This Order is prepared and filed by the Court:

MARY MCGINNIS and THOMAS WALSH MCGINNIS, Plaintiffs, vs. C. R. BARD, INC., AND JOHN DOES 1-20, Defendants.	SUPERIOR COURT OF NEW JERSEY BERGEN COUNTY-LAW DIVISION Docket No. BER-L-017543-14 Case No. 292 CIVIL ACTION ORDER

Before this court are motions in limine filed on behalf of plaintiffs, Mary McGinnis and Thomas Walsh McGinnis (hereinafter "Plaintiffs"), and motions in limine filed on behalf of the defendant, C.R. Bard, Inc., (hereinafter "Defendant"). Oral arguments on the motions were held on January 29, 30 and 31, 2018. The court issued oral opinions on the record in connection with these motions. The court hereby enters this order in connection with the motions and incorporates by reference its oral opinions regarding the various motions.

Plaintiffs' Motions:

In Limine Motion No. 1: Bard should not be permitted to defend based on the long history of use of polypropylene in the human body.

DENIED. Plaintiffs' request is overly broad. Parties may discuss the history of polypropylene and how polypropylene came to be used in the products involved in this matter.

In Limine Motion No. 2: Bard should not be permitted to defend based on FDA 510(k) clearance.

GRANTED. The FDA 510(k) clearance process is not equivalent to a premarket approval process. The premarket approval process determines a medical device's safety and efficacy. The Avaulta and Align products, which are the subject of this action, were classified as Class II devices and did not have to undergo the premarket approval process. The FDA conducts scientific and regulatory review to evaluate the safety and efficacy of Class III medical devices.

In Limine Motion No. 3: Plaintiffs assert that the Material Data Safety Sheets are admissible.

GRANTED. Defendant received from the manufacturer of the polypropylene used to make the products in this action Material Data Safety Sheets which 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 Defendant in connection with Plaintiffs' failure to warn claim. The Material Data Safety Sheets also go to the issue of the reasonableness of Defendant's conduct and whether Defendants should have taken any additional steps with regard to the products. As to the issue of the 2011 Public Citizens Petition,

Plaintiffs acknowledge that they do not intend to use same at trial, unless Bard "opens the door" regarding such matters.

In Limine Motion No. 4: Bard should not be allowed to state it had no duty to warn by assuming users knew undisclosed risks.

DENIED. The North Carolina Products Liability Act states in pertinent part: ". . . no manufacturer or seller of a product shall be held liable in any product liability action for failing to warn about an open and obvious risk or a risk that is a matter of common knowledge." Thus, a manufacturer does not have a duty to warn as to all risks related to a particular product.

In Limine Motion No. 5: Bard should be precluded from raising any defense based on physicians' professional education.

DENIED. A physician's professional education is relevant as to what the physician knew or learned regarding the products at issue. Defendant may present evidence regarding Plaintiffs' physician(s) to the extent Defendant is able to identify the professional educational materials provided to said physicians, including, but not limited to, Dr. Barbee.

In Limine Motion No. 6: Bard should not be allowed to claim complications are "rare."

DENIED. This is an issue that will be considered during the course of the trial based upon the testimony of the witnesses.

In Limine Motion No. 7: Plaintiff cannot be found to be contributorily negligent based on the record in this case.

GRANTED. Defendants do not intend to assert such a defense at trial.

In Limine Motion No. 8: Plaintiff cannot be found to have failed to mitigate or blamed for rejecting tests or treatment based on the record in this case.

The court defers on this motion until evidence is presented at trial as to Plaintiffs' alleged failure to mitigate. Such matters are more appropriately considered at the conference related to the jury charge/jury verdict sheet. Until evidence has been presented and considered, this motion is premature.

In Limine Motion No. 9: Plaintiffs assert that Defendant should be precluded from blaming Ms. McGinnis' treating physicians.

DENIED in part. Defendant acknowledges it will not seek to apportion fault to any physicians who treated Plaintiffs. However, Defendant may raise the issue of intervening causes in connection with Plaintiffs' claims. Such matters will be considered by the court during the jury charge conference and conference as to jury verdict sheet. As to an intervening negligence charge, the court makes no determination and reserves on this issue until evidence is presented and considered. Nevertheless, Defendant's counsel may <u>not</u> mention intervening causes or specifically seek to put blame on treating physicians during their opening statements.

In Limine Motion No. 10: Treating physicians cannot be used as experts.

GRANTED as it relates to matters such as whether it is necessary for physicians to serve as consultants to the pharmaceutical industry. This ruling does not go to issues related to causation or whether Plaintiffs' treating doctors can testify as to whether they would have proceeded with their use of the product in question if they had known certain information. Such matters are considered as part of Defendant's motion in limine no. 9. If there is a particular question which either party believes to be objectionable, the issue will be dealt with at sidebar.

In Limine Motion No. 11: Plaintiffs assert that Bard cannot argue that Avaulta and Align were "unavoidably dangerous."

GRANTED, without prejudice. Defendant's counsel agreed not to use the terms "unavoidably dangerous" or "unavoidably unsafe" during opening statement. The motion goes to issues to be discussed at the conference related to the jury charge and jury verdict sheet.

In Limine Motion No. 12: Plaintiffs assert that Defendant cannot introduce evidence related to professional society position papers.

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 Motion No. 13: Bard cannot introduce general FDA statements regarding the general attributes of mid-urethral slings.

GRANTED. See ruling on Plaintiffs' in limine motion no. 2.

In Limine Motion No. 14: Bard cannot introduce evidence or argument that the Align-TO or mid-urethral slings generally are the 'gold standard' or the standard of care for treatment of stress urinary incontinence.

DENIED in part and **GRANTED** in part. The term "gold standard" is used in the industry and may be referenced by the parties. To the extent that either party uses the term "standard of care," that party may not indicate it is the only standard of care.

In Limine Motion No. 15: Defendants shall make no reference to "Time to Rethink" Article.

GRANTED. This article relates to FDA determinations regarding products in question. See determination as to Plaintiffs' in limine motion no. 2. Since no references to the FDA are to be made by any party during the course of trial, references to the Time to Rethink article are precluded since the article was written in response to a safety communication update published by the FDA.

In Limine Motion No. 16: Bard cannot cite Ms. McGinnis's preexisting condition(s) or seek an apportionment for the same to defend causation or damages.

GRANTED in part and **DENIED** in part. Defendant acknowledges that it is not seeking to apportion any damages to Plaintiffs. However, Defendant may present facts of Plaintiff's medical condition(s) prior to the implantation of the products in question. Plaintiff's medical experts are aware of Plaintiff's pre-existing medical conditions and they have taken same into account with regard to their treatments and/or opinions. The lack of expressed percentage by Defendant or its experts does not preclude the presentation of factual information to the jury. Such information may place in context the opinions of the medical experts in this case. Furthermore, Plaintiff's pre-existing conditions are directly relevant to causation.

In Limine Motion No. 17: Bard cannot introduce evidence of risks of alternative procedures that Ms. McGinnis did not undergo to defend causation or damages.

DENIED. Defendant may introduce evidence of risks of alternative procedures even if Plaintiff did not undergo such alternative procedures. However, no expert may opine as to whether Plaintiff would actually have sustained any particular injury if she had undergone any of these alternative procedures.

In Limine Motion No. 18: Plaintiff asserts that Bard may not reference unrelated medical conditions as to Ms. McGinnis.

DENIED in part and **GRANTED** in part. **DENIED** as to fibromyalgia, autoimmune disorder, child birth, cyst on kidney, osteoporosis, inflammatory bowel disorder, and general anxiety disorder. With respect to such conditions, to the extent such medical conditions are referenced in Plaintiff's medical records and can be tied

into Plaintiff's current conditions and issues, Defendant's witnesses may discuss same. However, the motion is **GRANTED**, without prejudice, as to Plaintiff's other medical conditions, such as stroke, breathing issues, kidney stones, and gallbladder issues, which appear to have no reasonable relationship to the implantation/removal of pelvic mesh.

In Limine Motion No. 19: Mesh explant pathology reports should not be utilized at trial.

GRANTED, as it relates to the pathology report of PR Pathology & Clinical Labs. A pathology diagnosis is complex and the pathology opinions regarding the slides in question are central to various issues in this case. James v. Ruiz, 440 N.J. Super. 45 (App. Div. 2015); Nowacki v. Community Medical Center, 279 N.J. Super. 276, 280 (App. Div. 1995). At oral argument, the court indicated that it would nevertheless allow the experts to reference the pathology reports of third parties during their testimony. In response to a comment by Plaintiffs' counsel, the court indicated it would revisit the issue as to expert witnesses referencing the pathology opinions of non-testifying witnesses. The court has reviewed Nowacki and determined that its prior ruling as to allowing expert witnesses to reference the pathology reports was incorrect. Each party apparently has its own expert witness(es) who will provide pathology opinions. The use of the pathology report of PR Pathology & Clinical Labs is inconsistent with the holding of Nowacki and is precluded during the questioning of expert witnesses.

In Limine Motion No. 20: Plaintiffs assert Defendants should not advise the jury about all potential symptoms of prolapse.

GRANTED in part and **DENIED** in part. Defendant may present testimony as to what the products in question are intended to treat and how it does it. However, Defendant cannot argue that Ms. McGinnis has all symptoms related to prolapse.

In Limine Motion No. 21: Bard can make no reference to Ms. McGinnis' unhappiness with Dr. Barbee's care and treatment.

GRANTED. Counsel for each party agreed they will make no reference at trial to Ms. McGinnis' alleged unhappiness with Dr. Barbee.

In Limine Motion No. 22: Bard cannot suggest that Dr. Raz did not obtain informed consent from Ms. McGinnis.

GRANTED. The assertion that Dr. Raz did not obtain consent from Ms. McGinnis has no relationship to the treatment rendered by him. Further, any probative value is substantially outweighed by the prejudice of such evidence.

In Limine Motion No. 23: Defendant should be prohibited from using improper and misleading PowerPoint during opening.

WITHDRAWN. Counsel are to work together as to any PowerPoint presentation to be utilized by either side during opening statements. If issues arise, the court will resolve same in advance of the opening statements.

In Limine Motion No. 24: Plaintiffs assert that there should be no reference to irrelevant, misleading or prejudicial evidence.

GRANTED. There is to be no reference to tort reform, a litigation crisis or otherwise critical comments about lawsuits in general. There is to be no argument or discussion as to the conduct of counsel, witnesses or experts or as to family members, friends or other patients. There is to be no reference to increases in the costs of health care, or health products, by reason of medical lawsuits or claims. As to matters related to the collateral source rule, the parties have agreed to meet and confer as to Plaintiffs' medical bills in an effort to reach agreement as to same. Thus, the court reserves on the issues related to the collateral source rule.

Defendants' Motions

In Limine Motion No. 1: Evidence and argument related to the FDA 510 (k) process and clearance should be allowed.

DENIED. See determination as to Plaintiffs' in limine motion no. 2.

In Limine Motion No. 2: Evidence, testimony or arguments concerning any Materials Safety Data Sheets, C.R. Bard, Inc.'s procurement procedures regarding polypropylene resin from suppliers and third-party communications to the FDA regarding pelvic mesh devices should be excluded.

DENIED. See determination as to Plaintiffs' in limine motion no. 3. Further, the motion is denied as to Defendant's procurement procedures.

In Limine Motion No. 3: Defendant seeks to exclude any evidence, testimony, reference or argument on non-existent duties.

GRANTED in part and **DENIED** in part. **GRANTED** to exclude any reference of an owed or breach of a duty toward Ms. McGinnis directly since Defendant acknowledges no warnings were given to Ms. McGinnis directly. Defendant asserts that warnings were provided to Plaintiff's physicians pursuant to the learned intermediary doctrine. **DENIED** as to Bard's voluntary training program and references that Bard owed or breached an independent duty to conduct additional testing or inspection. Since Dr. Barbee and Dr. Raz attended Bard's sponsored training, this may be relevant as to what each of them learned or did not learn during training and may also go to issues related to Defendant's intervening causation defense. However, Plaintiffs are not to mention a duty to train during their opening. Furthermore, since FDA may not be referenced in this trial, Plaintiffs may not assert any duty of Defendant to file for a PMA. As to conducting additional independent testing, this will be allowed as this reference may be relevant to assist the jury in determining the reasonableness of Defendant's actions.

In Limine Motion No. 4: Defendant asserts that evidence or argument not relevant to Plaintiffs' claims should be excluded.

GRANTED in part and **DENIED** in part. **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. The parties have agreed that as to expert fees paid to expert witnesses they may only inquire as to evidence of payment(s) to expert witnesses in this case. This court reserves its decision as to the

issues related to the Avaulta Plus. Nevertheless, the motion is **GRANTED** to exclude references of the risk of the collagen portion of the Avaulta Plus, as it is not relevant to the issue on hand, and the probative value is substantially outweighed by the undue prejudice.

DENIED as to references to Bard's marketing or promotional activity.

Finally, this motion is also **DENIED** in part as to excluding evidence of pre-implant product complaints, adverse events reports, and medical device reports. Such complaints and reports which were rendered pre-implant are relevant to notice, knowledge, and causation. Any evidence as to post-implant complaints and reports may not be referred to at trial.

In Limine Motion No. 5: Plaintiffs should be barred from asserting that AUGS and other professional organizations were industry-promoted entities and their publications were "promotional pieces."

DENIED. Defendant 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 preparer of the "position papers" in openings or otherwise.

In Limine Motion No. 6: Bard seeks to preclude any evidence or argument concerning Bard's decision to stop selling the Align and Avaulta products or suggesting the Align and Avaulta products were recalled or withdrawn.

GRANTED. Defendant's decision to stop selling the products was a voluntary business decision unrelated to the issues in this case. This is particularly true since

the decision to stop selling would implicate the FDA 522 orders, and the determination has already been made that there is to be no reference to the FDA. Further, the court finds that the probative value of such information is outweighed by its undue prejudice and the issue would only serve to confuse the jury.

In Limine Motion No. 7: Evidence or arguments related to Bard's corporate intent, culture, policies, financial status, and notions of punishment should be excluded.

GRANTED in part and **DENIED** in part. Granted as reference to the "Golden Rule" and as to Defendant's financial status on Plaintiffs' claim for compensatory damages. Such matters may be appropriate during any punitive damages phase of this trial. **DENIED** as to evidence of Bard's intent, motives, ethics, and corporate culture. Such evidence is relevant to establish causation and reasonableness of Bard's actions. As to corporate policies, the only issue raised by Defendant related to alleged "kickbacks," which are irrelevant to the matters before the court. During the course of oral argument, the parties discussed notices in lieu of subpoena dated January 26, 2018, recently served by Plaintiffs as to the Bard/Becton Dickinson trials. The parties will meet and confer as to any issue related to said notices in lieu of subpoena.

In Limine Motion No. 8: Any evidence, testimony, reference or argument relating to the internal memorandum authored by Bobby Orr about the development of new products should be excluded.

DENIED, subject to laying a proper foundation, this evidence goes to the issues of Defendant's knowledge as to its products and potential concerns as to same. The scientific literature referenced in the Orr memoranda was in the public domain at the time the Avaulta product was launched.

In Limine Motion No. 9: Bard seeks to preclude non-retained treating physicians from testifying beyond their diagnosis and treatment of Plaintiff Mary McGinnis.

DENIED. Testimony as to whether physicians such as Dr. Barbee or Dr. Raz would have treated using the Defendant's products or performed the procedure(s) on Ms. McGinnis and their reasoning is relevant to the causation issue and failure to warn claim. See Stigliano v. Connaught Laboratories, Inc., 140 N.J. 305 (1995).

In Limine Motion No. 10: Any evidence, testimony, reference or argument concerning hypothetical and unsupported damages or relating to the impact of Plaintiffs' alleged injuries on family and friends should be excluded.

GRANTED in part and **DENIED** in part. **GRANTED** since Plaintiffs agree they are not seeking damages on behalf of third parties allegedly impacted by injuries to Plaintiffs. However, the court reserves as to testimony and evidence that may be presented at trial as to the impact of injuries on Plaintiffs directly, including their relationships with third parties and family members.

As to evidence or testimony of future types of damages, such as Plaintiff's claimed fear and anxiety as a result of the procedures, such issue is for the jury to consider, though the evidence will need to be tied into the issue related to Plaintiffs'

claims. As such, the motion as it relates to future damages is denied and will be considered during the course of the trial to the extent necessary.

In Limine Motion No. 11: Evidence, testimony, reference or argument in opening or at trial that include inflammatory, misleading and prejudicial comments, appeal to the sympathy of the jury, or reference the parties' litigation conduct should be excluded.

GRANTED. This matter has generally been dealt with and resolved in connection with Plaintiffs' motion in limine no. 24. 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 its opening. No determination is made as to the use of the analogy of PowerPoint slides during Plaintiffs' closing statement.

In Limine Motion No. 12: Evidence, testimony, reference, or argument concerning any alleged "copying" of content in Bard's IFU should be precluded.

DENIED. Plaintiffs may have an appropriate witness testify as to such matters, and Defendant may cross-examine Plaintiffs' witnesses, including Dr. Weber, on this issue.

In Limine Motion No. 13: Evidence, testimony, reference, or argument concerning Bard's invitation to Plaintiffs' experts to a conference, symposium or survey to bolster that expert's credibility should be precluded.

GRANTED in part and **DENIED** in part. **GRANTED** to the extent the conferences, symposia or surveys deal with products unrelated to this action. **DENIED** as to Avaulta and Align products.

In Limine Motion No. 14: Evidence, testimony, reference or argument regarding roping, curling, shrinkage or degradation of mesh should be precluded.

DENIED. See determination as to Plaintiffs' in limine motion no. 4. Plaintiffs may present evidence that is related to conditions or symptoms Ms. McGinnis experienced. Such evidence is to be presented through a qualified expert.

In Limine Motion No. 15: Evidence, testimony, reference, or argument concerning Dr. Anne M. Weber's health status should be precluded.

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 Motion No. 16: Evidence, testimony, reference, or argument concerning the Dollars for Docs website and/or unrelated payments from medical device and pharmaceutical companies should be granted.

GRANTED. 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 does not expect that the Dollars for Docs website will be used for impeachment

purposes. The court will allow the parties to revisit the issue regarding Dollars for Docs at trial, should they believe the matter is appropriate.

In Limine Motion No. 17: Evidence, testimony, reference, or argument concerning unrelated convictions, investigations, settlements, alleged bad acts, or alleged "illegal activity" should be precluded.

GRANTED. To the extent a party goes further than the scope discussed during arguments in their respective opening or at trial, this court may allow testimony that otherwise is precluded to rebut such contentions.

Dated: February 8, 2018

Hon. James J. DeLuca, J.S.C.