UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

EUNICE ARRUDA,

Plaintiff,

v. **No. 6:19-cv-1523 (TJM/ATB)**

C.R. BARD, INC.,

Defendant.

THOMAS J. McAVOY,
Senior United States District Judge

DECISION & ORDER

Before the Court is Defendant's motion for summary judgment. See dkt. # 50. Also before the Court are the parties' motions to exclude certain expert testimony. See dkt. #s 51, 58. The Court has determined to decide the matters without oral argument.

I. Background

This case emerges out of a multi-district litigation ("MDL") action that alleges a variety of claims related to defective pelvic mesh manufactured by the defendants to that litigation. Plaintiff Eunice S. Arruda had an Align TO Urethral Support System ("Align") implanted by Dr. James Pfeiff at Oneida Healthcare Hospital in Oneida, New York on December 4, 2008. Defendant's Statement of Material Facts in support of its motion for summary judgment ("Defendant's Statement") at ¶ 1.[1] Defendant C.R. Bard manufactured the Align device. Id.

[1]Both parties filed the statements of material facts with citations to the record (continued...)

Plaintiff was a New York resident when Dr. Pfeiff implanted the device. Id. at ¶ 2. The procedure that implanted the device occurred in New York, and Plaintiff continues to reside in the State. Id. The injuries she allegedly suffered from the device occurred in New York. Id.

Plaintiff's medical history includes a vaginal hysterectomy, and two vaginal childbirths. Id. at ¶ 3. The parties disagree about the amount of time that Plaintiff smoked. When asked whether she smoked or ever had smoked "tobacco products," Plaintiff responded that she had. See Plaintiff Fact Sheet, dkt. # 13. In response to the question, "how long have/did you smoke?" Plaintiff answered "40 years." Id. Defendant contends that this statement indicates that Plaintiff smoked for "over forty years." Id. Plaintiff contends that the statement does not establish she smoked for over forty years. Plaintiff's Response to Defendant's statement ("Plaintiff's Response"), dkt. # 55, at ¶ 3. The parties also disagree about whether Plaintiff's medical fact sheet indicates that Plaintiff underwent Kelly urethral plication.[2] Compare Defendant's Statement at ¶ 3 and Plaintiff's Response at ¶ 3.

Defendant contends that Plaintiff's treating physician, Dr. James Pfeiff, testified that if he treated Plaintiff today he would treat her in the same way. Defendant's Statement at ¶ 4. Plaintiff denies that claim, arguing that Dr. Pfeiff testified that he would have "altered his

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[1](...continued)
required by the local rules. The Court will cite to the Defendant's statement for uncontested facts and note where the parties disagree.

[2]"The purpose of the Kelly plication of the urethra is to reduce the diameter of the urethra." http://www.atlasofpelvicsurgery.com/2VaginalandUrethra/1AnteriorRepairandKellyPlication/chap2sec1.html (consulted July 16, 2020).

decision as to whether to prescribe" the Align device for Plaintiff if he had received "additional information regarding adverse events related to" that product. Plaintiff's Response at ¶ 4. Plaintiff also contends that Pfeiff also stated that he would not have implanted the device in Plaintiff if he had been "adequately warned of the risks." Id.

Defendant points to portions of Pfeiff's testimony as evidence that he would have made the same decision to implant the device even if he had additional information about potential dangers. Defendant's Statement at ¶ 5. Defendant notes the following exchange, which Defendant alleges came after Pfeiff was asked about "various risks that may not have been known to" him "at the time of implantation, as evidence that Dr. Pfeiff would not have used knowledge of those risks as reasons not to implant the Align device:

> Q: Doctor, so regardless of what warnings were alleged to be inadequate here, you would still have implanted the Bard Align in Mrs. Aruda, right?
> A: Yes.
> . . .
> Q: And Dr. Pfeiff, plaintiff's counsel presented several hypotheticals to you correct?
> A: Yes.
> Q: And is any–is there anything from that questioning that makes you think that you should have done something different in your treatment of Ms. Aruda?
> . . .
> A: No.

Id. (quoting Deposition of James L. Pfeiff, MD, dkt. # 19-2, at 88:1-17). Plaintiff responds that Defendant takes these statements out of context and points to other parts of Dr. Pfeiff's testimony where Pfeiff testified that he would not have implanted the device if he had adequate warning. Plaintiff's Response at ¶ 5. The parties further disagree about whether, had Dr. Pfeiff been aware of information on a Material Safety Data Sheet ("MSDS"), he would have implanted the product. Compare Defendant's Statement at ¶ 6 with Plaintiff's

Response at ¶ 6. Defendant contends that Dr. Pfeiff stated he would have to consider additional information before deciding, while Plaintiff contends that the information on the MSDS would have caused him not to implant the Align. Id.

The parties also disagree about why Dr. Pfeiff began to use a different mesh product than Defendant's. Compare Defendant's Statement at ¶ 7 with Plaintiff's Response at ¶ 7. Defendant, citing to one portion of Pfeiff's deposition, contends that Pfeiff made his decision because the other product "was 'easier and less complicated.'" Defendant's Statement at ¶ 7. Plaintiff, pointing to another portion of the deposition, contends that Dr. Pfeiff switched away from the Align because the other product "was 'easier to adjust and more successful.'" Plaintiff's Response at ¶ 7. The parties also disagree about whether Dr. Pfeiff found that the other product was more successful, and the context of any such statement. Defendant's Statement at ¶ 8; Plaintiff's Response at ¶ 8. Dr. Pfeiffer removed the Align from Plaintiff; she was the only patient from whom he removed an Align. Plaintiff's Response at ¶ 9.

The parties, citing different expert reports, disagree about whether the Align implanted in Plaintiff was manufactured according to Defendant's specifications. Compare Defendant's Statement at ¶ 10; Plaintiff's Response at ¶ 10. They also disagree about whether Plaintiff's expert, Dr. Donald Ostergard, opined that there were design alternatives that would have avoided the problems Plaintiff suffered from the implant. Compare Defendant's Statement at ¶ 11; Plaintiff's Response at ¶ 11. They likewise disagree over whether experts upon which Plaintiff relies have concluded that viable alternatives to Defendant's product exist. Compare Defendant's Statement at ¶ 12; Plaintiff's Response at ¶ 12. Defendant emphasizes that Plaintiff's experts cite hernia mesh products, not pelvic mesh products. Defendant's Statement at ¶ 12.

The FDA cleared the Align through the required 501(k) regulatory program. Id. at ¶ 13. That product has not been the subject of an FDA action, unlike other, similar, products. Id.

Plaintiff filed her Complaint through the MDL litigation. Id. at ¶ 14. Plaintiff admits that she does not assert all of the claims in the master MDL Complaint. Plaintiff's Response at ¶ 14. She "is not pursuing claims for breach of warranty, manufacturing defect, and violation of New York consumer protection laws." Id.

The Court in the Southern District of West Virginia transferred this case from the MDL docket in that District to this Court on September 26, 2019. See dkt. # 31. Pending before that Court were Defendant's motion for summary judgment and the parties motions to exclude certain expert testimony. See dkt. #s 19, 21, 24. The parties refiled those motions, relying largely on their earlier briefing and the record, in this Court. See dkt. #s 50, 51, 58. The parties have interposed additional filings to comply with this Court's rules, and the matters are ripe for disposition.

II. Legal Standard

Defendant seeks summary judgment. It is well settled that on a motion for summary judgment, the Court must construe the evidence in the light most favorable to the non-moving party, see Tenenbaum v. Williams, 193 F.3d 581, 593 (2d Cir. 1999), and may grant summary judgment only where "there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(a). An issue is genuine if the relevant evidence is such that a reasonable jury could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986).

A party seeking summary judgment bears the burden of informing the court of the

basis for the motion and of identifying those portions of the record that the moving party believes demonstrate the absence of a genuine issue of material fact as to a dispositive issue. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If the movant is able to establish a *prima facie* basis for summary judgment, the burden of production shifts to the party opposing summary judgment who must produce evidence establishing the existence of a factual dispute that a reasonable jury could resolve in his favor. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). A party opposing a properly supported motion for summary judgment may not rest upon "mere allegations or denials" asserted in his pleadings, Rexnord Holdings, Inc. v. Bidermann, 21 F.3d 522, 525-26 (2d Cir. 1994), or on conclusory allegations or unsubstantiated speculation. Scotto v. Almenas, 143 F.3d 105, 114 (2d Cir. 1998).

III. Analysis

Defendant seeks summary judgment on each of Plaintiff's claims. The Court will address them in turn.

A. Choice of Law

The parties agree that New York law applies to Plaintiff's claims.

B. Breach of Warranty Claims

Defendant argues that the statute of limitations bars Plaintiff's claims for breach of applied and express warranty. Even if such claims were available, Defendant contends, no facts support such claims. Plaintiff states that she is not pursuing any such claims. The Court will therefore grant the motion in this respect.

C. Manufacturing and Design Defect Claims

Defendant seeks summary judgment on Plaintiff's manufacturing defect and design defect claims. Plaintiff states that she does not pursue a manufacturing defect claim, but disputes that she lacks evidence sufficient to support her design defect claim. The Court will therefore grant Defendant's motion with respect to any manufacturing defect claim and address the sufficiency of the evidence for Plaintiff's design defect claim.

In New York, products liability law establishes that "a plaintiff may assert that the product is defective because of a mistake in the manufacturing process, or because of an improper design, or because the manufacturer failed to provide adequate warnings regarding the use of the product." Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 106-107 (1983) (internal citations omitted). "When a design defect is asserted, the focus is on whether the product, as designed, was not reasonably safe or presented an unreasonable risk of harm to the user." Fane v. Zimmer, 927 F.2d 124, 128 (2d Cir. 1991). In a design defect case, "[t]he decision whether a product is unreasonably designed is one for the jury, which it may determine after taking into account alternative designs, their costs, and the product's usefulness." Urena v. Biro Mfg. Co., 113 F.3d 359, 364 (2d Cir. 1997) (citing Voss, 59 N.Y.2d at 107). The burden lies with the plaintiff to produce "evidence that the product, as designed, presented a substantial likelihood of harm and feasibly could have been designed more safely." Id. Moreover, "to establish a prima facie case, the plaintiff" must "show that the defectively designed product caused [her] injury and the defect was the proximate cause of the injury." Voss, 59 N.Y.2d at 109. In this context, proving proximate cause means "show[ing] that the design defect in the product was a substantial factor in causing [the plaintiff's] injury." Id. at 110.

i. Failure to Warn

Plaintiff has also alleged that Defendant is liable for failing to warn her about the dangerous nature of the product in question. This issue is important to the strict products liability question at issue here, and the Court will address failure-to-warn before addressing the design defect claim itself. Defendant contends that the medical device at issue is an "unavoidably unsafe product" and that Plaintiff therefore cannot maintain a design defect claim without showing a failure to warn. "Unavoidably unsafe products are those that 'in the present state of human knowledge are quite incapable of being made safe for their ordinary intended use.'" Bravman v. Baxter Healthcare Corp., 984 F.2d 71, 75 (2d Cir. 1993) (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. K (1979)). In New York, "unavoidably unsafe products 'are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects.'" Id. at 75-76 (quoting Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980)).

Defendant contends that Plaintiff cannot prevail on a design defect claim unless she demonstrates a failure to warn. Defendant argues that a medical device that is implanted and requires a prescription is an unavoidably unsafe product to which strict products liability would not normally apply. Defendant largely relies on cases that involve prescription drugs. See, e.g., Martin v. Hacker, 628 N.E.2d 1308, 1311 (1993) ("even though its side effects may cause injury, a prescribed drug, accompanied by adequate warnings, is 'not defective, nor is it unreasonably dangerous.'") (quoting Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61 (4th Dept. 1979)); Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006, 1011 (Sup. Ct. NY Cty. 1985) (no defective design claim regarding vaccine "when accompanied by proper directions for use and adequate warnings of potential hazards."); Lindsay v. Ortho

Pharmaceutical Corp., 637 F.2d 87, 90 (2d Cir. 1980)(pharmaceutical drugs can be subject to strict products liability claims, but "these drugs, aptly described as 'unavoidably unsafe products', are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects."); Gensler v. Snolfi-Aventis, No. CV-08-2255, 2009 U.S. Dist. LEXIS 27333 at *20-21 (E.D.N.Y. Mar. 30, 2009).

While the Court agrees with Defendant that the law in New York is that strict products liability for design defects in pharmaceutical drugs is unavailable without a failure to warn or improper instructions, Defendant has not cited to any case from New York or the Second Circuit that holds that New York products liability law applies that standard to medical devices that require a prescription. The Court has found none. One Second Circuit case that Defendant points to, Bravman v. Baxter Healthcare Corp., 984 F.2d 71 (2d Cir. 1993), addresses that issue, but only as dictum. The case involved an artificial heart valve that plaintiff complained injured him by making "a loud and disruptive noise." Id. at 72. The trial court granted defendant summary judgment, finding that plaintiff's claim that his "mechanical heart was going to fail" did not allege an actual injury and that the noise from the heart valve "did not support a legally cognizable product defect claim under New York law." Id. at 73. The Court of Appeals reversed, finding that a jury should have determined whether plaintiff suffered an injury, and that evidence in the record about plaintiff's "awareness of the noise level, the excessiveness of the noise, and the availability of other mechanical valves with similar functionality and operation at a lower noise level," meant that plaintiff had a "viable" claim for failure to warn. Id.

The Court of Appeals also found that the district court properly dismissed plaintiff's

design-defect claims. Id. at 75. Plaintiff claimed that the district court erred in finding that the mechanical heart valve was an unavoidably unsafe product. Id. The Court of Appeals explained the law on unavoidably unsafe products and noted that "[w]e believe that despite the . . . valve's noise potential, it may be treated, at least at the time of [plaintiff's] surgery, as an unavoidably unsafe product." Id. at 76. The court cited a Fifth Circuit case, McPheron v. Searle Lab, Inc., 888 F.2d 31, 33 (5th Cir. 1989), that listed a "majority rule that medical devices that must be prescribed and inserted by a physician are unavoidably unsafe products." Id. "However, we note that the district court findings on the product and design defect claims did not depend upon this determination," the court found. Id. Instead, plaintiff's "product defect claim fails because he has offered no evidence to suggest that the excessive valve noise he has experienced is the result of a mistake in the manufacturing process." Id. Construing the claim as a design defect claim, the Court of Appeals found summary judgment proper because the evidence showed that the heart valve, despite the noise it created, had "an impressive record of prolonging the lives of its recipients" and therefore "'it is reasonable to conclude as a matter of law that the utility of their design outweighs isolated instances of excessively noisy valves.'" Id. (quoting Bravman v. Baxter Healthcare Corp., 794 F.Supp. 96, 102 (S.D.N.Y. 1992)).

At least one district court in the Second Circuit has examined whether Comment K applies to medical devices and concluded that it does not. See Williamson v. Stryker Corp., No. 12 Civ. 7083, 2013 U.S. Dist. LEXIS 104445 (S.D.N.Y. July 23, 2013). In that case, plaintiff raised a variety of claims, including strict products liability, when "Defendants' product, a surgically implanted knee device, broke while implanted in her leg." Id. at *1. In relevant part, the defendants moved to dismiss plaintiff's design defect claim, arguing that

"strict liability for 'unavoidably unsafe products' applies to this case, and that, as a result, Plaintiffs cannot assert a design defect claim under strict liability[.]" Id. at *15-16. The court noted that New York courts have "repeatedly applied the 'unavoidably unsafe products' exception to cases involving prescription drugs." Id. at *16-17. At the same time, the court could point to no New York cases that had "extend[ed] the 'unavoidably unsafe' products exception to all medical devices." Id. at *17. The court addressed Bravman, finding that the Court of Appeals:

> wrote that it believed that the mechanical heart valve at issue in the case was an 'unavoidably unsafe product.' But the court noted that the district court findings on the design defect claim did not depend on that determination. Instead, following the district court's reasoning, the Second Circuit assessed the viability of the design defect claim under the legal standard for such claims in New York–the utility/risk analysis–rather than by applying the unavoidably unsafe products exception. . . . Bravman at most stands for the proposition that a heart valve is an unavoidably unsafe product. That says nothing about medical devices in general. Furthermore, the precedential value of even that finding is questionable, since the court did not rely on the unavoidably unsafe product exception in its holding.[3]

Id. at *17-18.[4]

The Court is persuaded by this reasoning, and will not require Plaintiff to show a

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[3]The court also noted that courts in the Northern District of New York have declined to extend the "unavoidably unsafe product" exception to other medical devices. See Williamson, 2013 U.S. Dist. LEXIS 104445 at *18; (citing Henson v. Wright Med. Tech. Inc., 5:12-cv- 805 FJS/TWD, 2013 U.S. Dist. LEXIS 44295, 2013 WL 1296388, at *6-7 (N.D.N.Y. Mar. 28, 2013); Maxwell v. Howmedia Osteonics Corp., 713 F.Supp.2d 84, 90-94 (N.D.N.Y. 2010)).

[4] The Second Circuit has cited to Bravman only once, in a non-precedential opinion. Tomaselli v. New York & Presbyterian Hosp., 728 Fed. Appx. 41, 42 (2d Cir. 2018). The Circuit cited the case for the proposition that in New York, "a failure-to-warn claim requires a showing of both proximate cause and the warning's inadequacy." 728 Fed. Appx. at 42. The Court also noted that New York's "'learned intermediary doctrine' . . . applies to devices . . . that are available only by prescription." Id. at 43. The Court did not hold, however, that an adequate warning forecloses a design-defect claim against manufacturers of such devices.

failure to warn in order to maintain a design defect claim against the Defendant. The Court notes that Defendant seeks to have the court adopt a categorical approach to the exception stated in Comment K, finding that any medical device implanted pursuant to a prescription is unavoidably unsafe. Bravman, even if its conclusions about the heart-valve cases were the basis of the case's holding, did not offer a specific finding that all such devices were unavoidably dangerous. Bravman did offer a definition for such devices: "[u]navoidably unsafe products are those that 'in the present state of human knowledge are quite incapable of being made safe for their ordinary intended use.'" Bravman, 984 F.2d at 75 (quoting Restatement (Second) of Torts § 402A cmt. k (1979). Defendant makes no effort to explain why the Align device at issue in this case fits that category, and, given the expert testimony in this case discussed below, the Court cannot find that the device in question could not be made safe.

The text of Comment K also supports a finding that this particular device is not unavoidably unsafe within the meaning of that comment. Comment K provides as an "outstanding example" of such products:

> the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk.

RESTATEMENT (SECOND) OF TORTS § 402A, Comment K. No evidence in the record indicates

that the device in question shares a profile similar to the kinds of products described in Comment K. While the Court would not minimize the condition for which Plaintiff sought treatment, nothing in the record indicates that she faced death without the treatment she received. Nothing indicates that the severity of her condition required her to accept dangerous consequences in exchange for a chance to survive treatment. This device was not an experimental device, or one where the adverse consequences of using it were an unavoidable feature of its use. Unlike the rabies vaccine, which has potentially dangerous side effects which an informed user can choose to face in order to address a condition that would otherwise kill her, the evidence here indicates that the device in question may have actually exacerbated the conditions that device was supposed to treat. The evidence here does not support a finding that the device was unavoidably dangerous, and the Court would permit a strict liability claim of design defect even if the warnings were adequate.[5]

Of course, as explained, Defendant admits that Plaintiff could raise a design defect claim if she could produce evidence a jury could use to conclude that Defendant had not warned Plaintiff of the dangers of the Align product. "A plaintiff seeking to hold the manufacturer of a medical device liable for injuries under a failure to warn theory is required to establish that failure to warn adequately of the potential adverse side effects of the use of the product was a proximate cause of the injury." Banker v. Hoehn, 278 A.D.2d 720, 722

[5]The Court notes as well that permitting manufacturers to avoid design defect liability by offering a warning for all prescribed and implanted medical devices, regardless of the risk they address and present, would hardly serve the public-safety purpose of tort law. Medical devices are manufactured and engineered products. To permit the designer of such a product to avoid liability with a warning would permit that manufacturer to use less care in designing the product, relying on a detailed warning rather than careful design to avoid liability. That encourages manufacturers to cut corners on device that reside in people's bodies, which is hardly an encouragement to public safety.

(3d Dept. 2000). In cases involving implantable medical devices, "the duty to warn is owed to the medical community and, more specifically, to the treating physician who is to act as an 'informed intermediary' between the manufacturer and patient." Bravman, 984 F.2d at 75 (quoting Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d 305, 307 (1st Dept. 1990)). "The manufacturer's duty, under New York law, is to warn the medical community, not the patient, of the product's risk." Mulhall v. Hannafin, 45 A.D.3d 55, 58 (1st Dept. 2007). "The warning must provide sufficient information to that class of prescribing physicians 'who may be expected to have the least knowledge and experience with the' product." Id. (quoting Martin v. Hacker, 83 N.Y.2d 1, 9 (1993)). A manufacturer has a duty to "warn only of those dangers it knows of or are reasonably foreseeable." Id.

Defendant argues that Bard is entitled to judgment on Plaintiff's failure-to-warn claim because Pfeiff, her doctor, testified that he would have prescribed the Align even with additional warnings.[6] Under those circumstances, Defendant claims, Plaintiff cannot prove that any failure-to-warn was the proximate cause of her injuries. To prove such proximate cause, a Plaintiff must show that "had a different warning been given, this patient would not have used the product that caused her injury." Mulhall, 45 A.D. at 60. The parties disagree about whether Dr. Pfeiff's testimony provides such proximate cause.

The Court notes that Defendant does not attempt to argue the adequacy of the warnings, but instead relies solely on Dr. Pfeiff's statement that he still would have prescribed the Align device even if he had additional warnings suggested by the Plaintiff.

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[6]Plaintiff's expert reports, discussed below, discuss the adequacy of the warnings Bard provided. Defendant does not discuss the expert reports in this respect, and the Court will find that they, too, present evidence a reasonable juror could use to find the warnings inadequate.

Courts in New York have ruled, however, that "juries are to determine" whether a doctor's claims about how he would have used warnings are credible and thus whether the failure to warn was a proximate cause of the plaintiff's injury. See Bravman, 984 F.2d 71 ("Although the apparently highly qualified Dr. Spencer testified that he would not have passed on the noise information to Bravman even if he had received it, that testimony is insufficient to resolve the proximate cause question. It is up to the trier of fact to determine whether, and the extent to which, Dr. Spencer's testimony on this point is credible, or even if it is, whether it would be found by a jury to be material."). Indeed, "unless the physician's statement is self-disserving, the issue of the credibility of the physician's [statement] should ordinarily be left to the trier of the facts and should not be resolved by the court on a motion for summary judgment." Hoffman-Rattet v. Ortho Pharmaceutical Corp., 516 N.Y.S.2d 856, 857 (Sup. Ct. N.Y. Co. 1993).

Dr. Pfeiff testified that he could not recall whether Bard "ever provided [him] with any type of long-term study associated with the complications of the Align" device. Deposition of James L. Pfeiff, MD, Exh. A to Plaintiff's Brief in Opposition, dkt. # 26-1, at 69. Pfeiff's practice is to "relay warnings from the manufacturer's medical devices of the known risks to your patients so they can make an informed decision." Id. He shared such risks with Plaintiff before implanting the device. Id. Pfeiff testified that he did not discuss a "risk of permanent dyspareunia as a result of" the Align, and he could not recall Bard "informing" him of such "a potential risk of implantation of" the "device." Id. He also testified that he did not believe he would have implanted polypropylene mesh if he had been informed that such mesh was not appropriate for such use. Id. at 73-74. Pfeiff further stated that he was not informed of the dangers posed by exposure of polypropylene to bodily fluids or been warned

of the dangers of exposure. Id. at 74-75. Pfeiff admitted that he relied on Bard for information about the danger of the devices he used, and that he believed that at the time he implanted the device that Bard had provided him "accurate and complete" information. Id. at 77. He would have shared information on a variety of "adverse outcomes" with his patients had Bard provided such material. Id. at 78-81. As Defendant points out, Pfeiff also testified that he would still have implanted the device, "regardless of what warnings were alleged to be inadequate" in this matter. Pfeiff Deposition, Exh. B to Defendant's motion for summary judgement, dkt. # 19-2, at 88.

The Court will deny the motion in this respect and permit the jury to determine whether the warnings were adequate and whether, if they were not adequate, different warnings would have caused Dr. Pfeiff to refuse to use the device. While Dr. Pfeiff did testify that he would have implanted the device even with better warnings, his testimony was also that different warnings would have altered his opinion of the device. Moreover, since Dr. Pfeiff was "an actor in the transaction in question" and thus "an interested witness," his credibility is in question. Hoffman-Rattet, 516 N.Y.S.2d at 860-61. The jury must resolve the question of proximate cause.

ii. Design Defect

Defendant contends that Plaintiff has failed to meet her burden of showing a defective design. Defendant asserts that "Plaintiff has not offered competent, non-conclusory evidence supporting the required element of a feasible alternative design for the Align device." In addition, Defendant argues, Plaintiff has not offered an opinion from "any case-specific expert who has the opinion that there is a feasible alternative design that would have avoided" Plaintiff's injuries. Plaintiff disputes that her experts fail to offer safer

alternative designs. Those experts, she claims, point to the use of lighter-weight mesh, larger pores in the mesh, and non-mesh procedures as alterative product designs that would have prevented Plaintiff's injuries. Defendant responds that those expert reports do not support a conclusion that such safer alternatives were available at the time Bard designed the Align product. Defendant also argues that no evidence exists to support a finding that larger pores in the mesh would have prevented Plaintiff's injuries.

The parties appear to agree that the only issue before the Court on the sufficiency of Plaintiff's design-defect claim is whether she has offered evidence of a safer alternative design. Plaintiff points to the reports of several experts to claim that she has produced evidence of such a design. The Court will examine those reports. Plaintiff first submits the report of Donald R. Ostergard, MD. See Expert Report of Donald R. Ostergard, MD ("Ostergard Report"), Exh. B to Plaintiff's Response, dkt. # 26-2. Ostergard is a professor of Obstetrics, Gynecology, and Women's Health at the University of Louisville School of Medicine and the University of California Los Angeles School of Medicine. Id. at ¶ 1. He has been qualified as an expert on pelvic mesh products and permitted to testify in cases in California and Massachusetts. Id. at ¶ 4. Ostergard reports that Plaintiff had developed "stress urinary incontinence" ("SUI") which presented a danger of "kinking of the urethra" that could "[obstruct] the flow of urine and [create] a very slow egress of urine from the bladder." Id. at ¶ 5. That condition could make the bladder difficult to empty and lead to infections that could impact the kidneys and lead to a life-threatening kidney infection. Id. This condition, Dr. Ostergard opines, can be treated with "sub-urethral sling," but a "sling vaginal mesh device" like the Align involved in this case, can cause "vaginal mucosal dehiscence, mesh exposure, chronic pelvic, lower abdominal and vaginal pain, pain from

nerve entrapment, along with urinary frequency, recurrent urinary tract infections, urinary retention, painful intercourse, vaginal/mesh tenderness, vaginal rigidity, and failure to treat stress incontinence when causing other symptoms[.]" Id. at ¶¶ 6-7. Doctors often treat these complications by removing the device. Id. at ¶ 7.

When "erosion/exposure is early and small," the affected area can "respond to the use of intravaginal estrogen to stimulate the growth of the vaginal lining to cover the area of exposure." Id. If more pain or an allergic reactions develops, the "device erodes into adjacent organs" like "the urethra, anal sphincter, rectum, or other bowel," then a doctor needs to remove the device. Id. That procedure "is very difficult due the intense inflammatory reaction and the resultant fibrosis and scarring of the tissues where the device resides." Id. Align devices, Ostergard finds, cause particular problems and are difficult to remove completely because of "the degradation of the polypropylene which weakens the mesh to the point that it literally falls apart during dissection." Id. Removing the device can also "damage the nearby organs . . . due to the adherence of the device to those structures." Id. Removing the device often requires "[m]ultiple surgeries." Id. "[C]ontracture and shrinkage of the device and the vagina" can also lead to "painful and sometimes impossible" sex. Id. If a doctor is unable to remove the device completely, "a pelvic pain syndrome occurs which is very difficult to treat and narcotics may be required to control the pain." Id. After describing the course of Plaintiff's medical treatment and the injuries she allegedly suffered as a result of the Align device, Dr. Ostergard offers an opinion about the design of the Align. See id. at ¶¶ 10-63. He concludes that:

> As I have discussed in previous export reports and depositions, all of which I incorporate into this report, the Bard polypropylene mesh is heavy weight, small pore, impure, not inert, degrades, shrinks, causes chronic inflammation, and potentiates

> infection. The use of a safer product such as a cadaveric or autologous sub-urethral sling or a lighter weight, larger pore polypropylene mesh may have eliminated the risks associated with the defects inherent in this flawed device including chronic inflammation, degradation, shrinkage, and infection.

Id. at ¶ 63.

Plaintiff also offers the expert report of Alan Garely, MD. See Expert Report of Alan Garely, MD, Exh. C to Plaintiff's Brief in Opposition ("Garely Report"), dkt. # 26-3. Garely is a Clinical Professor of Obstetrics, Gynecology, and Reproductive Medicine at the Icahn School of Medicine at Mount Sinai in New York, New York. Id. at 2. Among other qualifications, he is Chair of Obstetrics and Gynecology and Director of Urogynecology and Pelvic Reconstructive Surgery at the South Nassau Communities Hospital in Oceanside, New York. Id. Garely participates in the accredited fellowship in Female Pelvic Medicine and Reconstructive Surgery at Mount Sinai. Id. He teaches medical students, residents and fellows. Id. He has "trained 17 fellows in Female Medicine and Reconstructive Surgery." Id. As of December 2014, he was Board Certified in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. Id. Garely has extensive experience with implanting and extracting the types of devices at issue in this case. Id. at 5 ("I have personally examined, diagnosed and treated thousands of patients with mesh complications."). Id. He is experienced with the Align device at issue in this case and has "personally removed Align TO mesh." Id. at 6. Garely opines that "Bard's design of the Align TO was unreasonably dangerous and defective," and that "Bard's own internal documents recognize that the design of the Align TO could be made safer by changing the product's design features." Id. Garely points to a number of design features of Defedant's product that "outweigh its benefits[.]" Id. at 7. He writes:

The flat mesh of the Align TO is pulled through a rounded trocar tunnel that is significantly smaller than the width of the mesh and through tissue, then exits the body through surgical wounds in the skin that are much smaller than the width of the mesh. This results in curling and rolling of the mesh. It does not lie as flat as intended [from Bard's design and training videos Bard provides]. The curled/rolled/pinched mesh can saw through tissue, leading to increased and chronic pain.

The pinching and curling of the Align TO mesh was also caused by the difficulty that surgeons had removing the Align TO sheath. Bard documents contain mutiple complaints by doctors and sales personnel that the force required to remove the sheath was deforming the mesh so that it would curl under the urethra . . . [I]n August 2010, Bard added a "dilator" in an effort to aid in sheath removal. The "dilator" is not much wider than the trocar needles and still much smaller than the width of the mesh. There, in my opinion, the "dilator" did not and does not prevent the mesh from curling and rolling. The mesh still significantly deforms when pulled into the trocar tracts that are much smaller than the width of the mesh.

As the Align TO mesh scars in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves and result in severe, permanent and difficult-to-treat or untreatable pain as a result of the chronic inflammatory response and fibrosis.

The Align TO mesh scars into tissue, which pulls asymmetrically on the central portion of the mesh, causing the center portion of the mesh to roll and curl. The mesh is intended to stay flat under the urethra during and after the implant. It does not. When the mesh is pulled and deformed, and contracts after implant, this causes pain and can also lead to erosion or extrusion of the mesh. The mesh pulls on its anchoring points in the obturator muscles towards the midline. This asymmetrical pulling on the muscles causes pain and can lead to erosion or extrusion of the mesh, and neurological adverse events (groin and/or leg pain) are morel likely to occur. The pain can become chronic and permanent.

The trocar-based insertion of Align TO causes the mesh to deform, curl and roll, which causes or contributes to excessive scarification and contraction of the mesh. In removing Align TO mesh, I have observed that the mesh has become hard and brittle, and I have observed banding of the mesh as a result of this scarification. This banding inhibits tissue ingrowth and, as the mesh contracts over time, causes the mesh to slice through and injure tissue. As the Align TO contracts, it pulls on the surrounding muscles and ligaments and causes pain.

The density of the Align TO mesh (61 g/m²) is almost twice the density that Bard recognized as the maximum safe density (35 g/m²). This increases the foreign body reaction to the mesh, which also contributes to a thicker and less compliant scar plate.

> The Marlex HGX-030-01 polypropylene used in the manufacture of the Align TO products is not medical grade.
>
> The blind passage of the metal trocars during implantation is unreasonably dangerous and presents the unnecessary risk of tissue damage, vascular damage, nerve damage, and internal trauma in the hands of many gynecological and urological surgeons.
>
> The transobturator approach of implanting the Align TO greatly increases the risks of groin pain and subsequent groin mesh removal surgery. The transobturator approach means that the Align TO mesh penetrates several layers of tissue, including obturator internus, obturator membrane, and obturator externus. The resulting chronic inflammatory reaction to mesh and the scarification that then occurs contributes to chronic and potentially permanent groin pain.
>
> The Align TO is implanted through a transvaginal approach, which means the mesh goes through the vagina. The bacteria present in the vagina can attach to the product, which the bacteria can proliferate, and which can exacerbate the inflammatory process. This is a particular problem when the mesh erodes and has constant exposure to the vagina.
>
> Removing the Align TO mesh after it has been implanted is difficult and traumatic to the patient. There is no evidence that Bard ever considered what should be done if the mesh caused complications and the mesh needed to be removed, or how to remove the product.
>
> Surgeries to attempt to remove the mesh increase the presence of scar tissue, which can create or contribute to the patient's pelvic pain, dyspareunia and abnormal function of the pelvic area. The patient who has experienced complications may continue to suffer complications, including pain, even after undergoing surgery. In fact, removal of transobturator slings have higher intra-operative complication rates when compared to retropubic and single incision slings.

Id. at 6-11.

Garely also opines that several safer alternative designs existed for the Align TO mesh. Id. at 18. Such alternative designs, he claims, would have "been . . . just as effective, if not more effective." Id. Bard could have altered the design by, he claims:

> eliminating the blind tocar implantation design and, if polypropylene were used, it should be of medical grade and should have larger pores and lighter weight and should not curl and roll when implanted. Bard has developed and sold soft tissue repair products that contain some or all of these safer design characteristics. For

> example, Bard's Large Pore Soft Mesh and Composix L/P hernia products both had much larger pore sizes, and its Nuvia product had pres greater than 3mm and also had a tube shape, not flat.

Id.

Plaintiff also offers the expert report of John Miklos, MD. See Report of John Miklos, MD ("Miklos Report"), Exh. D, to Plaintiff's Brief in Opposition, dkt. # 26-4. Dr. Miklos specializes in obstetrics and gynecology and relates that he has "been in practice exclusively dedicated to female pelvic floor disease and its surgical correction for 21 years." Id. at 2. Along with a partner, Miklos has "operated on approximately 10,000 patients from 50 states and 54 countries." Id. In addition to professional and academic credentials, Dr. Miklos has worked with "mesh used to treat pelvic floor defects" since 1998. Id. at 4. He has removed "more than 700 pieces of mesh from patients suffereing from complications that include chronic pain, dyspareunia, urinary retention, rectal, colon, urethral and bladder erosion and vaginal, groin and buttock pain, and epithelial extrusion." Id. at 5. Miklos also relates that he is "familiar with the Align sling kits specifically, as opposed to just mesh products and slings generally," because he has "attended lectures, seen videos and reviewed the Bard Align instructor's modules, and seen and handled Align products." Id. at 7. Miklos has also removed Align mesh from patients. Id. Miklos offers much the same criticism of the Align products as Garely. See id. at 7-13. The system for inserting the device, he finds, "prevents the mesh sling from remaining flat, throughout its ascent from the points of posterior fixation . . . . to the point of anterior fixation . . . and causes it to deform, fold, curl, and/or roll especially at the points of anterior and posterior fixation." Id. at 8. This problem causes scarring and pain, and makes such problems more difficult to treat. Id. at 9. These issues create pain in many daily activities, he finds, and are caused in part because

"[t]he Align mesh is almost twice the density that Bard recognized as the maximum safe density, which increases the foreign body reaction to the mesh, which can cause or contribute to a thicker and less compliant scar plate." Id. at 11. The "transvaginal implantation" of the mesh also causes problems, Miklos claims, because "normal vaginal flora" can become attached to the mesh and "[t]he presence of these bacteria attached to the mesh can cause inflammation, which in turn increases scarring, which increases the risk of chronic pain." Id.

Miklos points to alternative designs for "the Align product that would have been safer and just as effective if not more effective." Id. 13. Defendant's failure to use one of those alternatives, he claims "rendered the devices not reasonably safe and caused or substantially contributed to the complications and injuries" he described in his report. Id. One such alternative suggested by Miklos was:

> Larger pore, lighter weight mesh polypropylene. The mesh used should have large pores (at a minimum larger than 2 mm), and should be lightweight (not 61g/m², but less than 35 g/m²). Bard designed, developed, and marketed products that incorporate certain of these safer design features, including the Large Pore Soft Mesh hernia mesh, the Composix LP Hernia patch repair device, as well as Nuvia SI device for pelvic organ prolapse repair.

Id. at 13.

Plaintiff also submits the expert report of Ahmed El-Ghannam, PhD. See Report of Ahmed El-Ghannam ("Ghannam Report"), Exh. F. to Plaintiff's Brief in Opposition, dkt. # 26-6. El-Ghannam, an expert in biomaterials and bioengineering, reports that his research focuses on "the interaction between implanted medical devices and the body[.]" Id. at 2. His academic training includes a Master of Science in Engineering and PhD in Bioengineering from the University of Pennsylvania. Id. He currently serves as an Associate Professor in

the Department of Mechanical Engineering and Engineering Science at the University of North Carolina at Charlotte. Id. El-Ghannam's report uses a scanning electron microscope to examine products involved in the multi-district litigation, including the Align product involved in this case. Id. 5. Such analysis "showed deformation and severe surface damage of the polypropylene fibers of" pre-implanted "pristine mesh due to exposure to thermomechanical stresses." Id. 6. These defects pre-implantation "would enhance the degradation of the material after implantation." Id. After explaining how the manufacturing process could create these stresses in the mesh, Dr. El-Ghannam finds that "[t]he degredation of polypropylene inside the body causes an inflammatory response, which then perpetuates the degradation process." Id. at 20. That situation leads to "chronic inflammation of surrounding tissue." Id. According to El-Ghannam's report, "every [device involved in the ligitation] degrades inside the body as a result of this process until all of the polypropylene mesh material is either removed from the body, or until the material is completely degraded." Id. at 21. Various measures and methods of analysis of mesh devices removed from women ("explants") demonstrated that such degradation had occurred in those devices for the reasons Dr. El-Ghannam had predicted because of the nature of the material and the handling of such materials in manufacturing the mesh. Id. at 82.

El-Ghannam concludes:

> It is my opinion to a reasonable degree of scientific certainty that the Bard mesh products as designed are defective in that the average pore size is considerably less than the necessary pore size of 2.00 mm or greater required to promote adequate tissue ingrowth. [He also opines that] all of the Bard mesh products will degrade in vivo and cause the problems set forth in this report. . . . It is my opinion with reasonable scientific certainty that the Bard mesh products are defectively designed as their average pore size is significantly smaller than the necessary pore size

according to Bard and literature.

Id. Earlier he notes that the Bard products when measured by a microscope have an "average pore size" smaller than advertised for the products, and that "Bard's documents state that a larger pore size is necessary for adequate tissue growth[.]" Id. at 80. Moreover, he notes that "Bard's own documents show that it developed and marketed three mesh products . . . with pore sizes in excess of 2 mm." Id.

Defendant argues that these expert reports fail to support a design defect claim because "none of these experts opine that feasible alternatives were available on the market at the time and their claimed alternatives involve hernia mesh as opposed to pelvic mesh." The Court disagrees and finds that a reasonable juror could conclude from these reports that the products as designed were unreasonably dangerous and that a feasible alternative design was available. While Defendant is certainly free to argue with the experts' conclusions and present other evidence that disputes those conclusions, a reasonable juror could certainly find that the material that Bard used to make the pelvic mesh in question was not suitable for that use. That juror could also find from this evidence that Bard was aware that the pore size of its pelvic mesh could be dangerous. Finally, that juror could also use this evidence to conclude that other products and materials more suitable for that use were available, and some were made by Bard, and that failing to use such materials represented an unreasonably unsafe design. The Court will therefore deny the motion in this respect as well.

iii. Causation

Defendant also argues that "Plaintiff has presented no evidence–by way of an expert or otherwise–that Plaintiff's alleged harm could have been prevented." Moreover, Bard

insists, Plaintiff's medical history played a role in the failure of her device–she had a "vaginal hysterectomy, Kelly urethral plication, 2 vaginal childbirths" and smoked for more than 40 years. Plaintiff responds that she need not prove under New York law that her harm could have been prevented, but only that the design defect was a substantial factor in her injuries. She points to expert evidence in the form of Dr. Ostergard's report that establishes such injuries.

The Court will deny the motion in this respect. "To establish a prima facie case for design defect, the plaintiff must show that the defendant 'breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury.'" Hoover v. New Holland, Inc., 23 N.Y.3d 41, 54 (N.Y. 2014) (quoting Voss, 59 N.Y.2d at 106-107). Dr. Ostergard reviewed Plaintiff's course of treatment and her medical records, as well as her course of treatment. Ostergard Report at ¶¶ 5-51. Dr. Ostergard finds the design of the Align device defective, and that Plaintiff "suffered injuries and will continue to suffer from them" as a result of the "presence of this device in her body." Id. at ¶ 54. Dr. Ostergard points to the following conditions that developed as a result of the Defendant's device: persistent stress incontinence; dyspareunia; vaginal pain and pelvic pain; urinary obstruction; bladder hyperdistention with areflexia from bladder denervation; tender Align TO mesh with tender pelvic floor; and overactive bladder with urge and urge incontinence. Id. at 55-61. A reasonable juror could use this evidence to conclude that the Defendant's product was a substantial factor in Plaintiff's injuries. Defendant may of course use other medical evidence to dispute the role the device played in causing these injuries, but evidence exists to support Plaintiff's claims and summary judgment is not available in this

respect.

D. Negligence

Defendant next argues that Plaintiff's causes of action under negligence theories must fail to the extent they are distinct from her products liability claims. Defendant argues that Plaintiff alleges negligence in several forms: Plaintiff responds that she brings a single negligence claim under New York law, and has sufficient evidence to support such a claim. She points to evidence from other cases in the MDL which she claims shows that Bard breached its duties to consumers by selling and marketing products that Defendant knew posed unreasonable risks to consumers. Defendant responds that Plaintiff must point to the evidence in this case, not to general evidence and arguments in other cases in this MDL.

As a general matter, a New York plaintiff offers prima facie evidence of negligence when he shows that "(1) the defendant owed the plaintiff a cognizable duty of care; (2) the defendant breached that duty; and (3) the plaintiff suffered damage as a proximate result." Williams v. Utica Coll. of Syracuse Univ., 453 F.3d 112,116 (2d Cir. 2006). "Well settled it is that a manufacturer is under a duty to use reasonable care in designing his product when used in the manner for which the product was intended . . . as well as an unintended yet reasonably foreseeable use." Robinson v. Reed-Prentice Div. of Package Mach. Co., 480 (1980) (internal quotations omitted). A manufacturer is "'liable for injuries caused by ordinary negligence, and are therefore under a duty to exercise reasonable care so as to avoid the occurrence of injuries by any product which can reasonably be expected to be dangerous if negligently manufactured or sold.'" Saunders v. Farm Fans, div. of ffi Corp., 24 A.D.3d 1173, 1174 (4th Dept. 20) (quoting Gebo v. Black Clawson Co., 92 N.Y.S.2d 1009 (1980)). "'Proof that will establish strict liablity will almost always establish negligence.'" Id.

at 1174-1175 (quoting Lancaster Silo & Block Co. v. Northern Propane Gas Co., 75 A.D.2d 55, 62 (1980)). "Thus, is a *design defect* case there is almost no difference between a prima facie case in negligence and one in strict liability." Lancaster Silo, 75 A.D.2d at 62 (emphasis in original). Defendant's argument is that Plaintiff has not produced evidence "that Bard breached the applicable standard of care in the manner it inspected, marketed, packaged or sold Plaintiff's specific Align product" and argues that Plaintiff has therefore produced no evidence by which she could prevail on a negligence claim. Defendant has not pointed to any case law that holds that the specific torts of inspecting, marketing, packaging or selling exist as separate legal claims in New York. Instead, such claims appear to be theories of negligence. As explained above, however, the tort of negligence in New York can apply to a negatively designed product, and the evidence supporting that claim can be the same evidence as evidence supporting a strict products liability claim. The Court has already determined that evidence exists to support such a claim, and the Court likewise finds that evidence exists that a reasonable juror could use to conclude that Defendant breached its duty of care to the Plaintiff in designing the Align device in question, and that such a breach caused her injuries. The Court will therefore deny Defendant's motion in this respect as well.

E. New York Consumer Protection Law

Defendant seeks judgment on any claims brought under New York consumer protection laws. Plaintiff states that she pursues no such claims, and the Court will therefore grant the motion as unopposed.

F. Punitive Damages

Defendant next claims that, even if there were evidence to support Plaintiff's claims, such evidence would not support Plaintiff's attempt to obtain punitive damages. None of the evidence in this case, Bard insists, amounts to evidence of willful or wanton conduct. Plaintiff points to other cases in this MDL and argues that the Court should deny summary judgment on punitive damages for the same reasons stated by the judges in those case. She submits as an exhibit to her motion the response of Plaintiffs in the MDL case to Bard's motion for summary judgment on a punitive damages claim.

In New York, '[p]unitive damages . . . are awarded to punish a defendant for wanton and reckless or malicious acts and to protect society against similar acts.'" In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig., 725 F.3d 65, 127 (2d Cir. 2013) (quoting Rivera v. City of New York, 40 A.D.3d 334, 836 N.Y.S.2d 108, 117 (1st Dept. 2007)). New York courts have varied in their description of conduct justifying punitive damages "'but, essentially, it is conduct having a high degree of moral culpability which manifests a conscious disregard of the rights of others or conduct so reckless as to amount to such disregard.'" Id. (quoting Home Ins. Co. v. American Home Prods. Corp., 75 N.Y.2d 196, 203, 550 N.E.2d 930, 551 N.Y.S.2d 481 (1990)). Defendant's "conduct need not be intentionally harmful but may consist of actions which constitute wilful or wanton negligence or recklessness." Id. (internal citations omitted). A jury may award punitive damages when "the defendant 'acted with actual malice involving intentional wrongdoing' or where such conduct amounted to a 'wanton, willful or reckless disregard of plaintiffs' rights.'" Id. (quoting Ligo v. Gerould, 244 A.D.2d 852, 665 N.Y.S.2d 223, 224 (4th Dept. 1997)). Punitive damages must serve as a "'social exemplary remedy'" and are therefore appropriate for conduct "'sufficiently blameworthy' that punishing it 'advance[s] a strong public policy of the

state.'" Id. at 128 (quoting Randi A. v. Long Island Surgi-Ctr., 46 A.D.3d 74, 842 N.Y.S.2d 558, 564 (2d Dept. 2007)).

While the Court finds it rather feckless for an attorney to rely on evidence and arguments from other cases and decisions made by other judges to defeat a motion for summary judgment, the Court also recognizes that this case is an MDL and that the MDL procedure permits the use of such evidence in this case. Congress's purpose in enacting the statute establishing multi-district litigation "was to permit the centralization in one district of all pretrial proceedings 'when actions involving one or more common questions of facts are pending in different districts.'" In re New York City Mun. Sec. Litig., 572 F.2d 49, 51 (2d Cir. 1978) (quoting 28 U.S.C. § 1407). Transfer of cases under Section 1407 is appropriate when the cases in the proposed MDL "share numerous complex questions of fact," particularly when they relate to corporate conduct. In re Amoxicillin Patent & Antitrust Litigation, 449 F.Supp.601, 603 (Jud. Panel on Multidistrict Litg. 1978) (permitting transfer to a MDL of cases that "share numerous complex questions of fact relating to, *inter alia*: (1) the issues of validity and enforceability of the amoxicillin patents; (2) Beecham Group's conduct in the procurement of these patents; and (3) Beecham Group's alleged misuse of the patents by conspiring with Beecham, Inc., and Roche to restrain trade unreasonably in amoxicillin."). The Plaintiff has provided extensive evidence collected in discovery and used in the cases that Plaintiff cites in support of denying Defendant's motion to dismiss punitive damages.

The Court finds that evidence sufficient for a reasonable juror to conclude that Defendant engaged in wanton and willful conduct in designing, marketing and selling the Align TO device. See Exh. G to Plaintiffs Brief in Response to Defendant's motion, dkt. #s

26-7, 26-8.[7] The Court has examined the evidence submitted by the Plaintiff and concludes that the evidence is sufficient for a reasonable juror to find that Bard engaged in conduct that justifies awarding punitive damages. Briefly stated, the evidence indicates that Bard became aware that the manufacturer of the polypropylene mesh used as part of the Align TO device had stated that such material should not to be used as part of a permanent implant yet continued to use that material in the product anyway. Bard failed to warn users of the danger despite that knowledge. Moreover, when Bard officials became aware of the reluctance of a manufacture of material used in the mesh to supply the product, those officials attempted to find ways to continue to procure the product. They also offered to indemnify that supplier for any claims that arose from use of the material. A reasonable juror could conclude that such behavior represented an outrageous disregard of Plaintiff's health and safety and award punitive damages. The Court will deny the motion in this respect as well.

G. Motions to Exclude Expert Testimony

Having concluded that issues remain for trial, the Court must now address the motions of the parties to exclude expert testimony. Defendant and Plaintiff have each filed such a motion, which the Court will address in turn.

As a general matter, Federal Rule of Evidence 702 "governs the admissibility of expert testimony." Showers v. Pfizer, Inc., 819 F.3d 642, 658 (2d Cir. 2016). That Rule permits "[a] witness who is qualified as an expert by knowledge, skill, experience, training or education" to "testify in the form of an opinion" under certain conditions. FED. R. EVID. 702.

[7]Plaintiff would have made the Court's task easier here if the Plaintiff had pointed to specific evidence that amounted to conduct justifying punitive damages.

To be qualified to testify, the "expert's scientific, technical, or other specialized knowledge" must "help the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702(a). In addition, "the testimony" must be "based on sufficient facts and date" and be "the product of reliable principles and methods." FED. R. EVID. 702(b)-(c). Finally, the expert must have "reliably applied the principles and methods to the facts of the case." FED. R. EVID. 702(d). "The proponent of the testimony has the burden to establish these admissibility requirements." Showers, 819 F.3d at 642.

A district court has "broad discretion" in evaluating expert testimony. McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1042 (2d Cir. 1995). In carrying out its role as gatekeeper, a court must take a "flexible" approach that focuses on "the scientific validity–and thus the evidentiary relevance and reliability–of the principles that underlie a proposed submission." Daubert v. Merrell Dow Pharms., 509 U.S. 579, 594-95 (1993). The court is to concentrate only on "principles and methodology," and "not on the conclusions that they generate." Id. at 595. Of course, "the types of factors to consider" in evaluating expert testimony "will 'depend upon the particular circumstances of the particular case at issue[.]" Showers, 819 F.3d at 658 (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999)). The trial court's role is as "'gatekeeper," making sure "that the 'expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" Id. (quoting United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007)). "It is a well-accepted principle that Rule 702 embodies a liberal standard of admissibility for expert opinions[.]" Nimely v. City of New York, 414 F.3d 381, 395 (2d Cir. 2005). In determining whether the expert has the qualifications to testify, the court's role, "whether a witness's area of expertise was technical, scientific, or more generally 'experienced-based," is to "'[make] certain that the 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." Id. at 396.

Once a court determines that an expert is qualified to testify, "Rule 702 imposes on the trial judge an obligation to determine whether the expert's specialized knowledge will assist the trier of fact, i.e., will be not only be relevant, but reliable." United States v. Romano, 794 F.3d 317, 330 (2d Cir. 2015). "Expert testimony should be excluded where it is 'speculative or conjectural,' but arguments that the expert's assumptions 'are unfounded go to the weight, not the admissibility, of expert testimony.'" Robinson v. Suffolk County Police Dep't, 544 Fed. Appx. 29, 32 (2d Cir. 2013) (quoting Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996)). In determining whether expert testimony will assist the trier of fact, a court must be careful to remember that such testimony may not either "'usurp the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it[.]'" Nimely, 414 F.3d at 397 (quoting United States v. Blizerian, 926 F.2d 1285, 1294 (2d Cir. 1991). The testimony should not attempt to "'tell the jury what result to reach'" or "'substitute the expert's judgment for the jury's.'" Id. (quoting United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994)).

The Court will apply these standards in evaluating the parties' motions to exclude expert testimony.

i. Defendant's Motion

Bard moves to exclude or limit certain opinions and testimony of Dr. Ostergard, who Plaintiff has designated as her case-specific expert in this matter See dkt. # 21. The Court will address each portion of Defendant's motion in turn.

a. General Causation Opinions

Defendant argues that Plaintiff only disclosed Dr. Ostergard as a case-specific expert. Still, Defendant contends, Dr. Ostergard's report contains general causation opinions concerning polypropylene and concerning the product's design. Defendant further argues that at his deposition Dr. Ostergard "conceded that he would not offer general opinions related to 'polypropylene, AUGS, industry influence, MSDS, and pore size of the Align mesh.'" As a result, Defendant insists, the Court should prevent Ostergard from testifying on those subjects.

Defendant here does not argue that Dr. Ostergard is unqualified to form an opinion about the design of the product or the suitability of using polypropylene. Instead, Defendant simply argues that Ostergard's testimony should be limited to the specifics of Plaintiff's case. Of course, to testify about whether and how the Align TO device injured the Plaintiff, Ostergard will have to testify about the device itself, and how certain features of that device allegedly malfunctioned and caused Plaintiff specific injuries. Such opinions are relevant to the issue of whether the alleged design defects in question were a substantial factor in Plaintiff's injuries. Testimony on the relationship between Plaintiff's injuries and the alleged defects in design would therefore be relevant and helpful to the jury. Dr. Ostergard's expertise would help jurors understand the issue. As such, the Court will not at this point prevent Dr. Ostergard from testifying on those subjects.

The Court recognizes, however, that other experts will also testify on these issues. The Court notes that the Federal Rules of Evidence permit the Court to exclude relevant evidence when "its probative value is substantially outweighed by a danger of . . . presenting cumulative evidence." FED. R. EVID. 403. The Court doubts jurors will need to hear the

same evidence about design defects multiple times and warns Plaintiff about presenting cumulative evidence at trial. The Court will therefore deny the motion in this respect with leave to renew at an appropriate time during trial.

b. Dr. Pfeiff's State of Mind

Next, Defendant argues that "Dr. Ostergard should not be permitted to offer any opinion testimony regarding the knowledge or state of mind of" Dr. Pfeiff "relating to the MSDS and Bard's corporate documents." Such testimony, Defendant argues, addresses Dr. Pfeiff's state of mind and is not proper expert testimony. The jury can instead hear Dr. Pfeiff's testimony and determine what he knew or did not know about the Ailgn device and the his reasons for installing and then removing the device.

The Court agrees that Dr. Ostergard would likely be unable to testify to Dr. Pfeiff's state of mind at trial. Such an objection, however, is better raised at the time of Dr. Ostergard's testimony than at a motion *in limine* such as the instant motion. The Court will therefore deny the motion with leave to renew at an appropriate time at trial.

c. Possible Future Adverse Events

Next, Defendant argues that Dr. Ostergard should not be permitted to testify to the opinion stated in his expert report in paragraph 84 that:

> Since almost all of the implanted Align TO sling mesh (about 18 cm) remains in Ms. Arruda's body the potential exists for continuing overactive bladder symptoms, continued stress urinary incontinence, future exposures, continued dyspareunia, along with infections, abscesses, vaginal, groin, and pelvic pain, mesh contraction and degradation, cancer associated with the mesh and infection for as long as the mesh remains in her body which may necessitate future surgical and medical treatments.

Ostergard Report at ¶ 84. Defendant argues that these opinions are not helpful to jurors

because Plaintiff does not presently experience any of these symptoms and because Dr. Ostergard testified that he cannot "opine to a 'reasonable degree of medical certainty that any of these possible future adverse events will occur in Ms. Arruda.'" Plaintiff responds that courts have previously permitted Dr. Ostergard to testify on future health issues from the product in question. Plaintiff states, however, that Dr. Ostergard will not testify about any future cancer risk.

The Court reads this portion of the report to be that Dr. Ostergard concludes that the Align TO sling mesh caused Plaintiff to develop or exacerbated a number of symptoms, including overactive bladder, stress urinary incontinence, dyspareunia, infections, abscesses, pain, and that she also experienced mesh contraction and degredation. These symptoms, he found, were likely to continue. He also states that she may face future surgical and medical treatments, which he does not specify. During his deposition, Dr. Ostergard testified:

Q: Do you have any opinions in this case about future possible adverse events with respect to Ms. Arruda?
A: Not really opinions. I'm just listing these as possibilities for the future.
Q: Okay. So this is–and I read your prior depositions, Dr. Ostergard–and I think you're pretty fair on the future adverse events–you can't say to a reasonable degree of medical certainty that any of these possible future adverse events will occur in Ms. Arruda. Is that correct?
A: That's correct.
Q: And sitting here today, you can't say with a reasonable degree of medical certainty that she will need any additional or further surgeries; is that also right?
A: That is also right.

Deposition fo Donald Ostergard, M.D., Exh. B to Defendant's Motion to Preclude, dkt. # 21-2, at 104.

Defendant's position is that these opinions will not be helpful to the jury, and that Dr.

Ostergard admitted in his testimony that not opine to any degree of medical certainty about what future treatment Plaintiff will need. The Court finds the testimony more equivocal than the Defendant claims it is. The expert report concludes that Plaintiff will likely continue to suffer from the injuries and conditions that the Align device allegedly caused or exacerbated. During his deposition, Ostergard admitted that he could not say with certainty that Plaintiff would suffer any future "adverse events" and could not opine that she would likely have additional surgeries. He did not disclaim his positions about continuing injuries and pain from the device. The juror could find information about such issues helpful in assigning damages. Dr. Ostergard based these opinions on his medical training, experience with such devices, and examination of the record. The Court therefore cannot find inadmissible all of the statements in paragraph 84 of the expert report. Defendant may, of course, challenge any of these opinions during cross examination, and may be able to employ Dr. Ostergard's deposition testimony to do so.

d. Safer Alternative Design

Defendant next argues that Dr. Ostergard should not be permitted to testify on any safer alternative design that might exist for the product in question. Bard offers several bases for excluding those opinions, which the Court will address in turn.

Dr. Ostergard opined that "[t]he use of a safer product such as a cadeveric or autologous sub-urethral sling or a lighter weight, larger pore polypropylene mesh may have eliminated the risks associated with the defects inherent in this flawed device, including chronic inflammation, degradation, shrinkage, and infection." Ostergard Report at ¶ 85.

Bard first contends that Ostergard does not have any experience in product design and is therefore not qualified to testify on the issue of a safer design. He is a case-specific

expert on urogynecology not designated to testify on specific design issues. The Court has already explained Dr. Ostergard's extensive training and experience with urogynecology. While he may not have designed particular products, he certainly has the training, experience, and knowledge to determine how defects in design cause women injuries and to opine on how a different design or a different composition of a device would be safer. As to whether Ostergard should be able to testify beyond the particulars of Plaintiff's treatment and injuries, the Court relies on the reasons expressed above to permit such testimony. Moreover, Defendant has not pointed to any undue prejudice from Dr. Ostergard testifying on these issues. Defendant has a copy of Dr. Ostergard's report. Defendant has deposed Dr. Ostergard. Defendant has its own expert on these issues. While the Court will entertain objections to cumulative testimony, the Court will not exclude such testimony.

Second, Defendant argues, Dr. Ostergard should not be able to testify to as to alternatives because he has not identified an alternative safer design but instead recommended a different product altogether. Defendant cites to Kaiser v. Johnson & Johnson, No. 2:17cv114, 2018 U.S. Dist. LEXIS 19950 (N.D. IN, Feb. 7, 2018), a case involving a similar device made by a different manufacturer. In that case, the defendant had sought to exclude expert testimony about "nonsynthetic mesh procedures, such as abdominal sacrocolpopexy," which the expert contended was "a safer alternative for the surgical treatment of stress urinary incontinence." Id. at *18. The Court excluded such testimony because, "[a]t the risk of stating the obvious, design defect cases focus on the design of the *product* and if there was a feasible way to change the product to make it safer and avoid the injury at issue." Id. at *19. "[A] procedure or non-product" does not constitute a "safer alternative design" in a design defect case, the court concluded. Id. at 19-20. Still,

the availability of such treatments, the court found, could be evidence of the use of reasonable care in design of the product and thus evidence for plaintiff's negligent design claim. Id. at *20.

The Court is unpersuaded by Defendant's argument. Dr. Ostergard does not propose abandoning the sling device for some other procedure or treatment. He instead criticizes the material from which Defendant constructed the sling. He suggests that another material would be safer in serving the same function. That amounts to an argument for a safer alternative design, just as arguing that using aluminum instead of steel in a bike frame would make the frame stronger, lighter, and more durable, and thus safer. Further, the Defendant's complaint that Ostergard does not name a particular product in proposing a different design is an issue for cross-examination, not a reason to exclude his testimony. The Court will therefore deny the motion in this respect as well.[8] Third, Defendant argues that Ostergrad's opinion on an alternative design is simply speculative, based on "inferences drawn from his general background, qualifications,

[8]Defendant cites to another case which makes this point quite clearly. In Hines v. Wyeth, No. 2:04-0690, 2011 U.S. Dist. LEXIS 55419 (S.D. W.Va., May 23, 2011), the defendant sought summary judgment in a case involving claims of design defect when the plaintiff developed breast cancer after using hormone replacement therapy. Id. at *2-3. Defendant had argued that a safer alternative drug existed to the one that defendant supplied. Id. at *22-23. Defendant disputed that plaintiff had offered a real alternative design, but instead–by pointing to a different drug–offered "a different product altogether. Id. at *27. The court agreed that a safer alternative design could not be "'an altogether essentially different product.'" Id. at *27 (quoting Torkie-Tork v. Wyeth, 739 F.Supp.2d 895, 900 (E.D. Va. 2010). A design that "'alters a fundamental and necessary characteristic of the product'" is not an alternative design. Id. (quoting Torkie, 739 F.Supp.2d at 900). In other words, "'a motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle.'" Id. (quoting Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 385 (Tex. 1995)). Plaintiff's alternative design, which uses different materials for the same purpose, does not constitute a different product altogether.

and experience," and is therefore inadmissible. Defendant argues that Ostergard has not offered proof that the safer alternative design would actually have prevented the injuries the Algin TO allegedly caused. The Court is unpersuaded by this argument. Ostergard–and the other experts–criticize the design of the product and argue that the design caused particular injuries. They also contend that using a different material and design for the mesh in the product would have led to a sling that lasted longer, prevented infections, prevented injury, and better prevented incontinence. Defendant admits that Ostergard's suggestion for an alternative design grew out of his background, qualifications, and experience; in other words, his expertise. Defendant's criticism that Ostergard's opinion is too speculative, not feasible, and poorly researched will be an excellent subject for cross-examination, but it is not a reason to preclude the evidence. The motion will be denied in this respect as well.

Defendant's fourth argument, that Dr. Ostergard did not test any alternative design and therefore offers only a speculative opinion, fails for the same reasons. Dr. Ostergard's understanding of what designs might work was based on his extensive experience, expertise in urogynecology, use and observation of similar products, and his understanding of why the Align product allegedly failed. He had an expert basis for his opinion. Defendant can cross-examine Dr. Ostergard on the strength of and support for his opinions at trial. The motion is denied in this respect as well.

ii. Plaintiff's Motion

Plaintiff moves to exclude the expert testimony of Stephanie Molden, M.D., Bard's causation expert.

a. Molden's Opinion

Dr. Stephanie Molden submitted her expert report as part of this litigation. See Exh. A to Plaintiff's Motion to Exclude, dkt. # 24-1 ("Molden Report"). Dr. Molden serves as Medical Director of The Female Pelvic Health Center, LLC, in Newtown, Pennsylvania. Id. at 2. She is a certified specialist in Female Pelvic Medicine & Reconstructive Surgery and Obstetrics & Gynecology. Id. at 1. Dr. Molden has advanced training, including a three-year fellowship in pelvic medicine and reconstructive surgery. Id. at 1-2. She has engaged in research and published articles in peer-reviewed journals. Id. at 2. She has been a "course director" of "national surgical skill workshops in treatment of pelvic organ prolapse and urinary incontinence." Id. Those procedures are Dr. Molden's "area of expertise." Id. During her three-year fellowship, Dr. Molden "trained heavily in mesh use for both prolapse and incontinence." Id. She assisted in and/or performed more than 1000 surgeries. Id. She has researched mesh use and presented that research in "national and international arenas." Id. In her present work she "continue[s] to incorporate mesh use in many procedures for urinary incontinence and pelvic organ prolapse[.]." Id. She has performed more than 2000 surgeries, many of them using mesh slings and prolapse meshes "of different types and brands." Id. She also works on developing new products and procedures to address prolapse and incontinence. Id. Dr. Molden also advises research on pelvic medicine and reconstructive surgery, reviews journal articles, and participates in a large-scale study of procedures sponsored by the Food and Drug Administration. Id. at 2-3.

Dr. Molden's report describes the condition of stress urinary incontinence and typical treatments for that issue. Id. at 3-7. She explains the development and use of mesh slings to support the urethra and limit incontinence. Id. at 5-6. Dr. Molden concludes that "[t]he mesh midurethral sling is associated with less pain, shorter hospitalization, faster return to

activities, and reduced costs as compared to previous options." Id. at 6. These benefits have caused the "midurethral sling–either retropubic or transobturator–[to be] considered the 'gold standard' in surgical treatment of SUI." Id. She also describes complications that can come with the treatment, including "erosion into viscera or extrusion through the vagina, voiding dysfunction or urinary retention, infection/inflammation, bleeding/hematoma formation, damage to blood vessels or nerves in surrouding tissue, pain or dyspareunia, bladder perforation, and "rarely, bowel perforation and death." Id. Compared with other surgical options, Dr. Molden contends, "[t]he only unique risks to mesh sling surgical treatment for SUI versus other available surgical options are mesh erosion or extrusion." Id.

Dr. Molden describes her experience with mesh slings. Id. at 6-7. Most patients, she reports, experience "no recurrence or reoperation and either no or few complications." Id. at 6-7. She has also seen patients with complications, both patients treated with mesh and with other surgical methods. Id. at 7. She has "seen and treated non-mesh repairs for prolapse and incontinence with pain, dyspareunia, suture erosion, voiding dysfunction, and failures." Id. Like all surgical procedures, mesh slings present "risks and complications." Id. Still, Dr. Molden has "rarely seen true infections related to proper mesh placement." Id. She has not seen evidence that urinary tract infections are more common after the initial postoperative period with mesh than with other materials. Id. Molden's experience and the literature suggest that mesh produces "increased anatomical success rates and less reoperation for recurrence[.]" Id. She finds that "correct placement and dissection techniques" and "patient selection are important to decrease risks and complications" from mesh surgery. Id. Slings also have the benefit of being "a minimally invasive, quick procedure" that helps most patients. Id.

Dr. Molden describes the history of polypropylene mesh in surgery. Id. at 7-8. Millions of patients have had such mesh implanted in their bodies over the past fifty years. Id. at 7. Mesh is often used to repair hernias, and "[t]he translation of its use in pelvic surgery was a natural one and based on the success and tolerability noticed in hernia repair." Id at 8. Molden claims that "[t]he long-term durability, safety, and efficacy of pelvic surgery to treat incontinence has been demonstrated for polypropylene sling use for up to seventeen years in studies." Id. Molden describes the process by which such mesh becomes implanted in the body and discusses the "optimal" types of material for mesh devices. Id. She contends that "there is no consensus about a specific mesh design, in terms of pore size, knit design, etc., that produces the best clinical outcomes in SUI repairs with slings." Id.

Molden discusses Bard's devices, instructions for use, and training. Id. at 9-10. She argues that the instructions "give appropriate instructions on the use, delivery, contraindications and possible risks or complications associated with the Align device." Id. at 9. Those instructions "sufficiently [address] and [explain] the information the surgeon needs for safe and appropriate use of the Align device." Id. Bard offers training on using the device, Molden reports, that "is helpful to surgeons in advancing patient care" and that training "provide[s] appropriate information about product use, benefits, and risks." Id. at 10. Molden's report also discusses an investigation of the Food and Drug Administration ("FDA") into mesh slings and the position fo the American Urogynecologic Society ("AUGS") on those devices. Id. at 10-13.

Molden further opines on MSDS at issue in this case. Id. 14. She finds that a surgeon would not normally receive or review such information because the "sheet does not

address use of polypropylene in the form of grafts used in the human body and is aimed at identifying physical and chemical properties of the resin relating to processing, storage, handling and disposal." Id. Moreover, she points out, the FDA, not the manufacturer sets "[t]he standards for what materials can be used in an implantable medical device." The MSDS and "related documents" do not address the safety of Bard's devices, "which are made of a well-accepted material." Id.

Molden's report also addresses Plaintiff's particular case. Id. at 15-20. After reviewing the medical records, Molden offers an opinion on Plaintiff's medical condition. Id. at 17. Plaintiff, she finds, "is currently a 58-year-old woman with many medical issues and generally appears very unhealthy for her age." Id. Dr. Molden finds that Plaintiff's "pain is so diffuse, and she has so many reasons for the pain that it is nearly impossible to attribute the pain to any one cause (including her sling and especially after removal)." Id. She relates that Plaintiff had a long history of various pelvic, bladder, and urethral issues before having the sling implanted, and underwent different procedures to correct them. Id. at 17-18. In the end, Dr. Molden concludes that:

> Following a differential diagnosis analysis and based upon my knowledge and experience as a Board Certified Female Pelvic Medicine and Reconstructive Surgeon and to a reasonable degree of medical probability and certainty, Ms. Arruda's complaints are not likely caused by the Bard Align product; no defect or action or inaction on the part of Bard caused or contributed to this patient's alleged injuries or damages. Moreover, use of a different available mesh product for her SUI procedure likely would not have avoided Ms. Arruda's complaints.

Id. at 19.

b. Causation Opinions Related to the FDA

Plaintiff argues that the Court should not permit Dr. Molden to testify that she relies on the opinions of the FDA in making decisions about whether products are safe for human

use. Plaintiff notes that "Dr. Molden states that she relies 'on the FDA standards to guide the decisions of safety for human use.'" At the same time, however, Molden testified at her deposition that "she disagrees with the FDA's April 16, 2019 decision to halt the sale of mesh products for the treatment of pelvic organ prolapse." Molden criticized the FDA's decision "because 'they're not the ones using it and seeing it and treating patients every day."[9] Plaintiff reads these statements as demonstrating inconsistency in Dr. Molden's use of the FDA's findings, arguing that she "cherry-picks FDA opinions, using the FDA when it supports her agenda, but completely discounting it when she disagrees with it." Such treatment of the FDA's findings, Plaintiff claims, shows "Dr. Molden's flawed methodology, calling into question the foundations for her opinions and undermining her credibility as an expert witness."

The Court will deny the motion in this respect. Plaintiff does not dispute Dr. Molden's qualifications or capacity to testify as an expert witness. Instead, Plaintiff argues that Dr. Molden is not entirely consistent in her treatment of the FDA's findings, and that this inconsistency undermines her credibility. While that argument may be a fine topic for cross examination at trial, it does not provide a reason to preclude her testimony.

c. Specific Causation Opinions

Plaintiff initially argues that the Court should not permit Dr. Molden to testify on specific causation because her general causation opinions are not admissible. The only

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[9]Asked whether she could "rely on the opinions of the FDA," Dr. Molden testified that "that's a loaded question. It depends. Sometimes I do. But I can respectfully disagree when they're not the ones using it and seeing it and treating patients every day." Deposition of Stephanie Molden, MD, ("Molden Dep."), Exh. B to Plaintiff's Motion to Exclude, dkt. # 24-2, at 30. Molden agreed that she could not use a product not approved the FDA, but contended that "[i]t doesn't mean I agree with all of their commenting." Id.

argument that the Plaintiff has offered on general causation, however, is her criticism of Dr. Molden's use of FDA findings. The Court has explained why this argument must fail. Moreover, Dr. Molden has extensive experience using and evaluating the types of products here in question. She also has training and expertise in the medical specialty related to such device, as well as experience in the surgeries her in question. She may testify as an expert on the function, design, and use of such devices. Plaintiff offers other arguments for excluding those opinions, which the Court will address in turn.

1. Methodology and Principles

Plaintiff next argues that Dr. Molden's opinions are unreliable because her specific causation opinions use an unreliable differential diagnosis. "A differential diagnosis is 'a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes.'" Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (quoting Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1413 (D. Or. 1996) (internal quotations omitted). "'A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.'" Lancaster v. Ethicon, Inc., No. 19cv1377, 2020 U.S. Dist. LEXIS 27851 (N.D.N.Y. Feb. 19, 2020) (quoting Ellis v. Appleton Papers, Inc., No. 94-CV-558, 2006 U.S. Dist. LEXIS 7164, 2006 WL 346417, at *5 (N.D.N.Y. Feb. 14, 2006)). Courts have permitted experts to employ such methodology under the Daubert standard. See, e.g., McCullock v.

H.B. Fuller Co., 61 F.3d 1038, 1043-1044 (2d Cir. 1995). Indeed, "[c]ourts have consistently found specific causation opinions reached without the aid of a differential diagnosis to be unreliable and requiring exclusion." N.K. v. Abbott Labs., No. 14-CV-4875, 2017 U.S. Dist. LEXIS 77461 at *12 (E.D.N.Y. May 22, 2017) (citing Israel v. Springs Industries, Inc., No. 98 CV 5106, 2006 U.S. Dist. LEXIS 80863, 2006 WL 3196956, at *10 (E.D.N.Y. Nov. 3, 2006)).

Plaintiff first contends that Dr. Molden's different diagnosis is unreliable because Molden failed to identify a specific, single cause for Plaintiff's injuries. In her expert report, Dr. Molden concluded that Plaintiff's injuries were not likely caused by Defendant's product. When asked during her deposition to explain her methods, Plaintiff points out, Dr. Molden did not describe a process of examining a number of alternative causes and eliminating those causes until a single cause could be found. Dr. Molden also testified that she could not "rule out" the Align device as a cause of the injuries of which Plaintiff complained. Plaintiff further contends that Dr. Molden's analysis does not result in a differential diagnosis because she concluded that Plaintiff had such a variety of sources of pain that she could not identify a single cause of that pain.

The Court will deny the Plaintiff's motion in this respect. Plaintiff asks too much of a differential diagnosis in this respect. "Generally, courts have held that '[a] medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness.'" Bee v. Novartis Pharms. Corp., 18 F.Supp.3d 268, 305 (E.D.N.Y. 2014) (quoting Davids v. Novartis Pharms. Corp., 857 F.Supp.2d 267, 278 (E.D.N.Y. 2012)). "'While an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least

address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant.'" Adeghe v. Janssen Pharms., Inc., No. 16cv2235, 2017 U.S. Dist. LEXIS 139913 at *10 (S.D.N.Y. Aug. 30, 2017) (quoting DeRienzo v. Metro Transp. Auth., 694 F.Supp.2d 229, 236 (S.D.N.Y. 2010)). Dr. Molden's analysis meets this standard, and a jury should be permitted to decide whether to credit that analysis.

The Court notes, as well, that Plaintiff seems to shift the burden of proof to the Defendant in this case by arguing that Dr. Molden's analysis would not be helpful to the jury. In this case, the Defendant does not need to convince the jury that a defect in the Align device's design was the proximate cause of any injuries she faced; the Plaintiff must do that to prevail. An expert report that finds that the evidence does not support a clear finding that the Align TO caused Plaintiff's injuries would be helpful to the jury in deciding whether Defendant is liable. Moreover, even if a jury decides that the device caused Plaintiff's injuries, evidence that Plaintiff had injuries that may have been caused by other sources would be helpful to the jury in determining the amount of damages to award in this matter.

Plaintiff also argues that Dr. Molden's report is speculative, based on assumptions not supported by the record. Plaintiff points to portions of Molden's report and testimony that acknowledge that records are incomplete and which use somewhat tendentious language in describing the nature and source of an injury. Plaintiff argues that such testimony is "not scientifically valid and is likely to mislead a jury." The Court disagrees. Plaintiff can certainly point to uncertainties and equivocations in the report in cross-examining Dr. Molden, but the Court cannot find that a statement in a report that acknowledges gaps in the medical record or proceeds cautiously in explaining a diagnosis

amounts to unwarranted speculation, or makes the report so unreliable that a jury should not consider the opinion. The motion will be denied in this respect as well.

IV. CONCLUSION

For the reasons stated above, Defendant's motion for summary judgment, dkt. # 50, is GRANTED in part and DENIED in part, as follows:

1. The motion is GRANTED with respect to Plaintiff's breach of warranty, manufacturing defect, and New York Consumer Protection Law claims; and
2. The motion is DENIED in all other respects.

The Defendant's motion to exclude or limit certain expert opinions of Dr. Donald R. Ostergard, MD, dkt. # 51, is hereby GRANTED in part and DENIED in part, as follows:

1. The motion is GRANTED with respect to any testimony by Dr. Ostergard about Dr. Pfeiff's state of mind when he implanted the device in question;
2. The motion is DENIED in all other respects.

Plaintiff's motion to preclude the expert testimony of Dr. Stephanie Molden, dkt. # 58, is hereby DENIED.

IT IS SO ORDERED.

Dated: August 6, 2020

Thomas J. McAvoy
Senior, U.S. District Judge