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Superior Court of New Jersey, Law Division
Bergen County Justice Center
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This Order is prepared and filed by the Court:

JANE GASPER and MATTHEW GASPER, Plaintiffs, vs. C.R. BARD, INC., et al Defendants.	SUPERIOR COURT OF NEW JERSEY BERGEN COUNTY-LAW DIVISION Docket No. BER-L-03159-15 Master Case No. BER-L-17717-14 CIVIL ACTION

DIANE OLIVER and MICHAEL OLIVER, Plaintiffs, vs. C.R. BARD, INC., et al	SUPERIOR COURT OF NEW JERSEY BERGEN COUNTY-LAW DIVISION Docket No. BER-L-880-15 Master Case No. L-17717-14 CIVIL ACTION ORDER

Before this court is plaintiffs' JANE AND MATTHEW GASPER and DIANE AND MICHAEL OLIVER'S (hereinafter "plaintiffs"), motions *in limine* numbered 1-13 and defendants C.R. BARD, INC., et al's (hereinafter "defendants") motions *in limine* numbered 1-34. Oral argument was conducted on August 8 and 9, 2019.

Plaintiffs' Motions:

***In Limine I: Bard should not be permitted to defend based on the long history of use of polypropylene in the human body*: DENIED**. The plaintiffs' request is overly broad. The parties may discuss the history of polypropylene and how polypropylene came to be used in the products involved in this matter.

***In Limine II: Bard cannot defend based on 510(k) clearance or compliance with any FDA regulations*: GRANTED**. The FDA §510(k) clearance process is not equivalent to the premarket approval process (PMA). Only the PMA can find a medical device safe and effective. The Align-TO product was classified as a Class II device, which did not have to undergo the PMA process of a Class III medical device. The FDA only conducts scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. As such, the Align-TO cannot be presented to the jury as being approved by the FDA as safe and effective.

***In Limine III: The Material Safety Data Sheets (MSDS) are admissible*: GRANTED**. The defendants received the MSDS from the manufacturer of the polypropylene used to make the products in this action. The MSDS stated in pertinent part as follows:

> "Do not use material in medical applications in the human body. Do not use the material in medical applications involving brief or temporary application in the human body or contact with internal body fluids or tissue."

The Material Data Safety Sheets may be used at trial by Plaintiffs to show notice and knowledge of Defendants in connection with Plaintiffs' failure to warn claim. The Material Data

Safety Sheets also go to the issue of the reasonableness of Defendants' conduct and whether they should have taken any additional steps with regard to the products.

***In Limine IV: Bard's duty to warn cannot be abrogated by its unsupported assumption that users would have knowledge of the undisclosed risks*: DENIED**. Under the New Jersey Products Liability Act, a manufacturer has no duty to warn of all risks. "An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician." N.J.S.A. §2A:58C-4. The test uses an objective standard.

***In Limine V: Bard cannot generally refer to what was taught to physicians in "Professional Education" as a defense to the inadequate warnings provided with their products*: DENIED**. This evidence is relevant as to what physicians knew or learned regarding the product in question.

***In Limine VI: Bard cannot claim it had no duty to warn of severe complications*: DENIED**. This is an issue that will be considered during the course of the trial based upon the testimony of the witnesses.

***In Limine: VII: Treating physicians cannot be used as experts*: GRANTED**. During trial, Plaintiffs will object and approach the bench regarding questions they believe are improper to ask

of a treating physician on cross-examination. As an alternative, Plaintiffs' counsel may address the potential issues pertaining to these questions prior to the expert witness's testimony.

In Limine VIII: Bard cannot argue that the Align-TO was an unavoidably dangerous device. **GRANTED IN PART.** Defendants agree not to argue that the Align-TO was an unavoidably dangerous device during opening statements.

In Limine IX: Defendants cannot introduce evidence of professional society position papers to claim the Align-TO was the "standard of care": **DENIED.** Issues as to how, why and who created the position papers go to the weight of the papers and not their admissibility. To the extent any party intends to rely on such papers, the other party may seek to attack/discredit the reliability or credibility of such papers.

In Limine X: Bard cannot introduce general FDA statements regarding the general attributes of mid-urethral slings: **GRANTED**. See *In Limine* II above.

In Limine XI: The Time to Rethink article should not be referenced: **GRANTED**. This article is in response to the July 2011 FDA "Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." As all FDA testimony is precluded during this trial as a result of this court's decisions, this article will likewise be precluded at trial; it would be impossible to discuss this article without discussing the FDA. However, this court is aware that one of plaintiffs' expert witnesses, Dr. Richard Bercik, endorsed the conclusions set forth in this article. In the event Dr. Bercik should provide any statement at trial inconsistent

with the article, defense counsel shall approach the bench to address the situation to potentially utilize this article for impeachment purposes.

In Limine XII: Bard employees cannot be permitted to give improper expert opinion testimony: **RESERVED.** The depositions of these Bard corporate experts have recently been conducted. Any perceived issues as to improper expert opinions shall be raised with this court prior to their testimony before the jury.

In Limine XIII: Motions directed to irrelevant, misleading, and unduly prejudicial general evidence and arguments: **GRANTED** as to: a) there should be no reference to tort reform, a litigation crisis, or otherwise critical comments about lawsuits in general; b) there should be no argument or discussion by counsel, a defense witness, or expert regarding family members, friends or other patients; c) there should be no reference to increases in the costs of healthcare, or health products, by reason of medical lawsuits or claims; and d) collateral source rule: **RESERVED** in that the parties have agreed to meet and confer.

Defendants' Motions

In Limine 1: Admit evidence and argument related to the FDA 510(k) process and clearance: **DENIED.** See Plaintiffs' MIL #2.

In Limine 2: Exclude evidence, testimony, argument concerning MSDS and Bard's procurement procedures regarding polypropylene resin from suppliers: **DENIED.** See Plaintiffs' MIL #3

In Limine 3: Exclude evidence/argument that Bard owed or breached a duty to warn Plaintiffs directly: **GRANTED** as to a duty to warn Plaintiffs directly; Plaintiffs will not present such an argument in their opening statement. If this issue should be further developed during the course of the trial, the court shall address it at that time. **DENIED** as to whether the Plaintiffs would have refused surgery if they had been given different information. Plaintiffs may argue that they would have refused surgery if they had been given different information. This court disagrees with the defendants' position pertaining to proximate cause. This court finds that the inquiry does not end with whether or not the implanting physician would have prescribed the product in question had the doctor been given further or different warnings. The Appellate Division affirmed the Hon. Carol Higbee's decision in Gross v. Gynecare, 2016 WL 1192556 (NJ Super. App. Div. March 29, 2016), wherein she charged the jury that they could consider what decision the mesh patient, Linda Gross, would have made on her treatment if she was adequately warned by the implanting surgeon. Furthermore, the Appellate Division in the Accutane MCL recently reiterated this principle. Rossitto v. Hoffman-LaRoche, 2016 WL3943335 (App. Div. July 22, 2016).

***In Limine 4: Preclude evidence or argument related to Bard sponsored voluntary physician training programs*: DENIED** as to Bard's voluntary training program. Since plaintiffs' implanting physicians Dr. Domintz and Dr. Chao both attended Bard's sponsored training, this may be relevant as to what each of them learned or did not learn during training. If a manufacturer undertakes to train physicians and fails to exercise reasonable care in that undertaking, it may be held liable for harm caused to third parties as a result of its negligent undertaking. Plaintiffs are not precluded from presenting evidence regarding what affirmative actions were taken by Defendants to train the implanting physicians and what training Defendants gave to physicians.

***In Limine 5: Motion to exclude any evidence or argument that Defendants owed or breached an independent duty to conduct additional testing or file a PMA*: DENIED** as to references that Bard owed or breached an independent duty to conduct additional testing or inspection. As to conducting additional independent testing, this will be allowed as it may be relevant to assist the jury in determining the reasonableness of Defendants' actions. However, since the FDA may not be referenced in this trial, Plaintiffs may not assert any duty of Defendants to file for a PMA.

***In Limine 6: Motion to exclude evidence/arguments regarding other lawsuits, claims, verdicts, trials, investigations and settlements related to Pelvic Mesh generally, to Bard specifically, or any other manufacturer*: GRANTED** to preclude evidence of other lawsuits, claims, verdicts, trials, investigations and settlements involving pelvic mesh. **GRANTED** to exclude references of involvement of Bard's counsel or its experts in other lawsuits or legal proceedings. As to expert fees paid to expert witnesses, inquiry may only be made as to payment(s) to expert witnesses in

these two Plaintiff cases. While Plaintiffs have agreed not to submit information regarding other vaginal mesh lawsuits, they reserve the right to submit such information in the event "the door is opened" by Defendants.

In Limine: 7: Exclude arguments, evidence, reference, or argument regarding involvement of Bard's current counsel in other lawsuits, legal actions, or of Bard's experts' role as expert witnesses in other mesh-related lawsuits: **GRANTED** to exclude references to involvement of Bard's counsel or its experts in other lawsuits or legal proceedings.

In Limine 8: Motion to exclude evidence or argument related to Medical Device Reports (MDR), product complaints, adverse event reports: **DENIED**. This court finds that MDRs and other information regarding risks, complications, and bad outcomes with the product at issue constitute relevant evidence in this trial. Such complaints and reports that were rendered are relevant to notice, knowledge, and causation. These reports may demonstrate Defendants' knowledge as to the nature of complications sustained by patients which may impact on the design and warning claims presented by Plaintiffs.

In Limine 9: Exclude any evidence related to conditions or symptoms Plaintiffs did not experience: **RESERVED**. This court will make the appropriate rulings during trial should this issue arise.

In Limine 10: Motion to exclude evidence or arguments concerning marketing or promotional activity that did not impact Plaintiffs' prescribing physicians: **DENIED.** This motion is vague. There is no identification of the marketing or promotional activities that Bard seeks to exclude

under this motion, or for what purpose. For example, the admissibility of Bard marketing and promotional material may be relevant, even if a physician did not see the marketing or promotional material, if it is being utilized to demonstrate that Bard marketed other devices as safer.

In Limine 11: Exclude all evidence regarding Bard's post-implant conduct: **DENIED**. Bard does not specify what specific changes to the design and warnings of the Align-TO that they believed to constitute a remedial measure.

In Limine 12: Exclude any evidence regarding post-implant regulatory communications and governmental conduct: **RESERVED**. If a specific issue of post-implant regulatory communications and governmental conduct arises during trial, argument will be entertained at that time.

In Limine 13: Exclude any evidence, documents, witnesses testimony, literature, deposition designations, reference or argument concerning Avaulta products, Nuvia products, and other mesh products: **DENIED** as overbroad. Bard's expert reports make reference to prolapse systems and meshes, including the Avaulta. Dr. Villarraga and Dr. Reitman discuss Bard TVM products, inclusive of the prolapse and SUI systems, as a whole. The defense experts include the prolapse mesh literature in their reliance lists and go through the history and relevance of prolapse systems, relying in part on that literature to support the safety of the Align.

In Limine 14: Bar argument that "AUGS" and other professional organizations were industry-promoted entities and their publications were "promotional pieces": **DENIED**. Defendants

advised that it intends to rely on such material, including "position papers" and must lay a foundation as to the use of such position papers. Plaintiffs may seek to question the motive, the reliability or credibility of the authors of the "position papers" in openings or otherwise.

***In Limine 15: Preclude evidence/argument concerning Bard's decision to stop selling the Align-TO, that the Align-TO was recalled or withdrawn, or that the Align-TO is no longer sold*: GRANTED**. Defendants' decision to stop selling the products was a voluntary business decision unrelated to the issues in this case. Further, the decision to stop selling would implicate the FDA, and this court has already determined that there is to be no reference to the FDA during this trial.

***In Limine 16: Bar evidence/argument related to Bard's corporate intent, motives, or ethics*: DENIED** as to evidence of Bard's intent, motives, ethics, and corporate culture. Such evidence may be relevant to establish causation and the reasonableness of their actions. However, a witness cannot testify as to what is in the mind of Bard or of a particular author of a document. New Jersey law allows evidence of motive, corporate intent and ethics in relation to Plaintiffs' punitive damages claims.

***In Limine 17: Bar evidence or arguments related to Bard's corporate culture*: DENIED.** This motion is vague. Also, some evidence, which may be negative or derogatory relating to Bard, may be relevant to issues in this case as well as punitive damages.

***In Limine 18: Exclude evidence or arguments related to, Bard's corporate policy*: DENIED** in general as to corporate policies. This motion is vague. If this motion relates to the gift basket issue,

and it is going to be utilized at trial, argument will be entertained regarding this specific piece of evidence.

In Limine 19: Exclude evidence/arguments related to notions of punishment: **DENIED IN PART.** Plaintiffs have acknowledged New Jersey's prohibition of "Golden Rule" arguments at trial, basically asking jurors to award damages in the amount that they would want for their own pain and suffering. Plaintiffs recognize that a "send a message statement" is not proper to support compensatory damages in a civil action but it is appropriate during the punitive phase and argument. As punitive damages will not be bifurcated, a "send a message statement" can be stated at this trial.

In Limine 20: Preclude non-retained treating physicians from testifying beyond topics relating to their diagnosis and treatment of plaintiffs: **DENIED.** Defendants argue that Plaintiffs are precluded from eliciting testimony from treating physicians that they would not have used their devices had they been alerted to certain known risks. This court disagrees. Such testimony is permissible as it establishes an element of causation on Plaintiffs' failure to warn claims.

In Limine 21: Motion to exclude evidence, argument, testimony, or reference concerning hypothetical and unsupported damages or relating to the impact of plaintiffs' alleged injuries on family and friends: **GRANTED** in part and **DENIED** in part. **GRANTED** in part as Plaintiffs agree they are not seeking damages on behalf of third-parties allegedly impacted by injuries to Plaintiffs. However, this court reserves as to testimony and evidence that may be presented at trial as to the impact of injuries on Plaintiffs themselves, pertaining to their relationships with third-parties and family members.

As to evidence or testimony of hypothetical or unsupported damages, this motion provides no specific information. As such, the motion as it relates to hypothetical or unsupported damages is **DENIED** and will be considered during the course of the trial to the extent necessary.

In Limine 22: Motion to preclude inflammatory, misleading, or prejudicial evidence, testimony, analogies, statements, reference, or argument during opening trial: **GRANTED** as it relates to opening statements, Plaintiffs may not present in any PowerPoint presentation slides analogizing Bard products to rebar. However, Plaintiffs may make such analogy orally during opening. No determination is made as to the use of the analogy in PowerPoint slides during Plaintiffs' closing statement.

In Limine 23: Preclude Plaintiffs from producing to the jury, by video or transcript, the deposition testimony of any witness whose testimony has not yet been admitted into evidence at trial or where the witness is available to testify live at trial: **DENIED IN PART and GRANTED IN PART.** The parties are permitted to quote and summarize deposition testimony in their opening statements. The video of such testimony may not be played during opening statements.

In Limine 24: Motion to exclude evidence, argument, testimony, or reference that prejudicially appeals to the sympathy of the jury: **GRANTED IN PART AND DENIED IN PART.** Bard has identified four topics of concern in this motion. Plaintiffs agree that they will not make an argument at trial in violation of the "Golden Rule". Plaintiffs agree that they will not make any argument referencing the fact that plaintiffs' legal team is somehow at a disadvantage when compared to the size of Bard's defense team. Plaintiffs agree that they will not make reference to the amount of money Bard has spent investigating or defending plaintiffs' cases. As to the fourth

topic, the motion is **DENIED** as it pertains to excluding evidence of Bard's size, resources or overall financial condition. Bard's pursuit of profits or financial value is relevant and admissible.

In Limine 25: Motion to exclude evidence, reference, argument regarding the parties' litigation conduct: **DENIED.** Bard seeks to exclude all evidence relating to (1) its designation of documents as "confidential"; and (2) its litigation conduct, including objections lodged during discovery. It is impossible to determine the relevancy of any argument or evidence concerning these issues at this stage. A blanket exclusion of such evidence and argument would be premature at this time.

In Limine 26: Motion to exclude evidence, argument, testimony, reference regarding roping, curling, shrinkage or degradation of mesh: **DENIED**. Plaintiffs may present evidence that is related to conditions or symptoms experienced by Plaintiffs. Such evidence is to be presented through a qualified expert.

In Limine 27: Motion to exclude evidence, argument, reference, testimony concerning Dr. Weber's health status: **DENIED.** This court will advise the jury of at the beginning of Dr. Weber's testimony that because of certain health issues, Dr. Weber will stand during her testimony.

In Limine 28: Motion to exclude evidence, arguments, testimony, reference concerning the "Dollars for Docs" website and/or unrelated payments from medical device and pharmaceutical companies: **RESERVED**. During cross-examination, Plaintiffs may ask if the experts did consulting work for pharmaceutical/medical device companies (unrelated to other litigation) and how much they were compensated for the consulting activities. The court will allow the parties to revisit this issue regarding specific information obtained from the website Dollars for Docs at trial when and if it becomes relevant.

In Limine 29: Motion to exclude evidence, reference, testimony, argument concerning unrelated convictions, investigations, settlements, alleged bad acts, or alleged "illegal activity": **RESERVED**. This court understands that Plaintiffs do not intend to advise the jury of the bad acts or alleged "illegal activity" as specifically described in this motion in limine. However, Plaintiffs seek to reserve the right to use such evidence if Bard "opens the door" by eliciting any testimony from witnesses or arguments by defense counsel "suggesting that Bard is an ethical, caring, law-abiding company, or that Bard acts always in the best interest of patients, or any similar claims." In support of its argument, Plaintiffs' opposition to this motion in limine provides Bard Power Points that were utilized at a previous trial. This court will entertain argument regarding the Power Points to be utilized during this trial as well as the extent to which counsel for Bard will be discussing the reputation of the company prior to making its final ruling on this issue.

In Limine 30: Motion to preclude plaintiffs' use of non-party documents: **DENIED** as this court does not know what documents are at issue in this motion, there is no context and accordingly no decision can be rendered.

In Limine 31: Motion to exclude evidence/arguments related to alleged misconduct or wrongdoing by Bard's sales representatives: **DENIED**. Bard seeks an order of this court to exclude any arguments, evidence or testimony related to sales representatives. Factual testimony has already been elicited regarding the role of sales representatives and their interaction with the implanting physicians. This is relevant testimony. While this in limine motion is couched as seeking exclusion pertaining to alleged misconduct or wrongdoing, the motion brief seeks to exclude any argument, evidence or testimony at all related to sales representatives.

***In Limine 32: Motion to exclude evidence/argument regarding Dr. Weber's 2007 ACOG Practice Bulletin titled "Pelvic Organ Prolapse," including any opinion or argument that the Align-TO is "experimental" and all communications related to the same*: DENIED.** The defense experts also rely on prolapse mesh technology and literature in support of their own opinions. With regard to Bard seeking to prevent Plaintiffs from using an email dated March 2007, by Bard product manager Jonathan Conta in response to Dr. Weber's proposed practice bulletin, such email is admissible as it is probative of whether Bard acted reasonably upon learning of Dr. Weber's ACOG bulletin. Dr. Weber may testify that the Align was in her own opinion, "experimental," and the defense can present their evidence to the country

***In Limine 33: Motion to exclude evidence, testimony, reference, argument regarding Plaintiff Diane Oliver's temporary loss of health insurance:* DENIED IN PART.** This court does not agree that allowing evidence of Ms. Oliver's temporary loss of health insurance coverage is likely to cause the jury to improperly speculate as to Ms. Oliver's current financial condition and improperly sympathized with her past financial condition. This testimony is relevant to show why Ms. Oliver did not have more frequent medical care. This is especially so in light of the fact that defense expert Dr. Kennelly testified several times regarding Ms. Oliver's sparse medical records. In addition, her lack of medical coverage is only for a specific period of time. Plaintiff's counsel cannot imply that Ms. Oliver lost her health insurance as a result of the implant procedure or that her alleged injuries as a result of the procedure were exacerbated by her lack of insurance.

In Limine 34: Motion to exclude evidence/argument suggesting Dr. Molden's IME harmed plaintiff in any way: **DENIED IN PART**: Plaintiff may testify about her independent medical exam and how it made her feel during and after.

DATED: 8/29/2019

Rachelle L. Harz

Hon. Rachelle L. Harz, J.S.C.