2023 WL 4714042
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Supreme Court of New Jersey.

Elizabeth Hrymoc and
Tadeusz Hrymoc, Plaintiffs,
v.
Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare, and Johnson & Johnson, Defendants.
Mary McGinnis and Thomas Walsh McGinnis, Plaintiffs-Appellants/Cross-Respondents,
v.
C. R. Bard, Inc., Defendant-Respondent/Cross-Appellant,
and
Bard Medical Division, a Division of C. R. Bard, Inc., and Bard Urological Division, a Division of Bard Medical Division, Defendants.

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A-21/23 September Term 2021
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Argued February 27, 2023
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Decided July 25, 2023

On certification to the Superior Court, Appellate Division, whose opinion is reported at 467 N.J. Super. 42 (App. Div. 2021).

Attorneys and Law Firms

Adam M. Slater argued the cause for appellants/cross-respondents (Mazie Slater Katz & Freeman, attorneys; Adam M. Slater and Christopher J. Geddis, on the briefs).

David R. Kott argued the cause for respondent/cross-appellant (McCarter & English, attorneys; David R. Kott and Natalie H. Mantell, of counsel and on the briefs, and Meghan McSkimming and Benjamin D. Heller, on the briefs).

Jared M. Placitella argued the cause for amicus curiae New Jersey Association for Justice (Cohen, Placitella & Roth, attorneys; Jared M. Placitella and Christopher M. Placitella, of counsel and on the brief).

Daniel B. Rogers (Shook, Hardy & Bacon) 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 National Association of Manufacturers (Shook, Hardy & Bacon, attorneys; Philip S. Goldberg, on the letter-brief).

Charles W. Cohen argued the cause for amicus curiae New Jersey Defense Association (Hughes Hubbard & Reed, attorneys; Charles W. Cohen and Eric Blumenfeld, on the brief).

Ryan J. Kurtz argued the cause for amicus curiae New Jersey Civil Justice Institute (Patterson Belknap Webb & Tyler, attorneys; Ryan J. Kurtz and Michelle M. Bufano, of counsel and on the brief).

Ronald J. Levine submitted a letter-brief on behalf of amicus curiae Product Liability Advisory Council, Inc. (Herrick, Feinstein, attorneys; Ronald J. Levine, on the letter-brief).

Beth S. Rose submitted a letter-brief on behalf of amicus curiae Healthcare Institute of New Jersey (Sills Cummis & Gross, attorneys; Beth S. Rose, on the letter-brief).

Opinion

JUSTICE SOLOMON delivered the opinion of the Court.

This products liability matter[1] involving "pelvic mesh" medical devices poses two questions surrounding evidence of "Section 510(k) clearance," see 21 U.S.C. § 360c, which allowed the devices to be marketed without premarket clinical trials. First, we consider whether the trial court's determination that defendant C.R. Bard, Inc.,[2] could not present 510(k) clearance evidence to counter the product liability claims brought by plaintiffs Mary and Thomas Walsh McGinnis deprived defendant of a fair trial, given that plaintiffs' claims were governed by North Carolina products liability law, which -- unlike New Jersey's strict liability law -- features a negligence standard based on reasonableness. See N.C. Gen. Stat. § 99B-6(a). Second, we consider whether - - - New Jersey's Products Liability Act (PLA), N.J.S.A. 2A:58C, which governed plaintiffs' claims for damages in this case, precludes punitive damages in cases involving 510(k) clearance and, if not, whether fairness requires that defendant be able to present their 510(k) evidence during the punitive damages phase of the trial.

***4** Upon motions in limine from the parties about the admissibility of 510(k) evidence, the trial court barred the evidence entirely, finding that because the 510(k) clearance process determines substantial equivalency only, and not safety and efficacy, such evidence was inadmissible. The trial court further held that even if 510(k) evidence did have some probative value, any probative value was substantially outweighed by the risk of prejudice and potential juror confusion.

The Appellate Division reversed the trial court's judgment and remanded for a new trial, holding that the exclusion of any 510(k) evidence deprived defendant of a fair trial on the issue of negligence. The Appellate Division also determined that although punitive damages were not precluded by the PLA by the mere existence of 510(k) evidence, such evidence could be admissible in the punitive damages phase of a trial.

We agree that 510(k) evidence is generally inadmissible because the 510(k) clearance process solely determines substantial equivalency, and not safety and efficacy. However, in a products liability claim premised not only on principles of negligence, but particularly on the reasonableness of a manufacturer's conduct in not performing clinical trials or studies, evidence of 510(k) clearance has significant probative value under N.J.R.E. 401 that is not substantially outweighed by the risk of prejudice and potential juror confusion under N.J.R.E. 403. Therefore, under the specific facts and circumstances of this case, we agree with the Appellate Division. We affirm its judgment and remand for a new trial. We part ways with the Appellate Division's decision as to its suggestion that the scope and admissibility of 510(k) evidence should be determined in a Rule 104 hearing; we believe that the scope and admissibility of 510(k) evidence should be resolved at the hearing on a motion in limine, which is how the issue was and, presumably, will be raised.

I.

A.

The trial record reveals that the pelvic mesh medical devices that are the subject of this appeal attempt to address the medical conditions of pelvic organ prolapse (often referred to as "POP") and stress urinary incontinence ("SUI"). Plaintiff Mary McGinnis was diagnosed with both conditions, and her North Carolina surgeon, Dr. Elizabeth Barbee, implanted Bard's Align Transobturator Urethral Support System ("Align TO") to treat her SUI, and the Avaulta Solo Anterior Synthetic Support System ("Avaulta Solo") to correct her POP. The Align TO and Avaulta Solo are kits that include the mesh material to implant, the instrument to insert the mesh, and instructions for the surgical procedure. In the months following surgery, McGinnis returned to Dr. Barbee with symptoms that ultimately required numerous invasive surgeries at the hands of several physicians to remove the mesh and repair internal damage, with limited success.

In 2011, plaintiffs filed a complaint in Atlantic County[3] asserting products liability claims against defendant Bard under North Carolina law. Following defendant's response, counsel agreed that the substantive issues would be tried under the law of North Carolina (plaintiffs' home state and where plaintiff Mary McGinnis underwent surgery to implant the medical devices) but that the issue of damages would be tried under New Jersey law (where defendant C.R. Bard, Inc. has its principal place of business).

***5** Plaintiffs moved in limine to bar defendant from presenting any evidence of the devices' 510(k) clearance to the jury. The Food and Drug Administration (FDA)'s 510(k) clearance process, which we discuss in detail below, allows the marketing of certain medical devices that are "substantially equivalent" to ones previously approved for sale by the FDA.

The 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 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 judge elaborated further:

> 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 that he found persuasive, concluding that the North Carolina Products Liability Act did not bar plaintiffs' recovery because the 510(k) clearance process is "not a government standard."[4]

Alternatively, the judge held that 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 cases from other jurisdictions that admitting evidence of 510(k) clearance "would result in a mini trial about the strengths and weaknesses of the process[,] initiating a battle of the experts." The court considered whether a limiting instruction would cure the issue but determined that it would only further confuse the jury. Accordingly, the trial judge granted plaintiffs' motion in limine and held that no references "to the FDA or the 510(k) process" could be made during trial.

Shortly before trial, Bard moved for partial summary judgment, contending that punitive damages were precluded by the PLA, N.J.S.A. 2A:58C-1 to -11. Counsel argued that Section 5 of 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, "substantially equivalent" to a pre-1976 device already in use. The device which proceeds under 510(k) may be marketed without "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.

***6** The judge therefore concluded that the pelvic mesh products were not "licensed," "approved," or "generally recognized as safe and effective" by the FDA as those terms are used in the PLA.

Having failed in its effort to be shielded from punitive damages, Bard moved to admit 510(k) evidence during the punitive damages phase of the trial. The judge denied the motion.

B.

Trial lasted three weeks in March and April of 2018. At trial, several of plaintiffs' expert witnesses testified to Bard's failure to clinically evaluate its products and, throughout the trial, plaintiffs' counsel stated in a variety of ways that Bard did not conduct clinical trials of its products. The failure to conduct clinical trials, do clinical studies, and/or collect data was raised or referenced twelve times in plaintiffs' counsel's opening statements and more than sixteen times in summation. Plaintiffs' counsel emphasized that Bard knew it had very little data on its products, did not adequately study them, and that the responsible thing for Bard to do would have been to conduct clinical studies. For example, in opening remarks, plaintiffs' counsel made statements such as, "I'm going to say it again. They didn't think they needed to do a clinical study with this to see what happened in actual women," and "[t]hey did no clinical study on this one also. The theme continues."

Further, in closing, plaintiffs' counsel stated, "Bard had choices, folks. They could put clinical studies in place because they put patient safety first. That was a choice they could make, or they could put market share first and do no clinical study," and "[i]f Bard had done a reasonable and serious study, the only reasonable outcome would have been don't sell this because you're not getting the benefit, and the risks are very serious." Plaintiffs' counsel even referenced the court's instructions, stating that "[a]nd, by the way, you're going to see the instructions from the [c]ourt. It's what they knew or should have known. So their failure to do a real clinical study over time is held against them because we all know, and we're going to talk about some of the other studies by doctors, what they found when they actually did report on their own patients. This is what they were finding."

Plaintiffs' counsel also used the direct examination of witnesses to reiterate that Bard acted unreasonably in failing to perform clinical trials on its devices and consistently questioned their expert witnesses about Bard's lack of clinical trials. For example, during the de bene esse deposition of Bobby Orr, a program manager at Bard, which was played for the jury during trial, the following colloquy occurred:

> Q. And Bard never did a randomized control trial prospectively or retrospectively on the Avaulta Plus or Solo products, correct?
>
> A. There were no Bard-sponsored studies. There were retrospective studies in which physicians were gathering data after -- after the product was on the market.
>
> Q. There were no published studies, were there?
>
> A. None that I'm aware of.

And again, during the direct and redirect examination of Adam Silver, Bard's director of marketing for pelvic health products, including the Avaulta and Align products, from 2008 to 2011, plaintiffs' counsel likewise asked, "Bard never conducted clinical studies in actual women before these were sold on the market, correct?" To which Silver responded, "[n]o. We did not."

***7** Defense counsel objected to those lines of questioning throughout trial, frequently arguing that questioning about the necessity of clinical trials opened the door to allow admission of 510(k) evidence. Defendant also presented numerous witnesses and, to counter plaintiffs' emphasis on defendant's failure to conduct clinical studies, argued that it had followed and complied with extant regulatory requirements. For example, during her opening statement, defense counsel repeatedly argued that the devices at issue "met all the rules, all the standards, all the requirements ... to be sold and marketed when they were." Counsel also underscored that, "[a]t this point in time when the Align and Avaulta came to market, ... there was six years of data already."

With regard to the testimony of the doctors that defendant had presented as witnesses, defense counsel argued in summation that the doctors "said the designs were appropriate, reasonable, within industry standards. They said there was no reason to do an additional human clinical study on these devices. There was enormous data already. They were satisfied with that." Counsel added that "[n]o clinical studies, additional clinical studies, no human clinical studies were needed."

The jury ultimately found defendant liable under the North Carolina products 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 Mary McGinnis; (2) $10 million in loss of consortium damages to Thomas Walsh McGinnis; and (3) $35 million in combined punitive damages to both plaintiffs.

Defendant thereafter unsuccessfully moved for a new trial, judgment notwithstanding the verdict, and remittitur of the damages. 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 that plaintiffs had presented "sufficient evidence to support the jury's determination to award punitive damages." The judge thus declined to remit any of the damages awarded.

C.

Defendant appealed, claiming unfair prejudice from the court's exclusion of 510(k) evidence. The Appellate Division vacated the judgment reached in the trial court and remanded the matter for a new trial to be preceded by a Rule 104 hearing on the Section 510(k) evidence. Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 91 (App. Div. 2021).

After considering relevant 510(k) law, the approaches of other jurisdictions, evidentiary obligations under N.J.R.E. 403, and the in limine rulings and their impact on the trial, the Appellate Division held that "defendant[ ] should have been permitted to try to counter [plaintiffs' claims] 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." Id. at 76. The Appellate Division took issue with the fact that plaintiffs "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." Ibid. Although it did not "consider these arguments inappropriate," the Appellate Division found "inherent unfairness" in using the lack of clinical studies to bolster plaintiffs' claims without giving defendant an opportunity to explain why it chose not to perform such studies. Ibid.

The Appellate Division noted that "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." Ibid. (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 493-94 (1996)). But the court found

that "does not make a total ban on disclosure to the jury of the FDA's actual involvement fair or appropriate." Ibid.

***8** The Appellate Division disagreed that introduction of the 510(k) evidence would cause juror confusion, explaining that

> [m]any 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. 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.
>
> [Ibid. (footnote omitted).]

Turning to the issue of punitive damages, the Appellate Division stated that, "even if the FDA's 510(k) clearance process comparatively was not as rigorous as premarket approval," the court had "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." Id. at 77.

The court also explained that the New Jersey Punitive Damages Act (PDA) provides that "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." Ibid. (quoting N.J.S.A. 2A:15-5.12(a)). The appellate court underscored that "[t]he 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. (quoting N.J.S.A. 2A:15-5.12(a)).

Thus, the Appellate Division concluded that, instead of a categorical ban on 510(k) evidence, "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." Id. at 77-78. If done properly, disclosure of the FDA's 510(k) clearance "can be conveyed to the jurors effectively and plainly without extensive elaboration" and "need not devolve into a 'mini-trial' before the jury." Id. at 79. The proper vehicle to manage and address those issues, the Appellate Division held, is through a pretrial Rule 104 proceeding. Ibid.

D.

Plaintiffs petitioned for certification on the issue of the admissibility of 510(k) evidence. We granted their petition. 248 N.J. 564 (2021). Defendant filed a cross-petition for certification, arguing that the Appellate Division erred in affirming the trial court on the issue of punitive damages under Section 5 of the PLA, which we also granted. 248 N.J. 567 (2021).

In addition, we maintained the amicus curiae status of the Product Liability Advisory Council, Inc. (PLAC), the Healthcare Institute of New Jersey (HINJ), and the Advanced Medical Technology Association, the Chamber of Commerce of the United States of America, and the National Association of Manufacturers (collectively, Advanced), which were granted leave to participate by the Appellate Division. We additionally granted leave to appear as amici curiae to the New Jersey Association for Justice (NJAJ), the New Jersey Defense Association (NJDA), and the New Jersey Civil Justice Institute (NJCJI).

II.

***9** Plaintiffs argue that the evidence of defendant Bard's misconduct was "overwhelming" because defendant failed to listen to experts who suggested safer mesh and better warnings. Plaintiffs further allege that the decision not to admit the evidence of 510(k) clearance was discretionary on the part of the trial court, and consistent with "every other court overseeing a significant consolidation of pelvic mesh cases in the United States, three federal Courts of Appeals, and the United States Supreme Court." Because 510(k) offers only limited review and is vastly different from premarket approval, plaintiffs contend that allowing evidence of 510(k) would mislead the jury into believing that the product was approved by the FDA. Finally, plaintiffs argue that trial courts are in the best position to make evidentiary rulings and the Appellate Division, by adopting the minority view that such evidence is admissible, incorrectly applied the abuse of discretion standard. Plaintiffs submit therefore that the Appellate Division erred in remanding the case for a Rule 104 hearing on the issue of admission of 510(k) evidence

because Bard already made its arguments as to admissibility and neither party requested a Rule 104 hearing.

Defendant Bard, on the other hand, argues that the Appellate Division correctly ruled that 510(k) evidence should have been admitted and that the jury must consider that evidence when deciding liability. Bard argues that the evidence is admissible because plaintiffs opened the door by arguing that defendant did not conduct studies, though studies are not required by the FDA process in 510(k) clearance cases. Further, Bard submits that substantial prejudice resulted from excluding the 510(k) evidence because defendant could not explain its rationale for placing the pelvic mesh medical devices on the market. Bard contends that the relevant North Carolina statute applied by the court called for consideration of any applicable government standard, and because New Jersey used North Carolina law to decide the substantive issues, 510(k) evidence should have been admitted during trial to explain its conduct. Bard disputes plaintiffs' contention that every other court has agreed with its position and believes that the Appellate Division opinion is consistent with other recent cases that determined FDA evidence is admissible, and that the Appellate Division appropriately remanded for a new trial to include a Rule 104 hearing where both sides can present evidence in a fair manner and create a "fulsome record."

Bard also argues that the Appellate Division erred in failing to look to legislative history when interpreting Section 5 of the PLA. The PLA specifically calls for legislative history to be consulted when interpreting the Act; if the Appellate Division had looked to legislative history, Bard submits, it would have concluded that the Legislature intended to preclude punitive damages for devices regulated by the FDA. In addition, Bard argues that a plain reading of Section 5 of the PLA precludes punitive damages for devices classified as Class II devices and cleared under Section 510(k). This is because 510(k) clearly falls within the language of Section 5's use of the words "approved" and "licensed." Bard further contends that the PLA bars punitive damages for products that are generally recognized as safe and effective, and such a condition is satisfied in this case because the FDA found mesh to be safe and effective.

All amici except the NJAJ support the arguments advanced by Bard in terms of the application of punitive damages under the PLA. Amici NJDA, PLAC, and Advanced further agree with Bard about the admissibility of 510(k) evidence. In contrast, amicus NJAJ echoes plaintiffs' arguments that the Appellate Division was mistaken in overturning the trial court's decision and allowing the admission of 510(k) evidence during the liability phase of the trial.

III.

The first question raised in this appeal is about the admissibility of 510(k) clearance evidence. An appellate court reviews a trial court's evidentiary rulings, like those at issue here, with substantial deference and will not overturn such a ruling unless it constituted a clear abuse of discretion. State v. Cole, 229 N.J. 430, 449 (2017); Green v. N.J. Mfrs. Ins., 160 N.J. 480, 492 (1999). "A trial court's 'discretion is abused when relevant evidence offered by the defense and necessary for a fair trial is kept from the jury.' " State v. R.Y., 242 N.J. 48, 65 (2020) (quoting State v. Cope, 224 N.J. 530, 554-55 (2016)).

***10** Relevant evidence is any "evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. Pursuant to N.J.R.E. 402, all relevant evidence is admissible, except as otherwise provided by the Rules of Evidence or by law. Under N.J.R.E. 403, relevant evidence may be excluded by the trial court if its probative value is substantially outweighed by the risk of undue prejudice, juror confusion, or undue delay. Application of N.J.R.E. 403 thus requires a balancing of interests to achieve a fair result. A hallmark of our civil justice system is fairness. Pasqua v. Council, 186 N.J. 127, 146 (2006).

This first question raised in this case will therefore turn on whether it was an abuse of discretion for the trial court to exclude evidence that Bard complied with the 510(k) clearance process in marketing the Avaulta Solo and Align TO devices -- that is, whether Bard was deprived of its right to a fair trial by the exclusion of all 510(k) evidence. Our resolution of that question requires an in-depth review of the 510(k) clearance process.

A.

The Medical Device Amendments of 1976 (MDA), now codified at 21 U.S.C. §§ 360c to 360k, to the Federal Food, Drug, and Cosmetic Act of 1938 were enacted "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539 (1976). The MDA directed the FDA

to classify all medical devices in commercial distribution at that time into three categories based on the level of scrutiny needed "to provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(A) to (C). The degree of product scrutiny by the FDA therefore depends upon the risk to the public posed by the medical device. Lohr, 518 U.S. at 476.

Devices deemed the least dangerous are designated as Class I. Id. at 477. Class I devices are those for which "general controls," or controls authorized by or under other various sections of the Federal Food, Drug, and Cosmetic Act, "are sufficient to provide reasonable assurance of the" device's safety and efficacy, 21 U.S.C. § 360c(a)(1)(A)(i); or "insufficient information exists to determine that [general controls] are sufficient to provide reasonable assurance of" safety and efficacy, and the device "is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury," 21 U.S.C. § 360c(a)(1)(A)(ii).

"Devices that are potentially more harmful are designated Class II." Lohr, 518 U.S. at 477. Class II devices are those which cannot be classified as Class I devices

> because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, ... recommendations, and other appropriate actions as the Secretary [of Health and Human Services] deems necessary to provide such assurance.
>
> [21 U.S.C. § 360c(a)(1)(B).]

Finally, devices that cannot be classified as Class I or Class II and that are intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or that present "potential unreasonable risk of illness or injury" are designated as Class III. 21 U.S.C. § 360c(a)(1)(C). Those devices require premarket approval ("PMA") by the FDA to provide reasonable assurance of safety and effectiveness. The PMA process "is a rigorous one." Lohr, 518 U.S. at 477. To obtain PMA, a manufacturer must submit an application containing "detailed information regarding the safety and efficacy of its device, which the FDA then reviews, spending an average of 1,200 hours on each submission." Ibid.; 21 U.S.C. § 360e(c).

***11** For Class III devices, a manufacturer must provide, among other things, a "summary of studies" in its PMA application, including a "summary of the nonclinical laboratory studies submitted in the application," and a

> summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate.
>
> [21 C.F.R. § 814.20(b)(3)(v).]

Additionally, a manufacturer must provide its conclusions drawn from the studies, including a "discussion demonstrating that the data and information in the application constitute valid scientific evidence ... and provide reasonable assurance that the device is safe and effective for its intended use." 21 C.F.R. § 814.20(b)(3)(vi). In other words, PMA requires that a device undergo rigorous testing and clinical trials prior to being placed on the market.

Any new device introduced after the MDA's enactment in 1976 is "automatically" a Class III device,[5] and thus requires PMA or reclassification into Class I or II, unless one of the following two exceptions apply: (1) the device is "substantially equivalent" to one which was on the market prior to enactment of the MDA, or (2) the device is "substantially equivalent" to a type of device that was placed into Class I or II after enactment of the MDA. 21 U.S.C. § 360c(f)(1)(A).

A manufacturer who intends to market a "substantially equivalent" device for which PMA is not required goes through what is known as the 510(k) clearance process. To obtain 510(k) clearance, a manufacturer must first submit a "premarket notification" to the FDA demonstrating substantial equivalence, or that the new device has the same intended use as a "predicate device" already on the market, and that it has either (1) the same technological characteristics as the predicate device, or (2) different

technological characteristics, but does not raise different questions of safety and effectiveness than the predicate device. 21 U.S.C. § 360c(i)(1)(A).

Once the FDA reviews a 510(k) premarket notification and determines that the new device is substantially equivalent to the predicate device, the new device is placed into the same class and is subject to the same requirements as the predicate device, thus avoiding the rigorous PMA process and further regulatory scrutiny. Therefore, if a company can prove that a device is "substantially equivalent" to another already on the market, it can forego the strict requirements of PMA that reasonably ensure a device's safety and effectiveness, including the need for clinical trials and testing.

Thus, the 510(k) process primarily focuses on equivalence; though the safety and effectiveness of a new device factors into the FDA's 510(k) review, the analysis is comparative rather than independent. Lohr, _ - _ 518 U.S. at 493. In other words, there is no independent finding of the safety and effectiveness of a device during the 510(k) clearance process, only that a device is akin to an approved predicate device. Indeed, FDA regulations clarify that "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97.

***12** "[B]ecause of the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties, the FDA simply could not keep up with the rigorous PMA process." Lohr, 518 U.S. at 479. So, upon its introduction, the 510(k) process became the means by which most new medical devices were approved for distribution. Ibid. A 2018 FDA Statement stated that the "FDA's 510(k) program is the most commonly used device premarket review pathway. In 2017, [the FDA's Center for Devices and Radiological Health (CDRH)] cleared 3,173 devices through the 510(k) pathway, representing 82 percent of the total devices cleared or approved." Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Transformative New Steps to Modernize FDA's 510(k) Program to Advance the Review of the Safety and Effectiveness of Medical Devices, U.S. FDA (Nov. 26, 2018), https://www.fda.gov/news-events/pressannouncements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and.

The FDA placed general surgical mesh into Class II in 1988, 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. 21 C.F.R. § 878.3300. Beginning in 1992, the FDA accepted 510(k) submissions for surgical mesh used for POP repair under the general surgical mesh classification. See 81 Fed. Reg. 364, 365 (Jan. 16, 2016). Since then, the FDA has cleared more than one hundred 510(k) submissions for surgical mesh intended for POP repair.[6]

In 2008 and 2009, respectively, Bard provided 510(k) submissions to the FDA for the Avaulta Solo and Align TO devices. For both, the predicate devices were earlier versions of the same-named devices[7] marketed by Bard, which had also been cleared under the 510(k) process. The FDA gave Bard 510(k) clearance to market the Avaulta Solo in January 2009, and the Align TO in May 2010, without clinical trials, finding that the devices were substantially equivalent to the legally marketed predicate devices.

B.

There have been more than 100,000 pelvic mesh cases against various manufacturers filed and litigated in other federal and state courts. No reported decision applying North Carolina law has considered whether Section 510(k) clearance evidence should be admitted in such cases.

Unlike New Jersey products liability law, North Carolina law does not allow for strict liability in tort in products liability actions. See N.C. Gen. Stat. § 99B-1.1. Rather, products liability claims are assessed under a standard of reasonableness: "No manufacturer of a product shall be held liable in any product liability action for the inadequate design or formulation of the product unless the claimant proves that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product." N.C. Gen. Stat. § 99B-6(a) (emphasis added).

Under the North Carolina Products Liability Act, a jury must consider several factors in determining whether a manufacturer acted unreasonably, including "[t]he nature and magnitude of the risks of harm associated with the [product's] design" given its "intended and reasonably foreseeable uses,

modifications or alterations"; "[t]he likely awareness of product users" of those risks; the "extent to which the design or formulation conformed to any applicable government standard"; the product's utility; and the possibility of using -- and risks associated with using -- an alternative design. See N.C. Gen. Stat. § 99B-6(b)(1), (2), (3), (5), (6), (7). Issues bearing upon negligence, therefore, are central to this case in a way that they would not ordinarily be in New Jersey.

***13** In other jurisdictions that have a negligence standard for products liability cases, the relevance and admissibility of 510(k) evidence in products liability cases involving surgical mesh have been hotly contested. One of the key factors that has led courts to exclude such evidence is that the 510(k) clearance process does not require an independent finding of safety and effectiveness, as underscored by the Supreme Court in Lohr.

In Lohr, the Court considered whether the plaintiffs' negligence claims brought under Florida law were pre-empted by the MDA because of the "substantial equivalence" requirement of the 510(k) process. 518 U.S. at 481-84. Five Justices ultimately determined that the "substantial equivalence" provision did not pre-empt the plaintiffs' negligence claim, reasoning that "even though the FDA may well examine § 510(k) applications ... with a concern for the safety and effectiveness of the device," the clearance is designed to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." Id. at 493-94. "[S]ubstantial equivalence determinations," the Court stressed, "provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device." Id. at 493 (quotation omitted).

Drawing on Lohr, the Fourth Circuit has upheld a district court decision excluding 510(k) evidence, finding the evidence to be "of little or no evidentiary value." See In re C.R. Bard, Inc. (Cisson), 810 F.3d 913, 920 (4th Cir. 2016) (applying Georgia law). As in this case, Cisson involved transvaginal mesh used to treat POP, and the products liability claims were negligence-based. Bard, also the defendant in Cisson, made the same claim as it does here -- that 510(k) evidence was admissible to show that Bard's conduct was reasonable and was unfairly excluded. Id. at 919. But 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,' " the Fourth Circuit determined that the evidence presented "very substantial dangers of misleading the jury and confusing the issues," and would lead to a "mini-trial" that would "easily inflate the perceived importance of compliance and distract the jury from the central question before it." Id. at 921-22. The Fourth Circuit therefore affirmed the district court's exclusion of the 510(k) evidence on the grounds that it would be "substantially more prejudicial than probative." Id. at 922.

Likewise, in Eghnayem v. Boston Scientific Corp., the Eleventh Circuit found that the district court's exclusion of 510(k) evidence was not an abuse of discretion. 873 F.3d 1304, 1310-11 (11th Cir. 2017). In that case, the defendant Boston Scientific Corporation (BSC) claimed that the 510(k) evidence was relevant because the plaintiffs "based much of their case on the theory that BSC didn't perform sufficient safety testing." Id. at 1318. The circuit court, however, held that the admission of 510(k) evidence might have caused a "time-consuming mini-trial," noting that "the apparent significance of federal regulatory schemes very well might have misled the jury into thinking that general federal regulatory compliance, not state tort liability, was the core issue." Ibid. The court found that concerns of prejudice and confusion, therefore, "substantially outweighed the probative value of the evidence, which ... was low at best." Ibid. The court was not persuaded by BSC's argument that an appropriate jury instruction would shift the balance of prejudice and probative value sufficiently to render the district court's exclusion of the evidence an abuse of discretion. Id. at 1318-19.

***14** Conversely, the United States District Court of Arizona noted that a jury deciding a design defect claim under principles of negligence may consider whether a manufacturer "acted reasonably in choosing a particular product design." In re Bard IVC Filters Prods. Liab. Litig. (Booker), 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018) (quoting Banks v. ICI Ams., Inc., 450 S.E.2d 671, 673 (Ga. 1994)). The district court therefore held that a defendant's compliance with the 510(k) clearance process "may not render a manufacturer's design choice immune from liability, but it can be a 'piece of the evidentiary puzzle.' " Id. at 1048. The court determined that "evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, [was] nonetheless relevant to the reasonableness of Bard's conduct." Id. at 1047.

Having concluded that 510(k) evidence was relevant, the Booker court went on to discuss its Fed. R. Evid. 403 balancing analysis. Id. at 1048. Though the court understood the plaintiffs' concerns regarding the admission of 510(k) evidence -- that it may lead to juror confusion or devolve into a series of mini-trials -- it nonetheless determined that such concerns "can be adequately addressed without excluding relevant evidence to the detriment of [d]efendants." Id. at 1049. For example, the court stated that both sides would be permitted to tell the jury about the FDA's role in the oversight of medical device manufacturing and the details of 510(k) clearance "through appropriate expert testimony or other admissible evidence." Ibid. Further, the court explained that the defendants would not be permitted to argue that 510(k) clearance constituted FDA "approval," and that plaintiffs "certainly will be free to present evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence." Ibid. Moreover, the district court concluded that "any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process." Ibid.

The Booker court finally noted that "the absence of any evidence regarding the 510(k) process would run the risk of confusing the jury as well." Ibid. The court reasoned that, because "[m]any of the relevant events in this case occurred in the context of FDA 510(k) review," attempting to remove any reference to the 510(k) process "would risk creating a misleading, incomplete, and confusing picture for the jury." Ibid. Further, the court was satisfied that "efficient management of the evidence and adherence to the [c]ourt's time limits will avoid any risk of unnecessary or time-consuming mini-trials." Ibid.

C.

Here, at trial, plaintiffs' counsel repeatedly referred to Bard's failure to conduct clinical trials and studies prior to marketing the Avaulta Solo and Align TO devices as demonstrative of its unreasonableness. Indeed, Bard's failure to conduct clinical trials or studies before marketing the devices was central to plaintiffs' claims of Bard's negligence. It is clear from the record that plaintiffs' counsel exploited the pre-trial determination to exclude 510(k) evidence. As explained, plaintiffs' counsel referenced Bard's failure to conduct clinical trials countless times in his opening remarks, summation, and direct and cross-examinations of witnesses. Further, the trial court sua sponte added that the jury should consider "the extent to which Bard tested or studied the Avaulta Solo and/or the Align TO." This drew attention to both plaintiffs' claim of Bard's negligence in failing to do clinical trials, and Bard's inability to explain to the jury why it did not conduct clinical trials or studies.

***15** We agree with the Appellate Division that although plaintiffs' arguments were appropriate, it was unfair for the trial court not to allow Bard to explain in response that it received 510(k) clearance to market the devices without clinical studies or trials. Indeed, in making Bard's failure to conduct clinical trials or studies of the Align TO and Avaulta Solo devices a central theme of their case, plaintiffs "opened the door" to the admission of 510(k) evidence, notwithstanding the trial court's exclusion. State v. James, 144 N.J. 538 (1996) ("The doctrine of opening the door allows a party to elicit otherwise inadmissible evidence when the opposing party has made unfair prejudicial use of related evidence.").

Furthermore, we agree with the trial court and Appellate Division that 510(k) clearance is not an "applicable government standard" for purposes of the North Carolina Products Liability Act, which requires a jury to consider whether a design or formulation conformed to any applicable government standard in determining whether a manufacturer acted unreasonably. N.C. Gen. Stat. § 99B-6(b)(3). Rather, as the Appellate Division stated, the relevance and admissibility of 510(k) evidence falls within "the discretionary balancing-test ambit of Evidence Rules 401 and 403." Hrymoc, 467 N.J. Super. at 81.

We conclude that 510(k) evidence is generally inadmissible because the 510(k) clearance process solely determines substantial equivalency, and not safety and efficacy, and could therefore mislead the jury. However, in a products liability claim premised not only on principles of negligence, but particularly on the reasonableness of a manufacturer's conduct in not performing clinical trials or studies, evidence of 510(k) clearance has significant probative value under N.J.R.E. 401 that is not substantially outweighed by the risk of prejudice and potential juror confusion under N.J.R.E. 403. To use the Booker court's language, Bard's compliance with the 510(k) process is an important "piece of the evidentiary puzzle" in this case because plaintiffs opened the door by arguing that Bard acted unreasonably in failing to conduct clinical trials or studies. Booker, 289 F. Supp. 3d at 1048.

Though we share the Cisson court's concerns about the possibly misleading nature of 510(k) clearance evidence, we agree with the Booker court that a proper limiting instruction can cure any potential juror confusion in appropriate cases. Here, an appropriate limiting instruction explaining that consideration of 510(k) evidence is limited to the issue of Bard's failure to perform clinical trials or studies and including a brief statement that the 510(k) clearance process is a comparative analysis requiring only substantial equivalence would prevent Bard from asserting that 510(k) clearance is evidence of the devices' safety and efficacy.

As the Appellate Division noted, "[w]e should not underestimate the intelligence and conscientiousness of jurors." Hrymoc, 467 N.J. Super. at 79. We agree that "[i]t 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." Ibid. We are thus convinced that in this case, permeated by plaintiffs' claim that defendant acted unreasonably in failing to conduct clinical trials or studies, properly limited evidence that Bard received 510(k) clearance to market the Align TO and Avaulta Solo devices, guided by an appropriate limiting instruction, has significant probative value under N.J.R.E. 401 that is not substantially outweighed by N.J.R.E. 403 concerns.

Additionally, under the specific facts here, where plaintiffs emphasized that defendant acted unreasonably in failing to conduct clinical trials or studies, we share the Booker court's concerns that the omission of 510(k) evidence risks confusing and misleading the jury as well. On balance, there is less risk here in permitting the jury to hear evidence of 510(k) clearance, as long as it is accompanied by an appropriate limiting instruction.

***16** Therefore, because the trial court's refusal to allow Bard to explain its conduct unfairly prejudiced defendant in this case, we agree with the Appellate Division that the "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 unjust results, and was an abuse of discretion that deprived defendant of a fair trial. Id. at 80.

We disagree with the Appellate Division as to the method by which the trial court should determine the parameters of admissibility of 510(k) evidence. The issues before this Court were raised at trial by the parties on motions in limine. We believe that approach, rather than a pretrial Rule 104 hearing, is the proper procedure for resolution of the present evidentiary question -- admission of 510(k) evidence, limitations on its admission, and appropriate jury instructions. On remand, if plaintiffs again claim that defendant acted unreasonably in failing to conduct clinical trials or studies, the trial court will, at the hearing on the parties' motions in limine, fashion appropriate jury instructions conveying the limited use of 510(k) evidence -- to refute plaintiffs' claim that defendant acted unreasonably in failing to conduct clinical trials or studies.

Having determined that the Section 510(k) clearance evidence should have been admitted as to plaintiffs' substantive claim, we turn to the issue of punitive damages, which was tried under New Jersey law by agreement of counsel.

IV.

A.

Defendant claims that plaintiffs' punitive damages claims are barred by Section 5 of the PLA. The plain language of that provision and the nature of 510(k) clearance, however, defeat defendant's argument.

The PLA states in relevant part that

> [p]unitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration ... and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.
>
> [N.J.S.A. 2A:58C-5(c).]

510(k) clearance, however, "does not in any way denote official approval of the device" and, indeed, "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97. Approval of a medical device by the FDA evidences its safety and effectiveness; 510(k) clearance does not. See Lohr, 518 U.S. at - - - - - - - 493-94.

We therefore hold that the trial court and Appellate Division correctly found that Section 5 of the PLA does not bar plaintiffs' recovery of punitive damages, and we turn to the admissibility of 510(k) evidence in assessing punitive damages.

B.

Under New Jersey law, "[a]ny actions involving punitive damages shall, if requested by any defendant, be conducted in a bifurcated trial." N.J.S.A. 2A:15-5.13(a). "In the first stage of a bifurcated trial, the trier of fact shall determine liability for compensatory damages and the amount of compensatory damages or nominal damages. Evidence relevant only to the issues of punitive damages shall not be admissible in this stage." Id. at (b). "In the second stage of a bifurcated trial, the trier of fact shall determine if a defendant is liable for punitive damages." Id. at (d). Evidence relevant only to the issue of punitive damages that was inadmissible in the first stage is admissible in the second stage.

***17** New Jersey's PDA provides that punitive damages may be awarded if the plaintiff proves, by clear and convincing evidence, that the defendant acted with "actual malice" or "a wanton and willful disregard of persons who foreseeably might be harmed." N.J.S.A. 2A:15-5.12(a). The statute defines "[a]ctual malice" as "an intentional wrongdoing in the sense of an evil-minded act," and "[w]anton and willful disregard" as "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." N.J.S.A. 2A:15-5.10. "[A]ny degree of negligence[,] including gross negligence," is not enough to establish actual malice or wanton and willful disregard. N.J.S.A. 2A:15-5.12; see also Rivera v. Valley Hosp., Inc., 252 N.J. 1, 21-22 (2022). Rather, a defendant's conduct must amount to "a deliberate act or omission with knowledge of a high degree of probability of harm and reckless indifference to consequences." Berg v. Reaction Motors Div., Thiokol Chem. Corp., 37 N.J. 396, 414 (1962).

Considering a similar standard under Georgia law, the Fourth Circuit determined in Cisson that "the district court is entitled to put 510(k) evidence before the jury [as to punitive damages], but it is not obligated to do so." 810 F.3d at 922. In reaching that decision, the circuit court noted that "the decision to pursue 510(k) clearance was a choice to minimize the burden of compliance, potentially cutting in favor of punitive damages." Ibid.

We do not enter into such speculation because, as the Appellate Division pointed out, the PDA explicitly mandates that the trier of fact consider "all relevant evidence" in determining whether punitive damages are to be awarded. N.J.S.A. 2A:15-5.12(b). That includes the severity and duration of the conduct, and the defendant's "awareness [or] reckless disregard of the likelihood that the serious harm at issue would arise from [its] conduct," or, in other words, the defendant's state of mind. Ibid. When the 510(k) clearance process is pertinent to the defendant's state of mind in marketing a device and will refute the plaintiff's contention that the defendant acted willfully or wantonly, 510(k) evidence is admissible in determining whether punitive damages should be awarded. That may be true even when such evidence is deemed inadmissible in the first stage of trial.

In the present case, however, because we have determined that evidence of 510(k) clearance should have been admitted in the first stage of trial as relevant to the reasonableness of Bard's conduct in not performing clinical trials or studies, it would also be admissible in the second, punitive damages stage as relevant to whether Bard's failure to do clinical trials or studies amounted to "actual malice" or "a wanton and willful disregard of persons who foreseeably might be harmed." On retrial, should plaintiffs once again open the door to the admission of 510(k) evidence, the same approach would apply.

V.

The Appellate Division's judgment is affirmed as modified, and the case is remanded to the trial court for further proceedings consistent with this opinion.

CHIEF JUSTICE RABNER and JUSTICE PIERRE-LOUIS join in JUSTICE SOLOMON's opinion. JUDGE ACCURSO (temporarily assigned) filed a concurrence, in which JUSTICE WAINER APTER joins. JUSTICES PATTERSON and FASCIALE and JUDGE SABATINO (temporarily assigned) did not participate.

JUDGE ACCURSO (temporarily assigned), concurring.
I agree with the majority that Bard not being able to tell the jury it had 510(k) clearance from the United States Food

and Drug Administration (FDA) to market the Avaulta Solo and Align TO devices resulted in Bard not getting a fair trial here, and thus that the Appellate Division's decision should be affirmed. I write separately to express my view that 510(k) evidence for devices receiving FDA clearance under subparagraph II of 21 U.S.C. § 360c(f)(1)(A)(i) should ordinarily be admitted in both the liability and punitive damages phases of a products liability case whether tried under a negligence or strict liability theory.

***18** Class II medical devices receiving 510(k) clearance under subparagraph II, like the products at issue here, are devices the FDA has deemed "substantially equivalent to a type of device that was reclassified into Class ... II after May 28, 1976," the effective date of the MDA. Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 61 (App. Div. 2021) (quoting U.S. Food & Drug Admin., The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]; Guidance for Industry and Food and Drug Administration Staff 3 (510(k) Guidance Document)). Surgical mesh was reclassified as a Class II device in 1988, 21 C.F.R. § 878.3300, only after three different advisory panels convened by the FDA -- the General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel -- "review[ed] the device for safety and effectiveness," 21 C.F.R. § 860.84(c). Those panels determined surgical mesh had "an established history of safe and effective use," and that "premarket approval [was] not necessary to provide reasonable assurance of the safety and effectiveness of the device." General and Plastic Surgery Devices; General Provisions and Classification of 54 Devices, 47 Fed. Reg. 2810, 2817 (Jan. 19, 1982).

The FDA reviewed the studies on which the panels relied and agreed with their recommendations that surgical mesh be classified as a Class II device. Ibid. The agency determined "premarket approval [was] not necessary because of the extensive clinical usage of surgical mesh over a long period of time and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device." Ibid.

Contrast that with the Medtronic pacemaker lead cleared under 21 U.S.C. § 360c(f)(1)(A)(i)(I) and (ii), which the United States Supreme Court considered in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). The issue in Lohr was not admission of 510(k) evidence, but whether the MDA preempted the Lohrs' negligent design claim, among others, under Florida law. Id. at 474. Medtronic got its pacemaker lead cleared in 1982 by demonstrating it was "substantially equivalent" to a device in interstate commerce prior to the 1976 effective date of the Medical Device Amendments of 1976 (MDA), that is under subparagraph I of 21 U.S.C. § 360c(f)(1)(A)(i). Id. at 480.

Medtronic argued its pacemaker lead's substantial equivalence to a pre-1976 device "amount[ed] to a specific, federally enforceable design requirement that cannot be affected by state-law pressures such as those imposed on manufacturers subject to product liability suits." Id. at 492. The Supreme Court rejected Medtronic's argument out of hand, finding it "exaggerate[d] the importance of the § 510(k) process and ... the pacemaker's substantial equivalence to a grandfathered device." Id. at 492-93.

Writing for the Court, Justice Stevens echoed the circuit court's finding that "[t]he 510(k) process is focused on equivalence, not safety." Id. at 493 (alteration in original) (quoting Lohr v. Medtronic, Inc., 56 F.3d 1335, 1348 (11th Cir. 1995)). The Justice quoted a 1988 law review article critical of the FDA's implementation of the MDA, and particularly the agency's snail-like progress in moving Class III devices marketed before 1976 through the premarket approval (PMA) process -- resulting in the agency clearing huge numbers of devices through 510(k) without ever having regulated the pre-1976 devices to which they claimed substantial equivalence. Ibid. (citing Robert Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)). Justice Stevens quoted the writer's conclusion that

> substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.
>
> ***19** [Ibid. (quoting Adler, 43 Food Drug Cosm. L.J. at 516).]

Justice Stevens noted Medtronic's pacemaker lead, "as with the design of pre-1976 and other 'substantially equivalent' devices, has never been formally reviewed under the MDA for safety or efficacy." Ibid.

Unlike pacemaker leads, surgical mesh was not "grandfathered" under subparagraph I. It was "formally reviewed" by the FDA under the MDA for safety and efficacy in accordance with subparagraph II, resulting in it being regulated and reclassified in 1988 as a Class II device. That means the FDA has determined there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of surgical mesh, "including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title [section 510(k)]), recommendations, and other appropriate actions as the Secretary deems necessary." See 21 U.S.C. § 360c(a)(1)(B). The FDA issued guidance for the content of 510(k) premarket notification applications for surgical mesh in 1999, with which Bard claims to have complied in its submissions for the Avaulta Solo and the Align TO. U.S. Food & Drug Admin., Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (1999).

Thus, although it is certainly true that the 510(k) process under both subparagraphs I and II is a comparative one, there is a world of difference between comparing a device to a type the FDA has studied and classified "according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness," 510(k) Guidance Document, at 3 (footnote omitted), and comparing a device to one sold before 1976, the safety and efficacy of which the FDA has never evaluated.

Unfortunately, the weight of authority in the federal courts, most of it stemming from the rulings of one district court judge assigned to oversee the cases in the transvaginal mesh multidistrict litigation, Hrymoc, 467 N.J. Super. at 69, has failed to acknowledge the significant distinction between devices receiving approval under subparagraph I, as the pacemaker lead in Lohr, and those receiving approval under subparagraph II, as the Avaulta Solo and Align TO devices at issue here. See, e.g., Eghnayem v. Boston Sci. Corp., 873 F.3d 1304, 1317-19, 1318 n.3 (11th Cir. 2017) (affirming the inadmissibility of 510(k) clearance of the defendant's transvaginal mesh device and refusing to consider, because it was not raised below, the defendant's argument the FDA deemed its mesh "substantially equivalent to a post-1976 Class II device ... as opposed to a pre-1976 Class III device," thereby distinguishing the case from Lohr and Riegel v. Medtronic, Inc., 552 U.S. 312, 322-23 (2008) (following Lohr)).

Falling back on Lohr's pronouncement that "[t]he 510(k) process is focused on equivalence, not safety," 518 U.S. at 493 (alteration in original) (quoting Lohr, 56 F.3d at 1348), the entire 510(k) process, at least for surgical mesh, appears to have been largely discredited in the federal courts based on the "grandfather" provision in subparagraph I, permitting certain devices sold before 1976, and devices determined to be substantially equivalent to those pre-1976 devices, to be cleared for sale through 510(k) until the FDA eventually evaluates them for safety and effectiveness. See, e.g., In re C.R. Bard, Inc. (Cisson), 810 F.3d 913, 919-22 (4th Cir. 2016).

***20** That has led to trial courts undervaluing, or indeed entirely discounting, the probative value of 510(k) evidence for devices the FDA has evaluated and cleared under subparagraph II and overstating the potential for prejudice, confusion, and "mini-trials" over the meaning and significance of the 510(k) evidence, resulting in the decidedly tilted playing field on which this case was tried. Appellate courts by and large have not corrected the problem, relying on the considerable discretion trial judges enjoy in the admission of evidence, see, e.g., Hisenaj v. Kuehner, 194 N.J. 6, 25 (2008), instead of on the more robust standard of review appellate courts generally employ when a judge admits or excludes evidence based on the misinterpretation of a statute such as 21 U.S.C. § 360c(f)(1)(A)(i), see, e.g., Alves v. Rosenberg, 400 N.J. Super. 553, 562-63 (App. Div. 2008).

Once a court has determined the 510(k) clearance process "operate[s] to exempt devices from rigorous safety review procedures," Cisson, 810 F.3d at 920, and thus is not probative of a device's safety, or only slightly so, the outcome of the N.J.R.E. 403 balancing test -- that admission of 510(k) evidence is more trouble than it's worth -- follows logically. See, e.g., id. at 922 (noting 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," and thus the trial court did not abuse its discretion in finding "that allowing the 510(k) evidence in on the question of design defect would be substantially more prejudicial than probative"); see also State v. Medina, 201 N.J. Super. 565, 580 (App. Div. 1985) ("[T]he more attenuated and the less probative the evidence, the more appropriate it is for a judge to exclude it ....").

As earlier noted, 510(k) clearance under subparagraph II is based on comparing a new medical device to a predicate device instead of requiring an independent demonstration of the new device's safety and effectiveness in a PMA process. But the FDA's decision to clear a Class II device for sale under subparagraph II or approve a Class III device for sale in each case reflects the agency's "determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness' " of the device. 510(k) Guidance Document, at 7 (footnote omitted). Thus, it is inaccurate to say that 510(k) clearance under subparagraph II is not a determination going to safety and effectiveness; it is explicitly a determination about the device's safety and effectiveness, albeit one less rigorous and device-specific than premarket approval, based on the FDA's determination that premarket approval was not necessary to give "reasonable assurance" of the Class II device's "safety and effectiveness."

The majority correctly notes that 510(k) evidence under subparagraph II is not FDA approval that the device has been proven to be "safe and effective." Indeed, the FDA regulations make that clear and provide that "[a]ny representation that creates an impression of official approval of a device" receiving 510(k) clearance "is misleading and constitutes misbranding." 21 C.F.R. § 807.97. That does not mean, however, that 510(k) subparagraph II evidence should generally be omitted from a products liability trial.

It was Congress's choice in the MDA and The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511, to direct the FDA to classify all commercially marketed medical devices "[f]rom bedpans to brain scans," Lohr, 518 U.S. at 476 (alteration in original) (quoting Staff of H.R. Comm. on Energy & Com., 98th Cong., Medical Device Regulation: The FDA's Neglected Child 1 (Comm. Print 1983)), into three regulatory control categories, thereby electing to rely on "substantial equivalence" to regulate the safety and effectiveness of the vast majority of medical devices.[1] Indeed, the Commissioner of the FDA commented in 2018 that "Congress's creation of the 510(k) process was a paradigm shift from the FDA's regulation of drugs, ... recogniz[ing] the distinct challenges of regulating such a broad, diverse group of medical products." U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health (Nov. 26, 2018).

***21** The Commissioner explained, "[t]he 510(k) process allows the FDA to recognize that medical devices exist across a continuum of complexity and risk and that the scope of premarket review should reflect this risk continuum." Ibid. Our courts should likewise recognize Congress and the FDA's approach to regulating medical devices "across a continuum of complexity and risk" in the 510(k) process by routinely admitting 510(k) evidence for devices receiving FDA clearance under subparagraph II.[2] It is simply one fact among many of which the jury should be apprised in considering a device's safety and the manufacturer's conduct in bringing it to market. The devices could not lawfully be offered for sale without it.

510(k) clearance under subparagraph II reflects the FDA's "determination that a reasonable assurance of safety and effectiveness exists for the predicate device," 510(k) Guidance Document, at 7; that the device being compared "has the same technological characteristics as the predicate device," or that a "significant change in the materials, design ... or other features of the device" does not raise different questions of safety and effectiveness; and "that the device is as safe and effective as a legally marketed device," ibid. (quoting 21 U.S.C. § 360c(i)). 510(k) evidence under subparagraph II is therefore relevant to and probative of the safety and effectiveness of Bard's design and sale of the Avaulta Solo and Align TO devices. The evidence should be routinely admitted in products cases involving medical devices, whether the theory is strict liability or negligence.[3]

The concerns expressed by plaintiffs about prejudice and confusion of the jury by admitting 510(k) evidence are, in my view, overblown. Exclusion of the evidence can as easily result in unfair advantage, as it did here. Limiting instructions, a routine feature in complex trials, see Bardis v. First Trenton Ins. Co., 199 N.J. 265, 283-84 (2009) (Albin, J., concurring), can "restrict the evidence to its proper scope," N.J.R.E. 105; see State v. Cole, 229 N.J. 430, 455-56 (2017) (noting the utility of a limiting instruction to "provide important guidance" to a jury).[4]

The Appellate Division noted a useful analogy to the way we instruct jurors about the impact of FDA "approved or prescribed" warnings on a failure to warn claim, Model Civil Jury Charge 5.40D-4. Hrymoc, 467 N.J. Super. at 77 n.19. That charge instructs jurors that "[c]ompliance 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." Model Jury Charges (Civil), 5.40D-4, "Design Defects -- Defenses" (rev. Oct. 2001). The charge explicitly instructs

jurors that they "may find that the warnings or instructions were inadequate despite the F.D.A. approval." Ibid.

***22** Model Civil Jury Charge 5.40D-4 could be readily adapted to instruct jurors on how to think about 510(k) evidence. We trust and rely on jurors every day to follow the court's instructions in cases having enormous consequences to the parties. State v. Burns, 192 N.J. 312, 335 (2007) (noting jurors following the court's instructions is "[o]ne of the foundations of our jury system"). I don't see any reason why the jurors charged with deciding these complex medical device cases would be unable to grasp and properly apply 510(k) evidence in accordance with the trial court's instructions.

The keystone of our Rules of Evidence is that "all evidence relevant to the issues in controversy [should] be admitted, unless its admission would transgress some paramount policy of society and the law." Reinhart v. E.I. Dupont de Nemours, 147 N.J. 156, 165 (1996) (alteration in original) (quoting Reilley v. Keswani, 137 N.J. Super. 553, 555 (App. Div. 1975)). I discern no law or policy to justify the general inadmissibility of FDA 510(k) clearance under subparagraph II in a products liability case challenging the safety of a medical device. As this Court has declared, "[w]e would ill-serve the cause of truth and justice if we were to exclude relevant and credible evidence only because it might help one side and adversely affect the other." Stigliano by Stigliano v. Connaught Labs., Inc., 140 N.J. 305, 317 (1995).

Medical device liability cases are enormously complex. They involve a phalanx of experts offering opinions on a variety of arcane issues and are ordinarily litigated by very accomplished lawyers, who assiduously press every lawful advantage for their respective clients in trials that stretch weeks. I agree with the Booker court that a manufacturer's compliance with the 510(k) process, "while certainly not dispositive, is nonetheless relevant to the reasonableness" of the manufacturer's design and sale of these devices and simply one part "of the evidentiary puzzle" in these complicated cases. In re Bard IVC Filters Prods. Liab. Litig. (Booker), 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018) (citation omitted). And I echo the Appellate Division in expressing confidence that jurors will readily grasp the distinction between premarket approval and 510(k) clearance and will faithfully comply with any limiting instructions the trial court deems necessary.

Finally, I note the majority's clear direction that 510(k) evidence be admitted in the punitive damages phase under the PDA (while not posing an issue in this case because the evidence will also likely be admitted on liability) may present a problem in cases tried on a strict liability theory under New Jersey law if 510(k) evidence is not admitted in the liability phase. Although "strict products liability proofs center on the product" and "punitive damages proofs center on a defendant's conduct," Fischer v. Johns-Manville Corp., 103 N.J. 643, 655 (1986), 510(k) evidence under subparagraph II is relevant to both the manufacturer's design of the product and its state of mind in offering it for sale, see N.J.S.A. 2A:15-5.12(a); Hrymoc, 467 N.J. Super. at 77. Thus, jurors asked to consider a defendant's compliance with the 510(k) process in offering a medical device for sale in the punitive damages phase may well question why they didn't hear that evidence in deciding liability.

Because I do not believe there is a good answer to that question, I would hold that 510(k) evidence for devices receiving FDA clearance under subparagraph II of 21 U.S.C. § 360c(f)(1)(A)(i) should ordinarily be admitted in both the liability and punitive damages phases of a products case whether tried under a negligence or strict liability theory. See Old Chief v. United States, 519 U.S. 172, 188 & n.9 (1997) (discussing juror expectations of proper proofs and quoting Bruce A. Green, "The Whole Truth?": How Rules of Evidence Make Lawyers Deceitful, 25 Loy. L.A. L. Rev. 699, 703 (1992) ("[E]videntiary rules ... predicated in large measure on the law's distrust of juries [can] have the unintended, and perhaps ironic, result of encouraging the jury's distrust of lawyers." (alterations and omission in original))).

All Citations

--- A.3d ----, 2023 WL 4714042

Footnotes

1 The present case came before the Court as one of two appeals, consolidated solely for purposes of the Appellate Division opinion. The parties in the Hrymoc v. Ethicon case have since settled and are no longer parties to this matter.

2 The named defendants include C.R. Bard, Inc., Bard Medical Division, a Division of C.R. Bard, Inc., and Bard Urological Division, a Division of Bard Medical Division. We refer to defendants collectively as "Bard" or "defendant."

3 The case was later moved to Bergen County as part of a multicounty grouping of lawsuits ("MCL") involving pelvic mesh, specifically venued before the Law Division in Bergen County.

4 The extent to which a design or formulation conforms to any applicable government standard is relevant in determining whether a manufacturer acted unreasonably under the North Carolina products liability statute. N.C. Gen. Stat. § 99B-6(b)(3).

5 Class III devices on the market before 1976 are not subject to premarket approval. 21 U.S.C. § 360e(b)(1)(A).

6 In 2016, the FDA reclassified surgical mesh intended for POP repair as a Class III device requiring PMA. 21 C.F.R. § 884.5980.

7 The predicate device for the Avaulta Solo was the "Avaulta Support System," which was cleared in 2007. The predicate device for the Align TO was the "Align Urethral Support System," which was also cleared in 2007.

1 According to one study, "devices with 510(k) clearance comprise[d] 99% of the devices to reach the market" in the ten-year period between January 1, 2008, and December 31, 2017. Jonathan R. Dubin et al., Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017 (2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779577.

2 Of course the admission of evidence in any case is highly dependent on the facts presented, Rodriguez v. Wal-Mart Stores, Inc., 237 N.J. 36, 58 (2019), and there may be situations where introduction of 510(k) subparagraph II evidence would be substantially outweighed by the risk of undue prejudice under an N.J.R.E. 403 balancing test. My view that 510(k) subparagraph II evidence should be routinely admitted in medical device cases acknowledges it may not always be appropriate.

3 Although I might be inclined to find that 510(k) evidence is an "applicable government standard," thus compelling its admission under Section 99B-6(b) of the North Carolina Products Liability law, N.C. Gen. Stat. § 99B-6, the courts of North Carolina are much better suited to resolve this question of North Carolina law.

4 I do not read the majority's opinion to forbid courts from holding an N.J.R.E. 104 hearing if the court admits the 510(k) evidence in limine. At the hearing, the court could "impose limitations on ... 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." Hrymoc, 467 N.J. Super. at 78.

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