

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-01509

**EVIDENTIARY MOTIONS ORDER No. 16**

Before the Court is Defendants' Motion to Exclude the Testimony of Plaintiff's Rebuttal Expert Tamas Nagy, DVM, Ph.D. ([ECF No. 488](#)). For the reasons that follow, Defendants' motion is **GRANTED IN PART AND DENIED IN PART**.

**I. Background<sup>1</sup>**

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation, 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. The Food and Drug Administration 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

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<sup>1</sup> 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).

device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called “Septra Technology” (“ST”). *Id.* 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. *Id.* 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.

As set forth in Evidentiary Order No. (“EMO”) 3, Dr. Nagy did not initially submit an expert report. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, No. 2:18-md-2846, [2020 WL 8707603](#), at \*3 (S.D. Ohio Apr. 16, 2020). Defendants moved to strike Dr. Nagy as an expert for this reason. ([ECF No 26.](#)) In EMO 3, the Court declined to strike defense expert Dr. Stephen Badylak’s supplemental opinion relating to the ST hydrogel coating in photomicrograph slides from two animal studies conducted by Defendants. *In re Davol, Inc./C.R. Bard, Inc.*, [2020 WL 8707603](#), at \*7. Specifically, Dr. Badylak opined that the ST hydrogel

coating was present on the twenty-eighth day after implantation based on his review of these slides. *Id.* at \*6. In response, Plaintiff was permitted to have Dr. Nagy submit a rebuttal report to Dr. Badylak's opinion, and Defendants were permitted to depose Dr. Nagy based on his rebuttal report. *Id.* at \*7. Subsequently, Defendants' motion to strike Dr. Nagy as an expert was denied as moot, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, No. 2:18-md-2846, [2020 WL 2280657](#), at \*5 (S.D. Ohio June 4, 2021), and the majority of Dr. Badylak's photomicrograph ST-coating opinions, which he captured in his second supplemental report, were ruled admissible, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-1509, [2021 WL 2643110](#), at\*6 (S.D. Ohio June 28, 2021). Defendants filed the instant *Daubert* motion arguing that Dr. Nagy's rebuttal opinions are inadmissible, and the briefing is now complete. (ECF Nos. 488, 508, 510.)

## II. Analysis

In their motion to exclude Dr. Nagy's rebuttal testimony, Defendants argue that Dr. Nagy's opinions are unreliable and encompass inappropriate topics, that Dr. Nagy is unqualified to offer his opinions, and that Dr. Nagy should be precluded from offering certain opinions because the opinions exceed the proper scope of rebuttal. ([ECF No. 488 at PageID #26028–40.](#)) The focus of this *Daubert* motion is Dr. Nagy's deposition; Defendants concede that "Dr Nagy's rebuttal report generally stayed within the limits the Court imposed on him." (*Id.* at [PageID #26025.](#)) Dr. Nagy's rebuttal opinions are reliable, and he is qualified to offer them at trial, but some of his opinions exceed the scope of rebuttal.

### **A. Reliability**

Defendants assert that Dr. Nagy's opinions are unreliable because he did not use a reliable methodology to reach his opinions, because he did not base his opinions on sufficient facts or data, and because some of his opinions are mere speculation. (ECF No. 488 at PageID #26029–36.) The Court disagrees. Dr. Nagy's opinions are reliable, and much of Defendants' briefing evinces disagreement between opposing sides and their dueling experts, not a lack of reliability.

Federal Rule of Evidence 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 Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (citations omitted); see *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as “flexible” (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993))). 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.

Dr. Nagy relies on reliable methodology in formulating his rebuttal opinions. Dr.

Nagy was retained to “re-review[ ] the photomicrographs taken in [the] DB-300 as well as DB-364 [animal studies conducted by Defendants].” ([ECF No. 488-1 at PageID #26046](#).) At bottom, Dr. Nagy disagrees with Dr. Badylak’s conclusion that there was evidence of the ST coating on the photomicrographs. (*E.g.*, *id.* at [PageID #26050](#).) During his deposition, Dr. Nagy explained that he reached this conclusion by “look[ing] at the study materials, and I followed their histological evaluation criteria, and I just verified.” ([ECF No. 488-2 at PageID #26114](#), p. 158.) This is an adequate explanation of his methodology. This is particularly so considering that his analysis was a visual examination. As this Court has explained before, a visual examination of pathology slides is a reliable method of analysis if the expert has expertise as a pathologist. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, [2021 WL 2643114](#), at \*9 (S.D. Ohio June 28, 2021). Dr. Nagy has sufficient expertise as a veterinary pathologist. *Infra* Part II.B.

Defendants make much of Dr. Nagy’s deposition testimony that he did not follow or read the two formal protocols for the animal studies. ([ECF No. 488 at PageID #26030](#).) One protocol primarily addresses the surgical procedures used to implant the Ventralight ST device in porcine models. ([ECF No. 146-1 at PageID #9120–21](#).) Indeed, the only relevant portion of this protocol here is the “Histological Analysis,” which simply notes the procedure for fixing the slides, that analysis of the slides “was conducted by an independent board-certified veterinary pathologist,” and that the slides were reviewed with “a standardized scoring system.” (*Id.* at [PageID #9133](#).) And even though the other protocol goes into greater histological depth, the crux of the methodology is still to rely on a veterinary pathologist to fill out a scoring sheet ranging from “0” (undetectable

presence) to “4” (marked/very evident presence). ([ECF No. 146-2 at PageID #9323](#).) It is unclear what Dr. Nagy’s histological evaluation lacked considering the pertinent sections of the formal protocols. It is also important to note that Dr. Badylak did not appear to rely on these protocols when offering his dueling photomicrograph opinion related to the ST coating. *In re Davol, Inc./C.R. Bard, Inc.*, [2021 WL 2643110](#), at \*7–8.

Dr. Nagy’s rebuttal opinion is also based on sufficient facts and data. Defendants identify five ways that Dr. Nagy’s opinion is lacking. Dr. Nagy inadequately considers Dr. Badylak’s assessment of other identities of the ST coating on the slides, does not sufficiently explain why the staining on the slides is unable to support Dr. Badylak’s opinion, misinterprets the animal studies teams’ assessment of the ST coating on the slides, does not account for Dr. Badylak’s citation to photomicrographs, and misconstrues Dr. Badylak’s second supplemental report while concluding Dr. Badylak’s opinion is contradictory.<sup>2</sup> ([ECF No. 488 at 26031–34](#).) Defendants do not identify weaknesses in Dr. Badylak’s opinions that demonstrate unreliability, however. Defendants simply disagree with Dr. Nagy’s opinions, which does not render Dr. Nagy’s rebuttal opinions unreliable. Defendants may cross-examine Dr. Nagy on these weaknesses.

Defendants also argue that Dr. Nagy’s proposed alternative identifications of what Dr. Badylak labels ST hydrogel coating on the slides are too speculative. (*Id.* at PageID #26036.) Defendants specifically take issue with Dr. Badylak’s inability to identify the same features of the slides as edema, immature collagen, or fat with sufficient scientific certainty (greater than fifty percent) and his failure to utilize a differential diagnosis. (*Id.*)

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<sup>2</sup> Relatedly, Defendants contend that any opinion here that Defendants did not satisfy the standard of care regarding proper staining technique for the slides is beyond the scope of rebuttal. (ECF No. 488 at PageID #26034.) It does not appear that Dr. Nagy offers this opinion, but the Court agrees—conduct opinions are beyond the scope of rebuttal to Dr. Badylak’s supplemental opinion.

But Defendants misconstrue Dr. Nagy's opinion, which is not to identify the features on the slides per se, but to point out how Dr. Badylak's identification of the ST coating on the slides is inadequate. ([ECF No. 488-1 at PageID #26055](#) (“The Presence of Hydrogel Cannot be Adequately Supported”).) Dr. Nagy's opinion is that Dr. Badylak did not adequately consider other likely identities of what Dr. Badylak concludes is ST coating. Therefore, Dr. Nagy's inability to opine with scientific certainty which of the three alternatives the slide contains and that he did not rely on a differential diagnosis does not render his rebuttal opinion unreliable.

### **B. Qualifications**

Defendants next contend that Dr. Nagy is unqualified to offer his rebuttal opinions because he has no experience with hernia mesh or surgical mesh devices. ([ECF No. 488 at PageID #26038](#).) 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.”). Dr. Nagy is sufficiently qualified to offer his opinions.

Dr. Nagy is a veteran veterinary pathologist. ([ECF No. 488-1 at PageID #26045](#); 26068–70.) His experience certainly qualifies him to offer opinions on whether the area of the slides at issue here is biological, *i.e.*, porcine edema, collagen, or fat, or other, hydrogel. That Dr. Nagy lacks specific experience with these types of surgical devices and hydrogels, such as the ST hydrogel coating, is suitable for cross-examination but is insufficient to render him unqualified.

### **C. Corporate documents and state-of-mind opinions**

Next, Defendants assert that Dr. Nagy offers impermissible opinions on Defendants’ state of mind and corporate documents. ([ECF No. 488 at PageID #26036](#).) Defendants takes specific issue with Dr. Nagy’s discussion of internal documents to conclude that “it would be quite curious for Davol to possess the information espoused by Dr. Badylak [that the hydrogel lasts twenty-eight days, considering the lack of clinical data showing the coating lasted fourteen days,] and not present in its study report.” ([ECF No. 488-1 at PageID #26048](#).) This opinion exceeds the scope of rebuttal to Dr. Badylak’s pathological interpretation of the photomicrographs from Defendants’ two animal studies.

Dr. Badylak’s second supplemental report contains narrow opinions that inherently limit the reach of Dr. Nagy’s rebuttal opinions. In the three pages of the report, Dr. Badylak simply opines that the slides show “the expected and desirable tissue response with surgical mesh in this anatomic space,” consisting of mesothelialization, some areas of adhesion, and remaining hydrogel coating. ([ECF No. 488-5 at PageID #26169](#).) Moreover, the Court only permitted Dr. Nagy to respond to Dr. Badylak’s report. *In re Davol, Inc./C.R. Bard, Inc.*, [2020 WL 8707603](#), at \*7. Dr. Nagy’s opinion regarding



Defendants' possession of information is not a response to Dr. Badylak's interpretation of slides. Indeed, this verges on opinions regarding the propriety of Defendants' conduct. Dr. Nagy cannot offer this opinion because it exceeds the scope of rebuttal to Dr. Badylak's pathological interpretation of the photomicrographs. Thus, the Court need not address these opinions any further.

#### **D. Proper scope of opinions**

Finally, Defendants argue that Dr. Nagy should be precluded from offering other opinions beyond rebuttal to Dr. Badylak and those that Dr. Nagy disclaimed. ([ECF No. 488 at PageID #26040.](#)) Plaintiff responds that Dr. Nagy should be permitted to opine on the Good Laboratory Practice ("GLP") standards and what a reasonable animal pathologist would have noted when reviewing the photomicrographs at issue here. ([ECF No. 508 at PageID #26808.](#)) Plaintiff also clarifies that Dr. Nagy will not offer certain opinions. (*Id.* at [PageID #26809.](#)) Both parties' arguments succeed and fail.

Dr. Nagy's rebuttal report is confined to responding to Dr. Badylak's review of the slides. That the presence of the ST hydrogel would have been noted if observed and identified by the original animal pathologist, considering GLPs, goes to the accuracy of Dr. Badylak's interpretation of the slides. However, any opinion that Defendants through the independent veterinary pathologist violated a standard of care by not adhering to the GLPs is beyond the scope of rebuttal to Dr. Badylak's photomicrograph opinion.

Defendants point to Dr. Nagy's deposition, arguing he disclaimed any GLP opinion. ([ECF No. 510 at PageID #26896.](#)) Dr. Nagy agreed with the question that he had not "disclosed any opinions about a failure to comply with GLP requirements relation to any study done on any device at issue in this litigation." ([ECF No. 488-2 at PageID](#)

#26099, p. 98.) The question is simply too broad to determine what opinion Dr. Nagy disclaimed—the fact that the hydrogel would have been noted or that Defendants violated a standard of care. This issue is best resolved on cross-examination.

Defendants also argue that Plaintiff purports to offer Dr. Nagy’s opinion that no hydrogel coating was on the slides, but Dr. Nagy in reality only offers an opinion challenging Dr. Badylak’s opinion that the ST hydrogel coating was present on the twenty-eighth day. ([ECF No. 510 at PageID #26896–97.](#)) This is a distinction without a difference. Dr. Nagy’s opinion is that Dr. Badylak’s opinion that ST coating is present on day twenty-eight is in error because there is no presence of hydrogel on the slides. ([ECF No. 488-1 at PageID #26055–65.](#)) He even concludes his rebuttal report by stating that “the photomicrographs confirm[ ] the absence of any ST hydrogel.” (*Id.* at PageID #26065.)

As to the opinions Plaintiff contends Dr. Nagy will not offer, the Court agrees that this renders Defendants’ *Daubert* motion moot as to these opinions. Beyond that, the Court will not issue a sweeping opinion precluding opinions that Dr. Nagy does not appear to offer.

### **III. Conclusion**

Accordingly, Defendants’ motion to exclude Dr. Nagy’s rebuttal testimony ([ECF No. 488](#)) is **GRANTED IN PART AND DENIED IN PART.**

**IT IS SO ORDERED.**

8/16/2021  
DATE

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