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APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-5151-17
A-1083-18

ELIZABETH HRYMOC and
TADEUSZ HRYMOC,

Plaintiffs-Respondents,

v.

ETHICON, INC., ETHICON
WOMEN'S HEALTH AND
UROLOGY, a Division of
Ethicon, Inc., GYNECARE,
and JOHNSON & JOHNSON,

Defendants-Appellants.

MARY MCGINNIS and
THOMAS WALSH MCGINNIS,

Plaintiffs-Respondents,

v.

C. R. BARD, INC.,

Defendant-Appellant,

and

BARD MEDICAL DIVISION,
a Division of C. R. Bard, Inc.,
and BARD UROLOGICAL

DIVISION, a Division of Bard Medical Division,

Defendants.

Argued January 25, 2021 – Decided March 2, 2021

Before Judges Sabatino, Currier and Gooden Brown.

On appeal from the Superior Court of New Jersey, Law Division, Bergen County, Docket Nos. L-13696-14 and L-17543-14.

Maha M. Kabbash argued the cause for appellants Ethicon Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare, and Johnson & Johnson (Riker, Danzig, Scherer, Hyland & Perretti, LLP, Stephen D. Brody (O'Melveny & Myers, LLP) of the District of Columbia bar, admitted pro hac vice and Jason Zarrow (O'Melveny & Myers, LLP) of the District of Columbia bar, admitted pro hac vice, attorneys; Stephen D. Brody, and Jason Zarrow, of counsel; Kelly S. Crawford, on the briefs).

David R. Kott argued the cause for appellant C. R. Bard, Inc., (McCarter & English, LLP, Reed Smith LLP, Lori G. Cohen (Greenberg Traurig, LLP) of the Georgia bar, admitted pro hac vice, R. Clifton Merrell (Greenberg Traurig, LLP) of the Georgia bar, admitted pro hac vice, and Sean P. Jessee (Greenberg Traurig, LLP), of the Georgia bar, admitted pro hac vice, attorneys; David J. Cooner and David R. Kott, of counsel and on the brief; Natalie H. Mantell and Steven H. Del Mauro, on the brief).

Adam M. Slater argued the cause for respondents Elizabeth Hrymoc and Tadeusz Hrymoc

and Mary McGinnis and Thomas Walsh McGinnis (Mazie Slater Katz & Freeman, LLC, attorneys; Adam M. Slater, of counsel and on the brief; David M. Estes and Christopher J. Geddis, on the briefs).

Daniel B. Rogers (Shook, Hardy & Bacon LLP) of the Florida bar, admitted pro hac vice, argued the cause for amici curiae Advanced Medical Technology Association, Chamber of Commerce of the United States of America, and the National Association of Manufacturers (Daniel B. Rogers (Shook, Hardy & Bacon LLP) of the Florida bar, admitted pro hac vice, and Katherine G. Mastrucci (Shook, Hardy & Bacon LLP) of the Florida bar, admitted pro hac vice, attorneys; Philip S. Goldberg, Daniel B. Rogers, and Katherine G. Mastrucci, on the brief).

Herrick, Feinstein LLP, Chilton Davis Varner (King & Spalding LLP) of the Georgia bar, admitted pro hac vice, and J. Franklin Sacha, Jr. (King & Spalding LLP) of the Georgia bar, admitted pro hac vice, attorneys for amicus curiae Product Liability Advisory Council, Inc. (Ronald J. Levine, on the brief).

Sills Cummis & Gross P.C., attorneys for amicus curiae Healthcare Institute of New Jersey (Beth S. Rose, of counsel and on the brief; Vincent Lodato, on the brief).

The opinion of the court was delivered by

SABATINO, P.J.A.D.

In these related appeals, which we consolidate solely for purposes of this opinion, we consider arguments seeking to overturn separate

jury verdicts in favor of plaintiffs in two product liability actions involving pelvic mesh medical devices. The devices in question were designed and manufactured by the respective defendants. They were surgically implanted in the female plaintiffs in each case, and severe adverse complications ensued for them and their spouses.

In the Hrymoc case, Docket No. A-5151-17, a Bergen County jury found defendants liable under independent theories of defective design and inadequate warning under New Jersey products liability laws. The Hrymoc jury awarded the patient and her husband a total of $5 million in compensatory damages, and additionally awarded them punitive damages of $10 million.

In the McGinnis case, Docket No. A-1083-18, a different Bergen County jury found defendant liable for design and failure-to-warn defects under the products liability laws of North Carolina, the home state of those plaintiffs. The McGinnis jury awarded the patient and her husband a combined sum of $33 million in compensatory damages, plus stipulated medical expenses. The jury further awarded them $35 million in punitive damages.

Defendants now appeal, raising a host of evidentiary and substantive arguments. We reject those arguments, except for one important issue common to both cases that requires reversal.

Specifically, we conclude the two respective judges who tried these difficult, complex cases erred by categorically excluding any proof that defendants had obtained what is known as "Section 510(k) clearance" from the Food and Drug Administration ("FDA"), see 21 U.S.C. § 360c, for the devices implanted by plaintiffs' surgeons. We conclude the total disallowance of such proof had the patent capacity to deprive defendants of a fair trial, most poignantly with respect to the state-of-mind and venal conduct issues that underlie the punitive damages awards.

Although several courts in other jurisdictions have chosen in their discretion to exclude such 510(k) evidence from jury trials involving the design and safety of mesh devices, we adopt the approach of other courts that have deemed such proof admissible with appropriate limiting instructions. We are persuaded there is sufficient probative value of such evidence under N.J.R.E. 401 to justify informing the jurors, without extensive elaboration, that the products were reviewed by the FDA under the 510(k) clearance process before defendants' sales in these cases. The complete ban of such proof was unfairly and repeatedly capitalized upon by plaintiffs' counsel at both trials, in a manner that easily could have given the jurors a skewed impression of the totality of circumstances.

We are further persuaded that countervailing concerns under N.J.R.E. 403 about potential juror confusion and consumption of time, while legitimate, can be capably addressed by the trial court through appropriate means discussed in this opinion.

Accordingly, the verdicts in both cases are vacated. The matters are remanded for new trials to be preceded by N.J.R.E. 104 hearings, at which the trial court may consider adopting measures such as explanatory jury instructions, reasonable time and witness limits, and prohibitions on misleading demonstrative aids about the 510(k) clearance process. The Rule 104 hearings should address the potential use of the 510(k) evidence in the liability/compensatory damages phase of the retrials, and, if reached again by the jurors, the punitive damages phase.

Aside from this one point of reversal, we affirm the trial court in all other respects in both cases. Among other things, we uphold the Hrymoc court's rulings that: (1) plaintiffs at this trial met their burden of establishing defective design of the pelvic mesh devices under N.J.S.A. 2A:58C-2, and presented to the jury sufficient evidence of reasonably safer alternatives; (2) defendants failed to establish a viable "state-of-the-art" defense under N.J.S.A. 2A:58C-3(a), and thus no jury charge on that defense was warranted; and (3) plaintiffs

adduced sufficient evidence of proximate causation arising from a defective warning, as there was not "unequivocal" evidence that Mrs. Hrymoc's surgeon would have implanted a pelvic mesh device in her anyway if defendants had provided more complete material information about the product's dangers.

We address other issues raised on appeal in Hrymoc and McGinnis in an unpublished, latter portion of this opinion.

I.

A. Overview

These two products liability cases involve medical "pelvic mesh" devices manufactured and marketed by defendants. The cases are part of a multicounty grouping of lawsuits ("MCL") specially venued before the Law Division in Bergen County. The Hrymoc case, which was tried before a jury in late 2017, was the second pelvic mesh case that went to verdict in New Jersey. The McGinnis case, which was tried in 2018 before a different judge,[1] was the third. No other products liability cases involving pelvic mesh have been tried since in this state.[2]

[1] Apparently, the judge who had presided over the Hrymoc trial was unable to preside over the McGinnis trial during that particular time frame.

[2] Although it does not bear on the issues now before us, we note our 2012 published decision regarding defendants' access to physicians who implanted

We are advised by counsel that most of the pelvic mesh cases in New Jersey have been settled or dismissed, but at least several hundred remain pending. In addition, there have been over 100,000 pelvic mesh cases against various manufacturers filed and litigated in other federal and state courts. Some of those cases have generated published and unpublished opinions. Several have gone to trial, with varying results on liability and damages.

To frame the issues for legal analysis, we discuss aspects of the factual and procedural backgrounds, with the caveat that these two cases are remanded for a new trial and thus additional testimony and proofs may still emerge. We caution that the omission of details from our opinion does not signify we have overlooked them or deem them unimportant.

B. Pelvic Organ Prolapse and Stress Urinary Incontinence

Defendants' mesh devices are intended to address the medical conditions

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pelvic mesh products as potential expert witnesses. In re Pelvic Mesh/Gynecare Litig., 426 N.J. Super. 167 (App. Div. 2012) (reversing pretrial order barring the defendants from retaining as experts in pelvic mesh litigation any physicians who treated the plaintiffs).

In addition, our court issued an unpublished opinion in 2016 affirming a jury verdict for compensatory and punitive damages in a pelvic mesh products liability case against one of Ethicon's related entities. Gross v. Gynecare, No. A-0011-14 (App. Div. Mar. 29, 2016). Because that earlier opinion is non-precedential, we do not discuss or quote from it here. R. 1:36-3.

of pelvic organ prolapse (often referred to as "POP") and stress urinary incontinence ("SUI").

Pelvic organ prolapse occurs when the muscles that support the pelvic organs become weak, causing connective tissue attachments to stretch or break and the organs to become displaced. A POP may occur in the anterior or posterior vaginal wall, or in the vaginal apex. An anterior prolapse occurs when the bladder drops into the vagina (cystocele), a posterior prolapse occurs when the rectum protrudes upward (rectocele) or the intestine pushes the top part of the vagina, creating a bulge (enterocele), and an apical or medial prolapse occurs when the uterus pushes into the vagina (uterine prolapse), or, for women with hysterectomies, the top of the vagina pushes into the lower vagina (vaginal vault prolapse).

Multiple factors can cause POP, such as childbirth, increasing age, obesity, a chronic cough, and a hysterectomy. Depending on its severity, a prolapse may cause pelvic pressure and discomfort, pain, dyspareunia (i.e., pain during sexual intercourse), and urinary and bowel problems.

According to Daniel S. Elliott, a urologic reconstructive surgeon who testified on behalf of plaintiffs in Hrymoc, a pelvic organ prolapse can be "embarrass[ing]," affecting a woman's feelings about herself and her desire to

engage in intercourse. Anne M. Weber, the plaintiffs' expert in urogynecology in both cases, described "[r]ecurrent pelvic organ prolapse" as "one of the most vexing problems in reconstructive pelvic surgery," and recurrent anterior vaginal prolapse as its "Achilles heel."

Non-surgical treatments to manage prolapse include Kegel exercises to contract and relax the pelvic floor muscles, and the use of a pessary inside the vaginal area to hold back the prolapse. There also are several surgical options that do not involve the devices in these cases.

One surgical option is native tissue repair or colporrhaphy, which uses absorbable sutures to repair a patient's weakened connective tissues to support the descending organ. This procedure can have the disadvantage of a significant rate of recurrence of the prolapse.

Another surgical procedure is sacrospinous or uterosacral ligament fixation, which is used for vault prolapses. This procedure is performed through the vagina to suture it to various different structures to provide support.

Abdominal sacrocolpopexy, which is done with an incision, a laparoscope, or a robot, can be more durable. However, it is more invasive and marked by increased morbidity as compared with vaginal repairs.

Colporrhaphy and abdominal sacrocolpopexy, like all pelvic floor

surgeries, present risks of pain and dyspareunia. Other prolapse treatments have included biological grafts using tissue from a cadaver or tissue bank, and xenografts using tissue from a nonhuman source such as a pig or cow.

Mesh devices also have been used to treat patients with SUI, which is "leakage of urine as a result of coughing, straining, or some sudden voluntary movement, due to incompetence of the sphincteric mechanisms." Stedman's Medical Dictionary 962 (28th ed. 2006). Here, both Mrs. Hrymoc and Mrs. McGinnis were diagnosed with SUI in addition to POP. Each plaintiff had mesh implantation surgery to correct the condition: Mrs. Hrymoc's surgeon, Dr. Mark Mokzrycki, implanting Ethicon, Inc.'s ("Ethicon") TVT-Obturator ("TVT-O") device and Mrs. McGinnis's surgeon, Dr. Elizabeth Barbee, implanting C. R. Bard, Inc.'s ("Bard") Align Transobturator Urethral Support System ("Align TO") device.[3]

[3] The details of the plaintiffs' respective SUI diagnoses do not affect the legal issues before us because (1) the Hrymoc jury found no proximate cause between plaintiff's injuries and the TVT-O's inadequate warnings, and (2) Bard has not challenged on appeal the McGinnis jury's finding that plaintiff's injuries were proximately caused by the defective design and inadequate warnings of the Align TO.

C. Defendants' Pelvic Mesh Medical Devices

The Hrymoc case involves Ethicon's "Prolift" mesh device and associated TVT-O sling,[4] whereas the McGinnis case involves two mesh products developed and sold by Bard: the Avaulta Solo Anterior Synthetic Support System ("Avaulta Solo") and the Align TO.[5] The devices were marketed as "Class II" medical devices, upon the FDA finding them "substantially equivalent" to other mesh devices the FDA had either previously approved or cleared for sale, or which otherwise were already lawfully on the market.[6] Eventually, defendants withdrew these pelvic mesh devices from the market after pervasive complications arose, although the trial court disallowed plaintiffs

[4] Because the Hrymoc jury rejected plaintiffs' failure-to-warn claims concerning TVT-O, and plaintiffs have not cross-appealed that decision, we focus our factual discussion on the marketing and development of Prolift.

[5] The Prolift and TVT-O devices were produced and sold by defendant Ethicon, a medical device company owned by defendant Johnson & Johnson ("J&J"). Defendant Gynecare is a business unit within Ethicon, which later became known as Ethicon Women's Health and Urology ("EWHU"). The Avaulta Solo and Align TO devices were produced and sold by defendant Bard with the involvement of its medical and urological divisions. For the sake of simplicity, at times we use the term "defendants" to refer to one or more of these entities.

[6] We describe the FDA 510(k) clearance process more extensively in Part II of this opinion.

from informing the juries of that subsequent remedial measure. See N.J.R.E. 407. Plaintiffs have not cross-appealed that ruling.

1. Prolift's Development

In the late 1960s, Ethicon introduced Prolene sutures and a decade later it introduced Prolene Soft mesh for use in abdominal hernia repairs. At some point, Ethicon began working to develop a procedure for treating pelvic organ prolapse with a synthetic mesh. Before then, physicians had developed their own approaches using different mesh shapes. Ethicon wanted to develop a standardized approach to perform POP repairs with lighter-weight polypropylene meshes and lower recurrence rates.

In 2002 or 2003, Ethicon began to market a pelvic floor mesh called Gynemesh Prolene Soft ("Gynemesh PS"), which consisted of the same polypropylene fibers used in Prolene Soft. Gynemesh PS was initially developed for use in hernia repairs. Its purpose as a transvaginal mesh ("TVM") was to allow fibrous connective tissue to grow between the pores to stabilize the mesh and vaginal wall. Gynemesh PS was a sheet of mesh that the surgeon would trim and tailor to his or her patient and then place through the vagina. Gynemesh PS was the type of mesh eventually incorporated into the Prolift product.

The French TVM Group's R&D

In the early 2000s, nine gynecologists and urogynecologists in France began to develop a standardized procedure using TVM, aimed at treating pelvic organ prolapse with a low level of risk and an improved rate of recurrence (the "TVM group"). Their goal was to identify a procedure and mesh product to increase the success rate, while keeping complications as low as possible. The TVM group selected the same nonabsorbable mesh material as Gynemesh PS, based on their experiences with synthetic grafts and other types of repairs.

The TVM group designed the shape of the mesh. The prototype consisted of pre-cut mesh that could be surgically implanted through the vagina to repair an anterior (bladder), posterior (rectal), or total prolapse. The mesh involved the use of "arms" to fix the implant in place, instead of sutures. Axel Arnaud, a physician and Scientific Director of Ethicon Europe from 2001 to 2008, worked with the French TVM group to coordinate the project, which was called Project D'Art.

Meanwhile, Ethicon formed a team "to create a standardized procedure for pelvic organ prolapse repair that would present low levels of risks to the patient." The team consisted of Scott Ciarrocca, the research and development ("R&D") project leader, Sean O'Bryan, a senior project manager at Gynecare,

Gene Kammerer, a research and development engineer, Arnaud, and others. As verified at trial by Ciarrocca, the design intent was to develop a product that would "support organs and restore anatomical form" and place the implants in the body tension-free. The Ethicon team adapted the mesh shape developed by the TVM group.

Over time, Ethicon developed prototypes for the pelvic mesh device. To assess their safety and efficacy, the Ethicon team worked with the French TVM group and other physicians in the United States who performed surgeries on cadavers and provided feedback.

Ultimately, Ethicon designed single-use instruments for the pelvic implant, including a guide, cannula, and retrieval device. The guide created paths in the tissue to direct the placement of the cannula. The cannula was used in conjunction with the guide to facilitate passage of the arms through the "tunnels" while protecting the surrounding tissue.

As explained by Ciarrocca, "[t]he primary intent of the cannula is to keep the tissue in the tissue passage from being torn as the mesh arm is pulled into place." The cannula remained in place in the patient after the guide was withdrawn. The retrieval device facilitated placement of the arms as they passed through the cannula, until a loop on its distal end captured the arms as they were

drawn out. At the end of the procedure, the only thing that was supposed to remain in the patient was the mesh.

Ciarrocca's team conducted a device design safety assessment to assess the risks, a design failure modes and effects analysis to review the risks associated with product design, an application failure modes and effects analysis to anticipate ways the instruments could be misused, and a process failures modes and effect analysis to anticipate breakdowns in the manufacturing process.

Ciarrocca acknowledged the design process did not evaluate what would happen if a woman had complications and the mesh needed to be removed surgically. He asserted the only possible way to assess the consequences of mesh removal was through published data from other studies.

At an internal company meeting in June 2003, Ciarrocca sought funding to move the project from the concept stage to the feasibility stage. Ciarrocca and his team identified critical assumptions to help assure the project's success, including that the product would be a permanent implant, that it would enter the market before any "major competitive offerings with similar features or advantages," and that its features would justify a premium price. The team assumed that a clinical trial of Prolift implants with a six-month follow-up

would be sufficient to support the launch and that multiple kits would be required, as Ciarrocca put it, to "fully exploit the market." The June 2003 presentation also included a patient risk assessment.

In July 2003, Michel Cosson, a physician and member of the TVM group, advised Ciarrocca by email that the group was seeing problems with erosion and retraction of the Project D'Art TVM implant that could cause a recurrence.

Erosion, "a potential complication of any mesh-based repair," occurred when the mesh became exposed or went through the tissue. As explained by plaintiffs' expert Elliott, although the terms were often used interchangeably, mesh "exposure" referred to mesh that went through the vagina, whereas mesh "erosion" occurred when the mesh went through another organ such as the bladder or rectum. Retraction, also called contraction, occurred when scar formation caused tension on the mesh as the scar tissue contracted and pulled the mesh along with it. That could cause shrinkage of the pore size and increase the risk of foreign body reaction and inflammation. When mesh retraction occurred, the risk of recurrence increased. Despite these concerns about complications, Ciarrocca's team continued forward with the project.

In May 2004, Ophélie Berthier, Ethicon's marketing director in France and its commercial launch leader for Prolift, sent an email, noting, among other

things, that the researchers' "main concern is now the shrinkage of the mesh which may lead to pain [and] dyspareunia . . . now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh." She added that "[w]e will need to address this when thinking about a next generation mesh."

The same day, Kammerer of the project team responded to Berthier's email by presenting input from the Gynecare European Unit regarding mesh used for pelvic floor repair. He noted that Ethicon was working closely with Professor Bernard Jacquetin, the inventor of the pelvic floor repair technique and leader of the TVM group, and Cosson, but that the "competition" was ahead of Ethicon in this area. Kammerer wrote: "We need to think about how we can fast forward this project, get more support from both Gynecare and Ethicon as well as quickly optimize the construction."

In November 2004, Cosson and others in the TVM group published an article discussing advances in the surgical management of genital prolapse. They reviewed the relevant literature and identified various problems with mesh-based treatments such as chronic infection, erosion, retraction, and recurrence. They noted that retraction was highly variable and impossible to forecast, and that it implied the need to place mesh with "as low a tension as

possible." They further noted that no reported studies mentioned "the more worrying retraction phenomenon and its after-effects, the symptomatic manifestation of which is dyspareunia." The article concluded that the TVM technique should be reserved for Stage III and IV prolapse, "possibly as first-line treatment."

The Prolift Device's Instructions for Use (IFU)

Meanwhile, the medical affairs unit at Ethicon prepared the Instructions for Use ("IFU") for the Gynecare Prolift. The IFU was the booklet or "primary label" that came with every Prolift kit. It provided information about the product, including illustrations. The IFU was given to doctors so they would know what to tell their patients about specific risks.

David B. Robinson, a medical director at Ethicon from November 2005 until the end of 2010, testified that surgeons relied on the IFU to accurately disclose the risks associated with the use of the Prolift system. Debra Fromer, a urologist and the defense's expert in the field of female pelvic medicine and reconstructive surgery, testified that it was a "good idea" for surgeons to read the IFU in advance of operating on patients.

The IFU advised physicians that the "[f]ailure to properly follow instructions may result in improper functioning of the devices and lead to

injury," and that training on the use of the Prolift pelvic floor repair system was "recommended and available." The IFU stated that total, anterior, and posterior repairs were "indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse." Fascia are tissue that hold things within the body together such as tendons and ligaments.

In describing the device's performance, the IFU stated that animal studies showed that implantation of Gynemesh PS elicited "a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue." It noted that the mesh remained soft and pliable.

The IFU's section on warnings and precautions listed the following:

> - Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
>
> - Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
>
> - Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the

patient to return to her normal activities.

- Avoid placing excessive tension on the mesh implant during handling.

- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.

- The GYNECARE PROLIFT Pelvic Floor Repair System should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.

- Transient leg pain may occur and can usually be managed with mild analgesics.

- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

The IFU warned that potential adverse reactions were "those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." Other identified potential adverse reactions included "[p]unctures or lacerations of vessels, nerves, bladder, urethra or bowel" that might occur during guide passage and require surgical repair.

Charlotte Owens, the Worldwide Medical Director for Gynecare from 2003 until late August 2005, was involved in the preparation of the IFU. Owens contended the IFU communicated to physicians all necessary warnings, precautions and adverse reactions that were known to Ethicon at the time. She noted many of the adverse reactions of Prolift were common to all pelvic floor procedures, such as inflammation, infection, adhesion, fistula formation, scarring, lacerations and punctures, pain with sexual intercourse, and chronic pain.

Owens felt there was adequate and sufficient information to support the safety and effectiveness of Prolift. In this regard, she pointed to historical and retrospective data, and the results of a prospective study of over 600 women that was then underway. She did acknowledge, however, that certain representations in the IFU were based on what Ethicon had learned from animal studies.

Owens stressed that the company sold Prolift to physicians with expertise in pelvic floor repair, who could determine patients suitable for the product. She testified, "I can't emphasize enough how important it is for the surgeon and the patient to have that deeper conversation to ultimately make that final decision."

A Stronger Warning Is Proposed But Not Adopted

In January 2005, Arnaud, who was then the scientific director of Gynecare Europe, sent an email to Berthier suggesting they add a warning to the new version of the IFU. Arnaud proposed the following wording:

> WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in[to] consideration when the procedure is planned in a sexually active woman.

Berthier passed along the proposed warning to Ciarrocca, saying that she would like to incorporate the changes. Ciarrocca, in turn, forwarded the email to O'Bryan and Owens. O'Bryan responded: "We can change the adverse event to whatever is most appropriate without FDA implications. I will leave it to Charlotte [Owens] and Axel [Arnaud] to decide." He noted that the Prolift IFU "most likely has gone out for translations and final proof so unless it is absolutely necessary we should probably leave it as is." Ciarrocca replied: "We have already printed launch stock. This would be a 'next-rev' addition but they want it in there ASAP."

Owens approved the IFU without the suggested change. Although she knew a small number of patients had long-term impacts from Prolift, Owens explained she approved the IFU because the overall risk/benefit analysis showed that the Prolift was a safe and effective product. Neither the 2004 nor the revised IFU brochure issued in 2007 included Arnaud's proposed warning.

Although the Prolift IFU did not include the word "dyspareunia," Owens asserted "the words in there are synonymous to a surgeon with the possibility of dyspareunia." Even though the IFU did not mention that tissue contraction was a known risk, she explained that contraction was discussed under the definition of "clinical need," which stated that "[v]aginal repairs and retention may cause anatomical distortion of the vagina, affecting bowel and/or sexual functioning." She further asserted that surgeons were trained to know about complications as well as the risks of surgery in the area in which they operated.

Nonetheless, according to O'Bryan's deposition testimony, used in plaintiffs' case-in-chief, the Prolift IFU should not have omitted any important facts, such as potential significant injuries to patients. O'Bryan testified the need to reprint the IFU should not have played any role in the decision whether to add Arnaud's suggested warnings. Additionally, in other deposition testimony presented in plaintiffs' case-in-chief, Bryan Lisa, an associate design quality

engineer at Ethicon, contended Ethicon was obligated to change the language of the IFU and update it.

The Prolift Patient Brochure

Ethicon also prepared a patient brochure, which it used to market Prolift. The brochure described Gynecare Prolift as "a revolutionary surgical technique that offers promising results for women with pelvic organ prolapse." It explained that Prolift "employs a specially designed supportive soft mesh placed in the pelvis to restore pelvic support." "After insertion, the soft mesh is initially held in place by the friction created by long extension strap-like arms of mesh material weaved through the pelvis. The body tissues then quickly grow into the pores of the mesh, creating the final support."

The brochure noted that "[a]ll surgical procedures present some risks." It then stated:

> Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.

The brochure essentially included the same warnings and precautions, and adverse reactions as the IFU. It instructed patients to "[t]alk with your doctor or healthcare professional about pelvic organ prolapse and what you can do

about it."

Robinson acknowledged that patients relied on the brochure to learn about the risks and benefits of Prolift. He believed they would discuss the information with their doctors as part of their decision-making process. According to Robinson, the 2005 brochure conveyed that complications were "rare," meaning the "benefits far outweigh the risk."

The Prolift Clinical Expert Report

Late in Prolift's development process, Ethicon performed a design validation to test the completed product. To meet this requirement, Ethicon prepared a clinical expert report that compiled data supporting Prolift's safety and effectiveness, and which evaluated its benefits and risks.

It was Owens's responsibility to prepare, review, and sign the clinical expert report. In November 2004, Owens wrote an email regarding the report, in which she called for the release of thirty Prolift kits to experienced clinical investigators to obtain an in-vivo assessment of its performance. At that point, there had been no study of the Prolift system in women.

Ciarrocca prepared the draft clinical expert report. He relied on the Gynemesh PS clinical expert report from September 2002, regarding it as essentially the same mesh. Because there was never a clinical investigation of

Prolift in women, the draft Prolift report was instead "literature based."

Following the draft report's section on clinical evidence, Ciarrocca wrote: "Charlotte [Owens], Need to add TVM/Cosson Data." The draft report concluded that the Prolift kits were "safe and efficacious on the basis of large scale use of predicate devices over the last decade and a review of the clinical literature as described." Ciarrocca forwarded the draft report to Owens.

In December 2004, O'Bryan advised Owens, Ciarrocca, and others within the company that he had reviewed the draft clinical expert report and had "significant concerns about it." Since the report was taking a literature-based path, O'Bryan recommended that the company generate a new report that included sections on clinical evidence (based on reviews of published clinical literature), potential complications and side effects, and a clinical opinion as to the device's safety and efficacy for human use.

In January 2005, Owens approved and signed the clinical expert report. The report stated the Prolift system had been "extensively studied, refined, and proven in [c]adaveric evaluations." It included a section on clinical evidence and stated that "[b]ased on this and other literature it can be concluded that the use of polypropylene mesh for vaginal prolapse surgery is safe and efficacious." For potential complications, it listed "infection, mesh exposure, fistula,

hematoma and contraction." Despite such potential complications, the report described Prolift as safe and efficacious, based on "large-scale use of polypropylene over the last decade and a review of clinical literature and clinical trials as described."

Owens acknowledged she was familiar with the 2004 article by the TVM group, but did not refer to it in the clinical expert report or mention its finding that retraction was a potential complication that could cause severe pain, including dyspareunia. She also was aware at the time that some patients would develop severe complications that would result in lifelong pain and disability.

James Hart, who was Ethicon's Vice President of Medical Operations at the time of Prolift's launch, testified that he likewise was aware that Prolift could result in "life-changing complications, incapacitating pelvic pain, dyspareunia, [and] large-scale erosions exceedingly complex and not easily resolved." He further noted potential risks of chronic foreign body response, contraction, and the difficulty of mesh removal.

Hart agreed that, to the extent such complications were known, Ethicon needed to evaluate them in the clinical expert report and within the prelaunch design control risk analysis. He also agreed that if they were not considered, the prelaunch risk-and-benefit analysis was not valid. Hart conceded on cross-

examination that "a reasonable argument could be made that as a result of the very, very serious complications, the risk outweighed the benefit and it shouldn't have been sold."

Further Pre-Launch Events

In January 2005, the same month Owens approved and signed the clinical expert report, and about two months before the Prolift launch, Kammerer wrote an email saying a different material, UltraPro mesh, fit the requirements "as an interim step to reduce erosion and contraction," and "suggesting we market this mesh for pelvic floor repair." Unlike Prolene Soft, otherwise known as Gynemesh PS, UltraPro mesh was partially absorbable and lighter in weight with larger pores.

The following month, in February 2005, the TVM group released the results of its six-month follow-up study of forty women who underwent total repairs. The group considered success for a subject at six months as a Stage 0 or 1 prolapse at the treated site, and set the failure rate as 20% with a 95% confidence interval. The results in February 2005 showed the rate of failure over the 20% desired limit.

Prolift's Launch in March 2005

The market launch of Prolift took place in March 2005. The device was marketed in kits for total, anterior, and posterior pelvic floor repairs. The kits included pre-cut Gynemesh PS implants with a set of instruments to facilitate placement. The mesh for a total repair was shaped with six straps or arms to secure anterior and posterior portions of the implant. The anterior mesh implant had four arms to support the bladder, whereas the posterior mesh implant had two arms. The kits were accompanied by the 2004 IFU and the patient brochure.

Owens did not recall anyone at Ethicon suggesting more data was needed before the launch. Owens felt there was "adequate and sufficient information to support the safety and effectiveness" of Prolift as a "good option" for women.

Owens understood at the time of launch that Prolift could cause scarring that resulted in implant contraction, which could lead to chronic pelvic pain, dyspareunia, and recurrence of prolapse. She knew that vaginal erosions and contractions could interfere with or make it impossible for women to enjoy comfortable sexual relations. Nonetheless, she explained: "That is one of the risks that we expected [the patient's] surgeon to inform her of because it's not just with Prolift, it is also with any pelvic floor repair surgery."

Ciarrocca similarly asserted that Ethicon did not violate its own rules for bringing Prolift to market, and that the company followed the governing procedures for design and control. However, he did acknowledge that, up until the launch, "there never was a study of the Prolift as it comes out of the box with the actual instruments that it's sold with in human bodies."

In his own testimony, Arnaud stated that at the time of launch he did not understand the mechanism of erosion, know how to reduce mesh shrinkage, or understand the long-term consequences of potential complications.

Piet Hinoul, a urogynecologist who joined EWHU in October 2008 as director of medical affairs, testified that, by the time of launch, Ethicon had studied "the Prolift mesh in a prototype called PVM in two multi-center trials in the US and in France" and "could also leverage Prolene PS data in several hundred patients that had been used for over five years . . . in the pelvic floor." He asserted Ethicon weighed risks and benefits before putting the product on the market, although he acknowledged there was no long-term data on the Prolift system. He recognized that some complications could be "very, very serious" and "life-changing." He was aware of what he termed "a couple of case reports" of women who suffered "mutilated or destroyed vaginas due to the Prolift."

Post-Launch Events

In March 2005, Cosson and others published a retrospective study of Prolift that followed 277 patients, identified thirty-four cases of mesh exposure, and recommended experimental and clinical trials to reduce the exposure rate to less than five percent of cases. The study later expanded to include 687 patients.

In April 2005, Kammerer sent an email to co-workers at Ethicon, saying that scar contracture around the mesh had caused procedural complications and that surgeons who were Ethicon consultants wanted a mesh that was better than Prolene Soft. Kammerer identified those complications as prolapse recurrence, pain, stiffness, erosion, and discomfort during sex.

On November 8, 2005, Dieter Engel, a doctor and colleague in Ethicon Germany, wrote to Kammerer and others that he did not believe UltraPro could be used as an alternative mesh due to commercial limitations. He explained that "[r]eplacing Gynemesh by UltraPro would either reduce the market price, which is no[t] good business, or the UltraPro price would have to be increased, which is not possible." The next day, Kammerer wrote to Engel and others, saying Gynecare marketing and R&D looked into the mesh portion of Prolift and learned that surgeons wanted a mesh that addressed the issues of mesh erosion, scar contracture, and residual material. He indicated that the company's plan

was "not to simply substitute the UltraPro for the Gynemesh," but to find a more comprehensive and long-term answer.

In January 2006, Ciarrocca wrote to Jacquetin and Cosson, proposing to add a warning under the section on adverse reactions that the Prolift procedure had the potential to impair voiding. Cosson responded that impaired voiding was probably "a rare event," but that "we should add something about the potential pain or dyspareunia in the postoperative course."

In February 2006, Kammerer sent an email to Arnaud and others, saying he had met with Cosson and Jacquetin back in 2004 and they had expressed an "interest in a new mesh to control and reduce scar contraction." He wrote that the previous year the mesh team suggested the substitution of UltraPro for Gynemesh PS as a short-term solution. He noted an investigation showed that it could be done and that "[t]he team wanted to move forward, but then everyone got re-assigned, and so the project kind of went into limbo."

The June 2006 TVM Clinical Study Report

In June 2006, Cosson and the TVM group published a "Clinical Study Report" based on twelve months of data. The study looked at the results, complications, and efficacy of the TVM technique, which ultimately became Prolift. However, Ciarrocca acknowledged the TVM group study did not meet

the pre-defined criteria of a failure rate of less than 20%.

Efforts to Improve the Prolift

Cliff Volpe, who worked in Ethicon's R&D unit, testified that in early 2006, Ethicon formed a team to look into the improvement of Prolift, including other mesh materials that might be lighter and softer for use in the pelvis. In a November 2006 email, Robinson wrote to Volpe, saying he had several conversations with Cosson and Jacquetin, who were pressing for more changes in Prolift other than just the mesh. Volpe testified that his team looked at ways to improve the mesh material and determined that the increased size of the pores in UltraPro mesh would reduce fibrotic bridging. Hinoul similarly testified that the new team sought to upgrade Prolift with a mesh that had larger pores to prevent bridging, scarring, and subsequent erosion.

In August 2008, two months after Prolift was implanted into Mrs. Hrymoc, and three-and-a-half years after Prolift went on the market, an "executive summary" presentation given to high-level executives at Ethicon identified the need to "[r]educe vaginal stiffness, mesh exposure, [and] pain," to "[r]educe the rate of tissue contraction [and] folding," to "[l]ower [the] amount of foreign-body mass," to be "[e]asy to learn and use," and to result in a "[l]ow recurrence rate."

In February 2009, Scott Jones, a product director in Ethicon's Pelvic Floor Repair unit, wrote an email to a team of urogynecologists in St. Louis, saying he was "in the middle of launching a new product called PROLIFT+M." He described the product as "basically the same procedure as PROLIFT but utilizing a partially absorbable mesh material." The new mesh material was UltraPro. Defense expert Fromer testified that she was happy with the switch to Prolift+M, with its partially absorbable material, saying: "It seemed intuitively the right thing to do."

Withdrawal from the Market

As we have already mentioned, Ethicon ultimately withdrew Prolift from the market.

2. Bard's Development and Sale of Avaulta Solo and Align TO

Bard's development and marketing of the Avaulta Solo and Align TO pelvic mesh devices traced a different path, albeit one that prompted similar litigation themes in the McGinnis case.

Because defendant in McGinnis, unlike in Hrymoc, has not appealed the substance of the jury's design defect and failure-to-warn findings in that case and instead focuses on the 510(k) evidential admissibility issue and certain other matters, we need not detail here the chronology of Bard's Avaulta Solo and Align

TO as we did above with Prolift. For purposes of this portion of the opinion, it will suffice to note the following.

Decades before it developed pelvic mesh products, Bard produced mesh products designed to repair hernias. The mesh material was knitted from polypropylene monofilament by a division of Bard at a facility in Delran, New Jersey, which also finished and packaged the final medical device kit that included the mesh.

The Delran plant received "big spools" of polypropylene monofilament that had been extruded from pellets of polypropylene resin manufactured by Phillips Petroleum ("Phillips") and marketed under its Marlex brand ("Marlex resin").

Bard purchased the monofilament used in its surgical mesh products from Red Oak Sales ("Red Oak"). Red Oak did not purchase the Marlex resin it used to extrude the monofilament directly from Phillips, but instead obtained it from a distributor called Channel. Red Oak produced monofilament in different diameters according to Bard's specifications, using equipment purchased by Bard.

From about 1962 until 1997, Bard used the "Marlex" brand name in connection with its hernia-mesh products, pursuant to a licensing agreement

with Phillips. However, in 1997, Phillips requested that Bard cease using the name for any implantable mesh device because it was "concerned about litigation and the association [of] the Marlex name with a permanent medical implant." Phillips did not specifically advise Bard that it should discontinue using Marlex resin at that time.

Roger Darois, a former vice president of Bard's mesh-manufacturing division, acknowledged that from 1997 onward, Bard took steps to ensure that Phillips would not discover the use to which Bard put the Marlex resin. He contended that because Phillips had known decades earlier that Bard used the Marlex resin for surgical mesh products, Bard was not "hiding" anything from Phillips, but it "chose not to remind them." Darois explained in this regard:

> We just didn't know beyond 1997 if they still were aware of mesh use. So we had no reason to contact them. We had all biocompatibility testing, all the literature I've already testified on, we had no reason to contact Phil[l]ips and remind them that we were still using their resin. We were buying on it [sic] the commercial sale in free commerce from a distributor. There really is no way they can prevent us from buying this product legally.

In March 2004, Darois emailed an employee of a German affiliate of Bard who was looking for a vendor for polypropylene. Darois noted that "[t]hese suppliers will likely not be interested in a medical application due to product

liability concerns" and that "it is likely that they do not know of our implant application." He went on to state:

> Do NOT mention [Bard's division's] name in any discussions with these manufacturers. In fact, I would advise purchasing the resin through a third party, NOT the resin supplier, to avoid a supply issue once the medical application is discovered.

According to Darois, he was "trying to make sure that we didn't have an interruption of supply for the resin we relied on for all of these products," knowing that "one of the outcomes" of this information being discovered could be a prohibition by the resin manufacturer on Bard's use of the material.

In late 2007, a few months after Bard began selling its Align pelvic mesh, Darois learned that Phillips had what is known as a "material safety data sheet" concerning Marlex polypropylene (the "Marlex MSDS"). The Marlex MSDS stated, in part:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.
>
> Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips

> Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.
>
> Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

Darois eventually learned that Phillips began including this medical application caution on the Marlex MSDS in 2004. He was not concerned about the warning because he "viewed it as a legal statement" and because Bard had done testing and studies and had "five decades of successful use" of Marlex resin in its products.

The Avaulta and Align Solo devices that were implanted in plaintiff Mary McGinnis in March 2009 contained monofilament made from Marlex resin.

As we have noted, Bard eventually removed Avaulta Solo and Align TO from the market.

D. Plaintiffs' Backgrounds, Product Usage, and Medical Complications

1. Hrymoc

Plaintiff Elizabeth Hrymoc was born in 1946. She and her husband, co-plaintiff Tadeusz Hrymoc, met in 1961 and married in October 1967. They currently reside in New Jersey. Mrs. Hrymoc worked for seventeen years as a research laboratory technician before retiring. She then opened a deli with her

sister and later worked part-time as a medical receptionist before moving and helping to raise her grandchildren.

In November 2005, Mrs. Hrymoc, then fifty-nine years old, saw Dr. Mokrzycki, a urogynecologist who specialized in pelvic reconstructive surgery and the management of bladder, prolapse, and rectal problems in women. Dr. Mokrzycki was a consultant for Ethicon from October 2001 to February 2011. He worked with their engineers to develop techniques to treat prolapse and incontinence, trained their sales force on anatomy, and trained other physicians on Prolift surgery. He implanted about 100 to 200 Prolifts per year from 2005 until 2012, when the product was taken off the market.

Mrs. Hrymoc reported to Dr. Mokrzycki she was experiencing cramps and pressure, stress incontinence, and discomfort or pain during sexual relations. His examination revealed that Mrs. Hrymoc was suffering from a significant anterior vaginal wall prolapse (cystocele), which he estimated at trial as Stage II, a uterine prolapse, and a mild-to-moderate posterior prolapse (rectocele).

Dr. Mokrzycki discussed with Mrs. Hrymoc various options, explaining that "doing nothing" could lead to worse consequences, that "muscle exercises" were not appropriate for the majority of people at this stage, and that a pessary had "annoying side effects" and did not work for everyone. He recommended a

vaginal hysterectomy, an anterior repair with mesh, and a pubovaginal sling for SUI. Mrs. Hrymoc initially decided against surgery because she was not in pain and the prolapse was not uncomfortable enough.

In August 2007, Mrs. Hrymoc saw Karen Katz, a gynecological nurse practitioner for her annual pelvic examination. She reported having pain with intercourse. Katz's exam found that pelvic support was normal, meaning there was "no significant prolapse of the uterus [and] no significant abnormality of the vagina."

Mrs. Hrymoc returned to see Dr. Mokrzycki in March 2008 because her incontinence had become a "little bit worse." She also complained of discomfort during sexual relations, saying she was intimate with her husband "with a little bit of discomfort, but there was no pain." Dr. Mokrzycki found that the prolapse of the posterior vaginal wall had gotten worse and described it in her chart as "severe."

Dr. Mokrzycki discussed the benefits and potential risks of various procedures, "including bleeding, infection, damage to adjacent organs, possible mesh erosion and possible post-void dysfunction." He suggested a mesh implant, saying it was "a very simple procedure" and general anesthesia was not required.

He recommended Prolift, explaining that "it gave her the best chance to have a satisfactory long-term result," and that it was "the best product available." He explained at trial that the failure rates of traditional suture repairs were "too high considering her age." He typically did not discuss abdominal sacrocolpopexy with a patient because it came with "significant potential complications" that were not present with vaginal surgery.

Dr. Mokrzycki gave Mrs. Hrymoc a copy of the Prolift patient brochure, which she read to learn about the procedure and its risks. Mrs. Hrymoc understood that complications were rare, but she told Dr. Mokrzycki that she was "a little bit reluctant." He assured Mrs. Hrymoc that "all these risks [we]re very easily fixable," which was very important to her. Mrs. Hrymoc agreed to undergo a vaginal hysterectomy, a total Prolift, and a pubovaginal sling, "which was the TVT obturator [TVT-O] at that time." She understood the risks and signed the informed consent.

On June 10, 2008, Dr. Mokrzycki performed Mrs. Hrymoc's total Prolift repair. Dr. Mokrzycki used Prolift's specially designed trocars to place the anterior portion of the mesh under the bladder and between the bladder and vagina (cystocele repair), and the posterior portion between the vagina and rectum (rectocele repair). He took precautions to avoid placing tension on the

Prolift arms. He did not recall any problems during surgery. His postoperative diagnosis was severe prolapse of the uterus, cystocele, and rectocele with "weak connective tissues under the bladder and over the rectum."

Dr. Mokrzycki next saw Mrs. Hrymoc at her three-week postoperative visit in early July 2008, and he found the placement of the mesh was where he wanted it. She returned later that month, complaining of "something coming out again" and "persistent urge incontinence." He confirmed that there was no prolapse, but he thought she might have some inflammation around the sutures. She returned again in September 2008 for her three-month postoperative visit, with complaints of increasing discomfort on the left side. He felt "some tightness" in the area of the implant's left arm.

Also in September 2008, Mrs. Hrymoc returned to Katz for an annual pelvic exam. She complained of significant pain during intercourse and in an area on the left lateral wall of her vagina. Katz recalled that Mrs. Hrymoc expressed sadness about the loss of her intimate relationship with her husband and cried during the visit.

On September 17, 2008, Dr. Mokrzycki performed the first mesh removal operation and released a "tight band" on Mrs. Hrymoc's "left side towards the proximal end of the vagina" that had "some evidence of mesh exposure." His

operative report stated that "[t]his band was encased in scar tissue consistent with a strap of the mesh which was too tight and causing probable nerve entrapment," and testified that he released the band to free the mesh and scar tissue. The postoperative diagnosis was mesh exposure with pelvic pain caused by scar tissue secondary to the mesh in Mrs. Hrymoc's left side.

Mrs. Hrymoc's adverse symptoms continued. After several consultations, Dr. Mokrzycki performed another mesh revision on November 20, 2008. His postoperative diagnosis was "[m]esh complication from a previously placed posterior Prolift graft in the rectovaginal space. The complications include[d] pain and discomfort in the rectovaginal area[,] especially toward the left side[,] and the feeling of a bulge." Dr. Mokrzycki explained that the bulge was caused by the mesh and connective tissue bunching up, causing pain. He said it was "very dangerous" to remove the mesh because it required careful dissection to leave enough tissue to close. Mrs. Hrymoc described the pain as intense and said she "would do almost anything to get some relief."

Mrs. Hrymoc returned to see Dr. Mokrzycki six days later for an emergency follow-up. She had experienced vaginal bleeding and lower abdominal pain. His examination indicated two or three prematurely broken sutures and no active bleeding.

In early December 2008, Mrs. Hrymoc saw Dr. Christopher Fabricant, a gynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. She complained to him of urinary problems, painful intercourse, pelvic discomfort, and back pain. Dr. Fabricant noted tenderness in the area of the anterior mesh arms and prescribed estrogen cream.

Dr. Fabricant next saw Mrs. Hrymoc in January 2009. She complained of pelvic pain, scarring, exposed mesh, and obstructive urinary symptoms. He noted that she had "exquisite tenderness" in the proximal or upper portion of the Prolift anterior mesh. She wanted surgery to remove the Prolift mesh and the sling. He reviewed the risks and potential complications of surgery, including "[p]ain, bleeding, infection, injury to organ, urinary incontinence, incomplete removal of mesh, pneumonia, thromboembolism, recurrence of prolapse or incontinence." Mrs. Hrymoc explained at trial that she decided to have the surgery because she wanted relief from the pain and felt very tired, depressed, and unhappy at the time.

On March 16, 2009, Dr. Fabricant removed the sling to relieve the obstructive lower urinary tract symptoms. He then removed portions of the anterior mesh, but he encountered excessive blood loss requiring a blood

transfusion and stopped the procedure. No attempt was made to remove the posterior mesh.

In April 2009, Mrs. Hrymoc returned to Dr. Fabricant complaining, among other things, of SUI. Dr. Fabricant testified that he told Mrs. Hrymoc "in clear terms before surgery" that the stress incontinence would recur. He ordered physical therapy for bladder control. He next examined Mrs. Hrymoc in July 2009, and noted tenderness over the posterior mesh. She last saw Dr. Fabricant in November 2009, asking for removal of the posterior Prolift and a remaining portion of the proximal arm on the left side of the anterior Prolift mesh. It appears no further procedures were done after this appointment.

Mrs. Hrymoc testified that after Dr. Fabricant removed the TVT-O, she went to physical therapy to learn how to contract her muscles to improve her stress incontinence. The therapist also tried to improve her vaginal pain, a process which Mrs. Hrymoc described as "very painful" and "very unpleasant, and it was in a way humiliating." She ended the therapy, saying it helped a little to alleviate her stress incontinence, but did not improve the pain.

At her annual exams with Katz from 2009 through 2012, Mrs. Hrymoc reported being sexually inactive. She complained of pain during intercourse at her annual exams in 2015 and 2016. Katz said Mrs. Hrymoc was always in pain.

Mr. Hrymoc did not testify, but Mrs. Hrymoc described their marital relations during her trial testimony. Prior to her surgeries, Mrs. Hrymoc and her husband were sexually active, enjoying an intimacy that brought them "even close[r] together" and which Mrs. Hrymoc described as a "very important part of [their] life." After the surgeries, they tried numerous times to have intimate relations, but "[b]ecause of the pain, [they] had to stop," which Mrs. Hrymoc described as "very distressful" and "so sad."

2. McGinnis

Plaintiff Mary McGinnis was born in 1947. She knew Thomas McGinnis, co-plaintiff in this case, as a teenager, and married him in November 1967.

In 1977, the family moved from upstate New York to North Carolina. After moving, Mrs. McGinnis founded and ran a childcare program, Mary's Childcare, which was still operating at the time of trial.

At her annual gynecological examination in February 2009 with Dr. Barbee, Mrs. McGinnis reported incontinence and "urinary urgency" that she found "bothersome." Following testing, Mrs. McGinnis was diagnosed with: (1) urethral hypermobility, (2) SUI, and (3) a cystocele, which is a type of pelvic organ prolapse. Mrs. McGinnis was not aware she had POP until Dr. Barbee diagnosed it.

Mrs. McGinnis discussed treatment options with Dr. Barbee and elected to proceed with surgery involving an anterior repair with mesh and a suburethral sling. Dr. Barbee performed surgery on Mrs. McGinnis on March 12, 2009, implanting two surgical mesh medical devices manufactured by Bard, specifically (1) the Avaulta Solo, used to correct POP, and (2) the Align TO, used to treat SUI. The surgery took place in Raleigh, North Carolina, and was an "uncomplicated" and "normal" procedure.

The Avaulta Solo and Align TO are kits that include the mesh material to implant, the instrument to insert the mesh, and instructions for the surgical procedure.

In the months following surgery, Mrs. McGinnis returned to Dr. Barbee's office complaining of pain, incontinence, a vaginal discharge with odor, and abdominal distension. Additionally, in September 2009, Mrs. McGinnis complained of vaginal bleeding, irritation, and a burning sensation.

Mrs. McGinnis consulted Dr. AnnaMarie Connolly at the University of North Carolina. On December 28, 2009, Dr. Connolly performed surgery on Mrs. McGinnis to excise eroded vaginal mesh. Dr. Connolly found a "0.5 cm piece of eroded vaginal mesh along the midline anterior vaginal wall." Six

months later, on June 21, 2010, Dr. Connolly performed another surgery to remove additional eroded vaginal mesh.

Mrs. McGinnis continued to have significant vulvar pain that could not be alleviated with therapy. She also had groin pain, hip pain, lower back pain, and pain radiating down her medial and posterior thigh.

In February 2016, Mrs. McGinnis consulted Dr. Shlomo Raz, the director of pelvic medicine, reconstructive surgery at UCLA. Dr. Raz concluded that Mrs. McGinnis's pain was caused by the eroded mesh remaining in her body and that all the mesh needed to be removed. He noted that the hip, lower back, and thigh pain Mrs. McGinnis complained of was typical of a patient with "complications of obturator sling," and particularly a sling of "Avaulta type with needles and trocars through the obturator musculature."

Dr. Raz examined Mrs. McGinnis and found that Align TO mesh was "infiltrating the vaginal wall," making the tissue the consistency of "a hard cord" rather than normal tissue. Dr. Raz noted that Mrs. McGinnis had severe pain and tenderness in the area of the Align TO mesh. Mrs. McGinnis had less pain in the area of the Avaulta Solo mesh. Dr. Raz concluded:

> The patient had the insertion of two meshes, both of them with complications. One eroded around the vagina and the urethra, one eroded around the bladder.

> The mesh was partially removed and she continued to have pain, dyspareunia, systemic symptoms, groin pain, leg pain, back-of-the-thigh pain, hip pain. That's all for me eroded, complication of erosion of mesh and chronic mesh infection.

Dr. Raz stated the pain Mrs. McGinnis experienced was "all mesh complication" with a clear "cause/effect."

Dr. Raz described locating and removing all remaining mesh in Mrs. McGinnis as "a very delicate, difficult surgery." He stated that removing mesh "is one of the most difficult operations to do." He explained that the process was "a very difficult and delicate dissection" because the mesh was "deep, adhesed," as if it was "glued or cemented to the wall of the urethra, to the pubic bone, to the muscles." In addition, Mrs. McGinnis's prior surgeries had left the mesh "fragmented," making it more difficult to remove.

Dr. Raz also performed a reconstruction of the anterior vaginal wall, which was complicated because the vaginal wall was "extremely thin, infiltrated by the mesh." Finally, Dr. Raz performed an "injection of Botox in trigger points" in hopes that the injection would improve the pelvic pain in six-to-nine months. However, Dr. Raz acknowledged that not all patients benefited from the procedures he performed on Mrs. McGinnis. He explained:

> We did a study of almost 700 patients. 55% of the patients, totally cured of mesh removal; 20 to 25%

> improved, but 20, 25% we remove all the mesh and the pain continues, so there is neuropathy, nerve damage.

Following the removal surgery, Mrs. McGinnis's pain was somewhat improved, but she continued to have issues with incontinence. On February 23, 2017, Dr. Raz performed another surgery to repair a prolapse using Mrs. McGinnis's own tissue rather than mesh.

Mrs. McGinnis testified that, before the mesh implantation surgery, she had occasional back pain and "normal aches and pains" but she "never knew what severe pain was until [she] had the mesh." The pain she felt afterwards was "beyond debilitating." She testified, "It hurts so much, you can't cry, if that tells you anything." Mr. McGinnis testified that her pain would get worse as the day progressed and, "instead of walking as straight as she can," she would "start leaning over."

For two-and-a-half years, Mrs. McGinnis took the prescription Trileptal to combat nerve pain, but she found it "extremely hard to even adapt to" and she felt her "system was just fighting it all the way." Although it helped somewhat with the pain, she would still have episodes where the pain would "shoot up." Also, she felt like there was "a constant veil" over her mentally, where she was "doing everything in slow motion" and was "still hav[ing] the pain."

In April 2014, Mrs. McGinnis began doing sessions with a physical therapist, who would "work on the left side inside the vagina" and manipulate to "soften" the obturator muscles. Mrs. McGinnis found the process "more invasive than going to a gynecologist," saying that "on the human level, you never get used to it." However, her therapy kept her "pain level more even" and she continued to do it.

At the time of trial in 2018, Mrs. McGinnis continued to have severe pain. Sometimes she had an "attack," in which sharp pains "shoot up in the vagina and the pubic bone" and radiate to other areas of her body. She also felt "burning" that was "horrible." She had difficulty sitting because of an increased burning sensation and stiffness. She stated, "I've got to keep stretching my legs out to the side and everything, and it's just easier to stand up."

Additionally, after the implantation surgery Mrs. McGinnis could no longer operate Mary's Childcare without help. She could no longer lift the children, get on the floor to play with them, or dance with them. However, she did not want to close her childcare business because working with the children gave her "enrichment" and gave her "a reason to get out of bed in the morning." Mr. McGinnis consequently became involved in Mary's Childcare, obtaining training and certifications and, at the time of trial, Mr. and Mrs. McGinnis were

operating the business together. Mrs. McGinnis typically needed to lay down "for an hour or two" during the day and when the workday was done.

Mr. McGinnis also took on more household duties after his wife's implantation surgery. Among other things, he testified he now does all the lifting, cleaning, laundry, cooking, and grocery shopping. Before the surgeries, Mrs. McGinnis would do the shopping, which enabled Mr. McGinnis to do other things. He also commented that the two of them would sometimes argue over whether she was able to resume such activities.

Throughout their marriage before the implantation surgery, Mr. and Mrs. McGinnis were sexually active, and she experienced no pain from it. After the surgery, they attempted to have sex on one occasion, but it was too painful for her, so they did not try again. Mrs. McGinnis testified that "even being held tight is hard," and she had to be gentle in hugging her husband or other people. She felt "very guilty" that she was unable to be intimate with her husband. Nevertheless, they continued to have a good relationship and to hold hands.

Mr. McGinnis testified that "the sexual intercourse part" of their marriage was "gone," and he could no longer hug his wife tightly without causing her pain to "kick up." He also testified that, before the implantation surgery, he and his wife would often dance together. They also would "go on rides" of a few

hundred miles to "see some of the country that was around us and see some of the small towns that people talked about," staying overnight. They "did that quite a bit." Following the implantation surgery, they could no longer do these activities.

E. The Trials

At the respective trials, plaintiffs, represented by the same law firm in both cases, presented fact and expert witnesses supporting their claims that defendants were liable under two separate theories of products liability: namely, defective design and inadequate warning. Plaintiffs contended there were feasible and safer alternative designs for the mesh products, and, furthermore, that the product warnings unreasonably failed to alert their physicians and them of the severity of the dangers associated with the devices.

Defendants countered with their own series of fact and expert witnesses, who contended the devices were reasonably designed and safe as a treatment for prolapse, and that the warnings sufficiently alerted plaintiffs and their doctors to the risks of harm.

By agreement of counsel, the substantive issues were tried under the law of New Jersey in Hrymoc, and under the law of North Carolina (plaintiffs' home

state) in McGinnis. In both trials, also by agreement, the issue of punitive damages was tried under New Jersey law.

In Hrymoc, the jury found: (1) Prolift was defectively designed; (2) Prolift's defective design was a proximate cause of plaintiff's injury; (3) Prolift's warnings were inadequate; (4) Prolift's inadequate warnings were a proximate cause of plaintiff's injury; (5) TVT-O's warnings were inadequate; but (6) TVT-O's inadequate warnings were not a proximate cause of plaintiff's injury. The jury awarded compensatory damages of $5 million ($4 million for Mrs. Hrymoc and $1 million for her husband), plus punitive damages of $10 million, with $7.5 million allocated to plaintiffs' design defect claim and $2.5 million to their failure-to-warn claim.

In McGinnis, the jury found defendants liable under the North Carolina product liability statute for both design and warning defects. The jurors awarded plaintiffs $68,026,938.38, consisting of (1) $23 million in compensatory damages and $26,938.38 in stipulated medical expenses to Mrs. McGinnis; (2) $10 million in loss of consortium damages to Mr. McGinnis; and (3) $35 million in combined punitive damages to both plaintiffs.

F. Post-Trial Motions

Defendants in both cases unsuccessfully moved for a new trial, judgment notwithstanding the verdict, and remittitur of the damages. The trial judges denied those motions.

More specifically, the judge in Hrymoc concluded there was sufficient evidence for the jury to find that Prolift posed an unreasonable risk of harm, that there were feasible and safer alternative designs, and that Prolift's design and mesh were the cause of plaintiff's injuries. The judge denied defendants' reliance upon a state-of-the-art defense, finding their proofs essentially focused on the dangers of alternative surgical procedures and not on the state of the art of the technology for Prolift and its components.

The Hrymoc judge also ruled that the evidence supported the jury's failure-to-warn verdict. The judge found plaintiffs established that the Prolift Instructions for Use ("IFU"), patient brochure, and other materials contained "partial and vague warnings" regarding the extent of the risks. Citing the testimony of plaintiffs' experts, the judge noted the risks were "much greater than those typically associated with surgically implantable materials." The judge concluded that the evidence did not support defendants' claim that pelvic surgeons, including Dr. Mokrzycki, knew all of the unwarned-of risks.

Further, the Hrymoc judge ruled that the evidence supported the jury's award of damages. The judge noted the jury heard substantial evidence from plaintiff about her physical and emotional suffering. In addition, plaintiff testified "extensively" about the duration of her marriage, the strong bond with her husband, and the importance of their intimate life. The judge found nothing to suggest it would be manifestly unjust to sustain the award of $4 million to plaintiff and $1 million to her husband. She also deemed the evidence more than sufficient to establish defendants' willful and wanton disregard to sustain the award of punitive damages in an amount that was two times the compensatory award.

The trial judge in McGinnis cited similar reasons for denying defendants' post-trial motions. The judge found that plaintiffs "presented more than sufficient evidence to support their claim that Bard's design[] was inadequate and that Bard knew that the design of the Avaulta Solo and the Align TO were unreasonable and dangerous." The judge also found plaintiffs had presented "sufficient evidence to support the jury's determination to award punitive damages." The judge declined to remit any of the damages awards.

G. These Appeals

The present appeals ensued. With this court's permission, several business organizations filed amicus briefs in support of the defense.[7] The appeals were argued before this court in tandem.

In their main overlapping argument, defendants contend the trial judges each committed reversible error by excluding the FDA 510(k) clearance evidence from both the liability and punitive damages portions of the trials. Defendants also contest as excessive the amount of the damages awards.

Additionally, defendants in Hrymoc argue plaintiffs failed to establish feasible alternative designs that would have eliminated the harm, and that the trial judge erred in rejecting their request for a jury instruction on a state-of-the-art defense. They further argue, with respect to the failure-to-warn claim in Hrymoc, that plaintiffs did not prove proximate causation from any warning inadequacies because Dr. Mokrzycki would have prescribed the mesh implant surgery even if the products came with a stronger warning. Defendants also

[7] The amici are: (1) the Product Liability Advisory Council, Inc., (2) the HealthCare Institute of New Jersey, and (3) the Advanced Medical Technology Association, Chamber of Commerce of the United States of America, and the National Association of Manufacturers. No amici appeared in support of plaintiffs. By agreement of counsel, one attorney participated in oral argument on behalf of all amici, and he addressed the FDA 510(k) evidence issue.

argue the trial judge in Hrymoc erred in allowing plaintiffs to present evidence of the spoliation of certain company records.

Defendants in McGinnis do not raise issues on appeal concerning the merits. They do claim unfair prejudice, however, from the court's exclusion of the 510(k) evidence. They also contest the admission of improper opinion testimony from Mrs. McGinnis's surgeon and her chiropractor. As to the damages, they argue the compensatory damages awarded, particularly the per quod damages awarded to Mr. McGinnis, were excessive, and that the punitive damages were unjustified and exorbitant.

II.

The main issue for our consideration, one common to both appeals, is the trial court's exclusion of any evidence or information about the 510(k) FDA clearance of defendants' mesh products. To analyze that key issue, some regulatory background is in order.

A. The FDA 510(k) Clearance Process

1. General Requirements

The Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. §§ 301-399i ("FDCA"), mandated a premarket approval process for new drugs, but it did not do the same for new medical devices.[8] The Medical Device Amendments to the FDCA, 90 Stat. 539, now codified at 21 U.S.C. §§ 360c-360k ("MDA"), took effect on May 28, 1976, and those provisions conferred upon the FDA regulatory control over medical devices.

The MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. As explained in the FDA's July 28, 2014 publication entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]; Guidance for Industry and Food and Drug Administration Staff" (the "510(k) Guidance Document"):

> The MDA directed FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories: Class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness.

[8] The statutory history of the FDCA and relevant amendments was detailed by the U.S. Supreme Court in Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-80 (1996), and later in Riegel v. Medtronic, Inc., 552 U.S. 312, 315-20 (2008).

[510(k) Guidance Document, at 2.]

See also 21 U.S.C. § 360c(a)(1) (identifying the three "classes of devices intended for human use").

Class I devices were "subject to a comprehensive set of regulatory authorities called general controls that [we]re applicable to all classes of devices." 510(k) Guidance Document, at 2; see also 21 U.S.C. § 360c(a)(1)(A). Examples of such general controls include "prohibitions against adulteration and misbranding; records and reports; and good manufacturing practices." 510(k) Guidance Document, at 2 n.1.

Class II included devices "which cannot be classified as a [C]lass I device because the general controls by themselves [we]re insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there [wa]s sufficient information to establish special controls to provide such assurance." 21 U.S.C. § 360c(a)(1)(B). Following amendments to the MDA in 1990, special controls could include, in particular, "the promulgation of performance standards as well as postmarket surveillance, patient registries, development and dissemination of guidelines," and other actions deemed necessary by the FDA. 510(k) Guidance Document, at 2 n.2.

Lastly, Class III devices were those "for which general controls, by themselves, [we]re insufficient and for which there [wa]s insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device." Id. at 2; see also 21 U.S.C. § 360c(a)(1)(C). Class III devices that were on the market or were marketed after the MDA took effect had to go through the FDA's premarket approval (often referred to as "PMA") process. 510(k) Guidance Document, at 2-3; see also 21 U.S.C. § 360e(b)(1).

Any new medical device introduced after May 1976 was deemed "automatically" to be in Class III and was required to undergo PMA or reclassification by the FDA before it could be marketed, unless one of two exceptions applied. 510(k) Guidance Document, at 3. In particular, PMA or reclassification was not required for a device that either: (1) was "a type of device that was in commercial distribution prior to May 28, 1976," and was substantially equivalent to "another such device," or (2) was substantially equivalent to a type of device that was reclassified into Class I or II after May 28, 1976. Ibid. New Class III devices were typically subject to PMA even if they were substantially equivalent to a device already on the market, although some exceptions applied. Id. at 2, 2 n.3.

2. Substantial Equivalence

Since the adoption of the MDA, a manufacturer seeking to market a new medical device in the United States for which PMA is not required goes through a process known as 510(k) clearance and submits a "premarket notification" to the FDA. 510(k) Guidance Document, at 2-3. The 510(k) submission has to contain information about the device for which clearance is sought (the "submission device") and whether it is substantially equivalent to another device that is already on the market (the "predicate device"). Id. at 3.

To demonstrate substantial equivalence, the 510(k) submission has to show that the submission device has the same intended use as the predicate device, and that it has either: (1) the same technological characteristics of the predicate device, or (2) different technological characteristics but not in a way that "raises different questions of safety and effectiveness than the predicate device." 21 U.S.C. § 360c(i).

If the FDA reviews a 510(k) submission and determines that the submission device is substantially equivalent to the predicate device, the submission device is classified into the same class and is subject to the same requirements as the predicate device. 510(k) Guidance Document, at 3. Conversely, if substantial equivalence is not established, the submission device

is classified as Class III and is subject to PMA. Ibid. "Thus, 510(k) review is both the mechanism by which a manufacturer seeks marketing authorization for a new device and by which FDA classifies devices into their appropriate regulatory category." Ibid.

B. The FDA's Classification of Surgical Mesh and FDA Guidance

"Surgical mesh" was a general category of device already in existence when the MDA took effect. The FDA formally classified surgical mesh into Class II in 1988. 21 C.F.R. § 878.3300 (identifying surgical mesh as "a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone," such as in hernia repair and orthopedic surgery).[9]

In addition to the general 510(k) Guidance Document, the FDA published "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (the "FDA Mesh Guidance"). The FDA Mesh Guidance provided "specific guidance regarding the information to be contained in a premarket notification submission for general surgical meshes described in 21 CFR 878.3300." FDA Mesh Guidance, at 1. The FDA Mesh Guidance advised

[9] See also Effective Date of Requirement for Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair, 81 Fed. Reg. 364 (Jan. 5, 2016) (the "Reclassification Action Summary") (summarizing the history of surgical mesh and transvaginal mesh classifications) (codified at 21 C.F.R. § 884.5980 (2016)).

manufacturers to identify and describe the device, state its intended use, specify all material components, provide manufacturing and sterilization details, and include all labeling. Id. at 1-6. The FDA also advised the manufacturer to include a "[s]ummary of information regarding safety and effectiveness upon which an equivalence determination can be made, or a statement that such information will be made available to interested persons upon request." Id. at 1.

Beginning in 1992, the FDA cleared 510(k) submissions for surgical mesh intended for POP repair under the general Class II surgical mesh regulation. See Reclassification Action Summary. By January 2016, the FDA reportedly had cleared over one-hundred 510(k) submissions "for surgical mesh with a POP repair indication." Ibid.

C. FDA 510(k) Clearance of Prolift

As represented by Ethicon, in May 2000, the FDA classified its Modified Prolene Soft mesh, the same material used in Prolift, as a Class II surgical mesh device and cleared it for use under the 510(k) process.[10]

[10] The facts described here are taken from defendants' proffer of FDA evidence in Hrymoc. Defendants submitted the proffer to the trial judge for the record because she had excluded all evidence of the FDA's regulation of Ethicon devices. These facts consequently were not presented to the jury. A similar effort was made by Bard in McGinnis to present evidence of the 510(k) process.

In November 2001, Ethicon submitted to the FDA a 510(k) premarket notification for the sale of its Prolift Soft mesh for pelvic floor repair, and to market it for this new purpose as Gynemesh Prolene Soft ("Gynemesh PS"). On January 8, 2002, the FDA placed Gynemesh PS in Class II and Ethicon obtained 510(k) clearance from the FDA to use it in the pelvic floor. The FDA found that the product was substantially equivalent to another post-1976 surgical mesh device.

Ethicon started marketing Prolift in 2005 without first submitting to the FDA any premarket notification. See Kaiser v. Johnson & Johnson, 947 F.3d 996, 1005 (7th Cir. 2020) (describing this history). About two years later, in September 2007, Ethicon submitted a 510(k) premarket notification for the Gynecare Prolift system. As explained in Ethicon's and J&J's proffer of FDA evidence in Hrymoc, the mesh was identical to Gynemesh PS in material and composition, and "[t]he only modification was that it was provided in a pre-formed shape and that the system included a set of instruments—a guide, cannulas, and a retrieval device—to facilitate the mesh implant placement."

As explained in the Seventh Circuit's opinion in Kaiser, the "2007 submission asserted that Prolift was substantially equivalent to three devices: the Gynecare Gyn[e]mesh PS Prolene Soft mesh; the AMS Apogee Vault

Suspension System; and the AMS Perigee System," and that "Prolift had the same technological characteristics as these predicates." 947 F.3d at 1005.

On May 15, 2008, the FDA granted 510(k) clearance to Prolift as a Class II device, finding it was "substantially equivalent" to another predicate Class II surgical mesh device.

Three years later, the FDA undertook more vigorous action. As the court noted in Kaiser, "in 2011 the FDA ordered Ethicon and other transvaginal mesh manufacturers to submit plans for postmarket studies of the devices." 947 F.3d at 1006.

Ethicon discontinued the Prolift device after the FDA rejected its plan in 2012. Ibid. Ultimately, "[i]n 2016 the FDA reclassified all transvaginal mesh into Class III." Ibid. (citing 21 C.F.R. § 884.5980).

D. FDA 510(k) Clearance for Avaulta Solo and Align TO

Bard likewise provided 510(k) submissions to the FDA for the Avaulta Solo and Align TO devices. For the Avaulta Solo, Bard's "510(k) Summary of Safety and Effectiveness Information" portion of its submission stated that (1) the intended use and fundamental scientific technology were the same for the Avaulta Solo as for the predicate device, and (2) "[t]he appropriate testing to determine substantial equivalence" was conducted.

Similarly, Bard's "510(k) Summary of Safety and Effectiveness Information" portion of the submission for the Align TO indicated that (1) the intended use and fundamental scientific technology were the same for the Align TO as for the predicate device, and (2) "[t]he appropriate bench testing to determine substantial equivalence" was conducted.

For both products, the predicate device was an earlier version of the same-named device marketed by Bard, which was cleared under the 510(k) process by establishing substantial equivalence to another predicate device.

Bard received clearance from the FDA to market the Avaulta Solo on January 15, 2009. The clearance letter stated, in pertinent part:

> We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).
>
> You may, therefore, market the device, subject to the general provisions of the Act.
>
> [(Emphasis added).]

The clearance letter included this caveat: "Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

Bard received the same form of FDA clearance letter granting permission to market the Align TO on May 7, 2010.

E. The Trial Judges' Exclusion of 510(k) Clearance Proof

Plaintiffs in Hrymoc moved in limine before trial to bar defendants from presenting the jury with any evidence of the FDA's 510(k) clearance of Prolift. Defendants, in response, argued they were entitled to present such evidence.

In an order addressing this issue and over a dozen other pretrial applications, the Hrymoc judge granted plaintiffs' motion in limine to preclude a defense based on 510(k) clearance because it was not equivalent to the FDA's premarket approval process. The judge briefly stated in one paragraph of her lengthy in limine order these reasons for her ruling:

> Only the premarket approval process can find a medical device safe and effective. The Prolift and TVT-O were classified as Class II devices, which did not have to undergo the premarket approval 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, [t]he Prolift and TVT-O cannot be presented to the jury as being approved by the FDA as safe and effective.

Several months later, the judge in McGinnis likewise granted plaintiffs' motion in limine. He reviewed decisions from other jurisdictions, most of which had barred similar evidence. The judge acknowledged that some courts had allowed the evidence, but he did not find the reasoning in those cases persuasive.

The McGinnis judge reviewed Bard's 510(k) materials "in connection with both the Avaulta and the Align" products, including its submissions to the FDA and the FDA's correspondence and clearance. The judge noted in his oral decision that "what strikes me in reading [the FDA's] determinations is not that they are a determination as to safety but they are 'a determination solely as it related to substantial equivalency.'" The judge further observed:

> What is clear to me, based upon the submissions, is that the process is solely to determine substantial equivalency and not safety and efficacy. . . . [T]he individual who performed the review was only concerned about whether the other products that came before this product [were] substantially equivalent to either the Align or the Avaulta product.

In his written decision on the issue, the McGinnis judge further elaborated:

> 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.

The judge rejected Bard's argument that the application of North Carolina law distinguished the McGinnis case from those he found persuasive, finding that the 510(k) clearance process was "not a government standard for purposes of the North Carolina Product Liability Act."[11]

Alternatively, the judge held that the FDA 510(k) evidence should be excluded under the balancing test of N.J.R.E. 403, finding that any probative value under N.J.R.E. 401 was substantially outweighed by possible prejudice and juror confusion. The judge endorsed the concern raised in some cases from other jurisdictions that admitting evidence of the 510(k) clearance process "would result in a mini trial about the strengths and weaknesses of the process[,] initiating a battle of the experts." In addition, the judge concluded:

> Further, even if this court were to find that the §510(k) process had some probative value, its probative value is substantially outweighed by the prejudice and confusion that it would cause to the jury which, on the one hand, is being told it is not a government standard

[11] This argument will be more fully addressed in Part II(F)(5) of this opinion, infra.

> while at the same time having Bard argue that it complied with the §510(k) process. The court considered whether a limiting instruction would cure the issue and determined that such limiting instruction would only further confuse the jury.
>
> [(Emphasis added).]

Accordingly, the McGinnis judge held that no references to the FDA could be made during the liability trial.

Shortly before the McGinnis trial, Bard moved for partial summary judgment, contending that punitive damages were precluded under the New Jersey Products Liability Act ("PLA"), N.J.S.A. 2A:58C-1 to -11. They argued the PLA barred punitive damages because the Avaulta Solo and Align TO, as "the subject of 510(k) clearance by the FDA," were "approved, licensed or generally recognized as safe" by the FDA. The judge rejected this argument, explaining in his oral ruling:

> The [c]ourt in connection with various motions considered the impact of 510(k) and noted that it applies so long as the device is, quote, substantially equivalent to a pre-1976 device already in use. The device which proceeds under 510(k) may be marketed without, quote, pre-market approval as required by the FDA. Again, I will not reiterate all of the reasons but will indicate simply that, in my view, as in the view of others, 510(k) is not a safety and efficacy device. It is essentially an exemption to allow things—to allow

> products to go to market without running the gauntlet of the pre-market approval process.
>
> [(Emphasis added).]

The judge held the pelvic mesh products were not "approved" or "generally recognized as safe and effective" by the FDA as those terms are used in the PLA. Similarly, the judge held that the products were not "licensed" by the FDA as that term is used in the PLA.

Having failed in their PLA argument to be shielded from punitive damages outright, defendants moved again to admit the 510(k) evidence before the punitive damages phase of the trial. The judge denied the motion, essentially for the same reasons he had articulated previously.

F. Analysis

We review this pivotal issue of 510(k) admissibility mindful of several principles that guide the scope of appellate review of evidentiary rulings by a trial court. For one thing, subject to constitutional requirements, we must enforce statutes, rules, or other provisions that mandate the admission or exclusion of certain proofs.[12]

[12] See, e.g., N.J.R.E. 101 (instructing that, except for enumerated categorical exceptions, the New Jersey Rules of Evidence "shall apply in all proceedings, whether civil, criminal, family, municipal, tax, or any other proceeding

Where no such codified mandate exists, and the governing law instead reposes discretion in the trial court, our appellate courts generally afford considerable deference to the exercise of that discretion. Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999). In examining whether a trial court misapplied its discretion, we also cannot lose sight of the fact that a hallmark of our system of civil justice is fairness. Pasqua v. Council, 186 N.J. 127, 146 (2006); see also N.J.R.E. 102 (instructing, among other things, that the evidence rules are to be construed to "administer every proceeding fairly" and "eliminate unjustifiable expense and delay," "to the end of ascertaining the truth and securing a just determination"). We fall short of our institutional obligations and aspirations if the process that generated a civil judgment is not one that gave the parties a fair opportunity to present, within the confines of the Rules of Court and Rules of Evidence, their own "side of the story." See Old Chief v. United States, 519

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conducted by or under the supervision of a court"); N.J.R.E. 408 (prohibiting the admission of offers of compromise "either to prove or disprove the liability for, or invalidity of, or amount of the disputed claim"); N.J.R.E. 411 (declaring that "[e]vidence that a person was or was not insured against liability is not admissible on the issue of that person's negligence or other wrongful conduct"); N.J.R.E. 601 (declaring that "[e]very person is competent to be a witness," unless specified exceptions are satisfied); N.J.R.E. 802 (mandating that "[h]earsay is not admissible except as provided by these rules or by other law").

U.S. 172, 187 (1997) (highlighting the importance of "narrative" in trial practice).

1. Other Jurisdictions

The admissibility of 510(k) evidence in products liability cases involving surgical mesh products has been hotly debated in a few cases in other jurisdictions. As the McGinnis judge noted, it appears that the bulk of the opinions that have addressed the issue have favored the exclusion of such 510(k) evidence. They have generally done so on the grounds of potential juror confusion and consumption of time, although several of those cases have acknowledged the 510(k) evidence has some probative value.

That said, the case law from outside of New Jersey is not uniform on the subject. Most of these cases were decided, at the federal district court level, by Judge Joseph Goodwin, the judge assigned to oversee cases filed in the transvaginal mesh multidistrict litigation in the Southern District of West Virginia (the "federal MDL").

In In re C.R. Bard, Inc., 810 F.3d 913, 917 (4th Cir. 2016) ("Cisson"), the Fourth Circuit Court of Appeals affirmed Judge Goodwin's evidentiary ruling in the case that produced the first jury verdict arising from the federal MDL. The plaintiff in Cisson was implanted with Bard's Avaulta Plus device, and the jury

awarded her both compensatory and punitive damages on her design defect and failure-to-warn claims. Id. at 917-19. Bard argued to the Fourth Circuit that Judge Goodwin erred in excluding evidence of the 510(k) clearance process under Fed. R. Evid. 402 for lack of relevance and under Fed. R. Evid. 403 for being substantially more prejudicial than probative. Id. at 919.

The Fourth Circuit held that, even assuming the evidence was relevant, Judge Goodwin had discretion to exclude the evidence as more prejudicial than probative. Id. at 922-23. The appeals court observed that, "[w]hile some courts have found evidence of compliance with the 510(k) equivalence procedure admissible in product liability cases, the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value." Id. at 920. The court reasoned that "although the [510(k)] process is certainly not a rubber stamp program for device approval, it does operate to exempt devices from rigorous safety review procedures." Ibid. "[T]he district court [wa]s entitled to put 510(k) evidence before the jury, but it [wa]s not obligated to do so." Id. at 922.

The Fourth Circuit found that the probative value of the evidence was slight, stating that "[w]hile 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that

is specific." Ibid. By contrast, the court echoed Judge Goodwin's concern that admitting the evidence would result in a "mini-trial" about the strengths and weaknesses of the 510(k) process because Bard "was prepared to characterize the review process as 'thorough' and 'robust' and the FDA's clearance of the Avaulta Plus as 'an affirmative safety . . . decision' based on 'specific safety and efficacy findings,'" while the plaintiff argued "that these characterizations wildly inflate[d] the significance of the process." Id. at 921-22.[13]

In a similar vein, the Eleventh Circuit Court of Appeals, reviewing a federal MDL case that had been consolidated with three other similar matters and transferred to the Southern District of Florida for trial, affirmed Judge Goodwin's exclusion of the 510(k) evidence under Fed. R. Evid. 403, relying on the reasoning of Cisson. Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1318-19 (11th Cir. 2017). The court also noted "the PMA and 510(k) processes have distinct requirements and different goals" and that "[t]hese differences are

[13] See also Huskey v. Ethicon, Inc., 848 F.3d 151, 160 (4th Cir.) (noting that 510(k) evidence was properly excluded under Fed. R. Evid. 403 because "[w]e see no reason to distinguish Cisson here"), cert. denied, ___ U.S. ___, 138 S. Ct. 107 (2017); Campbell v. Bos. Sci. Corp., 882 F.3d 70, 77 (4th Cir. 2018) (rejecting argument that changes over time to the 510(k) process made evidence more significant and noting that "[a]dmitting the evidence on these grounds would invite a battle of the experts regarding the exact meaning of 510(k) approval in these circumstances, and would risk the same jury confusion we feared in Cisson").

reflected in the intensity of review" during each process. Id. at 1317. Accordingly, the Eleventh Circuit affirmed the exclusion of the 510(k) evidence for failing to meet the relevance threshold of Fed. R. Evid. 402. Id. at 1318-19.[14]

The Seventh Circuit Court of Appeals has also upheld the district court's discretionary exclusion of evidence regarding the 510(k) clearance process in a trial in the Northern District of Indiana relating to a surgical mesh device. Kaiser, 947 F.3d at 1018. The court noted that the device at issue "face[d] the same categorical problem as any device cleared to market through substantial equivalence: The FDA expressly disclaims any intent of 'approving' devices through the § 510(k) process." Ibid. (citing 21 C.F.R. § 807.97).

On the flip side, the judges in several other federal cases, including a reported district court opinion from Arizona, have ruled that evidence of the 510(k) clearance process should be admitted, with a limiting instruction for the jury. In the Arizona opinion, In re Bard IVC Filters Prods. Liab. Litig., 289 F.

[14] See also Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 755-56 (S.D. W. Va. 2014) (federal MDL case finding that the 510(k) process "is not a safety statute or administrative regulation" and excluding evidence regarding it under both Fed. R. Evid. 402 and Fed. R. Evid. 403); Albright v. Bos. Sci. Corp., 58 N.E.3d 360, 370 (Mass. App. Ct. 2016) (noting that the trial judge "would have been well within her discretion to exclude all reference to the § 510(k) clearance . . . because of its potential to mislead the jury and confuse the issues").

Supp. 3d 1045, 1047-48 (D. Ariz. 2018) ("Booker"), the district court found that the plaintiffs were correct "that the 510(k) process focuses on device equivalence, not device safety," but that difference of focus "d[id] not render evidence of the 510(k) process irrelevant." The court noted that a jury deciding a design defect claim may consider whether a manufacturer "acted reasonably in choosing a particular product design," id. at 1047 (quoting Banks v. ICI Ams., Inc., 450 S.E.2d 671, 673 (Ga. 1994)), and it held that a defendant's compliance with the 510(k) process "may not render a manufacturer's design choice immune from liability, but it can be a 'piece of the evidentiary puzzle.'" Ibid. (quoting Doyle v. Volkswagenwerk Aktiengesellschaft, 481 S.E.2d 518, 521 (Ga. 1997)).

As to the balancing test of Fed. R. Evid. 403, the Booker court recognized the plaintiffs' concern that "admission of such evidence would cause the case to devolve into a series of mini-trials regarding the 510(k) process and [the defendants'] compliance with it," but it held that the concern could be "adequately addressed without excluding relevant evidence to the detriment of [d]efendants." Id. at 1048-49. The court determined that "any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process." Id. at 1049.

Moreover, the Booker court held that the defendants would not be permitted "to present evidence or argument that the FDA 'approved' the [device] for market, or that clearance of the device under 510(k) review constitute[d] a finding by the FDA that the [device] [wa]s 'safe and effective.'" Ibid.[15]

In making its Fed. R. Evid. 403 assessment, the Booker court noted that "[m]any of the relevant events in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context." Ibid. Because of that, the court was concerned that excluding the evidence "would run the risk of confusing the jury as well" and "[a]ttempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury." Ibid.

The Booker court was also concerned that some evidence provided by the FDA and unrelated to the 510(k) clearance process was significant in the case, so it was "not convinced that all FDA-references could be removed" even if it excluded the 510(k) evidence. Ibid. Juror confusion or speculation could result

[15] Some unpublished district court opinions, which we will not cite here in accordance with Rule 1:36-3, have reached a result similar to Booker. At least one of those unpublished opinions suggested, like Booker, the use of a limiting instruction to guide the jurors. We are aware of, and likewise will not cite to, unpublished opinions supplied to us by plaintiffs that adopt the contrary view.

"if the evidence was half-baked, containing some references to the FDA but not explaining what role the FDA played with respect to" the device at issue. Ibid.

2. Weighing of Probative Value Against Offsetting Factors

Mindful that the case law from other jurisdictions is divided on the subject, albeit not evenly, we conduct our own independent analysis of the admissibility issue. As we do so, certain points are salient.

We agree with plaintiffs and the two Law Division judges that the FDA's regulatory clearance of a Class II medical device through the 510(k) review process is not a plenary determination of that device's safety and effectiveness. Instead, the clearance process simply confirms that the device maker's own product is "substantially equivalent" to a so-called predicate device that already has been reviewed by the FDA or otherwise has been allowed to be sold.

As case law has recognized, it is beyond reasonable dispute that the FDA's 510(k) clearance process is far less rigorous than the more elaborate and time-consuming process for obtaining the FDA's premarket approval of a Class III device. Indeed, the 510(k) clearance process is controversial, and it has been criticized by some as too weak and too frequently used.[16]

[16] See, e.g., Inst. of Med., Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years 196 (2001) (report of the National

Although it has evolved over the years, the process for obtaining 510(k) clearance requires an applicant to address a lengthy checklist of filing requirements. See FDA, Guidance for Industry and Food and Drug Administration Staff: Refuse to Accept Policy for 510(k)s 20-34 (last updated Sept. 13, 2019). Among other things, the FDA's review can encompass whether any differences in the submission device from the predicate device affect its safety and effectiveness, detailed information or data concerning adverse health effects, and, in some instances, clinical or scientific data, depending on if the applicant contends its device has the same technological characteristics as the predicate. See 21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.87; 21 C.F.R. § 807.92.[17]

Academy of Sciences which, among other things, pointed out various perceived shortcomings of the 510(k) clearance process for Class II devices and recommended replacement of the "substantial equivalence" standard with "an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle"). Although the parties and amici have cited other more recent articles on the subject, we do not cite them here because they generally post-date the clearances of the devices at issue in these two cases.

[17] Plaintiffs argue in their briefs that some of these considerations that appear in the regulations do not pertain here, because defendants submitted their 510(k) clearance documents under 21 U.S.C. § 360c(i)(1)(A)(i), which applies to applications based on devices claimed to have the same characteristics as the predicate device, rather than the more robust criteria of 21 U.S.C. § 360c(i)(1)(A)(ii). Neither trial judge addressed this technical point, and we decline to resolve it here except to note the subject can be addressed in a fulsome manner in a Rule 104 hearing on remand.

We must bear in mind that clearance through the less-rigorous 510(k) FDA review process does provide evidence that a device manufacturer obtained regulatory authorization to market the product at issue. We are persuaded, as several of the federal cases have noted, that evidence of such authorization does have probative value in evaluating the company's design and sale of the devices.

The bar for relevancy under N.J.R.E. 401 only requires a "tendency in reason" for evidence to prove or disprove a fact of consequence to the case. In making this determination, a court's "inquiry focuses on 'the logical connection between the proffered evidence and a fact in issue.'" Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (quoting State v. Hutchins, 241 N.J. Super. 353, 358 (App. Div. 1990)). The evidence "need not be dispositive or even strongly probative in order to clear the relevancy bar." State v. Buckley, 216 N.J. 249, 261 (2013); see also Biunno, Weissbard & Zegas, Current N.J. Rules of Evidence, cmt. 1 on N.J.R.E. 401 (2021) ("The test for relevance is broad and favors admissibility.").

On the other hand, we also recognize courts have the discretion to exclude relevant evidence under N.J.R.E. 403 if the opposing party establishes that its probative value is "substantially outweighed" by countervailing considerations. Such countervailing factors may include the risks of undue prejudice, confusing

or misleading jurors, or undue delay and waste of time. N.J.R.E. 403. "[T]he more attenuated and the less probative the evidence, the more appropriate it is for a judge to exclude it" under Rule 403. Green, 160 N.J. at 499-500 (quoting State v. Medina, 201 N.J. Super. 565, 580 (App. Div. 1985) (alteration in original)).

In reviewing these offsetting considerations here, we consider not only the pretrial in limine rulings of the trial judges on the 510(k) evidence, but how those rulings actually played out in these two trials. As defendants have emphasized, plaintiffs' counsel in both cases took considerable advantage of the judges' exclusion of the FDA clearance proof, by telling and reminding the jurors that defendants performed no clinical studies of the pelvic mesh devices before they were implanted in these patients.

As just a few examples, plaintiffs' counsel in McGinnis argued to the jury in opening and in summation that clinical studies were "needed" and "clearly required," and also made similar insinuations when cross-examining company officials. Similarly, plaintiffs' counsel in Hrymoc stressed in summation that the jury "never heard a witness . . . explain why [a study] wasn't done, why it wasn't necessary" before the product was marketed. In addition, plaintiffs' counsel in Hrymoc exhorted the jury to impose punitive damages to "punish"

defendants so they would "do clinical studies." We do not consider these arguments inappropriate, but defendants should have been permitted to try to counter them by allowing the jurors to at least know about the 510(k) clearance process and the fact that the FDA did not require such clinical studies.

To be sure, the absence of such a regulatory testing requirement does not preempt the ability of state law to impose liability upon manufacturers for selling a defective and unsafe product. Lohr, 518 U.S. at 493-94. But that does not make a total ban on disclosure to the jury of the FDA's actual involvement fair or appropriate. Many jurors in our present society would naturally expect that the FDA would have some involvement in the regulation of a new medical product being implanted in patients, and that the FDA would have had some oversight role concerning bringing a product to market.[18] We are not satisfied that the trial courts' apparent advice to potential jurors during voir dire to ignore the possible role of the FDA in regulating these devices was a fair or adequate solution, given how the cases were thereafter tried.

[18] Such a common expectation would be apt to be even more prevalent for cases to be tried after the current COVID-19 pandemic and the FDA's widely publicized involvement in approving COVID-19 vaccines and reviewing testing data from clinical studies.

The inherent unfairness of the situation as it unfolded is perhaps most pronounced in connection with the punitive damages aspect of these cases. Under the New Jersey Punitive Damages Act ("PDA"), punitive damages may be imposed if the jury finds a defendant behaved with "actual malice" or a "wanton and willful disregard of persons who foreseeably might be harmed" by that wrongful behavior. N.J.S.A. 2A:15-5.12(a). The PDA calls for the trier of fact to "consider all relevant evidence" on the subject, including such topics as the defendant's state of mind and the severity and duration of the conduct. Ibid.

Although we stop short of ruling that the PLA mandated the admission of the 510(k) evidence in these cases, we have substantial concerns that the complete exclusion of any mention of defendants' passage of the FDA clearance process could have easily led some jurors to incorrectly presume that defendants recklessly sold their defective mesh products to the public without any restraint or oversight whatsoever.[19] That is not true, even if the FDA's 510(k) clearance process comparatively was not as rigorous as premarket approval.

[19] For an analogy, see, e.g., Model Civil Jury Charge 5.40D-4, which explains to jurors the limited significance of FDA approval of drug warnings and instructions, and that the jury may find the manufacturer's warnings were inadequate despite that FDA approval. The instruction reads:

3. Limiting Instructions and Other Judicial Measures

Rather than adopt a categorical ban, we believe the more reasoned approach is for our courts to explore whether a limited amount of 510(k) information, through a well-crafted stipulation or a modest presentation of evidence by both sides, along with a cautionary instruction from the judge, could help assure a fair trial.

For instance, the judge could impose reasonable limits on the number of witnesses and the amount of trial time expended on the subject. The judge could also explain to the jury—in a neutral manner—the basic and rather

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> Defendant has offered evidence that the warnings and instructions were approved or prescribed by the Federal Food and Drug Administration. Plaintiff . . . contends that even if so approved, the warnings were still inadequate. Compliance with F.D.A. warnings and instructions does not mean necessarily that the warnings were adequate, but such compliance, along with the other evidence in this case, may satisfy you that they were. Defendant has the burden of proving that the warnings and instructions were approved by the F.D.A. If there has been compliance with the F.D.A. action, th[e]n [plaintiff] has the burden of proving that the approved warnings or instructions were, nevertheless, inadequate. You may find that the warnings or instructions were inadequate despite the F.D.A. approval.
>
> [Ibid. (emphasis added).]

understandable conceptual difference between Class II "substantial equivalency" clearance and the more rigorous Class III premarket approval that evaluates a device's safety and effectiveness in depth. As part of that explanation, the judge should consider advising the jurors that, as provided by an FDA regulation, "[a]ny representation that creates an impression of official approval of a device because of complying with" the 510(k) process "is misleading and constitutes misbranding." 21 C.F.R. § 807.97. Within such an instruction, the judge might helpfully clarify for the jurors that the FDA only concluded defendants' devices were substantially equivalent to a device already on the market, and it did not conduct an independent evaluation of the devices' own safety and effectiveness.

On the discrete subject of the absence of clinical trials, the trial court may consider specifically whether to allow disclosure (or admit proof) of portions of the pertinent FDA documents. For instance, in McGinnis, the FDA reviewer who recommended 510(k) clearance for Bard's device noted on the clearance form that "clinical data" was not "necessary to support the review." It is unclear from the appellate record the basis for that reviewer's assertion of non-necessity, and whether it stems from a finding of technological equivalence under § 360c(i)(1)(A)(i). The trial court may perform a similar review in Hrymoc of the

pertinence of language within the FDA clearance form for Prolift, which has not been furnished in our appellate record.

The judge further could impose limitations on demonstrative aids or forms of argument or questioning that might mislead the jurors about the limited significance of a 510(k) disclosure and any evidence admitted on the subject. Ideally, the judge, with the benefit of a Rule 104 hearing, could fashion a proposed stipulation and jury instruction that might curtail either party from allowing this subject to dominate the trial.

We should not underestimate the intelligence and conscientiousness of jurors. In fact, in her oral opinion denying defendants' post-trial motions, the Hrymoc judge remarked on how impressed she was with the jurors, noting they were "extraordinarily attentive" and "took copious notes." It is wrong to presume the jury would not have been able to understand and follow a limiting instruction from the judge about the proper use of 510(k) evidence. Jurors have a sworn obligation and assumed capability to abide by the court's guidance. Indeed, "[o]ne of the foundations of our jury system is that the jury is presumed to follow the trial court's instructions." State v. Burns, 192 N.J. 312, 335 (2007).

As we noted in our introduction of this opinion, we believe the revelation of the FDA's 510(k) clearance of these devices can be conveyed to the jurors

effectively and plainly without extensive elaboration. The subject need not devolve into a "mini-trial" before the jury. Prudent oversight measures by the court can assure that neither side goes too far in presenting evidence or making arguments to the jury about the 510(k) process. The playing field can be leveled without a dramatic alteration of the overall contest.

We join with other courts that have expressed similar confidence in the capacity of the judges to manage the process and the capacity of jurors to understand the concepts.

4. Rule 104 Proceedings

All of these matters are best addressed by the trial court in a fulsome pretrial Rule 104 proceeding. Although both judges here entertained argument on the topic (along with a host of other pretrial applications), they did not have the benefit of a more in-depth exploration at a Rule 104 hearing of exactly what proofs and counterproofs[20] about 510(k) clearance might be appropriately presented, what constraints on counsel might be sensible, and what the precise wording of a limiting instruction might contain. These cases should be

[20] For instance, without resolving the question here, plaintiffs might want the jurors to know that Ethicon initially began to market Prolift without first submitting a premarket notification to the FDA. That is precisely the sort of question that can be resolved by the court ahead of trial in a Rule 104 hearing.

remanded for new trials preceded by such Rule 104 hearings, ideally by a single judge whose rulings would govern both retrials and other MCL cases involving these devices.

In sum, we conclude the trial courts' complete ban on any disclosure of the 510(k) clearance process to the jurors, and the manner in which plaintiffs took undue tactical advantage of that exclusion, had the clear capacity to lead to possibly unjust results.[21] R. 2:10-2. The judgments are therefore vacated, and the matters scheduled for retrial preceded by Rule 104 proceedings in conformance with this opinion. We do not intimate in advance the proper outcome of the remand hearing, but simply convey our guidance that a categorical ban needs to be more deeply reconsidered, particularly with respect to the punitive damages issue. Specifically, the trial judge must consider the extent of admissibility of the 510(k) evidence for both the liability and punitive damages phases of the trial, as the analysis may differ under the application of the pertinent standards.

[21] Given the nature of the proofs we have described from these trials, it is certainly conceivable that new juries might reach comparable verdicts, even if they are made aware of the 510(k) clearance process. We do not forecast the outcome or opine on the possibilities. Our point is that defendants should be given a fair opportunity to have the trial court reconsider on remand the complete ban on disclosure to the jurors.

5. Related Statutory Issues

That all said, we should note for sake of completeness that we concur with the trial judge's rejection of Bard's argument in McGinnis that Section 99B-6(b) of the North Carolina Products Liability statute compels admission of 510(k) clearance evidence. That statute treats, as one of a litany of several factors, "the extent to which the design or formulation [of a product] conformed to any applicable government standard." N.C.S.A. § 99B-6(b)(3). The 510(k) clearance process does not oblige a device manufacturer to design a device in a particular way. It does not, for example, require that a device possess the same technological characteristics as a predicate device. We decline to construe the North Carolina statute as broadly as Bard wishes, and they cite to no reported opinion from that state adopting their interpretation. We instead regard the relevance of the proof as falling within the discretionary balancing-test ambit of Evidence Rules 401 and 403.

We likewise are unpersuaded by defendants' argument that Section 5 of the New Jersey PLA, N.J.S.A. 2A:58C-5(c), precludes their liability for punitive damages because they obtained the FDA's 510(k) clearance to sell the pelvic mesh devices. The cited New Jersey provision covers drugs or devices that were "subject to premarket approval or licensure" by the FDA. For the reasons we

have already explained, the 510(k) process is not one of substantive "premarket approval" or "licensure." In fact, FDA regulations disallow a manufacturer from making such a mischaracterization. See 21 C.F.R. § 807.97 (declaring such representations of the FDA's "official approval of the device" to be "misleading" and to constitute "misbranding").

Nor, for the reasons we have explained above, does 510(k) clearance signify the FDA has "generally recognized" a medical device to be "safe and effective" within the meaning of N.J.S.A. 2A:58C-5(c). The devices only have been found to be substantially equivalent to a predicate device, which is not the same rigorous test as a finding of safety and effectiveness. Hence, as the McGinnis judge correctly found, neither portion of Section 5 provides defendants with immunity from punitive damages here.

III.

Although it is not vital for us to do so in light of our vacature of the judgments on other grounds, we address defendants' remaining arguments.

A. Design Defect and State-of-the-Art Issues in Hrymoc

Defendants in Hrymoc argue that plaintiffs failed to present sufficient proof of feasible alternative designs to Prolift, and therefore fell short of their burden of proving a design defect under N.J.S.A. 2A:58C-2 and -3. In a related

argument, defendants maintain they were entitled to have the court issue a jury charge on a state-of-the-art defense under N.J.S.A. 2A:58-3(a)(1). The trial judge soundly rejected these arguments, and we adopt her determinations.

Section 2 of the PLA imposes liability for a design defect if the plaintiff establishes by a preponderance of the evidence that a "product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . was designed in a defective manner." N.J.S.A. 2A:58C-2(c). The decision whether a product is "not reasonably fit, suitable and safe" requires a risk-utility analysis to determine whether it creates a risk of harm that outweighs its usefulness. Jurado v. W. Gear Works, 131 N.J. 375, 385 (1993) (quoting O'Brien v. Muskin Corp., 94 N.J. 169, 181 (1983)). A plaintiff who asserts that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that was both practical and feasible at the time the product left the manufacturer's control. Lewis v. Am. Cyanamid Co., 155 N.J. 544, 571, 574-55 (1998).

Viewing the Hrymoc record, as we must, in a light most favorable to plaintiffs, we agree with the judge's post-trial assessment that plaintiffs presented the jury with more than ample evidence to establish that Prolift was defectively designed. Plaintiffs presented extensive expert and factual proof of

several alternative designs to Prolift that a jury could have logically found were reasonably safer than the product implanted in Mrs. Hrymoc, including a Prolift without arms and a Prolift composed of UltraPro mesh. The witnesses provided competing testimony about the risks and benefits of those two alternatives as compared with the product as sold, and the jury had ample grounds to find those alternatives were superior. We need not reach defendants' contention that the third option posed by plaintiffs, i.e., traditional surgical repairs, was not truly an alternative product "design." The evidence concerning the other two options was clearly sufficient as a matter of law.

The judge rightly declined to provide the jury with an instruction about a state-of-the-art defense. The statute affords such a defense only if "[a]t the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm [to the plaintiff] without substantially impairing the reasonably anticipated or intended function of the product." N.J.S.A. 2A:58C-3(a)(1). Here, as the trial judge correctly found, defendants did not present evidence contesting the technical feasibility of designing the Prolift without arms or using a different kind of mesh. The defense instead argued that such alternative designs were not practical and would have had their own downsides.

"The hazard in giving the state-of-the-art instruction in a case in which the manufacturer challenges only the alternative device's practicality is apparent because . . . the defendant has the attendant burden to 'prove' the state-of-the-art when that instruction is given." Cavanaugh v. Skil Corp., 164 N.J. 1, 9 (2000). The court did not err in declining to give the instruction on the record presented. "A jury instruction that has no basis in the evidence is insupportable, as it tends to mislead the jury." Lesniak v. Cnty. of Bergen, 117 N.J. 12, 20 (1989) (citations omitted).

Defendants argue that a state-of-the-art instruction was warranted because plaintiffs did not offer evidence that their proposed alternative designs would have "prevented the harm," invoking that phraseology from N.J.S.A. 2A:58C-3. They contend that design alternatives would have presented their own safety risks and thus would not have "prevented" harm. This argument misconstrues the statute.

A plaintiff with a design defect claim only needs to prove the manufacturer's product was not "reasonably" safe, see N.J.S.A. 2A:58C-2, not that other design alternatives were completely safe. The phrase "would have prevented the harm" within the state-of-the-art provision, N.J.S.A. 2A:58C-3, logically must be read to mean "prevented the degree of harm" caused by the

defendant's product, rather than total elimination of risk. Virtually all products have some inherent risk of harm. If we were to read the state-of-the-art provision as defendants here suggest and require plaintiffs to posit risk-free alternatives, that could eviscerate strict liability in design defect cases.

In sum, the design defect proofs were sufficient, and the court did not err in declining to issue the jury a state-of-the-art instruction.

B. Proximate Causation in Hrymoc

In an effort to overturn the Hrymoc jury's independent finding of inadequate warnings, defendants assert plaintiffs failed to show that more detailed warnings advising of Prolift's dangers were a proximate cause of their injuries. Relying on the role of her surgeon, Dr. Mokzrycki, as a "learned intermediary," defendants contend that stronger warnings could not have affected the decision to have Prolift surgically implanted in Mrs. Hrymoc. The trial judge correctly rejected this contention in her post-trial rulings, as there was ample evidence of proximate causation.

The PLA imposes strict liability if a product manufacturer or seller has failed to provide adequate warnings concerning the dangers posed by a product's use. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 524 (2007). It provides that a manufacturer shall be liable for harm caused by a product that

"was not reasonably fit, suitable or safe for its intended purpose" because it "failed to contain adequate warnings or instructions." N.J.S.A. 2A:58C-2(b). In a failure-to-warn strict liability case, a manufacturer has a duty to warn foreseeable users of the dangers of using its product. Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 207 (1984).

With respect to drugs and medical devices, our state law has adopted the "learned intermediary" doctrine, under which "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Perez v. Wyeth Labs. Inc., 161 N.J. 1, 10 (1999) (quoting Niemiera by Niemiera v. Schneider, 114 N.J. 550, 559 (1989)). This doctrine "recognizes that a prescribing doctor has the primary responsibility of advising the patient of the risks and benefits of taking a particular medication." In re Accutane Litig., 235 N.J. 229, 239 (2018). Thus, "it is the physician's responsibility to pass on to the parties the information that enables the patient to use the product safely." Niemiera, 114 N.J. at 565-66.

The PLA incorporates the "learned intermediary" doctrine through N.J.S.A. 2A:58C-4, under which a pharmaceutical manufacturer or seller is not

liable if the product "contains an adequate warning or instruction" about the product's dangers. The PLA defines "an adequate warning or instruction" as

> 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.]

Where a failure-to-warn case involves something advised by a physician, such as a prescription drug or a medical device, "the issue is whether the warning should have been given to the prescribing physician." London v. Lederle Labs., 290 N.J. Super. 318, 327 (App. Div. 1996), aff'd as modified sub nom. Batson v. Lederle Labs., 152 N.J. 14 (1997). A plaintiff must prove that the lack of a warning was a proximate cause of the harm. Ibid.; Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 63 (App. Div. 1998), aff'd, 158 N.J. 329 (1999).

It suffices if the proximate cause is a "substantial contributing factor to the harm suffered." Perez, 161 N.J. at 27 (emphasis added). Patients deprived of reliable medical information may "establish that the misinformation was a

substantial factor contributing to their use of a defective pharmaceutical product." Id. at 31 (emphasis added).

Defendants first argue that plaintiffs did not prove causation because Dr. Mokrzycki allegedly did not rely on the IFU in recommending the device or in warning plaintiff of its risks. Specifically, they argue that Dr. Mokrzycki testified that he did not rely on IFUs in selecting treatment for his patients and that he read the Prolift IFU once years earlier only in response to Ethicon's request for feedback. Instead, they claim he relied solely on medical literature, the patient's presentation, and his own training and experience.

Contrary to defendants' assertions, Dr. Mokrzycki testified that he reviewed the IFU "[a]s part of the process of learning about the Prolift," which also included training and testing the Prolift. He further acknowledged reviewing the IFU as an evaluator for Ethicon as part of a particular protocol. Moreover, he testified that he reviewed the draft IFU and suggested that Ethicon add something about bowel function.

The record reasonably supports plaintiffs' contention that Dr. Mokrzycki relied on the information in the IFU for his understanding of Prolift's risks and benefits. He assumed the information in the IFU was accurate. He took the section on adverse reactions and risks very seriously, explaining that as a doctor

he needed to know about them to protect patient safety. He explained that if something was "important enough that it was on the IFU and communicated to me, that would tell me at least the company has a significant amount of information that they're concerned about it, so, minimally, I would need to be concerned about it and translate that to the patient."

The trial testimony also shows Mrs. Hrymoc was familiar with the Prolift procedure and its disclosed risks. She testified that Dr. Mokrzycki discussed the patient brochure with her, including potential complications, and that when she expressed some reluctance, he assured her that "all these risks [we]re very easily fixable."

Dr. Mokrzycki explained that he learned how to perform the Prolift procedure by going through training and testing the instrument, not just by opening the IFU and reading it. Nonetheless, he said it was important for the IFU to contain accurate information that fairly represented the risks and benefits of the procedure. He described the risks as "always number one" to know before he counseled a patient. As he elaborated in his testimony, "It's a combined decision. It's my responsibility to explain the reality of those risks, but, ultimately, the patient makes the decision . . . ."

Thus, the record amply establishes that Dr. Mokrzycki relied on the IFU as well as the patient brochure to identify all adverse events and risks associated with the Prolift system, so that he could discuss them with Mrs. Hrymoc and she could consider them in making her decision.

Defendants further contend that Dr. Mokrzycki would not have changed his decision to prescribe and implant Prolift even if they had given more stringent warnings. They argue that plaintiffs did not meet their burden of proof because Dr. Mokrzycki testified that he did not "think" he "would be comfortable using a product" where there was a serious permanent injury, and that he would need more information. This argument is without merit.

The trial judge observed the proofs showed that Dr. Mokrzycki was not aware of the unwarned-of risks. He did not know about plaintiff's "long-term results" or "about certain complications until this case was brought to his attention." When asked whether he would have wanted to use Prolift if Ethicon had told him the outcome for some of his patients, he answered no.

The evidence, reasonably construed, shows that Ethicon knew about additional material risks before the Prolift launch, but it did not include them in the IFU. Such undisclosed risks included mesh contraction, chronic pain, vaginal distortion, dyspareunia, and the need for additional surgery. Indeed, a

company official proposed an additional warning for the IFU concerning complications that could impact a woman's ability to have sexual relations, but Ethicon did not include it in the 2004 IFU, because it had already printed the launch stock.

The record further supports a finding that Dr. Mokrzycki was not aware of all the material risks of patient harm known by Ethicon at the time of plaintiff's surgery. For example, Dr. Mokrzycki testified that Ethicon did not tell him about the risks of bridging fibrosis, scar plating and contraction, or about the risks associated with the removal of Prolift's arms. He also was not told that the French transvaginal mesh group had asked for a safer mesh before Prolift went on the market, that its study had shown a 20% exposure rate at one year, that it had recommended Prolift only for women with Stages III or IV prolapse and not for primary repair, or that its study found that 19.6% of patients suffered from painful vaginal examinations due to retraction. Moreover, according to his testimony, Dr. Mokrzycki did not know before plaintiff's surgery that Prolift could cause permanent and severe dyspareunia and that a patient might need multiple surgeries to treat recurrent mesh erosions. Ethicon also did not tell him that even if implanted properly, the Prolift arms could become scarred, contracted and tense, or provide him with guidance on how to

safely remove the arms if complications occurred. Dr. Mokrzycki described many of these issues as significant for him, saying he wanted more information.

Dr. Mokrzycki testified that if he had known about the unwarned-of risks, he would have considered them in his risk/benefit analysis. If Prolift put a patient at significant risk for problems, Dr. Mokrzycki did not know "if [he] would even offer it to a patient." He said his "biggest problem" after learning about the unwarned-of risks was "the word permanent." As Dr. Mokrzycki explained:

> I would need to know the number of people, you know, numerator and denominator that it happens in, and I would be very anxious about the word permanent, because anything that I do in a patient, I understand there may be issues, there may be complications, but I'm under the assumption that I should be able to get out of that, that I should be able to at least reverse what I've done and get the patient back to square one.
>
> So I don't think I've—I would be comfortable using a product where there is any serious permanent injury . . . .

The surgeon further explained that it would have been important to know about the unwarned-of risks because they would have impacted his decision on whether to offer Prolift to his patients, including plaintiff. He would have wanted to tell plaintiff about all the known risks so she could factor them into her decision on whether or not to use Prolift.

Defendants' focus on Dr. Mokrzycki's isolated statement that he did not "think" he would be comfortable using Prolift does not fairly consider his entire testimony. To the contrary, the evidence supports the finding that Dr. Mokrzycki would not have recommended Prolift to plaintiff if Ethicon had disclosed all known risks, especially the ones that could cause permanent and life-changing injuries.

We are mindful that under New Jersey law, the inadequacy of a warning cannot be the proximate cause of an injury where there is an intervening cause, that is, that the physician either did not read the warning, or had independent knowledge of the risks. Perez, 161 N.J. at 28. However, our case law also instructs that in order for dismissal of the lawsuit to be warranted on this basis, the evidence must be clear and unequivocal. See Strumph v. Schering Corp., 256 N.J. Super. 309, 323-28 (App. Div. 1992) (Skillman, J., dissenting) (concluding that "a defendant drug manufacturer may not be held liable for an alleged inadequate warning where the only evidence on the issue of causation is the prescribing doctor's unequivocal testimony that his or her decision to prescribe the drug was not affected by the warning") (emphasis added), rev'd on dissent, 133 N.J. 33, 34 (1993).

As a leading treatise has noted:

> Where the plaintiffs' prescribing physicians unequivocally testify that they had full knowledge of the dangers associated with a drug and that neither that knowledge nor anything in the enhanced post-injury warnings supplied by the manufacturer would have altered their decision to prescribe it, the plaintiff has failed to show that inadequate warnings are a proximate cause of injury and there must be a verdict for defendant.
>
> [Dreier, Karg, Keefe & Katz, N.J. Products Liability & Toxic Torts Law § 8:3-2 at 203 (2020) (emphasis added).]

"Where such a statement is not unequivocal the matter is properly for the jury." Ibid. The evidence here was by no means unequivocal.

Further, the "prescribing decision," insofar as it logically entails both a physician's recommendation and a patient's assent to follow that recommendation after being apprised of the pertinent risks, can be causally affected by the absence of stronger warnings. Although a physician can function as a "learned intermediary," it should not be assumed that a doctor will issue a prescription—let alone perform surgery upon—an informed patient who is unwilling to risk a medical product's side effects.

At the very least, the evidence shows that Dr. Mokrzycki would have informed plaintiff about the unwarned-of risks so she could have considered

them in her decision-making process. Niemiera, 114 N.J. at 565-66. Plaintiff testified that she would not have agreed to the Prolift procedure if she had known all the risks.

Defendants' failure to provide adequate warnings to Dr. Mokrzycki was reasonably found to be a substantial factor in not alerting plaintiff about the risk of permanent and life-changing complications, depriving her of the opportunity to avert the "medical catastrophe" that occurred. Id. at 566. The proof of proximate causation was more than ample to support the verdict on the failure-to-warn claim.

C. Other Issues

The balance of defendants' arguments do not require in-depth discussion. We very briefly mention them here for guidance to the parties.

The compensatory damages awarded in both cases, viewed in a light most favorable to plaintiffs, were reasonably supported by the evidence. Cuevas v. Wentworth, 226 N.J. 480, 488 (2016). They should not be set aside had we not ordered retrials because of the 510(k) issue.

The loss-of-consortium damages awarded to both Mr. Hrymoc and Mr. McGinnis, while substantial, were justified in light of the compelling testimony that showed the lasting detrimental impact their spouses' post-surgical

complications had on their intimacy, family life, and personal relationships. See Anderson v. A.J. Friedman Supply Co., 416 N.J. Super. 46, 71 (App. Div. 2010) (observing "[a] spouse is entitled to loss of consortium [recovery] upon showing of several factors, including a strong emotional reliance on each other, a relationship of long duration, and a high degree of mutual dependence"). It was not necessary for Mr. Hrymoc to provide cumulative testimony to corroborate his wife's own narrative on the subject.

Subject to this court's previous comments about the likely impact of the exclusion of the 510(k) evidence, the punitive damages in both cases, though sizeable, were reasonably supported by the trial proofs concerning defendants' conduct and knowledge of the products' dangers. The amounts awarded did not transgress the United States or New Jersey Constitutions. The awards were within the mathematical limits prescribed by N.J.S.A. 2A:15-5.14(b).

None of the other evidentiary items argued by defendants warrant reversal. The spoliation evidence presented in Hrymoc was sufficiently relevant to be admitted, and the trial judge imposed reasonable limits on its presentation and use, in lieu of more severe sanctions. Rosenblit v. Zimmerman, 166 N.J. 391, 404 (2001).

Also, the fleeting opinion testimony of Mrs. McGinnis's implanting surgeon with her views about defendants' corporate ethics and by her chiropractor about the perceived extent of her injuries did not manifestly produce harmful error, although should not be repeated on retrial.

We have fully considered all other arguments raised on appeal and find them without sufficient merit to require discussion. R. 2:11-3(e)(1)(E).

IV.

The judgments are vacated and remanded for new trials preceded by Rule 104 hearings on the 510(k) clearance evidence. In all other respects, affirmed.