UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ROBERT and KAROL AVENDT,

Plaintiffs,

v.

COVIDIEN INC.,
a Delaware Corporation

Defendant.
_____/

Case No. 11-cv-15538

Paul D. Borman
United States District Judge

Mona K. Majzoub
United States Magistrate Judge

OPINION AND ORDER (1) EXCLUDING CERTAIN TESTIMONY OF PLAINTIFF ROBERT AVENDT'S TREATING PHYSICIAN; (2) GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (ECF NO. 116); (3) DENYING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT (109); (4) DENYING AS MOOT DEFENDANT'S MOTION TO EXCLUDE TESTIMONY OF DAVID ANCELL (ECF NO. 110); (5) DENYING AS MOOT DEFENDANT'S MOTION TO EXCLUDE TESTIMONY OF DAVID HAMMEL (ECF NO. 113) AND (6) DISMISSING PLAINTIFFS' COMPLAINT WITH PREJUDICE

This is a product liability action involving Plaintiffs' claim that Defendant Covidien Inc. ("Covidien") failed to appropriately test, and therefore failed to adequately warn practicing physicians about the side effects of, a hernia repair mesh product that was used to repair Robert Avendt's recurrent hernia. Plaintiffs theorize that Covidien's hernia mesh product caused Mr. Avendt to have a chronic non-healing

wound that became infected and required further surgery. Covidien has moved to limit the testimony of Plaintiffs' only medical expert, Mr. Avendt's treating physician, and for summary judgment on Plaintiffs' claims. The Court has received extensive briefing from the parties on Covidien's motions and conducted two lengthy hearings, as discussed below. For the reasons that follow, the Court GRANTS Covidien's motion for summary judgment.

INTRODUCTION

This action involves Plaintiffs' claim that Covidien's biological surgical mesh product ("Permacol"), an FDA approved medical device which was implanted in Plaintiff Robert Avendt on December 17, 2008 to repair a third recurrent hernia, was not adequately tested before being released to market and therefore Covidien failed to adequately warn practicing surgeons of Permacol's propensity to fail due to its cross-linked design.[1] Plaintiffs claim that had Covidien performed "an adequate

[1] As discussed *infra*, Permacol is a biologic product (a porcine dermis or pigskin) that undergoes a processing called "cross-linking," through which bonds are established between collagen molecules and fibers by exposure to a solution, in the case of Permacol a solution called hexamethylene diisocyanate ("HMDI"), which gives the product different properties compared to non-cross-linked products. (ECF No. 116, Def.'s Mot. Summ. J. Ex. F, June 30, 2015 Deposition of David F. Williams 6:21-24.) Permacol is the only product on the market cross-linked through the HMDI process. (*Id*. at 38:23-24.) Mr. Williams explains that cross-linking increases the stability and therefore durability of the product because the cross-link bonds established between the molecules and the fibrils means that certain enzymes in the body which normally degrade collagen will find it more difficult to breakdown the collagen and therefore the product will be more durable and longer lasting, providing greater control between the properties of the biologic material (the porcine dermis)

clinical trial" on Permacol, and included the results of such a study in the Permacol instructions for use, the surgeon who placed the Permacol mesh in Mr. Avendt would not have chosen the Permacol cross-linked biologic mesh to repair Mr. Avendt's third recurrent hernia, and/or would not have left the Permacol in Mr. Avendt's abdomen after detecting a seroma, and Mr. Avendt would not have suffered the infected, chronic non-healing wound that allegedly caused his injuries.

I. PROCEDURAL BACKGROUND

On April 19, 2016, the Court issued an Opinion and Order in this case, *Avendt v. Covidien*, 314 F.R.D. 547 (E.D. Mich. 2016), partially granting Defendant's motion to limit the opinions and testimony of Plaintiff Robert Avendt's treating physician, Michael J. Rosen. The Court determined, after conducting an extensive hearing on Covidien's motion to limit Dr. Rosen's testimony, that it could resolve some but not all of Covidien's challenges to Dr. Rosen's proposed testimony. In summary, the Court determined that Dr. Rosen was required to file a full-blown Fed. R. Civ. P.

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and the speed at which that material is replaced with human tissue through ingrowth. In contrast to a non-cross-linked biologic, which is quickly remodeled after implantation (a matter of months maybe a year or so) by the natural collagen of the patient, this process is delayed in the cross-linked material so that the product retains its structure for a longer period of time. The advantage of this is that if the remodeling process goes too fast, then there is a period where the material has lost its characteristics and strength too quickly – before the tissue remodeling has really had a chance to take hold. *Id*. at 35:18-36:19. This process varies greatly from patient to patient and will depend on prior surgeries and on comorbidities, such as obesity and diabetes, of the patient. *Id*. at 36:20-25.

26(a)(2)(B) Report with respect to certain of the opinions that Plaintiffs seek to have him offer and that the Fed. R. Civ. P. 26(a)(2)(C) Disclosure that Plaintiffs filed on behalf of Dr. Rosen, *see* ECF No. 159-7, Pls.' Resp. to Mot. to Exclude Rosen, Ex. G, Plaintiffs' Fed. R. Civ. P. 26(a)(2)(C) Supplemental Disclosure, was insufficient under the Federal Rules of Civil Procedure as to certain of his proposed opinions. *Avendt*, 314 F.R.D. at 556-57 (observing the Federal Rules of Civil Procedure Rules and Commentary, which notes that "there is no reason to conclude that Rule 26(a)(2)C) was intended to allow treating physicians to give expert opinions that go beyond the scope of treatment and diagnosis without having to prepare a report with respect to those further opinions . . . It is not sufficient for the summary disclosures to mention that the treating physician is going to offer these additional expert opinions"). The Court concluded:

> Thus, the substance of a treating physician's testimony, and not his or her status as a treating physician, determine whether a Rule 26(a)(2)(C) disclosure will suffice. In making this call, the distinction made in pre-2010 case law, between treating physicians who opine only matters relating to their treatment and diagnosis on the one hand and treating physicians who offer opinions that fall outside the scope of the treating relationship on the other, continues to be determinative.

314 F.R.D. at 557 (collecting cases).

The Court thus concluded that Dr. Rosen, who did not file a Rule 26(a)(2)(B) expert report in this case, would be limited to testifying as a treating physician and

therefore limited to those opinions that were formed for purposes of, and within the scope of, his care and treatment of Mr. Avendt. The Court determined that certain of Dr. Rosen's opinions proposed in Plaintiffs' Rule 26(a)(2)(C) disclosure fell well outside any possible relation to his care and treatment of Mr. Avendt and would be excluded, including Dr. Rosen's proffered opinion that "there is clearly a need for further animal and human trials investigating how varied clinical settings affect the performance of different xenograft biologic meshes." 314 F.R.D. at 560 (finding that Plaintiffs' Rule 26(a)(2)(C) treating physician disclosure was insufficient and a full blown expert report was required with regard to the opinions proffered in paragraphs three, four, and five of Plaintiffs' Rule 26(a)(2)(C) disclosure).

With regard to other aspects of Dr. Rosen's proposed testimony as set forth in Plaintiffs' Rule 26(a)(2)(C) disclosure, Plaintiffs disclosed that Dr. Rosen would testify regarding certain matters about which Dr. Rosen clearly lacks expertise, as Covidien established in Dr. Rosen's deposition. The Court concluded that Dr. Rosen's "proposed" opinions on such matters, even if Plaintiffs could have established that Dr. Rosen formed them within the scope of his care and treatment of the Mr. Avendt, were well beyond his admitted area of expertise, and were excluded under *Daubert*[2] without necessity of further testimony at a *Daubert* hearing:

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[2] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 592 (1993).

> [Dr. Rosen] lacks sufficient expertise to opine on the topics of the material science of cross-linking, immunogenic response to cross-linked material or the scientific process related to the fatigue and breakdown of mesh. Similarly unsupported are any opinions relating specifically to the design and testing of Permacol. The Defendant's motion to strike all such opinions is GRANTED without need of a *Daubert* hearing.

314 F.R.D. at 562.

As to other aspects of Covidien's challenge to Dr. Rosen's testimony, the Court concluded that it lacked sufficient information and ordered that Dr. Rosen appear for a *Daubert* hearing. Due to Dr. Rosen's busy schedule and limited availability to appear as the Court ordered, the *Daubert* hearing did not take place until January 26, 2017. Following the *Daubert* hearing, the Court ordered the parties to submit a round of supplemental briefing on the admissibility of Dr. Rosen's opinions. Those supplemental briefs were submitted in March, 2017. (ECF Nos. 231, 232, 233.)

II. FACTUAL BACKGROUND

A. Plaintiff Robert Avendt's Treatment With Dr. Ash

Mr. Avendt began treating with Dr. Christopher J. Ash, D.O. in August, 2005, weighing approximately 280 pounds and presenting with complaints of a large ventral hernia. (ECF No. 116, Def.'s Mot. Summ. J. Ex. A, Treatment Notes of Dr. Christopher J. Ash, D.O.) Mr. Avendt was then 54 years old and a Type-2 diabetic with "multiple comorbidities," high cholesterol, hypertension and a history of abdominal surgeries that began in 1997 with a Hartmann procedure for diverticulitis.

(*Id*.) In 1998, Mr. Avendt had an emergency hernia repair related to an incarcerated ventral hernia, followed by a small bowel resection and primary repair of the ventral hernia. (*Id*.)

After consultation with Dr. Ash in 2005, Mr. Avendt decided to continue his efforts at weight loss and postpone any surgical repair of his hernia. (*Id*.) Mr. Avendt's hernia went untreated until June, 2008, when Mr. Avendt returned to Dr. Ash, having lost approximately 30 pounds, and seeking to have his abdominal hernia repaired. (*Id*.) On August 21, 2008, Dr. Ash repaired Mr. Avendt's recurrent hernia and implanted a large 25 cm x 25 cm Parietex synthetic surgical mesh. (Def.'s Mot. Summ. J. Ex. B, 8/21/08 Operative Note.)

Mr. Avendt had worsening abdominal pain following his August 21, 2008 surgery and his hernia recurred. On December 17, 2008, Dr. Ash performed another hernia repair. (Def.'s Mot. Summ. J. Ex. C, 12/17/08 Operative Note.) While Mr. Avendt's August, 2008 hernia repair had been done laproscopically, the December, 2008 surgery to repair the recurrence had to be "more invasive" and required a larger incision. (Def.'s Mot. Summ. J. Ex. D, July 11, 2012 Deposition of Christopher Ash 13:21-14:4.) Dr. Ash discovered that the Parietex mesh that he had previously placed in the first repair had "come loose," and "folded transversely" onto itself in the mid-portion of Mr. Avendt's abdomen. (Ash Dep. 75:10-25; 12/17/08 Operative Note.)

Dr. Ash removed the entire Parietex mesh, and had to dissect free some portions of the bowel that had adhered to the mesh. (12/17/08 Operative Note.)

In the course of the 12/17/08 surgery, Dr. Ash had "an issue in relation to some scar tissue and [Mr. Avendt's] bowels being up into his hernia." (Ash Dep. 14:7-8.) "[I]n doing the dissection [they] had some serosal injury to some of the small intestines and to some of the large intestine." (*Id.* at 14:5-6.) Dr. Ash testified that this injury created a "clean contaminated wound," which meant that Dr. Ash "cut into the surface of the bowel and bacteria could have escaped," but no excrement was visible. (*Id*. 24:21-25:3, 61:5-14.) Because of the involvement of the injury to the bowel, and the potential for contamination, Dr. Ash choose to use a Permacol biological mesh (rather than a synthetic mesh such as the Parietex that he removed) because he was "uncomfortable putting a plastic prosthetic into [Mr. Avendt's] abdominal cavity for risk of infection." (*Id.* at 14:8-12; 24:11-24.) Going into the December surgery, Dr. Ash had "intended to use a synthetic mesh," and had it not been for the "worry of infection," Dr. Ash "probably never would have put a biologic" in Mr. Avendt. (*Id*. at 61:5, 62:16-63:15.)[3]

[3] As discussed more fully *infra*, despite Dr. Ash's testimony that he thought he may have "nicked" Mr. Avendt's bowel, Plaintiffs have "adamantly" taken the position that Mr. Avendt's wound was a "clean," Class I non-contaminated wound while Mr. Avendt was under Dr. Ash's care, and that the wound was not contaminated by Dr. Ash's surgery and did not become contaminated and infected until after Dr. Ash reoperated on Mr. Avendt in 2009.

Dr. Ash had performed many surgeries with biological mesh but this was the first time he had used the Permacol biological mesh. (*Id*. at 14:13-14; 15:1-5.) Dr. Ash was "apprehensive" because of his lack of experience with the Permacol product. (*Id*. at 14:19.) But Permacol "fit the bill" because it was known to be "more resistant to infection" and tended "to fix better." (*Id*. at 15:18-21.) The Permacol sales representative was present in the operating room and provided the Permacol mesh to Dr. Ash. (*Id*. at 15:24-16:11.) The decision to use Permacol was completely Dr. Ash's decision. Dr. Ash testified that the Covidien representative, "Matt Aris would never make that decision." (*Id*. at 34:1-6.) Dr. Ash may have read some promotional literature about Permacol but had never discussed Permacol with any of the product representatives prior to using it on Mr. Avendt. (*Id*. at 25:13-21.) Dr. Ash fully understood the advantage of the Permacol mesh and explained why he consciously chose to place the Permacol in Mr. Avendt's wound:

> Q: Can you explain the benefits of using the Permacol in Mr. Avendt's case at the time?
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> * * *
>
> A: Alternatives to prosthetic meshes are one of two things, either you maintain a hernia or try to close it primarily, which in this case was just not physically possible, or you use a biologic. The only biologic available and the only one that we had experience or I had experience with prior was an Alloderm product. And we had had plagued recurrences with it, turns out it's a little too flexible to fix the holes. So this biologic mesh product is, and biologic products in general, are more resistant to infection and tend to fix better and more of a clean

contaminated type of situation. And this Permacol fit the bill.

(Ash Dep. 15:6-7, 11-21.) Prior to using the Permacol mesh on Mr. Avendt, Dr. Ash may have read a "brochure from Covidien" or "looked at some throw away material," but had not "met with the rep or had any formal education," reviewed the product literature or read any peer-reviewed materials about the Permacol product. (*Id*. at 25:7-26:11.) Nonetheless, Dr. Ash felt that he was well educated and informed on the use of biologics and qualified to use a product such as Permacol during a case if needed. (*Id*. at 61:21-62:2.) Dr. Ash intentionally chose Permacol because the previous biologic he had used was performing poorly and resulting in multiple hernia recurrences and he knew Permacol to be a more durable product and a "remarkably better choice" than doing nothing to repair Mr. Avendt's hernia. (*Id*. at 24:15-24.) Post-operatively Mr. Avendt's condition was pretty typical and when he did first present with a wound secreting liquid, Dr. Ash suspected an infection but the liquid "didn't grow back any bugs in culture" and so an infection was not present. (*Id*. at 36:12-14.)

The Permacol mesh comes out of its sterile packaging with a strong "cat urine smell," and required an extensive 10-15 minute "soaking" process to prepare the mesh for implantation. (*Id*. at 32:19-33:6, 33:12-25, 34:7-15.) Dr. Ash did not specifically discuss with Mr. Avendt in advance of the December, 2008 surgery the specific "type"

of mesh, i.e. synthetic or biologic, he was planning to use to do that repair because he believed the risks of both were "essentially the same." (*Id*. at 59:20-60:18.)

Following the December, 2008 surgery, Mr. Avendt was having increasing redness, swelling, pain and abdominal fluid collection. On May 18, 2009, Dr. Ash saw Mr. Avendt and suspected that he had developed a seroma (a collection of fluid anterior to Permacol mesh and peritoneum) that may have become infected. (Def.'s Mot. Summ. J. Ex. K, May 18, 2009 Letter from Dr. Ash to Dr. Daros.) Dr. Ash operated the next day, on May 19, 2009, to drain and debride the abdominal wall seroma. (Def.'s Mot. Summ. J. Ex. A, Treatment Notes; Def.'s Mot. Summ. J. Ex. L, 5/19/09 Operative Note.) Dr. Ash observed the Permacol mesh, which "appeared intact," but on closer examination after irrigating the wound and manipulating the mesh, it was found to be "quite brittle" and appeared to have some "cracks and holes." (5/19/09 Operative Note.) Dr. Ash opted to "stitch" the Permacol mesh and leave it in rather than remove the mesh altogether. (Ash Dep. 70:16-71:5.) Cultures taken from Mr. Avendt's wound after the May, 2009 drainage and repair did not show any sign of infection. (*Id*. at 69:2-22.)

Mr. Avendt continued having "difficult, chronic" problems with wound healing, drainage from the wound and ultimately "odd material," later determined by Dr. Ash to be pieces of the Permacol mesh, began coming out of Mr. Avendt's wound. (Ash

Dep. 18:20-19:22.) The expelled material varied in size from half-dollar to small flecks. (*Id*. at 37:15-21.) At no time did cultures taken by Dr. Ash come back positive for infection. (*Id*. at 36:14-15; 51:7-25; 69:2-22.)

Sometime after the May, 2009 operation, but before referring Mr. Avendt to Dr. Rosen, Dr. Ash presented Mr. Avendt's case at an Abdominal Wall Reconstruction Conference in Washington, D.C. (Ash Dep. 38:5-11.) Representatives from Covidien were present, and Dr. Rosen was a member of the open-mike panel. Dr. Ash said he got at least "five different opinions" from this panel of experts about how to proceed. (*Id*. at 38:15-40:12.) The Covidien representative asked Dr. Ash to send him more information on Mr. Avendt's case but Dr. Ash never did provide the information because the Covidien sales representative, Matt Aris, who provided Dr. Ash with the Permacol for the 2008 surgery, "had already been given all the information." (Ash Dep. 41:3-16, 73:22-74:25.)

Dr. Ash recorded, in a July, 2009 clinic note, that he had "vetted" Mr. Avendt's case with multiple specialists to discuss the proper course of treatment for Mr. Avendt:

> 07/13/09, Robert Avendt. He is in for follow up on his wound. We have vetted his operation with multiple specialists at multiple different conferences over the last month and the prevailing thought processes consist of two choices. One is that we take him back and clean out this area of the remaining Permacol, do a temporary closure versus a separation of components and primary closure. The second idea is to let

> him finish the Permacol expulsion which I believe he is close to doing, let the wounds close up and make a plan to move ahead with a primary repair with separation components and mesh placement of nonbiological nature.

(ECF No. 117, Sealed Exhibit 1 to Def.'s Mot. Summ. Judg., Ash Treatment Notes PgID 4220.) Ultimately, Dr. Ash elected to go with the second "consensus" option and decided to let the process of Mr. Avendt "expelling this biological mesh from his wound" continue to work itself through. When Mr. Avendt's hernia recurred again, Dr. Ash referred Mr. Avendt to Dr. Michael Rosen at Case Western, a leading national expert on hernia repair, "to fix [Mr. Avendt's] recurrent recurrence." (Def.'s Mot. Summ. J., Ex. A, Ash Treatment Notes PgID 4220; Ash Dep. 21:2-8, 35:10-25.)

B. Mr. Avendt's Treatment With Dr. Rosen

1. Dr. Rosen's deposition testimony.

Dr. Rosen, who was at Case Western University Hospital at the time of Mr. Avendt's surgery and is now at the Cleveland Clinic, is a specialist in hernia repair who has spoken, trained, practiced and published on the subjects of hernia repair and mesh, both synthetic and biologic. (Def.'s Mot. Summ. J. Ex. I, May 11, 2105 Deposition of Michael J. Rosen, M.D. 11:11-13; 14:12-21, 37:1-25, 39:18-40:16.)

Eighty percent of Dr. Rosen's practice is hernia repairs. He uses both synthetic and biologic mesh but "favor[s] synthetic meshes for the vast majority of hernias" he performs. (Rosen Dep. 41:4-12.) At the time of his deposition, Dr. Rosen was the

Principal Investigator of an FDA monitored study comparing synthetic and biologic mesh. (*Id*. at 41:15-18.) Outside of the trial study, he uses biologic mesh less than 2 percent of the time. (*Id*. at 41:18-20.) He uses Strattice biologic mesh and has never used Permacol. (*Id*. at 41:21-25.) Dr. Rosen identified obesity and diabetes as factors that predispose a patient to develop an incisional hernia and to have complications with wound healing. (*Id*. at 43:22-44:2.) Dr. Rosen testified that the success of most hernia operations comes down to good wound healing. Poor wound healing can affect the recurrence of hernias – patients with poor wound healing will have an increased incidence of recurrence. (*Id*. at 46:17-47:11.) Poorly controlled diabetes also increases the risk of recurrence of hernias due to the body's inability to lay down good collagen to form scar tissue. (*Id*. at 49:2-16.) Also, the risk of re-recurrence increases with each recurrence – as much as 40-50% following a third repair. (*Id*. at 50:19-51:18.) "Once you have a failed hernia, unless things change in some meaningful way, it's a vicious cycle." (*Id*. at 50:15-18.)

The Covidien synthetic mesh (not at issue in this case) is polyester and the BARD mesh is polypropylene. Dr. Rosen prefers polypropylene for open procedures. (*Id*. at 56:17-57:24.) For a biologic mesh, the Cleveland Clinic was using Permacol but is switching over to Strattice, which is a pigskin, non-cross-linked mesh. (*Id*. at 58:15-59:9.) Permacol biologic is also pigskin, but is cross-linked. Both have their

selling points. (*Id*. at 60:23-61:13.) The processing of the pigskin biologics is "proprietary" and there is "very little" in the way of clinical trial information available. (*Id*. at 60:15-22.) There is a lot of debate about which mesh is the best, and the ideal mesh has not been found, but "less than ideal meshes have been revealed." (*Id*. at 62:8-22.)

Dr. Rosen reviewed the Permacol Instruction-For-Use ("IFU") document for a paper that he wrote and recalls that it contained a warning or a contraindication in the presence of infection or contamination which he feels is not what a surgeon wants to hear when they are "reaching for a biologic mesh." (*Id*. at 63:19-21; Def.'s Mot. Ex. E, IFU.) Dr. Rosen explained that use of the term "infected" is a bit misleading and prefers to refer to the CDC "crystal clear guidelines" for the four wound classes: Class I (clean), Class II (clean-contaminated), Class III (contaminated) and Class IV (dirty). (*Id*. at 70:1-5.)[4]

All mesh on the market is approved for use in a "clean" Class I wound for "reenforcement where soft tissue weakness exists," and that is the Permacol IFU

[4] As explained in greater detail *infra*, the Centers for Disease Control ("CDC") has clear guidelines for classifying wounds by level of contamination. Class I (clean) wounds are those in which there has been no contamination or potential for contamination; Class II (clean-contaminated) wounds are those in which there has been no observable contamination but there has been a "breach" that creates the possibility of contamination; Class III (contaminated) wounds are those in which contamination has been observed to be present; and Class IV (dirty or infected) wounds are those in which the presence of an overt infection has been detected.

terminology. (*Id*. at 67:3-9.) When bacteria get on these materials, "there is a concern that collagenations in the bacteria can break down the mesh and affect its long-term performance." (*Id*. at 67:9-13.) While every company would like to be able to market a mesh with the indication for use in a contaminated field, "no company is going to take the risk of a randomized controlled trial that might disprove that their mesh is worthwhile and spend millions of dollars." (*Id*. at 68:23-69:2.) So, no mesh on the market is FDA "approved" for use in anything other than a Class I wound, but biologic mesh is "believed" to tolerate an infected environment better than a synthetic mesh.

As noted *supra*, Dr. Rosen has been the Principal Investigator on trials involving synthetic and biologic mesh products. (*Id*. at 41:15-18, 65:18-66:3.) In 2007 or 2008, the FDA tried to start a trial, which Rosen reviewed, to remove infected mesh and replace it with Permacol but the consensus was that it would probably fail so the trial never got going. (*Id*. at 67:18-25.) Because such a trial was "beyond the scope of what the FDA requires," companies decided not to take the business/financial risk of undertaking the trial. (*Id*. at 68:6-9.) At the time of his deposition, Dr. Rosen was involved in a randomized trial for Covidien comparing synthetic to biologic mesh in clean and clean contaminated wounds. (*Id*. at 70:4-11.) If in his practice he was faced with a patient with a Class II or III wound, he would have a conversation with

the patient about the risks and benefits of both synthetic and biologic, explaining that the synthetic will have a lower recurrence rate but the biologic, although having a higher long term recurrence rate, "potentially can handle an infection better." (*Id*. at 71:6-25.)

While at Case Western University Hospital in 2007-2009, Dr. Rosen conducted basic science work in his lab on all different types of meshes to determine how they respond to presence of contamination. (*Id*. at 72:4-11.) The determinants are multi-factorial and include the size of the pores, the weight of the material, the type of material but the studies "to date" (in 2015) indicate that "the larger pore synthetic materials are surprisingly resistant to infection." (*Id*. at 73:7-9.) When you place a mesh into a contaminated field, "it basically becomes a race for ingrowth into the tissue or bacterial coating of the material and then infection, puss, biofilms." (*Id*. at 73:17-22.) So, the quicker things "ingrow," the more resistant the site will be to bacterial colonization that propagates the infection. (*Id*. at 73:22-25.) In Dr. Rosen's opinion, the best synthetic product for a contaminated wound would be a large pore polypropylene and the best biologic would be a "non-cross-linked porcine dermis," (pigskin). (*Id*. at 74:18-75:4.) For patients who are very infection averse and more tolerant of a recurrence, he might suggest the biologic and for those who are averse to a recurrence but will risk the infection, he would suggest the large pore

polypropylene synthetic. (*Id*. at 75:12-23.)

While Dr. Rosen has been involved in several clinical trials involving mesh products, he has not studied the underlying design of the product in terms of the methods, such as cross-linking, employed to produce the mesh. (*Id*. at 78:20-79:8.) Indeed, although Dr. Rosen testified that he doesn't use Permacol because "he [doesn't] like cross-linking," Dr. Rosen could not explain the process involved in cross-linking and could not identify the difference between the biologic mesh that he uses (Strattice) and the Permacol biologic mesh other than the fact that the Strattice product is not cross-linked. (*Id*. at 83:8-84:1.) Nor does Dr. Rosen profess to have expertise in the area of human immune response to the various mesh materials, although he is aware of the data resulting from mostly animal-based studies. (*Id*. at 80:23-82:8.) His expertise is in the clinical aspects of the competing types of mesh, a subject that is still very much under study. He describes the current competing clinical observations as follows:

> Q: So what do you tell your patients about the risks and benefits with your synthetic option versus your biologic option?
>
> A: Well, I think with the large pour [sic] polypropylene mesh, we talk about the fact that it tends to be fairly durable, to have a lower recurrence rate and in our clinical experience up to date, it seems to be fairly resistant to infection and will still incorporate in the face of infection. But the point of the study is that we're trying to figure out if that's actually true.

> The biologic mesh tends to be less durable long term, because you have to lay down your own scar tissues and things like that, so recurrence rates can be a little bit higher. But if you were to get an infection, it's often something we can treat through and don't need to reoperate and it might dissolve and go away and you'd be left with a recurrence but not a chronic infection problem.

(Rosen Dep. at 86:18-87:13.)

Dr. Rosen did the initial portion of the procedure on Mr. Avendt on January 28, 2010. His role was to go in, "get down all the scar tissue, lice the bowel adhesions, remove as much of the infected mesh [sic] and then kind of leave a hole" where they were going to try to reconstruct the herniated area with just a flap, not using any other material or mesh, to try to cure his infection, which was a Class IV wound on the date of surgery. (*Id*. at 98:17-99:12, 101:20-22.) Dr. Rosen completed his portion of the procedure and was followed immediately by Dr. Salgado, who took skin, fascia and muscle from Mr. Avendt's thighs to create the flap for the abdominal repair. (*Id*. at 100:12-101:1.) Dr. Salgado placed drains at the surgical site and closed the wound. (*Id*. at 101:8-19.)

Six months following the surgery by Drs. Rosen and Salgado, Mr. Avendt had developed a recurrence of his hernia and an infection on his right leg where Dr. Salgado had removed the skin for the abdominal flap. *Id*. at 105:2-106:20. Mr. Avendt reported to Dr. Rosen on November 5, 2010, that his hernia was fairly asymptomatic but he was having a lot of weakness and pain in his leg and difficulty

getting around. (*Id*. at 107:9-108:5.) Dr. Rosen opines that the hernia recurrence following the surgery performed by Dr. Rosen and Dr. Salgado was due to the fact that the "defect was so big after what had happened to him in the past and in the presence of a Class 4 wound" the ultimate goal was to get the wound to heal and accept a fairly high chance of a recurrence. (*Id*. at 113:18-25.)

Dr. Rosen recalls discussing generally with Mr. Avendt the issues about infection with hernia mesh repairs but did not tell Mr. Avendt that Permacol was a defective product and never wrote to the FDA or told anyone in his hospital that Mr. Avendt had a defective mesh. (*Id*. at 116:17-117:21.) Dr. Rosen did not recall whether he looked into the pathology of Mr. Avendt's removed Permacol mesh or if he included Mr. Avendt's case in any of his case studies. (*Id*. at 119:13-121:12.)

Dr. Rosen is of the opinion that in 2009, Permacol was not a reasonably safe product for use based on the data then available which indicated that a cross-linked material would not behave like a biologic mesh and, in 2009, Dr. Rosen would not have chosen a cross-linked biologic material. (*Id*. at 127:19-25.) Although not "the scientist who vetted it," Dr. Rosen opines that in looking at the Permacol mesh the problem was that "they decided to heavily cross-link that material" and consequently made it tougher to break down and more of a barrier to ingrowth. (*Id*. at 132:7-133:15.) Dr. Rosen opines that every company knows that their biologic mesh 90%

of the time is being put in a Class II or III wound situation and even though the FDA does not require biologic mesh to specifically have clearance for use in Class II or III wound, a surgeon asking for a biologic mesh product would reasonably assume that the product was designed to perform in that wound class. (*Id*. at 142:11-144:22.) Dr. Rosen opines that if Mr. Avendt had received a non-cross-linked biologic mesh, he likely would have had a recurrence but it would have been in a clean field. (*Id*. at 148:12-149:2.) With a non-cross-linked mesh, the body would have cleared the infection and he would have had a recurrence that could have been repaired with a synthetic mesh. "But because of the size of the hernia, the complexity of the hernia and the active infection in a Class IV wound, that's when essentially all of his reconstructive options were burned due to the chronic, ongoing infection with the big hernia." (*Id*. at 149:2-7.) Because the Permacol mesh was cross-linked, "it behaved like a synthetic mesh and was unable to be cleared. That's why it was an ongoing infection when I saw him." (*Id*. at 149:18-21.)

Dr. Rosen is clear that he does not know, and does not profess to know, the scientific process by which the Permacol mesh is cross-linked and is not sure if he has ever even examined a Permacol mesh although he knows it smells like cat urine. He is not a material scientist or a biomedical engineer although he has collaborated with many such experts on his papers. (*Id*. at 151:24-152:18, 164:4-165:10.) In essence,

Dr. Rosen is of the opinion that Covidien knew that Permacol was being used in situations for which it was contraindicated, i.e. off label in Class II or III wounds, and should have studied whether it was safe in those off label applications. (*Id*. at 151:12-23.)

Dr. Rosen has written extensively about the clinical performance of cross-linked materials and testified that he supports his conclusions about the cause of Mr. Avendt's damages by his observations during Mr. Avendt's surgery of the Permacol mesh with puss sitting around it and based on his experience with cross-linked biologic mesh, which doesn't go away due to its cross-linking and "just sits there" and doesn't dissolve. (*Id*. at 154:7-155:16.) Dr. Rosen testified that he would use a Permacol mesh only in a situation in which a synthetic mesh would be indicated, i.e. in a clean or Class I wound. (*Id*. at 157:1-11.) Dr. Rosen testified that at the Cleveland Clinic, 100% of the uses of biologic mesh is off-label, outside of its indication, because no mesh is indicated for use in a contaminated wound. Dr. Rosen would never elect to use a cross-linked mesh in such a situation. (*Id*. at 157:11-22.) His only criticism of the Permacol mesh is that it is cross-linked and in his clinical experience, he has never seen a mesh in sitting in puss outside of cross-linked material. (*Id*. at 167:19-24.) He has never taken care of a case of a non-cross-linked biologic mesh where he has had to go back in and remove an infected piece of mesh.

The non-cross-linked biologic mesh will dissolve and clear in the face of infection and at most you are left with a recurrence. (*Id*. at 169:14-18.) Dr. Rosen has reviewed articles that indicate that other non-cross-linked biologic mesh products are safe in Class II and III wounds, but he has never seen such a statement regarding a Permacol mesh. (*Id*. at 171:11-172:16.)

Dr. Rosen summarized his opinion that the cross-linking of the Permacol mesh caused Mr. Avendt's injuries:

> Q: So in terms of what was your methodology in coming to your conclusion of the case that it was the cross-linking that –
>
> A: Sure. So my hypothesis was, he had a chronic draining sinus because there was a piece of foreign material in there, Permacol. So my observation was that the wound did not heal for a year. In my experience in maybe managing 2 to 3,000 of these cases, typically when wounds don't heal, there's some remaining foreign body that the body cannot clear.
>
> So when we operated on him and performed the experiment, we drilled down and actually were able to observe and document unincorporated Permacol cross-linked mesh sitting in a bed of puss and granulation tissue due to ongoing nonhealing. And when we removed it all, you know, my conclusion, even in the setting of contamination, the wound healed. So to me that's conclusive, that for one year the wound didn't heal, you take out the one thing and everything heals from an infectious standpoint, to me, that's pretty good scientific evidence that it's conclusive.

(Rosen Dep. 174:17-175:16.)

When asked his understanding of his role in testifying in this matter, Dr. Rosen

responded:

> Q: Do you understand that you're only designated as a treating doctor? Have you had any conversation with the plaintiff's lawyers about that?
>
> A: I asked like what exactly my role is in this and I think they said I'm like a hybrid, so where I was the treating doctor and obviously I can provide expert testimony just because of my clinical experience.
>
> Q: And that's what you expect to do at trial?
>
> A: Sure.
>
> Q: Your opinions about cross-linking were not formed because of Mr. Avendt; they were formed outside of that, correct?
>
> A: Well, no, they were not formed exclusively because of him. They were formed because of my clinical experience in the lab and treating patients with complications related to cross-linked materials.
>
> Q: Was that before 2009 or after 2009?
>
> A: I think it started before and has continued to date.

(Rosen Dep. 190:11-191:9.)

2. Dr. Rosen's testimony at the *Daubert* hearing.

Dr. Rosen is of the opinion, and has expressed the view in written peer-reviewed publications, that Permacol is acceptable to use in a Class I wound although personally he prefers other "less expensive" and "more durable materials" that are available for use in a Class I wound. (ECF No. 222, Transcript of January 26, 2017 *Daubert* Hearing 10:11-19, 10:14-16.)

In 2009, just prior to Mr. Avendt's surgery, Dr. Rosen co-authored an article titled "Major Complications Associated With Xenograft Biologic Mesh Implantation in Abdominal Wall Reconstruction," that was published in the peer-reviewed journal "Surgical Innovation." (*Daubert* Tr. 19:21-23, 21:19-25; Joint Exhibit List Ex. 2, K.C. Harth, M.J. Rosen, "Major Complications Associated With Xenograft Biologic Mesh Implantation in Abdominal Wall Reconstruction," Surgical Innovation (2009); 16(4):324-329 (Dec.).) This article analyzed data obtained from the Manufacturer and User Facility Device Experience ("MAUDE") data base, which is maintained by the Food and Drug Administration ("FDA") and collects voluntary electronic reporting that aims to capture adverse events ("AEs") related to medical devices approved by the FDA. (Joint Exhibit List Ex. 2, "Major Complications" at 325, PgID 6913.) In this article, Dr. Rosen and his colleagues conclude that: "Based on the available literature and the review of the FDA MAUDE database, it seems reasonable to conclude that cross-linked meshes seem to behave reasonably well in clean [Class I] and clean-contaminated [Class II] cases." (*Daubert* Tr. 22:8-18; Joint Exhibit List, Ex. 2, "Major Complications" at 327, PgID 6915.) The article goes on to suggest that "the effect of cross-linking on infected and contaminated ventral hernia repair remains largely unknown at this time and requires careful evaluation." (*Daubert* Tr. 22:19-23; "Major Complications" at 327, PgID 6915.)

Dr. Rosen explained at the *Daubert* hearing that these comments regarding the cross-linked meshes performing "reasonably well" in clean and clean-contaminated cases has to be read in the context of how little overall published literature there was at that time on the performance of cross-linked meshes due to the very small number of clinical trials with very poor follow up. (*Daubert* Tr. 99:4-13.) Dr. Rosen testified that his overall conclusion based on this MAUDE database article was that it was "a strong signal" that there were "safety issues" with these cross-linked meshes that required "careful and further evaluation." (*Daubert* Tr. 98:6-99:3.) Dr. Rosen explained that the MAUDE anonymous database is a very helpful tool for getting "safety signals and major complication signals" about medical devices. (*Daubert* Tr. 99:13-24.) Dr. Rosen stated that he "would always love to see a randomized controlled trial on any material that is being released," but "that's a bar that probably no material can actually achieve – or has achieved . . . ." (*Daubert* Tr. 99:25-100:10.) Dr. Rosen testified that a prospective randomized trial would give surgeons the best information about the risks and benefits of the product, but admits that such studies were not routinely done on available mesh products in 2009. (*Daubert* Tr. 100:2-20.) Without such studies, Dr. Rosen explains, "there's very little instructions about what to expect for the surgeons or the patients," resulting in "life threatening" situations for patients when surgeons don't "know how to handle complications." (*Daubert* Tr.

100:17-101:5.) Dr. Rosen interprets the results of the 2009 MAUDE database study as indicating a problem that should have prompted further study and he "would have liked to have seen a prospective trial started to address whether this is an error or whether or not this is a true signal." (*Daubert* Tr. 101:17-21.)

In January, 2010, the same month that Dr. Rosen operated on Mr. Avendt, Dr. Rosen published a peer-reviewed article that he co-authored titled "Biological Mesh for Abdominal Wall Reconstruction: A Critical Appraisal," which purported to review the then-available peer-reviewed publications discussing biological grafts for abdominal wall reconstruction. (*Daubert* Tr. at 13:12-14:6; ECF No. 223, Joint Stipulated Exhibit List Ex. 1, Michael J. Rosen, "Biologic Mesh for Abdominal Wall Reconstruction: A Critical Approach," Am. Surg. 2010 (Jan): 76(1).) The article included a study of Permacol and in it the authors conclude, and inform surgeons reading this peer-reviewed article, that "Permacol seems to behave reasonably well in clean cases, Class I wounds." (*Id*. at 19:1-17.)

In 2012, Dr. Rosen co-authored an article in the peer-reviewed publication Plastic and Reconstructive Surgery titled "The Biology of Biologics: Basic Science and Clinical Concepts," in which the authors conclude that: "Permacol seems to behave reasonably well in clean cases: however, the effect of cross-linking on infected and contaminated ventral hernia repair remains largely unknown at this time and

requires careful evaluation." (*Daubert* Tr. 23:19-24:25; Joint Exhibit List, Ex. 3, "The Biology of Biologics: Basic Science and Clinical Concepts," Plast. Reconstr. Surg. 130 (Suppl. 2:9S, 2012), at 14S, PgID 6924.) Dr. Rosen admits that he has never authored an article stating that Permacol is not reasonably safe for use in a Class I wound and has never recommended to anyone in the medical community in any publication that surgeons should not use Permacol in a Class I wound. (*Daubert* Tr. 25:24-26:5.) Dr. Rosen is of the further opinion, however, despite these conclusions, that there was "a lack of overall information available" at the time these articles were published. (*Daubert* Tr. 25:6-19.)

In 2013, Dr. Rosen co-authored an article titled "Abdominal Wall Reconstruction," in the publication "Current Problems in Surgery." (*Daubert* Tr. 40:11-25; Joint Exhibit List, Ex. 6, C.D. Butler, D. Bauman, J. Janis, M. Rosen, "Abdominal Wall Reconstruction," Current Problems in Surgery 50 (2013) 557-586.) The authors of this article conclude that a number of biologics, including Permacol, "appear to tolerate placement in a clean-contaminated field," – a Class II wound. (*Daubert* Tr. 41:11-25.)

Dr. Rosen also testified at the *Daubert* hearing that he has recommended and used a certain type of "large pore" synthetic mesh, which never remodels in the body as a biologic mesh is designed to do, in Class II and Class III wounds. (*Daubert* Tr.

26:11-27:5.) Dr. Rosen espoused this opinion in a 2013 article published in the Journal of American College of Surgeons and in a 2015 podcast, i.e. that a "large pore" synthetic mesh would be safe and reasonable to use in Class II (clean contaminated) and even Class III (contaminated) wounds. (*Daubert* Tr. 27:6-28:9; Joint Exhibit List Ex. 4, August 3, 2015 Behind the Knife: The Surgery Podcast – Audio, Ex. 5 "Outcomes of Synthetic Mesh in Contaminated Ventral Hernia Repairs," J. Am. Coll. Surg. 2013: 217:991-998 (Dec.).) Specifically, Dr. Rosen acknowledged at the *Daubert* hearing that he advised in the 2015 podcast that if he encountered a surgical situation in which he nicked the bowel but observed no spillage (the situation that Dr. Ash testified he believed may have occurred when he implanted Permacol in Mr. Avendt), it would be "perfectly appropriate" to use a synthetic "lightweight polypropylene mesh." (*Daubert* Tr. 27:15-28:11; Joint Exhibit List, Ex. 4, 2015 Podcast PgID 6930.)

Although Dr. Rosen explained at the *Daubert* hearing that it was a "very small class of synthetic materials," i.e. "a large pore synthetic mesh," that would be appropriate in such a case, he made no such distinction at his deposition when he testified that he would use a Permacol mesh in any situation in which a synthetic mesh would be indicated. At the *Daubert* hearing, Dr. Rosen was reminded of this testimony from his deposition:

> Q: So you can't think of a single scenario where Permacol mesh is appropriate for use in a patient? Is that fair?
>
> A: The only circumstance that I would think that it's appropriate for use would be when synthetic mesh is appropriate at a fraction of the price.

(*Daubert* Tr. 31:23-32:7.) Dr. Rosen is certainly not a fan of biologic mesh and has significant concerns regarding the cost to the healthcare system of the biologic meshes, concluding that "100 pieces of synthetic mesh cost the same as 1 biologic graft," and wonders whether "the continued use of biologic mesh can be financially solvent." (Joint Exhibit List, Ex. 5, "Outcomes of Synthetic Mesh" 997, PgID 6938.) But while his published opinions may support the conclusion that certain synthetics may be more cost effective than a biologic, none suggest that Permacol should not have been an available tool for surgeons in 2009. As Dr. Rosen and his co-authors concluded in Abdominal Wall Reconstruction in 2013:

> The ideal mesh has not yet been developed but would cause minimal or no inflammatory reaction and be chemically inert, resistant to mechanical stress, sterilizable, noncarcinogenic, hypoallergenic, and reasonably priced. Each of the commercially available meshes has some but not all of these properties. . . . The use of lightweight polypropylene mesh in the setting of contamination has received renewed interest as a more cost-effective approach than bioprosthetic mesh. Several authors have demonstrated that lightweight polypropylene mesh is relatively resistant to bacterial colonization in experimental models, and small case series have demonstrated safety when utilized in clean-contaminated colorectal cases. . . . Use of bioprosthetic materials is a relatively new area in hernia surgery, and further animal and clinical studies are needed to answer many important questions. Currently, these grafts [including Permacol] appear to tolerate placement in a clean-contaminated field, but

> their long term durability and role in hernia recurrence are largely unknown. Although bioprosthetic meshes are much more expensive than synthetic meshes, the long-term cost effectiveness of these materials, particularly in contaminated cases, may be better.

(Joint Exhibit List, Ex. 6, Abdominal Wall Reconstruction 563, PgID 6947, 6949.)

Dr. Rosen testified at the *Daubert* hearing, reviewing his clinic notes, that he first saw Mr. Avendt in December, 2009. (*Daubert* Tr. 49:5-6.) Mr. Avendt had undergone three prior hernia repairs when he presented to Dr. Rosen in December, 2009. (*Daubert* Tr. 50:11-14.) Dr. Rosen could not specifically recall whether, in 2009, he had seen the operative notes relating to Mr. Avendt's 2008 surgery in which Dr. Ash implanted the Permacol mesh, prior to being asked to testify in this case, but he testified that his "typical practice" was to obtain such records before a case if possible. (*Daubert* Tr. 51:22-52:9, 58:13-25.) Dr. Rosen had no knowledge of what was available to Dr. Ash to use at the time he elected to use Permacol to repair Mr. Avendt's hernia and Dr. Rosen does not know what went in to Dr. Ash's decision, he did not recall the wound classification at the time of Dr. Ash's implantation of Permacol nor does he know whether Dr. Ash read the Permacol IFU. (*Daubert* Tr. 53:3-55:2.)

During his treatment of Mr. Avendt, Dr. Rosen never told Mr. Avendt that he believed that the Permacol implanted by Dr. Ash was defective, or that Mr. Avendt's problems were caused by the Permacol mesh. (*Daubert* Tr. 61:1-7.) Dr. Rosen never

told any of his colleagues of the experience explanting Permacol from Mr. Avendt, he never made a report to the FDA MAUDE database, none of Dr. Rosen's treatment records mention Permacol or cross-linking and Dr. Rosen never told Dr. Ash that he believed that Permacol was defective. (*Daubert* Tr. 61:8-62:1.) Dr. Rosen never expressed the opinions he offers in this case until he was asked, which was when counsel for Mr. Avendt called him about testifying in this litigation. (*Daubert* Tr. 62:2-5.)

Dr. Rosen believes that the sequence of events that led to Mr. Avendt's infection started shortly after Mr. Avendt's surgery in August, 2008, when Dr. Ash implanted the Permacol. (*Daubert* Tr. 62:6-18.) Dr. Rosen was aware that Dr. Ash performed another abdominal surgery on Mr. Avendt in May, 2009 when Dr. Ash "went back for the seroma." Dr. Rosen was not aware that a wound culture done at the time of Mr. Avendt's May, 2009 surgery, when Dr. Ash elected to leave the Permacol in place, showed no sign of infection. (*Daubert* Tr. 62:19-63:4.) Dr. Rosen, who concedes that he is not an expert on how the human immune system reacts to Permacol mesh, does not recall that he ran any tests on the explanted Permacol to determine the presence and/or existence of any ingrowth, and did not perform wound cultures on Mr. Avendt's wound at any time. (*Daubert* Tr. 63:10-64:2.) Dr. Rosen does not recall seeing Mr. Avendt's mesh specimen again after removing it, or

following up on any pathology report. (*Daubert* Tr. 65:13-66:9.)

Dr. Rosen recalled that Dr. Ash's notes from the May, 2009 surgery indicated that Dr. Ash found cracks in the Permacol and repaired those cracks with 3-0 vicryls suture. Dr. Rosen did not recall that Dr. Ash indicated he found "healing Permacol" and "manipulated" the Permacol which created cracks and holes, that Dr. Ash then repaired with an absorbable synthetic suture that would maintain its strength for six to eight weeks. (*Daubert* Tr. 67:2-68:11.) When shown Dr. Ash's operative report from the May 19, 2009 surgery, Dr. Rosen conceded that Dr. Ash did state that in draining the seroma that had formed, he observed "the healing Permacol mesh," and it appeared that "the Permacol was in fact quite brittle and continuous manipulation of the Permacol appeared to have created some cracks and holes in the Permacol." (Joint Exhibit List, Ex. 11, 5/19/2009 Dr. Ash Operative Report PgID 6994.) Dr. Ash sutured the holes in the Permacol with "a 3-0 Vicryl stitch" with a "box stitch" and "closed the crack in the Permacol mesh in a running fashion." (*Id*.) Although Dr. Rosen had to admit that the words Dr. Ash used were as they were written in Dr. Ash's operative note, he insisted that "determining healing with a mesh that is falling apart when you touch it [was] not consistent with his understanding of the operative report" because in his experience with thousands of patients with mesh, touching a mesh and having it fall apart is "not supposed to happen" with a healing mesh.

(*Daubert* Tr. 70:10-73:4.) Dr. Rosen was unaware of any textbooks or published studies that describe the technique Dr. Ash used to stitch the Permacol mesh back together but he believed that "any reasonable person faced with this would do something to try to get it back together." (*Daubert* Tr. 73:6-21.)

Dr. Rosen is of the opinion, despite his published, peer-reviewed works proclaiming that Permacol performs reasonably well in clean and clean contaminated cases, that Permacol was not reasonably safe for use in 2009 due to its cross-linked nature and further believes that cross-linked biologic mesh products have not been properly vetted and therefore their potential for failure and complication have been inadequately explained to practicing surgeons. To summarize his opinion testimony at the *Daubert* hearing:

> I think what that means to a clinician like myself is that when these materials are cross-linked, they are resisting degradation by a collagenase. . . . And the way clinicians perceive a biologic mesh, and I believe the way it has been marketed to us is that this is a biologic material that allows cells to grow in, fibroblast to come in, regenerate into native tissue which should resist infection and eventually be replaced with host tissue. And I think this is where the confusion and lack of complete knowledge about how these cross-linked materials are going to change that perception was never fully vetted in that we're starting to see that the collagenase aren't able to break up the graft and they're not being replaced with normal tissue and they're starting to behave very similar to what we see with the synthetic material, particularly certain types of synthetic materials that stick around and create issues with infection. . . . [O]n the spectrum of biologic to synthetic it is unclear exactly where this mesh is going to behave and there will be synthetic features to this at times. . . . [T]his is why it was

> so important to have this information up front, because there is going to be some positive features to having a synthetic-like response in that it might improve durability of the hernia repair. But the unintended and unstudied consequences of getting that synthetic material in a thick, nonporous graft is what was showing up on the MAUDE database and is what I think we're seeing, Mr. Avendt, is that these materials are at times dissolving an infection, at times sticking around and not going away. And so they're very, very difficult to predict their behavior when placed in challenging environments. . . . In Mr. Avendt's case it's clear that he had a chronic infection that required a major reconstructive procedure where we had to go in and remove unincorporated mesh. . . . In my opinion, based on what I understand about cross-linking mesh and having seen many cross-linked failures in our research, [the cause of the product failure] is the fact that the unpredictable behavior and unstudied behavior of the material resulted in the surgeon at the time when he placed that material and suffered a complication from it, was not really informed on exactly what to do and left behind a piece of mesh that, ultimately, did not become incorporated. We came back, it was covered in pus and resulted in now what in my opinion is the hardest hernia to fix [which] is a CDC Class IV wound with a very large defect.

(*Daubert* Tr. 105:25-108:16.) Dr. Rosen holds this opinion with knowledge that in May of 2009, when Dr. Ash left the Permacol in Mr. Avendt's abdomen, he left it in a Class I clean wound. (*Daubert* Tr. 108:17-25.)

Plaintiffs' counsel elicited from Dr. Rosen testimony at the *Daubert* hearing that Mr. Avendt's comorbidities were common among his patients – "everybody I take care of has those pre-existing conditions," my "typical patient [is] overweight, diabetic, hypertensive, 20 pounds or more overweight." (*Daubert* Tr. 111:18-112:8.) Dr. Rosen spoke at length at the *Daubert* hearing about the hundreds of prosthetic mesh infections that he has treated, major reconstructive failed hernias, including

some involving Permacol, none of which Dr. Rosen could specifically recall. (*Daubert* Tr. 112:14-23.)

When asked about Dr. Ash's decision to leave the Permacol in place in May, 2009, and to stitch it up rather than remove it, Dr. Rosen is not critical of Dr. Ash's decision, which Dr. Rosen suggests was made due lack of insufficient information available to guide Dr. Ash in his decision:

> Q: In May of 2009, Dr. Ash chose to leave the Permacol in the – in place. Is it your opinion that that should have been removed or is it – do you have another opinion?
>
> A: Well, I think at the time, in 2008, we didn't know any better. I think there just wasn't any data to instruct surgeons about how to manage these type of complications. I think at the time any reasonable surgeon would have thought this was a biologic mesh like all other biologic mesh and it will regenerate, revascularize and I'll be okay. And I think, as we can see in this data and mounting data, that's just not bearing out to be the case.
>
> Q: And . . . is it your opinion based on your experience, research, review of the literature and knowledge of the patient, is it your opinion that Permacol caused the injury to . . . Mr. Avendt that you repaired in January of 2010?
>
> A: Yes, it is, because when I operated on him in January, it was right there, unincorporated piece of Permacol mesh that was clearly infected, that was leading right to all the sinuses that required a lot of debridement to his abdominal wall and left him with an enormous hernia and this infected situation.

(*Daubert* Tr. 113:17-114:14.) Dr. Rosen also opined as to the insufficiency of the Permacol IFU:

> Q: Did Doctor – did the instructions for use direct users to remove Permacol in the event of a seroma or an infection?
>
> A: I'm not aware that it says that, no.
>
> Q: Is it your professional opinion now that it should say that?
>
> A: It's my professional opinion that there should be more information to inform that IFU particularly for the type of cases and the type of hernias that these products are being placed in, and that should be able to be informed [sic] of surgeons who are putting this in human beings so that we can predict to some reasonable degree what might happen.
>
> Q: Is it your opinion that Permacol should have sufficient labeling to inform a doctor of these side effects?
>
> A: In the absence of a prospective clinical trial that's better than the MAUDE database, that disputes this data in a well-designed trial that I think this should be made much more clear to surgeons who are putting this in people . . . .

(*Daubert* Tr. 115:1-20.)

Although of the opinion that the Permacol IFU is insufficient, Dr. Rosen has no opinion on what the Permacol IFU should say and acknowledges that he has never written anywhere, in any of publications, as to the substance of the "something more" that he opines the IFU should state. According to Dr. Rosen, he has "never seen a trial that would actually allow me to have that level of certainty to answer that question." (*Daubert* Tr. 138:17-139:3.)

Dr. Rosen concludes, based on the data in the MAUDE database article, that cross-linked meshes are "not safe," and that this data is "a very loud safety signal that

something is happening and we need to go back and look very carefully and figure out who it's happening to, why this is happening so that we can either modify the material or make a change to make it safer for patients." (*Daubert* Tr. 117:2-20.)

C. Testimony of David Williams

Mr. Williams, a scientist not a physician, is a professor of biomaterials at the Wake Forest Baptist Medical Center in North Carolina. (Def.'s Mot. Ex. F, June 30, 2015 Deposition of David F. Williams 6:21-24.) Mr. Williams, an expert for Covidien, testified at his deposition that the development and design of the Permacol mesh was appropriate and in accordance with industry standards and sound engineering and biologic practices and principles. (*Id*. at 42:12-17.) Mr. Williams further testified that the design and manufacture of the Permacol is reasonable and that the product is safe and appropriate for its intended use. (*Id*. at 47:6-11.) Plaintiffs have not objected to the admissibility of Mr. Williams' testimony and opinions.

Mr. Williams' area of expertise is tissue engineering, using biomaterials and cells of the human body, especially adult stem cells harvested from blood and fatty tissue, to try to encourage regeneration where it did not occur naturally. (*Id*. at 11:9-20.) Mr. Williams has done research and given expert testimony in several cases regarding tissue ingrowth into polypropylene mesh and the impact of mesh degradation on infection rates. (*Id*. at 19:15-20:25.) Mr. Williams explains that there

are advantages to utilizing "natural tissue products," such as Permacol. (*Id*. at 31:4-8.) In specific, Mr. Williams testifies about the nature and advantages of products, such as Permacol, based on proteins and more specifically based upon collagen which is derived from either animal or human sources. (*Id*. at 31:9-17.) In contrast to synthetic mesh, comprised of say polypropylene or polyester, which is non-degradable and non-absorbable and designed to remain in the human body for the life of the patient, natural tissue products, such as the porcine (pig) dermis (skin) used in Permacol, provide initial strength and form and architecture to a repair but slowly degrade and are replaced by the patient's own tissue through ingrowth. (*Id*. at 31:18-32:13, 33:3-5. The result is tissue that has totally repaired and regenerated rather than relying on a synthetic structure. *Id*. at 32:11-13.)

Mr. Williams explains that Permacol is a "cross-linked porcine dermal implant" that, like all other xenogenic (deriving from animals) products, first undergoes a decellularization process to remove the cells of the collagen to which the human body could be allergic. (*Id*. at 37:19-38:16.) In addition to decellularization, Permacol undergoes a further processing called "cross-linking," through which bonds are established between collagen molecules and fibers by exposure to a solution, in the case of Permacol a solution called hexamethylene diisocyanate ("HMDI"), which gives the product different properties compared to non-cross-linked products. (*Id*. at

33:7-21, 38:20-25.) Permacol is the only product on the market cross-linked by HMDI. (*Id*. at 38:23-24.) Unlike other cross-linking products which leave behind a toxic residue, HMDI does not leave toxic residues behind in the collagen. (*Id*. at 39:8-40:4.)

Mr. Williams explains that cross-linking increases the stability and therefore durability of the product because the cross-link bonds established between the molecules and the fibrils means that certain enzymes in the body which normally degrade collagen will find it more difficult to breakdown the collagen and therefore the product will be more durable and longer lasting, providing greater control between the properties of the biologic material (the porcine dermis) and the speed at which that material is replaced with human tissue through ingrowth. (*Id*. at 34:1-25.) In contrast to a non-cross-linked biologic, which is quickly remodeled after implantation (a matter of months to maybe a year or so) by the natural collagen of the patient, this process is delayed in the cross-linked material so that the product retains its structure for a longer period of time. The advantage of this is that if the remodeling process goes too fast, then there is a period where the material has lost its characteristics and strength too quickly – before the tissue remodeling has really had a chance to take hold. (*Id*. at 35:18-36:19.) This process varies greatly from patient to patient and will depend on prior surgeries and on comorbidities such as obesity and diabetes, of the

patient. (*Id*. at 36:20-25.)

In forming his opinion that Permacol was developed and designed in accordance with industry standards and sound engineering and biologic practices and principles, Mr. Williams closely examined the design history file for Permacol and reviewed papers published in the 1980s by the designers of Permacol. (*Id*. at 42:12-25.) The file contained 15 different volumes of data representing all stages of the design process which included over 200 different tests that were performed on Permacol which in Mr. Williams' opinion "was a very, very extensive process of testing and validation." (*Id*. at 43:1-13.) In his opinion, the data was very sound and was probably "in advance of industry standards [what the industry in general was doing with the development and ultimate marketing of medical devices] back in the '90s." (*Id*. at 43:14-44:19) (alteration added). His review of the development and design of Permacol revealed no adverse biologic responses which were anticipated or seen in experiments which could adversely impact the patient in which they were placed. (*Id*. at 48:12-18.) Finally, he found no evidence of any defect in the manufacturing of Mr. Avendt's implant, i.e. all standard operating procedures and other specifications called for in the documentation was strictly followed. (*Id*. at 4922-50:11.) Mr. Williams was of the opinion that the potential temperature variant to which Mr. Avendt's implant may have been exposed in transit to the hospital would

not have had any effect on the integrity of the implant. (*Id*. at 78:13-79:20.)

D. Testimony of Raymond Dunn, M.D.

Dr. Dunn is the Chief of the Division of Plastic Surgery at U Mass Memorial, University of Massachusetts Medical School. (Def.'s Mot. Ex. J, June 8, 2015 Deposition of Raymond M. Dunn, M.D. at 6:22-23, 11:6-9.) Dr. Dunn, an expert for Covidien, oversees the general surgery/plastic surgery integrated residency program at U Mass. (*Id*. at 11:25-12:24.) Dr. Dunn is also the director of the wound clinic at U Mass. (*Id*. at 16:9-24.) Dr. Dunn testified at his deposition regarding the clinical indications for use of biologic mesh and the considerations that a clinician takes into account in deciding whether to use a biologic mesh and which biologic mesh best suits certain clinical presentations. (*Id*. at 44:20-46:6.) Plaintiffs have not objected to the admissibility of Dr. Dunn's testimony.

Dr. Dunn has participated in studies examining the implantation of biologic hernia grafts and specifically, in a single case study, studied the long-term histologic and mechanical results of a Permacol abdominal wall explant. (*Id*. at 23:19-24:12, 38:22-40:25.) In the case study, which Dunn concedes is one small piece of data with no statistical significance, the woman presented two years after a Permacol hernia repair with a fluid collection behind the Permacol. (*Id*. at 39:3-18, 43:13-22.) During surgery to drain the fluid a biopsy of the Permacol was taken and was found to have

integrated in a healthy way into the tissue, with normal blood vessel ingrowth integration and no inflammation. The Permacol porcine collagen no longer existed and had been replaced by all human collagen. (*Id*. at 39:19-40:10.) Although a single case study with no statistical validity, the study was unique because it examined for the first time the histology and mechanical performance of an explant of Permacol, giving some insight into the how the biologic grafts perform in the human body, a subject that clinicians and scientists are still trying to understand. (*Id*. at 43:21-44:12.)

Dr. Dunn has published papers discussing the clinical indications for the use of biologics for hernia repairs and specifically discussing considerations regarding cross-linking in biomaterials. (*Id*. at 47:16-48:5.) Dr. Dunn opines that biologics are indicated when the clinician cannot ascertain the wound status in a complex hernia environment but are not indicated in any overtly infected abdominal wound. (*Id*. at 47:16-22.) Dr. Dunn opines that the clinician, the surgeon, must understand and consider the characteristics of the product they choose in view of the particular circumstances of each patient and each surgical presentation, i.e. patient comorbidities, clean or contaminated field, etc. (*Id*. at 57:5-58:18, 73:8-22.) Dr. Dunn explains that cross-linking is a chemical process that increases the intrafibrillar bonds between collagen fibers, affecting to varying degrees the healing process of the graft, which involves blood vessels growing into the graft and providing the graft with

oxygen and metabolism. The structure of the graft, its thickness and poressness, will affect the rate at which ingrowth or integration of the graft will occur. (*Id*. at 50:18-51:12, 56:21:-57:20, 55:11-57:4.) Dr. Dunn, as a clinician and not as an expert in cross-linking, explains that Permacol is a "partially cross-linked" material that is designed to increase the number of collagen bonds between the collagen fibers of the porcine dermis. (*Id*. at 66:1-12; 67:2-16.) In a 2012 published animal study comparing the healing properties of three biologic cross-linked implants, one of which was Permacol, the cell infiltration (i.e. the ability of the blood vessels to grown into the graft) of the Permacol implant was somewhere between that of the other two products, presumably due to the effect of the differences in degree of cross-linking, i.e "highly cross-linked" versus "partially cross-linked." (*Id*. at 61:5-62:19, 66:2-12.) It is Dr. Dunn's understanding as a clinician (concededly not an expert in the field of cross-linking) that the agent used to partially cross-link Permacol, HMDI, is designed to "leave enough holes between molecules to allow a favorable and reasonable pace of integration of other cellular elements in a biologic system for healing as compared to some other cross-linking subjects." (*Id*. at 136:23-138:12.)

The comparative evaluation of the clinical data on cross-linked versus non-cross-linked grafts is "quite limited." (*Id*. at 59:3-13.) In Dr. Dunn's opinion, choosing the appropriate biologic graft in any given situation can be "quite

challenging" for the surgeon, who is called upon to use his or her judgment based on the available data pieces and to closely consider patient characteristics. (*Id*. at 57:11-58:18, 73:8-74:3.) Dr. Dunn acknowledges that no biologic graft is indicated by the FDA guidelines for use in anything but a Class I clean wound and any use of a biologic graft in a Class II, III or IV wound is "off-label." (*Id*. 150:5-25.)

Dr. Dunn is of the opinion that Dr. Ash's use of the Permacol mesh to repair Mr. Avendt's hernia was "off-label" based on the indications in the operative reports of a Class II wound and Dr. Ash's admission in his deposition that there was a "bowel violation." (*Id*. at 149:12-22, 151:7-9, 153:13-154:9.) Dr. Dunn expressed the opinion that the IFUs, even in an off-label procedure, can provide some guidance to the clinician but absolutely cannot be completely relied upon. (*Id*. at 10-23.) Dr. Dunn is of the opinion that Dr. Ash's off-label use of the Permacol in Mr. Avendt's case was appropriate and that the failure was one of healing due to the presence of the seroma, which prevented cellular integration to the graft, and the presence of possible contamination in the wound. (*Id*. at 152:15-155:10.)

E. The Permacol IFU and the FDA 510(k)

Permacol is a regulated, prescription medical device approved to market by the FDA through the 510(k) notification procedure. (Def.'s Mot. Summ. J. Ex. G, FDA Market Approval Letter.) The 510(k) process is "a streamlined process that

determines only whether a medical device is 'substantially equivalent' to another device already on the market," and "does not comment on safety." *Rodriguez v. Stryker Corp*., 680 F.3d 568, 572-73 (6th Cir. 2012). Permacol is FDA cleared to market for use only in CDC Class I/Clean wounds and is not approved to market for use in CDC Class II, III, or IV use. (Rosen Dep. 126:3-5.) No hernia mesh product is FDA approved for use in CDC Class II, III, or IV wounds. (*Id*. at 126:13-16, 127:6-10.)

The Permacol IFU warns that "[i]f [Permacol] is used in a contaminated or infected wound this may lead to a weakening or breakdown of the implant" and further warns that "exposure to high concentrations of digestive enzymes may lead to a weakening or breakdown of the [Permacol] implant." (Def.'s Mot. Summ. J. Ex. E, Permacol Surgical Implant, Instructions for Handling and Use PgID 4172.) Dr. Rosen recalled the warning in the Permacol IFU indicating that use in a contaminated or infected wound may lead to weakening of the implant and found that contraindication odd for a biologic mesh:

> Q: Did you remember anything in the IFU that you felt was just wrong?
>
> A: . . . I will tell you that there was terminology in it that I recall about either a warning or a contraindication in the presence of infection or contamination. . . . It certainly made me feel like when surgeons reached for a biologic mesh, that is not what they thought would be a warning or an indication.

(Rosen Dep. 63:9-22.)

III. STANDARD OF REVIEW

A. Federal Rule of Civil Procedure 56

Pursuant to Federal Rule of Civil Procedure 56, a party against whom a claim, counterclaim, or cross-claim is asserted may file a motion for summary judgment "at any time until 30 days after the close of all discovery," unless a different time is set by local rule or court order. Fed. R. Civ. P. 56(b). Summary judgment is appropriate where the moving party demonstrates that there is no genuine dispute as to any material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); Fed. R. Civ. P. 56(a). "Of course, [the moving party] always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*, 477 U.S. at 323. *See also Gutierrez v. Lynch*, 826 F.2d 1534, 1536 (6th Cir. 1987).

A fact is "material" for purposes of a motion for summary judgment where proof of that fact "would have [the] effect of establishing or refuting one of the essential elements of a cause of action or defense asserted by the parties." *Kendall v. Hoover Co.*, 751 F.2d 171, 174 (6th Cir. 1984) (quoting Black's Law Dictionary 881

(6th ed. 1979)) (citations omitted). A dispute over a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Conversely, where a reasonable jury could not find for the nonmoving party, there is no genuine issue of material fact for trial. *Feliciano v. City of Cleveland*, 988 F.2d 649, 654 (6th Cir. 1993). In making this evaluation, the court must examine the evidence and draw all reasonable inferences in favor of the non-moving party. *Bender v. Southland Corp.*, 749 F.2d 1205, 1210-11 (6th Cir. 1984). "'The central issue is whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Binay v. Bettendorf*, 601 F.3d 640, 646 (6th Cir. 2010) (quoting *In re Calumet Farm, Inc.*, 398 F.3d 555, 558 (6th Cir. 2005)).

If this burden is met by the moving party, the non-moving party's failure to make a showing that is "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," will mandate the entry of summary judgment. *Celotex*, 477 U.S. at 322-23. "[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 324. "The test is whether the party bearing the burden of proof has presented a jury question as to each element in

the case. The plaintiff must present more than a mere scintilla of the evidence. To support his or her position, he or she must present evidence on which the trier of fact could find for the plaintiff." *Davis v. McCourt*, 226 F.3d 506, 511 (6th Cir. 2000) (internal quotation marks and citations omitted). In doing so, the non-moving party may not rest upon the mere allegations or denials of his pleadings, but the response, by affidavits or as otherwise provided in Rule 56, must set forth specific facts which demonstrate that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). The rule requires the non-moving party to introduce "evidence of evidentiary quality" demonstrating the existence of a material fact. *Bailey v. Floyd County Bd. of Educ.*, 106 F.3d 135, 145 (6th Cir. 1997); *see Anderson*, 477 U.S. at 252 (holding that the non-moving party must produce more than a scintilla of evidence to survive summary judgment). "A party asserting that a fact . . . is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record." Fed. R. Civ. P. 56(c)(1)(A).

"Rule 56(e)(2) leaves no doubt about the obligation of a summary judgment opponent to make [his] case with a showing of facts that can be established by evidence that will be admissible at trial. . . . In fact, '[t]he failure to present any evidence to counter a well-supported motion for summary judgment alone is grounds for granting the motion.' Rule 56(e) identifies affidavits, depositions, and answers to

interrogatories as appropriate items that may be used to support or oppose summary judgment." *Alexander v. CareSource*, 576 F.3d 551, 558 (6th Cir. 2009) (quoting *Everson v. Leis*, 556 F.3d 484, 496 (6th Cir. 2009)). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses, and we think it should be interpreted in a way that allows it to accomplish this purpose." *Celotex*, 477 U.S. at 323-34.

B. Admissibility of Expert Testimony

Even if permitted as properly within the scope of treatment, a treating physician's testimony remains subject to the requirement set forth in *Daubert* that an expert's opinion testimony must "have a reliable basis in the knowledge and experience of his discipline." *See Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009) (noting that "a treating physician's testimony remains subject to the requirements set forth in *Daubert*"); *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 704 (7th Cir. 2015) ("Treating physicians are no different than any other expert for purposes of Rule 702; before proffering expert testimony, they must withstand *Daubert* scrutiny like everyone else.") (alteration added). *See also In re Aredia and Zometa Pdcts. Liab. Litig.*, 483 F. App'x 182, 187 (6th Cir. 2012) ([A] treating physician's testimony is subject to *Daubert*.").

Under *Daubert*, before allowing an expert's testimony to be considered by the

jury, a trial court must determine whether: 1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence of to determine a fact in issue;" 2) "the testimony is based on sufficient data;" 3) "the testimony is the product of reliable principles and methods;" and 4) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. "Pertinent considerations" in making these determinations include: 1) whether a theory or technique can be (and has been) tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) whether there is a known potential error rate inherent in a given technique; and 4) whether the theory or technique has been generally accepted in the relevant scientific field. *Daubert*, 509 U.S. at 593-94. If the "scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff's injury," the court may grant summary judgment. *Daubert*, 506 U.S. at 596 (citing *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir. 1992)). If the "analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide . . . a jury should not be asked to speculate on the issue of the causation." *Turpin*, 959 F.3d at 1360-61. *See also Glaser v. Thompson Med.* Co., 32 F.3d 969, 972 (6th Cir. 1994) ("If a court concludes that the evidence

supporting the expert's position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, then the court remains free to prohibit the case from proceeding to the jury."); *In re Dow Corning Corp*., 541 B.R. 643, 648 (E.D. Mich. 2015) ("Exclusion of expert testimony may result in the entry of summary judgment and is reviewed on appeal for abuse of discretion."). "No matter how good experts' credentials may be, they are not permitted to speculate." *Tamraz v. Lincoln Elec. Co*., 620 F.3d 665, 671 (6th Cir. 2010) (internal quotation marks, citation and brackets removed). An expert "may be a distinguished doctor, and his conjecture about causation may be worthy of careful attention . . . . but the courtroom is not the place for scientific guesswork, even of the inspired sort." *Id*. (internal quotation marks and citation omitted) (ellipsis in original).

"While the specific language used by courts vary to some degree, all jurisdictions require expert testimony [in a products liability action] at least where the issues are medically complex and outside common knowledge and lay experience." *In re Lipitor*, __F.Supp.3d__, 2017 WL 83509, at *10 (D.S.C. Jan. 3, 2017) (collecting cases nationwide.) *See Schaendorf v. Consumers Energy Co.*, No. 281001, 2009 WL 563904, at *8 (Mich. Ct. App. March 5, 2009) ("expert testimony is indispensable to prove causation where 'it is to the scientific community that the law must look for the answer'") (quoting *Nelson v. American Sterlizer Co*., 223 Mich.

App. 485, 489 (1997)).

The Court must determine whether Dr. Rosen's knowledge and experience qualify him to render the opinions he proffers, whether those opinions will assist the trier of fact in understanding the evidence or help the trier of fact to determine a fact in issue and whether those opinions reliable. "'Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity.'" *Dow v. Rheem Mfg. Co.*, 527 F. App'x 434, 437 (6th Cir. 2013) (quoting *Newell Rubbermaid Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012)).

IV. ANALYSIS

Plaintiffs' Two-Count Complaint in this action (Count I - Product Liability and Count II - a wholly derivative claim for Loss of Consortium), challenges the testing, marketing (failure to warn), manufacturing and design of the Permacol mesh. Product liability claims in Michigan are founded on statute. *See* Mich. Comp. Laws § 600.2946a, *et seq*. To establish a *prima facie* case of product liability under Michigan law, Plaintiffs must demonstrate that Defendant "supplied a product that was defective and that the defect caused the injury." *Auto Club Ins. Ass'n v. Gen. Motors Corp.*, 217 Mich. App. 594, 604 (1996). A product defect "can be established through a variety of theories, including: (1) negligent design of the product; (2) negligent manufacture

of the product; (3) negligent failure to warn about some aspect of the product; (4) breach of an express or implied warranty; or (5) misrepresentation or fraud." *Eiben v. Gorilla Ladder Co.*, No. 11-cv-10298, 2013 WL 1721677, at *8 (E.D. Mich. Apr. 22, 2013) (citation omitted).

Until the summary judgment hearing on this matter, the Court understood Plaintiffs to be claiming that Permacol, while only approved by the FDA to be marketed for use in Class I (clean) wounds, was actually known by Covidien to be utilized by surgeons in Class II and above wounds, i.e. off-label, and that Covidien's failure to warn that Permacol's cross-linking made it inappropriate for such off-label use caused Mr. Avendt's injuries in this case. However, at the summary judgment hearing and again at the *Daubert* hearing, Plaintiffs' counsel adamantly clarified that Plaintiffs in fact claim that Dr. Ash, despite his deposition testimony suggesting the possibility of a Class II scenario, placed the Permacol in Mr. Avendt into a Class I, clean wound. Plaintiffs' counsel informed the Court that Plaintiffs "dispute" Defendant's claim that Dr. Ash had "nicked" Mr. Avendt's bowel and created a Class II wound and suggest that the facts demonstrate that this was "a clean site." (ECF No. 217, Transcript of December 22, 2015 Hearing 47.) Plaintiffs' counsel insisted that the Permacol "was implanted into our view a clean wound." (*Id*. at 48.) Plaintiffs' counsel reiterated that Mr. Avendt's wound "was clean without indication of

infection." (*Id*. at 49.) Plaintiffs also take the position that Mr. Avendt's wound remained clear of contamination and/or infection, i.e. was still a Class I wound, when Dr. Ash reoperated and let the Permacol remain in Mr. Avendt's abdomen in May, 2009, an understanding that Dr. Rosen shared. (Rosen Dep. 108:17:22.)

Analysis of Plaintiffs' claims is complicated by the "evolution" of their theory of liability. Consequently, at the commencement of the January 26, 2017 *Daubert* hearing, the Court asked Plaintiffs' counsel to state on the record the theory of liability under which they are proceeding in this case. Plaintiffs' counsel explained that their theory now focuses solely on a failure to test/failure to warn:

> The Court: I'd like you to clarify what your theory of negligence is in this case. At the December 22, 2015, hearing, page 65 of the transcript, you announced that you were proceeding on a theory of failure to test. Is that your theory?
>
> Mr. Witt: It is part . . . The product was, as set forth in our Complaint, a failure to test and a failure to warn –
>
> The Court: The IFU? You're talking about the IFU?
>
> Mr. Witt: Yes, Your Honor. . . . And the failure to test, failure to warn . . . . substantively there are the two primary claims.
>
> The Court: Okay. And what is your understanding of the elements that you need to prove on your theories to survive summary judgment in this case? In other words, what do you have to show with regard to each of those two?
>
> Mr. Witt: First, that a duty existed on behalf of Covidien and that duty to warn on the second claim existed. They breached that duty by failing

> to provide materially relevant information that would be useful to a practicing doctor such as Dr. Ash, such that failure resulted in damages that were factual, foreseeable and that actually occurred. . . . And specifically the side effects associated with the product were not known because the company failed to develop information so that the doctor could be informed about such side effects. A clinical trial was warranted based on a reasonable physician's, reasonable practitioner's need for that information. If the medical device failed to perform and in its represented fashion this failure could have been – and the damages reduced had the physician been informed of the results of an adequate clinical trial, and it is our position that a clinical trial would have resulted in information that the doctor could have acted upon in a way that would not – that would have allowed the patient not to have been injured. But as it was, the information that was not provided that was generally recognized had not been sufficiently developed by the company with respect to its product. And he left, Dr. Ash, left the device in the patient because that was the generally accepted medical practice at the time. Had the company informed him that there was a risk this device would fail to disintegrate, which is well-known, and we'll have testimony to that effect today, that the patient would not have suffered his injury. So a failure to test and a failure to warn is the essence of the claim.
>
> The Court: Thank you, sir. Okay. Have a seat.

(*Daubert* Tr. 6:17-8:17.)[5]

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[5] Accordingly, the Court does not address Plaintiffs' theories of negligent manufacturing and design, which have now been abandoned. In any event, Plaintiffs have not presented sufficient evidence to fit their claim into the design defect box. Plaintiffs' only expert, Dr. Rosen, has never examined the testing and design files relating to Permacol, he has no knowledge of how Permacol is cross-linked, he offers no alternative design that science has shown offers the same durability and Plaintiffs offer no data concerning the safety and effectiveness of an "alternative"product. *Jacobs v. Tricam Indus., Inc.*, 816 F. Supp. 2d 487, 493-94 (E.D. Mich. 2011) (noting that a plaintiff must show sufficient evidence that a safer alternative design was available at the time defendant manufactured its product and excluding proffered expert opinion on alternative design which articulated no scientific principles or other indicia reliability regarding proposed alternative) (citing *Gawenda v. Werner Co.*, 932 F. Supp. 183, 188 (E.D. Mich. 1996) (quotation marks omitted). Plaintiff's

A plaintiff can show that a product was rendered defective by the manufacturer's "failure to warn about dangers regarding the intended uses of the product, as well as foreseeable misuses" of the product. *Gregory v. Cincinnati Inc.*, 450 Mich. 1, 11 (1995). "The Michigan Legislature has codified a product manufacturer's duty to warn end-users about dangers associated with a product's use." *Mitchell v. City of Warren*, 803 F.3d 223, 226 (6th Cir. 2015). The statute provides:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

Mitchell, 803 F.3d at 226-27 (quoting Mich. Comp. Laws § 600.2948(3)). "A company does not have a duty to warn of *all* theoretically possible dangers." *Id*. at 231 (emphasis in original). *See also Greene v. A.P. Products, Ltd*., 475 Mich. 502, 508, 510 (2006) (observing that tort reform legislation enacted in 1995 "displaced the common law" and now governs a manufacturer's or seller's duty to warn and does not

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manufacturing defect is similarly unsupported by the evidence submitted. No expert has opined that Permacol was defectively manufactured. Plaintiffs made a half-hearted effort to establish a claim related to the effects of a potential temperature variant when the Permacol was en route with Fed Ex to the hospital. Mr. Williams, the only material science expert in the case, opines that the temperature variant would have had no effect on the product, and Plaintiffs offer no evidence (only unsupported speculation) that such a variant *would* have had an adverse effect on the product. The Court concludes that there is insufficient evidence in the record to create a jury submissible claim on either of these issues.

require a manufacturer to warn of "possible" injuries that might occur or of "specific" injuries).

To recover on a failure to warn theory, a plaintiff must prove that: (1) the defendant owed a duty to the plaintiff; (2) the defendant violated that duty; (3) the defendant's breach was a proximate cause of the plaintiff's injuries; and (4) the plaintiff suffered damages. *Warner v. Gen. Motors Corp*., 137 Mich. App. 340, 348 (1984). The issue of whether a manufacturer has a duty to warn is one for the Court. *Mitchell*, 803 F.3d at 230-31 (finding no duty to warn as a matter of law, and noting that a "jury may not speculate that a manufacturer should have known about one risk because a separately known risk revealed the mere possibility of the first"); *Brown v. Drake-Willock, Intern., Ltd.*, 209 Mich. App. 136, 146 (1995) ("The question whether a duty exists is for the trial court. If the trial court determines that a defendant did not owe the plaintiff a duty, summary disposition is appropriate."); *Mills v. Curioni, Inc.*, 238 F. Supp. 2d 876, 892 (E.D. Mich. 2002) ("The issue of whether a defendant owes a plaintiff an actionable duty is a question of law to be decided by the court.") (citing *Antcliff v. State Employees Credit Union*, 414 Mich. 624, 327 N.W.2d 814 (1982)).

Michigan has adopted and follows the learned intermediary doctrine, which holds that a manufacturer has no duty to warn the ultimate consumer if the product is provided for use by a sophisticated consumer. *Brown*, 209 Mich. App. at 148. This

doctrine has been expressly applied in the prescription drug and medical device context, with the result that adequate warnings are owed to physicians and surgeons and not to their patients:

> We now hold that the reasoning and policy behind the learned intermediary rule applies not only to prescription drugs, but also to prescription devices such as dialysis machines. Under the learned intermediary rule, the hospital or physician was the proper recipient of necessary information or warnings, not plaintiff.

Id. at 149. *See Tice v. Zimmer Holdings, Inc.*, No. 15-cv-134, 2015 WL 4392985, at *5-6 (W.D. Mich. July 15, 2015) (denying defendants' motion to dismiss and holding that the learned intermediary doctrine did not bar plaintiff's failure to warn claims where defendants had a duty to provide adequate warnings to plaintiff's physicians). Thus any duty in this case would be one owed to practitioners and surgeons, not to Mr. Avendt.[6]

In essence then, Plaintiffs assert that Covidien insufficiently tested and then marketed Permacol as a "biologic mesh," when in fact Permacol, due to its cross-linking, performs like a synthetic mesh. Plaintiffs argue that this characteristic of

[6] Plaintiffs also assert, as part of their failure to warn claim, a "failure to test" claim. "A manufacturer's duty of reasonable care includes a duty of product inspection and testing during and after the course of manufacture as is reasonably necessary to render the product safe for its users." *Taylor v. Wyeth Laboratories, Inc*., 139 Mich. App. 389, 296 (1984). Plaintiffs' failure to test claim under the circumstances of this case stands or falls with Plaintiffs' failure to warn case. *Rodriguez v. Stryker Corp*., 680 F.3d 568, 574 (6th Cir. 2012) (finding that failure to test claim "collapses into the failure-to-warn" claim). In any event, as discussed *infra*, Plaintiffs have no expert testimony to support a failure to test claim.

Permacol to behave like a synthetic mesh, which Plaintiffs claim was not sufficiently studied and disclosed by Covidien, caused Mr. Avendt's injuries. Plaintiffs summarized their claim in their summary judgment response brief as follows:

> Permacol's cross-linked nature caused it to behave like a synthetic mesh when implanted into Mr. Avendt (i.e., failed to ingrow with the host tissue) and it was therefore unable to clear Mr. Avendt's infection. In essence, Covidien sacrificed quick ingrowth for the ability to be able to characterize Permacol as "durable." When patients develop infections with a synthetic mesh, there is a high probability that the patient will have to undergo additional surgery to explant the synthetic device, as it is unable to clear the infection due to its synthetic composition. Therefore, the surgical advantage of using a biologic mesh is that if the patient's wound becomes infected, the infection can be treated without reoperation; the implant should dissolve on its own and go away leaving the patient with a recurrent hernia, but not a chronic infection problem. . . . . This defect – the propensity of the Permacol to exhibit characteristics normally associated with a synthetic mesh in an abdominal wall repair surgery – [which was known to Covidien and about which Covidien failed to warn consumers] should have been discoverable through testing [and proximately caused Mr. Avendt's injuries].

(ECF No. 178, Pls.' Resp. to Mot. Summ. J. 17-18, 22, 23 (alteration added)).

In support of this theory of liability, Plaintiffs seek to have Dr. Rosen, Plaintiffs' only proposed medical expert who did not file an expert report and is testifying only as a treating physician in this case, offer the opinion that Permacol was not reasonably safe to use in 2009 because it behaves like a synthetic mesh due to its cross-linking and thus was the cause of Mr. Avendt's chronic non-healing wound. (ECF No. 232, Pls.' Supp. *Daubert* Br. 12, PgID 7077). Plaintiffs' claims cannot

survive summary judgment if the Court concludes that Dr. Rosen's opinions fall outside the scope of his care and treatment of Mr. Avendt and/or are inadmissible under *Daubert*.

A. Dr. Rosen's Opinion That Permacol Was Not Reasonably Safe For Use in 2009 Due to Its Cross-linked Structure is Inadmissible

As an initial matter, as discussed *supra* and at length in this Court's prior Opinion and Order, the Court has concluded that Dr. Rosen, who did not file a Rule 26(a)(2)(B) expert report in this case, will be limited to testifying as a treating physician and therefore limited to those opinions that were formed for purposes of, and within the scope of, his care and treatment of Mr. Avendt. While Dr. Rosen may have held the opinion, in 2009 when he operated on Mr. Avendt, that Permacol was not reasonably safe for use, this opinion certainly was not formed "for the purpose of" or "within the scope of" his care and treatment of Mr. Avendt. Further, Dr. Rosen concedes that none of his medical records mention Permacol, that he never told Dr. Ash or any of his colleagues that Mr. Avendt had a defective Permacol mesh, that he never reported Mr. Avendt's case to the FDA MAUDE database, that he never told Mr. Avendt during the course of treatment that he believed the Permacol placed by Dr. Ash was defective or that it caused his injuries, and Dr. Rosen never performed, or caused to be performed, any follow-up testing on the Permacol mesh. (Rosen Dep. 118:13-16; *Daubert* Tr. 61:1-23.) Dr. Rosen found a piece of Permacol mesh in a bed

of pus, removed the Permacol and treated the infection. Dr. Rosen had no need to form any opinion regarding whether Permacol was safe for use in 2009 in order to diagnose and treat Mr. Avendt's chronic nonhealing wound and infection. His opinion regarding the safety of Permacol due to its cross-linking was unnecessary to, and was not formed for purposes of, his care and treatment of Dr. Rosen.

Even if this opinion was formed for purposes of Dr. Rosen's care and treatment of Mr. Avendt, and even if Dr. Rosen's clinical experience with mesh products qualifies him to offer an opinion regarding the safety of Permacol due to its cross-linking, his opinion that in 2009 Permacol was not safe for use in Mr. Avendt's Class I wound due to its cross-linked structure is not supported by the application of generally accepted (or even personally accepted) reliable scientific principles or methods.

Dr. Rosen has repeatedly expressed the view in written peer-reviewed publications that Permacol is acceptable to use in a Class I wound, although personally he prefers other "less expensive" and "more durable materials" that are available for use in a Class I wound. (*Daubert* Tr. 10:11-19, 10:14-16.). Dr. Rosen admits that he has never authored an article stating that Permacol is not reasonably safe for use in a Class I wound and has never recommended to anyone in the medical community in any publication that surgeons should not use Permacol in a Class I

wound. (*Daubert* Tr. 25:24-26:5.)

As discussed at greater length, *supra*, the following peer-reviewed articles and opinions expressed by Dr. Rosen contradict his now proffered opinion that in 2009 Permacol was not reasonably safe for use in a Class I clean wound and undermine the reliability of such an opinion:

- In 2009, just prior to Mr. Avendt's surgery, Dr. Rosen co-authored an article in which Dr. Rosen and his colleagues conclude that: "Based on the available literature and the review of the FDA MAUDE database, it seems reasonable to conclude that cross-linked meshes seem to behave reasonably well in clean [Class I] and clean-contaminated [Class II] cases." (*Daubert* Tr. 22:8-18; "Major Complications" at 327, PgID 6915.) The article goes on to suggest that "the effect of cross-linking on infected and contaminated ventral hernia repair remains largely unknown at this time and requires careful evaluation," but makes no similar statement suggesting the same unstudied consequences when Permacol is used in Class I and Class II wounds needed further study. (*Daubert* Tr. 22:19-23; "Major Complications" at 327, PgID 6915.) While Dr. Rosen attempted to back away from these conclusions by noting the limited amount of data that was available at the time, he does not dispute the conclusions that were reached and published in this peer-reviewed journal.

- In January, 2010, the same month that Dr. Rosen operated on Mr. Avendt, Dr. Rosen published a peer-reviewed article that he co-authored titled "Biological Mesh for Abdominal Wall Reconstruction: A Critical Appraisal," which purported to review the then-available peer-reviewed publications discussing biological grafts for abdominal wall reconstruction, and informs surgeons reading this peer-reviewed article, that "Permacol seems to behave reasonably well in clean cases, Class I wounds." (*Daubert* Tr. at 13:12-14:6, 19:1-17; Joint Exhibit List Ex. 1.)

- In 2012, Dr. Rosen co-authored an article in the peer-reviewed publication Plastic and Reconstructive Surgery titled "The Biology of Biologics: Basic Science and Clinical Concepts," in which the authors conclude that: "Permacol seems to behave reasonably well in clean cases: however, the effect of cross-

linking on infected and contaminated ventral hernia repair remains largely unknown at this time and requires careful evaluation."

- In 2013, Dr. Rosen co-authored an article titled "Abdominal Wall Reconstruction," in the publication "Current Problems in Surgery." (*Daubert* Tr. 40:11-25; Joint Exhibit List, Ex. 6, C.D. Butler, D. Bauman, J. Janis, M. Rosen, "Abdominal Wall Reconstruction," Current Problems in Surgery 50 (2013) 557-586.) The authors of this article conclude that a number of biologics, including Permacol, "appear to tolerate placement in a clean-contaminated field," – a Class II wound. (*Daubert* Tr. 41:11-25.)

- Dr. Rosen also testified at the *Daubert* hearing that he has recommended and used a certain type of "large pore" synthetic mesh, which never remodels in the body as a biologic mesh is designed to do, in Class II and Class III wounds. (*Daubert* Tr. 26:11-27:5.) Dr. Rosen expressed this opinion in a 2013 article published in the Journal of American College of Surgeons and in a 2015 podcast, i.e. that a "large pore" synthetic mesh would be safe and reasonable to use in Class II (clean contaminated) and even Class III (contaminated) wounds. (*Daubert* Tr. 27:6-28:9; Joint Exhibit List Ex. 4, August 3, 2015 Behind the Knife: The Surgery Podcast – Audio, Ex. 5 "Outcomes of Synthetic Mesh in Contaminated Ventral Hernia Repairs," J. Am. Coll. Surg. 2013: 217:991-998 (Dec.).) Specifically, Dr. Rosen acknowledged at the *Daubert* hearing that he advised in the 2015 podcast that if he encountered a surgical situation in which he nicked the bowel but observed no spillage (the situation that Dr. Ash testified he believed may have occurred when he implanted Permacol in Mr. Avendt), it would be "perfectly appropriate" to use "a lightweight polypropylene mesh." (*Daubert* Tr. 27:15-28:11; Joint Exhibit List, Ex. 4, 2015 Podcast PgID 6930.)

Plaintiffs adamantly assert that Mr. Avendt's wound was a Class I clean wound in December, 2008, when Dr. Ash implanted the Permacol, and was still a Class I clean wound in May, 2009, when Dr. Ash reoperated to drain a seroma and left the Permacol in place. In multiple peer-reviewed publications, including the MAUDE database article that Dr. Rosen co-authored shortly before Mr. Avendt's surgery, and

in his deposition and at the *Daubert* hearing, Dr. Rosen agreed that Permacol is appropriate for use whenever it would be appropriate to use a synthetic, i.e. in a Class I wound situation. There is no criticism by Dr. Rosen, or in any of the medical literature in evidence, of Permacol for use in a Class I wound (apart from its price point) and Dr. Rosen's own research and publications, discussed at length *supra*, support the conclusion that Permacol is appropriate for use in a Class I wound (and in fact even in a Class II "clean contaminated" wound). Even assuming the validity of the criticism of Permacol advanced by the Plaintiffs, i.e. that it acts like a synthetic mesh rather than a non-cross-linked biologic, there can be no claim that Permacol was defective when it was used in precisely the situation, i.e. a Class I wound, that calls for a product with the properties of a synthetic mesh. Dr. Rosen's opinion that "Permacol behaved like a synthetic mesh," even if scientifically valid and supportable under Rule 702, simply does not get Plaintiffs across the finish line on their claim that this characteristic rendered Permacol unsafe for use in a Class I wound.

Plaintiffs continuously criticize Permacol's "inability to clear Mr. Avendt's infection," and Permacol's "propensity to exhibit characteristics normally associated with a synthetic mesh," but there is no dispute that a synthetic mesh would have been wholly appropriate for placement in a Class I clean wound. If Dr. Ash had placed a synthetic mesh in a Class I wound (perfectly appropriate and Dr. Rosen's standard

practice) and the site became infected, it would not be because the mesh was defective. Because Plaintiffs claim that Dr. Ash implanted (and left) Permacol in a Class I clean wound, and because Plaintiffs' own expert and his supporting research and publications unequivocally indicate that Permacol is appropriate for use in a Class I clean wound (and even in a Class II clean contaminated wound), Dr. Rosen's opinion that Permacol was unsafe for use in Mr. Avendt's Class I wound in 2009 due to its cross-linked nature blatantly contradicts his own peer-reviewed publications and is not the product of generally accepted (or even personally accepted) reliable scientific principles or methods and is inadmissible.

B. Any Opinion That Dr. Rosen May Seek to Offer Related to the Sufficiency of the Testing of Permacol or the Adequacy of the Warnings in the Permacol IFU Is Indamissible

Plaintiffs seek to have Dr. Rosen opine to the jury that Permacol was improperly vetted before being marketed as a biologic mesh product, resulting in an inadequate warning to practitioners like Dr. Ash about using Permacol in "challenging environments." At the *Daubert* hearing, Plaintiffs' counsel elicited the following testimony from Dr. Rosen:

> And so [biologic mesh products are] very, very difficult to predict their behavior when placed in challenging environments. . . . In my opinion, based on what I understand about cross-linking mesh and having seen many cross-linked failures in our research, [the cause of the product failure] is the fact that the unpredictable behavior and unstudied behavior of the material resulted in the surgeon at the time when he placed that

> material and suffered a complication from it, was not really informed on exactly what to do and left behind a piece of mesh that, ultimately, did not become incorporated. We came back, it was covered in pus and resulted in now what in my opinion is the hardest hernia to fix [which] is a CDC Class IV wound with a very large defect.

(*Daubert* Tr. 107:9-11, 108:7-16.)

This is the *real* opinion that Plaintiffs seek to have Dr. Rosen place before the jury in this case – that the cause of Mr. Avendt's inability to heal and properly incorporate the Permacol mesh was Dr. Ash's decision in May, 2009, "to le[ave] behind a piece of mesh that, ultimately, did not become incorporated." But Dr. Rosen does not blame Dr. Ash for this decision – he blames Covidien for failing to adequately warn Dr. Ash about how he should have proceeded in May, 2009, when he reoperated on Mr. Avendt to drain a seroma. However, this opinion, regardless of its potential reliability and relevance, is completely unrelated to Dr. Rosen's care and treatment of Mr. Avendt and most certainly was not formed for purposes of, or within the scope of, his treatment of Mr. Avendt. Such an opinion appears nowhere in the records of Dr. Rosen's care and treatment of Mr. Avendt, indeed Permacol is not even mentioned in those medical records. As discussed *supra*, and in this Court's April 19, 2016 Opinion and Order excluding certain aspects of Dr. Rosen's proffered testimony and setting a *Daubert* hearing, Dr. Rosen is limited in this case to testifying in his capacity as Mr. Avendt's treating physician and therefore is limited to those opinions

that were formed for purposes of, and within the scope of, his care and treatment of Mr. Avendt. In order to proffer Dr. Rosen's "opinion" about the vetting of Permacol's design and the adequacy of the Permacol warnings, Plaintiffs were required to have Dr. Rosen prepare a Rule 26(b)(2)(B) expert report setting forth the scientific or experiential basis for this theory, and giving Covidien the opportunity to properly defend against such a theory with experts of its own. This prerequisite was not met. For this reason, Dr. Rosen is precluded from offering any opinion about the insufficiency of Covidien's "vetting" of Permacol or about the adequacy of the warnings in the Permacol IFU.

Even if Dr. Rosen were permitted to offer such an opinion, there is insufficient evidence on this record establishing the reliability and relevance of his opinions on the adequacy of the Permacol IFU warnings and no basis to conclude that different warnings in the Permacol IFU would have changed Dr. Ash's decision to use Permacol in this case. First of all, in his numerous peer-reviewed publications, discussed at length *supra*, concluding that Permacol performs reasonably well in Class I (and even Class II) wounds, nowhere does Dr. Rosen advise against using Permacol in Class I wound because of the potential that a Class I wound may, in certain patients, "evolve" into a Class III or Class IV wound. While these publications expressly conclude that further study of the use of cross-linked mesh in Class III and Class IV

wounds is necessary, *none* of these publications suggests that further study is necessary before Permacol can be used in a Class I wound, which is how it was used here according to the Plaintiffs. Indeed Dr. Rosen testified that Permacol would be appropriate (although costly) anytime a synthetic mesh would be appropriate (Class I wounds).[7]

Although the reasonableness of a warning is generally a question for the jury, the question of duty is one for the Court and juries cannot be left to speculate that a manufacturer should have known and warned about a particular harm. *Mitchell*, 803 F.3d at 230. Plaintiffs offer insufficient evidence on which a reasonable juror could conclude exactly *what more* the Permacol IFU *should* have said that would have dissuaded Dr. Ash (even assuming that Dr. Ash read it, which he testified he did not) from implanting it in December, 2008, and leaving it in place in May, 2009. Plaintiffs argue that the Permacol IFU should have warned practitioners "to remove Permacol in the event of a seroma or an infection." But there is no expert opinion in the record, including from Dr. Rosen, that would permit a reasonable juror to conclude that Covidien had a duty to provide this particular directive in its IFU. When asked specifically whether it was his opinion that the Permacol IFU should direct users to

[7] In fact Dr. Rosen's more recent published articles suggest that a certain class of large pore synthetics may perform reasonably well even in Class III and Class IV wounds.

remove Permacol in the event of a seroma or infection, Dr. Rosen responded only that "there should be more information" about the type of cases and the types of hernias where cross-linked biologics should be used:

> Q: Did Doctor – did the instructions for use direct users to remove Permacol in the event of a seroma or an infection?
>
> A: I'm not aware that it says that, no.
>
> Q: Is it your professional opinion now that it should say that?
>
> A: It's my professional opinion that there should be more information to inform that IFU particularly for the type of cases and the type of hernias that these products are being placed in, and that should be able to be informed [sic] of surgeons who are putting this in human beings so that we can predict to some reasonable degree what might happen.
>
> Q: Is it your opinion that Permacol should have sufficient labeling to inform a doctor of these side effects?
>
> A: In the absence of a prospective clinical trial that's better than the MAUDE database, that disputes this data in a well-designed trial that I think this should be made much more clear to surgeons who are putting this in people . . . .

(*Daubert* Tr. 115:1-20.) Dr. Rosen absolutely did not agree with Plaintiffs' counsel that the Permacol IFU should direct a practitioner to remove Permacol in the face of a seroma or infection. He agreed only that "there should be more information" – of an unspecified type – regarding "side effects." But in fact, the Permacol IFU warns of precisely the "side effects" that Mr. Avendt suffered. The Permacol IFU warns that "[i]f [Permacol] is used in a contaminated or infected wound this may lead to a

weakening or breakdown of the implant" and further warns that "exposure to high concentrations of digestive enzymes may lead to a weakening or breakdown of the [Permacol] implant." (Def.'s Mot. Summ. J. Ex. E, Permacol Surgical Implant, Instructions for Handling and Use PgID 4172.) Dr. Rosen testified that he was surprised by this contraindication in the Permacol IFU and found it odd for a biologic mesh, which is typically marketed as a better alternative than a synthetic mesh in the presence of contamination, yet there it was, right in the Permacol IFU:

> Q: Did you remember anything in the IFU that you felt was just wrong?
>
> A: . . . I will tell you that there was terminology in it that I recall about either a warning or a contraindication in the presence of infection or contamination. . . . It certainly made me feel like when surgeons reached for a biologic mesh, that is not what they thought would be a warning or an indication.

(Rosen Dep. 63:9-22.)

Plaintiffs have provided no evidence that would support the opinion they seek to put before a jury that the Permacol IFU should have directed practitioners to remove Permacol in each instance of a seroma (which Mr. Avendt presented with in May, 2009) or infection (which Mr. Avendt did not have either at the time of his December, 2008 surgery or his May, 2009 surgery). In fact, Dr. Ash had another patient, a woman with a smaller defect than Mr. Avendt, who experienced the same issues with seroma formation and expulsion of Permacol that Mr. Avendt experienced.

(Ash Dep. 42:3-44:16.) This woman was able to be treated conservatively and non-operatively and her wound ultimately healed on its own, allowing Dr. Ash to do a successful hernia repair one year later. This single case is anecdotal and isolated to be sure but evidence nonetheless that removal of the Permacol would not have been the appropriate directive for that patient. In short, Plaintiffs have proffered no scientifically reliable peer-reviewed opinion that the Permacol IFU should have directed practitioners to remove Permacol in the face of a seroma or an infection.

Plaintiffs also seek to have Dr. Rosen offer the related opinion that Covidien should have conducted a randomized prospective human clinical trial before making Permacol available to surgeons, which, according to Plaintiffs, would have enabled Covidien to provide a more helpful warning to practitioners. There is insufficient evidence in the record to establish that this was the "standard of care" for taking a medical device to market in 2009 such that Covidien had a duty to conduct such a trial before making Permacol available to practitioners. Indeed Dr. Rosen testified he "would always love to see a randomized controlled trial on any material that is being released," but "that's a bar that probably no material can actually achieve – or has achieved . . . ." (*Daubert* Tr. 99:25-100:10.) Despite the lack of prospective clinical trial on the effects of Permacol, Dr. Rosen also acknowledges that one of the advantages of Permacol is that it has a significant number of clinical trials associated

with it, unlike other biologics that have "zero." (*Daubert* Tr. 139:4-7.) These other biologics that have "very few clinical trials" include Strattice, a mesh product that Dr. Rosen has used himself in his clinical practice at the Cleveland Clinic. Indeed, Dr. Rosen testified at the *Daubert* hearing that at the time of Mr. Avendt's surgery, there were no peer-reviewed animal or human data available for Strattice, the biologic that Dr. Rosen testified would have been the best alternative for a Class II or Class III wound in 2009. (*Daubert* Tr. 36:24:37:9.) Plaintiffs' assertion that Covidien should have performed a prospective "adequate clinical trial" on Permacol before releasing it to market seeks to hold Covidien to a standard that Plaintiffs' own expert concedes is not a realistic bar. The issue of duty is one for the Court, *Mitchell*, 803 F.3d at 230-31, and Court finds insufficient evidence in this record to conclude that Covidien had a duty to perform a prospective randomized clinical trial on Permacol before seeking 510(k) approval and marketing Permacol to practitioners.

Finally, there is no evidence in this case that Dr. Ash read or relied on the Permacol IFU. Prior to using the Permacol mesh on Mr. Avendt, Dr. Ash may have read a "brochure from Covidien" or "looked at some throw away material," but had not "met with the rep or had any formal education," reviewed the product literature or read any peer-reviewed materials about the Permacol product. (*Id*. at 25:7-26:11.) Nonetheless, Dr. Ash felt that he was well educated and informed on the use of

biologics and qualified to use a product such as Permacol during a case if needed. (*Id*. at 61:21-62:2.) The decision to use Permacol was completely Dr. Ash's decision. Dr. Ash testified that the Covidien representative, "Matt Aris would never make that decision." (*Id*. at 34:1-6.) Dr. Ash may have read some promotional literature about Permacol but had never discussed Permacol with any of the product representatives prior to using it on Mr. Avendt. (*Id*. at 25:13-21.)

As discussed *supra*, sometime after the May, 2009 operation, but before referring Mr. Avendt to Dr. Rosen, Dr. Ash presented Mr. Avendt's case at an Abdominal Wall Reconstruction Conference in Washington, D.C. (Ash Dep. 38:5-11.) Representatives from Covidien were present, and Dr. Rosen was a member of the open-mike panel. Dr. Ash said he got at least "five different opinions" from this panel of experts about how to proceed. (*Id*. at 38:15-40:12.) The Covidien representative asked Dr. Ash to send him more information on Mr. Avendt's case but Dr. Ash never did provide the information because the Covidien sales representative, Matt Aris, who provided Dr. Ash with the Permacol for the 2008 surgery "had already been given all the information." (Ash Dep. 41:3-16, 73:22-74:25.)

Dr. Ash recorded, in a July, 2009 clinic note, that he had "vetted" Mr. Avendt's case with multiple specialists to discuss the proper course of treatment for Mr. Avendt:

> 07/13/09, Robert Avendt. He is in for follow up on his wound. We have vetted his operation with multiple specialists at multiple different conferences over the last month and the prevailing thought processes consist of two choices. One is that we take him back and clean out this area of the remaining Permacol, do a temporary closure versus a separation of components and primary closure. The second idea is to let him finish the Permacol expulsion which I believe he is close to doing, let the wounds close up and make a plan to move ahead with a primary repair with separation components and mesh placement of nonbiological nature.

(ECF No. 117, Sealed Exhibit 1 to Def.'s Mot. Summ. Judg., Ash Treatment Notes PgID 4220.) Ultimately, Dr. Ash elected to go with the second "consensus" option and decided to let the process of Mr. Avendt "expelling this biological mesh from his wound" continue to work itself through. When Mr. Avendt's hernia recurred again, Dr. Ash referred Mr. Avendt to Dr. Rosen, "a leading national expert on hernia repair," to allow Dr. Rosen "to fix [Mr. Avendt's] recurrent recurrence." (Def.'s Mot. Summ. J., Ex. A, Ash Treatment Notes PgID 4220; Ash Dep. 21:2-8, 35:10-25.)

Dr. Ash did not read the Permacol IFU before deciding to implant it or leave it in Mr. Avendt because he felt that it was unnecessary – he felt that his knowledge of the product was such that he did not need to consult the IFU. "Under these circumstances no failure to warn claim will lie." *Eiben*, 2013 WL 1721677, at * 17-18.

Dr. Rosen's opinion regarding the "vetting" of Permacol and the adequacy of its warnings were not formed for the purpose of, or within the scope of his care and

treatment of Mr. Avendt, and are inadmissible for this reason alone. Even were such an opinion otherwise admissible in this case, Plaintiffs have offered no scientifically reliable peer-reviewed opinion to support their claim that Defendant had a duty to include in the IFU an instruction to surgeons that Permacol should be removed in the presence of a seroma or infection. Finally, even assuming Plaintiffs could establish some type of informational defect, Plaintiffs cannot prove causation on any failure to warn theory because Dr. Ash testified that he never read the Permacol IFU and chose to use Permacol based on his general knowledge of the product and decided to let the process of expulsion continue based on his "vetting" the issue with numerous specialists. Accordingly, Defendant is entitled to summary judgment on Plaintiffs' failure to warn claim.

C. Dr. Rosen's Opinion That Permacol's Cross-linking, and Tendency to Behave Like a Synthetic Mesh, Caused Mr. Avendt's Chronic Nonhealing Wound and Class IV Wound is Inadmissible

Plaintiffs assert that when Dr. Rosen operated on Mr. Avendt in January, 2010, Dr. Rosen, having "[t]aken care of hundreds of mesh infections," observed the Permacol, a 'foreign body not incorporated into the tissue, sitting in a bed of pus,' and "visually inspected the mesh and concluded that the mesh was the cause of Mr. Avendt's infection because Mr. Avendt's infection cleared upon removal of the remaining unincorporated mesh." (ECF No. 232, Pl.'s Supp. *Daubert* Br. 20, PgID

7085.) There can be no question that Dr. Rosen, given his vast experience with failed and infected hernia repairs, knows an infected mesh when he sees it. But "the ability to diagnose medical conditions is not remotely the same . . . as the ability to deduce . . . in a scientifically reliable manner, the causes of those medical conditions." *Tamraz*, 620 F.3d at 673-74 (internal quotation marks and citation omitted). Dr. Rosen testified at the *Daubert* hearing and in his deposition that obesity, diabetes, hypertension, immunosuppressant drug therapy and prior abdominal surgeries are known to negatively affect wound healing. (*Daubert* Tr. 73:22-79:13; Rosen Dep. 43:22-44:2.) Dr. Rosen testified in his deposition that "ultimately most hernia operations come down to good wound healing." (Rosen Dep. 46:17-19.) Although Dr. Rosen did a good bit of dancing around the issue, his testimony revealed that while he knew generally that Mr. Avendt was an obese diabetic, he did not know, and did not consider and/or rule out the causative effect of, Mr. Avendt's BMI or his glucose levels or any details relating to his blood pressure history or any use of immunosuppresants, either at the time he operated on him or at the time Dr. Ash operated on him. (*Daubert* Tr. 73:22-79:13.) Dr. Rosen suggested that he typically is aware of glucose numbers before operating and was sure he had that value then, but could not locate the value in the medical records nor could Dr. Rosen recall what those levels were. (*Daubert* Tr. 82:5-23.)

Although Plaintiffs' counsel attempted to elicit a different opinion from Dr. Rosen at the *Daubert* hearing, Dr. Rosen explicitly acknowledged in his deposition that general awareness of these comorbidities and conditions is insufficient to enable him to determine their effect on wound healing. In his deposition Dr. Rosen stated specifically that in order to answer the question posed to him, i.e. whether Mr. Avendt's obesity and diabetes affected his wound healing, Dr. Rosen would need to know specifically what Mr. Avendt's glucose numbers and his BMI were. (Rosen Dep. 94:12-22.) At his deposition, Dr. Rosen was specifically asked whether he had any opinion whether or not Mr. Avendt has difficulty healing. He responded that he did not have any opinion on the subject of Mr. Avendt's ability to heal and would need to know "what his HbA1c is, what his glucoses were and what his actual BMI is" in order to answer that question. (Rosen Dep. 93:12-21, 94:12-25.) Dr. Rosen did not know this information at his deposition and he did not know this "necessary" information at the *Daubert* hearing. Even Dr. Ash, shortly after the May, 2009 surgery, observed that "[n]o one is going to feel comfortable operating [on Mr. Avendt] for these problems until his BMI <35." (Def.s' Mot. Summ. Judg. Ex. A, Ash Note 7/13/09 PgID 4220.) And Dr. Rosen testified in his deposition that he personally prefers not to operate on obese individuals, because of the increased risk of complications: "I prefer not to operate on obese patients. I mean, I'll be clear on

that. . . . It's technically harder, they have more tissues. Whether it results in longer term more failures, I'm not a hundred percent sure, but certainly shorter term more issues." (Rosen Dep. 45:8-16.)

Dr. Rosen also acknowledged that his own published textbook, titled Atlas of Abdominal Wall Reconstruction, instructs that patients with prior abdominal surgeries, such as Mr. Avendt, have an increased risk of infection: "Prior studies have demonstrated an increased risk of infection in patients with an abdominal hernia. Although many of these operations appear at first glance to be "clean" operations, they are, in fact, more susceptible to infection. . . . In patients with a prior abdominal repair, the risk of infection continues to increase 43 percent versus 12 percent." (Joint Exhibit List, Ex. C, Michael J. Rosen (editor), Atlas of Abdominal Wall Reconstruction, Elsevier 2012 at 210.) Indeed, as Dr. Rosen acknowledged at the *Daubert* hearing, Mr. Avendt's wound became infected after Dr. Rosen and Dr. Salgado's surgery, when there was no mesh involved at all. (*Daubert* Tr. 80:20-24.)

"A court must examine for itself whether the expert properly considered other potential causes for the plaintiff's injuries." *Harvey v. Novartis Pharm. Corp*., 895 F. Supp. 2d 1206, 1210 (N.D. Alabama 2012). Plaintiffs have not presented sufficient evidence for a jury to conclude that Dr. Rosen considered and ruled out Mr. Avendt's significant comorbidities, each of which is known to negatively affect wound healing,

in reaching the conclusion that the Permacol mesh, and not Mr. Avendt's individual immunological response to the Permacol mesh, caused his non-healing wound. A single case in point is the outcome of Dr. Ash's female patient, who experienced the same "occurrence" as Mr. Avendt experienced with the Permacol mesh, but whose situation fully resolved with conservative, non-operative treatment followed by a successful hernia repair. (Ash Dep. 42:3-44:16.) Dr. Rosen's testimony gives a jury no scientifically reliable basis for determining why Mr. Avendt developed a chronic non healing wound that developed into an infection when other patients do not. Indeed, Dr. Rosen admits that he is not an expert in the body's immunological response to mesh products and for that reason the Court has previously precluded him from offering any such opinion in this case.

"If a court concludes that the evidence supporting the expert's position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, then the court remains free to prohibit the case from proceeding to the jury." *Glaser*, 32 F.3d at 972. While Dr. Rosen's published articles often conclude that the effects of cross-linking are "largely unknown," Dr. Rosen purports to "know" that effect here, but fails to support this conclusion with the caliber of evidence required under Rule 702 that would give a jury a reasonable basis to conclude that the Permacol mesh, and not Mr. Avendt's own immunological response to that mesh due

to his multiple comorbidities, caused his non-healing wound. "[T]here is simply too great an analytical gap between the data and the opinion proffered." *Mitchell*, 803 F.3d at 230-31. "Mere possibility . . . cannot establish a fact to the degree of certainty necessary to justify reliance on that fact." *Id*. at 230. The failure to consider other possible causes in Mr. Avendt's case is a "red flag" of unreliability. *Rheem*, 527 F. App'x at 437; *Amerson v. Stechly*, No. 12-10375, 2015 WL 6436341 (E.D. Mich. Oct. 22, 2015) (where treating physician did not testify that he considered alternative causes consistent with plaintiff's symptoms or that he employed any method to determine alternative causes were less likely, his testimony was excluded under 702.) Dr. Rosen conceded that there was no way to test his theory of causation in this case, comparing his conclusion to what an individual perceives in a piece of art – "you can't do statistics for art," and "you can't do statistics for one case." (*Daubert* Tr. 83:15-84:6.) "Dr. [Rosen] may be a 'distinguished' doctor, and 'his conjecture' about causation may 'worthy of careful attention. . . . But the courtroom is not the place for scientific guesswork, even of the inspired sort." *Tamraz*, 620 F.3d at 671.

V. CONCLUSION

Dr. Rosen has been limited to testifying in this case to those opinions that were formed for purposes of, and within the scope of, his care and treatment of Mr. Avendt. When Dr. Rosen operated on Mr. Avendt he diagnosed a mesh infection and he

treated that infection. He did not endeavor to, and he did not need to, determine the cause of that mesh infection in order to treat Mr. Avendt. Indeed, none of Dr. Rosen's treatment records even mention Permacol or cross-linking and Dr. Rosen never mentioned to Mr Avendt that Permacol may have been the cause of his non-healing wound. Dr. Rosen's proffered opinions that Permacol was not reasonably safe for use in Mr. Avendt's Class I wound, or that the Permacol IFU was inadequate, or that the cross-linking of Permacol caused Mr. Avendt's non-healing wound, fall well outside the scope of his care and treatment of Mr. Avendt. Such opinions are inadmissible in this case for that reason alone.

Even were such opinions within the permissible scope of Dr. Rosen's testimony in this case, the proffered opinions fail to pass scrutiny under *Daubert* on the evidence in this record. "As the proponent of the expert testimony, [Plaintiffs] bore the burden of establishing that [Dr. Rosen's] testimony met the requirements of Rule 702." *Thomas v. Novartis Pharmaceuticals Corp*., 443 F. App'x 58, 61 (6th Cir. 2011). Plaintiffs have failed to meet that burden here. Even if Plaintiffs had established a jury submissible theory of product defect (which they have not), they have proffered no scientifically reliable peer-reviewed opinion on which a jury could reasonably conclude that it was more likely than not that Permacol caused Mr. Avendt's chronic non-healing wound.

Dr. Rosen, while admittedly an eminently qualified clinician and surgeon with a significant amount of clinical experience with abdominal wall reconstruction, has not reliably applied his proposed methodology to the facts of this case and cannot therefore offer his proposed opinion that the cross-linking of Permacol caused Mr. Avendt's injuries in this case. There is simply no evidence that Dr. Rosen made a scientifically reliable determination at the time of Mr. Avendt's 2009 surgery as to whether cross-linking, alone or in combination with Mr. Avendt's multiple comorbidities that are known to negatively affect wound healing, caused Mr. Avendt's injuries. In addition, there is no evidence in this case that Dr. Ash relied on the Permacol IFU that Plaintiffs claim was deficient.

Plaintiffs have failed to proffer expert evidence, sufficient under *Daubert*, to support their contention that Permacol, or specifically the cross-linking of Permacol, caused Mr. Avendt's injuries in this case. This requires the Court to grant Defendant's motion for summary judgment. *See Schaendorf*, 2009 WL 563904, at *8 ("expert testimony is indispensable to prove causation where it is to the scientific community that the law must look for the answer"); *Thomas*, 443 F. App'x at 63 (finding that specific causation is "an essential element" of a products liability claim, and concluding that summary judgment was appropriately entered where plaintiff's treating physicians were precluded from giving expert opinions regarding specific

causation).

For these reasons, the Court GRANTS Defendant's Motion for Summary Judgment (ECF No. 116). The Court also DENIES Plaintiffs' Motion for Summary Judgment as to Liability (ECF No. 109) and DENIES as MOOT Defendant's Motions to Exclude the Opinions of Robert Ancell (ECF No. 110) and Defendant's Motion to Exclude the Opinions of David Hammel (ECF No. 113).

Plaintiffs' Complaint is DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

s/Paul D. Borman
PAUL D. BORMAN
UNITED STATES DISTRICT JUDGE

Dated: July 5, 2017

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing order was served upon each attorney or party of record herein by electronic means or first class U.S. mail on July 5, 2017.

s/Deborah Tofil
Case Manager