15-P-633 Appeals Court

DIANE ALBRIGHT vs. BOSTON SCIENTIFIC CORPORATION.[1]

No. 15-P-633.

Middlesex. April 15, 2016. - September 13, 2016.

Present: Cypher, Katzmann, & Massing, JJ.

Conflict of Laws. Negligence, Defective product, Design, Adequacy of warning, Duty to warn. Evidence, Relevancy and materiality, Rebuttal, Bias. Error, Harmless. Practice, Civil, Instructions to jury.

Civil action commenced in the Superior Court Department on March 8, 2012.

The case was tried before Diane M. Kottmyer, J.

Jonathan D. Orent (Dennis A. Costigan with him) for the plaintiff.

Robert T. Adams, of Missouri (Susan M. Donnelly Murphy with him) for the defendant.

KATZMANN, J. The plaintiff Diane Albright, an Ohio resident, brought this action in the Superior Court against

[1] Albright's amended complaint asserts claims against John Doe Corporations 1-50. The judgment entered in the Superior Court dismissed the action against the John Doe defendants as well as Boston Scientific Corporation.

defendant Boston Scientific Corporation (BSC), a Massachusetts-based company, seeking damages for injuries that she sustained after having BSC's "Pinnacle Pelvic Floor Repair" kit (Pinnacle device) surgically implanted to treat her pelvic organ prolapse (POP) condition.[2] BSC designed, manufactured, and marketed the Pinnacle device and sold it to the Ohio hospital where Albright's surgery took place. After a three-week trial, a jury found for BSC on Albright's claims of defective design and inadequate warning.

On appeal, Albright challenges the exclusion of the medical application caution (caution) contained within the 2004 material safety data sheet (MSDS)[3] that had been provided to BSC by its supplier of the polypropylene material used to fabricate the mesh in the Pinnacle device. Albright offered the caution for the limited purpose of showing notice and knowledge on the part of BSC. Albright also claims error from the exclusion of two letters that the United States Food and Drug Administration (FDA) sent to BSC in 2012.[4] We conclude that, in the context of the case as it unfolded at trial, it was prejudicial error to

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[2] POP occurs when a pelvic organ drops or bulges (i.e., prolapses) into the vagina. See Stedman's Medical Dictionary 1573 (28th ed. 2006).

[3] A 2007 MSDS that contained an identical caution was excluded as well.

[4] Albright also assigns as error the judge's refusal to give certain proposed jury instructions, discussed infra.

exclude the proffered caution and FDA letters. The judgment in favor of BSC shall therefore be vacated and the case remanded to the Superior Court for a new trial.

Background. There was evidence from which the jury could have found the following.[5]

1. Surgeries. In 2008, Albright had surgery to treat POP symptoms involving her bladder. Dr. Jay Meyer performed a procedure[6] that did not involve the implantation of surgical mesh. Less than twelve months later, Albright experienced a recurrence of the bulging sensation in her pelvic area. During a follow-up visit with Dr. Meyer, Albright reported feeling "something give" in her pelvis after lifting a heavy table. Dr. Meyer advised Albright that if she could tolerate this sensation of a bulge or pressure in her pelvic area, surgery could be avoided. Albright was not able to do so; she met again with Dr. Meyer, voicing a desire to have "something done."

Dr. Meyer informed Albright of an option to permanently implant a mesh device in her pelvic cavity to shore up weakened tissue. Albright agreed.[7] With the aid of an experienced

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[5] We reserve mention of certain evidence for our discussion of Albright's claims of error.

[6] A hysterectomy with anterior-posterior repair of the vaginal walls using native tissue.

[7] Dr. Meyer, who had not previously used the Pinnacle device, suggested that the procedure be performed by a

colleague, Dr. Meyer performed the implant procedure at Mary Rutan Hospital, located in Bellefontaine, Ohio, on March 9, 2010. Mary Rutan Hospital had purchased the Pinnacle device from BSC on May 15, 2009. At the time, Dr. Meyer was pleased with the surgical outcome, commenting favorably that the Pinnacle device worked "as advertised."

BSC marketed the Pinnacle device as a safe implant for use in the treatment of POP. The Pinnacle device is intended to shore up and repair tissue that holds and supports pelvic organs in place. The FDA had cleared the device for sale in the United States pursuant to the agency's § 510(k) process.[8]

2. Postsurgery complications. Within six months, Albright experienced pain and discomfort when urinating and other "hard-to-describe" pain in her pelvic area. On examining Albright in September, 2011, Dr. Meyer found no indication of mesh erosion.

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specialist affiliated with the Ohio State University (at Columbus) medical center, Dr. Andrew Hundley. Albright asked Dr. Meyer to do the surgery, citing concerns about traveling to Columbus, which was some distance from her home.

[8] The FDA's review of a medical device for substantial equivalence is known as the § 510(k) process. Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008). A new medical device need not undergo a rigorous premarket approval process if the FDA (as it did here) finds the new device is substantially equivalent to another device already on the market that is exempt from premarket approval. Ibid. Devices that enter the market through the § 510(k) process have not been formally reviewed by the FDA for safety or efficacy. Id. at 323.

He suspected that Albright might have interstitial cystitis.[9] No diagnosis was made linking Albright's symptoms and complications to the mesh. Similar findings were made by Dr. Andrew Hundley during visits with Albright in 2011 and 2012, and by Dr. Maurice Chung, a gynecologist who examined Albright in 2012 and 2014.

Albright was also examined by Dr. Niall Galloway, a urologist and gynecologist affiliated with Emory University, and Dr. John Steege, a professor in the department of gynecology and obstetrics at the University of North Carolina. Drs. Galloway and Steege concluded that Albright was suffering from painful bladder syndrome and other complications due to the erosion and degradation of the mesh in her body.[10]

3. Trial proceedings. Albright alleged that the Pinnacle device was defective due to a flawed design that failed to guard against the foreseeable risks of harm stemming from the mesh design. She also claimed that BSC had failed to adequately warn Dr. Meyer of the foreseeable risks that the Pinnacle device posed to her. BSC maintained that the Pinnacle device was safe for implantation inside Albright's body to treat POP. The jury never reached the disputed factual question whether the Pinnacle

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[9] More than one expert testified that the terms "interstitial cystitis" and "painful bladder syndrome" are often "used interchangeably" in the medical community.

[10] At trial, Drs. Galloway and Steege testified as experts on behalf of Albright.

device caused Albright's injuries because of their finding that Albright had not shown by a preponderance of the evidence that the device was "defective" under Ohio law.

a. Design. Compared to other transvaginal surgical mesh devices on the market in 2009 for the treatment of POP, the Pinnacle device called for a sizable amount of dense mesh with small "pores" (i.e., openings in the mesh). The design premise for the Pinnacle device is that when implanted in the body, its mesh will promote tissue growth through the mesh pores, and, by doing so, this new growth will anchor and stabilize the device in the patient's body. BSC, however, did not conduct clinical tests to assess mesh shrinkage or degradation in the body.

Experts for both sides addressed the scientific properties of BSC's polypropylene mesh. Janice Connor, the clinical programs director of BSC's urology and women's health division, testified that her review of scientific literature confirmed that mesh devices, like the Pinnacle device, were a safe and effective medical option for women, especially when compared to native tissue repair surgeries which resulted in a recurrence rate of thirty to seventy percent. Doreen Rao, an engineer in BSC's urology group, stated that polypropylene is "inert" and does not undergo changes once it is implanted in the human

body.[11] On the other hand, Albright's experts focused on "oxidation," the response of tissue cells to the presence of a foreign body, in this case the implanted Pinnacle device.

Scott Guelcher, a chemical engineering professor and polymer chemist, explained what happens when tissue cells react to polypropylene material. Guelcher was among the first to discover that polypropylene materials, "which were normally considered stable," did, in fact, degrade. Guelcher described this reactive process, testifying that human cells produce, or secrete, reactive oxygen species, which "settle on and attach to" the implant. The response of human cells to implanted material is a "surface-driven" effect. The cell-generated reactive oxygen species continuously break down and degrade the polypropylene mesh until it is destroyed or removed. This means that the oxidation process results in a "bigger problem" where there is more polypropylene surface, as is the case with the Pinnacle device, which uses relatively more mesh than other POP mesh devices. Guelcher added that polypropylene is one of the

[11] Rao was also the "core team leader" for BSC's Polyform mesh kit, which contained the same mesh used in the Pinnacle device. On occasion, Rao had to address inquiries from physicians (and others) about mesh shrinkage. In one such instance, a project manager for the BSC urology group suggested that BSC "piggyback" on the shrinkage data of a mesh made from a different manufacturer (Gynemesh) "until we can prove otherwise." Again, BSC did not perform clinical tests to assess shrinkage of the mesh in the human body.

most easily oxidized materials, a fact that, in his view, is important to know for biomaterial design purposes.

Dr. Thomas Barker, a professor of biomedical engineering at the university level, also testified for Albright. Dr. Barker described a further nuance to the chemical reactive process. Dr. Barker testified that, upon implantation of the mesh device, human cells populate "dense portions" of the mesh (i.e., where its fibers are in close proximity to one another). Tissue cells are activated to "apply force" and to pull on the mesh material. As a result, Dr. Barker testified, tissue then grows <u>across</u> mesh fibers ("fibrotic bridging"), rather than <u>inside</u> mesh pores, the latter of which is what the Pinnacle device is intended to promote. This fibrotic bridging process may form a scar around the implant, which can cause pain to the patient. Dr. Barker opined that there was a "mechanical mismatch" between the Pinnacle device and the anatomical space (the pelvic cavity) where the device is implanted. As opposed to hernia mesh on the abdominal wall, the implanted Pinnacle mesh has two millimeters of soft tissue to protect it from extruding into the patient's vaginal cavity (a complication about which Albright complains). This mismatch can lead to foreseeable biomedical risks, including mesh contracture, mesh shrinkage, and abrasions. Dr. Donald Ostergard, another of Albright's expert witnesses, testified at trial that the Pinnacle device was not appropriate

for its intended use to treat POP because of the volume, weight, and pore size of its mesh. Albright's experts -- Guelcher, Barker, and Ostergard -- testified that, prior to marketing the Pinnacle device, BSC ignored or otherwise failed to account for the oxidation process as it affects the Pinnacle mesh when implanted to treat POP.

b. Warning and directions for use. Albright presented expert evidence that BSC had failed to warn Dr. Meyer of the risk that the mesh's density and volume posed in terms of the frequency, permanence, and potential severity of complications caused by degradation of the mesh inside the body. This included painful bladder syndrome and pudendal neuralgia, as well as the harm that would follow from a procedure to remove some or all of the mesh to address such complications. BSC sought to show that the potential or anticipated risks associated with the Pinnacle device were fully disclosed in its directions for use (DFU). The DFU for the Pinnacle device identified incontinence, dyspareunia, erosion, extrusion, and contracture, among other risks. BSC's expert, Dr. Matthew Davies, testified that BSC had adequately warned Dr. Meyer of the risks in using its device.

Discussion. 1. Ohio products liability law. Based on accepted conflict of laws principles, the judge ruled that Albright's substantive claims were controlled by Ohio law and

that evidentiary issues were governed by the law of Massachusetts, the forum State. See Hodas v. Morin, 442 Mass. 544, 549-550 (2004); Feeney v. Dell, Inc., 454 Mass. 192, 206 (2009); Fire Ins. Exch. v. Pring-Wilson, 778 F. Supp. 2d 116, 125 (D. Mass. 2011).[12] We therefore provide a brief overview of Ohio products liability law.

It is a deeply rooted principle in Ohio that a manufacturer is liable for foreseeable harm stemming from a product defect that could have been avoided or mitigated by exercising reasonable care.[13] This principle is at the core of the Ohio Products Liability Act (OPLA), a comprehensive and detailed statutory plan that employs negligence concepts, such as foreseeable risk of harm and reasonable care. See Ohio Rev.

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[12] See generally Restatement (Second) of Conflict of Laws § 145 (1971) ("The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties . . .").

[13] In 1908, the Ohio Supreme Court explained the common-law principle as follows: "[The] defendant in an action for negligence can be held to respond in damages only for the immediate and proximate result of the negligent act complained of, and in determining what is direct or proximate cause, the rule requires that the injury sustained shall be the natural and probable consequence of the negligence alleged; that is, such consequence as under the surrounding circumstances of the particular case might, and should have been foreseen or anticipated by the wrongdoer as likely to follow his negligent act." Miller v. Baltimore & Ohio S.W. R.R., 78 Ohio St. 309, 325 (1908), overruled on other grounds by Schultz v. Barbeton Glass Co., 4 Ohio St. 3d 131 (1983). See Sutowski v. Eli Lilly & Co., 82 Ohio St. 3d 347, 351 (1998).

Code Ann. §§ 2307.71-2307.80 (West 2004 & Thomson Reuters Supp. 2016).[14] The term, "foreseeable risk," as used in the OPLA, defines the scope of a manufacturer's duty of care, which, simply put, is to guard against a known risk of harm or risks that the manufacturer "should recognize while exercising" reasonable care. Ohio Rev. Code Ann. § 2307.71(A)(6)(b) (Supp. 2016).[15] See Ohio Rev. Code Ann. § 2307.75 (Supp. 2016) (design defect). See also Ohio Rev. Code Ann. § 2307.76 (2004) (warning defect).

While a manufacturer is not an insurer or guarantor of the safety of its products, it is nonetheless not free to ignore recognizable, or reasonably foreseeable, risks to consumers who use its products as intended. Sutowski v. Eli Lilly & Co., 82 Ohio St. 3d 347, 352 (1998). See Briney v. Sears, Roebuck & Co., 782 F.2d 585, 587 (6th Cir. 1986) (stating that product need not be "foolproof"). With this backdrop, we turn to the specific statutory claims in question.

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[14] As amended, the OPLA abrogates all common-law product liability causes of action that accrue after April 7, 2005. See Doty v. Fellhauer Elec., Inc., 175 Ohio App. 3d 681, 686 (2008).

[15] Section 2307.71(A)(6)(b)(i)-(ii) specifies that a manufacturer should exercise both "[t]he attention, perception, memory, knowledge, and intelligence that a reasonable manufacturer should possess" and "[a]ny superior attention, perception, memory, knowledge, or intelligence that the manufacturer in question possesses."

a. Design claim. For the design claim, Albright had the burden to show, by a preponderance of the evidence, that when the Pinnacle device "left the control of [BSC], the foreseeable risks associated with its design . . . exceeded the benefits." Ohio Rev. Code Ann. § 2307.75(A). See Welch Sand & Gravel, Inc. v. O & K Trojan, Inc., 107 Ohio App. 3d 218, 224 (1995). Foreseeability "usually depends on the defendant's knowledge." Menifee v. Ohio Welding Prod., Inc., 15 Ohio St. 3d 75, 77 (1984). The jury must principally focus on a given product's features so as to understand the product manufacturer's conscious design choices. OPLA sets out a nonexhaustive list of factors that a jury may consider in determining whether a design defect exists. A jury may look to factors such as: (1) the "nature and magnitude" of the risks connected with the design in light of the product's "intended" use; (2) the "likely awareness of product users . . . of those risks"; and (3) the "likelihood" that the chosen design "would cause harm" in light of the product's intended use. Ohio Rev. Code Ann. § 2307.75(B)(1)-(3). The first and third factors are instructive here.

The jury were required to closely scrutinize whether the mesh design for the Pinnacle device was suitable or appropriate for its intended use as a surgical implant to treat bladder POP. Suitability demands close attention to the actual area in the body where the Pinnacle mesh will remain implanted for many

years, not other areas of a patient's body (e.g., the abdomen) where surgical mesh has historically been used with positive results. Albright was also required to present evidence of a practical and feasible alternative mesh design. See Ohio Rev. Code Ann. § 2307.75(F).[16]

b. Warning claim. For the warning claim, Albright bore the burden to show that BSC failed to adequately inform Dr. Meyer of foreseeable risks associated with the Pinnacle device. See Seley v. G.D. Searle & Co., 67 Ohio St. 2d 192, 202-203 (1981) (discussing learned intermediary doctrine); In re Meridia Prod. Liab. Litigation, 328 F. Supp. 2d 791, 811-812 (N.D. Ohio 2004) (listing factors relevant to whether warning for prescription drug is adequate).[17] "Merely mentioning a possible injury or adverse effect is not necessarily adequate." Id. at 812.

Section 2307.76, which codifies a cause of action for inadequate warning, focuses the trier of fact on many of the

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[16] Albright did so, presenting evidence of a lightweight and smaller mesh containing larger pores, a design that was then available on the market.

[17] The relevant factors include, but are not limited to, the following: whether the warning adequately indicates the scope of the danger; whether the warning reasonably communicates the extent or seriousness of the harm that could result from misuse of the product; whether the physical aspects of the warning adequately alert a reasonably prudent person to the danger; and whether the means to convey the warning are adequate in the given circumstances. In re Meridia Prod. Liab. Litigation, supra at 812.

same issues applicable to a product design claim. A plaintiff must prove that the defendant manufacturer "knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the [plaintiff] seeks . . . compensatory damages," and that "[t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, [both] in light of the likelihood that the product would cause harm of the type for which the [plaintiff] seeks . . . compensatory damages and in light of the likely seriousness of that harm." Ohio Rev. Code Ann. § 2307.76(A)(1)(a)-(b). The OPLA, for both design and warning claims, uses the negligence concepts of reasonable care and foreseeable risk of harm[18] to guide a jury in determining liability. "A warning is adequate if it reasonably discloses all inherent risks, and if the product is safe when used as directed." Phan v. Presrite Corp., 100 Ohio App. 3d 195, 200 (1994). See Seley v. G.D. Searle & Co., 67 Ohio St. 2d at 197-

[18] For an illuminating discussion as to foreseeability generally, see Heng Or v. Edwards, 62 Mass. App. Ct. 475, 486 (2004), where Justice Kaplan described the jury's role in a negligence case: "[T]he jury tries to reproduce the picture of what a reasonable person, as of the moment before the negligent act, would have foreseen as the likely harmful consequences of that act; alongside this picture the jury is to set the picture of the actual happening, and then to observe, in a general sense, how far the harm in fact experienced resembles any of the harms reasonably to have been foreseen" (footnote omitted).

198; Crislip v. TCH Liquidating Co., 52 Ohio St. 3d 251, 255 (1990). This fact-based issue was sharply contested at trial.

2. Evidentiary errors. a. MSDS caution. Albright claims prejudicial error from the exclusion of the caution on BSC's polypropylene supplier's MSDS. The MSDS contained the following "MEDICAL APPLICATION CAUTION":

> "Do not use this [polypropylene] material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."

Albright offered the caution to show notice to BSC of a risk in using polypropylene for its implant device. The judge excluded the caution on the grounds that Albright had not established its scientific basis and that the record was inconclusive as to the rationale of the supplier for including the caution on the MSDS.

In Massachusetts, trial judges have wide discretion in ruling on the admissibility of evidence, and the judge's exercise of discretion is afforded much deference. See, e.g., Dahms v. Cognex Corp., 455 Mass. 190, 198 (2009). A balancing principle, however, is that "relevant evidence should be admitted unless there is a quite satisfactory reason for excluding it." DeJesus v. Yogel, 404 Mass. 44, 47 (1989), quoting from Crowe v. Ward, 363 Mass. 85, 88-89 (1973).

We conclude that the MSDS caution was relevant, material evidence admissible for the limited purpose of showing that BSC,

which had received the MSDS well before 2009, had notice or knowledge of the content of the caution. See McNamara v. Honeyman, 406 Mass. 43, 55 (1989) (statement admissible to show that medical staff was alerted to possibility that patient was suicidal); Pardo v. General Hosp. Corp., 446 Mass. 1, 18 (2006) (memorandum admissible to show notice and knowledge).

When considered solely for the purpose of demonstrating notice or the extent of BSC's knowledge, the caution was not hearsay. See Mass. G. Evid. § 801(c) note (2016) (statement only hearsay if offered in evidence to prove truth of matter asserted as opposed to, inter alia, notice or effect of statement on hearer). This is a long-standing rule in this Commonwealth. See McNamara v. Honeyman, supra; Pardo v. General Hosp. Corp., supra.

Though the trial judge was understandably concerned about the scientific basis of the caution,[19] here, where the caution

[19] See, e.g., Moore v. Ashland Chem. Inc., 151 F.3d 269, 278 (5th Cir. 1998) (holding that MSDS had limited scientific value when it was not known what tests were conducted in generating MSDS); Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1209 (8th Cir. 2000) (holding that MSDS indicating that breathing product dust may irritate nose and throat and aggravate respiratory diseases was not sufficient basis for expert opinion where expert did not rely upon MSDS and "nothing in the record demonstrate[d] what scientific tests or information [the manufacturer] used to generate its MSDS"); Johnson v. Arkema, Inc., 685 F.3d 452, 462-463 (5th Cir. 2012) (concluding that Federal District Court did not abuse its discretion in disregarding MSDS where proponent failed to come forth with any scientific data to support its warning).

was not offered to establish causation or as the basis of an expert opinion but solely for the notice effect it had, or should have had on BSC, the absence of a scientific foundation for the MSDS caution is not a bar to admission. See In re C.R. Bard, Inc., 810 F.3d 913, 923, 925-926 (4th Cir. 2016) (affirming Federal District Court's conclusion in suit for design defect and failure to warn that MSDS from polypropylene manufacturer was admissible as nonhearsay for limited purpose of showing that statement was made and that defendant was aware of it). Cf. Sanchez v. Boston Scientific Corp., 38 F. Supp. 3d 727, 743 (S.D. W. Va. 2014), quoting from Cal. Civ. Code § 3294(c) ("A reasonable jury could find that by ignoring a warning on the MSDS and failing to conduct clinical testing, BSC's actions were 'despicable conduct' with willful and conscious disregard of the safety of consumers").

As to the materiality of the caution, it is enough to say that the crux of this case has to do with BSC's "knowledge" (as of May 15, 2009) of the foreseeable risks connected with its Pinnacle device. This evidentiary link is obvious when the caution is considered in the context of disputed factual issues under the OPLA. The jury might have considered the caution's implications for BSC under both § 2307.75(A) to determine "foreseeable risks" (if any) tied to the Pinnacle design and § 2307.76(A)(1) to determine the warning that a prudent

manufacturer exercising reasonable care would have provided concerning a risk of harm to Pinnacle users.[20] Any concerns about the jury's possible misuse of the caution for causation purposes or otherwise could have been addressed by an appropriate limiting instruction, and, if necessary, by a tailored statement in the jury charge.

b. FDA letters. Albright also contends that it was prejudicial error to exclude two letters from the FDA to BSC. The first letter ordered BSC to conduct a "postmarket surveillance" study of the Pinnacle device to address concerns as to the safety and efficacy of the device in treating POP. The second letter agrees to a request from BSC to suspend its postmarket surveillance study because it planned to discontinue the manufacture and marketing of the Pinnacle device in this country.[21] We conclude that, in the unique context of this lengthy trial, Albright ought to have been allowed to use the letters for the limited purpose of cross-examining BSC's witnesses, who had testified, without qualification, that the Pinnacle device was safe as of the time of trial. Such a

[20] Albright had the burden to prove that her surgeons would have acted differently if provided with adequate warnings. See Sanchez v. Boston Scientific Corp., supra at 732.

[21] As tried, there was no error in excluding a 2011 FDA public health notification, particularly since such postimplantation evidence was not relevant to Albright's alleged injuries or Dr. Meyer's decision to use the Pinnacle device for Albright's March 9, 2010, implant procedure.

limited use, to show bias or to rebut the witness's opinion testimony, would be reasonable cross-examination. See generally Mass. G. Evid. § 611(b), (d).

We add that the judge would have been well within her discretion to exclude all reference to the § 510(k) clearance (see note 8, supra) because of its potential to mislead the jury and confuse the issues. "That a device has been given clearance through the FDA's [§] 510(k) process is not relevant to state tort law. . . . The prejudicial value of evidence regarding the [§] 510(k) process far outweighs its probative value." Sanchez v. Boston Scientific Corp., 38 F. Supp. 3d at 744, quoting from Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014). However, having permitted BSC to invoke the 510(k) clearance, it was error to preclude Albright from using the later-in-time (2012) letters in cross-examination of BSC experts or employees, who had addressed the FDA clearance, to rebut BSC's claim that its product was, in essence, "cleared" as a safe device.

Having concluded that it was error to exclude the MSDS caution and prohibit Albright's use of the FDA letters for cross-examination purposes, we must determine whether any error was harmless or prejudicial.

c. Prejudice. As a broad, general rule, error in the exclusion of evidence should not be grounds for a new trial

unless the error "has injuriously affected the substantial rights of the parties." G. L. c. 231, § 119. Construing this statutory text, the Supreme Judicial Court has held that "the substantial rights of a party are adversely affected when relevant evidence is erroneously excluded that, viewing the record in a commonsense way, could have made a material difference." DeJesus v. Yogel, 404 Mass. at 48. This case, in our opinion, falls within that narrow band of appellate decisional law that has ordered a new trial for prejudicial evidentiary error. See, e.g., Grant v. Lewis/Boyle, Inc., 408 Mass. 269, 274-275 (1990); Peterson v. Foley, 77 Mass. App. Ct. 348, 356-357 (2010).

Here, exclusion of the MSDS caution substantially affected Albright's rights as, without this key piece of evidence, the jury did not have a complete picture of the information bearing on the safety of the Pinnacle device that BSC either knew of or, in the exercise of reasonable care, should have known about. As noted above, the state of BSC's knowledge is a crucial aspect of the foreseeability analysis that underlies the claims in this case. No other evidence before the jury served a similar function.

The MSDS caution would have linked the scientific expert testimony and opinions of Guelcher and Barker regarding the reactive process of human tissue to surgically implanted mesh of

the volume and type used in the Pinnacle device to the primary concepts that were to guide the jury's determination of liability under the OPLA. With respect to the design claim, the jury could have used the caution in conjunction with the expert oxidation evidence to assess BSC's evaluation of the risks and benefits connected with the design of the Pinnacle device.[22] The caution is also material to the warning claim. The ramifications of the caution in light of Albright's expert evidence would have been essential for the jury's ability to determine whether BSC exercised reasonable care in warning about the foreseeable risks associated with the Pinnacle device.

In short, much of Albright's case depended on the limited admissibility of the MSDS caution to show notice on the part of BSC as to the unsuitability of polypropylene material for permanent implantation in the human body, particularly for use in the pelvic cavity. The MSDS caution was not cumulative of other evidence in the case, including the unredacted portions of the MSDS document that were admitted in evidence. BSC's challenge to the caution (that it was added at the insistence of legal counsel in response to liability concerns) goes to the

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[22] The jury could consider the cautionary warning as it pertained to the intended permanent implantation of the Pinnacle device in the human body where it would be in constant contact with internal body fluids and tissues and the extent to which BSC reasonably explored the likelihood that its chosen design would cause harm when used as intended.

weight of the caution, not its limited admissibility to show notice and knowledge. See Sacco v. Roupenian, 409 Mass. 25, 28-30 (1990); Beal Bank, SSB v. Eurich, 444 Mass. 813, 815-816 (2005).

Further, the prejudice stemming from the exclusion of the caution was exacerbated by the inclusion of the FDA's clearance of the Pinnacle device in 2008, a point that BSC's counsel emphasized in closing argument.[23] The judge also injected the issue of FDA approval into the trial, delivering a preliminary instruction informing the jury that the FDA had "cleared" the Pinnacle device for sale in this country in accordance with its § 510(k) process. The repeated reference to the FDA's clearance aided BSC's defense, and handicapped Albright's case, on the central product safety issue in the case. Against this trial backdrop, the MSDS caution and the FDA letters added necessary context to the § 510(k) clearance. The exclusion of this evidence therefore left the jury with an incomplete picture of the events in question. See note 18, supra.

[23] Outside the presence of the jury, the judge admonished BSC's counsel for "exceed[ing] the permissible scope of argument on the FDA by referring to the fact that the [Pinnacle device] was cleared and all of these other [surgical mesh-related] products were cleared." The judge determined that it was necessary to instruct the jury that they "may not consider the fact that the Pinnacle was cleared by the FDA as evidence that the Pinnacle was a safe or effective medical device."

3. Other claims of error. Based on our disposition here, there is no need to resolve Albright's claims respecting the judge's refusal to instruct the jury on the "heeding presumption" and a manufacturer's postsale duty to warn. We address them only briefly to provide guidance in the event that these issues arise again at any retrial.

a. Postsale duty to warn. There was little (if any) evidence at trial to suggest that BSC became aware of a new risk associated with the Pinnacle device subsequent to the March, 2010, implant procedure. While a manufacturer has a postsale duty to warn under Ohio Rev. Code Ann. § 2307.76(A)(2), the trial record did not warrant a further instruction on a postsale duty, particularly where the trial judge had delivered a proper instruction concerning BSC's duty to warn under Ohio law and the factors that the jury should consider in determining whether the warning and directions for use were adequate.

b. Heeding presumption. Albright contests the judge's refusal to instruct the jury that they could presume that an adequate product warning by BSC would have been followed by the surgeon who performed the implant procedure. Should this issue arise at a retrial, we would expect the parties to provide guidance to the trial judge as to the propriety of such an instruction based on well-settled Ohio law. See Seley v. G.D.

Searle & Co., 67 Ohio St. 2d at 200; Miller v. ALZA Corp., 759 F. Supp. 2d 929, 936 (S.D. Ohio2010).

Conclusion. The judgment is vacated and the case remanded to the Superior Court for proceedings consistent with this opinion.

So ordered.