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Superior Court of New Jersey, Appellate Division.

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.

DOCKET NO. A-5151-17

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A-1083-18

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Argued January 25, 2021

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Decided March 2, 2021

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

Attorneys and Law Firms

[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).

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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).

Before Judges [Sabatino](#), [Currier](#) and [Gooden Brown](#).

Opinion

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

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 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 Mokrzycki, 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

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

[At the court's direction pursuant to Rule 1:36-3, the published version of this opinion omits Parts I(C)(1) and (2), which discuss: the development of the Prolift and TVT-O devices by Ethicon and the Avaulta Solo and Align TO devices by Bard; internal company communications concerning product design, safety, and marketing; product warnings; FDA Section 510(k) clearance; patient complications; and the eventual removal of these devices from the market.]

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

[At the court's direction, the published version of this opinion omits Parts I(D)(1) and (2), which discuss the respective plaintiffs' backgrounds and medical conditions, the surgical implant of Prolift and TVT-O in Mrs. Hrymoc in June 2008 and of Avaulta Solo and Align TO in Mrs. McGinnis in December 2009, their ensuing adverse medical complications and surgeries to remove the devices, and lifestyle impacts upon them and their spouses.]

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 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.

[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 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

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 preformed 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 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

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 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 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. 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 “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

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

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.

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.

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 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 counterproofs²⁰ 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 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.

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. Mokrzycki, 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

[At the court’s direction, the published version of this opinion omits Part III(C), which discusses issues concerning other alleged evidential errors, as well as defendants’ challenges to the juries’ respective awards of compensatory and punitive damages.]

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.

All Citations

--- A.3d ----, 2021 WL 787039

Footnotes

- 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 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 nonprecedential, we do not discuss or quote from it here. [R.](#) 1:36-3.
- 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.
- 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.
- 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.

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).

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 \(2016\)](#)).

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.

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

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 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”).

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](#)”).

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”).

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.

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 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 postdate 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.

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.

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:

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).]

- 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.
- 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.