS ESTABLISHED THROUGH BAYER'S ADOPTION OF THE PROGESTASERT LABEL

Against the above background, Plaintiffs first note that this is an unusual case. When FDA prepared its Mirena Medical Review, [redacted] Bayer

agrees that the perforation risks are the same for Progestasert and Mirena, and it acquiesced in FDA's recommendation of the Progestasert warnings when it did not object to the Progestasert label. *See* discussion of Progestasert facts above at Part II(B).[11]

1. Bayer Adopted The Progestasert Perforation Warnings

Under these facts, the Progestasert perforation warnings are an "adoptive admission" of Bayer pursuant to Fed. R. Evid. 801(d)(2)(B). As discussed above in Part III(B), adoption of another person's statement can be shown "by any appropriate means, such as language, conduct or silence." *Penguin Books*, 262 F. Supp. 2d at 258 (citations omitted). There is no evidence of record in this case to suggest that Bayer ever voiced any concern with or objection to the Progestasert warnings, and Bayer had great business incentives to do so if it felt those warnings were inappropriate for Mirena.

An opposing party's admissions are to be freely admitted into evidence, *Pappas*, 963 F.2d at 537, and the Progestasert warning should be admitted as an adoptive admission of Bayer. If Bayer chooses to argue that the Progestasert warning means something other than what it says, that is a fact issue for the jury, not an impediment to admissibility.

2. The Progestasert Label Admits That The Complained-Of Injury Can Occur

Bayer does not and cannot reasonably argue that the Progestasert perforation warning FDA recommended for Mirena fails to address the risk of secondary perforation.[12] The Progestasert label states: **"Partial or total perforation of the uterus may occur *at the time of***

[11] Bayer admits general causation through IUD labels, letters, internal documents, and deposition testimony. All of Bayer's admissions will be addressed chronologically within each of those categories, starting here with Bayer's first admission: the Progestasert perforation warnings.

[12] Bayer sketches such an argument regarding the warning it prepared for the 2014 Mirena label at p. 16 of its Memorandum, to which Plaintiffs respond in Part IV(D)(1) below.

***or after* PROGESTASERT system insertion."** Ex. 13 (1987 Progestasert label) (emphasis added); OSMF ¶ 16. Bayer's position (when in court) is that Mirena perforates or starts to perforate only when inserted, but the Progestasert label makes it clear that perforation can also start after insertion. At a minimum, however, interpretation of the Progestasert label presents a fact question for the jury, which defeats this motion. *See, e.g.*, *Schering Corp.*, 712 F.2d at 9-10 ("summary judgment cannot be granted where, as here, the party opposing summary judgment propounds a reasonable conflicting interpretation of a material disputed fact").

C. GENERAL CAUSATION IS ESTABLISHED THROUGH BAYER'S "SKYLA" LABEL

Bayer received FDA approval for Skyla, a slightly smaller version of Mirena, in January 2013. Bayer's Skyla label contains the following perforation language:

> 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.

Ex. 16 (Skyla label, January 2013) (emphasis added); OSMF ¶ 17. As with Progestasert, Bayer and its experts agree that the perforation risks for Skyla and Mirena are the same. See discussion of Skyla facts above at Part II(C).

The issues with Bayer's Skyla admission are essentially the same as for the Progestasert label admission discussed above in Part IV(B), but Skyla is manufactured by Bayer, which is directly responsible for its label. This makes the Skyla label a *direct* admission of Bayer under Rule 801(d)(2)(A), rather than an *adoptive* admission under Rule 801(d)(2)(B).

Bayer questions whether its Mirena label is sufficient to constitute an admission. *See* Bayer's Mem., p.16. The 2013 perforation warning quoted above for Skyla is identical to the 2014 perforation warning for Mirena, except for the substitution of the product names "Skyla" and "Mirena." Plaintiffs' response to Bayer's argument regarding the 2014 Mirena label is stated below in Part IV(D)(1), and applies with equal force to the Skyla label.

D. GENERAL CAUSATION IS ESTABLISHED THROUGH BAYER'S REVISED MIRENA PERFORATION WARNING LABEL (2014)

The new perforation language used for Skyla in 2013 was approved by FDA for use in Mirena in May 2014. That language is identical to the Skyla language quoted in the preceding section, save for the use of "Mirena" in place of "Skyla":

> 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. 19 (Mirena label, May 2014) (emphasis added); SUMF ¶ 18. This is the perforation language in effect for Mirena today. Ex. 20. *See* discussion of Mirena facts above at Part II(D).

The basic issues regarding the 2014 Mirena label admission are again the same as for the Progestasert label discussed above in Part IV(B). As with Skyla, however, since Mirena is made by Bayer, the Mirena label is a direct admission of Bayer rather than an adoptive one. This direct admission should, by itself, end the discussion regarding Bayer's admissions of general causation.

1. Bayer's Challenge To The Sufficiency Of Its 2014 Mirena Label

Bayer argues that its 2014 Mirena label "does not explicitly state that Mirena causes secondary perforation." Bayer's Mem., p. 16. Bayer goes on to say that, in its view, what its label *really* means is "a partial perforation … may occur at insertion, but may not become a complete perforation … until after insertion[.]" *Id*. However, that is clearly not what the label says. It says "total or partial" perforations may occur "most often during insertion," which in common English means they *also* occur at times *other than insertion*, i.e., *after* insertion. Again, as with the Progestasert warning, Bayer's argument raises, at most, a fact issue regarding

interpretation, which precludes summary judgment. *See* discussion and case law cited at Part IV(B)(2) above.[13]

E. GENERAL CAUSATION IS ESTABLISHED THROUGH BAYER'S HEALTH CANADA LETTERS

Bayer issued a Public Communication and a Dear Health Care Professional letter in Canada in 2010, directed to the Mirena perforation issue. The documents specifically noted that **"uterine perforation may occur with Mirena at the time of insertion *or after the insertion* with limited clinical symptoms."** Exs. 21 & 22 (emphasis added); OSMF ¶ 19. *See* discussion of Health Canada facts above at Part II(E).

1. Bayer's "Wrong Company" Argument Should Be Rejected

Bayer argues that the Health Canada letters were "written by" a Canadian company, Bayer, Inc. Bayer's Mem., p.25 n.6. Regardless of who wrote them, the letters were printed on letterhead bearing the "Bayer Healthcare Pharmaceuticals" name associated with Defendant Bayer. Similarly, the letters were signed by an employee of Bayer Healthcare Pharmaceuticals, Shurjeel Choudhri, M.D. Accordingly, the letters appear to be either *direct* admissions of Bayer (if it actually wrote the letters) or *adoptive* admissions of Bayer (if the Canadian entity, Bayer, Inc., wrote them). Either way, Bayer should be bound by the admission in the letters that perforation occurs *either* "at the time of insertion" *or* "after the insertion."[14]

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[13] Bayer also makes the closely related argument that the lack of clarity of its perforation warning should keep it from being deemed an admission. *See* Bayer's Mem., pp.16-17. Plaintiffs agree that the Mirena label is poorly written. Even a cursory review of the labels for comparable IUDs like ParaGard and Progestasert shows that Mirena's perforation warnings fall far below industry standards. However, the fact that Mirena's warnings are substandard does not mean they cannot be used as admissions of general causation. To the extent that Bayer argues otherwise, it is again raising issues of interpretation that are not appropriate for summary judgment.

[14] Regarding signatories and the use of letterhead, *see, e.g., Att'y Gen. v. Irish N. Aid Comm.*, 530 F. Supp. 241, 252 (S.D.N.Y. 1981) ("With respect to the correspondence included in the file,

At page 25 n.7 of its Memorandum, Bayer argues that in order to attribute the admissions in the Health Canada letters to Bayer, Plaintiffs would "have to establish that the Canadian entity, Bayer Inc., was acting as an agent of one of the parties when it sent the letter to Canadian healthcare providers." In support of this contention, Bayer cites *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). Setting aside for the moment that any role by the alleged Canadian company, Bayer, Inc., in the Health Canada letters appears minimal or nonexistent, the "agency" approach taken by the *Zenith* court has been rejected for cases like this MDL.

This issue was addressed in *United States v. AT & T*, 1981 WL 2047, at *4 (D.D.C. Apr. 9, 1981), where the court noted that while the *Zenith* court's application of agency law "may be valid in the abstract," it was not a good fit for situations where related companies work together on the same project. The court described *Zenith* as a "conglomerate situation," where "the substantive activities of the two companies are unrelated[.]" *Id*. This was contrasted with the situation before the court, where there was "a close functional relationship among the component entities of the Bell System." *Id*. The court found that it would be "highly artificial … to separate out statements of [one company's] employees from those working for [other related companies] for admissions purposes." *Id*. The *AT&T* court then held that "it is appropriate to allow the various reports, memoranda, and conversations of employees of the Bell Operating Companies to be admitted as defendants' admissions." *Id*. at *5.

The same approach should be taken here as in *AT&T*. This is not a situation in which an

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those papers written on INAC's letterhead, those signed by INAC's representatives, and those that are unsigned but clearly emanating from the INAC office, are not hearsay. Under F.R.E. 801(d)(2), they constitute admissions by defendant.").

effort is being made to bind a corporate conglomerate to admissions made by a distinct subsidiary that was engaged in entirely different projects. Rather, Plaintiffs seek only to bind Bayer to admissions regarding Mirena. If, as Bayer claims, other Bayer entities were also working with it on Mirena, admissions made by the employees of those companies should be binding on Bayer in this litigation because all of the related companies were working on Mirena.

Finally, it would simply be unfair to let Bayer escape the reach of its admissions based on a hyper-technicality. Plaintiffs were told that they had sued the "proper parties" for personal injury claims concerning Mirena, and that those defendants "will not raise any defenses that any other foreign Bayer entity(ies) with a principal place of business outside the United States are/were the proper party to the lawsuit." ECF No. 706 (First Amended Proper Party Order), § 3(G). As a practical matter, Bayer is now raising such a defense with respect to Plaintiffs' ability to use admissions regarding Mirena, and that should not be allowed.

2. Bayer's Argument Regarding Foreign Regulatory Action Should Be Rejected

Bayer also argues that its Health Canada letters are "foreign regulatory actions" that should be excluded as prejudicial pursuant to Rule 403. Bayer's Mem., p.26-27. First, the letters at issue were *Bayer's* action, not that of a foreign regulator. Second, the admissions in Bayer's Health Canada letters pose no risk of confusion or unfair prejudice because they do not rely on any aspect of foreign law. For this purpose, Plaintiffs are not saying that Bayer "should have done in the United States what it did in Canada." Rather, they are saying that the *words* used in the Health Canada letters *admit* that perforation can occur either at insertion or after insertion, which meets the general causation requirement in this case. As the Sixth Circuit explained in its *Meridia* opinion, it is not the *fact* of the warning that is significant, only its *wording*; and just as

FDA standards were not implicated in *Meridia*, Canadian standards are not implicated here. *See Meridia*, 447 F.3d at 866, and discussion above at Part IV(A)(8).

F. GENERAL CAUSATION IS ESTABLISHED THROUGH BAYER'S INTERNAL DOCUMENTS

Bayer's employees have acknowledged in emails and other documents that secondary perforation occurs with Mirena. *See* discussion of facts regarding Bayer's internal documents above at Part II(F). Bayer now argues that those documents are inadmissible hearsay, or inadmissible for other reasons. *See* Bayer's Mem., pp.14-29. ach of Bayer's internal documents will be addressed in turn below.

[redacted]

The email [redacted]

[redacted]

[redacted]

(emphasis added); OSMF ¶ 20. This statement is not a direct admission that secondary perforation occurs. Rather, it is an admission that forces in the womb can push Mirena out of place, which in turn provides an explanation of how secondary perforation can occur. Bayer says the statement refers only to expulsion (Bayer's Mem., p.21), but that is again a matter of interpretation unsuited for summary judgment. *See* discussion above in Part IV(B)(2).

Emails between employees are admissible against their employer as admissions. *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 454 F. Supp. 2d 966 (C.D. Cal. 2006). Bayer's claim that admissions somehow run afoul of Rules 701 and 702, and *Daubert* (Bayer's Mem., pp.28-29), is completely wrong, and a product of its misplaced reliance on the flawed

Aliotta decision. *See* Part IV(A)(5) above. The [redacted] email was sent in the course and scope of employment (OSMF ¶ 20), and is therefore an admission under Rule 801(d)(2)(D).[15]

[redacted]. This acknowledges that perforations occur unrelated to insertion. [redacted] *Id*. (emphasis added).

Bayer asserts that the [redacted] email "merely summarize[s] and relay[s] information about adverse event reports," and cites *In re Zoloft*, 2016 WL 1320799 *9 (E.D. Pa. April 5, 2016), in opposition. Bayer's Mem., pp.20-21. First, the [redacted] email is discussing [redacted] *own views* on Mirena perforations, rather than summarizing any views expressed in adverse event reports. If Bayer disagrees, that is again a factual dispute for the jury to resolve. Second, unlike this case, the *Zoloft* case actually *did* involve the attempted use of adverse event reports. *See* 2016 WL 1320799 at *9 ("Plaintiffs cite reports in which doctors or patients reported adverse events…. These reports … are insufficient to create a material question of fact on general causation."). Plaintiffs in the instant case are not relying on any such reports.

[15] The documents at issue here either come directly from highly-ranked Bayer employees or highly-ranked employees of its predecessor companies (Leiras, Berlex, Scherling AG). Statements of a predecessor corporate employee are admissible against the successor under Rule 801(d)(2). *See, e.g., Jim Henson Prods., Inc. v. John T. Brady & Assocs., Inc.,* 16 F. Supp. 2d 259, 287 (S.D.N.Y. 1997).

The [redacted] email falls within the course and scope of [redacted] employment with Bayer's corporate predecessors. OSMF ¶ 21. It is therefore admissible against Bayer as an admission pursuant to Rule 801(d)(2)(D). *See, e.g., A.H. Robins*, 575 F. Supp. at 724; *JAV Auto Ctr.*, 2008 WL 9392107 at *3.

[redacted]

In November 2004, [redacted]

(emphasis added); OSMF ¶ 22.

Plaintiffs understand that [redacted] email refers to data from the Drug Safety group. By forwarding that information to her fellow employee, [redacted], the information became an adoptive admission of [redacted], and hence of Bayer. *See, e.g., White Indus., Inc. v. Cessna Aircraft Co.*, 611 F. Supp. 1049, 1062-63 (W.D. Mo. 1985) ("adoption by use" occurs "where the party forwards the document to another in response to some request (or perceived need) for information of the sort contained in the document."). Neither [redacted] nor [redacted] questioned the validity of the statement that "in some cases the perforation obviously occurs late and not associated to insertion procedure." This admission is again admissible against Bayer because [redacted], prepared the email in the course [redacted],[16] and the email was written within the scope of

[16] Leiras Oy originally developed the Mirena IUD in Finland, before licensing the rights to Schering AG to market Mirena in the United States through its subsidiary, Berlex. Bayer acquired Schering (and the rights to Mirena) in approximately 2006.

her employment relationship. OSMF ¶ 22. *See, A.H. Robins, supra*; *JAV Auto Ctr., supra*.

[redacted]

The December 21, 2006 [redacted] (emphasis added). A further admission is made that secondary perforation can occur when [redacted] *Id*. (emphasis added). As with the other email admissions discussed above, [redacted] was acting within the course and scope of his employment with Bayer [redacted] when he made these admissions. OSMF ¶¶ 23, 25. The admissions are properly admissible against Bayer.

[redacted]

The May 2008 [redacted] Mirena PowerPoint unequivocally states that secondary perforation occurs: [redacted] Ex. 31 ([redacted]), p.16 (emphasis added). [redacted] was again acting within the course and scope of his employment as [redacted] when he gave the [redacted] OSMF ¶¶ 24-25. His admission of general causation – that secondary perforation can occur – is properly admissible against Bayer under Rule 801(d)(2)(D). *See, e.g., A.H. Robins, supra*; *JAV Auto Ctr., supra*.

G. GENERAL CAUSATION IS ESTABLISHED THROUGH THE DEPOSITION TESTIMONY OF [redacted]

[redacted] OSMF ¶¶ 26-27. He admitted under oath that while [redacted] he agreed that [redacted] Ex. 34 ([redacted] Dep. Tr.), p. 28:5-8. Bayer mischaracterizes [redacted] testimony as stating that "perforation unrelated to insertion is just a 'possibility.'" Bayer's Mem., p.23. [redacted] never referred to secondary perforation as "just" a possibility. Rather, he was clear in acknowledging that it could happen. This is a direct admission from a high-ranking executive officer of Bayer, whose work specifically encompasses the Mirena IUD. OSMF ¶¶ 26-27. Bayer is bound by that admission.

H. PLAINTIFFS CAN ESTABLISH SPECIFIC CAUSATION

Bayer raises several arguments about specific causation in its Memorandum at pp.29-34. These appear to be largely repackaged versions of its underlying theory that the Mirena cases are unusually complex and require expert testimony. Nonetheless, three of the arguments will be briefly discussed below.

1. General Causation Will Be Established By Admissions

Bayer claims repeatedly that summary judgment must be entered on *specific* causation because *general* causation has not yet been established. That argument is unavailing. Plaintiffs have demonstrated above that there are multiple ways in which general causation can be established through Bayer's admissions, and this approach to general causation is fully supported by the courts. *See*, *e.g.*, cases discussed above in Part IV(A)(7).

2. Treating Providers Are Expert Witnesses, And Can Testify To Specific Causation

Bayer is particularly harsh on treating medical providers, suggesting that they are not

experts, and that they cannot testify to specific causation issues. *See*, *e.g.*, Bayer's Mem., p.32:

> 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.

That assertion is unfounded and simply wrong for several reasons.

First, treating providers *are* experts. Those who insert IUDs are presumably qualified to do so by their knowledge, skill, experience, training or education as described in Rule 702. Treating providers are regularly asked in personal injury cases for their opinions regarding what caused an injury, and whether the treatment they provided to the patient was appropriate. That testimony is routinely admissible, as alluded to by the Court during the April status conference:

> THE COURT: … [I]f you're the doctor and you're there, and you think it went fine, and you don't think any of your instruments, you know, made contact with the endometrium and everything seems cool, you couldn't say with a straight face, "More likely than not, I didn't cause any injury?"

Ex. 1 (Apr. 5, 2016 Status Conf. Tr.), 13:4-8. Bayer made no serious effort to answer the Court's question at the status conference, nor did it make such an effort in its Memorandum.

Second, the deadline for identifying specific causation experts for the Second Disposition Pool and later pools has not passed. It is likely that a number of treating providers will be identified as experts when the time comes.

Finally, Bayer has cited no precedent for precluding a treating medical provider from testifying that the treatment he or she provided was appropriate and did not cause injury. Because treating providers routinely testify to such specific causation issues at trial, there is no reason they should be barred from doing so here.

3. "Ruling In" And "Ruling Out" Does Not Need To Be Done With Mathematical Certainty

Bayer makes multiple references to the need for experts to "rule in" and "rule out" potential causes of injury, always implying that this process needs to be done with 100 percent

certainty. The law, however, requires only a *reasonable degree* of medical certainty when ruling a particular cause in or out. *See DeRienzo*, 694 F. Supp. 2d at 236-37 ("reasonable explanation" required) (citing *In re Fosamax Prods. Liab. Litig.*, 688 F. Supp. 2d 259, 268 (S.D.N.Y. 2010) (in turn quoting *Israel v. Spring Indus.*, 2006 WL 3196956 at *5 (E.D.N.Y. Nov. 3, 2006)).

I. PLAINTIFFS CAN SUCCEED WITHOUT GENERAL CAUSATION EXPERTS

In light of the above, Plaintiffs can successfully prosecute Mirena perforation cases without general causation experts for two separate and independent reasons: (1) Bayer has admitted general causation; and (2) these are not complex cases.[17]

1. Bayer Has Admitted General Causation

As detailed in this Memorandum, the Mirena perforation cases can be pursued without general causation experts because, by admitting that secondary perforation occurs, Bayer has admitted general cause. If Bayer is allowed to argue about the interpretation of certain admissions, that will be an issue for the jury at trial, not summary judgment. This requires the denial of Bayer's motion for summary judgment.

2. Mirena Perforation Cases are Not Complex

In light of Bayer's many admissions of general causation, any analysis of how the Mirena cases should be characterized (complex vs. simple) is irrelevant. As discussed previously, however, Plaintiffs typically describe Mirena cases as simple soft-tissue cases that do not require experts for general causation, while Bayer describes them as highly complex "toxic torts" with convoluted causation issues that require experts. This Court has said: "Well, it's clearly between the two." Ex. 1 (Apr. 5, 2016 Status Conf. Tr.) 19:12-13. In the absence of Bayer's

[17] As noted in Part IV(H) above, Plaintiffs will have experts for specific causation, many of whom are likely to be the treating medical providers.

admissions, the relevant questions would then become: *where* on the spectrum will each state put this issue, and *how* will it be resolved?

Categorizing the Mirena cases 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.[18] In view of the many unknowns, Plaintiffs respectfully submit that trying to resolve these issues on summary judgment for all 50 states could be an awkward fit for an MDL.[19] Because the law on how Mirena will be handled is not settled in any of the 50 states, much less all of them, Bayer cannot show how each state will resolve the issues, and therefore cannot meet its Rule 56 burden of establishing that it is "entitled to judgment as a matter of law." Accordingly, even without consideration of Bayer's admissions, its omnibus summary judgment motion should be denied.

J. PLAINTIFFS REQUEST THE OPPORTUNITY FOR SUR-REPLY

Given the importance of the issues, Plaintiffs respectfully request the opportunity to submit a 10-page sur-reply within 14 days of the filing of Bayer's reply. Bayer's motion seeks to terminate *every* plaintiff's recovery rights in this MDL. Given those grave and sweeping consequences and the limitations of Bayer's opening Memorandum, Plaintiffs should be afforded an opportunity to respond to Bayer's reply.

VII. CONCLUSION

For the reasons set forth above, the Court should deny Bayer's motion.

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[18] *See, e.g.*, Bayer's Ex. 1 (53-Jurisdiction Survey), which contains no reference to any state decision on whether Mirena cases will be categorized as complex or simple. Query also whether *any* state would regard a uterine perforation occurring, say, a year or more after an uneventful insertion to be so "complex" that it required general causation experts.

[19] *E.g.*, David F. Herr, *Annotated Manual for Complex Litigation, Fourth*, § 22.36, at 535-36 (rev. ed. 2016) (when summary judgment motions rest on application of transferor court's substantive law rules, remand may be appropriate because transferor judge may be able to decide motions most efficiently).

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