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:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-01022

EVIDENTIARY MOTIONS OPINION & ORDER No. 30

Before the Court is Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert Dr. David Kessler, M.D. (ECF No. 215.) For the reasons that follow, Defendants' motion is **GRANTED IN PART**, **DENIED IN PART**, and **DENIED IN PART AS MOOT**.

I. Background[1]

Plaintiff's case is the third 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 at PageID #1–2.)

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff's claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff's injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug's shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, 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: design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff's claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

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).

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 and seek to exclude the opinions of Plaintiff's expert Dr. David Kessler on multiple grounds. Defendants also moved to exclude Dr. Kessler's opinions in the first two bellwether cases, *Johns v. C.R. Bard, Inc., et al.*, Case No. 18-cv-1509, and *Milanesi, et al. v. C.R. Bard, Inc., et al.*, Case No. 18-cv-1320. In both cases, the Court denied Defendants' motions as moot because the plaintiffs indicated that he would not be serving as a witness. (Case No. 18-cv-1509, ECF No. 448; Case No. 18-cv-1320, Evidentiary Motions Order ("EMO") No. 24, ECF No. 274 at PageID #16820.)

A. FDA Regulatory Violations, 510(k), PMA, and Legal Opinions

Defendants first seek to exclude what they consider Dr. Kessler's "legal opinions." In *Johns* and *Milanesi*, the Court held that expert witnesses would not be permitted to opine on the background or legal meaning of the 510(k) process.[2] (Case No. 18-cv-1509, Motions *in Limine* ("MIL") Order No. 4, ECF No. 355 at PageID #18768; Case No. 18-cv-1320, MIL Order No. 15, ECF No. 276 at PageID #16830–33.) Defendants claim that, in spite of the Court's rulings, Dr.

[2] For a more complete description of the 510(k) and PMA processes, see MIL Order No. 4 (Case No. 18-cv-1509, ECF No. 355 at PageID #18767–69).

Kessler "has entire sections of his report devoted to just that." (ECF No. 215 at PageID #8314.) Plaintiff responds that Dr. Kessler will not offer opinions concerning the FDA that have been previously excluded by the Court. However, Plaintiff opposes Defendants' motion "to the extent Defendants seek to exclude broader swaths of Dr. Kessler's testimony regarding FDA regulations and guidance and how they apply to medical device development, adverse event reporting, and labeling and promotion." (ECF No. 220 at PageID #8818.) He also argues that if Defendants intend to rely on their "add to file" memorandum as justification for their decision not to submit a 510(k) application, Dr. Kessler should be permitted to "address the sufficiency of the document from a regulatory perspective." (*Id.*) Dr. Kessler does not intend to offer opinions about specific violations of FDA regulations, but Plaintiff contends that it is permissible for Dr. Kessler to "offer testimony regarding the meaning of FDA regulations and Defendants' course of conduct in relation to those regulations." (*Id.*)

As the Court held in *Johns*, an expert cannot opine that Defendants violated an FDA regulation because that would be a legal conclusion. (Case No. 18-cv-1509, MIL Order No. 3, ECF No. 332 at PageID #17281–82.) However, the Court noted that it also would depend on "the framing of the question" and some broader lines of questioning that did not call for a legal conclusion would be permissible. (*Id.*) The Court sees no reason to depart from this reasoning and therefore adopts its prior ruling. Defendants also point to the Court's ruling in *Johns* regarding the premarket approval ("PMA") process intended for Class III devices. Similar to the Ventralight ST at issue in *Johns*, the PerFix Plug is not a Class III device and therefore, Defendants argue, evidence regarding the PMA process or opinions regarding the differences between the 510(k) and PMA processes should be excluded. (ECF No. 215 at PageID #8314.) Plaintiff agrees that Dr. Kessler will not offer opinions as to the legal meaning of the 510(k) process and Defendants'

ability to obtain a PMA. (ECF No. 220 at PageID #8820.)

Next, Defendants claim that Dr. Kessler impermissibly opines that Defendants violated FDA regulations in violation of the Court's prior rulings and Rule 702. In doing so, Dr. Kessler "intend[s] to undertake the role of the jury, [and] he also assumes the role of the Court" by discussing caselaw and offering legal definitions and conclusions. (ECF No. 215 at PageID #8316.) Plaintiff agrees that Dr. Kessler will not offer opinions about federal preemption or legal conclusions (ECF No. 220 at PageID #8820–21), therefore this issue is moot.

B. Knowledge, Intent, or Motivations of Defendants, the FDA, or Surgeons

The Court has previously held that "[a]lthough expert witnesses may discuss certain subjects about which they possess specialized knowledge, this does not mean that they may speculate regarding corporate intent, state of mind, and/or motivations." (Case No. 18-cv-1320, MIL Order No. 29, ECF No. 302 at PageID #17320.) Defendants therefore seek to preclude Dr. Kessler from opining about the knowledge, intent, or motivations of Defendants, the FDA, or surgeons. (ECF No. 215 at PageID #8317.) Plaintiff agrees that Dr. Kessler will not offer opinions about "state of mind or subjective intent," but argues that Dr. Kessler may testify about Defendants' knowledge when it is established in the factual record. (ECF No. 220 at PageID #8821.) As Defendants point out, the Court has held that an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his otherwise admissible opinions. (Case No. 18-cv-1320, EMO No. 25, ECF No. 342 at PageID #18797–98.) The same reasoning applies here, and the Court adopts its prior ruling.

C. Factual Narratives

Defendants claim that Dr. Kessler's report contains factual narrative summaries requiring no specialized expert knowledge, which should be excluded as "improper advocacy that invade[s]

the fact-finding province of the jury." (ECF No. 215 at PageID #8318.) As the Court noted above, Dr. Kessler may only testify about his review of internal corporate documents to the extent that it provides a basis for his otherwise admissible opinions. "A history without any expert analysis or other application of the expert's expertise is a factual narrative that 'should be presented to the jury directly.'" (Case No. 18-cv-1509, EMO No. 15, ECF No. 501 at PageID #26754 (quoting *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010)).)

D. Devices Not at Issue and Injuries Not Alleged

Defendants ask the Court to exclude as lacking fit Dr. Kessler's device-specific opinions on three devices not at issue in this case, and injuries not alleged, including death. (ECF No. 215 at PageID #8319–23.)

1. Ventralight ST, Ventralex, and 3DMax

Dr. Kessler offers device-specific opinions as to the Ventralight ST, Ventralex, and 3DMax devices, which are at issue in the first, second, and fourth bellwether cases respectively. (*See* Case Nos. 18-cv-1509, 18-cv-1320, 18-cv-1440.) According to Defendants, these opinions "fail to implicate the notice of or connectivity to Plaintiff's alleged injuries." (*Id.* at PageID #8321.) Plaintiff argues that opinions regarding the other devices are admissible because "the adequacy for [Defendants'] warnings for [their] other hernia mesh devices is relevant to demonstrating a pattern of inadequate warnings." (ECF No. 220 at PageID #8823.) However, as Defendants point out, the Court has ruled multiple times that such opinions are not admissible for that purpose. (*See* Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23421–22 ("In this MDL, evidence related to FDA compliance of other devices is impermissible character or propensity evidence under Federal Rule of Evidence 404(b) if offered to prove FDA compliance with the Ventralight ST"); Case No. 18-cv-1509, MIL Order No. 11, ECF No. 415 at PageID #22188 (rejecting the

plaintiff's argument that Defendants' conduct during another time period showed a "pattern of conduct" because "[e]vidence showing that the Defendants were later in noncompliance is not only irrelevant and prejudicial for the reasons set forth above, but it is also propensity reasoning prohibited by Federal Rule of Evidence 404(a)"); Case No. 18-cv-1509, EMO No. 9, ECF No. 457 at PageID #22389 (holding that evidence of FDA compliance regarding other devices was impermissible propensity evidence).) The same reasoning applies here. Plaintiff's attempt to use noncompliance or inadequate warnings with respect to other devices is impermissible character evidence, therefore Dr. Kessler will not be permitted to offer such opinions.

Plaintiff also claims that opinions regarding the other devices are relevant because they show that Defendants had notice of the dangers of polypropylene. (ECF No. 220 at PageID #8823.) However, Defendants argue that Dr. Kessler's opinions as to the other devices "do not at all relate the 'dangers' of polypropylene—his opinions are about specific issues unique to each of the other devices, none of which involves polypropylene." (ECF No. 222 at PageID #9016.) Dr. Kessler's opinions regarding the 3DMax pertain to that device's warnings or lack thereof related to chronic pain (Kessler Report, ECF No. 215-3 at PageID #8481–85), his opinions regarding the Ventralight ST pertain to the resorption of that device's hydrogel barrier (*id.* at PageID #8486–94), and his opinions regarding the Ventralex pertain to that device's risks of "buckling" and infection associated with ePTFE (*id.* at PageID #8496–8515). These opinions do not show that Defendants were on notice regarding the alleged risks of polypropylene and are therefore irrelevant and inadmissible.

2. Complications Not Alleged in This Case

Defendants argue that Dr. Kessler should not be permitted to offer opinions regarding complications not alleged by Plaintiff, including death, because such opinions are irrelevant and

lack fit with this case. (ECF No. 215 at PageID #8322.) In his report, Dr. Kessler claims that Defendants failed to warn about "the risk of migration leading to death." Dr. Kessler cites to a case report in which the PerFix Plug "had fistulated into the small bowel," and the patient died several weeks later. (Kessler Report, ECF No. 215-3 at PageID #8475.) The case report contains no information as to the patient's cause of death, such as whether it was related to the surgeries or was due to a completely unrelated cause. Therefore any opinions regarding that patient's cause of death would be speculation. (*Id.*; ECF No. 215-4.) Dr. Kessler cites to no other sources to support his opinion that migration of the PerFix Plug may be fatal.

Plaintiff attempts to justify this opinion by claiming that Dr. Kessler is a medical doctor and "is more than qualified to discuss the complications that can arise from a fistula, which include infection, sepsis, and death." (ECF No. 220 at PageID #8824.) However, this argument goes to Dr. Kessler's qualifications, not his methodology or whether he relied on sufficient facts when forming this opinion. Dr. Kessler does not provide a sufficient basis for his opinions that the PerFix Plug can lead to death, and he will therefore not be permitted to offer such opinions. Additionally, as the Court ruled in the previous bellwether cases and reiterated in this case with respect to Dr. Grischkan, "an expert's opinions are irrelevant if they lack a connection to the plaintiff's theory of injury or the injuries themselves." (EMO No. 26, ECF No. 227 at PageID #9161; Case No. 18-cv-1320, EMO No. 21, ECF No. 271 at PageID #16766.)

E. Opinions Regarding the 2009 Add-To-File[3]

Dr. Kessler opines that Defendants' representations in a 2009 add-to-file submitted to the

[3] In 2009, at the FDA's request, Defendants submitted an "add-to-file" memorandum for the Marlex Mesh Dart documenting their decision not to submit a 510(k) application for the PerFix Plug, which included details about the PerFix Plug's design and construction and a summary of clinical data regarding the PerFix Plug's outcomes. For a more complete description, see DMO No. 7 (ECF No. 225).

FDA misrepresented the safety and efficacy of the PerFix Plug. (Kessler Report, ECF No. 215-3 at PageID #8477–78.) Defendants claim this opinion is inaccurate, and argue that the complaints Dr. Kessler relied on are not sufficient support. (ECF No. 215 at PageID #8324–25.) Additionally, information in the add-to-file that was submitted seventeen years after the PerFix Plug's release has no bearing on Plaintiff's claims and could only be used to support a fraud on the FDA claim. (*Id.* at PageID #8325.) According to Defendants, Dr. Kessler's opinion regarding the add-to-file is not related to information used in connection with bringing the device to market, and the add-to-file is not labeling or marketing material. (*Id.*)

Plaintiff responds that, "to the extent Defendants intend to rely on their 'Add to File' memorandum (and the FDA's subsequent acceptance of that memorandum) as justification for [their] decision not to submit a 510(k) clearance application for the PerFix Plug, Dr. Kessler should be able to address the sufficiency of the document from a regulatory perspective." (ECF No. 220 at PageID #8818.) However, Defendants "certainly will not (and could not) rely on that document as 'justification' for [their] no-510(k) decision," considering that it was submitted seventeen years after the PerFix Plug was brought to market. (ECF No. 215 at PageID #9010.) Therefore, this issue is moot.

F. Chronic Pain and Migration Warning Opinions

Defendants next argue that Dr. Kessler's opinions that Defendants failed to warn of the risks of chronic pain and migration are irrelevant and should be excluded because Plaintiff's implanting surgeon was already aware of those risks. However, the Court has already addressed this argument and found that there is an issue of fact as to whether the PerFix Plug's warnings were sufficient and whether Dr. Tan was sufficiently aware of the device's risks (DMO No. 7, ECF No. 225 at PageID #9128), therefore this portion of Defendants' motion is denied.

G. Migration Opinions

Defendants argue that Dr. Kessler's migration opinions should be excluded because they are not based on sufficient facts or data. Defendants point to two categories of opinions in particular: opinions regarding marketing materials, and opinions regarding the PerFix Plug's IFU.

1. Marketing Materials

Dr. Kessler opines that Defendants failed to adequately warn of the risk of migration in three of their marketing materials: a 2001 PerFix Plug brochure, a 2008 Technique Guide, and a 2008 PerFix Plug Fact Sheet. (Kessler Report, ECF No. 215-3 at PageID #8480–81.) According to Defendants, "[t]he information in these materials w[as] accurate at the time they were created and nothing Dr. Kessler relies on to support his opinions suggests otherwise." (ECF No. 215 at PageID #8328.) They point to three complaints cited by Dr. Kessler, two from 2010 and one from 2012, which "cannot plausibly inform information [Defendants] distributed about the PerFix Plug in 2001 or 2008." (*Id.*) Similarly, minutes from a "brainstorming" meeting held in 2010 cannot be used to show what Defendants knew in 2001 or 2008. (*Id.*)

Defendants also point to five journal articles on which Dr. Kessler relied. Only two of the articles had been published by the time the 2001 brochure was created: one article related to abdominal wall hernias that does not mention the PerFix Plug, and one case report observing a single incidence of migration. (*Id.* at PageID #8329.) Two more case reports had been published prior to the 2008 Technique Guide and Fact Sheet, and Defendants claim that the case reports do not support Dr. Kessler's opinions that Defendants misrepresented the risk of migration in the 2008 documents. (*Id.*) Defendants point to "ample actual studies involving the PerFix Plug" prior to 2008 that supported the statements in the Technique Guide and Fact Sheet, and argue that the case reports are insufficient to contradict the findings of those studies.

Plaintiff responds that these arguments go to the weight of Dr. Kessler's opinions, rather than their admissibility. (ECF No. 220 at PageID #8824–25.) He also claims that "product labeling and promotional materials fall under the scope of [Dr. Kessler's] expertise and as discussed below, Dr. Kessler is more than qualified to opine on the types of information that typically support warnings in IFUs and marketing materials, and whether the warnings that accompanied the PerFix Plug were adequate from a regulatory perspective." (*Id.* at PageID #8812–13.)

Plaintiff does not address Defendants' argument that the sources which postdate the 2001 brochure and 2008 Technique Guide and Fact Sheet "cannot plausibly inform information [Defendants] distributed about the PerFix Plug in 2001 or 2008." (ECF No. 215 at PageID #8328.) The Court agrees that Dr. Kessler cannot rely on sources dated after the brochure, Technique Guide, or Fact Sheet to inform his opinions regarding those materials. However, as to information that predates the brochure, Technique Guide, and Fact Sheet, Defendants' arguments attack the strength, accuracy, and persuasiveness of Dr. Kessler's opinions and his sources. This goes to the weight of his opinions, not their admissibility. "[M]ere 'weaknesses in the factual basis of an expert witness'[s] opinion . . . bear on the weight of the evidence rather than on its admissibility.'" *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000) (quoting *United States v. L.E. Cooke Co.,* 991 F.2d 336, 342 (6th Cir.1993)).

2. PerFix Plug IFU

Defendants argue that Dr. Kessler's opinion that the PerFix Plug's IFU did not adequately warn of a risk of migration is similarly based on insufficient facts. Defendants point to three PerFix Plug complaints on which Dr. Kessler relied when forming his opinions, two of which Defendants claim do not even mention migration, and they argue that a single complaint is insufficient to

warrant including a warning in an IFU. (ECF No. 215 at PageID #8330.) Defendants also argue that five journal articles published between 1997 and 2008 are not sufficient support for Dr. Kessler's failure to warn opinions. According to Defendants, one article relates to abdominal hernia repair and does not mention the PerFix Plug, whereas the others make up only "four case reports over the course of eight years that each reported a single instance of migration." (*Id.* at PageID #8331.) Similar to his response regarding the marketing materials, Plaintiff claims that this argument goes to the weight of Dr. Kessler's opinions, not their admissibility. (ECF No. 215 at PageID #8824–25.)

Defendants criticize the strength of the complaints and the frequency of the journal articles as insufficient bases for Dr. Kessler's opinions. However, these arguments go to the weight of Dr. Kessler's opinions, not their admissibility. If Defendants take the position that Dr. Kessler's opinions are weak because of the number of complaints and journal articles on which he relied, they may cross examine him to that effect. *See Daubert*, 509 U.S. at 596 ("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.").

H. Areas in Which Dr. Kessler is Not Qualified as an Expert

Defendants argue that Dr. Kessler is not qualified as an expert in several areas, and therefore should not be able to offer opinions on those subjects. First, Defendants argue that Dr. Kessler is not a medical expert with respect to "hernias, the use of mesh for hernia repair, or causation of injuries due to hernia mesh." (ECF No. 215 at PageID #8332.) Plaintiff responds that Dr. Kessler "does not intend to offer testimony regarding hernias, the use of mesh for hernia repair or the design, testing and safety of mesh, and hernia mesh labeling outside of the intersection of those topics with FDA regulations." (ECF No. 220 at PageID #8826.) Therefore, this portion

of Defendants' motion is moot.

Second, "Dr. Kessler is not an expert in the design, testing, and safety of mesh," although Defendants acknowledge that he does not disclose any opinions on the testing or design of the PerFix Plug. (ECF No. 215 at PageID #8333.) Plaintiff claims that Dr. Kessler is qualified to offer opinions on the intersection between FDA regulations and design, testing, and safety of mesh. (ECF No. 220 at PageID #8828.) However, this argument as to Dr. Kessler's qualifications ignores that his opinions regarding the PerFix Plug relate to labeling and warnings, and he did not disclose any opinions on the testing or design of the PerFix Plug. Therefore, this portion of Defendants' motion is granted.

I. MSDS Opinions

Consistent with the Court's prior rulings, Defendants argue that Dr. Kessler's MSDS opinions are inadmissible. (ECF No. 215 at PageID #8334–35.) Plaintiff responds that Dr. Kessler "will only opine that the MSDS put Defendant[s] on notice of a potential safety issue and Defendants did not act on this notice." (ECF No. 220 at PageID #8828–29.) Plaintiff states that Dr. Kessler's "supplemental opinions concerning the MSDS" offered during his deposition were in response to statements made by Defendants' regulatory expert, Dr. Tillman. (ECF No. 220 at PageID #8816.) However, as the Court ruled in EMO No. 27 (ECF No. 237), Dr. Tillman's MSDS opinions are inadmissible. Therefore, this portion of Defendants' motion is moot.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude the Opinions and Testimony of Dr. Kessler (ECF No. 215) is **GRANTED IN PART**, **DENIED IN PART**, and

DENIED IN PART AS MOOT.

IT IS SO ORDERED.

6/6/2023
DATE

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