

**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

MOTIONS IN LIMINE OPINION & ORDER No. 8

Plaintiff Steven Johns and Defendants C.R. Bard, Inc. and Davol, Inc. filed various motions in limine to exclude evidence in this case. Now before the Court are Parts 13, 18, and 19 of Plaintiff's Motion in Limine No. 1 to Exclude Certain Subjects from Evidence at Trial ([ECF No. 235](#)), Defendants' Motion in Limine No. 17 to Exclude Evidence and Argument Concerning Unrelated Investigations, Convictions, Congressional Committee Proceedings and Letters, Settlements, or Alleged Bad Acts ([ECF No. 220](#)), and Plaintiff's Motion in Limine No. 8 to Exclude Certain Evidence Related to UCSF ([ECF No. 237](#)).

I. Background¹

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, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-

¹ The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc., 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).

md-02846, [ECF No. 1](#) at PageID #1–2.)² This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. [2020 WL 5223363](#), at *1. The Food and Drug Administration (“FDA”) cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid (“PGA”) fibers, and a bioresorbable coating called “Sepra Technology” (“ST”). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants’ allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body and that the PGA fibers created an increased inflammatory response. *Id.* at *4. The crux of Plaintiff’s claims is that the ST coating on Ventralight ST devices resorbs too quickly. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The adhesions were diagnosed during a subsequent laparoscopic surgery in October 2016 by Plaintiff’s implanting surgeon. *Id.* at *5.³ After summary judgment, 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

² Unless otherwise noted, record citations are to the docket for this case, No. 18-cv-01509.

³ The Court granted Defendants’ motion for summary judgment on Plaintiff’s other alleged injuries because Plaintiff failed to demonstrate a material fact dispute regarding causation. [2020 WL 5223363](#), at *14.

punitive damages. *Id.* at *6–25. Now, various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses three motions in limine: Plaintiff’s Motion in Limine No. 1, specifically Parts 13, 18, and 19 ([ECF No. 235 at PageID #12918–20](#)), Defendants’ Motion in Limine No. 17 ([ECF No. 220](#)), and Plaintiff’s Motion in Limine No. 8 ([ECF No. 237](#)).

II. Legal Standards

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*.” *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, [348 F. Supp. 3d 698, 721](#) (S.D. Ohio 2016). The practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of trials.” *Luce v. United States*, [469 U.S. 38, 41 n.4](#) (1984). “The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial.” *In re E.I. du Pont*, [348 F. Supp. 3d at 721](#) (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, [326 F. Supp. 2d 844, 846](#) (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, [2 F. Supp. 2d 1385, 1388](#) (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, [519 F.2d 708, 712](#) (6th Cir. 1975). Unless the moving party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—“evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, [326 F. Supp. 2d at 846](#); see also *Koch*, [2 F. Supp. 2d at 1388](#) (“[A] court is almost always better situated during the actual trial to assess the value and utility of evidence.”). The denial, in whole or in part, of a motion in limine does not give a party

license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, [326 F. Supp. 2d at 846](#).

Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” [Fed. R. Evid. 401](#). “Irrelevant evidence is” inadmissible. [Fed. R. Evid. 402](#). A court may exclude relevant evidence under Federal Rule of Evidence 403 “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” [Fed. R. Evid. 403](#). 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); *see also Paschal v. Flagstar Bank*, [295 F.3d 565, 576](#) (6th Cir. 2002) (“In reviewing the trial court’s decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.”).

III. Analysis

A. Plaintiff’s Motion in Limine No. 1

In this motion, Plaintiff argues that twenty subjects should be excluded at trial. ([ECF No. 235](#).) During the hearing, the parties confirmed that on almost all subjects, they had reached an agreement, leading the Court to grant Plaintiff’s motion in limine as to seventeen of the twenty parts. ([ECF No. 311 at PageID #16824–37](#).) The Court reserved judgment on Parts 13, 18, and 19 and ordered supplemental briefing. *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 6605576](#), at *1 (S.D. Ohio Sept. 11, 2020). The briefing is complete.

1. Part 13

In Part 13 of his motion, Plaintiff argues that any evidence about Defendants' actions for societal good either by manufacturing devices or by performing charitable acts should be excluded. ([ECF No. 235 at PageID #12918.](#)) This part of the motion includes reference to Defendants' devices as "lifesaving," COVID-19 related endeavors, and charitable acts, including a donation of devices to Dr. Jensen. (*Id.* at PageID #12918–19.) Motions in Limine Opinion and Order No. 7 addresses the characterization of Defendants' devices as "lifesaving." *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 7065764](#), at *9 (S.D. Ohio Dec. 3, 2020). And Defendants will be permitted to explain briefly what their companies do and produce, which may include some reference to COVID-19 related efforts (if they are significant and form a large part of Defendants' business) or the fact that their devices are designed to be useful, treat medical conditions, etc. ([ECF No. 311 at PageID #16836–37.](#)) As Defendants correctly point out, parties are generally allowed to describe the nature of their business so long as it will assist the jury in understanding the factual issues in the case. *E.g.*, *In Re Bard IVC Filters Prods. Liab. Litig.*, Nos. MDL 15-02641-PHX DGC, CV-16-00474-PHX-DGC, [2018 WL 934795](#), at *2 (D. Ariz. Feb. 15, 2018); *Knight v. Boehringer Ingelheim Pharms., Inc.*, [323 F. Supp. 3d 837, 854](#) (S.D.W. Va. 2018). Therefore, Plaintiff's motion is denied with regard to these aspects.

This leaves evidence of Defendants' "good acts in the community and relationship with surgeons," including their device donation to Dr. Jensen for his mission trip. ([ECF No. 257 at PageID #13602.](#))

i. Good acts

Evidence of Defendants' good or charitable acts in the community fall within a different category than flattering background information about Defendants. Rule 404(a) prohibits character or propensity evidence, "[e]vidence of a person's character or character trait" used "to prove that on a particular occasion the person acted in accordance with the character or trait." Fed. R. Evid. 404(a). Rule 404(b) prohibits evidence of other acts "to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). Evidence of Defendants' charitable acts that are unrelated to the development of its devices is propensity evidence, attempting to induce the jury to conclude that because Defendants have a good corporate character, it is unlikely that they behaved poorly in manufacturing and marketing the Ventralight ST. *See Knight*, 323 F. Supp 3d. at 854 ("The Court will not permit Defendant to adduce evidence or argument related to its own good, company-wide reputation, its unrelated "good" or charitable acts, or other corporate practices indicative of its social conscious that are unrelated to [the product at issue]."). Accordingly, Plaintiff's motion is granted on this point and the evidence will be excluded.

Defendants counter that this evidence is relevant to whether punitive damages are appropriate. (ECF No. 257 at PageID #13602; ECF No. 307 at PageID #16691–92.) Evidence of Defendants' conduct in relation to the Ventralight ST, whether merely negligent or, as required by Utah law for punitive damages, Utah Code. Ann. § 78B-8-201, willful, malicious, intentionally fraudulent or knowingly and recklessly indifferent is relevant because the nature of Defendants' conduct is at issue at this liability stage. *See* 2020 WL 6605576, at *2 (explaining that evidence of Defendants' "financial condition" would be the subject of separate punitive damages proceedings). But general evidence of Defendants' charitableness has no relevance to the nature of Defendants'

conduct in relation to the Ventralight ST. Therefore, this evidence is inadmissible, and this part of Plaintiff's motion is granted.

ii. Donation to Dr. Jensen

In his supplemental brief, Plaintiff argues that this evidence is irrelevant under Rules 401 and 402, prejudicial under Rule 403, and improper evidence of good character under Federal Rule of Evidence 404. Defendants contend that this evidence is relevant to rebut the bad intent that Plaintiff "ascribe[s]" to Defendants in his argument that Defendants concealed certain evidence from Dr. Jensen, which Dr. Jensen averred would have led him to not use the Ventralight ST in Plaintiff's surgery. ([ECF No. 307 at PageID #16690.](#))

Plaintiff is clear that he will argue that Defendants intentionally concealed information from Dr. Jensen and all medical providers ([ECF No. 320 at PageID #17188](#)), which is relevant to Plaintiff's failure-to-warn claims, specifically whether the warning for the Ventralight ST was adequate. Defendants are free to rebut this evidence, but only with relevant evidence. It is unclear how evidence that Defendants donated devices, which do not appear to have been the Ventralight ST or a similar device, for charitable mission trips challenges evidence that Defendants purposefully concealed from Dr. Jensen information related to the Ventralight ST.

Defendants argue that this evidence contextualizes Dr. Jensen's relationship with Defendants and helps explain why he decided to use the Ventralight ST in Plaintiff's surgery. ([ECF No. 307 at PageID #16692.](#)) But this evidence has no probative value to whether Defendants concealed important information about the Ventralight ST from Dr. Jensen. Rather, is character evidence, enticing the jury to infer that because Defendants previously acted benevolently toward Dr. Jensen, they are less likely to have misled him here. [Fed. R. Evid. 404\(a\), \(b\).](#)

Defendants do not provide any authorities to the contrary. They cite *In re Bard IVC Filters Products Liability Litigation*, Nos. MDL 15-02641-PHS-DGC, CV-16-00474-PHX-DGC, [2018 WL 934795](#) (D. Ariz. Feb. 15, 2018), but the court in that case did not consider similar evidence. There, the district court considered and admitted “evidence regarding the nature, quality, and usefulness of their products . . . and the fact that their products are designed to promote health and save lives.” *Id.* at *2. The court concluded that Defendants could “rebut Plaintiffs’ themes” by presenting “evidence regarding the nature of Defendants’ business.” *Id.* Evidence of donations made to Dr. Jensen’s Guatemala mission trip is not evidence of the nature of Defendants’ business. This is a discrete instance that has little to do with the nature of Defendants’ businesses as device manufacturers.

For these reasons, the Court grants Plaintiff’s motion in this respect.

2. Parts 18 & 19

Next, Plaintiff argues in his motion that evidence should be excluded if offered to prove “that state warning defect or failure-to-warn laws pressure manufacturers to add unsubstantiated, false, or invalid warnings in order to avoid lawsuits” and “that too many warnings of serious injuries will dilute the effectiveness of warnings generally.” ([ECF No. 235 at PageID #12919–20.](#)) The Court ordered the parties to further clarify their positions in supplemental briefing. [2020 WL 6605576](#), at *1. In his supplemental brief, Plaintiff identified his chief concern, that Defendants would argue generally that the state-law tort systems undermine congressional intent, presumably as represented by the Food, Drug, and Cosmetic Act of 1938, [21 U.S.C. §§ 301–399g](#), and undermine FDA regulations. ([ECF No. 308 at PageID #16708.](#)) He also explains that if the Defendants argue generally that too many warnings dilute the effectiveness of warnings, the jury may conclude that they cannot find for Plaintiff even if his failure to warn claims have merit. (*Id.*

at PageID #16711.) Defendants respond that they agree that this sort of generalized evidence is inappropriate, but that evidence from a qualified expert about the adequacy of Defendants' warnings is admissible. ([ECF No. 317](#) at PageID #17121–22.)

The adequacy of Defendants' warnings is a crucial element of Plaintiff's failure to warn claims. *Feasel v. Tracker Marine, LLC*, [460 P.3d 145, 152](#) (Utah Ct. App.) (negligence), *cert. granted sub nom., Feasel v. Tracker Marine*, [466 P.3d 1072](#) (Utah 2020); *Christison v. Biogen Idec Inc.*, No. 2:11-CV-01140-DN-DBP, [2014 WL 7261300](#), at *8 (D. Utah Dec. 18, 2014) (strict liability). Evidence that Defendants considered the effects of warning dilution in writing the instructions for use and evidence that surgeon end-users are impacted by warning dilution may be relevant and admissible to the adequacy of a warning. *See, e.g., Mahaney ex rel. estate of Kyle v. Novartis Pharms. Corp.*, [835 F. Supp. 2d 299, 321](#) (W.D. Ky. 2011) (“Overwarning, or warning fatigue, is a legitimate concern of manufacturers when creating labels for consumers.”) (denying Plaintiff's motion to exclude any evidence about warning dilution), *vacated on other grounds*, No. 1:06-CV-00035-R, [2012 WL 12996015](#) (W.D. Ky. Jan. 4, 2012).⁴ The Court notes that the precise testimony to be offered on this point has not been identified.

Therefore, the Court grants in part Parts 18 and 19 of Plaintiff's motion regarding generalized evidence but denies it in part to the extent that it would prevent the admission of evidence regarding the adequacy of the warnings for the Ventralight ST, including the possible effect of warning dilution here. The Court reiterates, however, that an expert must be qualified to testify as to the adequacy of warnings from a regulatory or legal perspective and an expert must be qualified to testify as to whether a warning adequately disclosed risks to the surgeon end-user.

⁴ In Evidentiary Motion Opinion No. 5, the Court explained that Dr. Grischkan was qualified to give an opinion about whether the Ventralight ST's instructions for use completely disclosed the pertinent risks to a medical provider as the end-user of the device. *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 6605542](#), at *16 (S.D. Ohio Sept. 1, 2020).

In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig., [2020 WL 6605542](#), at *16–17.

B. Defendants’ Motion in Limine No. 17

In this motion in limine, Defendants argue that three discrete types of evidence should be excluded. Each is addressed in turn.

1. Evidence of guilty pleas in relation to cardiac catheter devices

First, Defendants argue that evidence of Bard’s and former employees’ 1994 guilty pleas to concealing issues from the FDA and selling defective heart catheters that the FDA did not approve for use should be excluded under Federal Rules of Evidence 401, 402, 403, 404, and 609. ([ECF No. 220 at PageID #12070–75.](#)) Plaintiff responds that he will only offer this evidence under Rule 609 in the event that Defendants open the door by discussing their good character⁵ or history of prioritizing patient safety. ([ECF No. 289 at PageID #16028.](#)) The parties stumble into two gray areas of law in this circuit: the applicability of Rule 609 to impeachment-by-contradiction evidence and the applicability of Rule 609 to corporate witnesses.

Rule 609 governs impeachment of a witness with evidence of a criminal conviction. Under this rule, the use of prior convictions attacks a witness’s general character for truthfulness or untruthfulness. [Fed. R. Evid. 609\(a\)](#); Victor J. Gold, 28 Fed. Prac. & Proc. Evid. § 6133 (2d ed.), Westlaw (database updated Oct. 2020). This rule is premised on the idea that those who have been convicted before of a felony or other crimes based upon dishonesty or false statements are more likely to commit perjury now. *United States v. Noble*, [754 F.2d 1324, 1331](#) (7th Cir. 1985) (citing Conf. Rep. No. 1597, 93rd Cong., 2d Sess., *reprinted in* 1974 U.S.C.C.A.N. 7051, 7098,

⁵ Rule 404 prohibits the admission of character evidence without exception, *i.e.* whether the propensity evidence addresses a good or bad character. [Fed. R. Evid. 404](#). The Court proceeds with this in mind, specifically that Defendants cannot introduce evidence of their good character to prove that they acted in a manner consistent with this character.

7103). Impeachment under Rule 609 is a blanket attack, used to demonstrate that the witness's testimony should not be credited in any regard. Extrinsic evidence of a conviction is permissible. Fed. R. Evid. 608(b).

Impeachment-by-contradiction evidence, however, is a targeted attack upon a witness's credibility. This type of evidence "permits courts to admit extrinsic evidence that specific testimony is false, because [the testimony is] contradicted by other evidence." *United States v. Craig*, 953 F.3d 898, 904 (6th Cir. 2020) (quoting *United States v. Kincaid-Chauncey*, 556 F.3d 923, 932 (9th Cir. 2009)). More precisely, impeachment by contradiction shows that the witness is mistaken, "that something he said is not so," but does not identify the source of the witness's mistake, be it an instance of untruthfulness, bias, misperception, lack of knowledge, etc. Christopher B. Mueller & Laird C. Kirkpatrick, *Federal Evidence* § 6:85 (4th ed.), Westlaw (database updated May 2020); *see also* Roger Park & Tom Lininger, *The New Wigmore. A Treatise on Evidence* § 4.1 (1st ed. Supp. 2021) ("This form of impeachment shows an indefinite capacity to err. It does not tell us the source of the error."). Impeachment by contradiction is a custom inherent to our adversarial system, recognized by the vast majority of federal courts and commentators alike, though the Federal Rules of Evidence do not expressly contemplate (much less forbid) the method. Mueller & Kirkpatrick, *supra*, at § 6:90; *see also* Park & Lininger, *supra*, at § 4.1. Extrinsic evidence of prior convictions offered to impeach via contradiction of a witness's specific testimony is not prohibited by Rules 608 and 609, or even Rule 404; it is governed simply by Rule 403. *E.g.*, *United States v. Gilmore*, 553 F.3d 266, 271–73 (3d Cir. 2009); *United States v. Benavides*, 470 F. App'x 782, 790 (11th Cir. 2012); *see also* Fed. R. Evid. 608 advisory committee's note to 2003 amendment ("The Rule has been amended to clarify that the absolute prohibition on extrinsic evidence applies only when the sole reason for proffering that evidence is

to attack or support the witness' character for truthfulness." (collecting authorities)). Although the Sixth Circuit has "expressed skepticism as to whether impeachment by contradiction is permissible in this circuit," *Craig*, 953 F.3d at 905, the Sixth Circuit has upheld the admission of such evidence, though it does not specify that it is doing so and often purports to be applying Rule 609, *e.g.*, *United States v. Bender*, 265 F.3d 464, 471 (6th Cir. 2001).

The distinction between Rule 609 evidence and prior convictions serving as impeachment-by-contradiction evidence frequently does not matter for the ultimate question of admissibility. For example, in a civil case, evidence of a prior felony conviction would be subject to Rule 403 whether introduced under Rule 609 or to impeach by contradiction. Fed. R. Evid. 609(a)(1)(A). The distinction matters in some cases, however. A conviction for a crime requiring proof of dishonesty or false statements that is less than ten years old must be admitted in a civil case or criminal case against a witness under Rule 609(a)(2); there is no Rule 403 backstop. Fed. R. Evid. 609(a)(2) (including mandatory language, "must be admitted"). And if a conviction is more than ten years old, the more demanding balancing test in Rule 609(b)(a)(2) applies, presenting a higher hurdle for the party offering the conviction to impeach a witness's general character for truthfulness, as opposed to a party offering the conviction to contradict a witness's specific statement, to which Rule 403 applies. The Sixth Circuit has not yet expressly considered the distinction between convictions offered under Rule 609 and those offered to impeach by contradiction.

Even another wrinkle presented by Rule 609 must be addressed. When a corporate witness will testify, it is undecided if evidence of the corporation's conviction is properly admissible under Rule 609 to impeach the testifying corporate witness when the witness was uninvolved in the conduct giving rise to the prior conviction. *Hickson Corp. v. Norfolk S. Ry. Co.*, 124 F. App'x 336,

342–43 (6th Cir. 2005) (declining to decide this issue).⁶ If a corporate witness were uninvolved in the conduct underlying the conviction, it would not tend to suggest that this particular corporate witness has an untruthful character. *Gold, supra*, at § 6133 n.49 (“There is limited authority suggesting that a conviction of a corporation may be employed to impeach the officers, directors, or managing agent of the corporation, even if they were not personally convicted themselves.” (collecting cases)). The Third Circuit—the only court of appeals to decide this issue—put it succinctly: “Criminal acts are relevant to a witness’ credibility only if that witness actually participated in the criminal conduct. It strains logic to argue that an employee’s credibility is properly brought into question by the mere fact that he or she is presently employed by a corporation that in some unrelated manner was guilty of dishonest acts, no matter how egregious those acts may have been.” *Walden v. Ga.-Pac. Corp.*, 126 F.3d 50, 523–24 (3d Cir. 1997).⁷ However, impeachment-by-contradiction would clearly be permissible for a corporate witness regardless of their involvement in acts giving rise to a corporate conviction because the aim is to demonstrate that the witness is objectively mistaken.

⁶ The parties do not expressly state whether the witnesses were involved in the 1994 convictions. But based on the arguments, the Court assumes that none of the corporate witnesses were involved in the conduct leading up to the 1994 convictions, nor were they themselves convicted of a crime. (See ECF No. 220 at PageID #12073; ECF No. 289 at PageID #16030.)

⁷ Plaintiff points to one case permitting use of a corporation’s convictions to impeach a corporate witness, reaching this conclusion because “a corporation cannot testify as a witness but through testimony of its employees and representatives.” (ECF No. 289 at PageID #16030 (quoting *Stone v. C.R. Bard*, No. 02 CIV 3433 WHP, 2003 WL 22902564, at *2 (S.D.N.Y. Dec. 8, 2003).) This may be the case, but this statement does nothing to show that Rule 609 should be applied when the corporate witness was uninvolved in the activity giving rise to the conviction. The court in *Stone* relied on agency theory to permit impeachment of a corporate witness’s testimony under Rule 609. *Stone*, 2003 WL 22902564, at *2. But if the corporate witness was uninvolved in the activity underlying the conviction, the witness was not then the corporation’s agent, and agency law provides no rationale for permitting impeachment of the corporate witness under Rule 609. This rationale is only sensible when the witness was somehow involved in the conduct leading to a conviction. See *CGM Contractors, Inc. v. Contractors Env’t Servs., Inc.*, 383 S.E.2d 861, 866 (W. Va. 1989) (holding that a corporate conviction is admissible against a witness only if the witness “held a managerial position at the time the crime occurred such that it may be fairly inferred that he shared responsibility for the criminal act, or have actually participated in the criminal act”); see also *Walden*, 126 F.3d at 524 n.16 (declining to expressly adopt West Virginia’s conclusion, but concluding that it was consistent with its own reasoning).

The Court concludes that Rule 609 does not govern the admissibility of the 1994 convictions because Plaintiff seeks does not propose an attack on a corporate witness's general character for truthfulness. Instead, Plaintiff explains that he will offer evidence of Defendants' guilty plea to contradict specific testimony that Defendants may offer. This is not Rule 609 evidence, or evidence that the witness generally has an untruthful character; this is impeachment-by-contradiction evidence, or evidence that contradicts a witness's specific assertion.⁸ But even if Rule 609 applied under these circumstances, it is inapplicable to these corporate witnesses. As the Third Circuit concluded, it would make little sense to apply Rule 609 when the prior convictions offered by the opposing party go to corporate conduct in which the corporate witness played no part.⁹ Therefore, Defendants' Rule 609 argument does not find traction.¹⁰

This does not end the analysis, however. Evidence that directly contradicts a witness's testimony is relevant impeachment evidence, but it still must pass Rule 403's balancing test. In the Rule 403 context, the age of a prior conviction may lessen its probative value and increase the risk of prejudice. *See Gilmore*, 553 F.3d at 266. The weighing of the probative value of the

⁸ Because the issue is contradiction, not character, Plaintiff's argument that Rule 405 permits admission of extrinsic evidence of character once a party opens the door to it is similarly off base. (ECF No. 289 at PageID #16031.) As with Rule 609, Rule 405 finds no foothold when the corporate witness was uninvolved in the criminal conduct leading to the corporate convictions because the conviction does not speak to the witness's character.

⁹ If it were the witness's conviction or if the witness were involved in the criminal activity such that the 1994 convictions were proper evidence of a character for untruthfulness, it would be necessary to contend with the overlap of impeachment-by-contradiction evidence and Rule 608's prohibition on introducing extrinsic evidence of to demonstrate a witness's character for untruthfulness. A party must take the witness's answer pursuant to Rule 608 if the party "first asks a witness about something she did that suggests untruthfulness," as opposed to "the very different situation in which a witness gives *direct testimony* on some point that bears in the case." Mueller & Kirkpatrick, *supra*, at § 6:90 (emphasis in original).

¹⁰ In any case, Plaintiff incorrectly argues that Defendants' 1994 conviction is covered by Rule 609(a)(2) (ECF No. 289 at PageID #16030), which requires the admission of convictions based on fraud or dishonesty, Fed. R. Evid. 609(a)(2). Defendants' conviction, though fraud-based, is over ten years old. Rule 609(b), the limit on using convictions older than ten years, applies regardless of what type of conviction is at issue. Fed. R. Evid. 609(b) ("This subdivision (b) applies if more than 10 years have passed since the witness's conviction"). This makes no difference for Plaintiff, however, because convictions older than ten years are admissible to impeach a witness once the witness opens the door to his criminal history, or here, his corporation's criminal history, with his testimony. *Fathera v. Smyrna Police Dep't*, 646 F. App'x 395, 401 (6th Cir. 2016); *Bender*, 265 F.3d at 471 (concluding that the door had been opened to the admission of a more-then-ten-year-old conviction).

contradiction, however, depends in part on the exact testimony offered. For example, a “broad denial” of ever misleading the FDA would increase the probative value of Defendants’ 1994 conviction, though “[a] more limited denial,” such as one that denies ever misleading the FDA in relation to the Ventralight ST, would decrease the probative value of the prior conviction while drastically raising the risk of unfair prejudice to Defendants. *See id.* at 273. For this reason, the Court cannot determine outside of trial whether evidence of Defendants’ prior convictions is admissible to impeach Defendants.

Defendants offer no compelling arguments that the Court should decide the Rule 403 issue now. Defendants argue that any evidence of their 1994 convictions would lead the jury punish them for their actions in 1994, instead of those at issue here. ([ECF No. 220 at PageID #12074.](#)) But this risk is small if used only to impeach a defense witness on a narrow and specific assertion. Moreover, Defendants can avoid the issue in the first place by avoiding opening the door, which suggests that the Court should withhold its judgment until trial.

Defendants also argue that if evidence of the 1994 convictions were admitted, they would have to describe the actions they took to rectify their alleged transgressions against the FDA, such as selling the division of Bard implicated in 1994 and implementing a new compliance program. (*Id.* at PageID #12074.) Evidence about selling off unrelated divisions appears to be inadmissible because it is irrelevant to the merits of Plaintiff’s claims and does not appear to serve a rehabilitative purpose. As for evidence of corporate changes to avoid further liability, this would appear to behoove Defendants, lengthening the trial only to demonstrate how Defendants’ corporation is now in compliance with FDA regulations, which help define the standard of care. *Downing*, [194 P.3d at 948](#). The prejudice to Defendants is not so clear that the Court can grant Defendants’ motion on the basis of Rule 403.

For these reasons, this part of Defendants' motion is denied, subject to the following. Because the prior conviction has a high degree of potentially unfair prejudice, no party may mention or introduce testimony on the subject without prior approval of the Court.

2. Evidence of 2013 investigation and settlement related to Defendants' brachytherapy seeds

Next Defendants argue that evidence of a 2013 False Claims Act settlement and investigation related to Defendants' brachytherapy seeds, a treatment for prostate cancer, is irrelevant under 401, likely to cause confusion under Rule 403, and inadmissible as evidence of a settlement under Federal Rule of Evidence Rule 408. ([ECF No. 220 at PageID #12075.](#)) During the hearing, Defendants confirmed that this settlement did not contain an admission of liability. ([ECF No. 380 at PageID #20390.](#)) Plaintiff argues, as he did in relation to the 1994 guilty plea and conviction, that if Defendants open the door, he may present this evidence. ([ECF No. 289 at PageID #16029.](#))

Evidence of the fact that this settlement exists is not categorically prohibited by Rule 408. Rule 408 prohibits admission of offers and promises of "valuable consideration in compromising or attempting to compromise the claim" and conduct and statements made during these negotiations if offered "to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction." [Fed. R. Evid. 408\(a\)](#). Such evidence may be admitted for another purpose, however. [Fed. R. Evid. 408\(b\)](#). The dispositive inquiry for Rule 408 is whether the settlement or evidence of statements made during settlement negotiations are offered to prove or disprove the validity or amount of a claim. *Appalachian Reg'l Healthcare, Inc. v. U.S. Nursing Corp.*, [824 F. App'x 360, 373](#) (6th Cir. 2020); *Arnold v. Wilder*, [657 F.3d 353, 367](#) (6th Cir. 2011). Here, evidence of the settlement would not be introduced to prove or disprove the validity of that 2013 settlement. Accordingly, Rule 408 is inapplicable.

The relevance and prejudice of this evidence is unclear. Plaintiff argues he would offer this evidence to impeach and rebut witness testimony, but just how probative and material or how prejudicial and confusing this evidence is depends on the context at trial. For example, if a corporate witness for Defendants testified that Bard or Davol has never made a false statement about its devices, evidence of this settlement would likely be relevant and admissible. Additionally, the parties pay little attention to this argument, focusing more on the 1994 conviction arguments. Thus, this part of the motion generally lacks detail and context necessary to decide before trial whether evidence of the 2013 settlement is admissible.

Therefore, this part of Defendants' motion is denied, subject to the following. Neither party shall mention or offer testimony on the 2013 settlement without prior approval of the Court.

3. Evidence of congressional proceedings and correspondence

Finally, Defendants argue that evidence of correspondence from the United States Senate Special Committee on Aging, specifically a letter sent eight months after a hearing, should be excluded as irrelevant, confusing, and inadmissible hearsay. ([ECF No. 220 at PageID #12076.](#)) Defendants explain that this letter notes the FDA's 2011 Public Health Notification addressing vaginal mesh, discusses the lawsuits regarding vaginal and hernia mesh, and makes inquiries about Defendants' recall and post-marketing surveillance practices. (*Id.*) Plaintiff counters that this evidence is relevant to demonstrate what Defendants knew or should have known about the risks caused by polypropylene in mesh implants, that any correspondence from Defendants is admissible as a party-opponent statement, and that the correspondence is a public report admissible under Federal Rule of Evidence 803(8)(iii). ([ECF No. 289 at PageID #16032–35.](#))

Plaintiff is right on the first two points. To the extent that evidence related to the congressional Committee is indicative of Defendants' understanding of the risk posed by

polypropylene, which is the raw material used in both vaginal and hernia mesh, and how this knowledge informed Defendants' conduct goes to the reasonableness of Defendants' conduct. Notice or knowledge is a non-hearsay use for out-of-court statements. *Biegas v. Quickway Carriers, Inc.*, [573 F.3d 365, 379](#) (6th Cir. 2009). And any of Defendants' correspondence with Congress would fall within the party-opponent exemption from hearsay. [Fed. R. Evid. 801\(d\)\(2\)](#).

However, not every piece of congressional correspondence necessarily falls within Rule 803(8)(iii). The Rule provides, in relevant part, that a public record is an exception to the rule against hearsay if the statement from a public office sets out "factual findings from a legally authorized investigation." [Fed. R. Evid. 803\(8\)\(A\)\(iii\)](#). The requirement that the statement contain *factual* findings is inflexible. For example, subjective findings from Congress do not satisfy Rule 803(8)(A)(iii). *Bright v. Firestone Tire & Rubber Co.*, [756 F.2d 19, 23](#) (6th Cir. 1984). Plaintiff points to nothing that would suggest that a record of the proceedings or the letter from a congressional committee to Defendants would qualify as factual findings from an investigation. Rather, the letter appears to ask questions of Defendants and set forth concerns. But neither Defendants nor Plaintiff attaches the evidence at issue or provides a record citation so that the Court may view the evidence regarding the congressional proceedings.¹¹ The Court declines to rule definitively without the benefit of viewing the letter.

For these reasons, this part of Defendants' motion is denied, subject to the following. Neither party may refer to or offer testimony of the congressional correspondence, referenced here and without prior approval of the Court.

C. Plaintiff's Motion in Limine No. 8

¹¹ Of course, Plaintiff bears the ultimate burden of demonstrating admissibility as the proponent of the evidence. *United States v. Brika*, [416 F.3d 514, 529](#) (6th Cir. 2005). But the movant bears the burden at the motion-in-limine stage. *Supra*, Part II.

Finally, the Court turns to Plaintiff's Motion in Limine No. 8. ([ECF No. 237](#).) In his motion, Plaintiff raises three arguments, some of which the Court has already addressed. Plaintiff argues that evidence of the exemption of his expert, Dr. David Kessler, from a compensation policy at University of California San Francisco ("UCSF") should be excluded. ([ECF No. 237 at PageID #12957](#).) The Court granted in part and denied in part this aspect of Plaintiff's motion. ([ECF No. 266 at PageID #18932](#).) He also contends that a webpage on UCSF's website is inadmissible. ([ECF No. 237 at PageID #12958](#).) The Court granted in part and denied in part this part of Plaintiff's motion and stated that a reasoned decision would follow. ([ECF No. 366 at PageID #18932](#).) Plaintiff finally argues that evidence of Dr. Kessler's termination should be excluded ([ECF No. 237 at PageID #12956](#)), which led Defendants to argue that evidence of related to the employment history of their expert, Dr. Donna Bea-Tillman, from the FDA should also be excluded ([ECF No. 264 at PageID #14084 & n.1](#); [ECF No. 360 at PageID #18848-49](#).) The Court ordered supplemental briefing on the exclusion of Dr. Tillman's employment history and reserved judgment as to the admissibility of both Dr. Kessler's and Dr. Tillman's employment histories. ([ECF No. 366 at PageID#18932](#).)

1. UCSF Webpage

Plaintiff argues that a webpage from UCSF's Department of Surgery titled "Laparoscopic Ventral Hernia Repair" should be excluded because it is an unauthenticated document and inadmissible hearsay. ([ECF No. 237 at PageID #12958-59](#).) Defendants counter that the webpage is admissible hearsay, like FDA websites, and that they should be permitted to examine Dr. Kessler regarding the opinion of his employer during cross examination. ([ECF No. 264 at PageID #14086-87](#).) The Court concluded that substantively, the webpage was inadmissible, though it may be admissible for cross-examination purposes. ([ECF No. 360 at PageID #18852-53](#).)

The webpage is not admissible substantively because it is inadmissible hearsay. Hearsay is an out-of-court statement offered for the truth of the matter asserted, Fed. R. Evid. 801(c), and it is inadmissible unless a federal statute, the Federal Rules of Evidence, or a Supreme Court opinion provide otherwise, Fed R. Evid. 802. To the extent that Defendants offer the webpage to prove its content, it is hearsay, and Defendants do not successfully show that the webpage is admissible. Defendants cite to cases that rely on Federal Rule of Evidence 803(8) while concluding FDA webpages are admissible, such as *Musgrave v. Breg, Inc.*, No. 2:09-cv-01029, 2011 WL 450232, at *6 (S.D. Ohio Sept. 28, 2011), though they do not address Rule 803(8) themselves. (ECF No. 264 at PageID #14086–87.) Rule 803(8) encompasses statements from public offices, Fed. R. Evid. 803(8), which UCSF is not.

However, it is possible that the UCSF webpage would be admissible to cross examine Dr. Kessler as an expert witness at trial. Under these circumstances, the webpage would be admitted not to demonstrate the truth of the webpage's contents, but to test Dr. Kessler's awareness or knowledge of the webpage posted by his employer and colleagues.

The relevance, prejudice, delay, and risk of confusion of this evidence is uncertain at this time. The Court has ruled that it will explain the premarket notification § 510(k) process. (ECF No. 355 at PageID #18767–69.) It is unclear in light of this decision how much FDA-related expert testimony will be presented at trial. The risk of the jury mistaking the webpage as substantive evidence that adhesions are a common risk of laparoscopic hernia repairs (ECF No. 360 at PageID #18852 (explaining the contents of the webpage)) also cannot be predicted outside of the context of Plaintiff's impeachment of Dr. Kessler. Although Rule 403 concerns lurk, at this time it is inappropriate at this time to exclude all possible uses of the UCSF webpage.

Therefore, this part of Plaintiff's motion is denied.

2. Experts' Termination Histories

The parties also argue that aspects of their FDA experts' employment histories should be excluded. In his motion, Plaintiff argues that evidence related to Dr. Kessler's termination as a dean at UCSF should be excluded because he was terminated as a result of a whistleblower complaint regarding financial irregularities, he maintained his medical employment, and UCSF later apologized for the termination from his deanship. ([ECF No. 237 at PageID #12956–57.](#)) In response, Defendants contend that Dr. Kessler's employment history is relevant for impeachment purposes, but that they will agree to a limitation regarding Dr. Kessler's termination as dean if Plaintiff agrees not to introduce certain employment-history evidence of Defendants' FDA expert, Dr. Tillman. ([ECF No. 264 at PageID #14083.](#)) Plaintiff explains that he will not agree to this limitation because Dr. Tillman draws from her FDA experience—the source of the disputed employment history—while Dr. Kessler does not, and that this particular aspect of her employment history is relevant to her credibility. ([ECF No. 363 at PageID #18868.](#)) Dr. Tillman was accused of a manufacturer-slanted bias in employee complaints while she was at the FDA. ([ECF No. 363 at PageID #18871.](#))

Federal Rule of Evidence 702 makes clear that an expert witness's experience and training, *i.e.* their employment, forms a part of their expertise. [Fed. R. Evid. 702](#). But Rules 401 and 403 still apply. Dr. Kessler's termination from a deanship does not form any basis for his expertise as offered in this case. Accordingly, Defendants may not attack Dr. Kessler's credibility by referring to his termination. Any discussion about the details of his termination as a dean would also unduly delay trial, confuse the jury, and prejudice Plaintiff. However, Defendants will be permitted to walk through the door if Plaintiff opens it, such as by asking Dr. Kessler if he was ever fired and if Dr. Kessler responds, "no," because this would go to Dr. Kessler's truthfulness as a witness.

Dr. Tillman presents a harder case. The employment history at issue here pertains to Dr. Tillman's tenure at the FDA, upon which she bases her expertise—a feature of her testimony that Defendants do not dispute. Thus, Dr. Tillman's experience at the FDA would be generally relevant to her expertise. Aspects of otherwise relevant employment history, however, can be excluded under Rules 401, 402, and 403 if it is irrelevant to the expert's expertise or their credibility. Dr. Kessler's termination above is such an example. Similarly, if an FDA expert were accused of mishandling an interpersonal dispute between two subordinates at the FDA, it is difficult to conclude that this is relevant work history to their expert testimony about the FDA.

Here, however, Plaintiff points to complaints that Dr. Tillman had a bias toward manufacturers. The Supreme Court has defined bias as “the relationship between a party and a witness which might lead the witness to slant, unconsciously or otherwise, [her] testimony in favor of or against a party.” *United States v. Sumlin*, 956 F.3d 879, 890 (6th Cir. 2020) (alteration in original) (quoting *United States v. Abel*, 469 U.S. 45, 52 (1984)). But courts recognize that bias may be even broader, including “[f]avor or friendly feeling toward a party [as] evidenced by . . . the witness's conduct or expressions evincing such feeling.” 1 McCormick on Evid. § 39 (8th ed. Westlaw Jan. 2020 Update) (emphasis in original) (collecting cases); see also *Robinson v. Mills*, 592 F.3d 730, 737 (6th Cir. 2010) (explaining that “[b]ias is ‘not limited to personal animosity against a defendant or pecuniary gain.’” (quoting *Schledwitz v. United States*, 169 F.3d 1003, 1015 (6th Cir. 1999))). Indeed, the Sixth Circuit has recognized the vast variety of situations from which biases may stem:

Extrinsic testimony, or that elicited by cross examination to show the bias or interest of a witness in a cause, covers a wide range and the field of external circumstances from which probable bias or interest may be inferred is infinite. The rule encompasses all facts and circumstances which, when tested by human experience, tend to show that a witness may shade his testimony for the purpose of helping to establish one side of a cause only.

Majestic v. Louisville & N.R. Co., [147 F.2d 621, 627](#) (6th Cir. 1945) (citations omitted).

Most importantly, “[t]he partiality of a witness is subject to exploration at trial, and is ‘always relevant as discrediting the witness and affecting the weight of his testimony.’” *Davis v. Alaska*, [415 U.S. 308, 316–17](#) (1974) (quoting 3A Wigmore, Evidence § 940 (Chadbourn rev. 1970)); *Schledwitz*, [169 F.3d at 1015](#) (“Bias is always relevant in assessing a witness’s credibility.”). And although “the Federal Rules of Evidence do not specifically so state, prior misconduct of a witness which is probative of the bias of that witness may be proved by extrinsic evidence.” *United States v. Phillips*, [888 F.2d 38, 41](#) (6th Cir. 1989); *Abel*, [469 U.S. at 51](#) (concluding that Rules 608 and 610 contemplate impeachment of a witness for bias and the inclusion of extrinsic evidence to do so). Determining the credibility of a witness, which includes “[a]ssessing the potential bias of the expert witness,” is ultimately an issue for the jury. *Cruz-Vazquez v. Mennonite General Hosp., Inc.*, [613 F.3d 54, 59](#) (1st Cir. 2010).

Dr. Tillman’s alleged bias in favor of manufacturers could shade her expert testimony on behalf of Defendants, making these complaints about her supposed bias relevant. Although a bias in favor of manufacturers is perhaps a less typical bias with which an expert is normally impeached, *Majestic* is clear that bias may come in many forms. Accordingly, evidence of the complaints against Dr. Tillman are not inadmissible.

Defendants’ arguments to the contrary are unsuccessful. First, they argue that this amounts to a collateral attack upon Dr. Tillman. ([ECF No. 365 at PageID #18882](#).) But as set forth above, a witness’s bias is not a collateral matter. Next, Defendants contend that “courts routinely exclude evidence about the prior litigation history and the disciplinary records of expert witnesses.” (*Id.* at [PageID #18883](#) (quoting *Ferris v. Tennessee Log Homes, Inc.*, [2010 WL 1049852](#) (W.D. Ky. Mar. 19, 2010).) But Defendants dodge the key inquiry, which is whether that history “is of sufficiently

probative value.” *Ferris*, [2010 WL 1049852](#), at *2. This line of cases is no bar to the admission of the complaints about Dr. Tillman because they are probative of her credibility as a witness in that the complaints address a potential bias.

Defendants then argue that courts exclude attacks on an expert’s credibility when those attacks are based on allegations and rely on extrinsic evidence ([ECF No. 365 at PageID #18883–85](#)), but this argument fails because it does not recognize the difference between bias and a character for truthfulness or mendacity. Defendants are correct that Plaintiff only references complaints against Dr. Tillman, not findings. But this is no bar to admission. Rule 608, upon which Defendants’ authorities rely, *e.g.* *United States v. Ahmed*, No. 14-cr-277 (DLI), [2016 WL 3647686](#), at *3 (E.D.N.Y. July 1, 2016), provides that when impeaching a witness for a character for truthfulness or untruthfulness, only reputation or opinion evidence is admissible; no extrinsic evidence is permitted except for prior criminal convictions permitted under Rule 609. [Fed. R. Evid. 608](#). But because Plaintiff offers the complaints to impeach Dr. Tillman’s credibility by demonstrating a bias, Rule 608 and its narrow allowance of convictions as extrinsic evidence is inapplicable. *United States v. Baker*, [494 F.2d 1262, 1266](#) (6th Cir. 1974) (“And, although a witness's credibility generally cannot be impeached by showing arrest, indictments or other acts of misconduct not resulting in a conviction, acts demonstrating a basis for bias and prejudice may be explored to a reasonable degree.”). Thus, Plaintiff need not show that the complaints resulted in a formal finding of wrongdoing, much less a conviction. Of course, Defendants are free to point out to the jury that the FDA declined to act in response to the complaints against Dr. Tillman, which the jury may use to weigh the impeachment value of the complaints.

Defendants’ generalized argument against extrinsic evidence fails for the same reason: Rule 608 is inapplicable, and so its bar on extrinsic evidence is inapplicable. A witness’s bias may

indicate that the witness is testifying untruthfully, but “if offered for another purpose,” such as to show bias, Rule 608 does not apply. *Adams v. Mem'l Hermann*, 973 F.3d 343, 351 (5th Cir. 2020). The Supreme Court has held as much, stating that “[i]t would be a strange rule of law which held that relevant, competent evidence which tended to show a bias on the part of a witness was nonetheless inadmissible because it also tended to show that the witness was a liar.” *Abel*, 469 U.S. at 56.

Although evidence of the complaints against Dr. Tillman are not clearly inadmissible at this pretrial stage, there are several issues that must be resolved prior to any admission of the complaints. Evidence of the complaints offered to show Dr. Tillman’s bias are not prohibited by Rule 608 and the complaints are clearly relevant because they go to her credibility, but the rule against hearsay and Rule 403 still apply. *Marcus & Millichap Inv. Servs. of Chi., Inc. v. Sekulovski*, 639 F.3d 301, 308 (7th Cir. 2011). At this point, the Court cannot assess whether the evidence Plaintiff intends to introduce is hearsay. Plaintiff argues that the records he will admit are “an official FDA record” (ECF No. 363 at PageID #18871), but he does not attach these records. It would be inappropriate to assess whether the complaints satisfy Rule 803(8) without the records in front of the Court.

Similarly, the probative value of this impeachment evidence in relation to the length of time it would take to present at trial and the risk of confusing the jury is unclear. Defendants provide Dr. Tillman’s affidavit, in which she explains that the complaints involve different devices, FDA advisory committees, and FDA regulations, policies, and practices not at issue here. (ECF No. 365 at PageID #18884.) These features could unnecessarily prolong the trial. But it is difficult to determine now if this would result in an undue delay because it is unclear what these policies are and why the FDA rejected the complaints. For example, if the FDA assessed the

complaints for evidence of Dr. Tillman's bias, it would be a different analysis than if the FDA simply concluded that Dr. Tillman followed FDA procedure. Moreover, the Rule 403 analysis is informed by the probative value of the impeachment evidence. Outside of the trial context, the court cannot determine what FDA expert testimony will be offered for and how much the parties will rely on it.

For these reasons, this part of Plaintiff's motion in limine is granted, which only pertains to Dr. Kessler, and the Court declines to decide whether the complaints against Dr. Tillman are ultimately admissible.

IV. Conclusion

For the reasons set forth above, the remaining parts of Plaintiff's Motion in Limine No. 1 ([ECF No. 235](#)) are **GRANTED IN PART AND DENIED IN PART**, Defendants' Motion in Limine No. 17 ([ECF No. 220](#)) is **DENIED**, and Plaintiff's Motion in Limine No. 8 ([ECF No. 237](#)) is **GRANTED IN PART AND DENIED IN PART**. And, though not a motion in limine, the Court declines to decide whether evidence of the complaints against Dr. Tillman are admissible at this stage of the litigation.

IT IS SO ORDERED.

12/30/2020
DATE

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