IADC 2024 Product Liability Roundtable

When the End is Just the Beginning – How Remanded Cases Can Make or Break Multidistrict Litigation

Speakers:

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Moderator:

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Multidistrict litigation (MDL) has grown to become a cornerstone of federal civil litigation in the United States, particularly litigation involving products liability claims. MDL judges, keen to streamline the resolution of this voluminous and complex litigation, are increasingly turning to remands—or orders returning cases to the plaintiffs' home district. Once an afterthought in MDL litigation, remands are now critical. Fortunately, if handled correctly, remands present an opportunity for product manufacturer defendants to secure favorable settlements or, better yet, dismissal of cases without any settlement.

MDL Litigation in the United States

The MDL statute, 28 U.S.C. § 1407, was enacted in 1968 to streamline the management of complex litigation involving numerous parties and cases. The statute established the Judicial Panel on Multidistrict Litigation (JPML), a panel of federal judges that has the authority to transfer cases from multiple federal district courts to a single district court for coordinated or consolidated pretrial proceedings if certain criteria are met.

The MDL process has undoubtedly impacted the landscape of federal litigation. By 2024, the number of MDL cases in the country totaled more than 418,000, a number that might actually *underestimate* the total given that some MDL judges often allow claimants to delay filing their complaints.[1] For perspective, MDL cases comprise well over half of federal civil cases most years.[2] And the growth in MDLs is accelerating: According to Lawyers for Civil Justice, it took

[1] MDL Statistics Report – Distribution of Pending MDL Dockets by Actions Pending, United States Judicial Panel on Multidistrict Litigation (July 1, 2024), *available at* https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Actions_Pending-August -1-2024.pdf.

[2] Alan Fuchsberg & Alex Dang, *MDLs Are Redefining the US Legal Landscape,* Law360 (Oct. 30, 2019), *available at* https://www.law360.com/articles/1214276/mdls-are-redefining-the-us-legal-landscape.

39 years from the enactment of the MDL statute to reach 250,000 total cases filed in MDLs, but only seven more years to reach 500,000 and just seven more to top 1 million, a milestone reached in 2021.[3] Product manufacturers should take particular note of this trend given that nearly 40 percent of pending MDLs—and each of the largest ten MDLs—involve products liability cases.[4]

The Increasing Role of Remand Discovery or "Wave Orders" in MDL

Coupled with the growth in the number and size of MDLs is another noteworthy trend: the use of the so-called "remand." Pursuant to 28 U.S.C. § 1407(a), "[e]ach action so transferred [to an MDL] shall be remanded by the [P]anel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated . . . ." Put more simply, after the MDL court resolves common discovery issues, cases in an MDL are remanded back to the plaintiff's home district for trial.

For much of the history of the MDL statute, remands were the exception, not the rule. The very rare exception, actually. Indeed, between 1968—when the MDL process was created—and 2013, just 13,432 cases—or less than 1 percent of the total number of MDL cases—were remanded for trial.[5] As one experienced defense attorney aptly described, remand is "a place generally known to most lawyers, but an area where most attorneys—even experienced MDL practitioners—have seldom traveled."[6]

But remands have become more popular with MDL courts. For example, in the pelvic mesh MDLs—a group of nine products liability MDLs that encompassed more than 100,000 cases—District Judge Joseph Goodwin employed a strategy of "remand discovery waves." Over a period of nearly four years, Judge Goodwin entered up to a dozen docket control orders, each order requiring the parties to prepare hundreds or even thousands of cases for remand. Any case still pending at the end of discovery and motion practice would be remanded back to the plaintiff's home district for trial. Reflecting on his experience managing the pelvic mesh MDLs, Judge Goodwin observed that establishing a firm deadline for remanding unresolved cases is "the most

[3] Lawyers for Civil Justice, *MDLs Reach 1 Million Case Milestone* (Mar. 18, 2021), *available at* https://www.rules4mdls.com/mdls-reach-1-million-case-milestone.

[4] United States Judicial Panel on Multidistrict Litigation, *Calendar Year Statistics, January Through December 2023*.

[5] United States Judicial Panel on Multidistrict Litigation, *Judicial Business 2013*.

[6] Richard B. North, Jr., *MDL Remands: A Defense Perspective*, UMKC Law Review Vol. 89 No. 4, Article 20 (2021).

critical step in multidistrict litigation."[7] Judge Goodwin is not alone in experienced MDL judges who believe in the power of remands to resolve massive litigation.[8]

The Challenges—and Opportunities—of MDL Remands

Threating remand works because it applies pressure. As Judge Goodwin recognized, "[k]nowing that your cases will be dispersed across the country if you do not settle before the remand or transfer deadline will be strong incentive to prepare earlier, evaluate sooner, and negotiate seriously." Plaintiffs who were content to sign a few papers and wait for their payday now must sit for a deposition. Their counsel have dozens or more clients to contact, discovery and deposition requests to respond to, and motions to answer. Counsel for the defendants have records to collect, doctors to locate, and depositions to prepare for. And both sides need experts to review records, write a report, and sit for a deposition. To state the obvious, completing these tasks in hundreds or even thousands of cases can be incredibly expensive, making settlement more attractive.

Added to the challenge is that MDL judges typically do not make the remand process comfortable for the parties. To the contrary, remand discovery orders often require discovery and motions be completed at a whirlwind pace. For example, Judge Goodwin in one pelvic mesh MDL entered a series of orders, some separated by just a few months, directing the parties to work up thousands of cases in short order, sometimes as little as five months:

Remand Discovery Wave	Number of Cases	Date of Wave Order	Close of Discovery
1	200	8/9/2015	2/16/2016[9]
2	200	11/20/2015	7/1/2016
3	200	12/18/2015	8/30/2016
4	400	10/25/2016	3/17/2017
5	400	2/21/2017	7/19/2017
6	400	4/27/2017	9/25/2017
7	150	9/8/2017	2/9/2018
8	13,200	1/30/2018	9/4/2018
9	185	8/27/2018	5/20/2019
10	1,256	10/31/2018	4/29/2019
11	551	2/4/2019	8/1/2019
12	3,264	5/1/2019	10/25/2019
13	113	6/20/2019	12/13/2019

[7] Judge Joseph R. Goodwin, *Remand: The Final Step in the MDL Process – Sooner Rather than Later*, UMKC Law Review Vol. 89 No. 4, Article 19 (2021).

[8] *See* Judge Clay D. Land, *Multidistrict Litigation After 50 Years: A Minority Perspective from the Trenches*, 53 Ga. L. Rev. 1237, 1242 (2019).

[9] *See In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D. W. Va. Aug. 19, 2015), Pretrial Order # 192 (Docket Control Order – Wave 1 Cases). This remand wave order is included as an attachment.

Judge Casey Rogers overseeing the Combat Arms Earplugs MDL – the largest MDL in the history of the federal judiciary – similarly ordered aggressive wave discovery with 500 cases per wave for four waves. Challenging as they are, remand opportunities also present an opportunity. As mentioned, pressure is applied to both sides, and both sides must work. Corporate defendants can often take advantage of the pressure felt by plaintiffs' counsel and their clients to secure a favorable resolution. Better yet, remand discovery orders often uncover "marginal claims," or cases filed by plaintiffs who never used the product at issue, did not suffer an injury, or did not file their claims before the statute of limitations lapsed. These marginal claims can often be identified early with simple records collection or other discovery.

Again, the pelvic mesh MDL is instructive. Of the 20,519 cases that were included in one of the thirteen remand discovery wave orders listed above, only 974 (or 4.7%) actually completed discovery and were included in a remand or transfer order to the plaintiff's home district. And just 641 (or 3.1%) were actually remanded or transferred. The vast majority of the thousands of cases included in the wave orders either resolved or were dismissed for one reason or another.

How to Survive a Remand Discovery Order

Coordination. Litigation of any type requires coordination, particularly when it involves multiple law firms representing a product manufacturer. But thriving when facing hundreds of thousands of product liability cases—simultaneously—demands a sizeable defense team that can efficiently and effectively work together.

Ideally, remand discovery will be managed by a defense team that is intimately familiar with the issues presented by the MDL litigation. Knowledge of general discovery (the product and company discovery, including company witnesses and documents) and litigation history (such as key rulings by the MDL judge) is imperative for coordinating counsel. Coordinating counsel should consider ways to share knowledge of the litigation with additional defense counsel, including training sessions or materials, examples of effective depositions, and witness outlines.

Coordinating counsel should establish written protocols for consistent communication with any additional defense counsel brought on to manage remand discovery. Protocols for written discovery, records, collection, expert discovery, and depositions should be established and shared with all counsel navigating remand discovery.

Coordination is made easier with centralized resource management such as SharePoint or Relativity for paralegals and lawyers.

Communication. Coordinating counsel should conduct regular team calls to update additional defense counsel of key developments. To manage the expense of these team calls, coordinating counsel should be clear about which team members should (and which should not) participate. Detailed written agendas should be prepared and circulated so that calls are efficient.

Prioritization. In-house counsel of a manufacturer might ordinarily choose a "leave-no-stone-unturned" approach to defending a lawsuit. Collecting records from every medical provider,

deposing every fact witness, retaining an expert witness in every relevant field, and filing every possible motion might be the best approach in one-off cases. But such an approach is not feasible when there are hundreds or thousands of pending claims.

Coordinating counsel should have a frank discussion with the client to discuss the scope of remand work. Depending on the litigation, some areas of potential cost-savings include:

- Records collection: Rather than seeking records from every medical provider to have treated the plaintiff, consider instead limiting the temporal scope of records collection (for example, five years before the plaintiff's exposure to the product and after) or limiting the type of provider from whom records are sought (for example, foregoing mental health providers or employers).
- Depositions: Depositions are among the most time-consuming and expensive steps in remand discovery. Consider establishing protocols limiting the number of depositions taken. Often, the plaintiff, spouse, and key prescribing/treating physician will be sufficient. In several MDLs there have been time limitations set for depositions and orders to avoid re-deposing experts on general reports.
- Experts: Expert discovery must necessarily be limited in remand discovery. Will each case have a case-specific expert (that is, an expert who has written a report specific to the plaintiff at hand), or will there instead be some cases with general experts only? If coordinating counsel and the client elect to have a case-specific expert in every case, there are ways to minimize the expense. For example, providing the expert with a manageable set of key medical records. It is important to consider the remand jurisdiction when making expert assignments during the remand discovery process.
- Motions: Templates that can easily be modified from one case to the next can oftentimes allow the defense to file dispositive and Rule 702 motions in each case without undue expense. Also consider which motions you should avoid filing until the case has been remanded.

Finally, defense counsel should keep in mind that, for cases that survive remand discovery and are remanded to the plaintiff's home district, the remand court may well provide the defense an opportunity to reopen discovery or refile motions. As a result, initial prioritization might not foreclose a broader approach down the road.

MDL remand discovery orders present significant challenges for defense counsel, but with careful planning and strategic execution, these challenges can be managed effectively. By prioritizing cases, conducting early case assessments for resolution, conducting efficient discovery, developing a deep bench of experts, collaborating as a virtual firm, standardizing processes, and maintaining strong communication, defense teams can navigate the complexities of MDL discovery and position themselves for successful outcomes before and after remand.

Managing Cases Post-Remand

Even if the vast majority of cases included in a remand discovery order are resolved or dismissed before remand, there is still the potential for dozens or more cases to be remanded from the MDL to the plaintiffs' home district simultaneously.

Coordinating counsel again plays a pivotal role post-remand. At least one member of coordinating counsel should be involved in each case that is remanded from the MDL court. One effective strategy is for coordinating counsel to assign various state managers to provide consistent coordination with remand counsel, which may be needed for all 50 states The remand court will likely have many questions about the history of the case and the litigation, and coordinating counsel must continue to be involved to address these issues. Coordinating counsel must also make sure that the defense team is taking consistent positions across remanded cases on key issues like reopening discovery, choice of law, and motions *in limine*. Being prepared for remands is crucial due to the significant variability and lack of uniformity that cases face when returned to their respective home jurisdictions. Each jurisdiction can have different procedures, requirements, and timelines. Defense teams must be organized, strategically aligned, and proactive to handle remand cases effectively.

Shortly after remand, defense counsel should consider requesting a status conference with the remand court and offering to provide a status report of the case and litigation history. This status conference or report is a prime opportunity to request any additional discovery, to seek leave for additional motions, or to otherwise attempt to fill any gaps in the case.

Defense counsel must also be cognizant of the record on remand. In later stages of an MDL, it is not uncommon for the parties in individual cases to incorporate motions or other filings from the general MDL docket. For example, the parties might simply incorporate by reference a general Rule 702 motion that the MDL judge has ruled on repeatedly, rather than refiling the same motion in the individual case. Defense counsel must make sure that the remand court—and possibly any appellate court—has access to all motions and other key filings in the record of the remanded case.[10]

Coordinating counsel should also recognize that simultaneous remand of many cases might place stress on company witnesses. It is not uncommon for an MDL to involve a product designed and developed many years before the litigation arose. By the time of remand, a dozen years or more might have passed since product development, and the stable of company witnesses might be limited as a result. To the extent a company witness remains with the client, he or she might be unable to testify in simultaneously remanded cases. Coordinating counsel should guard against this outcome early in the MDL by conducting direct, trial examinations of every company witness who is deposed in the MDL.

Trying a remand case can present unique challenges. Trial counsel should understand that, because of prioritization during remand discovery, there might be gaps—small or large—in the evidence to put on at trial. The defense might not have a case-specific expert; there might be significant gaps in the plaintiff's medical records; or there might not be a company witness for the jury to hear from live during the defense case. In all likelihood, plaintiffs' counsel will face similar limitations.

[10] This is easier than it sounds. An example of a chart jointly prepared by the parties in a recent MDL is attached and shows just how complicated it can be to determine what motions are pending in a remanded case.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION **MDL No. 2327**

THIS DOCUMENT RELATES TO
THE CASES LISTED ON EXHIBIT A

PRETRIAL ORDER # 192
(Docket Control Order – Wave 1 Cases)

At my request, the parties recently submitted a joint list of 200 of the oldest cases in the Ethicon MDL that name only the Ethicon, Inc., Ethicon, LLC and/or Johnson & Johnson (the "Ethicon defendants") or allege claims against only the Ethicon defendants' products. These cases, attached hereto as Exhibit A, will be known as the "Ethicon Wave 1 cases," and it is **ORDERED** as follows:

A. SCHEDULING DEADLINES. The following deadlines shall apply in the Ethicon Wave 1 cases:

Plaintiff Fact Sheets.	10/19/2015
Defendant Fact Sheets.	11/19/2015
Deadline for written discovery requests.	01/04/2016
Expert disclosure by party with burden of proof.	12/17/2015
Expert disclosure by opposing party.	01/18/2016
Expert disclosure for rebuttal purposes.	02/01/2016
Deposition deadline and close of discovery.	02/16/2016
Filing of dispositive and *Daubert* motions.	03/07/2016
Responses to dispositive and *Daubert* motions.	03/21/2016
Reply to response to dispositive and *Daubert* motions.	03/28/2016

1. **Discovery Completion Date.** The last date to complete depositions shall be the "discovery completion date" by which all discovery, including disclosures required by Federal Rule of Civil Procedure 26(a)(1), and (2), but not disclosures required by Federal Rule of Civil Procedure 26(a)(3), shall be completed.

2. **Limitations on Interrogatories, Requests for Admissions and Depositions**. The following limitations apply:

   a. Defendants are limited to 10 interrogatories and 10 requests for admission per plaintiff.

   b. Plaintiffs are limited to 10 interrogatories and 10 requests for admission to the Ethicon defendants.

   c. Depositions of plaintiff's friends and family members may be taken at any time prior to trial provided the deposition is requested before the discovery completion date.

   d. Depositions of any witness are limited to 3 hours absent agreement of the parties.

   e. The court will consider modifications to the above limitations upon good cause shown.

3. **Limitations on Experts.** The following limitations related to experts apply:

   a. The parties may conduct general and specific expert discovery on the products at issue in Ethicon Wave 1. In light of the bellwether trials that already occurred and the substantial discovery conducted to date on the Ethicon defendants' products, the parties are cautioned not to engage in duplicative general expert discovery, but instead, to tailor their discovery to

the remaining Ethicon defendants' products at issue (to the extent such discovery is necessary), supplementing any discovery already completed and conducting specific causation discovery for the Ethicon Wave 1 plaintiffs. In light of the common products involved in Ethicon Wave 1, the likelihood of overlap in expert opinion from one case to another (except as to specific causation) and the need to streamline discovery in these cases, **each side is limited to no more than five (5) experts per case (exclusive of treating physicians)**. It is the court's expectation that these experts will overlap for plaintiffs who have the same product(s), to some extent, if not entirely.

b. The parties shall coordinate the depositions of general causation experts. Insofar as multiple plaintiffs utilize the same general causation expert or experts, those experts shall be deposed only once on the issue of general causation. As to Bard's experts, plaintiffs are instructed to choose a lead questioner.

c. The court encourages the coordination of depositions of specific causation experts to the extent there is overlap in the parties' use of specific causation experts for multiple plaintiffs.

d. The court will consider modifications to the above limitations upon good cause shown.

B. MOTION PRACTICE.

1. **Early Dispositive Motions.** If discovery (e.g., the deposition of plaintiff and her implanting physician) reveals facts that could support a motion that would be dispositive of the

entirety of a plaintiff's claims (e.g., causation, the statute of limitations), either party may seek the court's leave *in the individual member case* to file an early dispositive motion on that issue. If such leave is granted, the court shall set a briefing schedule at that time.

2. ***Daubert* Motions.** For the filing of *Daubert* motions on general causation issues only, the parties are instructed to file one *Daubert* motion per expert in the main MDL (MDL 2327) instead of the individual member case. Each side may file one response and one reply in the main MDL to each *Daubert* motion. This limitation does not apply to specific causation *Daubert* motions, responses and replies. Specific causation *Daubert* motions, responses and replies must be filed in the individual member cases. To the extent an expert is both a general and specific causation expert, the parties may file a general causation motion in the main MDL 2327 and an individual specific causation motion in an individual member case.

3. **Hearings.** Hearing dates for dispositive and *Daubert* motions, if any, will be set at a future status conference.

4. **Page Limitations.** The page limitations provided in Local Rule of Civil Procedure 7.1(a)(2) apply to memoranda in support of all dispositive and *Daubert* motions, oppositions, and replies, and the court will not be inclined to grant motions to exceed the page limit.

5. **Confidential Documents.** In the past, the court has permitted parties to file placeholder exhibits in support of *Daubert*, dispositive and other motions, responses and replies in the place of confidential documents that may be sealed and then, within five days, redact/dedesignate the documents or file a motion to seal. *Moving forward, the court will no longer permit this practice. Parties may no longer file placeholder exhibits.* The court expects leadership counsel for plaintiffs and the Ethicon defendants to resolve issues related to confidential designations well before the filing of motions. Filings containing placeholder

exhibits will be struck. In the event there are issues related to sealing of confidential documents that the parties are unable to resolve, they must be brought to the court's attention in a consolidated manner as follows: A consolidated motion to seal is due on or before **February 8, 2016**, any response is due **February 16, 2016** and any reply is due **February 23, 2016**.

6. **Locations of Filings.** With the exception of the general causation *Daubert* motions as outlined above, the parties are reminded that they must file dispositive and *Daubert* motions on specific causation, responses and replies in the applicable member cases only, not in the Ethicon MDL.

C. CASES READY FOR TRANSFER, REMAND OR TRIAL

1. **Venue Recommendations.** By no later than **January 11, 2016**, the parties shall meet and confer concerning the appropriate venue for each of the cases, and the parties shall submit joint venue recommendations to the court by **January 19, 2016**. The parties' joint recommendation(s) shall identify the cases about which the recommended venue is in dispute. The court may then request briefing concerning the venue for those cases about which the parties disagree. Each party reserves the right to object to the venue selected by its adversary or the court.

2. **Transfer and Remand.** At the conclusion of pre-trial proceedings, the court, pursuant to PTO # 15 and 28 U.S.C. § 1404(a), will transfer each directly-filed case to a federal district court of proper venue as defined in 28 U.S.C. § 1391. In the alternative, pursuant to PTO # 15 and 28 U.S.C. § 1407, cases that were transferred to this court by the MDL panel shall be

remanded for further proceedings to the federal district court from which each such case was initially transferred.[1]

3. **Trial Settings.** If a case is to be tried in the United States District Court for the Southern District of West Virginia (either by agreement of the parties or where venue in the Southern District is determined to be proper by the court), the case shall be deemed trial-ready when discovery is completed and the court rules on the parties' pretrial motions. The trial date for cases transferred or remanded to other federal district courts shall be set by the judge to whom the transferred or remanded case is assigned (including the undersigned through intercircuit assignment).

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327 and in the cases listed on Exhibit A. The court further **DIRECTS** the Clerk to designate these cases as Ethicon Wave 1 cases on the docket. In cases subsequently filed in this district after 2:15-cv-12499, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: August 19, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[1]As expressly contemplated by PTO # 15, the Ethicon defendants do not waive their right to seek transfer—pursuant to 28 U.S.C. § 1406(a) or any other available ground—of any case to a court of proper venue, regardless of whether that case was transferred to or directly-filed in the Southern District of West Virginia.

Case No.	Case Style
2:11-cv-00809	Wilma Johnson v. Ethicon, et al.
2:12-cv-00256	Amy and Brent Holland v. Ethicon, et al.
2:12-cv-00258	Carrie Smith v. Ethicon, et al.
2:12-cv-00261	Mary F. Cone v. Ethicon, et al.
2:12-cv-00265	Doris Chappell Jackson v. Ethicon, et al.
2:12-cv-00276	Cathy and John Warlick v. Ethicon, et al.
2:12-cv-00277	Joy and Kevin Essman v. Ethicon, et al.
2:12-cv-00279	Susan Thaman v. Ethicon, et al.
2:12-cv-00286	Quillan R. and Thomas W. Garnett v. Ethicon, et al.
2:12-cv-00322	Linda B. Ryan v. Ethicon, et al.
2:12-cv-00335	Sandra Wolfe v. Ethicon, et al.
2:12-cv-00337	Kathleen Wolfe v. Ethicon, et al.
2:12-cv-00341	Helen M. Brown and Robert E. Ruttkay v. Ethicon, et al.
2:12-cv-00344	Rose and Jesus Gomez v. Ethicon, et al.
2:12-cv-00347	Deborah and Felipe Lozano v. Ethicon, et al.
2:12-cv-00351	Kathy Barton v. Ethicon, et al.
2:12-cv-00352	Charlotte Hargrove v. Ethicon, et al.
2:12-cv-00358	Amanda and Raymond Deleon v. Ethicon, et al.
2:12-cv-00368	Sharon and Michael Boggs v. Ethicon, et al.
2:12-cv-00369	Dawna Hankins v. Ethicon, et al.
2:12-cv-00376	Charlene Logan Taylor v. Ethicon, et al.
2:12-cv-00378	Tina and Kenneth Morrow v. Ethicon, et al.
2:12-cv-00379	Teri Key and Johnny Shively v. Ethicon, et al.
2:12-cv-00380	Terrie S. and Ralph R. Gregory v. Ethicon, et al.
2:12-cv-00381	Susan C. and Leonard Hayes v. Ethicon, et al.
2:12-cv-00387	Maru LuEllen and Thomas Lawrence Kilday v. Ethicon, et al.
2:12-cv-00389	Janice Renee Swaney v. Ethicon, et al.
2:12-cv-00397	Deborah A. Smith v. Ethicon, et al.
2:12-cv-00401	Carol Jean Dimock v. Ethicon, et al.
2:12-cv-00423	Pamela Free v. Ethicon, et al.
2:12-cv-00443	Holy and Jason Jones v. Ethicon, et al.
2:12-cv-00455	Pamela Gray-Wheeler and Stan Wheeler v. Ethicon, et al.
2:12-cv-00468	Amelia R. and Ernest B. Gonzales v. Ethicon, et al.
2:12-cv-00469	Patricia Tyler v. Ethicon, et al.
2:12-cv-00470	Mary Jane and Daniel Olson v. Ethicon, et al.
2:12-cv-00476	Harriet Beach v. Ethicon, et al.
2:12-cv-00481	Miranda Patterson v. Ethicon, et al.
2:12-cv-00483	Carey Beth and David Cole v. Ethicon, et al.
2:12-cv-00485	Danni Laffoon v. Ethicon, et al.
2:12-cv-00486	Karen and Joel Forester v. Ethicon, et al.
2:12-cv-00489	Melissa and Charles Clayton v. Ethicon, et al.
2:12-cv-00490	Shirley and William Freeman v. Ethicon, et al.
2:12-cv-00491	Gwendolyn T. Young v. Ethicon, et al.
2:12-cv-00493	Nancy and Daniel Hooper v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00494	Penelope Ann Link and Dan Richard Saurino v. Ethicon, et al.
2:12-cv-00495	Andrea Carol and Mark Thomas Chandlee v. Ethicon, et al.
2:12-cv-00496	Sonya M. and James R. Moreland v. Ethicon, et al.
2:12-cv-00497	Dina Sanders Bennett v. Ethicon, et al.
2:12-cv-00498	Myndal Johnson v. Ethicon, et al.
2:12-cv-00499	Kimberly Thomas v. Ethicon, et al.
2:12-cv-00500	Krystal and Gregory Teasley v. Ethicon, et al.
2:12-cv-00501	Jennifer and David Sikes v. Ethicon, et al.
2:12-cv-00504	Donna T. and James W. Pilgreen v. Ethicon, et al.
2:12-cv-00505	Mary and Kenneth Thurston v. Ethicon, et al.
2:12-cv-00506	Martha and Stuart Newman v. Ethicon, et al.
2:12-cv-00510	Charlene Miracle v. Ethicon, et al.
2:12-cv-00511	Nancy Williams v. Ethicon, et al.
2:12-cv-00516	Patricia Conti v. Ethicon, et al.
2:12-cv-00517	Joann Lehman v. Ethicon, et al.
2:12-cv-00539	Ann Louise Ruppel and Robert Dean Fuller v. Ethicon, et al.
2:12-cv-00540	Nancy and Kenneth Feidler v. Ethicon, et al.
2:12-cv-00547	Brenda and James Riddell v. Ethicon, et al.
2:12-cv-00548	Rhoda Schachtman v. Ethicon, et al.
2:12-cv-00554	Sharon and Gardner Carpenter v. Ethicon, et al.
2:12-cv-00555	Carolyn Sue Doyle v. Ethicon, et al.
2:12-cv-00567	Noemi and Cesar Padilla v. Ethicon, et al.
2:12-cv-00571	Mary Catherine Wise v. Ethicon, et al.
2:12-cv-00591	Beverly Kivel v. Ethicon, et al.
2:12-cv-00594	Frances Ann and Herman Cortez v. Ethicon, et al.
2:12-cv-00595	Mary and Thomas Hendrix v. Ethicon, et al.
2:12-cv-00601	Deanna Jean and Bennie G. Thomas v. Ethicon, et al.
2:12-cv-00609	Patricia O. Powell v. Ethicon, et al.
2:12-cv-00651	Robin Bridges v. Ethicon, et al.
2:12-cv-00652	Maria C. and Mark A. Stone v. Ethicon, et al.
2:12-cv-00654	Stacy and Kevin Shultis v. Ethicon, et al.
2:12-cv-00657	Judy G. Williams v. Ethicon, et al.
2:12-cv-00663	Ana Ruebel v. Ethicon, et al.
2:12-cv-00666	Donna and Leon Loustaunau v. Ethicon, et al.
2:12-cv-00669	Teresa and Ricky J. Stout v. Ethicon, et al.
2:12-cv-00679	Lisa and Henry Stevens v. Ethicon, et al.
2:12-cv-00683	Louise Grabowski v. Ethicon, et al.
2:12-cv-00736	Karen and Thomas Daniell v. Ethicon, et al.
2:12-cv-00737	Beth and Stuart Harter v. Ethicon, et al.
2:12-cv-00738	Sheri and Gary Scholl v. Ethicon, et al.
2:12-cv-00746	Margaret Kirkpatrick v. Ethicon, et al.
2:12-cv-00747	Karyn E. and Douglas E. Drake v. Ethicon, et al.
2:12-cv-00748	Myra abd Richard Byrd v. Ethicon, et al.
2:12-cv-00749	Jennifer D. and Willem C.J. Van Rensburg v. Ethicon, et al.

Case No.	Case Style
2:12-cv-00751	Raquel and Ernesto De La Torre v. Ethicon, et al.
2:12-cv-00755	Cheryl Lankston v. Ethicon, et al.
2:12-cv-00756	Dee and Michael Woolsey v. Ethicon, et al.
2:12-cv-00757	Barbara Jean and Keith Bridges v. Ethicon, et al.
2:12-cv-00759	Diane and Robert Matott v. Ethicon, et al.
2:12-cv-00760	Lois and Gerald Durham v. Ethicon, et al.
2:12-cv-00761	Barbara J. and Gary L. Ware v. Ethicon, et al.
2:12-cv-00762	Janet D. Jones v. Ethicon, et al.
2:12-cv-00765	Rachel and Dwan Taylor v. Ethicon, et al.
2:12-cv-00766	Kimberly Garnto v. Ethicon, et al.
2:12-cv-00767	Rebecca and Charles Oehring v. Ethicon, et al.
2:12-cv-00768	Sandra and Christian LaBadie v. Ethicon, et al.
2:12-cv-00769	Kimberly T. Burnham v. Ethicon, et al.
2:12-cv-00772	Harmony Minniefield v. Ethicon, et al.
2:12-cv-00773	Tina and Keith Patterson v. Ethicon, et al.
2:12-cv-00779	Dee and Timothy McBrayer v. Ethicon, et al.
2:12-cv-00783	Wendy Hagans v. Ethicon, et al.
2:12-cv-00784	Schultz et al v. Ethicon, Inc. et al
2:12-cv-00786	Swint et al v. Ethicon, Inc et al
2:12-cv-00787	Joplin v. Ethicon, Inc et al
2:12-cv-00799	Quijano v. Ethicon, Inc. et al
2:12-cv-00800	Morrison et al v. Ethicon, Inc et al
2:12-cv-00806	Hill et al v. Ethicon, Inc. et al
2:12-cv-00807	Sweeney et al v. Ethicon, Inc. et al
2:12-cv-00811	Zoltowski et al v. Johnson & Johnson et al
2:12-cv-00821	Barr et al v. Ethicon, Inc. et al
2:12-cv-00828	Nix et al v. Ethicon, Inc. et al
2:12-cv-00829	Georgilakis et al v. Ethicon, Inc et at
2:12-cv-00830	Parrilla v. Ethicon, Inc. et al
2:12-cv-00842	Stubblefield v. Ethicon, Inc. et al
2:12-cv-00846	Raines et al v. Ethicon, Inc. et al
2:12-cv-00848	Fisk v. Ethicon, Inc et al
2:12-cv-00854	Ballard et al v. Ethicon, Inc et al
2:12-cv-00856	Massicot v. Ethicon, Inc. et al
2:12-cv-00859	Olmstead v. Ethicon, Inc. et al
2:12-cv-00860	Pelton v. Ethicon, Inc. et al
2:12-cv-00861	Smith et al v. Ethicon, Inc. et al
2:12-cv-00863	Gunter et al v. Ethicon, Inc
2:12-cv-00864	Nolan v. Ethicon, Inc. et al
2:12-cv-00867	Rock v. Ethicon et al
2:12-cv-00873	Walker et al v. Ethicon, Inc. et al
2:12-cv-00875	Holzerland et al v. Ethicon, Inc. et al
2:12-cv-00876	Hoy et al v. Ethicon, Inc. et al
2:12-cv-00878	Fox et al v. Johnson & Johnson, Inc. et al

Case No.	Case Style
2:12-cv-00880	Massey et al v. Ethicon, Inc. et al
2:12-cv-00883	Wroble et al v. Ethicon, Inc et al
2:12-cv-00886	Umberger et al v. Ethicon, Inc. et al
2:12-cv-00887	Kaiser et al v. Johnson & Johnson et al
2:12-cv-00888	Bruhn et al v. Ethicon, Inc et al
2:12-cv-00899	Barker et al v. Ethicon, Inc. et al
2:12-cv-00921	Wilson v. Ethicon, Inc et al
2:12-cv-00923	Atemnkeng et al v. Ethicon, Inc. et al
2:12-cv-00931	Collins v. Ethicon, Inc. et al
2:12-cv-00938	Kriz et al v. Ethicon, Inc. et al
2:12-cv-00939	Reyes et al v. Ethicon, Inc. et al
2:12-cv-00956	Justus v. Ethicon, Inc. et al
2:12-cv-00957	Funderburke v. Ethicon, Inc. et al
2:12-cv-00958	White et al v. Ethicon, Inc. et al
2:12-cv-00960	Amsden et al v. Ethicon, Inc. et al
2:12-cv-00961	Greene v. Ethicon, Inc. et al
2:12-cv-00967	Shepherd v. Ethicon, Inc. et al
2:12-cv-00995	Blake et al v. Ethicon, Inc. et al
2:12-cv-00997	Springer et al v. Ethicon, Inc. et al
2:12-cv-01004	Frye v. Ethicon, Inc. et al
2:12-cv-01011	Hankins et al v. Ethicon, Inc. et al
2:12-cv-01013	Lee et al v. Ethicon, Inc. et al
2:12-cv-01018	Gwinn et al v. Ethicon, Inc. et al
2:12-cv-01021	Ruiz v. Ethicon, Inc. et al
2:12-cv-01023	Burkhart v. Ethicon, Inc. et al
2:12-cv-01052	Babcock v. Ethicon, Inc. et al
2:12-cv-01053	Baugher v. Ethicon, Inc. et al
2:12-cv-01071	Schnering et al v. Ethicon, Inc. et al
2:12-cv-01081	Dixon v. Ethicon, Inc. et al
2:12-cv-01088	Wheeler et al v. Ethicon, Inc. et al
2:12-cv-01090	Wright v. Ethicon, Inc. et al
2:12-cv-01119	Rhynehart v. Ethicon, Inc. et al
2:12-cv-01121	Guinn v. Ethicon, Inc. et al
2:12-cv-01124	Bellito-Stanford et al v. Ethicon, Inc. et al
2:12-cv-01145	Constance Daino v. Ethicon, Inc. et al
2:12-cv-01146	Monica Freitas v. Ethicon, Inc. et al
2:12-cv-01148	Denise Sacchetti v. Ethicon, Inc. et al
2:12-cv-01149	Cindy Smith v. Ethicon, Inc. et al
2:12-cv-01150	Roberta Warmack v. Ethicon, Inc. et al
2:12-cv-01151	Laura Waynick v. Ethicon, Inc. et al
2:12-cv-01171	Patti Ann Phelps v. Ethicon, Inc. et al
2:12-cv-01198	Stacy Pangborn v. Ethicon, Inc. et al
2:12-cv-01199	Lisa Thompson v. Ethicon, Inc. et al
2:12-cv-01202	Diane Kropf v. Ethicon, Inc. et al

Case No.	Case Style
2:12-cv-01203	Joan Adams v. Ethicon, Inc. et al
2:12-cv-01206	Jeanie Holmes v. Ethicon, Inc. et al
2:12-cv-01215	Karen Bollinger v. Ethicon, Inc. et al
2:12-cv-01216	Christine Wiltgen v. Ethicon, Inc. et al
2:12-cv-01225	Ida Deanne Evans v. Ethicon, Inc. et al
2:12-cv-01262	Saundra Landes v. Ethicon, Inc. et al
2:12-cv-01267	Angela Coleman v. Ethicon, Inc. et al
2:12-cv-01273	Rebekah Barlett v. Ethicon, Inc. et al
2:12-cv-01274	Janice Colonna v. Ethicon, Inc. et al
2:12-cv-01275	Long v. Johnson & Johnson et al
2:12-cv-01277	Duncan v. Ethicon, Inc et al
2:12-cv-01278	Nix v. Ethicon, Inc. et al
2:12-cv-01279	Bertoni et al v. Ethicon, Inc. et al
2:12-cv-01283	Cyrus v. Ethicon, Inc. et al
2:12-cv-01284	Floyd v. Ethicon, Inc. et al
2:12-cv-01285	Simpson et al v. Ethicon, Inc. et al
2:12-cv-01286	Wilson v. Ethicon, Inc. et al
2:12-cv-01293	Costello v. Ethicon, Inc. et al
2:12-cv-01294	Herrera-Nevarez v. Ethicon, Inc
2:12-cv-01299	Destefano-Rasten et al v. Ethicon, Inc. et al
2:12-cv-01304	Irwin et al v. Ethicon, Inc. et al
2:12-cv-01305	Lager v. Ethicon, Inc. et al
2:12-cv-01311	Ridgley et al v. Ethicon, Inc. et al
2:12-cv-01318	Banks v. Johnson & Johnson, Inc. et al

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

ALICE FOSTER and WILLIAM FOSTER,	)	
Plaintiffs,	)	CASE NO. 2:19-CV-00420-TLS-JEM
v.	)	
ETHICON, INC. and JOHNSON & JOHNSON,	)	
Defendants.	)	

Parties' Roadmaps Showing Relevant General *Daubert* Filings, Rulings, and Undecided Issues, and Positions on Additional Discovery

Pursuant to the Court's Order on May 27, 2021 (Dkt. No. 93), the Parties have met and conferred and submit the following roadmaps showing *Daubert* filings, rulings, and undecided issues from the MDL:

[SEE FOLLOWING PAGES]

I. Defendants' Roadmap: Plaintiffs' General Expert Witnesses

a. Bruce Rosenzweig, M.D.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 8 (adopting Wave 7 briefing): Defs.' Wave 8 Notice of Adoption of Wave 7 Mot. Exclude and Reply (Dkt. No. 56-13, MDL Dkt. No. 6852). **Wave 7 (adopting part of Wave 3 briefing):** Defs.' Wave 7 Mot. Exclude (Dkt. No. 56-9, MDL Dkt. No. 5332); Defs.' Wave 7 Mem. Supp. (Dkt. No. 56-10, MDL Dkt. No. 5333);	**Wave 8:** Pls.' Wave 8 Notice of Adoption of Prior *Daubert* Opp. (Dkt. No. 56-14, MDL Dkt. No. 6960). **Wave 7:** Pls.' Wave 7 Mem. in Opp. (Dkt. No. 54-11, MDL Dkt. No. 5482).	**Wave 7:** MDL Dkt. No. 6519, attached as Ex. "A". **Wave 1:** MDL Dkt. No. 2668, attached as Ex. "B".	1. Denied Ethicon's challenge to Dr. Rosenzweig's qualifications to offer expert testimony on the clinical differences between mechanical-cut and laser-cut mesh. MDL Dkt. No. 2668 at 6. 2. Denied Ethicon's reliability challenge to Dr. Rosenzweig's opinion that Ultrapro mesh was a safer alternative design for stress urinary incontinence devices. *Id.* at 7–8. 3. Denied Ethicon's challenge to the relevance of Dr. Rosenzweig's opinion that Ethicon mesh's Instructions for Use	**Note:** Dr. Rosenzweig did not author a general expert report for Prolift, and Ethicon objects to him providing any opinions about that product beyond what is contained in his case-specific report. 1. Ethicon's Wave 7 challenge, which adopted its Wave 3 expanded argument, that Dr. Rosenzweig's opinions on the distinction between mechanically-cut mesh and laser-cut mesh are unreliable. Dkt. No. 56-10 at 6, MDL Dkt. No. 5333 (adopting Dkt. No. 56-7 at 4–6, MDL Dkt. No. 2818). The MDL Court adopted the Wave 1 Order in Wave 7, which reserved judgment on Ethicon's reliability challenge to Dr. Rosenzweig's opinions on	1. Ethicon's Wave 7 challenge to the relevance of Dr. Rosenzweig's testimony about complications no relevant plaintiffs had suffered. Dkt. No. 56-10 at 10, MDL Dkt. No. 5333. The MDL Court did not rule on this objection, instead adopting its Wave 1 Order and reserving for trial any new or unaddressed challenges. 2. Ethicon's Wave 7 argument to exclude all opinions by Dr. Rosenzweig that rely on citations to unspecific prior reports, and that Dr. Rosenzweig should be precluded from offering opinions not explicitly included in the report but instead based on this vague reference to prior reports. Dkt. No. 56-10 at 2–3, MDL Dkt. No. 5333. The MDL

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Defs.' Wave 7 Reply (Dkt. No. 56-12, MDL Dkt. No. 5548). **Wave 3:** Defs.' Wave 3 Mot. Exclude (Dkt. No. 56-6, MDL Dkt. No. 2817); Defs.' Wave 3 Mem. Supp. (Dkt. No. 56-7, MDL Dkt. No. 2818); Defs.' Wave 3 Reply (MDL Dkt. No. 3024). **Wave 1:** Defs.' Wave 1 Mot. Exclude (MDL Dkt. No. 2047); Defs.' Wave 1 Mem. Supp.	**Wave 3:** Pls.' Wave 3 Mem. In Opp. (Dkt. No. 56-8, MDL Dkt. No. 2931). **Wave 1:** Pls.' Wave 1 Opp. (MDL Dkt. No. 2163).		should have included warnings of the duration, severity, and frequency of the risks of the device. *Id.* at 8. 4. Denied Ethicon's challenge to the reliability and relevance of Dr. Rosenzweig's biomaterials opinions, including the opinions that polypropylene degrades, is subject to fraying and particle loss, and is cytotoxic. *Id.* at 8–9. 5. Denied Ethicon's motion to the extent it challenged Dr. Rosenzweig's reliance on the MSDS for polypropylene resin for his opinions on the	the relative safety of mechanical and laser cut mesh. MDL Dkt. No. 6519 (adopting MDL Dkt. No. 2668 at 6–7). 2. Ethicon's Wave 7 relevancy challenge to Dr. Rosenzweig's opinion that alternative procedures are safer than Ethicon's mesh products. Dkt. No. 56-10 at 3–6, MDL Dkt. No. 5333. The MDL Court in Wave 7 adopted its Wave 1 Order, which explicitly reserved judgment on the alternative procedures issue, finding that the issue was "better decided on a case-by-case basis." MDL Dkt. No. 6519 (adopting MDL Dkt. No. 2668 at 6).[1]	Court did not rule on this objection, instead adopting its Wave 1 Order and reserving for trial any new or unaddressed challenges. MDL Dkt. No. 6519. 3. Ethicon's Wave 7 challenge to Dr. Rosenzweig's qualifications to testify on the adequacy of product warnings. Dkt. No. 56-10 at 6, MDL Dkt. No. 5333. The MDL Court did not rule on this objection, instead adopting its Wave 1 Order and reserving any new or unaddressed challenges. MDL Dkt. No. 6519 at 2. 4. Ethicon's Wave 7 argument that the Court should more specifically exclude Dr. Rosenzweig's opinions regarding adverse

[1] More recently, as is indicated by the Wave 7 briefing, Judge Goodwin definitively ruled that a procedure is not a product in terms of an alternative, feasible design. *Mullins*, 236 F.Supp.3d at 942 ("I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures."). The MDL Court in *Mullins* found that "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture . . . ." *Id.* at 944.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
(MDL Dkt. No. 2049); Defs.' Wave 1 Reply (MDL Dkt. No. 2241).			basis that it did not support his opinions and because he was unqualified to offer opinions based on an MSDS. *Id.* at 9–10. 6. Denied Ethicon's challenge to Dr. Rosenzweig's opinion that Ethicon's mesh causes cytotoxicity and that Ethicon should have warned physicians of this risk. *Id.* at 10. 7. Granted Ethicon's motion to the extent it challenged Dr. Rosenzweig's qualification to testify on the adequacy of Ethicon's testing of its devices. *Id.* at 10–11. 8. Denied Ethicon's challenge to Dr. Rosenzweig's qualification to opine on the design of its		event reporting. Ethicon noted that the MDL Court had excluded Dr. Rosenzweig's opinions regarding compliance with or violation of the FDA's labeling and adverse event reporting regulations in Wave 1, and asked the Court to clarify that ruling to provide that all of Dr. Rosenzweig's adverse event reporting opinions are excluded, not only those relating to specific FDA regulations. Dkt. No. 56-10 at 7–8, MDL Dkt. No. 5333.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
			mesh products, as well as its challenge to the reliability of those opinions. *Id.* at 12–13. 9. Granted Ethicon's challenge to Dr. Rosenzweig's opinion that Ethicon inappropriately marketed mesh devices to certain groups. *Id.* at 13. 10. Granted Ethicon's motion to the extent it seeks to exclude Dr. Rosenzweig's opinions on Ethicon's compliance with FDA adverse event reporting requirements. *Id.* at 14. 11. Granted Ethicon's motion to the extent it seeks to preclude Dr. Rosenzweig from offering state-of-mind and legal conclusion testimony. *Id.* at 16.		

b. Dionysios Veronikis, M.D.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 8 (adopting Wave 3 briefing): Defs.' Notice of Adoption of Wave 3 Mem. in Opp. (Dkt. No. 56-18, MDL Dkt. No. 6854); Defs.' Notice of Adoption of Wave 3 Reply (Dkt. No. 56-20, MDL Dkt. No. 7156). **Wave 3:** Defs.' Wave 3 Mot. Exclude (Dkt. No. 56-15, MDL Dkt. No. 2820); Defs.' Wave 3 Mem. Supp. Mot. Exclude (Dkt. No. 56-21,	**Wave 8:** Pls.' Notice of Adoption of Prior *Daubert* Mem. in Opp. (Dkt. No. 56-19, MDL Dkt. No. 6964). **Wave 3:** Pls.' Wave 3 Mem. In Opp. (Dkt. No. 56-16, MDL Dkt. No. 2890).	**Wave 3:** MDL Dkt. No. 4196, attached as Ex. "C". **Wave 1:** MDL Dkt. No. 2712, attached as Ex. "D".	1. Denied as moot Ethicon's challenge to Dr. Veronikis's opinions about the general safety of all polypropylene mesh products; Plaintiffs agreed not to offer the opinions at trial. MDL Dkt. No. 2712 at 6–7. 2. Denied Ethicon's reliability challenge to Dr. Veronikis's opinion that the TVT mesh is defective because it frays, degrades, and experiences particle loss. *Id.* at 7. 3. Denied Ethicon's request to exclude Dr. Veronikis's opinions about product warnings after rejecting the argument that these opinions are	**Note:** Dr. Veronikis did not author an expert report for Prolift, and Ethicon objects to him providing any opinions about that product. If Plaintiffs intend to call Dr. Veronikis to provide general opinions on Prolift, this objection necessitates a ruling by this Court. The issues that remain to be decided by this Court only relate to Ethicon's TVT product. 1. Ethicon's Wave 3 relevancy challenge to Dr. Veronikis's opinion about the safety of the surgical technique used to implant TVT. Dkt. No. 56-21 at 2–7, MDL Dkt. No. 2821. In Wave 1, the MDL Court held that "relevance of a matter like this is best assessed in context during trial" and reserved ruling.	1. Ethicon's Wave 3 argument that Dr. Veronikis should be precluded from offering opinions about products for which he did not provide an expert report, such as Prolift. Dkt. No. 56-21 at 1 n.1, MDL Dkt. No. 2821. The MDL Court did not address Ethicon's argument. 2. As to TVT, Ethicon's Wave 3 expanded arguments regarding Dr. Veronikis's lack of qualifications to render opinions on the adequacy of Ethicon's warnings. Dkt. No. 56-21 at 2–7, MDL Dkt. No. 2821. The MDL Court in Wave 3 did not address the arguments, instead adopting its Wave 1 Order and expressly reserving any additional argument for later

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
MDL Dkt. No. 2821); Defs.' Wave 3 Reply Mem. (Dkt. No. 56-17, MDL Dkt. No. 3033). **Wave 1:** Defs.' Wave 1 Mot. Exclude (MDL Dkt. No. 2270) Defs.' Wave 1 Mem. Supp. Mot. Exclude (MDL Dkt. No. 2271); Defs.' Wave 1 Reply Mem. (MDL Dkt. No. 2313).	**Wave 1:** Pls.' Wave 1 Mem. in Opp. (MDL Dkt. No. 2284).		founded solely on a review of internal company documents. *Id.* at 7–8. 4. Granted Ethicon's motion to the extent it challenged Dr. Veronikis's opinions that are legal conclusions. *Id.* at 11. 5. Granted Ethicon's motion to the extent it challenged Dr. Veronikis's opinions on Ethicon's knowledge, motive, or intent. *Id.* at 11.	MDL Dkt. No. 2712 at 8. The Wave 3 Order adopted the Wave 1 Order. MDL Dkt. No. 4196 (adopting MDL Dkt. No. 2712). 2. Ethicon's Wave 3 reliability challenge to Dr. Veronikis's opinions about safer alternatives to Ethicon mesh products. Dkt. No. 56-21 at 9–11, MDL Dkt. No. 2821. In Wave 1, the MDL Court expressly reserved until trial ruling on Ethicon's challenge, finding, "I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on this issue." MDL Dkt. No. 2712 at 6. The Wave 3 Order adopted the Wave 1 Order. MDL Dkt. No. 4196 (adopting MDL Dkt. No. 2712).	resolution. *See* MDL Dkt. No. 4196 at 2.

c. Scott Guelcher, Ph.D.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 8 (adopting Wave 5 briefing): Defs.' Wave 8 Notice of Adoption of Wave 5 Mot. Exclude (Dkt. No. 55-21, MDL Dkt. No. 6641); Defs.' Wave 8 Notice of Adoption of Wave 5 Reply Mem. (Dkt. No. 55-23, MDL Dkt. No. 7120). **Wave 5:** Defs.' Wave 5 Mot. Exclude (Dkt. No. 55-13 –55-16, MDL Dkt. No. 4573); Defs.' Wave 5	**Wave 8:** Pls.' Wave 8 Notice of Adoption of Prior *Daubert* Mem. In Opp. (Dkt. No. 55-22, MDL Dkt. No. 6951). **Wave 5:** Pls.' Wave 5 Mem. in Opp. (Dkt. No. 55-18 – 55-19, MDL Dkt. No. 4675).	**Wave 4:** MDL Dkt. No. 6401, attached as Ex. "E". **Wave 2:** MDL Dkt. No. 2698, attached as Ex. "F".	1. Granted Ethicon's challenge to Dr. Guelcher's qualifications to offer complication opinions related to mesh degradation. MDL Dkt. No. 2698 at 6. 2. Denied Ethicon's argument that Dr. Guelcher's degradation opinions are unreliable and should be excluded because he has chosen not to rely on his own testing regarding oxidative degradation. *Id.* at 6. 3. Denied Ethicon's argument that Dr. Guelcher's degradation opinions are unreliable and should be excluded	None.	1. Ethicon's Wave 5 new relevancy and reliability challenges to Dr. Guelcher's opinions on alternative procedures as alternative designs to Ethicon's mesh products. Dkt. No. 55-17 at 18–20, MDL Dkt. No. 4574.[2] The MDL Court did not address this new argument, instead adopting its Wave 1 Order and reserving for trial any new or unaddressed challenges. MDL Dkt. No. 6401 at 1–2. 2. Ethicon's Wave 5 expanded challenge to Dr. Guelcher's opinions on mesh degradation, asserting that Dr. Guelcher's opinions are unreliable because they are based on a study he co-authored which itself is based on unreliable methodology. Dkt. No. 55-17 at 2–15, MDL Dkt. No.

[2] *See supra* footnote 1.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Mem. Supp. Mot. Exclude (Dkt. No. 55-17, MDL Dkt. No. 4574); Defs.' Wave 5 Reply Mem. (Dkt. No. 55-20, MDL Dkt. No. 4692). **Wave 1:** Defs.' Wave 1 Mot. Exclude (MDL Dkt. No. 1977); Defs.' Wave 1 Mem. Supp. Mot. Exclude (MDL Dkt. No. 1981); Defs.' Wave 1 Reply Mem. (MDL Dkt. No. 2210).	**Wave 1:** Pls.' Wave 1 Mem. in Opp. (MDL Dkt. No. 2164).		because he relies on literature that does not account for the differences between polypropylene and Prolene. *Id*. at 6–7. 4. Denied Ethicon's argument that Dr. Guelcher's opinions are unreliable because they are based in part on unpublished Ethicon studies that allegedly do not support his opinion. *Id.* at 7–8. 5. Granted Ethicon's Motion on its challenge to Dr. Guelcher's opinions on Ethicon's knowledge and state of mind. *Id.* at 10–11. 6. Granted Ethicon's Motion to the extent that Dr. Guelcher parrots facts found in corporate documents		4574. The MDL Court did not address this expanded argument, instead adopting its Wave 1 Order and reserving for trial any new or unaddressed challenges. MDL Dkt. No. 6401 at 1–2.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
			without using the facts to explain the basis for his expert opinions. *Id.* at 11.		

d. Daniel Elliott, M.D.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1 and Wave 7	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 8 (adopting Wave 7 briefing): Defs.' Wave 8 Notice of Adoption of Wave 7 Mot. Exclude (Dkt. No. 55-11, MDL Dkt. No. 6842). **Wave 7 (adopting portions of Wave 3 briefing):** Defs.' Wave 7	**Wave 8:** Pls.' Wave 8 Notice of Adoption of Wave 7 Mem. in Opp. (Dkt. No. 55-12, MDL Dkt. No. 6922). **Wave 7:** Pls.' Wave 7 Mem. in Opp. (Dkt. No. 55-10, MDL Dkt. No. 5491).	**Wave 7:** MDL Dkt. No. 6522, attached as Ex. "G". **Wave 1:** MDL Dkt. No. 2666, attached as Ex. "H".	1. Granted Ethicon's motion to exclude Dr. Elliott from offering expert testimony that polypropylene is incompatible with strong oxidizers and should not be used in the vagina on the basis of the MSDS. MDL Dkt. No. 2666 at 6. 2. Granted Ethicon's reliability challenge to Dr. Elliott's opinion testimony linking alleged degradation of mesh used in its mesh	1. Ethicon's Wave 7 challenge to the relevance of Dr. Elliott's opinions that certain alternative procedures are safer than Ethicon's mesh products. Dkt. No. 55-9 at 4–5, MDL Dkt. No. 5340. Ethicon specifically pointed to the MDL Court's decision in *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940 (S.D.W. Va. 2017) for the proposition that evidence on alternative procedures is not relevant to alternative design arguments. In Wave 1, the MDL Court expressly	1. Ethicon's Wave 7 argument, which adopted its Wave 3 argument, challenging the reliability of Dr. Elliott's "barbed-wire effect" opinion. Dkt. No. 55-9 at 13, MDL Dkt. No. 5340 (adopting Dkt. No. 55-5 at, 17, MDL Dkt. No. 2815). The MDL Court did not rule on this objection in Wave 1. 2. Ethicon's Wave 7 argument that Dr. Elliott should be precluded from testifying about irrelevant complications that no particular plaintiff (here,

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1 and Wave 7	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Mot. Exclude (Dkt. Nos. 55-7 – 55-8, MDL Dkt. No. 5339); Defs.' Wave 7 Mem. Supp. Mot. Exclude (Dkt. No. 55-9, MDL Dkt. No. 5340). **Wave 3:** Defs.' Wave 3 Mem. Supp. Mot. Exclude (Dkt. No. 55-5, MDL Dkt. No. 2815). **Wave 1:** Defs.' Wave 1 Mot. Exclude (MDL Dkt. No. 2082); Defs.' Wave 1 Mem. Supp. Mot. Exclude (MDL Dkt. No. 2085); Defs.' Wave 1 Reply	**Wave 3:** Pls.' Wave 3 Mem. in Opp. (Dkt. No. 55-6, MDL Dkt. No. 2952). **Wave 1:** Pls.' Wave 1 Am. Mem. In Opp. (MDL Dkt. No. 2191).		products to clinical harm. *Id.* 3. Denied Ethicon's challenge to Dr. Elliott's opinion testimony regarding shrinkage and contraction of its mesh products. *Id.* at 7. 4. Denied Ethicon's challenge that Dr. Elliott is unqualified to opine on the tensioning of the TVT mesh. *Id.* 5. Denied Ethicon's challenge to Dr. Elliott's testimony that the "TVT has the 'potential' for being cytotoxic." *Id.* 6. Granted Ethicon's challenge to prohibit Dr. Elliott's opinions regarding Ethicon's	reserved ruling on a similar argument, noting that "this expert testimony is better decided on a case-by-case basis." MDL Dkt. No. 2666 at 8.[3] 2. Ethicon's challenge to the reliability of Dr. Elliott's opinions about safer alternative procedures. Dkt. No. 55-9 at 4–8, MDL Dkt. No. 5340. The MDL Court reserved ruling on this issue in Wave 1, finding that it was "without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on an expert's clinical experiences." MDL Dkt. No. 2666 at 8–10. 3. Ethicon's Wave 7 challenge, adopting its Wave 3 challenge, to the	Ms. Foster) actually suffered. Dkt. No. 55-9 at 13–14, MDL Dkt. No. 5340. The MDL Court did not rule on this objection in Wave 1.

[3] *See supra* footnote 1.

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1 and Wave 7	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
(MDL Dkt. No. 2215).			marketing strategies as the opinions amount to discussions of corporate conduct and state-of-mind. *Id.* at 8. 7. Denied Ethicon's challenge to Dr. Elliott's qualifications to offer expert testimony about alternative designs. *Id.* at 9. 8. Granted Ethicon's challenge to Dr. Elliott's expert testimony that laser-cut mesh is a safer alternative to mechanical-cut mesh. *Id.* at 10. 9. Granted Ethicon's challenge to Dr. Elliott's opinions based upon the FDA's adverse event reporting regulations. *Id.* at 10–11.	reliability of Dr. Elliott's alternative design opinions. Dkt. No. 55-9 at 10, MDL Dkt. No. 5340 (adopting Dkt. No. 55-5 at 6–10, MDL Dkt. No. 2815). The MDL Court reserved a ruling on the issue in Wave 1, finding that it was "without information sufficient to assess whether [Dr. Elliott's clinical experience] is a reliable foundation." MDL Dkt. No. 2666 at 8–10. 4. Ethicon's Wave 7 argument that Dr. Elliott was unqualified to testify about Ethicon's research and testing of its products. Dkt. No. 55-9 at 2–3, 10–13, MDL Dkt. No. 5340. In its Wave 1 Order, the Court has classified the argument as a "recurring issue" and reserved for trial. *See* MDL Dkt. No. 2666 at 11–13.	

Ethicon's Motion to Exclude, Mem. in Support, and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1 and Wave 7	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
			10. Granted Ethicon's Motion to the extent it sought to preclude Dr. Elliott from opining in the form of narrative summaries of Ethicon corporate documents. *Id.* at 13–14. 11. Granted Ethicon's challenge to Dr. Elliott's qualifications to opine on the adequacy of warnings for mesh devices. Wave 7 Order, MDL Dkt. No. 6522 at 1–2.		

e. Peggy Pence, PhD, RAC, FRAPS[4]

Ethicon's Motion to Exclude, Mem. in Support,` and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 8 (adopting Wave 3	**Wave 8:** Pls.' Wave 8 Notice of	**Wave 3:** MDL Dkt. No. 4180,	1. Denied Ethicon's challenge to Dr. Pence's qualification	1. Ethicon's Wave 3 challenge to Dr. Pence's opinions about premarket	1. Ethicon's Wave 3 challenge to Dr. Pence's opinions that the product

[4] Recognizing the MDL Court's prior orders excluding evidence of Ethicon's compliance with the FDA 510(k) process, Plaintiffs conditionally designated Dr. Pence in the event of a contrary ruling.

Ethicon's Motion to Exclude, Mem. in Support,` and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
briefing): Defs.' Wave 8 Notice of Adoption of Wave 3 Mot. Exclude (Dkt. No. 56-3, MDL Dkt. No. 6821); Defs.' Wave 8 Notice of Adoption of Wave 3 Reply (Dkt. No. 56-5, MDL Dkt. No. 7177). **Wave 3** Defs.' Wave 3 Mot. Exclude (Dkt. No. 55-24, MDL Dkt. No. 2759); Defs.' Wave 3 Mem. Supp. Mot. Exclude (Dkt. No. 56, MDL Dkt. No. 2760); Defs.' Wave 3 Reply (Dkt. No. 56-2, MDL Dkt. No. 3017).	Adoption of Prior *Daubert* Opp. (Dkt. No. 56-4, MDL Dkt. No. 6958). **Wave 3:** Pls.' Wave 3 Opp. (Dkt. No. 56-1, MDL Dkt. No. 2949). **Wave 1:** Pls.' Wave 1 Mem. in Opp. (MDL Dkt. No. 2172).	attached as Ex. "I". **Wave 1:** MDL Dkt. No. 2664, attached as Ex. "J".	to testify on the adequacy of product Instructions for Use. MDL Dkt. No. 2664 at 6. 2. Denied Ethicon's challenge to the reliability of Dr. Pence's opinions on product labeling and warnings because she had not spoken to physicians to assess their knowledge of labeling and warnings. *Id.* at 7. 3. Denied Ethicon's challenge to Dr. Pence's qualifications to opine on premarket testing of medical devices. *Id.* at 7. 4. Granted Ethicon's Motion on its challenge to Dr. Pence's opinion that Ethicon did not meet the FDA's post-market	testing of medical devices—including the TVT product—based on unreliability and lack of qualifications. Dkt. No. 56 at 12–14, MDL Dkt. No. 2760. The MDL Court adopted the Wave 1 Order, which denied the motion as to Dr. Pence's qualifications but reserved ruling on Ethicon's reliability challenge to Dr. Pence's premarket testing opinions. MDL Dkt. No. 4180 (adopting, MDL Dkt. No 2664 at 7).	labeling of the TVT and Prolift devices was inadequate and should be excluded because she failed to apply the correct legal standard. Dkt. No. 56 at 3–7, MDL Dkt. No. 2760. Although the MDL Court adopted its Wave 1 Order for Dr. Pence, which rejected Ethicon's argument that Dr. Pence's testimony was unreliable "because she never spoke to any physicians about labeling and their knowledge," MDL Dkt. No. 4180 (adopting MDL Dkt. No. 2664 at 6), the MDL Court did not address Ethicon's expanded arguments concerning the application of the incorrect legal standard for product labeling of the TVT and Prolift devices, including that Dr. Pence's opinions should be excluded because her methodology conflicts with the legal standard that applies in this case. Dkt. No.

Ethicon's Motion to Exclude, Mem. in Support,` and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
Wave 1: Defs.' Wave 1 Mot. Exclude (MDL Dkt. No. 2075); Defs.' Wave 1 Mem. Supp. Mot. Exclude (MDL Dkt. No. 2078); Defs.' Wave 1 Reply (MDL Dkt. No. 2214).			standard of care with respect to adverse event reporting; the MDL Court determined that such testimony constitutes a legal conclusion and is unhelpful to a jury. *Id.* at 9. 5. Granted Ethicon's Motion to the extent it challenged the relevance of Dr. Pence's opinion that Prolift was adulterated and misbranded when it went on to market because Ethicon had not filed a 510(k) application; the MDL Court determined that such testimony constitutes a legal conclusion and is unhelpful to a jury. *Id.* at 8–9. 6. Granted Ethicon's Motion to the extent it challenged the		56 at 3–7, MDL Dkt. No. 2760.

Ethicon's Motion to Exclude, Mem. in Support,` and Reply	Plaintiffs' Opposing Mem.	Prior MDL Orders	MDL Rulings from Wave 1	Issues Reserved	Issues Neither Granted, Denied, Nor Reserved
			relevance of Dr. Pence's opinion that Ethicon reported false and misleading information to the FDA regarding Prolift; the MDL Court determined that such testimony constitutes a legal conclusion and is unhelpful to a jury. *Id.* 7. Granted Ethicon's Motion to the extent it challenged Dr. Pence's use of terms with specific legal meanings, including that a device was "misbranded" or "adulterated"; the MDL Court ruled that "an expert may not offer expert testimony using 'legal terms of art.'" *Id.* at 11.		

f. Issues Reserved As to All Plaintiffs' Experts

1. As to each of Plaintiffs' general experts, the MDL Court expressly reserved ruling on the relevance and potential prejudicial impact of opinion testimony of Ethicon's compliance with design control and risk management standards. MDL Dkt. No. 2668 at 14–16 (Dr.

Rosenzweig); MDL Dkt. No. 2712 at 9–10 (Dr. Veronikis); MDL Dkt. No. 2698 at 9–10 (Dr. Guelcher); MDL Dkt. No. 2666 at 11–13 (Dr. Elliott); MDL Dkt. No. 2664 at 9–10 (Dr. Pence).
2. As to each of the Plaintiffs' general experts, the MDL Court expressly reserved ruling on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments. MDL Dkt. No. 2668 at 14–16 (Dr. Rosenzweig); MDL Dkt. No. 2712 at 9–10 (Dr. Veronikis); MDL Dkt. No. 2698 at 9–10 (Dr. Guelcher); MDL Dkt. No. 2666 at 11–13 (Dr. Elliott); MDL Dkt. No. 2664 at 9–10 (Dr. Pence).

II. Defendants' Position on Additional Discovery

Defendants propose the following timeline for additional discovery:

1. Updated Plaintiff Fact Sheet and authorizations for new treaters: 60 days from order
2. Updated Defendant Fact Sheet, if warranted: 90 days from order
3. Deposition of Plaintiff on health condition since last deposition: 120 days from order
4. Depositions of treaters who treated Plaintiff since the close of MDL discovery: 180 days from order
5. Both parties update case-specific expert reports with information not previously available at the time of the initial disclosures: 210 days from order

PLAINTIFF'S ROADMAP OF MOTION PRACTICE FROM THE MDL AND DISCOVERY STATUS

1. **Motions That Have Been Resolved[5]:**

- Defendants' *Daubert* Motions Filed Against Plaintiffs' General Experts:
  - Bruce Rosenzweig, M.D. (Ex. A[6], MDL Dkt. 6519; Ex. B, MDL Dkt. 2668)
  - Dionysis Veronikis, M.D. (Ex. C, MDL Dkt. 4196; Ex. D, MDL Dkt. 2712)
  - Scott Guelcher, Ph.D. (Ex. E, MDL Dkt. 6401; Ex. F, MDL Dkt. 2698)
  - Daniel Elliott, M.D. (Ex. G, MDL Dkt. 6522; Ex. H, MDL Dkt. 2666)
  - Peggy Pence, Ph. D, RAC, FRAPS (Ex. I, MDL Dkt. 4180, Ex. J, MDL Dkt. 2664)
- Plaintiffs' *Daubert* Motions Filed Against Defendants' General Experts:
  - Larry Sirls, M.D. (Ex. K, MDL Dkt. 3549)
  - Marc Toglia, M.D. (Ex. L, MDL Dkt. 2658)
  - Timothy Ulatowski (Ex. M, MDL Dkt. 2649)
  - Juan Carlos Felix, M.D. (Ex. N, MDL Dkt. 2695)
  - Shelby Thames, M.D. (Ex. O, MDL Dkt. 4201; Ex. P, MDL Dkt. 2723)

2. **Issues That Remain Pending:**

- Defendant's Motion for Partial Summary Judgment was re-filed on April 30, 2021 (Dkt 88-89); and Plaintiff's Response was re-filed on June 11, 2021 (Dkt 96).

3. **Issues That Remain Pending and Have Not Yet Been Re-Filed in This Case**

- *Daubert* motions

[5] The referenced Exhibits A through O represent the MDL orders resolving the various Daubert motions. The specific rulings on the various issues raised in those motions are contained in attached Appendix I (Plaintiffs' Experts) and Appendix II (Defense Experts) and are organized by expert into three sub-groups: 1. Denied; 2. Granted; 3. Reserved. With respect to the "Reserved" rulings, it was Judge Goodwin's specific directive that those rulings should be made at the time of trial during live testimony. For this reason, Plaintiff does not consider the "Reserved" rulings as pending issues that this Court must address at this time or before trial.

[6] Plaintiffs' Exhibits correlate with those referenced and attached by Defendants, so they will not be attached hereto.

4. Discovery Issues

- Plaintiffs agree to the staggered 60/90 days to supplement PFS and DFS with the expectation that both parties either supplement or alternatively verify under oath their answers are complete and up-to-date.

- Plaintiffs maintain their objection to a supplemental deposition of Mrs. Foster. This request is untimely, and there has been no showing of excusable neglect under FRCP 6. (See also Bowman v. Korte). There has been no showing of "good cause" under FRCP 6. Moreover, the information provided thus far provides an adequate foundation upon which to extrapolate the nature of Plaintiff's ongoing complaints, treatment, and quality of life. (Vincent v. BSC). The Defendants have also failed to point to any material change in the Plaintiff's medical condition that would justify a second deposition. (Munoz v. Ethicon) This is in spite of the fact that the Defendants have ordered and received updated medical records. Finally, if the passage of time permits the Defendants to re-depose the Plaintiff, Plaintiff should likewise be permitted to conduct supplemental depositions of Ethicon fact witnesses deposed years ago in the MDL (Munoz v. Ethicon). Finally, Judge Goodwin urged transferee courts to "immediately" set this case for trial. In his transfer order Judge Goodwin also stated, in bold and italic text, that "further discovery will only result in unjust delay. Extensive development of these cases over a period of years had made such further action completely unnecessary."

- Plaintiff opposes additional discovery of unnamed medical providers or providers who have already been deposed in this case. This request is vague, untimely and contravenes the deadlines and protocols set forth in pre-trial order 303. We also note that the Defendants have access to all medical records to date through signed authorizations.

APPENDIX I: MOTIONS THAT HAVE BEEN RESOLVED.

A. *DAUBERT* CHALLENGES TO BRUCE ROSENZWEIG, M.D. (Plaintiff's Expert)

1. DENIED AS TO:

a. Testimony regarding clinical differences between mechanical cut and laser cut mesh. (MDL Dkt. 2688 at 6);

b. The reliability of Dr. Rosenzweig's expert testimony about Ultrapro mesh as an alternative. (MDL Dkt. 2688 at 7-8);

c. Testimony regarding the relevant Instructions for Use adequately warned about the duration, severity, and frequency of risks. (MDL Dkt. 2688 at 8);

d. Opinions as to degradation and other biomaterials opinions—specifically his opinions that Ethicon's mesh devices degrade, are subject to fraying and particle loss, and are cytotoxic. (MDL Dkt. 2688 at 8-9);

e. Use of the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that the mesh at issue should not be used in the vagina. (MDL Dkt. 2688 at 9);

f. Opinions based on the MSDS. (MDL Dkt. 2688 at 9-10);

g. Opinions relating to his allegations that TVT causes cytotoxicity and that Ethicon should have warned physicians of that fact. (MDL Dkt. 2688 at 10)

h. Opinions on the design of the mesh products, including the reliability of those opinions on basis of qualifications. (MDL Dkt. 2688 at 12-13);

i. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 2688 at 17);

j. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2688 at 17).

2. GRANTED AS TO:

a. Opinions that Ethicon's testing was insufficient. (MDL Dkt. 2688 at 10);

b. Opinions that the shorter length of laser-cut mesh in the TVT Abbrevo leads to more complications. (MDL Dkt. 2688 at 11);

c. Testimony regarding whether its products were inappropriately marketed to, or less effective or less safe for, certain patient populations. (MDL Dkt. 2688 at 13);

d. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations. (MDL Dkt. 2688 at 13-14);

e. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. at 2688 at 16).

f. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2688 at 16-17.)

3. RESERVED AS TO:

a. Testimony that alternative procedures are safer than Ethicon's mesh products. (MDL Dkt. 2688 at 6);

b. Reliability of testimony regarding mechanical-cut and laser-cut mesh. (MDL Dkt. 2688 at 6-7);

c. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2688 at 15);

d. Testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. (MDL Dkt. 2688 at 15);

e. Expert testimony that may constitute hearsay (MDL Dkt. 2688 at 17);

f. *Daubert* challenges not previously addressed in the MDL's court's August 26, 2016 Order on Daubert challenges to Bruce Rosenzweig, M.D. (MDL Dkt. 6519 at 1-2).

APPENDIX I: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

B. DAUBERT CHALLENGES TO DIONYSIOS VERONIKIS, M.D. (Plaintiff's Expert)

1. DENIED AS TO:

a. Opinion whether all polypropylene mesh products are safe or unsafe, as moot. (MDL Dkt. 2712 at 6-7);

b. Reliability of opinion that the TVT mesh is defective because it frays, degrades, and experiences particle loss. (MDL Dkt. 2712 at 7);

c. Testimony regarding product warnings, including testimony about the adequacy of the relevant Instructions for Use ("IFU"). (MDL Dkt. 2712 at 7-8).

d. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 2712 at 11-12);

e. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2712 at 12).

2. GRANTED AS TO:

a. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2712 at 11);

b. Testimony relating to state-of-mind and legal-conclusions. (MDL Dkt at 2712 at 11);

c. Testimony is solely a conduit for corporate information. (MDL Dkt 2712 at 11).

3. RESERVED AS TO:

a. Expert testimony about safer alternatives to Ethicon mesh products on grounds of reliability. (MDL Dkt. 2712 at 6);

b. Opinion testimony about the safety of the surgical technique used to implant the relevant mesh product is irrelevant. (MDL Dkt. 2712 at 8);

c. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2712 at 10);

d. Testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. (MDL Dkt. 2712 at 10);

e. Expert testimony that may constitute hearsay (MDL Dkt. 2712 at 12);

f. *Daubert* challenges not previously addressed in the MDL's court's September 1, 2016 Order on *Daubert* challenges to Dionysios Veronikis, M.D. (MDL Dkt. 4196 at 1-2).

APPENDIX I: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

C. DAUBERT CHALLENGE AS TO SCOTT GUELCHER, PH.D.
(Plaintiff's Expert)

1. DENIED AS TO:

a. Degradation opinions against claims they are unreliable because (1) they are not based on his own testing and/or (2) he does not account for the differences between polypropylene and Prolene (MDL Dkt. 2698 at 6.)

b. Testimony Based in part on unpublished Ethicon studies—a Prolene suture study and a "seven-year dog study" of Prolene sutures—that allegedly do not support his opinion. (MDL Dkt. 2698 at 7.)

c. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 2698 at 11-12);

d. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2698 at 12).

2. GRANTED AS TO:

a. Complications opinions, based on qualifications and reliability. (MDL Dkt. 2698 at 6);

b. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2698 at 6-7);

c. Testimony relating to state-of-mind and legal-conclusions. (MDL Dkt. 2698 at 10-11)

d. Testimony solely a conduit for corporate information. (MDL Dkt 2698 at 11).

3. RESERVED AS TO:

a. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2698 at 9-10);

b. Expert testimony that may constitute hearsay (MDL Dkt. 2698 at 10-11);

c. *Daubert* challenges not previously addressed in the MDL's court's August 31, 2016 Order on *Daubert* challenges to Scott Guelcher, Ph. D. (MDL Dkt. 6401 at 1-2).

APPENDIX I: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

D. DAUBERT CHALLENGE AS TO DANIEL ELLIOT, M.D.
(Plaintiff's Expert)

1. DENIED AS TO:

a. Testimony regarding shrinkage and contraction of Ethicon's mesh products. (MDL Dkt. 2666 at 7);

b. Qualifications to opine regarding tensioning of the TVT mesh. (MDL Dkt. 2666 at 7);

c. Testimony that the "TVT has the 'potential' for being cytotoxic". (MDL Dkt. 2666 at 7);

d. Qualifications to testify about alternative designs (e.g., mesh with larger pore size or less weight). (MDL Dkt. 2666 at 9);

e. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 2666 at 14);

f. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2666 at 14).

g. Opinion about the TVT Exact product, as moot, as Dr. Elliot has no disclosed opinion on this topic. (MDL Dkt. 6522 at 2).

2. GRANTED AS TO:

a. Use of the MSDS—specifically the MSDS statement that polypropylene is incompatible with strong oxidizers—as the basis for his opinion that Ethicon's mesh should not be used in the vagina. (MDL Dkt. 2666 at 6.)

b. Opinions linking alleged degradation (which Ethicon admits occurs) to any clinical harm. (MDL Dkt. 2666 at 6.)

c. Opinions as to Ethicon's successful marketing strategies. (MDL Dkt. 2666 at 8);

d. Testimony that laser-cut mesh is a safer alternative to mechanical-cut mesh. (MDL Dkt. 2666 at 10);

e. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt 2666 at 11);

f. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt 2666 at 13);

g. Testimony that is solely a conduit for corporate information. (MDL Dkt 2666 at 13-14);

h. Testimony regarding product warnings, which includes expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). (MDL Dkt. 6522 at 1-2).

3. RESERVED AS TO:

a. Testimony that alternative procedures are safer than Ethicon's mesh products. (MDL Dkt. 2666 at 8);

b. The reliability of testimony on alternative design. (MDL Dkt. 2666 at 10);

c. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2666 at 11-12);

d. Expert testimony that may constitute hearsay (MDL Dkt. 2666 at 14);

e. *Daubert* challenges not previously addressed in the MDL's court's August 26, 2016 Order on *Daubert* challenges to Daniel Elliot, M.D. (MDL Dkt. 6522 at 1-2).

APPENDIX I: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

E. DAUBERT CHALLENGE AS TO PEGGY PENCE, PH. D. (Plaintiff's Expert)

1. DENIED AS TO:

a. Testimony about the adequacy of the relevant Instructions for Use ("IFU"). (MDL Dkt. 2664 at 6);

b. The reliability of Dr. Pence's expert testimony despite her not having spoken to any physicians about labeling and their knowledge. (MDL Dkt. 2664 at 6);

c. Qualifications to offer expert testimony about premarket testing of medical devices. (MDL Dkt. 2664 at 7);

d. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 2664 at 11-12);

e. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2664 at 11-12).

2. GRANTED AS TO:

a. Dr. Pence's opinion that Prosima should have been removed from the market before it was actually removed from the market and, by failing to do so, Ethicon violated its commitment to patient safety. (MDL Dkt. 2664 at 7-8);

b. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2664 at 8-9);

c. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 2664 at 11);

d. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2664 at 11).

3. RESERVED AS TO:

a. Whether Dr. Pence can offer expert testimony about whether the relevant IFUs "are adequate for doctors to obtain informed consent of their patients" based on qualifications, reliability and relevance. (MDL Dkt. 2664 at 6);

b. The reliability of Dr. Pence's expert testimony because she does not apply the standards on which she relies to determine whether Ethicon met those testing standards. (MDL Dkt. 2664 at 7);

c. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2664 at 10);

d. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2664 at 10);

e. Expert testimony that may constitute hearsay (MDL Dkt. 2664 at 12);

f. *Daubert* challenges not previously addressed in the MDL's court's August 25, 2016 Order on Daubert challenges to Peggy Pence, Ph.D.) (MDL Dkt 4180 at 1-2).

APPENDIX II: MOTIONS THAT HAVE BEEN RESOLVED

E. DAUBERT CHALLENGES TO LARRY SIRLS, M.D. (Defendants' Expert)

1. DENIED AS TO:

a. All matters raised in Plaintiff's motion except as otherwise stated below. (MDL Dkt. 3549 at 10);

b. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL Dkt. 3549 at 9-10);

c. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 3549 at 9-10).

2. GRANTED AS TO:

a. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 3549 at 6-7);

b. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 3549 at 8);

c. Testimony that is solely a conduit for corporate information. (MDL Dkt. 3549 at 9).

3. RESERVED AS TO:

a. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 3549 at 7);

b. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 3549 at 7-8);

c. Expert testimony that may constitute hearsay. (MDL Dkt. 3549 at 9).

APPENDIX II: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

F. DAUBERT CHALLENGES TO MARC TOGLIA, M.D. (Defendants' Expert)

1. DENIED AS TO:

a. Lack of qualifications to testify because he is neither a chemical nor bio-mechanical engineer and does not possess a "basic understanding of what is meant by the terms 'lightweight' and 'heavyweight." MDL Dkt. 2658 at 6);

b. The reliability of Dr. Toglia's opinions on polypropylene safety, durability, biocompatibility, and materials. (MDL Dkt. 2658 at 6-7);

c. Lack of qualifications to testify about the risks and complication rates of alternative procedures. (MDL Dkt. 2658 at 8);

d. The reliability of Dr. Toglia's opinions on complications rates and risks of alternative procedures. (MDL Dkt. 2658 at 8-9);

e. The reliability of opinions regarding immunologic response (MDL Dkt. 2658 at 9);

f. Testimony that may be inconsistent with the expert's deposition or report or the like. (MDL Dkt. 2658 at 14);

g. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2658 at 15);

h. Opinions related to the MSDS, as moot, because Dr. Toglia does not include MSDS opinions in his expert report (MDL Dkt. 2658 at 10-11).

2. GRANTED AS TO:

a. Opinions on complication rates and patient follow-up rates in his own practice. (MDL Dkt. 2658 at 8);

b. Testimony regarding the adequacy of the relevant Instructions for Use and what should or should not be included in an IFU. (MDL Dkt. 2658 at 9-10);

c. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2658 at 11-12);

d. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 2658 at 13-14);

e. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2658 at 14).

3. RESERVED AS TO TESTIMONY:

a. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2658 at 12-13);

b. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2658 at 13);

c. Expert testimony that may constitute hearsay. (MDL Dkt. 2658 at 13).

APPENDIX II: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

G. DAUBERT CHALLENGES TO TIMOTHY ULATOWSKI (Defendants' Expert)

1. DENIED AS TO:

a. Testimony that may be inconsistent with the expert's deposition or report or the like (MDL MDL Dkt. 2649 at 9-10);

b. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL MDL Dkt. 2649 at 10).

2. GRANTED AS TO TESTIMONY:

a. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2649 at 6-7);

b. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 2649 at 8-9);

c. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2649 at 9).

3. RESERVED AS TO TESTIMONY:

a. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2649 at 8);

b. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2649 at 8);

c. Expert testimony that may constitute hearsay. (MDL Dkt. 2649 at 10).

APPENDIX II: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

H. DAUBERT CHALLENGES TO JUAN CARLOS FELIX, M.D.
(Defendants' Expert)

1. DENIED AS TO:

a. Criticisms of Dr. Iakovlev, Plaintiff's pathology expert (MDL Dkt. 2695 at 6-7);

b. Testimony relying on Dr. Steven MacLean (MDL Dkt. 2695 at 8);

c. Testimony that may be inconsistent with the expert's deposition or report or the like. (MDL Dkt. 2695 at 13-14);

d. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer. (MDL Dkt. 2695 at 14).

2. GRANTED AS TO:

a. Opinion that TVT does not cause pain (MDL Dkt. 2695 at 9-10);

b. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2695 at 10-11);

c. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 2695 at 13);

d. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2695 at 13).

3. RESERVED AS TO:

a. Dr. Felix's opinions in their entirety on the basis that his experience and review of the scientific literature is insufficient to render his opinions reliable (MDL Dkt. 2695 at 6);

b. The reliability of opinion that polypropylene does not degrade *in vivo* (MDL Dkt. 2695 at 7-8);

c. The reliability of opinion regarding contracture, specifically that TVT mesh does not contract *in vivo* (MDL Dkt. 2695 at 8-9);

d. The reliability of opinion regarding cytotoxicity (MDL Dkt. 2695 at 9);

e. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2695 at 11-12);

f. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by

ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2695 at 12);

g. Expert testimony that may constitute hearsay. (MDL Dkt. 2695 at 14).

APPENDIX II: MOTIONS THAT HAVE BEEN RESOLVED (CONT.)

I. DAUBERT CHALLENGES TO SHELBY THAMES, M.D.
(Defendants' Expert)

1. DENIED AS TO:

a. The reliability of the opinion that the data collected from the seven-year dog study "validates toughness improvement after initial implantation." (MDL Dkt. 2723 at 6-7);

b. Opinions on translucent flakes detected on prolate explants and the presence of extrusion lines, as not properly addressed in the instant motion. (MDL Dkt. 2723 at 7);

c. The cleaning protocol employed by Dr. Thames in his plaintiff-specific examination of mesh (MDL Dkt. 2723 at 7);

d. Testimony that may be inconsistent with the expert's deposition or report or the like. (MDL Dkt. 2723 at 11);

e. Testimony that is not specifically identified but that the moving party claims the expert is not qualified to offer (MDL Dkt. 2723 at 11).

2. GRANTED AS TO:

a. Testimony mischaracterizing Ethicon's degradation dog study results on molecular weight change ("no significant change" vs. "no change") (MDL Dkt. 2723 at 6);

b. Expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, as well as opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulation. (MDL Dkt. 2723 at 8);

c. Testimony regarding state-of-mind and legal-conclusions. (MDL Dkt. 2723 at 10);

d. Testimony that is solely a conduit for corporate information. (MDL Dkt. 2723 at 10-11).

e. Dr. Thames's reliance on August 8, 2016 Supplemental Report and all testimony that relies on that report on timeliness grounds. (MDL Dkt. 4201 at 2).

3. RESERVED AS TO:

a. Design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2723 at 9);

b. The relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by ruling on design process and control standards testimony, whether rooted in the FDA or otherwise. (MDL Dkt. 2723 at 9-10);

c. Expert testimony that may constitute hearsay. (MDL Dkt. 2723 at 11).

Respectfully submitted,

s/ Terrence M. Quinn (with consent)
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