16-2890-cv(L), 16-3012-cv(CON)

United States Court of Appeals

for the

Second Circuit

IN RE: MIRENA IUD PRODUCTS LIABILITY LITIGATION

MIRENA MDL PLAINTIFFS,

Plaintiff-Appellant,

– v. –

BAYER HEALTHCARE PHARMACEUTICALS INCORPORATED,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF AND SPECIAL APPENDIX FOR PLAINTIFF-APPELLANT

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INTRODUCTION

Plaintiff-Appellants ["*Plaintiffs*"] are all women who have suffered injury due to secondary perforation of the uterus, a complication known and admitted to have been caused by the Mirena contraceptive intrauterine device (IUD) manufactured by Defendant-Appellees Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG and Bayer OY [*"Bayer"*].

This appeal addresses two errors committed by the court below, the first in excluding evidence based on a determination of scientific fact, in derogation of both *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993) ["*Daubert*"] and Fed. R. Evid. 702, and second, the application of the discredited reasoning of *Aliotta v. Nat'l R.R. Passenger Corp.*, 315 F.3d 756 (7th Cir. 2003) ["*Aliotta*"] to negate Plaintiffs' proof of general causation by party admissions under Fed. R. Evid. 801(d)(2). These errors, which subjected Plaintiffs to summary judgment, stem from scientific determinations by the district court which were incompatible with its permissible role under *Daubert* and at odds with a decade of scientific facts known and admitted by Bayer: that secondary perforation both exists and can cause the injuries suffered by Plaintiffs.

Though law may lag science, as the district court suggested, it cannot ignore it. By the same token, it has no permission to rewrite science, either by addition or omission. The end result of such liberties, if permitted, will "doom hundreds of cases",[1] leaving over a thousand injured women without their day in court.

STATEMENT OF JURISDICTION

Nearly 1,300 cases are part of this Multi-District Litigation [MDL], certified on April 8, 2013, pursuant to 28 U.S.C. § 1407. Federal courts had diversity jurisdiction over each case under 28 U.S.C. § 1332. Final judgment was entered on Bayer's omnibus summary judgment motion on July 29, 2016, in Case No. 13-MC-2434 [Doc. 226] and on August 2, 2016, in Case No. 13-MD-2434 [Doc. 3271], disposing of all MDL cases. On August 19, 2016, Plaintiffs timely filed their Notice of Appeal [Doc. 227] establishing appellate jurisdiction in this Court under 28 U.S.C. § 1291.

ISSUES PRESENTED FOR REVIEW

1. Did the court below misapply *Daubert* and Rule 702 by substituting its judgment for that of the jury, excluding the testimony of

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[1] *In re Mirena IUD Products Liab. Litig.*, ["*Mirena II*"] --- F. Supp. 3d. ---, 2016 WL 4059224 at *17 (July 28, 2016) [A-301, at A-339].

Plaintiffs' experts upon grounds that went to its weight, rather than its admissibility?

2. Did the court below err in granting summary judgment to Bayer on the ground that there was no proof of general causation, when general causation was established through Bayer's own admissions that Mirena could cause both secondary perforation of the uterus and the injury alleged by Plaintiffs?

STATEMENT OF THE CASE

A. Procedural History and Rulings Presented for Review

The Mirena IUD MDL was established in the Southern District of New York [Seibel, J.]. Several cases were then selected from those nearly 1,300 cases to be part of an Initial Disposition Pool ("IDP") and go through full discovery. [Docs. 883, 1524] As these cases progressed, the parties selected two cases, *Danley* and *Hayes*, as their first trial selections.

In preparation for trial, Plaintiffs named and submitted reports for several experts, including Drs. Roger Young, Susan Wray, and John Jarrell. On October 22, 2015, Bayer moved to exclude each of those experts under *Daubert*. [Docs. 2679-2699] Plaintiffs argued that these experts'

opinions were admissible under both *Daubert* and Rule 702 as they were relevant and reliable. [Docs. 2772-2787] At the district court's request, Plaintiffs appeared on January 12, 2016, to argue for the admissibility of Dr. Young's testimony.

On March 8, 2016, the district court issued an Opinion and Order excluding all of Plaintiffs' general causation experts, Drs. Young, Wray and Jarrell. [A-160], [Doc. 3073], *In re Mirena IUD Products Liab. Litig.*, ["*Mirena I*"] 169 F. Supp. 3d 396 (S.D.N.Y. 2016). This is the first ruling presented for review here.

On May 4, 2016, Bayer moved for summary judgment in all the Mirena MDL cases, claiming that Plaintiffs were now left without any experts to testify as to general causation, i.e., that Mirena was capable of causing secondary perforation. [Doc. 3172 at 1-2] In opposition, Plaintiffs submitted that general causation had been established by Bayer's own admissions. Those very admissions, at a minimum, also posed a jury question as to whether or not Plaintiffs had established such general causation. [Doc. 3227-3230] Following reply and sur-reply [Docs. 3245, 3262], the district court granted the motion for summary judgment on

July 28, 2016. [A-340, *Mirena II*]. This is the second ruling presented for review here,[2] dismissing all Mirena lawsuits in the MDL.

B. Statement of Facts

1. The Mirena IUD and Secondary Perforation

The Mirena IUD ["Mirena"] is manufactured by Bayer and has been sold in the United States since it was approved by the Food and Drug Administration (FDA) in December 2000. [Doc. 3228, ¶ 10] More than two million women in the United States use Mirena. [Doc 3228, ¶ 11]

Mirena is sometimes referred to as a "hormonal IUD" or an "intra-uterine system" ("IUS") because the device incorporates a birth control hormone, levonorgestrel, which is slowly released into the uterus. Mirena is inserted by a trained health care provider using an inserter provided by Bayer. [Doc. 3226-1, Ex. 2, at 2-3] Properly inserted, and remaining correctly positioned in the uterus, Mirena can provide birth control protection for up to five years. [Doc 3228, ¶ 9]

Plaintiffs' claims arise out of Bayer's inadequate Mirena warnings prior to 2014. Specifically, while the Mirena label has always warned of

[2] The entry of final judgments eliminated all the Mirena MDL cases on July 29, 2016 (Case Nos. 13-MC-2434 and 13-MD-2434) [SPA-1-2].

the risk of uterine perforation occurring in connection with the insertion of the device at the beginning of its use, until a label revision in 2014, Bayer's label failed to warn that Mirena could also perforate the uterus notwithstanding proper insertion at the outset. [Doc 3228, ¶¶ 18-19] This perforation, occurring after a proper insertion, is sometimes referred to as "secondary perforation," "spontaneous perforation," or "spontaneous migration" [collectively "secondary perforation"].

Secondary perforation means that Mirena travels through the uterus and enters a woman's abdominal cavity. Mirena can then become lodged in an internal organ or in the peritoneum that lines the abdominal wall. This can cause increasingly serious complications, including infections, abscesses, and damage to other organs, particularly since a woman may be unaware that Mirena has left her uterus. Mirena also stops providing contraception once it leaves the uterus, which can result in unwanted pregnancy. When Mirena perforates the uterus and enters the abdominal cavity, it must be removed through surgery. Following this initial removal surgery, additional surgeries may be necessary if the secondary perforation caused damage to internal organs, infection, or other complications.

2. Bayer Has Repeatedly Admitted that Secondary Perforation Can Occur with Mirena Use

For well over a decade, Bayer has admitted, *everywhere but in the courtroom*, that Mirena can perforate the uterus even *after* proper insertion. These admissions included several made by upper Bayer management and even one adopted by Bayer following an official recommendation by the FDA.

a. The 2004 Jaakkola Admission: "Of Course" Secondary Perforation Exists

Bayer and Leiras, a predecessor company that helped develop Mirena, have known and admitted internally for well over a decade that "of course" the risk of secondary perforation exists with Mirena use. On April 2, 2004, an internal email from Dr. Kimmo Jaakkola, Senior Drug Safety Physician for Leiras, to Chuck Walsh, a Drug Safety Officer for Bayer, was explicit:

> Wh[en it] comes to uterine perforation versus IUS migration, we handle all the cases in which the IUS by any means ends up in the abdominal cavity as uterine perforations no matter whether it happened in association with insertion or later. That is because we believe in many cases when the IUS is found in abdomen there has been [a] uterine perforation. ... **Of course cases in which the IUS was properly in situ first but migrates through the uterine wall by itself or with help of uterine contractions exist.**

[Doc 3228, ¶ 21, Ex. 24 (emphasis added)]

b. The 2004 Sallinen Admission: In Some Cases Secondary Perforation "Obviously" Occurs

On November 24, 2004, Pirjo Sallinen, who served as Mirena's Project Manager, International Project Manager, and Global Project Manager, noted the following when discussing a new inserter for Mirena with Steven White, then a Senior Manager for New Product Commercialization and Business Development at Bayer:

> [T]he exact time of perforation (in association with insertion versus later) is in many cases not known and **in some cases the perforation obviously occurs late and not associated to insertion procedure.**

[Doc 3228, ¶ 22, Ex. 28 (emphasis added)]

c. The 2008 Walsh Admission: Secondary Perforation "Can Occur"

In May 2008, Chuck Walsh, the same person who was Bayer's Drug Safety Officer in 2004 when he received the Jaakkola Admission, was Bayer's Global Product Expert for Women's Healthcare Products.[3] On May 8, 2008, Walsh prepared a "Lunch & Learn" PowerPoint about Mirena. [Doc 3228, ¶ 24, Ex. 31, at 1] The PowerPoint was presented to members of Bayer's drug safety department. The slide discussing

[3] Walsh later became Bayer's Pharmacovigilance Director.

Mirena's embedment and perforation issues *admits and concludes precisely what Plaintiffs allege occurs with Mirena*, and exactly what Plaintiffs established as to general causation:

> **Migration into the abdomen (spontaneous perforation unrelated to insertion) can occur.**

[Doc 3228, ¶¶ 24-25, Ex. 31, at 16 (emphasis added)] Obviously, nothing had changed in four years and secondary perforation had become part of Mirena's drug safety history as far as Bayer was concerned.

d. The 2013 Costales Testimonial Admission: "We Do Acknowledge That It Could Happen"

Dr. Antonio Costales, Bayer's Global Medical Expert, Women's Healthcare, in 2013 testified and admitted that Bayer understands that Mirena can perforate the uterus unrelated to insertion:

> Q. So Doctor, then would you agree that it is biologically plausible that Mirena can perforate the uterus in a non-insertion related manner?
>
> A. . . . **[F]or a perforation happening unrelated to insertion, rare as it may be, that's not the usual thing, but we believe – we do acknowledge that it could happen.**

[Doc 3228, ¶¶ 26-27, Ex. 34, at 28:5-8 (emphasis added)]

e. The 2013 Label Admission - Bayer's "Skyla" IUD Label

In spite of any prior public or private admissions to the contrary, Bayer has completely denied in this case that secondary perforation can occur. Yet, Bayer began openly warning the public about it several years ago on their labels for Skyla, Bayer's IUD similar to Mirena (though slightly smaller).[4] In January 2013, Bayer received FDA approval for Skyla. In the "Perforation" section of the original 2013 Skyla label, *Bayer openly acknowledged that perforations may occur unrelated to insertion*, even while noting that perforation (total or partial), however, occurs "most often" during insertion:

> 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.

[Doc 3228, ¶ 17, Ex. 16 (emphasis added)] This is the same language Bayer uses for the Skyla label today. [Doc 3228, ¶ 17, Ex. 17 (Sept. 2013 label)]

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[4] Bayer its expert witnesses agree that the perforation risks for Skyla and Mirena are the same. [Doc 3228, ¶ 17, Ex. 18 at 264:14-17 and Exs. 5-9]

f. The 2014 Label Admission: Bayer's Revised Mirena Label

The explicit admission by Bayer that secondary perforation may occur with Mirena was reiterated, once again, in the 2014 version of the Mirena label approved by FDA. The label reads:

> 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.

[Doc 3228, ¶ 18, Ex. 19 (May 2014) (emphasis added)] This perforation language remains unchanged in Mirena's current label as well. [Doc 3228, ¶ 18, Ex. 20 (Oct. 2015)].

g. Bayer's Adoptive Admission: the Progestasert Label

At the time of Mirena's FDA approval, there were only two other IUDs approved by FDA and sold in the United States, ParaGard and Progestasert. [Doc 3228, ¶ 12, Ex. 4 (FDA Medical Review for Mirena, NDA 21-225, at 11)]. The FDA label language used approved and used by Progestasert clearly stated that perforation *unrelated to insertion* could occur. Specifically, Progestasert's Patient Information section informed women that: "Partial or total perforation of the uterus may occur at the

time of *or after PROGESTASERT system insertion*." [Doc 3228, ¶ 16, Ex. 13 (1987 Progestasert label) (emphasis added)][5]

FDA recommended that Progestasert's warnings – whether for migration, perforation or other risks – be *included* in the Mirena label. [Doc 3228, ¶ 12, Ex. 4 (FDA Medical Review for Mirena, NDA 21-225, at 6)] Bayer never opposed nor objected to the use of the Progestasert perforation warnings for Mirena, despite having a great economic incentive to do so because otherwise, Bayer knew that FDA could require it to use these warnings for the millions of units of the product it planned to sell.[6] By failing to object to FDA's recommendation of the Progestasert perforation warning, Bayer made an adoptive admission that perforation unrelated to insertion *can occur*.

[5] Progestasert was approved by FDA in 1976 and discontinued in the U.S. market in 2001. OSMF ¶ 16.

[6] Bayer's failure to object to those warnings, in light of its knowledge that FDA deemed them appropriate for Mirena, renders the warnings additional, "adoptive admissions" under Rule 801(d)(2)(B) of the truth of the statements contained in those warnings.

SUMMARY OF ARGUMENT

Of the two major errors of law presented on this appeal, the first concerns the district court adopting the mantle of amateur scientist and usurping the role of the trial jury in a manner neither intended nor authorized by *Daubert* or Rule 702. The court did so by excluding the testimony of Plaintiffs' experts who were providing opinions regarding general causation[7] on grounds that went to the weight of their testimony, rather than its relevance or reliability. In its effort to determine facts and draw conclusions, the district court also erred in applying a different, more stringent, standard for the admissibility of Plaintiffs' experts' opinions than it applied to its evaluation of the admissibility of Bayer's experts' opinions.

Second, the district court then compounded its error by relying on this exclusion and applying the same roundly discredited reasoning used by the Seventh Circuit in *Aliotta* to hold, in plain error, that Plaintiffs

[7] "General causation bears on whether *the type of injury at issue can be caused or exacerbated* by the defendant's product. 'Specific' causation bears on whether, in the particular instance, *the injury actually was 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).

could not establish general causation through years of repeated and express admissions of fact under Rule 801(d)(2); admissions that conceded that Plaintiffs' alleged injuries *do* in fact occur, even if rarely, with Mirena use. In making this ruling, the district court intimately examined Bayer's Rule 801(d)(2) statements, including statements made on Mirena's 2014 FDA-approved label, and then, rather than viewing them in the light most *favorable* to Plaintiffs and granting them every reasonable inference, drew all such inferences in Bayer's favor instead. This was manifest legal error and a negating of a district court's role on a motion for summary ruling.

Moreover, the district court held that the jury would have required additional expert testimony, presumably at trial, to properly assess these admissions notwithstanding that the admissions stand on their own and include the same warnings that FDA and Bayer placed on packaging for patients to read and understand on their own. Thus, the district court erroneously held that the exclusion of Plaintiffs' experts' testimony was also fatal to the use of Bayer's admissions to prove general causation, even though that single, immutable fact -- that secondary perforation occurs -- was already established, admitted by Bayer, and accepted in the

literature. For *Daubert* and Rule 801(d)(2) purposes, nothing more was needed than what Plaintiffs demonstrated below. Then, by adding requirements addressing weight and credibility – normally decided by a jury – the district court obviated the need for any trier of fact. Indeed, it adopted that role as its own.

ARGUMENT

I. The District Court's Exclusion of Plaintiffs' Experts' Testimony Was Error Under *Daubert* and Rule 702

A. Standard of Review

The decision of a district court respecting the admissibility of expert testimony will not be disturbed on appeal unless it was the result of an abuse of discretion. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999), *citing GE v. Joiner*, 522 U.S. 136, 138-139, 118 S. Ct. 512, 517 (1997) ["manifestly erroneous"]. That standard, however, does not grant the court below "unfettered" discretion; a district is not free to ignore the liberal requirements of Rule 702 and may not stray outside the bounds of the limited, gatekeeping function it has under *Daubert*. *In re Pfizer, Inc. Securities Litig.*, 819 F.3d 642, 658 (2d Cir. 2016) (*citing Kumho Tire Co.*, 526 U.S. at 152).

B. The District Court's Exclusion of Plaintiffs' Experts' Testimony Betrayed a Rigidity and an "Overly Pessimistic" View of "the Capabilities of the Jury, and of the Adversary System Generally" which Caused it to Usurp the Jury's Factfinding Role

Under this Circuit's standard, the district court improperly excluded Plaintiffs' experts, Drs. Young, Jarrell, and Wray, by applying a far more draconian standard for admissibility than permitted. *Daubert* permits a gatekeeper to only balance the need to keep "junk science" out of the courtroom while liberally applying the framework of Rule 702 in order to allow parties to present expert opinions to a jury.

Rule 702 requires a trial court to focus only on the principles and methodology employed by the expert, not the conclusions the expert reaches. *In re Pfizer Securities Litig.*, 819 F.3d at 662. If an expert's testimony "both rests on a reliable foundation and is relevant to the task at hand," the weight and credibility of that conclusion is the jury's task, and "excluding [the testimony] was abuse of discretion." *Id.* at 667. Under *Daubert* the gatekeeper is to decide only whether the proffered experts' testimony was sufficiently relevant and reliable to be placed before the jury. The rest is up to them.

> The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the

> scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission. The focus, of course, must be solely on the principles and methodology, not on the conclusions they generate.

Daubert, at 594-95, 2797; *id.* at 593, 2796 ("we do not presume to set out a definitive checklist or test").

Here, however, there was no need for a jury, because the court below made findings of fact for them, focusing rigidly on a "checklist" of factors and weighing the conclusions reached by Plaintiffs' experts. The district court weighed the facts, expert reports, and testimony of Plaintiffs' experts for itself, drew the conclusions it believed and rejected those it didn't, and decided the pivotal question in the case – whether a properly placed Mirena IUD could perforate a uterus. The court then premised its ruling excluding Plaintiffs' experts' testimony on its own determination of this question of fact, not on the reliability and relevancy of their opinions.

Here, as in *In re Joint E. & S. Dist. Asbestos Litig.*,

> the district court impermissibly made a number of independent scientific conclusions – without granting plaintiff[s] the requisite favorable inferences – in a manner not authorized by *Daubert*. As Chief Justice Rehnquist has written, the law does

> not 'impose[] on [judges] either the obligation or the authority to become amateur scientists.'

52 F.3d 1124, at 1137 (2d Cir. 1995), quoting *Daubert*, 601, 2800 (Rehnquist, C.J., concurring in part and dissenting in part).

The perils of a judge deciding cases on the motion bench rather than a jury in the jury box is compounded by the absence of *viva voce* testimony, and the direct and cross-examination of expert witnesses, from which the trier of fact can determine credibility.[8] The court below improperly prevented the parties from presenting scientific theories and issues to a jury for a factual determination. Our system demands more and our caselaw requires it.

In 1993, the Supreme Court in *Daubert* concluded that the bright-line "general acceptance" test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) was at odds with the "liberal thrust" of the Federal Rules of Evidence, which allowed for a more relaxed and flexible standard for the

[8] The adversarial cross-examination of witnesses at trial has been described as "'the greatest legal engine ever invented for the discovery of truth'". *Howard v. Walker*, 406 F.3d 114, 128 (2d Cir. 2005), citing *California v. Green*, 399 U.S. 149, 150, 90 S.Ct. 1930 (1970). By its immutable nature, it is "a better engine of truth-determination than a judge's assessment of the reliability of uncross-examined hearsay." *Mungo v. Duncan*, 393 F.3d 327, 335 (2d Cir. 2004).

assessing of expert testimony. 509 U.S. at 588-89, 113 S. Ct. at 2794. The Court made clear that in its now limited "gatekeeping" function under Rule 702, district courts are charged only with "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand" so that it may assist the factfinder. *Id.* at 597. This means that the trial court would make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Campbell v. Metropolitan Prop. & Cas. Ins. Co.*, 239 F.3d 179, 184 (2d Cir. 2001) (internal citations omitted). While the "Daubert inquiry" might "vary from case to case" [*Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal quotations marks omitted and citations omitted)], the limited gatekeeping function would not.

At its core, the *Daubert* inquiry is fueled by Rule 702's liberality and governed by its admissibility standard:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony

> is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702. Accordingly, this Circuit has construed expert qualification requirements liberally and flexibly because of Rule 702, which permits opinion testimony from a witness qualified as an expert by knowledge, skill, experience, training or education. *U.S. v. Jakobetz*, 955 F.2d 786, 797 (2d Cir. 1992) (the federal rules emphasize "liberalizing expert testimony" and that any doubts about usefulness should be resolved in favor of admissibility "unless there are strong factors such as time or surprise favoring exclusions") (internal quotations and citations omitted). Had that standard been applied by the district court, there would have been no error to review.

Because the exclusion of expert testimony denies the jury an opportunity to judge expert opinions for itself, any "[d]oubts about whether an expert's testimony will be useful should generally be resolved in favor of admissibility[.]" *Lappe v. American Honda Motor Co.*, 857 F. Supp. 222, 226, *aff'd*, 101 F.3d 682 (2d Cir. 1996); *Jakobetz*, 955 F.2d at 797 ("[t]he jury is intelligent enough, aided by counsel, to ignore what is unhelpful

in its deliberations") (internal quotations and citations omitted). So powerful is that premise that only the trier of fact may decide the facts, that while Plaintiffs may bear the burden of proving the admissibility of their experts' opinions by a preponderance of the evidence, "*Daubert* reinforces the idea that there should be a presumption of admissibility of evidence". *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995). This is a presumption that the court below ignored, thus running astray of *Daubert*'s limited purpose and creating an impermissible presumption in the opposite direction as its starting point.

The court below "overstepped the boundaries set forth in *Daubert*" when it crossed the line from assessing evidentiary reliability to usurping the role of the jury to pass judgment on the conclusions reached by Plaintiffs' experts. *See, e.g., In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d at 1131. In determining reliability the court must "focus ... on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595, 113 S. Ct. at 2798.

Importantly, *Daubert* does not require a party proffering expert testimony to carry the burden of proving the expert's assessment of the situation is correct. Rather, as long as an expert's scientific testimony rests

upon "good grounds, based on what is known[,]" *Daubert*, 509 U.S. at 590, 113 S. Ct. at 2795, the expert's testimony should be presented to the jury, and its proper test is through the adversary process. *Id.* at 596, 2798. "[C]ontentions that the assumptions are unfounded go to the weight, not the admissibility, of the testimony." *Anderson Group, LLC v. City of Saratoga Springs,* 805 F.3d 34, 50 (2d Cir. 2015), quoting *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996).

While *Daubert* left open the possibility of a district court's granting summary judgment in cases where "'the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true,'" *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d at 1132 (quoting *Daubert*, 509 U.S. at 595, 113 S. Ct. at 2798), exclusion of expert evidence is limited to situations such as when "it is based on assumptions that are 'so unrealistic and contradictory as to suggest bad faith,' or to be in essence an 'apples and oranges comparison,'" *Boucher*, 73 F.3d at 21 (internal citations omitted). Thus, *Daubert* retained "a tone of optimism about juries' ability to sort out the veracity of competing scientific evidence." *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d at 1132.

To the extent that the district court's criticisms might undercut the evidentiary weight of the studies cited by Plaintiffs' experts, those criticisms are useless for *Daubert* purposes. Such criticisms would "not leave the jury without a basis for concluding that the studies tended to prove plaintiff[s'] claim," which is the only standard for their acceptance of such testimony, or any portion of it. Since the district court has a duty "to consider the evidence in the light most favorable to plaintiff and to grant plaintiff 'every reasonable inference that the jury might have drawn in its favor'" in considering a motion for judgment as a matter of law, *In re Joint E. & S. Dist. Asbestos Litig.*, at 1134-35 [quoting *Purgess v. Sharrock*, 33 F.3d 134, 140 (2d Cir. 1994)], its analysis ends before such "criticisms" begin. "In this regard, the district court is not to 'assess the weight of conflicting evidence, pass on the credibility of witnesses, or substitute its judgment for that of the jury.'" *Id.* at 1131 (additional citation omitted); *Cameron v. City of New York*, 598 F.3d 50, 59–60 (2d Cir. 2010), quoting *Reeves v. Sanderson Plumbing Prods., Inc.,* 530 U.S. 133, 150, 120 S. Ct. 2097, 2110 (2000) [the court "may not make credibility determinations or weigh the evidence"].

This overstretching of the gatekeeper function is precisely what the district court did. Rather than viewing the evidence in the light most favorable to Plaintiffs and granting them every reasonable inference, the court assessed the weight of Plaintiffs' evidence, found it wanting and disputed the conclusions reached by Plaintiffs' experts, making a jury unnecessary in rendering judgment.

The testimony offered by Plaintiffs' experts was admissible because it was based upon sufficient facts and data and was the product of reliable procedures and principles applied to these facts. Instead of following that most basic equation, the district court made the factual determinations regarding Plaintiffs' experts' opinions, shifting its focus from *evaluating* the reliability and relevancy of the methodologies to a scientific *determination* of their truth and weight.

Significantly, there is no finding below that the conclusions of Plaintiffs' experts were based on assumptions that were "'so unrealistic and contradictory as to suggest bad faith,'" *Boucher*, 73 F.3d at 21. Instead, to avoid *Daubert's* limitations, the district court fixated on its evaluation of Plaintiffs' experts' opinions as unfounded, or in the words

repeated time and again by the court below, unsupported "say-so." [A-203, A-205, A-212, A-228, A-292, A-294, A-338]

But in this Circuit, contentions that a qualified expert's opinion are unfounded "go to the weight, not the admissibility, of the testimony." *Anderson Group,* 805 F.3d at 50; *Boucher¸* 73 F.3d at 21; *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d at 1132. Furthermore, "[i]n certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony." Rule 702 advisory committee's note; *Kumho Tire Co.*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). Thus, in excluding a Plaintiffs' expert's testimony on the basis that it was "unfounded" on anything other than the expert's experience, observations, scientific literature, and the logical conclusions drawn from these sources, the district court made its own contrary factual conclusions regarding the correctness of the Plaintiffs' experts' opinions and methodologies, and "overstepped the boundaries set forth in *Daubert*[,]" and "impermissibly crossed the line from assessing evidentiary reliability to usurping the role of the jury." *In re Joint E. & S. Dist. Asbestos Litig.*,

52 F.3d at 1131. This intrusion into the fact-finding province of the jury was a repudiation of *Daubert*. Reversal of the ruling below is appropriate.

C. The Court Below Erred in Weighing the Facts and Data Relied on, and the Conclusions Reached, by Plaintiffs' General Causation Experts

1. Dr. Young

The court below misapplied *Daubert* and Rule 702 through a rigid adherence to an artificial checklist and a deep dive into the merits of the experts' conclusions. In its misapplication of *Daubert* and Rule 702, the district court not only disregarded the law of this Circuit, but even misconstrued several critical components of Dr. Young's report and testimony as well.

The district court assessed the credibility and weight of Dr. Young's sources and hypothesis, rather than their relevance and reliability. *Daubert,* 509 U.S. at 594-95, 2797. The court equated an *untested* theory with an *unreliable* theory. It made factual assumptions regarding the scientific literature Dr. Young cited in support of his hypothesis, refusing to analyze the body of literature cited by Dr. Young as a whole, which supported his hypothesis. *Daubert,* 509 U.S. at 579-80, 2790 ["scientific knowledge" connotes "a body of known facts or of ideas inferred from such

facts or accepted as true on good grounds"]. Instead, the court below dissected each piece in isolation. Each of these acts are contradictory to *Daubert's* liberal thrust, and are antithetical to the scientific methodology described by Dr. Young.

The district court delved so deeply into the merits of the articles upon which Plaintiffs' experts, including Dr. Young, relied that the court ultimately substituted its own, lay opinion for the conclusions of learned articles. Rather than accept Dr. Young's theory as separate, independently tested mechanisms, the court discharged the entirety of his theory as *ipse dixit*. [A-203, A-205] This reflected the worst fears of those who have cautioned that the motion court judge must function as a lawyer, not a scientist. *Daubert*, 601, 2800

Under *Daubert*, the "fact of publication (or lack therefor) in a peer reviewed journal [] will be relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Daubert*, 509 U.S. at 594, 113 S. Ct. at 2797. An expert need not "back his or her opinion with published studies that unequivocally support his or her conclusions." *Amorgianos*, 303 F.3d at 266. Yet, the district court found particular fault with Dr.

Young's opinion for this precise reason, relying on an unreported decision from the District Court for the Middle District of Florida: "At Steps 1 through 4 of his mechanism, Dr. Young cites studies and publications that he alleges support his theory of the mechanism for secondary perforation. A closer look, however, shows that Dr. Young draws impermissibly speculative conclusions from these studies that 'exceed the limitations the authors themselves place[d] on the[se] stud[ies].'" [A-202, citing *In re Accutane Prods. Liab.*, No. 04-MD-2523, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd,* 378 F. Appx. 929 (11th Cir. 2010)]. Even if the district court excluded his testimony regarding the mechanism, the court was wrong that such testimony as to mechanism is required; the question of whether Mirena was correctly inserted is a question of fact and does not rely on scientific theory or published articles.

The court also criticized Dr. Young's theory for not being subjected to peer review, publication, or testing [A-199-200], yet *Daubert* does not mandate any of these for finding admissibility. Unlike many toxic tort cases or other cases involving epidemiologic studies, no studies determin-

ing the exact mechanism by which Mirena perforates the uterus via secondary perforation exist because it is unethical to conduct studies to purposely perforate a uterus.[9] However, Dr. Young testified that although no specific study or article exists showing the exact mechanism of secondary perforation with Mirena, his expertise allowed him to apply "basic physiology and [his] understanding of the physiology and the effects of hormones on the smooth muscle and the connective tissue that the smooth muscle lays down" to the interaction of Mirena within the uterus. *Id.* at 310:22-311:3. Dr. Young's reliance on his experience, expertise, and education, combined with numerous studies and other sources of reliable scientific information, support his reliability for *Daubert* purposes.

Daubert recognized that unpublished theories which are "too particular, too new or of too limited interest" are nonetheless admissible, emphasizing that courts must make their inquiry flexible to weed out "junk science" while leaving room for novel scientific theories, so long as they are relevant and reliable. *Daubert*, 509 U.S. at 593; *In re Joint E. &*

[9] Also unlike a toxic tort case where a person can develop cancer or other injury independent of the product at issue, a perforation can only happen when Mirena is present.

S. Dist. Asbestos Litig., 52 F.3d at 1137 (courts should not "exclude [scientific] testimony simply because the conclusion was 'novel' if the methodology and the application of the methodology were reliable"). The Supreme Court anticipated, and specifically devised a standard to allow scientists to espouse a novel or relatively new scientific theory that has not, yet, satisfied the extraordinarily high level of proof necessary for general acceptance in the scientific community. This is because "a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony.'" *Daubert*, 509 U.S. at 588, 113 S. Ct. at 2794. *Daubert* reaffirmed both the primacy of Rule 702 and the sun setting on the *Frye* standard.

Yet, while the district court appeared to dutifully follow this liberal thrust in assessing the credentials of *Bayer's* experts and the reliability of their opinions, it employed a more stringent standard when evaluating those of *Plaintiffs'* experts. Citing an opinion finding that clinical experience is highly indicative of reliability, the court found the experience of Defendant's expert, Dr. Goldberg, "as a medical doctor specializing in OB/GYN and his familiarly and experience in placing and teaching how

to place IUDs *qualify him to opine* on the effects of LNG on the uterus and on Plaintiffs' theory of secondary perforation, *and are indicative of the reliability of his opinions*." [A-184, citing *In re Fosamax*, 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) (emphasis added)] Yet, when examining *Dr. Young's* background, the court, while acknowledging his clinical experience, stopped short of recognizing that Dr. Young's credentials were also indicative of such reliability. The district court could not avoid the obvious: "Dr. Young's academic and clinical background in obstetrics and gynecology, … as well as his specific research on the functioning of the uterus, including effects of hormones and uterine contractions, *make him qualified to opine* on the issue of whether an IUD such as Mirena is capable of perforating a uterus unrelated to insertion." [A-199, (emphasis added)]

Instead, the district court drew an impermissible inference from those findings, assuming instead that Dr. Young's opinion was inadmissible because it was "*ipse dixit*," [A-203] notwithstanding his unassailed qualifications. How unlike Bayer's expert's opinion, with similar qualifications, which was valid *ab initio* on the same reliability grounds. [A-184]. Nothing in Dr. Young's report or testimony overextends the bounds

of the medical literature, textbooks, animal studies, and other forms of evidence regularly used by experts in our courts in complex medical products cases. His opinion is based on his application and analysis of those sources, based on his credentials and experience; nonetheless, the court below excluded Dr. Young's expert opinion as unsupported "say-so." [A-203]

The fact that secondary perforation occurs was already established and accepted in the literature, as well as having been admitted by Bayer for over a decade.[10] Dr. Young's starting point for his analysis was based upon the observed facts in Plaintiffs' cases, such as the proper placement of the Mirena device at the outset of its use, the lack of any observed or reported injury during that insertion, placement check(s) that showed no improper placement of the device, and the later discovery of the Mirena device *outside* the uterus. These facts all logically supported his initial

[10] In finding fault it deemed sufficient to exclude Dr. Young's opinions entirely, the district court misconstrued the meaning of the word "hypothesis." Merriam-Webster defines it as "a: an assumption or concession made for the sake of argument[,]" "b: an interpretation of a practical situation or condition taken as the ground for action". Here, Dr. Young's hypothesis was the assumption that a properly placed Mirena made it into a patient's abdomen, as a starting point for his scientific investigation into how such an injury would occur. [A-201; CA-356, at CA-357]

hypothesis that secondary perforation occurs and was reasonably supported by his observations, clinical research and review of both the literature and Bayer's documents. Under *Daubert,* Plaintiffs were not required to prove that Dr. Young's theory on the mechanism of precisely how such secondary perforation could occur was *correct* in order for it to be *admissible* as both relevant and reliable, flowing from legitimate scientific process and diagnostic methodology. The role of "gatekeeper" requires no more, though the role of "juror" might well. The practice of medicine is very frequently the sort of "reverse engineering" the district court concluded was unreliable when utilized by Dr. Young to explain the observed location of Mirena outside the uterus where it had been placed. [A-201] As lawyers, we use a different process to solve problems, but doctors are presented with a patient suffering certain observed or communicated symptoms, and in order to treat that patient, the doctor must hypothesize, based on his or her experience and knowledge base, the reason or mechanism by which the symptoms were created in order to then treat that underlying cause.

Dr. Young's report outlined the mechanism of perforation by describing individual steps, based on his training, experience and published

literature. Each step in his analysis was supported by the same resources used by other professionals in his field. *See In re Ephedra Prod. Liab. Litig.,* 393 F. Supp. 2d at 188 ("Experts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called 'general truths derived from . . . specialized knowledge.").[11] Dr. Young's methodology was precisely the type of intellectual rigor employed in the medical or scientific field. *Kumho Tire Co.*, 526 U.S. at 153, 119 S. Ct. at 1177. This is all that *Daubert* requires, particularly when viewed in the light most favorable to Plaintiffs and granting them every reasonable inference.

[11] Dr. Young was tasked with reconstructing how Mirena perforates a woman's uterus, an assignment similar to the engineering expert in *Kumho*, asked to determine the mechanism that caused the tire to blow. *Kumho Tire Co.*, 526 U.S. at 153, 119 S. Ct. at 1177. The Supreme Court in *Kumho* did not fault the engineer for reconstruction, understanding its necessity to determine causation. Dr. Young is no different. He applied his experience, training and extensive work with the uterus and myometrium in developing his opinion. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) ("Fuller's contention that Fagelson did not base his opinion on 'scientific knowledge' [] fails . . . Fagelson based his opinion on a range of factors, including his care and treatment of McCullock; her medical history . . . pathological studies; review of Fuller's MSDS; his training and experience; use of a scientific analysis known as differential etiology . . . and reference to various scientific and medical treatises.").

The district court rejected these principles and fixated on a particular four factor test. [A-199-202] The problem is that this test, chosen by the court, required live testing on human beings, and does not lend itself well to novel theories or situations, such as the mechanism by which secondary perforation occurs. It would be patently unethical to purposely allow a human uterus to be perforated in any controlled, randomized, or blinded study. As the Supreme Court noted in *Daubert*, "in some instances well-grounded but innovative theories will not have been published….Some propositions, [] are too particular, too new, or of too limited interest to be published." *Daubert*, at 509 U.S. at 593. In such cases, as here, the court below was required to exercise only its gatekeeping function under *Daubert* to properly judge the reliability of an expert under standards flexible enough to meet the ethical limitations of the injury. It did not do so.

The district court's intricate analysis and critique of Dr. Young's theory at every step was the most damaging sort of "amateur" science, of no value for *Daubert* and in denial of Rule 702's parameters and the standard for judgment as a matter of law. By "'assess[ing] the weight of conflicting evidence, pass[ing] on the credibility of the witnesses [and]

substitut[ing] its judgment for that of the jury[,]'" the district court defied the well established law of this Circuit. *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d at 1131 [quoting *Mattivi v. S. African Marine Corp., Huguenot*, 618 F.2d 163, 167 (2d Cir 1980)]. The district court misapplied itself and misunderstood the very science behind Dr. Young's theory. This was based upon the court's ability to judge truth, not the jury's, when the court had no better prospect, and no right, to do so. The jury, hearing testimony and cross-examination, would have been far better equipped, which is why the law leaves that job to them.

2. Dr. Jarrell

Dr. Jarrell, Ph.D., P.E., "a qualified and impressive engineer," [A-223] has a Bachelor's and Masters of Science degree in Materials Science and Engineering and a Doctorate in Biology, Medical Science and Engineering, and his career has centered around the analysis of mechanical and biological systems. [A-213, A-214-15] In addition to possessing the requisite experience to opine that the "tips of the Mirena arms contain relatively sharp edges compared to the smoother adjacent surfaces, based on [his] inspection under microscopy and with metrology." [A-217; CA-91, at CA-109] Dr. Jarrell's expert opinion also was relevant and based on

reliable scientific methodology in his field, satisfying the *Daubert* standard. A multi-discipline engineer specializing in the analysis of complex designs and failures involving materials, and mechanical and biological systems, Dr. Jarrell sought to testify regarding how Mirena's design contributes to the perforation process. Yet, in its opinion, the court below quibbled with Dr. Jarrell's direct observations as to the sharpness of the Mirena device, concluding that Dr. Jarrell's personal and professional experience as an engineering expert was unreliable, finding fault in the absence of literature defining "sharpness," opining that Dr. Jarrell could not reasonably apply scientific literature from other fields to support his own findings and theories, and culminating in its opinion that Dr. Jarrell's engineering opinions were unreliable *ipse dixit* in their entirety. [A-214, A-216-27]

The court below intimately engaged with Dr. Jarrell's scientific analysis at every step [A-217-27], based on its own unfounded factual assumptions, an incomplete understanding of complex scientific literature and methodology regarding how "sharpness" is defined, and its contrary scientific conclusion that simulating Mirena under pressure outside the

uterus is not a proper means of deriving intelligible information regarding how Mirena acts under pressure inside the uterus. [A-219-22] In doing so, the court below pitted its own improper, contrary factual assumptions and undefined scientific expertise against that of the proffered expert. This is antithetical to the limited, gatekeeping role envisioned in *Daubert*. Moreover, the extent of the discussion of Dr. Jarrell's opinion stands in mute contrary testimony to it being dismissed by the court below as being ipse dixit in nature. [A-214-27]

As it had done in evaluating the admissibility of Dr. Young's expert opinion, the district court applied the same overly rigid adherence to the four-factor checklist to Dr. Jarrell's opinions as well. As an expert, under *Daubert* Dr. Jarrell was permitted to apply established scientific knowledge[12] to his own particular areas of knowledge and expertise in order to determine what injuries Mirena could produce under pressure. *Compare* A-222-26 *with* CA-1, at CA-53 *and* CA-115]. However, the court

[12] Such knowledge included the rate of uterine contraction, the average force of uterine contraction, the pressure-point at which wounds form, and the wide acceptance by the medical community of pressure wound necrosis as a phenomenon. [A-182, n.14 and A-224 (discussion of the Goldstuck study); A-224-25; Jarrell Report, 22, 24, 29-32; Jarrell Dep., 268:12-23]

found that the mere absence of any live testing of this hypothesis warranted its exclusion. [A-223-24] The district court faulted Dr. Jarrell for failing to provide scientific literature supporting his opinion that Mirena is "sharp" [A-217], and used the absence of any such studies as a reason to reject that testimony. In the process, the district court ignored Dr. Jarrell's explanation of the scientific procedures, mechanical testing, and measurements he performed. [CA-101] This methodology, employed by a materials science, medical science, and engineering expert is far from "playing around" as suggested by the district court [A-220], but is applying the scientific method to test his theory. It is certainly at least equal to the district court's own unspecified expertise in live testing on humans or the failure of modern science to define the term "sharp" for medical purposes based on what the object so defined does when it comes into contact with a woman's internal organs.

3. Dr. Wray

The Court likewise overextended its role in finding the opinion of Plaintiffs' expert Dr. Susan Wray inadmissible under *Daubert*. Dr. Wray is a professor of physiology and one of the world's experts on the uterus,

with over thirty years of experience. According to Dr. Wray, the "contractions of the myometrium can cause the transport of the Mirena device through the uterine wall into the peritoneal cavity and beyond (e.g. bladder, bowel)" even if no injury occurred during insertion. [A-228; CA-279, at CA-282] Yet, despite her decades of experience and the depth of her research on the uterus, in blind fealty to its overly rigid application of the four-factor checklist [A-231-232], the district court still pitted its own scientific expertise against Dr. Wray's conclusions [A-233-244], rejecting Dr. Wray's expert testimony as unreliable. Ignoring *Daubert*, the court equated an *untested* theory with an *unreliable* one [A-235], substituted *its* interpretation of the cited articles as the *only* credible interpretation [A-236-43], misapplied *Daubert* to require *general acceptance* of Dr. Wray's theory before it could be admitted [A-232], and created a *new*, artificial requirement that experts *be excluded* from offering any opinions if they did not consider contradictory evidence *in their reports and depositions* [A-233, A-233 n. 45].

The district court also improperly weighed the credibility of Dr. Wray's *sources* when she cited to literature supporting her mechanism theory, rather than the reliability of the methodology of relying on such

literature. No gatekeeping authority extends so far as to reach behind an expert's opinion for purposes if its *admissibility* alone and question its sources. In order to make this credibility assessment, the court below had to give greater weight to other sources when there was a difference of authoritative opinion. [A-237-40]. Weighing authorities is what the trying jury does, not the judge under *Daubert*. This is because *Daubert* analysis "does not require absolute certainty before an expert can proffer an opinion. . . The fact that an expert witness speaks in probabilities, rather than certainties, does not by itself make the testimony unreliable." *Deutsch*, 768 F. Supp. 2d at 437-38; *see Amorgianos*, 303 F.3d at 266 (finding that an expert need not always "back his or her opinion with published studies that unequivocally support his or her conclusions.").

D. The Exclusion of all of Plaintiffs' General Causation Experts' Opinions in their Entirety was Manifest Error

In weighing the correctness of the conclusions reached by Drs. Young, Jarrell, and Wray, it is patent that the district court abused its discretion in excluding their opinions in their entirety, contrary to the requirements established in this Circuit under *Daubert*, Rule 702, and its summary judgment standards. This ruling should be reversed.

II. The District Court Erred in Ruling that a Party's Admissions Cannot be Used as Evidence of General Causation

A. Standard of Review

This Court reviews rulings granting summary judgment *de novo*. *Aslanidis v. United States Lines, Inc.*, 7 F.3d 1067, 1072 (2d Cir.1993). 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). Finally, all evidence must be construed in the light most favorable to Plaintiffs as the non-moving party, and all reasonable determinations must be drawn in their favor. *In re Joint E. & S. Dist. Asbestos Litig.*, at 1134-35; *Kerzer*, 156 F.3d at 400 (additional citation omitted); *Kerzer v. Kingly Mfg.*, 156 F.3d 396, 400 (2d Cir. 1998), citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 2513 (1986).

B. Under Rule 801(d)(2), Opposing Party Statements Are to be Freely Admitted Into Evidence

Under the Federal Rules of Evidence, an opposing party's statement is not hearsay when offered against that party. Rule 801(d)(2); *see generally* 4 Weinstein's Evidence ¶ 801(d)(2).[13] 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 employer under Rule 801(d)(2)(D).

Admissions need not reflect only the direct statements of a party. "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. 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." 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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[13] 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."

All types of Rule 801(d)(2) admissions, whether made directly by employees or adopted from others, enjoy "liberal admissibility" and 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.

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 USA, Inc. v. New Christian Church*, 262 F. Supp. 2d 251, 259, citing *United States v. Tocco*, 135 F.3d 115, 119 (2d Cir. 1998).

C. There is No Authority, Either Controlling or Persuasive, Barring Statements Under Rule 801(d)(2) from Being Admitted for the Purposes of Proving General Causation.

The district court in *Mirena II* based its decision to bar the admission of party statements as to general causation under Rule 801 on not only its perception of an absence of authority, but a convenient re-casting of authority to the contrary. The court was forced to concede that there

was no question that "the alleged admissions are admissible against Bayer as a matter of the law of evidence" and, instead, addressed the issue as to "whether as a matter of substantive products liability law admissions can substitute for expert evidence of causation," but only if one adopted its conclusion that there was a "widely held principle that expert testimony is required in cases involving a complex or technical question outside the ken of the average lay juror." [A-316]. The defect in the court's analysis is that the lay jury that would consider the Bayer admissions would *not* have to deal with the "complex or technical question" of secondary perforation, for Bayer's admissions would have already *admitted* that fact.

Without doubt, the district court's suggestion that "[a] review of the cases cited by Plaintiffs" and "common sense" might make such statements by a party opponent rare, but rare or not, that is precisely what occurred here. No matter how remarkable that situation might appear to the district court, it had no choice but to admit that if such a circumstance presented itself, there was no proscription against the admissibility of such statements for general causation purposes. The only opposing view

the court could muster was a caution 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."[14] [A-318] If a case was being tried under state law which did *not* require expert testimony to prove general causation, the district court cited no authority which would bar a plaintiff from proving general causation through evidence of party statements under Rule 801.

In *In re Meridia Prods. Liab. Litig.*, ["*Meridia I*"] 328 F. Supp. 2d 791 (N.D. Ohio 2004), the district court noted that "there is no federal rule requiring expert testimony in support of general causation in mass tort claims," citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 750-52 (3d Cir. 1994), *reh'g denied, cert. denied*, 513 U.S. 1190, 115 S.Ct. 1253 (1995). "The court noted that such a rule would be, in part, (1) a rule regarding what types of evidence are admissible in mass tort cases, and (2) an aspect of a party's burden of proof. To the extent that such a rule

[14] Any discussion of whether the court's concern addresses the admissibility of such evidence or its weight is beyond the parameters of this appeal.

affects a party's burden of proof, it is a substantive law under Erie analysis, and federal courts operating under diversity jurisdiction must apply state law on that issue." *Meridia I*, at 802.

The district court here felt comfortable in discarding the *Meridia* reasoning because it held, *directly opposite* to the *Meridia* court, that "all (state) jurisdictions have such a requirement" and that such a finding was "[f]atal to Plaintiffs' argument." [A-319] However, the finding of the court below was *not* that all states required expert testimony for prove general causation, but that all states require expert testimony of help lay jurors understand evidence which is outside their everyday experience. "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 [district court] and *Meridia* 2 [circuit court] are not applicable to this case." [A-319] The lay jury here was being asked to weigh the evidence of Bayer's *admissions* that secondary perforation could occur following the normal insertion of the Mirena device. Holding one to his word, especially when that word is given against the speaker's own interest, is scarcely outside of the ken of any lay juror.

In *Meridia Prods. Liab. Litig. v. Abbott Labs.*, ["*Meridia II*"] 447 F.3d 861 (6th Cir. 2006), the Sixth Circuit correctly noted that there are "only a handful of cases" that address using admissions to satisfy general causation and that none of them[15] directly considered the precise admission scenario presented here. [A-317] There was no reason, from those decisions, to doubt that admissions can be used to prove general causation in the same manner as proving any other principle at trial. The *Meridia* decisions demonstrate how party statements admitting general causation are no less proof of that fact than any other such statements under Rule 801, nor do they require the help of experts to be understood by a jury for what they are. For example, the trial court in *Meridia I* held that statements in the Meridia label which admitted "Meridia's potential to cause [harm]" were just that and needed nothing further to be weighed by the jury. 328 F. Supp. at 810. The Sixth Circuit affirmed, finding "no fault with the district court's treatment of the causation factor[.]" 447 F.3d at 866. In order to reject that reasoning, notwithstanding its harmony with Rule 801, the trial court here had to conclude that the *Meridia*

[15] *See generally* A-317-20 [discussion of the decisions considered by the district court, including *Meridia I and II*].

trial court only held that expert testimony is not always required, the opposite conclusion than that reached here by the district court. [A-319]

Whether or not the decision of the court below that notwithstanding the *admission* of general causation any state would then require essentially repetitious expert testimony to the same effect might be sustainable was broached in *In re Accutane Prods. Liab. Litig.*, 511 F. Supp. 2d 1288 (M.D. Fla. 2007). This case involved alleged admissions of causation by a drug that were contained in adverse event reports. Although the district court factually found that the causality assessments in the reports were not admissions of general causation (they reflected only the opinions of the persons *reporting* the events, not the opinions of the drug's manufacturer or its employees), *Accutane* recognized that such admissions could have been used to prove general causation. Had there been *actual* admissions of general causation by the drug manufacturer or its employees, the court would not even have had to analyze expert admissibility issues at all:

> Dr. Fogel also bases his opinion of causation, in part, on Hoffmann-LaRoche documents in which, he says, Defendants have admitted Accutane causes IBD. ***If such were true of this case, this Court could have saved a lot of time – this opinion would have been unnecessary.***

Id. at 1296 (emphasis added). *Accutane*'s acknowledgement that expert testimony becomes superfluous when general causation has been admitted is precisely the point on this appeal.

Under Rule 801, party statements are admissible to prove general causation and the law requires nothing more to oppose a motion for summary judgment, in the same manner as any other fact needed to be proved at trial. At the very least, such admissions raise a genuine issue of disputed material fact requiring a trial on the merits.[16]

In *Rhodes v. Bayer Healthcare Pharmaceuticals, Inc.,* 2013 WL 12289050 (W.D. La. Mar. 26, 2013), plaintiff sought to use Bayer's labeling information as an admission of general causation. In that case, Bayer's label was found to address only *reporting*, not *causation*. See 2013 WL 1289050 at *6, n.3 ("rare cases … have been reported"). The court in *Rhodes* noted no objection to the use of admissions to prove general causation, whether those admissions appeared on the label or elsewhere.

[16] Cf. *Howell v. Centric Group, LLC*, 2011 WL 4499372, at *5 (D. Colo. Sept. 27, 2011), aff'd, 508 Fed.Appx. 834 (10th Cir. 2013) ("Taking the evidence in the light most favorable to Mr. Howell, as the Court must in evaluating Centric's motion for summary judgment, the MSDS alone might be sufficient to raise an issue of fact regarding general causation[.]" The district court considered *Howell*, but was not convinced. [A-320-21]

Every court that has engaged in an analysis of this issue has either expressly found that general causation can be established by admissions, or has indicated a willingness to use a party's admissions for that purpose. The rejection of those authorities by the district court here in favor of *Meade v. Parsley*, 2010 WL 4909435 (S.D.W.Va. Nov. 24, 2010), a singular unreported, non-precedential trial court opinion where the admissions issue was addressed only in *dicta*, making no reference to Rule 801(d)(2), is scarcely authoritative and belies the paucity of authority supporting the opinion below.

D. The District Court's Rejection of Rule 801 and its Acceptance of the Reasoning of the *Aliotta* Case is Error Requiring a Reversal of Summary Judgment

The district court compounded its error by adopting the reasoning of *Aliotta v. Nat'l R.R. Passenger Corp.*, 315 F.3d 756 (7th Cir. 2003). [A-317, n.16] For good reason, *Aliotta* has been comprehensively discredited for its incorrect interpretation of the use of party admissions.

Bayer relied on *Aliotta* here, arguing that the admissions made by its *employees* were unreliable "scientific opinions" barred by Rules 701 and 702, and *Daubert*. Bayer argued that under *Aliotta*, party-opponent admissions are "[not] always free from the requirements of Rule 701(c),

Rule 702, and *Daubert*." 315 F.3d at 763. That view, that party admissions can be excluded as improper when they were not authored by "experts," has been widely and unequivocally rejected.

"[I]t is well settled that the opinion rule does not apply to a party's admissions." 30B Fed. Prac. & Proc. Evid. § 7015 (2014 ed.); *see also* Fed. R. Evid. 801(d)(2) advisory committee note ("the restrictive influences of the opinion rule" do not apply to admissions). Indeed, *Aliotta's* reasoning is not consistent with Rule 801(d)(2) and is not even followed as precedent in the Circuit in which it was decided. *See*, *e.g.*, *Jordan v. Binns*, 712 F.3d 1123, 1128 (7th Cir. 2013) ("party admissions … are not subject to the personal-knowledge requirement of FRE 602 or the restrictions of the opinion rule of FRE 701.") (internal citations omitted).

Far from being persuasive authority, *Aliotta* has given commentators the opportunity to re-emphasize the effect of an admission of facts needed to be proved at trial:

> **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***[.]"
>
> …

> 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, n. 12 (emphasis added).

Arguing its unsupportable position, the district court supposed that it was not adopting the *Aliotta* holding in its decision below. [A-317, n.16] But, the district court did in fact follow, and apply, *Aliotta's* reasoning nonetheless.

The district court held that admissions of general causation *cannot* be admitted into evidence unless they meet the expert witness "opinion" requirements of both Rule 702 and *Daubert* if those admissions answer "complex technical questions" [A-317, n.16], ostensibly because even if a party admits a scientific fact, a jury could not possibly understand it without expert opinion. This is exactly the result harshly criticized by Federal Practice & Procedure as "a truly bad decision that should not be

followed." The district court's decision to reject the better and accepted rule as to admissions was error.

E. The District Court Erred in Holding that Expert Witness Testimony is Required to Establish General Causation.

It is rare for a drug manufacturer to deny in court what it admits everywhere else, but that is the situation here. Bayer has admitted that perforation unrelated to insertion occurs, and since that is the injury alleged in this case, Bayer's admissions satisfy general causation.

1. Bayer's Admissions that Mirena can Perforate the Uterus Unrelated to Insertion are Competent Evidence on the Issue of General Causation

Bayer's admissions are competent evidence on general causation sufficient to defeat summary judgment. As discussed above, under Fed. R. Evid. 801(d)(2), statements by a party opponent and its agents are not hearsay; they are admissible for the truth of the matters asserted. *See* 30B Charles A. Wright, *et al.*, Fed. Prac. & Proc. § 7015, at 188 (2014) ("Admissions are substantive evidence."). When evaluating the evidence for a summary judgment motion, admissions must be considered (*Celotex, supra*), and all reasonable inferences must be drawn in favor of the non-moving party (*Kerzer*, *supra*).

Neither Rule 801(d)(2) nor applicable case law excludes general causation from the universe of facts that can be admitted through a party's statements. It is also improper for a court to exclude such admissions out of concerns that they may be unreliable: "No guarantee of trustworthiness is required in the case of an admission." *Mayor of City of Philadelphia v. Educ. Equal. League*, 415 U.S. 605, 646 (1974); see also Fed. R. Evid. 801(d)(2) advisory committee note (same).

Admissions are treated in this manner because of the distinctive basis for admitting a party-opponent's own statements; namely, the principles of the adversarial process, which appropriately holds parties responsible for their own acts and words. See 4 Mueller & Kirkpatrick, Federal Evidence § 8:44 (4th ed. 2016); *Jewell v. CSX Transp. Inc.*, 135 F.3d 361, 365 (6th Cir. 1998) (admissibility of party-opponent's statements is based on "estoppel or waiver" principles); 30B Fed. Prac. & Proc. Evid. § 7015 (2014 ed.) ("The adversary theory supports introduction as substantive evidence of admissions of a party-opponent. You said it – the jury will hear it.").

The principles set forth above make it clear that it is *not* the role of the court in our adversarial system to spare a party from the jury's consideration of its own statements; rather, the party "may dispute whether [it] made the purported statement and/or the truth of the purported statement at trial." *Id.*; see also *Jordan*, 712 F.3d at 1128. A party cannot avoid the consequences of its own statements by asserting they are unreliable.

Coupled with the fact that Bayer has admitted on multiple occasions for over a decade that spontaneous perforation unrelated to insertion can occur – sometimes using that exact phrase – the rationale behind the admissibility of a party's admissions against its own interest establish that Bayer's admissions are competent evidence on the issue of general causation which, at a minimum, pose fact issues that should have precluded the entry of summary judgment.

2. The District Court's Error Resulted from a Serious Mistake of Law

The district court erroneously granted summary judgment for Bayer because the court misunderstood Plaintiffs' burden of proof on general causation. This mistake on ta fundamental issue of law both explains the incorrect outcome, and requires that it be reversed.

It is clear from the District Court's Order that the court was under the impression that Plaintiffs could not meet their burden of proof on general causation without establishing, *through expert opinion*, precisely *how* Mirena perforates the uterus unrelated to insertion. *See, e.g.,* A-333, ("without an expert to opine on the mechanism of secondary perforation, the jury would have to speculate").[17] Given the District Court's view that the law required Plaintiffs to produce expert testimony on the mechanism of injury even in light of Bayer's admissions, the outcome it reached is not surprising. However, the District Court misunderstood what the law required.

"Causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*." *Daubert v. Merrell Dow*

[17] Furthermore, after the district court excluded the Plaintiffs' expert testimony that would aid the jury, it dismissed the case because the jury would have to evaluate the plain meaning of warning labels for itself without the benefit of scientific expert testimony. The district court set up the problem for itself, and then dismissed the hundreds of cases in the MDL based on the problem it had created, notwithstanding that the warnings the district court did not trust the jurors to evaluate for themselves are the same warnings that the FDA and Bayer placed on packaging for laypersons to read and understand.

Pharmaceuticals, Inc., 43 F.3d 1311, 1314 (9th Cir. 1995) (emphasis in original).[18] This proposition is widely accepted across jurisdictions, and applies in the context of individual tort claims as well as pharmaceutical MDLs like this one. See, e.g., *In re Welding Fume Products Liab. Litig.*, 2010 WL 7699456, at *33 (N.D. Ohio June 4, 2010) (quoting above passage from *Daubert II*); *In re Nuvaring Products Liab. Litig.*, 2013 WL 791787, at *7 (E.D. Mo. Mar. 4, 2013) (same); *Lyman v. Pfizer, Inc.*, 2012 WL 2971550, at *3 (D. Vt. July 20, 2012) (same); *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1198–99 (9th Cir. 2014) (same).

Plaintiffs are not required to demonstrate *how* the product causes the harm in this case. Bayer has admitted repeatedly that Mirena can perforate the uterus unrelated to insertion, and that is sufficient to establish causation. The District Court's grant of summary judgment to Bayer, driven by the court's mistaken belief that Plaintiffs needed "an expert to opine on the mechanism of secondary perforation," must be reversed.

[18] This is the case often referred to as *Daubert II*, decided on remand following the Supreme Court's *Daubert* decision.

F. It was Reversible Error for the District Court to Weigh the Evidence, Assess Credibility, and Resolve All Ambiguities and Draw All Inferences in Favor of the Moving Party, Bayer.

The admissions made by Bayer, detailed above and discussed in the Statement of Facts are each, individually and collectively, admissible evidence of general causation. Those admissions create a fact issue on general causation that needs to be resolved by the jury at trial, not by the district court via summary judgment. The district court improperly concluded that there were no fact issues only because it misapplied the strict standard for summary relief, inappropriately weighing evidence, assessing credibility and resolving ambiguities, compounded by then drawing inferences *in favor of Bayer* instead of Plaintiffs, as non-movants. Had the summary judgment standards been properly applied, Bayer's motion would have been denied.

CONCLUSION

For the foregoing reasons, the orders below should be reversed and this matter returned to the district court for trial.

Respectfully submitted,

PARKER WAICHMAN LLP

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December 2, 2016

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 32(a)(7)(c) and L.R. 32.1(a)(4)(A), the undersigned certifies that this brief complies with the applicable type-volume limitations. This brief was prepared using Microsoft Word 2010, using Century Schoolbook, a proportionally spaced font, set at 14 points. Utilizing the word count system of this software, the word count is 11,973.

Dated: December 2, 2016

/s/ Jay L. T. Breakstone

Attorney for Appellant

SPECIAL APPENDIX

SPECIAL APPENDIX
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SPA-1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

IN RE:

MIRENA IUD PRODUCTS LIABILITY LITIGATION

This Document Relates To All Actions

----------X

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

JUDGMENT

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 byfore this Court as part of a multi-district litigation ("MDL"); (Case Management Order No. 1, (13-MD-2434 Doc. 8; before the Court is Defendants' Omnibus Motion for Summary Judgment, and the matter having come before the Honorable Cathy Seibel, United States District Judge, and the Court, on July 28, 2016, having rendered its Opinion and Order granting Defendants' Omnibus motion for summary judgment, and directing the Clerk of Court to terminate the pending motions, (13-MD-2434 Doc. 3172; 13-MC-2434 Doc. 215), and enter judgment in and close all remaining members cases in this MDL, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion and Order dated July 28, 2016, Defendants' Omnibus Motion for Summary Judgment is granted; 13-MD-2434, 13-MC-2434 and remaining member cases in this MDL are closed.

Dated: New York, New York
July 29, 2016

SPA-2

RUBY J. KRAJICK

Clerk of Court

BY:

Deputy Clerk

THIS DOCUMENT WAS ENTERED ON THE DOCKET ON 7/29/2016

SPA-3

United States District Court
Southern District of New York

Ruby J. Krajick
Clerk of Court

Dear Litigant:

Enclosed is a copy of the judgment entered in your case. If you disagree with a judgment or final order of the district court, you may appeal to the United States Court of Appeals for the Second Circuit. To start this process, file a "Notice of Appeal" with this Court's Pro Se Intake Unit.

You must file your notice of appeal in this Court within 30 days after the judgment or order that you wish to appeal is entered on the Court's docket, or, if the United States or its officer or agency is a party, within 60 days after entry of the judgment or order. If you are unable to file your notice of appeal within the required time, you may make a motion for extension of time, but you must do so within 60 days from the date of entry of the judgment, or within 90 days if the United States or its officer or agency is a party, and you must show excusable neglect or good cause for your inability to file the notice of appeal by the deadline.

Please note that the notice of appeal is a *one-page* document containing your name, a description of the final order or judgment (or part thereof) being appealed, and the name of the court to which the appeal is taken (the Second Circuit) – *it does not* include your reasons or grounds for the appeal. Once your appeal is processed by the district court, your notice of appeal will be sent to the Court of Appeals and a Court of Appeals docket number will be assigned to your case. At that point, all further questions regarding your appeal must be directed to that court.

The filing fee for a notice of appeal is $505 payable in cash, by bank check, certified check, or money order, to "Clerk of Court, S.D.N.Y." *No personal checks are accepted*. If you are unable to pay the $505 filing fee, complete the "Motion to Proceed *in Forma Pauperis* on Appeal" form and submit it with your notice of appeal to the Pro Se Intake Unit. If the district court denies your motion to proceed *in forma pauperis* on appeal, or has certified under 28 U.S.C. § 1915(a)(3) that an appeal would not be taken in good faith, you may file a motion in the Court of Appeals for leave to appeal *in forma pauperis*, but you must do so within 30 days after service of the district court order that stated that you could not proceed *in forma pauperis* on appeal.

For additional issues regarding the time for filing a notice of appeal, see Federal Rule of Appellate Procedure 4(a). There are many other steps to beginning and proceeding with your appeal, but they are governed by the rules of the Second Circuit Court of Appeals and the Federal Rules of Appellate Procedure. For more information, visit the Second Circuit Court of Appeals website at **http://www.ca2.uscourts.gov/.**

SPA-4

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____

(List the full name(s) of the plaintiff(s)/petitioner(s).)

-against-

_____

(List the full name(s) of the defendant(s)/respondent(s).)

_____CV_____ ( )( )

NOTICE OF APPEAL

Notice is hereby given that the following parties: _____

(list the names of all parties who are filing an appeal)

in the above-named case appeal to the United States Court of Appeals for the Second Circuit from the ☐ judgment ☐ order entered on: _____

(date that judgment or order was entered on docket)

that: _____

(If the appeal is from an order, provide a brief description above of the decision in the order.)

Dated _____ Signature* _____

Name (Last, First, MI) _____

Address _____ City _____ State _____ Zip Code _____

Telephone Number _____ E-mail Address (if available) _____

* Each party filing the appeal must date and sign the Notice of Appeal and provide his or her mailing address and telephone number, EXCEPT that a signer of a pro se notice of appeal may sign for his or her spouse and minor children if they are parties to the case. Fed. R. App. P. 3(c)(2). Attach additional sheets of paper as necessary.

Rev. 12/23/13

SPA-5

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____

(List the full name(s) of the plaintiff(s)/petitioner(s).)

-against-

_____

(List the full name(s) of the defendant(s)/respondent(s).)

_____CV_____ ( )( )

MOTION FOR EXTENSION OF TIME TO FILE NOTICE OF APPEAL

I move under Rule 4(a)(5) of the Federal Rules of Appellate Procedure for an extension of time to file a notice of appeal in this action. I would like to appeal the judgment entered in this action on _____ (date) but did not file a notice of appearance within the required time period because:

_____

_____

_____

(Explain here the excusable neglect or good cause that led to your failure to file a timely notice of appeal.)

Dated: _____ Signature _____

Name (Last, First, MI) _____

Address _____ City _____ State _____ Zip Code _____

Telephone Number _____ E-mail Address (if available) _____

Rev. 12/23/13

SPA-6

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____

(List the full name(s) of the plaintiff(s)/petitioner(s).)

-against-

_____

(List the full name(s) of the defendant(s)/respondent(s).)

_____CV_____ ( )( )

MOTION FOR LEAVE TO PROCEED IN FORMA PAUPERIS ON APPEAL

I move under Federal Rule of Appellate Procedure 24(a)(1) for leave to proceed *in forma pauperis* on appeal. This motion is supported by the attached affidavit.

Dated _____ Signature _____

Name (Last, First, MI) _____

Address _____ City _____ State _____ Zip Code _____

Telephone Number _____ E-mail Address (if available) _____

SPA-7

Application to Appeal In Forma Pauperis

_____**v.** _____ Appeal No. _____

District Court or Agency No. _____

Affidavit in Support of Motion	**Instructions**
I swear or affirm under penalty of perjury that, because of my poverty, I cannot prepay the docket fees of my appeal or post a bond for them. I believe I am entitled to redress. I swear or affirm under penalty of perjury under United States laws that my answers on this form are true and correct. (28 U.S.C. § 1746; 18 U.S.C. § 1621.)	Complete all questions in this application and then sign it. Do not leave any blanks: if the answer to a question is "0," "none," or "not applicable (N/A)," write that response. If you need more space to answer a question or to explain your answer, attach a separate sheet of paper identified with your name, your case's docket number, and the question number.
Signed: _____	Date: _____

My issues on appeal are: (required):

1. *For both you and your spouse estimate the average amount of money received from each of the following sources during the past 12 months. Adjust any amount that was received weekly, biweekly, quarterly, semiannually, or annually to show the monthly rate. Use gross amounts, that is, amounts before any deductions for taxes or otherwise.*

Income source	**Average monthly amount during the past 12 months**		**Amount expected next month**	
	You	Spouse	You	Spouse
Employment	$	$	$	$
Self-employment	$	$	$	$
Income from real property (such as rental income)	$	$	$	$

Interest and dividends	$	$	$	$
Gifts	$	$	$	$
Alimony	$	$	$	$
Child support	$	$	$	$
Retirement (such as social security, pensions, annuities, insurance)	$	$	$	$
Disability (such as social security, insurance payments)	$	$	$	$
Unemployment payments	$	$	$	$
Public-assistance (such as welfare)	$	$	$	$
Other (specify):	$	$	$	$
Total monthly income:	**$** 0	**$** 0	**$** 0	**$** 0

2. *List your employment history for the past two years, most recent employer first. (Gross monthly pay is before taxes or other deductions.)*

Employer	**Address**	**Dates of employment**	**Gross monthly pay**
			$
			$
			$

3. *List your spouse's employment history for the past two years, most recent employer first. (Gross monthly pay is before taxes or other deductions.)*

Employer	**Address**	**Dates of employment**	**Gross monthly pay**
			$
			$
			$

4. *How much cash do you and your spouse have? $_____*

Below, state any money you or your spouse have in bank accounts or in any other financial institution.

Financial Institution	**Type of Account**	**Amount you have**	**Amount your spouse has**
		$	$
		$	$
		$	$

If you are a prisoner seeking to appeal a judgment in a civil action or proceeding, you must attach a statement certified by the appropriate institutional officer showing all receipts, expenditures, and balances during the last six months in your institutional accounts. If you have multiple accounts, perhaps because you have been in multiple institutions, attach one certified statement of each account.

5. *List the assets, and their values, which you own or your spouse owns. Do not list clothing and ordinary household furnishings.*

Home	**Other real estate**	**Motor vehicle #1**
(Value) $	(Value) $	(Value) $
		Make and year:
		Model:
		Registration #:

Motor vehicle #2	**Other assets**	**Other assets**
(Value) $	(Value) $	(Value) $
Make and year:		
Model:		
Registration #:		

6. *State every person, business, or organization owing you or your spouse money, and the amount owed.*

Person owing you or your spouse money	**Amount owed to you**	**Amount owed to your spouse**
	$	$
	$	$
	$	$
	$	$

7. *State the persons who rely on you or your spouse for support.*

Name [or, if a minor (i.e., underage), initials only]	**Relationship**	**Age**

8. *Estimate the average monthly expenses of you and your family. Show separately the amounts paid by your spouse. Adjust any payments that are made weekly, biweekly, quarterly, semiannually, or annually to show the monthly rate.*

	You	**Your Spouse**
Rent or home-mortgage payment (including lot rented for mobile home) Are real estate taxes included? ☐ Yes ☐ No Is property insurance included? ☐ Yes ☐ No	$	$
Utilities (electricity, heating fuel, water, sewer, and telephone)	$	$
Home maintenance (repairs and upkeep)	$	$
Food	$	$
Clothing	$	$
Laundry and dry-cleaning	$	$
Medical and dental expenses	$	$

Transportation (not including motor vehicle payments)		$	$
Recreation, entertainment, newspapers, magazines, etc.		$	$
Insurance (not deducted from wages or included in mortgage payments)			
	Homeowner's or renter's:	$	$
	Life:	$	$
	Health:	$	$
	Motor vehicle:	$	$
	Other:	$	$
Taxes (not deducted from wages or included in mortgage payments) (specify):		$	$
Installment payments			
	Motor Vehicle:	$	$
	Credit card (name):	$	$
	Department store (name):	$	$
	Other:	$	$
Alimony, maintenance, and support paid to others		$	$
Regular expenses for operation of business, profession, or farm (attach detailed statement)		$	$
Other (specify):		$	$
Total monthly expenses:		**$** 0	**$** 0

9. *Do you expect any major changes to your monthly income or expenses or in your assets or liabilities during the next 12 months?*

☐ Yes ☐ No If yes, describe on an attached sheet.

10. *Have you spent — or will you be spending —any money for expenses or attorney fees in connection with this lawsuit?* ☐ Yes ☐ No

If yes, how much? $ _____

11. *Provide any other information that will help explain why you cannot pay the docket fees for your appeal.*

12. *Identify the city and state of your legal residence.*

City _____ State _____

Your daytime phone number: _____

Your age: _____ Your years of schooling: _____

Last four digits of your social-security number: _____

United States District Court
Southern District of New York

HOW TO APPEAL YOUR CASE TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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