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:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-1320

EVIDENTIARY MOTIONS OPINION & ORDER No. 25

Defendants C.R. Bard, Inc. and Davol, Inc. seek to exclude the opinion and testimony of Plaintiffs', Antonio Milanesi and his wife Alicia Morz De Milanesi, expert Michael Beatrice, Ph.D. (ECF No. 322.) For the reasons set forth below, Defendants' motion is **GRANTED IN PART**, **DENIED IN PART**, and **DENIED IN PART AS MOOT**.

I. Background[1]

Plaintiffs' case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

at PageID #1–2.)[2]

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages.

The relevant facts here are that Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

The crux of Plaintiffs' claims is that Defendants knew of the risks presented by the Ventralex device but marketed and sold the device despite these risks and without appropriate warnings. Plaintiffs point to three specific issues with the Ventralex. First, they argue that polypropylene resin oxidatively degrades *in vivo*. (ECF No. 87 at PageID #6591–92.) Plaintiffs claim that Defendants were aware of these risks because the Material Safety Data Sheet for polypropylene noted that the material should not be used for human implantation because it can oxidize in the body. (*Id.* at PageID #6592.) Second, Plaintiffs contend that the ePTFE layer contracts more quickly than the polypropylene, which in combination with the too-weak memory

[2] All docket citations are to the docket in the instant case, Case No. 18-cv-1320, unless otherwise noted.

coil ring causes the device to fold or buckle or "potato chip."[3] (*Id.* at PageID #6594–95.) According to Plaintiffs, the buckling leads to some of the Ventralex patch pulling away from the abdominal wall and curving in toward the bowel, exposing the bare polypropylene side of the Ventralex to the bowel. (*Id.* at PageID #6598–99.) Plaintiffs explain that Defendants knew about this issue due to the Composix Kugel device recall for broken memory coil rings but opted to use the same size rings in the Ventralex device despite this knowledge and despite the fact that more buckle-resistant options were available. (*Id.* at PageID #6596–97.) Third, Plaintiffs argue that the ePTFE layer was prone to infection due to the ePTFE layer's small pore size, which is big enough for bacteria to grow in but too small for white blood cells to enter to intercept the bacteria. (*Id.* at PageID #6600–01.) Plaintiffs argue that this risk was known by Defendants' employees, as illustrated by their internal documents. (*Id.*)

II. Legal Standard

Evidentiary rulings are made subject to the district court's sound discretion, *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019), including the admissibility of expert testimony, *United States v. Dunnican*, 961 F.3d 859, 875 (6th Cir. 2020). This role, however, is not intended to supplant the adversary system or the role of the jury. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531–32 (6th Cir. 2008). Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury. *Id.* "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

[3] The technical name of this double-curved shape is a hyperbolic paraboloid. A popular potato chip packaged in tubes and horseback-riding saddles have the same shape.

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is 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*] 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.").

The district court's role in assessing expert testimony is a "gatekeeping" one, ensuring that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert*, 509 U.S. at 597). 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 at 529 (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)); 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*, 509 U.S. at 591 (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 reliably applied the principles and methods 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.

III. Analysis

Defendants challenge Dr. Beatrice's 510(k), complaint handling, testing and design control, failure to warn, intent, Material Safety Data Sheet ("MSDS"), and allegedly disclaimed opinions. Defendants also challenge any of Dr. Beatrice's opinions that allegedly fall outside of the scope of opinions offered by Plaintiffs' original expert, Dr. David A. Kessler, M.D. Dr. Beatrice's opinions are admissible in part, and the Court will not address opinions that Dr. Beatrice

does not offer or those that Plaintiffs do not intend to offer.

A. Scope of Dr. Beatrice's Opinions

Defendants repeatedly argue that many of Dr. Beatrice's opinions should be excluded because they exceed the scope of opinions offered by Dr. Kessler. In the first bellwether trial, *Johns v. CR Bard et al.*, Case No. 18-cv-1509, the plaintiff originally intended to use Dr. Kessler as a regulatory expert, but Dr. Kessler was appointed as the Chief Science Officer for the Biden administration's COVID-19 Response Task Force in January 2021. (Case No. 18-cv-1509, ECF No. 452 at PageID #23324.) Because of this appointment, the *Johns* plaintiff was forced withdraw Dr. Kessler as an expert and find a replacement expert, Dr. Beatrice. (*Id.*) The Court found that there was good cause for the substitution of Dr. Beatrice but did not allow Dr. Beatrice to present new opinions and limited Dr. Beatrice's opinions to the scope of those offered by Dr. Kessler to avoid causing prejudice to Defendants. (Case No. 18-cv-1509, ECF No. 453.) Defendants received Dr. Beatrice's expert report on May 24, 2021. (Case No. 18-cv-1509, ECF No. 449 at PageID #22731.) The order allowing substitution and limiting the scope of Dr. Beatrice's testimony was entered on June 18, 2021, approximately one and a half months prior to the start of the *Johns* trial. (Case No. 18-cv-1509, ECF No. 453.) In their motion to exclude the testimony of Dr. Kessler in this case, Defendants again argue that various opinions offered by Dr. Beatrice that exceed the scope of opinions offered by Dr. Kessler should be excluded. (*See generally* ECF No. 322.) Defendants point to the Court's ruling in *Johns* and argue that the same limits should apply here. (*Id.*)

In response, Plaintiffs argue that this case is "situated differently than the *Johns* case, in which due to the pendency of the trial, there were heightened concerns about having time to respond to purportedly 'new opinions.'" (ECF No. 327 at PageID #17860.) Plaintiffs contend that

the considerations here are different, and that "Defendants have had notice of Dr. Beatrice's opinions since May 2021, they have watched him testify at trial, and have had months to prepare for his deposition in December 2021. They can make no showing of unfair surprise or undue prejudice." (*Id.*) This Court agrees. Although Plaintiffs were not certain whether Dr. Kessler or Dr. Beatrice would be testifying as a regulatory expert in this trial until late November 2021, Defendants have had Dr. Beatrice's expert report since May 2021, almost a year before trial is set to begin in this case. Additionally, Dr. Beatrice's deposition for this case was conducted in December 2021, approximately three months prior to trial. The postponements of the trial in this case have given Defendants even more time to prepare with respect to Dr. Beatrice. In *Johns* the timeframe was much shorter. Defendants do not face the same risk of prejudice in this case, having had much more time to prepare. Therefore, the Court will not limit the scope of Dr. Beatrice's opinions to fit within the scope of opinions offered by Dr. Kessler.

B. 510(k) Opinions

The Ventralex comes in three sizes: small, medium, and large. (*Id.*) The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") on July 16, 2002.[4] (ECF No. 57-5 at PageID #653–56.) Defendants listed the Composix Kugel Mesh as the predicate device. (*Id.* at PageID #656.) The large size was subsequently brought to market via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (ECF No. 57-8 at PageID #673.) A no-510(k) rationale is when a 510(k) application does not need to be submitted because the manufacturer has made changes that do not "significantly affect the safety or effectiveness of the device." (ECF No. 57-9 at PageID

[4] The 510(k) premarket approval process has been described previously in this MDL in *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 *7–8 (S.D. Ohio Oct. 20, 2020) (MIL No. 4).

#675–76 (citation omitted).)

Defendants claim that Dr. Beatrice's opinion regarding Defendants' decision not to submit a 510(k) application for the Ventralex Large was not disclosed in his expert report and was disclosed for the first time at his deposition. Pursuant to Federal Rule of Civil Procedure 26(a)(2)(B)(i), an expert witness's report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Defendants point to Dr. Beatrice's deposition testimony that he had "not disclosed a specific statement that gives [him] an opinion on whether or not a no 510(k) decision was made, but throughout [his] report [he] indicate[s] what the problems were, and any competent regulatory expert would have had other options other than no 510(k) decision. As a matter of fact, that was evident in [his] report even if [he] didn't make a specific statement." (ECF No. 322-1 at 28:17–24.) Defendants claim that none of the mentions of the 510(k) process in Dr. Beatrice's report "suggest that Dr. Beatrice was opining that [Defendant]'s decision not to submit a 510(k) for the Ventralex large was inappropriate and/or did not comply with FDA regulations." (ECF No. 322 at PageID #17491.) In addition, Defendants argue that Dr. Beatrice's 510(k) opinions should be excluded because they are "fundamentally different than any opinion offered by Dr. Kessler." (ECF No. 322 at PageID #17492.) The Court addressed Dr. Beatrice's opinions as they relate the scope of Dr. Kessler's opinions above. *Supra* Part III.A.

In response, Plaintiffs claim that Dr. Beatrice's 510(k) opinions were not undisclosed. (ECF No. 327 at PageID #17857–59.) Plaintiffs argue that, although the opinion was "not explicitly stated in Dr. Beatrice's report word-for-word," Defendants fail to acknowledge what should have been "plain as day, given the multiple criticisms offered by Dr. Beatrice of the development and launch of the Large Ventralex[.]" (*Id.* at PageID #17857.) Plaintiffs also argue

that, even though Defendants claim that these opinions were undisclosed, Defendants moved in limine to exclude evidence or argument that Defendants improperly failed to get 510(k) clearance two months prior to Dr. Beatrice's deposition, which was denied in the Court's Motions in Limine ("MIL") Order No. 15, also prior to Dr. Beatrice's deposition. The MIL Order noted that "Plaintiffs are not presenting evidence that the Ventralex Large Hernia Patch was illegally on the market. Instead, they are simply disagreeing with Defendants that [Defendants] utilized the appropriate route to market." (ECF No. 276 at PageID #16837.) Plaintiffs claim that because Defendants' counsel initiated the line of questioning regarding Dr. Beatrice's opinion on the no 510(k), Defendants' claim that they were unaware of the opinion is implausible.

Defendants counter that in their MIL No. 25, they did not mention Dr. Beatrice, and "nothing about the [MIL] in any way suggests that [Defendants] had notice that Dr. Beatrice intended to offer an undisclosed opinion concerning the regulatory pathway [Defendants] chose for the Ventralex [L]arge. Rather, as [they] did in *Johns*, [Defendants] merely moved to exclude a category of evidence and argument offered by Plaintiffs that [they] considered irrelevant and unduly prejudicial." (ECF No. 333 at PageID #18368.) As to defense counsel's questioning at Dr. Beatrice's deposition, Defendants note that they questioned Dr. Beatrice about multiple opinions not disclosed in his report as a basis for exclusion at trial. (*Id.*) Defendants "w[ere] not suggesting that [they] secretly believed Dr. Beatrice would be offering these undisclosed opinions at trial. Rather, [they were] confirming that Dr. Beatrice would not be ambushing [Defendants] at trial with undisclosed opinions." (*Id.*)

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony, requiring parties to disclose the identity of any witness it may use a trial to present evidence under Federal Rule of Evidence 702, 703, or 705. *See* Fed. R. Civ. P. 26(a)(2)(A). That disclosure must

be accompanied by a written report that contains, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B). The parties must make their expert disclosures "at the times and in the sequence that the court orders" and supplement "when required under Rule 26(e)." Fed. R. Civ. P. 26(a)(2)(D)–(E). If a party fails to provide information as required by Rule 26(a) or (e), they may not use that information at trial "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). The Court may also impose other sanctions. *Id*.

Defendants claim that Dr. Beatrice's 510(k) opinions are undisclosed "surprise" opinions, and that Defendants should not be required to "read between the lines" to deduce Dr. Beatrice's conclusion that the decision not to submit a 510(k) for the Ventralex Large was inappropriate. However, as Defendants pointed out in relation to one of their own expert witnesses in *Johns*, "courts have distinguished between new opinions and further development of opinions contained in the expert report. Indeed, an expert is permitted to expand on proposed testimony relating to the same core opinions as in the report, so long as the underlying opinions remain the same." (Case No. 18-cv-1509, ECF No. 146 at PageID #9111 (citing *Level 3 Communications, LLC v. Floyd*, Case No. 1:09-0082, 2011 WL 1106420, at *3–4 (M.D. Tenn. Mar. 23, 2011)).) In Evidentiary Motions Order ("EMO") No. 3, the Court agreed with Defendants' arguments that the allegedly undisclosed opinions were evident in the expert's report:

> Put more simply, Bard's position appears to be that Dr. Badylak disclosed in his supplemental report that his opinions related to the animal studies were consistent with the study reports, and that the study reports are consistent with his testimony that he observed the presence of the ST coating at 28 days.
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> Bard contends "courts have distinguished between new opinions and further development of opinions contained in the expert report. Indeed, an expert is permitted to expand on proposed testimony relating to the same core opinions as in the report, so long as the underlying opinions remain the same." (*Id*. at 7) (citing

> cases). According to Bard, "Dr. Badylak's challenged opinion is consistent with what is in his Supplemental Report and what is shown in the DB-300 and DB-364 study reports" and that the challenged opinion "does not contradict any of Dr. Badylak's prior opinions, nor does it constitute a material change in opinion." (*Id.* at 8.)
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> Bard's arguments are well-taken. Though the Court agrees with Plaintiffs that the specific opinion regarding the presence of the ST coating was not included in either of Dr. Badylak's written reports, Rule 26 "contemplates that the expert will supplement, elaborate upon, explain and subject himself to cross-examination upon his report." *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201, 1203 (6th Cir. 2006) ("Section 26(a)(2)(B) does not limit an expert's testimony simply to reading his report. No language in the rule would suggest such a limitation."). It was evident from Dr. Badylak's supplemental report that he reviewed the materials for the animal studies and that his opinions were consistent with the study reports. Plaintiffs' counsel knew Dr. Badylak had reviewed the animal studies, and it was Plaintiffs' counsel who initiated the line of questioning regarding Dr. Badylak's review of the animal studies at his deposition.
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> . . .
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> Plaintiffs claim to be surprised by this opinion. But as Plaintiffs themselves claim, "[o]ne of the core issues from the beginning of the Bard hernia mesh cases involving Sepra Technology ("ST") is the early resorption of the ST hydrogel coating…which results in bare polypropylene being exposed to visceral tissues such as the bowel, liver, spleen, and omentum." (Pls.' Mot. to Strike at 1-2.) Plaintiffs sought, and obtained through this Court's CMO 24, access to the animal studies at issue here and a schedule for each side's experts to submit reports regarding those studies. Plaintiffs are thus very familiar with the issues to which Dr. Badylak's challenged opinion relates: the alleged early resorption of ST coating and the animal studies.

(Case No. 18-cv-1509, EMO No. 3, ECF No. 157 at PageID # 9511–13.) The same analysis applies here. Plaintiffs' 510(k) arguments are a central part of their case and are hardly a surprise to Defendants. As Plaintiffs noted, the issue has already come up in a MIL. Additionally, "Rule 26 contemplates that the expert will supplement, elaborate upon, explain and subject himself to cross-examination upon his report," exactly as Dr. Beatrice did in his deposition. (*Id.*) Dr. Beatrice's report focuses heavily on the 510(k) process and Defendants' use of it, and "[Rule] 26(a)(2)(B) does not limit an expert's testimony simply to reading his report. No language in the rule would suggest such a limitation." *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201, 1203

(6th Cir. 2006). Dr. Beatrice's opinions regarding the 510(k) process as it relates to the Ventralex Large are not new opinions, but further development of the core opinions stated in his report. Accordingly, Dr. Beatrice's 510(k) opinions will not be excluded as impermissible undisclosed opinions.

C. Complaint Handling Opinions

Defendants point out that in *Johns*, the Court concluded that although Dr. Kessler summarized certain complaints in his expert report, he did not offer any affirmative opinion on Defendants' complaint handling process, and Defendants argue that the same is true here of Dr. Beatrice. (ECF No. 322 at PageID #17492.) Defendants also note that in *Johns*, the plaintiff agreed not to elicit testimony on Dr. Beatrice's complaint handling opinions, but reserved his right to offer the opinions in rebuttal if appropriate. (*Id.*) Dr. Beatrice intends to offer the following opinions at trial: 1) that Defendants failed to adequately monitor complaints of buckling mesh products; 2) that Defendants failed to adequately track and monitor trending complaints of infection; and 3) the inadequacies in Defendants' complaint handling processes would have impacted the accuracy of complaint rate calculations. (*Id.*) According to Defendants, at his deposition Dr. Beatrice also opined that certain medical device reports ("MDRs") provided Defendants notice of the risk of buckling prior to Mr. Milanesi's implant surgery, but Defendants claim that Dr. Beatrice's expert report identifies only post-implant MDRs as the basis for this opinion. (*See* MIL Order No. 44, ECF No. 320 (holding that evidence of Defendants' conduct occurring after Mr. Milanesi's surgery is not admissible to show notice and is only admissible to show malice or reckless disregard for the purpose of punitive damages).) Defendants argue that none of the post-implant MDRs would have put Defendants on notice of any alleged risks prior to Mr. Milanesi's implant surgery. (ECF No. 322 at PageID #17493.) Defendants further argue that

these opinions should be excluded under Rule 702 because they are not based on sufficient facts and data. (*Id.* at PageID #17493–94.) Defendants say that Dr. Beatrice relies on incorrect assumptions about actions Defendants took or did not take with respect to the investigation and reporting of certain complaints. (*Id.*) Defendants also argue that Dr. Beatrice's complaint handling opinions exceed the scope of Dr. Kessler's opinions. The Court addressed Dr. Beatrice's opinions as they relate the scope of Dr. Kessler's opinions above. *Supra* Part III.A.

Plaintiffs acknowledge that Dr. Beatrice reviewed some post-implant complaints, and note that he also looked at complaint data from prior to Mr. Milanesi's surgery. (ECF No. 327 at PageID #17861.) Dr. Beatrice also relied on reports about the Composix Kugel and Ventralex family of products. (*Id.*) Plaintiffs claim that Defendants fail to acknowledge that the Court did not exclude MDRs on the basis of when they were received or reported but restricted the admissibility of MDRs to those that were "substantially similar" to this case. (*Id.* at PageID #17862.) Plaintiffs argue that Dr. Beatrice should be permitted to offer opinions based on the reports and complaints and how they were handled or responded to by Defendants. (*Id.*) Plaintiffs point to the December 15, 2021 pretrial conference, at which the Court ruled that post-surgery FDA reports regarding late-filed complaint reports were admissible to show malice. (ECF No. 330 at PageID #18296–97.)

The Court has previously addressed the issue of the admissibility of MDRs. In MIL Order No. 34, the Court ruled that pre-surgery MDRs that were "substantially similar" to this case based on certain criteria may be used to show notice or knowledge. (MIL Order No. 34, ECF No. 310.) In MIL Order No. 44, the Court addressed the issue of post-surgery evidence and ruled that such evidence may not be used to show notice or knowledge, but only to show malice or disregard for the purposes of punitive damages. (MIL Order No. 44, ECF No. 320.) The Court again addressed

the specific issue of post-surgery MDRs at the December 15, 2021 pretrial conference. The Court ruled that evidence of Defendants' reporting and complaint handling procedures "[may not] come in for proof of anything substantive. It goes to either malice or recklessness" for purposes of punitive damages. (ECF No. 330 at PageID #18297.) Because the Court has already specifically addressed the issue of the admissibility of both pre-surgery and post-surgery MDRs and for what purposes they may be used, the Court will not again delve into this argument. Dr. Beatrice's opinions that are based on substantially similar pre-surgery MDRs may be used to show Defendants' notice or knowledge, and post-surgery MDRs are limited to show malice or reckless disregard for the purpose of punitive damages.

Defendants' arguments regarding Dr. Beatrice's complaint handling opinions primarily focus on the scope of Dr. Kessler's opinions and the use of post-surgery MDRs. Additionally, Defendants also argue that Dr. Beatrice's complaint handling opinions are not based on sufficient facts and data, and that pre-implant complaints were not cited in his report. (ECF No. 333 at PageID #18371.) However, Dr. Beatrice does cite to his review of Defendants' reports and data, including pre-surgery MDRs. (ECF No. 327-1 at ¶¶ 257.1–257.5.) Although Defendants may disagree with Dr. Beatrice's interpretation, that goes to weight rather than admissibility and is something Defendants are free to argue at trial. Dr. Beatrice does base his opinions on sufficient facts and data, and therefore his complaint handling opinions are admissible.

D. Testing and Design Control Opinions

Defendants argue that Dr. Beatrice's opinions on testing and design control should be excluded. Defendants note that in *Johns*, the Court allowed Dr. Beatrice's design control opinions because they formed the basis for his testing opinions, and because Dr. Beatrice's experience with the FDA and elsewhere made him qualified to give an opinion about Defendants' design controls.

(ECF No. 322 at PageID #17495–02; *see* EMO No. 15, Case No. 18-cv-1509, ECF No. 501.) The Court also ruled that Dr. Beatrice's reliance on the methodology he was trained to use at the FDA rendered his opinions reliable. Here, Defendants again seek to exclude these opinions because they argue that the opinions fall outside the scope of Dr. Kessler's opinions, and because the opinions at issue in this case are specific to the Ventralex and the grounds for exclusion are different, so a different result is warranted. The Court addressed Dr. Beatrice's opinions as they relate the scope of Dr. Kessler's opinions above. *Supra* Part III.A.

According to Defendants, Dr. Beatrice is not qualified to opine on the adequacy of Defendants' testing of the Ventralex Large. (ECF No. 322 at PageID #17500.) Defendants argue that Dr. Beatrice lacks the requisite biomechanical engineering, medical, and biocompatibility experience to render opinions on the subject, and that Dr. Beatrice has no experience with hernia mesh devices. Defendants acknowledge that the Court rejected this argument in *Johns*, and restate the argument in this case for the purposes of appeal. (*Id.*; *see* EMO No. 15, Case No. 18-cv-1509, ECF No. 501.) Plaintiffs claim that Defendants are recycling arguments that they made in *Johns*, and that Defendants have not raised any issues that warrant a different finding in this case. (ECF No. 327 at PageID #17866.) This Court agrees. Dr. Beatrice is qualified as an expert by knowledge, skill, experience, training, or education. Dr. Beatrice is a regulatory expert, which includes design control and labeling experience. He has over 40 years of experience in FDA regulatory work, including serving as a consultant on these issues to this day. (ECF No. 322-2 at ¶¶ 1, 4.) Dr. Beatrice worked for the FDA as a regulator, inspector, and reviewer. (*Id.* at ¶10.) Then he spent more than 16 years working in regulatory compliance in high-seniority positions for

private companies. (*Id.* at ¶¶ 10–13.)

As the Court noted in *Johns*,

> Courts have considered an expert's regulatory experience and training as sufficient indicators of reliability under these circumstances, including in the FDA regulatory context. *Id.* (pointing to the expert's pharmacy experience and expertise with Texas pharmacy regulations); *Par Pharm., Inc. v. Hospira, Inc.*, No. 17-944-JFB-SRF, 2019 WL 2396748, at *3 (D. Del. June 6, 2019) (holding an FDA regulatory expert's opinion was reliable due to her knowledge and experience). In *Baldonado v. Wyeth*, for example, the district court concluded that an FDA regulatory expert's opinion that additional testing was necessary according to FDA labeling regulations was reliable due to her knowledge of and training on the FDA regulations and her experience advising drug manufacturers on these regulations. No. 04 C 4312, 2012 WL 3234240, at *5 (N.D. Ill. Aug. 6, 2012) (collecting cases). The expert specifically used the methodology that she was trained to use at the FDA. *Id.*
>
> Dr. Beatrice relies on his knowledge and expertise on FDA regulations, rendering his opinions reliable. He worked for the FDA for twenty-two years as a regulator, inspector, and reviewer; spent 13 years at a multinational corporation as a regulatory and quality compliance officer, and since then has served as a consultant doing the same. (ECF No. 467-1 at ¶¶ 4–15.) Like the expert in *Baldonado*, Dr. Beatrice relies on the methodology he was trained to use at the FDA. (ECF No. 467-2 at pp. 14–15, 26.) This methodology is evident in Dr. Beatrice's report. First, Dr. Beatrice sets forth the relevant design control and labeling regulations. (ECF No. 467-1 at PageID ¶¶ 54–62, 80.) Then, he applies these regulations to the facts matter at hand.

(EMO No. 15, Case No. 18-cv-1509, ECF No. 501 at PageID #26761–62.) The same analysis applies here. Accordingly, Dr. Beatrice is qualified to offer his opinion.

Defendants argue that Dr. Beatrice's testing and design control opinions are not based on sufficient facts or reliable methodology. (ECF No. 322 at PageID #17497–500.) Although the Court allowed such opinions in *Johns*, Defendants claim that those opinions should be excluded in this case because they are based on incorrect facts and assumptions controverted by the evidence. (*Id.* at PageID #17497.) Defendants claim that Dr. Beatrice incorrectly assumes that the Ventralex is larger than the models of the Composix Kugel that were recalled because of ring breaks; according to Defendants, there is no history of failures of the 0.030" memory coil rings in

any Composix Kugel product similar in size, shape, and implantation technique to the Ventralex Large. (*Id.*) Although the Court ruled in MIL Order No. 38 that Plaintiffs can offer some evidence of the Composix Kugel ring breaks, Defendants say that this does not obviate Dr. Beatrice of the need to have a sufficient basis for his opinions on design control issues for the Ventralex. (*Id.*) Defendants also claim that Dr. Beatrice disregarded contrary evidence. According to Defendants, Dr. Beatrice's report ignores testing that Defendants conducted on the Ventralex to confirm that issues observed in the Composix Kugel did not affect the Ventralex line. (*Id.* at PageID #17497–98.) Dr. Beatrice discusses issues with various devices, but Defendants claim that he does not tie those issues to the device in this case, the Ventralex Large. (*Id.* at PageID #17498.) According to Defendants, Dr. Beatrice does not explain how issues during the redesign of the Extra Large Composix Kugel models that were recalled have any bearing on the Ventralex. (*Id.*) Defendants say that other than an assertion that the Ventralex and Composix Kugel are similar in design and made from similar materials, Dr. Beatrice does not say how or why the issues he identifies with the Composix Kugel implicate the Ventralex. (*Id.* at PageID #17498–99.) Defendants also point to the fact that Dr. Beatrice repeatedly opines that Defendants' testing was inadequate but does not say which additional tests should have been conducted or what "appropriate tests" would have shown. (*Id.* at PageID #17499.) Defendants claim that this is a "negligence in the air" opinion and it is insufficient under *Daubert*. (*Id.*) Defendants concede that the Court rejected their similar argument in *Johns*, and note that they are only raising this argument again for the purposes of appeal.

Plaintiffs argue that Defendants offer no specific evidence in support of their arguments, instead relying on their own general interpretation of the evidence. (ECF No. 327 at PageID #17865.) Plaintiffs claim that Defendants fail to acknowledge that Dr. Beatrice reviewed the

design history and 510(k) files for the Ventralex and Composix Kugel products, which should contain any of the studies mentioned by Defendants to the extent that they exist. (*Id.*) Moreover, Plaintiffs argue, Defendants focus on ring breaks but the deposition testimony that Defendants cite to has nothing to do with Dr. Beatrice's concerns about buckling after implantation. (*Id.*) Plaintiffs point out that, as stated in Dr. Beatrice's deposition, Defendants never conducted long-term testing to evaluate the issue. (*Id.*)

Defendants claim that Dr. Beatrice's design control opinions are unreliable because he does not opine as to what tests should have been conducted, or what the "appropriate tests" would have shown. (ECF No. 322 at PageID #17499.) Defendants made a similar argument in *Johns*. The Court noted that Defendants "contend[ed] that Dr. Beatrice does not point to other manufacturers' practices or identify an additional study or test that they could have done to satisfy the regulations," but found that "[t]here is no discernable basis for requiring Dr. Beatrice's opinions to address these topics. Dr. Beatrice approaches his opinions from a regulatory aspect, so it is sufficient that he identifies applicable regulations and opines that Defendants did not satisfy those regulations based on his knowledge and experience." (Case No. 18-cv-1509, EMO No. 15, ECF No. 501 at PageID #26763.) The Court similarly rejects this argument here. Dr. Beatrice's opinions are not unreliable simply because he does not lay out what additional testing Defendants could have done.

Defendants claim that evidence of ring failures in the Composix Kugel does not form a sufficient basis for Dr. Beatrice's opinions, and this argument seems to be a reiteration of their argument that evidence of the Composix Kugel ring breaks should not be admissible. As with MDRs, the Court has already addressed the admissibility of evidence of the Composix Kugel ring breaks. (MIL Order No. 38, ECF No. 314.) Defendants claim that although the Court allowed such evidence, it does not "obviate Dr. Beatrice of the need to have a sufficient basis for his

opinions on design control issues for the Ventralex." However, Dr. Beatrice's reliance on the Composix Kugel data does form a sufficient basis for his Ventralex opinions. Defendants understate the connection between the Ventralex and the Composix Kugel. The Composix Kugel is the predicate device for the Ventralex under the FDA's 510(k) process, and both products use or used a 0.030" ring. Dr. Beatrice does not claim that the ring breaks occurred in the Ventralex but uses the Composix Kugel ring breaks to draw the conclusion that the ring breaks should have led Defendants to do more testing when it came to the Ventralex, which uses the same ring. Similar to the issue of MDRs, the Court will not revisit the overarching issue of the Composix Kugel ring breaks which it has already addressed in MIL Order No. 38. (ECF No. 314.) As the Court stated, "[i]nformation from the Composix Kugel design process, including the post-market surveillance, would have informed Defendants' decisions that were being made in the Ventralex Large Hernia Mesh design process. These similarities underscore why evidence of the Composix Kugel problems, and ultimately its recall, are relevant." (Id. at PageID #17422.) As for Defendants' argument that Dr. Beatrice's opinions are based on incorrect facts and assumptions, "[i]t is not the district court's role under *Daubert* to evaluate the correctness of facts underlying an expert's testimony." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 856 (Fed. Cir. 2010). Accordingly, Dr. Beatrice's use of the Composix Kugel data to conclude that Defendants' testing and design control for the Ventralex was insufficient is reliable.

As for Defendants' claim that Dr. Beatrice "did not consider the testing [Defendants] conducted on the Ventralex to confirm that issues observed in the Composix Kugel devices did not impact the Ventralex line" (ECF No. 322 at PageID #17497-98), as Plaintiffs note, "Defendants do not point to any specific study in support of this statement . . . [and] fail to acknowledge that Dr. Beatrice reviewed the design history and 510(k) files for the Ventralex and Composix Kugel

products, which should contain such studies, to the extent that they exist" (ECF No. 327 at PageID #17865; ECF No. 322-2 at ¶¶ 273, 281-82). Dr. Beatrice's reliance on Defendants' own design history and 510(k) files to form his opinions is sufficiently reliable.

E. Failure to Warn Opinions

Defendants take issue with three of Dr. Beatrice's opinions regarding warnings in the Ventralex Instructions for Use ("IFU"): 1) that Defendants failed to adequately warn "physicians and patients" about the potential of the Ventralex Large to buckle or contract; 2) that Defendants failed to warn "surgeons and patients" about higher rates of infection with the Ventralex Large; and 3) that Defendants failed to warn about the use of the Ventralex Large in immunocompromised patients who were more susceptible to infection. (ECF No. 322 at PageID #17501.) Defendants claim that these specific opinions differ from those offered by Dr. Beatrice in *Johns*, and that the opinions should therefore be excluded in this case. In *Johns*, Defendants sought to exclude Dr. Beatrice's failure to warn opinions based on qualifications and methodology, and here Defendants seek to exclude different warning opinions on the grounds that they exceed the scope of Dr. Kessler's opinions and are irrelevant. (*Id.*) The Court addressed Dr. Beatrice's opinions as they relate the scope of Dr. Kessler's opinions above. *Supra* Part III.A. Defendants point to the Court's MIL Order No. 42, which ruled that testimony or evidence regarding a duty to warn patients or the general public was inadmissible. (ECF No. 318 at PageID #17457–58.) Therefore, Defendants argue, Dr. Beatrice should be precluded from making statements at trial concerning an alleged failure to warn patients.

Defendants also argue that Dr. Beatrice's failure to warn opinions are unreliable. Defendants claim that such opinions run contrary to the Court's orders on post-implant conduct. (*See* MIL Order No. 44, ECF No. 320.) According to Defendants, Dr. Beatrice claims that

Defendants failed to warn of certain alleged risks without indicating what changes should have been made to the device's warning language or what additional language should have been included. (ECF No. 322 at PageID #17502–03.) Defendants also claim that Dr. Beatrice did not analyze whether the IFU was accurate or inaccurate with respect to the risk of remote bowel erosion and fistula. (*Id.* at PageID #17502.) Defendants argue that this calls into question Dr. Beatrice's methodology, and that Dr. Beatrice cannot reliably opine that there is insufficient warning language without knowing what sufficient language would have been. (*Id.* at PageID #17502–03.)

Defendants claim that Dr. Beatrice's opinions on failure to warn of infection are irrelevant because the implanting physician, Dr. Gill, was aware of the infection risk associated with microporous ePTFE. (*Id.* at PageID #17503.) Defendants argue that under Florida law, even if a manufacturer fails to adequately warn of a risk, it "is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." (*Id.*; *Olmo v. Davol, Inc.*, No. 13-62260-CIV, 2017 WL 1367231, at *5 (S.D. Fla. Apr. 10, 2017), *aff'd,* 710 F. App'x 861 (11th Cir. 2018) (quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995).) Defendants note that during his deposition, Dr. Gill testified that it is well known that microporous ePTFE can affect the body's ability to fight infection, and testified that he was aware of that in 2007. (ECF No. 322 at PageID #17503.) As such, Defendants claim, Dr. Beatrice's opinion on Defendants' alleged failure to warn of alleged increased infection risk with ePTFE is irrelevant and inadmissible. (*Id.*) Defendants also claim that Dr. Beatrice's opinions on the use of Ventralex in immunocompromised patients are also inadmissible because it does not apply to Mr. Milanesi and is therefore irrelevant. (*Id.*)

Plaintiffs argue that Dr. Beatrice's failure to warn opinions are admissible. According to Plaintiffs, Defendants characterize the opinions as only relying on the IFU, but Dr. Beatrice did not limit his opinions to the IFU and also refers to Ventralex promotional pieces which also fall under FDA regulations. (ECF No. 327 at PageID #17866.) Second, Plaintiffs argue that to the extent the Court finds that warnings to patients or lack thereof are excluded, Dr. Beatrice can narrow his testimony to physicians and wholesale exclusion of the failure to warn opinions is not necessary. (*Id.*) As to Defendants' argument that Dr. Gill already knew of the risk of infection, Plaintiffs claim that argument is misleading because Dr. Gill testified that if he had been warned about the risk of infection with the Ventralex Large, he would have considered different options for Mr. Milanesi. (*Id.* at PageID #17867–68; ECF No. 327-5 at 98:18–99:1.) Regarding Defendants' argument regarding the use of Ventralex in immunocompromised patients, Plaintiffs argue that these opinions still go to notice and to Defendants' conduct, particularly with respect to malice and reckless disregard for safety. (ECF No. 327 at PageID #17868.)

Defendants correctly point out that in MIL Order No. 42, the Court ruled that Plaintiffs "point to no source of a duty" to warn the general public, and therefore Plaintiffs may not "speak to a 'duty to warn' [Plaintiffs or the general public]." (MIL Order No. 42, ECF No. 318 at PageID #17458.) Accordingly, Dr. Beatrice may not present opinions regarding a failure to warn patients or the general public. However, the Court agrees with Plaintiffs that this does not warrant a wholesale exclusion of Dr. Beatrice's failure to warn opinions.

Defendants' argument that Dr. Beatrice's failure to warn opinions are unreliable because he did not opine what additional language should have been included mirrors their argument regarding Dr. Beatrice's testing and design control opinions. The Court has already rejected this reasoning. As the Court stated above, "[t]here is no discernable basis for requiring Dr. Beatrice's

opinions to address these topics." (Case No. 18-cv-1509, EMO No. 15, ECF No. 501 at PageID #26763.) The Court similarly rejects this argument here. Dr. Beatrice's opinions are not unreliable simply because he does not lay out what additional language Defendants could have added.

Dr. Gill testified that he knew microporous ePTFE may affect the body's ability to fight infection. (ECF 322-5 at 218:15–21.) Therefore, Defendants may certainly argue that in this case Dr. Gill as "the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Olmo*, 2017 WL 1367231, at *5. However, Dr. Gill also testified that, had he known about the risk of infection with the Ventralex, he would have "more likely than not [chosen] another option." (ECF No. 327-5 at 98:18–99:1.) "'Where the reliability of the evidence is in dispute, it is more appropriate for a judge to admit the evidence than to keep it from the fact-finder because "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."'" *Little Hocking Water Ass'n, Inc.*, *v. E.I. du Pont de Nemours & Co.*, 90 F. Supp. 3d 746, 752 (S.D. Ohio 2015) (quoting *Daubert*, 509 U.S. at 596). Accordingly, Dr. Gill's testimony regarding microporous ePTFE does not render Dr. Beatrice's failure to warn opinions irrelevant or unreliable.

As to Dr. Beatrice's opinions regarding the use of Ventralex in immunocompromised patients, the Court agrees that those opinions are not relevant to this case. Therefore, Dr. Beatrice will not be permitted to present his opinions regarding the use of Ventralex in immunocompromised patients.

F. Opinions Regarding Motives, State of Mind, or Intent

Defendants note that in *Johns*, Defendants moved for the exclusion of Dr. Beatrice's opinions on Defendants' and the FDA's state of mind, knowledge, or intent. (ECF No. 322 at

PageID #17505.) The Court held that opinions on state of mind or intent were inadmissible, but Dr. Beatrice could opine on Defendants' knowledge. (Case No. 18-cv-1509, EMO 15, Docket No. 501; *see also* MIL Order No. 29, ECF No. 302.) Defendants say that although Dr. Beatrice agreed not to testify regarding the FDA's state of mind, his report and testimony suggest that he intends to offer the opinion that Defendants chose to use the 0.030" ring in the Ventralex Large to avoid having to submit a 510(k) application. (ECF No. 322 at PageID #17504.) According to Defendants, this is an improper opinion on Defendants' motivation and intent and should be excluded.

Plaintiffs respond that, consistent with the Court's prior rulings, Dr. Beatrice will not opine on Defendants' motives, state of mind, or intent. (ECF No. 327 at PageID #17868–69.) Plaintiffs provide that Dr. Beatrice will opine on information that was known and/or available to Defendants. (*Id.*) With respect to Defendants' argument that Dr. Beatrice should not offer an opinion on Defendants' choice to use the 0.030" ring in the Ventralex Large, Plaintiffs argue that Dr. Beatrice may discuss that choice because it is stated in his report and related documents that Defendants' employees were aware that changing the design of the Ventralex Large would require a 510(k) application which could cause delay. (*Id.* at PageID #17869.)

Plaintiffs agree that Dr. Beatrice will not offer opinions on Defendants' state of mind, motive, or intent. The Court also addressed this issue in MIL Order No. 29, in which it ruled that expert witnesses may not "speculate regarding corporate intent, state of mind, and/or motivations." (MIL Order No. 29, ECF No. 302 at PageID #17320.) The Court's ruling in MIL Order No. 29 applies to Dr. Beatrice's opinions regarding the use of the 0.030" ring in the Ventralex; Dr. Beatrice "may testify about his [] review of internal corporate documents [related to the use of the 0.030" ring] solely for the purpose of explaining the basis for his [] opinions—assuming the

opinions are otherwise admissible." Such opinions may not contain speculation as to Defendants' state of mind, motive, or intent, as the Court has already ruled. Because Plaintiffs agree that Dr. Beatrice may not offer opinions regarding Defendants' motive, state of mind, or intent, the Court will not decide a non-existent dispute. Defendants' motion as it relates to state of mind, motive, and intent opinions is denied as moot.

G. MSDS Opinions

Defendants argue that the Court should exclude Dr. Beatrice's opinions regarding MSDS because they exceed the scope of opinions offered by Dr. Kessler, and because the Court limited the use of MSDS to show notice only. (ECF No. 322 at PageID #17506; MIL Order No. 32, ECF No. 308.) Defendants also argue that Dr. Beatrice's opinions exceed the scope of what the Court allowed with respect to foreign regulatory evidence and post-implant conduct. (MIL Order No. 40, ECF No. 316; MIL Order No. 44, ECF No. 320.)

Plaintiffs respond that, consistent with the Court's prior rulings, Dr. Beatrice's opinions regarding MSDS will be limited to notice. (ECF No. 327 at PageID #17868.) With respect to Defendants' arguments related to foreign regulations, Plaintiffs say that consistent with the discussion at the December 15, 2021 pretrial conference, Plaintiffs do not intend to introduce any such testimony unless Defendants open the door. (*Id.*)

Defendants reply that Dr. Beatrice's opinions "relate only to the meaning of the medical application disclaimer and whether [Defendants] should have submitted certain MSDSs to [the] FDA or a foreign regulatory body." (ECF No. 333 at PageID #18376.) According to Defendants, such opinions are irrelevant to notice and should be excluded. (*Id.*)

Consistent with the Court's prior rulings, evidence and testimony related to MSDS can only be used for notice. (MIL Order No. 32, ECF No. 308.) Plaintiffs state that Dr. Beatrice's

opinions related to MSDS will be limited to notice. Additionally, Plaintiffs conceded that they will not introduce testimony regarding the foreign regulations unless Defendants open the door to that testimony. Accordingly, the Court will not decide a non-existent dispute, and Defendants' motion as it relates to MSDS opinions is denied as moot.

H. Disclaimed Opinions

Defendants claim that at his deposition, Dr. Beatrice disclaimed several opinions including opinions on alternative methods, devices, and designs (had "no specific statement that compares the risk of any complication with Ventralex compared to another available device that could be used for umbilical repair back in 2007" (ECF No. 322-1 at 55:1–6)); medical causation and biocompatibility (would not offer opinions "about medical causation . . . medical causation is not my area of expertise (*id.* at 53:13–23)); incidence or rate of buckling; ISO (would offer "no specific opinions relating to ISO" (*id.* at 118:11–15)); and all case-specific opinions (would not offer "any case-specific opinions about anything relating to Mr. Milanesi or Dr. Gill or any other doctor in this case" (*id.* at 47:24–48:11; 53:12–23)). (ECF No. 322 at PageID #17506.) According to Defendants, Dr. Beatrice also testified that he would not offer opinions regarding: regulatory violations with respect to the 510(k) for the original Ventralex models in 2002 (did not offer specific statement that "there were regulatory violations in relation to the 510(k) submitted for the original Ventralex models back in 2002" (ECF No. 322-1 at 37:16–22)); the Composix Kugel, Kugel, Composix, and Composix E/X (did not "specifically disclose" any opinions "about the 510(k)s for Composix Kugel, Kugel, Composix or Composix E/X" (*id.* at 110:23–111:6)); or that the Ventralex Large was not legally marketed in 2007 ("didn't say the specific opinion [that the Ventralex Large] wasn't legally marketed" in 2007 (*id.* at 149:2–5)). (ECF No. 322 at PageID

#17506.)

Plaintiffs "do not agree with the categorizations of disclaimed opinions offered by Defendants or that their cited testimony is consistent with such categorizations," but agree that Dr. Beatrice will not offer the following opinions at trial: general or case-specific causation opinions; opinions on alternative surgical techniques or medical devices; opinions on incidence rates or risk ratios for injuries for Ventralex products or the predicate Composix Kugel beyond those contained in any documents or literature included in his report or discussed at his deposition; opinions that Defendants committed regulatory violations in their submission of the 510(k) for the original Ventralex models in 2002; and opinions on whether the Ventralex Large was legally marketed in 2007. (ECF No. 327 at PageID #17869.)

Defendants reply that Plaintiffs were silent on several of the allegedly disclaimed opinions. (ECF No. 333 at PageID #18376–77.) Specifically, while Plaintiffs agreed Dr. Beatrice would not offer case-specific causation opinions, Defendants argue that Dr. Beatrice should be prevented from offering *all* case-specific opinions. (*Id.*) Defendants also claim that Plaintiffs did not address: comparative risk opinions (would make "no specific statement that compares the risk of any complication with the Ventralex compared to another available device that could be used for umbilical repair back in 2007" (ECF No. 322-1 at 55:1 6)) or any opinion critical of the 510(k)s for the Composix Kugel, Kugel, Composix, and Composix E/X; opinions concerning the biocompatibility of the Ventralex Large; or compliance or noncompliance with any ISO.

Plaintiffs specifically agreed not to offer certain opinions disclaimed by Dr. Beatrice. Accordingly, the Court will not decide a non-existent dispute. As to the remaining disclaimed opinions not mentioned by Plaintiffs, the Court "decline[s] to order an expert not to offer a disclaimed opinion because it is simply an admonishment to follow the law." (Case No. 18-cv-

1509, EMO No. 15, ECF No. 501 at PageID #26764.) Therefore, Defendants' motion as it relates to disclaimed opinions is denied as moot.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude the Testimony of Plaintiffs' Expert Michael Beatrice, Ph.D. (ECF No. 322) is **GRANTED IN PART**, **DENIED IN PART**, and **DENIED IN PART AS MOOT**.

IT IS SO ORDERED.

2/15/2022
DATE

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