**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
MACON DIVISION**

TERRESSA WILLIAMS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**CIVIL ACTION NO. 5:20-CV-234 (MTT)**
	)	
ETHICON, INC., *et al.*,	)	
	)	
Defendants.	)	
	)	

ORDER

This case has returned to this District from *In re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation*, MDL No. 2327, Judge Joseph R. Goodwin presiding. Docs. 1; 80. Plaintiffs Terressa Williams and her husband Russell Williams allege that the Ethicon Prolift device implanted in Terressa was defective.[1] Doc. 1 at 1-4. The Court ordered the parties to submit *Daubert* motions on issues not decided by Judge Goodwin. Doc. 94. The plaintiffs and Ethicon each submitted two *Daubert* motions. Docs. 99; 101; 102; 103.

I. STANDARD

Rule 702 of the Federal Rules of Evidence provides:

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

[1] Specifically, the plaintiffs allege claims for negligence, manufacturing defect, failure to warn, and design defect. Docs. 1 at 4-5; 91.

> expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Trial courts are to act as "gatekeepers" to ensure that speculative and unreliable opinions do not reach the jury. *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 589 n.7 (1993). Trial courts must (1) determine whether the expert has the qualifications to offer his opinions, *Poulis-Minott v. Smith*, 388 F.3d 354, 359 (1st Cir. 2004); *see also United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004); (2) "'conduct an exacting analysis' of the *foundations* of expert opinions to ensure they meet the standards of admissibility," *Frazier*, 387 F.3d at 1260 (quoting *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002)) (emphasis in original); and (3) ensure that the expert testimony is relevant and will assist the jury, *see Daubert*, 509 U.S. at 591.

II. DISCUSSION

A. Plaintiffs' Motion to Limit Crohn's Disease Opinions

The plaintiffs have moved to limit the opinions of three of Ethicon's case-specific experts: Dr. Jaime L. Sepulveda, Dr. Joye Lowman, and Dr. Thomas C. Wright, Jr. Doc. 99. The plaintiffs contend that these experts should not be allowed to testify that Williams's "complications and injuries were purportedly due to her suffering from Crohn's disease rather than from Defendant's mesh product." *Id.* at 1. But their real point is narrower—they argue that the experts are both not qualified to opine that Williams has Crohn's disease and that they have not utilized reliable methodology to come to their conclusions. Rather, the plaintiffs assert that the experts are merely parroting the diagnosis of Dr. Kent McBride, a general surgeon, who diagnosed Williams with Crohn's disease in 2006. In response, Ethicon argues the doctors are

"qualified to diagnose Ms. Williams's Crohn's Disease," and that their diagnoses are derived from "reliable methodology." Doc. 107-1 at 2-8. That's a bit of an odd approach because none of the experts claim to have reached a diagnosis. Nonetheless, two did state in their reports that Williams has Crohn's disease.

Significantly, a diagnosis of Crohn's disease, unlike many other illnesses, is not done with one simple test or x-ray. Rather, it is the result of a differential diagnosis, requiring the elimination of the other possible causes of a patient's symptoms. Doc. 99-11 at 43:5-44:1. This process often requires a team of doctors and is based on a battery of tests and procedures, physical examinations, laboratory findings, and correlation of diverse symptoms. Docs. 99-7 at 23:23-25, 25:10-18, 30:23-31:5, 39:2-40:19; 99-9 at 23:5-44:1.

1. Dr. Sepulveda

Dr. Jaime L. Sepulveda is a pelvic surgeon and a urogynecologist. Doc. 99-7 at 19:7. Dr. Sepulveda testified that he does not diagnose patients with Crohn's disease in his practice. *Id*. at 24:18-25:9. Instead, a gastroenterologist or a colorectal surgeon makes the diagnosis and Dr. Sepulveda "follows their lead." *Id*. Nonetheless, in his expert report, Dr. Sepulveda states that "Ms. Williams has Crohn's disease diagnosed by pathology report and improved on ASAcol." Doc. 99-1 at 15. Dr. Sepulveda's basis for this statement is found in Williams's medical history—specifically the fact that Dr. McBride diagnosed her with Crohn's disease in 2006. *Id.* at 8. Sepulveda noted that Dr. McBride's colonoscopy findings were deemed suspicious for Crohn's disease and that Dr. McBride ordered a pathology test which "described chronic active ileitis consistent with inflammatory bowel disease/Crohn's disease." *Id*. The pathology report

was especially important to Dr. Sepulveda, who testified that without that pathology report he would not be able to say Williams has Crohn's disease. Doc. 99-7 at 71:3-6. Dr. Sepulveda is clearly basing his statement that Williams has Crohn's disease on Dr. McBride's diagnosis and the findings in the pathology report. Other than accepting these findings as true, Dr. Sepulveda does not explain how he reached an opinion, as opposed to a mere recapitulation of what he read, that Williams has Crohn's disease.

In short, if Dr. Sepulveda intended to opine that Williams has Crohn's disease, neither his report nor his testimony establishes that he reached that opinion based on a reliable methodology. Instead, he relies on and parrots other doctors' conclusions and notes. In its response brief, Ethicon asserted that "Ms. Williams's medical records aptly support [Dr. Sepulveda's] conclusion that she has Crohn's disease." Doc. 107-1 at 5. Ethicon then cited excerpts from Williams's medical records that, perhaps do, "aptly" show she had Crohn's disease. *Id*. at 5-6. However, each of the excerpts merely shows other doctors noting their own beliefs, findings, and conclusions.[2] This does not satisfy *Daubert*'s reliable methodology prong. Accordingly, Dr. Sepulveda may not testify that Williams has Crohn's disease.

[2] Each of the records listed in Ethicon's response brief begins by stating a treating doctor "noted" something:

- "On July 18, 2006, Dr. McBride performed a colonoscopy, in which he noted ulceration of the terminal ileum that was suspicious for Crohn's disease … The pathology report for this procedure noted chronic active ileitis consistent with Crohn's disease.
- July 19, 2006, Dr. McBride noted that Ms. Williams's colonoscopy suggested underlying Crohn's disease.
- At a July 24, 2006 visit with Ms. Williams, Dr. McBride noted confirmed Crohn's disease.
- On August 3, 2009, Dr. McBride noted that Ms. Williams had a history of Crohn's disease.
- At an August 30, 2012 visit with Ms. Williams, Dr. Douglas Brewer noted that Ms. Williams had Crohn's disease.
- On September 24, 2012, Dr. Brewer again noted Ms. Williams's history of Crohn's disease[.]" Doc. 107-1 at 5-6 (citations omitted).

2. Dr. Lowman

Dr. Lowman also states that Williams suffers from Crohn's disease. Doc. 99-2 at 41. In her practice, Dr. Lowman refers patients she suspects of having Crohn's disease to gastroenterologists. Doc. 99-8 at 19:5-9. She has never alone diagnosed a patient with Crohn's disease—she relies on gastroenterologists or colorectal surgeons. *Id*. at 21:24-22:18. Consequently, Dr. Lowman too relies on Dr. McBride's diagnosis of Crohn's disease. For example, in her expert report, Dr. Lowman relies on the fact that "Williams apparently wasn't diagnosed formally with Crohn's disease until July 2006 when Dr. McBride, her gastroenterologist performed a colonoscopy with biopsies[.]"[3] Doc. 99-2 at 44. While Dr. Lowman testified that Williams's symptoms correlate with a Crohn's disease diagnosis, she acknowledged that she did not consider other possible causes of Williams's symptoms besides Crohn's disease because "Dr. McBride has already done that work. Dr. McBride is the person who did the ileocolonoscopy, that took the biopsies and sent them to the pathologist who confirmed that she had Crohn's … there's no reason to consider anything else." Docs. 99-8 at 78:6-21; 99-2 at 43-45. In other words, Dr. Lowman did nothing to independently conclude that Williams has Crohn's disease; she simply parrots Dr. McBride. Thus, Dr. Lowman cannot testify that Williams has Crohn's disease.

3. Dr. Wright

Dr. Wright is a pathologist. Doc. 99-9 at 4. While Dr. Wright's expert report states that he conducted his own pathology analysis on biopsies from Williams and reviewed previous pathological findings of other pathologists, he never opined that

[3] Dr. McBride is not a gastroenterologist; he is a general surgeon.

Williams has Crohn's disease. *See generally* Doc. 99-3. Further, at the *Daubert* hearing, Ethicon's counsel stated that Dr. Wright would not testify that Williams has Crohn's disease, but would instead "talk about the pathology report and the specific findings in the pathology report as they relate to Crohn's disease."[4] Doc. 122 at 7:19-8:5. Whether Dr. Wright may testify about certain pathological features of Crohn's disease and whether they appear on a pathology report is not at issue. However, because Dr. Wright did not disclose in his report an opinion that Williams has Crohn's disease, he may not testify at trial that Williams has Crohn's disease.

B. Plaintiffs' Motion to Exclude FDA Expert Timothy Ulatowski and to Limit the General Expert Opinions of Jamie Sepulveda and Joye Lowman

Perhaps a more apt title for this motion would be "motion to adopt the reasoning of Judge Goodwin, the Supreme Court, the Eleventh Circuit, and apparently every other court to address the issue." That issue is whether evidence of the FDA's 510(k) approval process that is available for some medical devices, including Prolift, is admissible. Very briefly, the 510(k) process turns on equivalency to similar devices that have been approved and does not involve the rigorous safety evaluation otherwise required before a new device can enter the market. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Every court addressing this issue has concluded that 510(k) evidence is not relevant, and even if it were, any probative value the evidence may have is far outweighed by its prejudicial impact. This is because the 510(k) process has nothing or little to do with safety, and the admission of the evidence would result in a "mini trial" as

[4] It is not surprising that Dr. Wright is hesitant to commit on diagnosing Williams with Crohn's disease. He testified that while he can conclude that a pathological finding on a biopsy is *consistent* with Crohn's disease, that finding is a tool for a gastroenterologist to use in his or her diagnostic process. Doc. 99-9 at 35:20-36:13.

the parties fought over the meaning and effect of 510(k) review. *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1318 (11th Cir. 2017); *In re C. R. Bard, Inc.*, 810 F.3d 913, 921-23 (4th Cir. 2016); *In Re: Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab. Litig.*, No. 1:17-MD-2782-RWS, doc. 690 at 18 (N.D. Ga. Nov. 25, 2020).

Ethicon acknowledges that if the Court follows these cases, the plaintiffs' motion should be "denied as moot." Doc. 108-1 at 1. The question is not a close one, and the Court adopts the reasoning and analyses in Judge Goodwin's orders (Docs. 103-1; 103-2; 103-3) and excludes any potential testimony regarding evidence of standards and regulations promulgated by the FDA and testimony about whether Ethicon complied with those standards. But this conclusion, rather than mooting the plaintiffs' motion, means that it should be granted, and it is.

Beyond that adoption, only one point made by Ethicon merits discussion. Ethicon properly notes that *Lohr* addressed only one "use" of 510(k). Not at issue there, but applicable here according to Ethicon, is another provision of 510(k), which does at least mention safety. Specifically, the 510(k) process at issue here involved the determination of whether the Prolift device "was cleared based on equivalence in *safety* and effectiveness[.]" Doc. 108-1 at 4 (emphasis added). Ethicon argues this is a critical distinction because "the 510(k) process at issue here clearly relates to safety, and it is a crucial part of the story[.]" *Id.* at 8. Ethicon made the same argument before Judge Story in the Northern District of Georgia, and he concluded that, even accepting Ethicon's proposition that the 510(k) process had a "safety component," the 510(k) safety and effectiveness equivalence pathway to approval still "does little to inform as to its safety." *In Re: Ethicon Physiomesh Flexible Composite Hernia Mesh Prod. Liab.*

Litig., No. 1:17-MD-2782-RWS, doc. 690 at 17 (N.D. Ga. Nov. 25, 2020). The Court agrees but adds to Judge Story's analysis.

The main witness Ethicon planned to use to get 510(k) evidence before the jury is Timothy Ulatowski, a consultant on medical device regulations, who authored a 106-page report explaining his opinions. But simply noting the number of pages, while significant, does the report little justice. Using single spacing and a small font, Mr. Ulatowski managed to cram 38,319 words into his 106 pages. Prior to the *Daubert* hearing, the Court pored through that report to see what Mr. Ulatowski had to say about the safety analysis in the 510(k) process for the Prolift device. The poring yielded nothing of consequence. Consequently, at the *Daubert* hearing, the Court asked counsel if she could help locate any reference to safety, if there was one. Counsel responded that at page twenty-four of the report, there is a flow chart describing the 510(k) process and in that flow chart the following words appear: "Does new evidence have technological characteristics that raise new types of safety or effectiveness questions?" Docs. 103-6 at 25; 122 at 29:9-32:13. That's it. Clearly, Mr. Ulatowski can add little about whether there was any significant evaluation of the safety of the Prolift device. The length of his report does suggest one point on which courts may not have quite got it right. Opening the door to 510(k) evidence would not result in a mini trial, it would be a maxi trial. Accordingly, the plaintiffs' motion to exclude testimony related to FDA regulatory compliance is **GRANTED**.[5]

[5] At oral argument, Ethicon raised the possibility that Mr. Ulatowski's industry practice opinions about IFUs might be necessary to rebut the plaintiffs' potential argument about "known risks." Doc. 122 at 32:15-33:14. Concerns about improper argument can be addressed by motions in limine.

C. Ethicon's Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge

Ethicon has moved to limit Dr. Uwe Klinge's testimony concerning opinions about alternative designs to the Prolene Soft Mesh, the type of mesh used in the Prolift device.[6] Doc. 101-1 at 5-9. Dr. Klinge, an abdominal surgeon and biomaterial researcher, intends to testify that "lighter weight, larger pore meshes were known by Ethicon to be superior to heavier weight smaller pore meshes in terms of risk profile and represented a safer alternative design." Docs. 123 at 6; 101-4 at 10:20-21. Specifically, Dr. Klinge stated in his expert report that "[t]he superiority of lightweight, large pore meshes over the classical heavyweight, small pore mesh materials (like Marlex and Prolene) is now widely accepted. These large pore or "macroporous" meshes, defined as pore sizes of >1mm in all directions, after accounting for stretch and pore deformation, have a decreased surface area, and compared to classical mesh materials, they induce a reduced inflammatory reaction with a decreased amount of clinical complications." Doc. 101-2 at 12-13.

Ethicon does not dispute Dr. Klinge's qualifications,[7] but argues that Dr. Klinge's opinions about alternative designs are unreliable because he has not tested his theories or cited supporting scientific literature. Doc. 101-1 at 5-9. Given Dr. Klinge's qualifications and experience, it is arguable that his experience-based opinions would

[6] Ethicon also moved to limit Dr. Klinge's opinions about fraying and particle loss. Doc. 101-1 at 9-12. However, the plaintiffs stated in their post-*Daubert* hearing brief that fraying is not at issue in this case and that Dr. Klinge will not give an opinion about particle loss. Doc. 123 at 2, 5-6. Accordingly, the Court need only decide whether Dr. Klinge's testimony about alternative designs will be allowed.

[7] Dr. Klinge is clearly qualified to opine on the topic of mesh products. Dr. Klinge has spent decades studying mesh products and has "authored or co-authored approximately 200 peer-reviewed publications in PubMed, over 100 of which involve hernia and/or surgical mesh." Doc. 101-2 at 2. Significantly, Dr. Klinge helped study and develop Vypro, a lightweight, large pore mesh that was marketed by Ethicon. *Id.* at 3.

be reliable in the absence of support from peer-reviewed studies. But in fact, Dr. Klinge references a scientific study ("Okulu Study") that concluded "Ultrapro mesh can be used in sling surgery due to its higher success rates, and its lower vaginal and urethral extrusion and de novo urgency rates." Doc. 106 at 11-12 (quoting Emrah Okulu, *et al*, *Use of three types of synthetic mesh material in sling surgery. A prospective randomized clinical trial evaluating effectiveness and complications,* 47, Scandinavian Journal of Urology and Nephrology, 217-24 (2013)). Ethicon responds that the Okulu Study is irrelevant because it analyzed Ultrapro and Prolene meshes when used in urinary stress incontinence surgeries and not pelvic organ prolapse surgeries. Doc. 110 at 4. True, but the study is relevant to show Ultrapro mesh results in fewer complications than Prolene mesh in some procedures. Doc. 110-1 at 2-3, 7. For example, the Okulu study concluded Ultrapro mesh incorporated with tissue more successfully because of its "macropores," which is the point of Dr. Klinge's opinion. *Id*. at 7. The Okulu study supports Dr. Klinge's opinions that Ultrapro is a safer alternative. The weight of that support is a matter for the jury.

Furthermore, Dr. Klinge cited another scientific study in his expert report which found "there can be worse biocompatibility of lightweight meshes compared with heavyweight meshes, if the lightweight mesh has very small pores." Doc. 101-2 at 13. This study found that "the amount of implanted mesh was not the main independent determinant of biocompatibility (expressed as successful incorporation and diminished foreign body reaction) but the size of the pores" was. *Id*. (quoting Dirk Weyhe, *et al*., *Experimental comparison of monofile light and heavy polypropylene meshes: less*

weight does not mean less biological response, 30, World Journal of Surgery, 1586-91 (2006)).

In short, Dr. Klinge's opinions regarding safer alternative designs are supported by scientific literature. Accordingly, Ethicon's motion to limit these opinions on the grounds that Dr. Klinge lacked such support is **DENIED**.

D. Ethicon's Motion to Exclude Certain General Opinions of Daniel Elliott, M.D.[8]

1. Instructions for Use ("IFU") Warnings

Ethicon has moved to limit the IFU warning opinions of Dr. Daniel Elliott, a pelvic floor surgeon who specializes in treating pelvic organ prolapse, to be consistent with Judge Goodwin's prior order, which limited these types of opinions to "the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." Doc. 102-1 at 4. The plaintiffs seem to agree that Dr. Elliott will not testify about the IFU warnings beyond this scope and that his opinions—based on his clinical experience—will not "deviate from Judge Goodwin's standard[.]" Doc. 122 at 63:9. Instead, he only intends to "identify what the risks are … and whether those are reflected by the warning." *Id.* at 63:18-20. Further, the plaintiffs state that Dr. Elliott does not intend to testify on whether the warnings were, by FDA standards, properly noted in Prolift's IFU. Docs. 123 at 1. Accordingly, to the extent it is still relevant, Ethicon's motion that Dr. Elliott's testimony be limited to the scope set by Judge Goodwin is **GRANTED**.

[8] Some of Dr. Elliott's potential testimony that Ethicon moved to exclude is no longer at issue. These areas of testimony include opinions suggesting a causal link between degradation and clinical harm, any legal conclusions, adverse event reporting, speculation on Ethicon's state of mind, narrative summaries of corporate documents, and opinions on Ethicon's training of surgeons. Docs. 123 at 1-2, 5; 105 at 5 n.1.

2. Research/Testing

Ethicon argues that Dr. Elliott "is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed" and therefore, any opinions regarding the adequacy of Ethicon's testing and research should be excluded. Doc. 102-1 at 7. The plaintiffs respond that Dr. Elliott will not testify on the "adequacy of the testing done by Ethicon—but merely on the lack of testing from a factual standpoint and how that impacted his opinions." Doc. 105 at 6. At oral argument, the parties agreed that Dr. Elliott will not testify about regulatory matters, but he will testify about problems he encountered with the Prolift device in his practice and whether, as a matter of fact, those problems were the subject of testing. Doc. 121 at 74:24-75:23. Dr. Elliott may not testify about regulatory testing and research requirements. But whether Ethicon researched or performed tests on such problems is a factual matter that does not implicate Rule 702. Dr. Elliott will not testify that Ethicon, from a regulatory standpoint, should have performed such research or tests. Accordingly, Ethicon's motion to limit opinion testimony about research and testing is **GRANTED**.

3. Non-synthetic mesh procedures as safter alternatives

Ethicon has moved to preclude Dr. Elliott from testifying that non-synthetic mesh procedures, such as native tissue repair surgeries like sacrocolpopexies and colporrhaphies, are safer alternatives to a procedure that implants the Prolift device. Doc. 102-1 at 10-14. Ethicon argues that a procedure that does not use synthetic mesh and does not place a foreign object into the body cannot be compared to a procedure that does and thus, should not be considered as a safer alternative. *Id*. at 11. The

plaintiffs argue that the availability of an alternative procedure that treats the same issue but does not use synthetic mesh is relevant under Georgia's risk-utility analysis.

The Georgia Supreme Court adopted a risk-utility analysis for product defect cases in *Banks v. ICI Americas, Inc.* 264 Ga. 732, 450 S.E.2d 671 (1994). In *Banks*, the court listed several factors that could be considered in the risk-utility analysis, including alternative safe designs. In discussing alternative safe designs, the court said "[a]lternative safe design factors include: the feasibility of an alternative design*; the availability of an effective substitute for the product which meets the same need but is safer*; the financial cost of the improved design; and the adverse effects from the alternative." *Id.* at 736 n.6 (emphasis added).

Originally citing no Georgia authority, Ethicon argues that because native tissue repair is not an improvement of Prolift's *design*, it is not evidence of a safer alternative design and should be excluded.[9] Doc. 102-1 at 14. The plaintiffs, however, argue that evidence of a procedure that treats the same issue is evidence of Prolift's utility because it shows "the availability of an effective substitute for the product which meets the same need but is safer." Doc. 105 at 14 (quoting *Dotson v. Am. Med. Sys., Inc.*, 2020 WL 2844738, at *3 (N.D. Ga. Mar. 11, 2020) (holding that an expert may testify that a native tissue repair procedure is evidence of a safer alternative to surgeries using mesh). The plaintiffs also note that the same question—whether non-mesh treatment alternatives are admissible in showing availability of a safer alternative design—was

[9] After oral argument, Ethicon brought to the Court's attention an order from the Northern District of Georgia holding that opinions concerning alternative, non-mesh surgeries were inadmissible. Doc. 128 at 1 (citing *Williams v. Ethicon*, *Inc.*, 2021 WL 857747, at *6 (N.D. Ga. Mar. 8, 2021)). However, the Court is not persuaded by that court's analysis, which did not address Georgia law and thus did not address the relevance of alternative therapies to show the "availability of an effective substitute for the product which meets the same need but is safer." *Banks*, 264 Ga. at 736 n.6.

recently decided in the Northern District of Georgia. *Dotson,* 2020 WL 2844738 (N.D. Ga. Mar. 11, 2020). There, the court held that testimony concerning alternative non-mesh procedures is admissible to show the availability of a safer alternative design to a device using mesh. *Id*.

Based on *Banks*, evidence of non-mesh procedures addressing the same problem Prolift was intended to address is relevant under Georgia's risk-utility analysis. Such procedures may show the "availability of an effective substitute for the product which meets the same need but is safer." *See Banks*, 264 Ga. at 736 n.6. Accordingly, Ethicon's motion to limit Dr. Elliott's testimony on native tissue repairs as a safer alternative is **DENIED**.

4. Devices with a different type of mesh as safer alternatives

Finally, Ethicon argues that Dr. Elliott should not be permitted to opine that a different type of mesh would be a safer alternative to the Prolene Soft mesh used by Ethicon. Doc. 102-1 at 14-17. Ethicon states that Dr. Elliott has "never tested his alternative designs nor does he cite any literature that these alternative meshes would be safer and still effective for treating prolapse." *Id.* at 15. Specifically, Ethicon points to Dr. Elliott's expert report and argues that his statement that based on "vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are lower weight (less surface area), larger pore size … result with fewer complications," is a conclusory statement with no citation to scientific literature. Doc. 112 at 12. However, Ethicon somehow overlooks the first sentence in the paragraph: "An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicates there is a strong and direct

relationship between postoperative mesh complications and mesh design." This sentence is followed by citation to eleven sources. Doc. 102-2 at 9. Ethicon has not argued that these sources are unreliable; it merely argued, incorrectly, that Dr. Elliott's opinions cited no scientific literature. Accordingly, Ethicon's motion to limit Dr. Elliott's testimony on alternative mesh as a safer alternative is **DENIED**.

III. CONCLUSION

For the foregoing reasons, the plaintiffs' motion to limit the testimony of Drs. Sepulveda, Lowman, and Wright (Doc. 99) is **GRANTED**—none of the experts may testify that Williams has or had Crohn's disease. This does not mean they cannot, within the scope of their qualifications, testify *about* Crohn's disease. The plaintiffs' motion to exclude FDA testimony from Mr. Ulatowski, Dr. Sepulveda, and Dr. Lowman (Doc. 103) is **GRANTED**. Ethicon's motion to limit the testimony of Dr. Klinge (Doc. 101) is **DENIED**. And finally, Ethicon's motion to exclude certain general opinions of Dr. Elliott (Doc. 102) is **GRANTED in part** and **DENIED in part**.

SO ORDERED, this 22nd day of March, 2021.

S/ Marc T. Treadwell
MARC T. TREADWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT