UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al.*,**
Case No. 2:18-cv-1509

EVIDENTIARY MOTIONS OPINION AND ORDER NO. 13

This Opinion addresses Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Stephen Badylak, D.V.M., Ph.D., M.D. (ECF No. 96) and Plaintiff's Motion to Strike the Supplemental Opinions and Report of Defense Expert Stephen Badylak (ECF No. 408). For the reasons that follow, Plaintiff's motions are both **GRANTED IN PART AND DENIED IN PART**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs.

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

The Food and Drug Administration ("FDA") cleared it for use through the premarket notification 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. *Id.* at *4. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *2–4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. *Id.* at *13. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25.

Plaintiff filed a motion to exclude Dr. Badylak's opinions and testimony based on Dr. Badylak's initial expert report. (ECF No. 96.) Dr. Badylak provided his second supplemental expert report on June 12, 2020, which included opinions related to the presence of the ST coating, a hydrogel coating, on photomicrographs of slides from Defendants' clinical animal study on the Ventralight ST. (ECF No. 408-1 at PageID #21343.) Later, Plaintiff filed a motion to strike Dr.

Badylak's second supplemental report because it contained undisclosed opinions, which the Court denied. (ECF No. 372 at PageID #4838.) However, the Court permitted Plaintiff's expert, Dr. Nagy, to submit a rebuttal report and allowed both Dr. Badylak and Dr. Nagy to be re-deposed on their ST-coating opinions. (*Id.*) Dr. Badylak then submitted a rebuttal report to Dr. Nagy's rebuttal report. (ECF No. 413-5.) Plaintiff filed another motion to strike Dr. Badylak's ST-coating opinions in Dr. Badylak's second supplemental expert report. (ECF No. 408.) Oral argument was held on the motion to exclude and the second motion to strike. (ECF No. 437 at PageID #22661.) The motions to exclude and strike Dr. Badylak's opinions are now ripe for adjudication.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial

so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

Expert testimony, *i.e.* testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be

qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); *see also* Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509

U.S. 579, 591 (1993) (quoting 3 J. Weinstein & M. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Plaintiff argues that some of Dr. Badylak's opinions and testimony from his initial expert report and his second supplemental report are inadmissible. For three reasons, the

Court construes Plaintiff's motion to strike Dr. Badylak's opinions in his second supplemental expert report as a motion to exclude expert opinions and testimony: (1) the nature of his arguments, *i.e.* those under Rule 702; (2) the fact that Plaintiff identifies no other basis for invoking Federal Rule of Procedure 37, *i.e.* no other discovery violations under Federal Rule of Civil Procedure 26; and (3) the Court already declined to strike Dr. Badylak's second supplemental report and opinions as previously undisclosed opinions (ECF No. 372 at PageID #4836).

A. Opinions and testimony in Dr. Badylak's initial expert report

In his *Daubert* motion, Plaintiff argues that four of Dr. Badylak's opinions should be excluded. He contends that Dr. Badylak (1) offers unreliable corporate-state-of-mind opinions on the Material Safety Data Sheets ("MSDSs"), (2) is unqualified to offer case-specific opinions on risk/benefit analysis or the safety and efficacy of the Ventralight ST, (3) is unqualified to offer specific-causation opinions, and (4) is unqualified to offer opinions about the adequacy of the Ventralight ST's Instructions for Use ("IFU"). Dr. Badylak may offer all but his IFU opinion.

1. MSDS state-of-mind opinions

Plaintiff argues that Dr. Badylak's MSDS opinion is inadmissible because he purports to opine on the state of mind of polypropylene manufacturers that created the MSDSs. (ECF No. 96 at PageID #6902.) As an initial matter, Dr. Badylak does not offer a state-of-mind opinion (ECF No. 96-1 at PageID #6927), which would be inadmissible, *e.g.*, *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *23 (S.D.W. Va. Feb. 7, 2015); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 575 (S.D.W. Va. 2014). Rather, he explains that an MSDS is designed to disclose occupational hazards of handling a material, here,

polypropylene. (ECF No. 96-1 at PageID #6927.)

Nevertheless, Dr. Badylak's MSDS opinion is irrelevant. This Court ruled that the Marlex MSDS was only admissible as evidence of Defendants' knowledge and inadmissible hearsay if offered to demonstrate that polypropylene was unsafe for permanent implantation in the human body. *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *4–5 (S.D. Ohio Oct. 20, 2020). Therefore, Dr. Badylak's opinion as to the meaning of MSDSs, specifically that they are not indicative of safety for consumers or end users, is irrelevant to what Defendants actually thought the MSDS meant or what they otherwise knew about the risks of the polypropylene at the time the Ventralight ST was designed and marketed. For this reason, Dr. Badylak's MSDS opinion is inadmissible.

2. Qualifications to give case-specific or specific-causation opinions

Next, Plaintiff argues that Dr. Badylak is unqualified to give opinions relating to "case-specific risk/benefit analysis for the use of polypropylene mesh devices, or their overall safety and efficacy," or specific-causation opinions for Plaintiff. (ECF No. 96 at PageID #6906–07.) Based on this Court's review of Dr. Badylak's expert report, Dr. Badylak does not offer any case-specific or specific-causation opinions. Accordingly, there is no opinion that falls within the ambit of Plaintiff's motion and can be excluded.

Plaintiff counters in his reply brief that if Dr. Badylak does not offer case-specific opinions, then "he should also be precluded from testifying about risk/benefit analysis for the use of polypropylene devices, or their overall safety and efficacy specific to Plaintiff and his medical conditions." (ECF No. 133 at PageID #8648.) But an expert need not give a specific opinion in order to offer a more general opinion, so long as the opinion is

relevant and assists the trier of fact. *See* Fed. R. Evid. 702(a); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016) ("A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case.") Additionally, Plaintiff cannot cast Dr. Badylak's general testimony as specific simply because Dr. Badylak considered at the same phenomena that Plaintiff claims he experienced (contraction and degradation).

Moreover, Dr. Badylak is qualified to offer opinions related to the overall safety and efficacy of the Ventralight ST device. Dr. Badylak is an expert in the field of biomaterials, focusing since 1985 on tissue response to materials, including polypropylene. (ECF No. 96-1 at PageID #6912–13.) His experience studying tissue response is pertinent to this case because it encompasses the reaction of the body to the polypropylene and its ability to integrate into the human body safely, which includes considering adhesion formation, as well as whether there is any evidence that polypropylene degrades in the body. (*Id.* at PageID #6914–26.) Plaintiff points out that Dr. Badylak has no clinical experience with hernia surgery (ECF No. 96 at PageID #6906), but this ignores Dr. Badylak's other medical and research qualifications and experience studying tissue response. *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 731 (N.D. Ohio 2011) ("[I]nsistence on a certain kind of degree or background is 'at odds with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony."' (quoting *Daubert*, 509 U.S. at 588)).

Accordingly, none of Dr. Badylak's opinions are inadmissible as case-specific or specific-causation opinions.

3. Qualifications to offer IFU opinions

Next, Plaintiff argues that Dr. Badylak is not qualified to offer opinions about the adequacy of the Ventralight ST IFU. (ECF No. 96 at PageID #6907.) Plaintiff points to Dr. Badylak's deposition testimony and contends that Dr. Badylak's lack of hernia surgery experience renders him unqualified. (*Id.* at PageID #6907–08.) Plaintiff is correct.

Experts may not testify as to the legal or regulatory adequacy of warnings, but this Court has determined in this case that experts may offer opinions about whether the warnings sufficiently apprised medical doctors of the risks of the Ventralight ST from the vantage point of the end-user. *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *15–17 (S.D. Ohio Sept. 1, 2020); *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605612, at *10 (S.D. Ohio, Sept. 11, 2020). Although an expert opining as an end-user need not have experience with the Ventralight ST specifically, he must have some on-point experience, such as conducting hernia surgeries with mesh devices. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605542, at *16 (holding that Dr. Grischkan was qualified as a hernia surgeon with experience using a variety of mesh devices); *see also In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605612, at *10 (concluding that Dr. Renton was "qualified to testify, as an experienced hernia surgeon, as to the risks he perceives that the Ventralight ST poses to patients and whether those risks were disclosed on the product's warnings"). In other words, experts opining on the sufficiency of warnings from the perspective of an end-user must actually have experience as an end-user. *See Lareau v. Page*, 840 F. Supp. 920, 932–33 (D. Mass. 1993) (concluding that a physician was unqualified to opine on the adequacy of warnings

for a radioactive contrast dye used in the plaintiff's neurosurgery because he was "not himself a neurosurgeon and has never, in the course of his professional practice, ever dealt with the medical decision that faced [the treating neurosurgeon] here"); *see also Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1329 (M.D. Fla. 2015) ("Hyman's lack of medical training *or expertise in the relevant medical specialty* renders him further unqualified to offer an opinion on the adequacy or appropriateness of the G2 filter's warning label." (emphasis added)) (collecting cases).

Dr. Badylak is unqualified to offer an opinion that the IFU is sufficient. In response to Plaintiff's counsel's question whether Dr. Badylak would be offering an opinion as to the adequacy of the IFU, Dr. Badylak responded, "If I'm interpreting your question correctly, I understand it to mean *as a physician*, if I read the IFUs, would I believe that it covered all the potential problems also in relation to what I do for a living. The answer is yes." (ECF No. 96-3 at PageID #6938 (emphasis added).) Dr. Badylak opines, at least in part, as if he were an end-user of the device, but he has no applicable medical experience that would permit him to offer this opinion, either as a hernia surgeon or a medical doctor making similar decisions as a hernia surgeon considering implanting a medical device.

Defendants offer no compelling counterarguments. First, they suggest that Dr. Badylak's involvement at each step of device development, "from concept through development and creation of IFUs, regulatory," is enough to qualify him. (ECF No. 124 at PageID #8398.) This is too general to assess whether Dr. Badylak has other experience that would qualify him to conclude that the Ventralight ST IFU adequately apprised end-users of the risks. For example, it is unclear if Dr. Badylak regularly consulted on the drafting of IFUs, wrote IFUs, or reviewed IFUs. *See Tillman*, 96 F. Supp. 3d at 1329. Second, Defendants argue that medical doctors who are not

surgeons may still opine on surgical issues. (ECF No. 124 at PageID #8399.) This may be true in some circumstances, but of the varied cases that Defendants point to, none permitted a doctor without surgical experience using a similar device to offer opinions on an IFU from the perspective of an end-user. (*See id.* at PageID #8399–8400.)[2] Dr. Badylak cannot offer his IFU opinion.

B. Dr. Badylak's ST-coating opinions and supplemental report

In his motion to strike, Plaintiff contends that four aspects of Dr. Badylak's opinions about the ST coating of the Ventralight ST are inadmissible. Plaintiff argues that judicial estoppel bars Dr. Badylak's opinion that that the ST coating would be present on day 30 after implantation, that his opinion that the ST coating was present on day 28 after implantation is unreliable, that his ST-coating opinions are irrelevant, and that Dr. Badylak is unqualified to opine on the practices or decision-making of hernia surgeons. (ECF No. 408 at PageID #21326–35.) Only part of Dr. Badylak's opinion regarding the practices of decision making of hernia surgeons is inadmissible, however.

1. Judicial Estoppel

Plaintiff argues that Defendants are judicially estopped from offering at trial Dr. Badylak's opinion that the ST coating is present on day 30 due to Defendants' premarket notification 510(k) application to the FDA. (ECF No. 408 at PageID #21326.) Defendants respond that judicial estoppel does not apply to the 510(k) application process and that even if it did, Dr. Badylak's opinion is not clearly inconsistent with Defendants' application. (ECF No. 413 at PageID #21760–62.) Judicial estoppel does not apply to the 510(k) process, and thus it is unnecessary to determine whether Dr. Badylak's opinion

[2] Plaintiff also asserts that Dr. Badylak is unqualified to offer this opinion because he "did not review any medical records pertaining to the bellwether plaintiffs, including Plaintiff Johns." (ECF No. 96 at PageID #6908.) But Dr. Badylak is offering a general opinion, and so this critique falls flat. *Supra* Part III.A.2.

is clearly inconsistent with the statements in Defendants' 510(k) application.

The purpose of the doctrine of judicial estoppel is "to protect the integrity of the judicial process." *Edwards v. Aetna Life Ins. Co.*, 690 F.2d 595, 598 (6th Cir. 1982). "The doctrine of judicial estoppel prevents a party who successfully assumed one position in a prior legal proceeding from assuming a contrary position in a later proceeding." *Mirando v. U.S. Dep't of Treasury*, 766 F.3d 540, 545 (6th Cir. 2014) (citing *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)).[3] Even the decision *not* to apply judicial estoppel is based on protecting the essential functions of judicial institutions; judicial estopped is applied cautiously "because the doctrine precludes a contradictory position without examining the truth of either statement," thus impeding "the truth-seeking function of the court." *Audio Technica U.S., Inc. v. United States*, 963 F.3d 569, 575 (6th Cir. 2020). For this reason, judicial estoppel is applicable to quasi-judicial administrative and agency proceedings. *See, e.g.*, *Edwards*, 690 F.2d at 599 (considering whether judicial estoppel precluded claims based on a plaintiff's prior benefit claims before the Veterans Administration).

Defendants are not judicially estopped from offering Dr. Badylak's testimony because the 510(k) application is not part of a judicial or quasi-judicial process. In a 510(k) application, the applicant is not filing a legal claim or a claim for a benefit to which they may be entitled, there is no proceeding with an arbiter, and there is no appeal. The FDA simply reviews the application.

[3] Courts in this circuit apply federal law applying the doctrine of judicial estoppel, even when sitting in diversity. *Edwards v. Aetna Life Ins. Co.*, 690 F.2d 595, 598 n.4 (6th Cir. 1982) (assessing the plaintiff's positions before a federal agency, Veterans Affairs, and before a federal court sitting in diversity); *Pennycuff v. Fentress Cnty. Bd. of Educ.*, 404 F.3d 447, 452 (6th Cir. 2005) (stating that "[f]ederal standards govern the application of judicial estoppel in federal court" while assessing a party's positions in a previous state proceeding and a federal diversity suit (quoting *Warda v. C.I.R.*, 15 F.3d 533, 538 n.4 (6th Cir.1994)); *see also Shufeldt v. Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.*, --- F. App'x ----, No. 20-5877, 2021 WL 1235832, at *3 n.6 (Apr. 2, 2021) (citing *Edwards*, 690 F.2d at 589 n.4)); *see generally* Edward H. Cooper, 18B Fed. Prac. & Pro. Juris. § 4477.8 (2d ed.), Westlaw (database updated April 2021).

Even the denial of a 510(k) application does not lead to a quasi-judicial proceeding like other administrative applications do. For instance, the denial of an application to the Social Security Administration for social security benefits results in quasi-judicial proceedings, which include at least a reasoned decision from an Administrative Law Judge, if not a hearing. *E.g.*, *Griffith v. Wal-Mart Stores, Inc.*, 135 F.3d 376, 379 (6th Cir. 1998); *see also id.* at 380–83 (considering whether judicial estoppel applied). Nor does it appear that 510(k) applicants swear or otherwise affirm that the facts contained within their applications are true. *Compare* ECF No. 408-3 *with Griffith*, 135 F.3d at 378–79. The 510(k) application process bears no resemblance to a judicial proceeding, and so concerns about the integrity of judicial or quasi-judicial institutions are not at play. Thus, applying the doctrine of judicial estoppel would run counter to precedent and to the purpose of the doctrine.

Plaintiff points to a list of persuasive authorities in which the court concluded judicial estoppel applies to administrative proceedings: "Judicial estoppel applies just as much when one of the tribunals is an administrative agency." (ECF No. 408 at PageID #21330 (quoting *Trs. In Bankr. of N. Am. Thread Co., Inc. v. United States*, 593 F.3d 1346, 1354 (Fed. Cir. 2010).). But there is no tribunal from the FDA involved in this application process and Plaintiff does not point to characteristics of the 510(k) process that suggest otherwise. For these reasons, Dr. Badylak's opinions are not barred by judicial estoppel. Plaintiff may rely on the 510(k) application to cross-examine Dr. Badylak, however.

2. Reliability of ST-coating opinions

Next, Plaintiff argues that Dr. Badylak's opinion that the photomicrographs from the clinical animal study show the presence of ST coating, a hydrogel, at 28 days is unreliable. (ECF No. 408 at PageID #21332.) Plaintiff contends that the opinion is

unreliable for three reasons: Dr. Badylak fails to identify the principles that he relied on to reach his ST-coating opinion, he failed to consider and exclude alternate explanations, and he relied on an improper staining method. (*Id.* at PageID #21333–34.) Considering Dr. Badylak's rebuttal report and testimony, his opinion is sufficiently reliable.

First, Plaintiff argues that Dr. Badylak did not identify the principles that he relied upon while reviewing the photomicrographs to conclude that there was evidence that the hydrogel was present. (*Id.* at #21333.) The Court disagrees. In his second supplemental report, Dr. Badylak explains that the hydrogel was present on the photomicrograph because he determined that the gel was stained light blue or was clear but sandwiched between the visible mesh and cell coating/viscera, and because he identified the existence of mesothelialization, *i.e.* the beginning of mesothelial cells coating the exposed tissues and/or viscera. (ECF No. 408-1.) Dr. Badylak elaborates in his rebuttal report that the space where he concluded the hydrogel was present was uniform in depth. (ECF No. 413-5 at PageID # 21938–39.)

Plaintiff counters that he is not challenging Dr. Badylak's 28-day opinion, but his opinion that the hydrogel would be present on day 30 as well because it could not completely resorb two days later. (ECF No. 421 at PageID #22303.) But it is clear that, at the least, Plaintiff also challenges Dr. Badylak's 28-day opinion. (ECF No. 408 at PageID #21332 ("Dr. Badylak's opinions regarding the presents of ST hydrogel at 28 days are inadmissible under Rule 702").) More importantly, Dr. Badylak does not offer a 30-day opinion; he merely responded to counsel's questioning. Plaintiff's counsel did not ask for the basis of this opinion.[4] It does not appear that Dr. Badylak intends to offer a 30-day opinion, and should

[4] Plaintiff treats Dr. Badylak's affirmative opinion that the ST coating is present at 28 days as if it were the same as Dr. Badylak's response that the ST coating would likely be present at 30 days. (*E.g.*,

Plaintiff ask again whether the hydrogel would be present at 30 days, cross-examination of Dr. Badylak will be sufficient.

Second, Plaintiff argues that Dr. Badylak did not consider and exclude alternative explanations for what he observed in the photomicrographs. (ECF No. 408 at PageID #21333.) The record belies this contention. In his rebuttal report, Dr. Nagy explains why the hydrogel, as he has identified it, could not be "edematous fluid, immature collagen, or fat, " including a lack of "organized appearance and intense staining" and presence of uniform spacing. (ECF No. 413-5 at PageID #21939.) During his deposition, Dr. Nagy further explained that the lack of vasculature in the blue-stained or clear layer meant that the layer could not be edema fluid. (ECF No. 413-4 at PageID #21928.)

Finally, Plaintiff argues that Dr. Badylak's method is unreliable because the photomicrographs used Masson's trichrome staining, as opposed to Alcain blue staining. (ECF No. 408 at PageID #21333.) But there is no indication that Masson's trichrome staining is not a widely accepted method; indeed, Dr. Badylak testified that were he to have constructed the animal study leading to the photomicrographs himself, he would still have used Masson's trichrome, albeit with hematoxylin and eosin stain, the addition of which assists in "distinguishing sometimes difficult tissues that might look a bit alike," "particularly [for] people who aren't used to looking at histology a lot." (ECF No. 408-4 at PageID #21394–95.) Hyaluronic acid, the primarily component of the ST coating does not stain with Masson's trichrome, but the record shows that the materials around it would and that the other possible identities of the empty space on the photomicrographs,

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ECF No. 421 at PageID #22304 (indicating in a heading that Plaintiff challenges the 28-day opinion but analyzing the 30 day opinion; ECF No. 437 at PageID #226664, 22672 (referring to Dr. Badylak's 28-day opinion and 30-day response interchangeably).

such as edema fluid, would have cells, such as vasculature, present that do stain. Whether Dr. Badylak's identification through a lack of staining of staining is a better method than using Alcain blue staining is fodder for cross examination, but not a ground for concluding his opinion is unreliable and thus inadmissible.

For these reasons, this opinion is reliable and thus admissible.

3. Relevance of ST-coating opinions

Plaintiff argues that Dr. Badylak's opinion regarding the number of days that the hydrogel or ST coating is present on the photomicrographs is irrelevant to notice, *i.e.* whether Defendants knew the ST coating resorbed too quickly. (ECF No. 408 at PageID #21334.) This argument is puzzling because throughout the pretrial proceedings Plaintiff has focused on number of days it takes for the Ventralight ST to resorb, noting that at various points Defendants were aware that the coating was gone around a week, despite their representations to the FDA and the public that the coating lasted 28 days. (*E.g.*, ECF No. 69 at PageID #3969.) Indeed, whether the ST coating was present at 28 or 30 days after implantation and whether Defendants knew there was evidence that the ST coating lasted that long is relevant to Plaintiff's design defect claims, failure to warn, and warranty claims. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 5223363, at *11–14, 16–24 (denying Defendants' summary judgment motion on these claims while considering Plaintiff's evidence related to the amount of time in which the ST coating resorbed). Plaintiff attempts to distinguish the duration of the hydrogel from whether the hydrogel minimizes adhesions. (ECF No. 421 at PageID #22306.) But until this point, Plaintiff's theory of the case has been that the ST coating resorbed too quickly—an assertion which lends itself to measurement via the number of days—not that the hydrogel fails to inhibit

adhesions regardless of resorption time. This opinion is certainly relevant.

4. Qualifications to opine on hernia surgeon practices

Finally, Plaintiff argues that Dr. Badylak is unqualified to opine that most hernia surgeons prefer intraperitoneal surgery to fix hernias, meaning that they would prefer mesh with coatings to try to minimize adhesions, such as the Ventralight ST. (ECF No. 408 at PageID #21335.) Dr. Badylak may offer opinions on the general circumstances that necessitated his research, but he may not speculate about why hernia surgeons perform intraperitoneal surgery over other techniques.

Dr. Badylak is qualified to testify about the circumstances leading to the need for the type of devices that he researches. Dr. Badylak testified that the intraperitoneal approach is "the most used" to fix hernias, which leads to surgeons attempting to minimize adhesions with coated devices. (ECF No. 408-4 at PageID #21387.) Dr. Badylak has medical training and ample experience in researching the tissue response to devices used in hernia repairs. Part of that research involves understanding why there is a need for the type of device he researches. Here, intraperitoneal surgeries present a risk of adhesions that extraperitoneal approaches do not, and the coated mesh devices purport to solve this problem. Thus, Dr. Badylak may give some background about the need for his research.

However, Dr. Badylak may not rely on his anecdotal, non-expert experience, draw inferences for the jury, or speculate. Dr. Badylak testified that surgeons using the intraperitoneal approach would not perform that type of procedure with a coated device unless they "believe they're going to get the best clinical result" and that he doesn't "know any surgeon who would use an approach that . . . involved placing a device in the

abdominal cavity that felt that they could get an equal or better result by using another approach, otherwise they would use it." (*Id.* at PageID #21387–88.) At best, this statement stems from Dr. Badylak's personal knowledge, not his expertise. Personal knowledge alone is not a permissible topic of expert testimony. Fed. R. Evid. 701 & 702. Alternatively, Dr. Badylak is drawing inferences from the alleged trend that most hernia surgeons use the intraperitoneal approach, *i.e.* because most surgeons use that approach then they must believe it is safe. But only a jury can draw inferences like this. *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 914 (S.D. Ohio 2015). And to the extent that Dr. Badylak is speculating about why surgeons have tended to favor this approach, his testimony is inadmissible. *See* Fed. R. Evid. 702(b)–(d).

IV. Conclusion

For these reasons, Defendants' motion to exclude Dr. Badylak's opinions and testimony from his initial expert report (ECF No. 96) is **GRANTED IN PART AND DENIED IN PART** and Defendants' motion to strike Dr. Badylak's ST-coating opinions (ECF No. 408) is **GRANTED IN PART AND DENIED IN PART.**

IT IS SO ORDERED.

6/28/2021
DATE

s/ Edmund A Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE