IN THE SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
Docket No. A-001083-18T1

MARY MCGINNIS and THOMAS WALSH MCGINNIS, Plaintiffs-Respondents, v. C. R. BARD, INC., Defendant-Appellant, and BARD MEDICAL DIVISION, a Division of C. R. Bard, Inc., BARD UROLOGICAL DIVISION, a Division of Bard Medical Division, and JOHN DOES 1-2, Defendants.	On Appeal from: SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, BERGEN COUNTY DOCKET NO.: BER-L-017543-14 Sat Below: Hon. James J. DeLuca, J.S.C. Civil Action

AMICI CURIAE **BRIEF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS**

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PRELIMINARY STATEMENT

The trial court wrongfully prevented the jury from learning key facts relevant to the questions it confronted. This is a product liability case in which the jury was charged to assess allegations that a medical device was defective and Defendant is liable for punitive damages for bringing that device to market. The jury confronted consequential questions of whether (1) the device was defective for its intended use; (2) Defendant's decision to sell the cleared device was unreasonable; and (3) if so, that decision was so egregious as to warrant punitive damages. But the court refused to let the jury hear evidence regarding the federal approval process the device underwent, which was relevant to answering each of these questions.

Specifically, the trial court prevented Defendant from presenting any evidence of the process that Congress and the Food and Drug Administration ("FDA") developed to assure the safety and effectiveness of medical devices, including the mesh product here, and the manufacturers' compliance with that process. The FDA categorized the mesh product in this case as a Class II medical device, requiring it to go through the 510(k) clearance process. It determined the product was substantially equivalent, including for safety and effectiveness, to a predicate device that had been subject to a rigorous safety review and cleared the device for use. The fact that Defendant

adhered to the process that Congress and the FDA mandated before selling the device, provided FDA with the data it required for these assessments, and received FDA's clearance to sell its device are relevant to the key questions before the jury.

In excluding this evidence, the lower court improperly relied on a description of an early version of a 510(k) process that was not relevant to this case. Thus, if left to stand, this ruling threatens significant consequences for manufactures who participate in good faith in federal, state and other procedures designed to assure the safe production and marketing of life saving devices. It further has significant implications for Defendant here and other medical device manufacturers as it hampers their fundamental right to due process and the ability to present a fair defense. Excluding this key evidence, therefore, prejudiced Defendant and denied it a fair trial.

INTEREST OF *AMICI CURIAE*

Amici curiae are the Advanced Medical Technology Association ("AdvaMed"), the Chamber of Commerce of the United States of America ("Chamber"), and the National Association of Manufacturers ("NAM"). These organizations have members that manufacture, research, produce, and sell medical devices regulated by FDA through the 510(k) process. Under this regime, FDA assesses the safety and effectiveness of medical devices through "substantial equivalence" determinations based on

references to predicate devices. *Amici* have a substantial interest in the admissibility of evidence that FDA reviewed, assessed, and cleared a device before it was sold. Their members, as well as the consuming public, will be adversely impacted if courts reach liability decisions based on an improper understanding of the principles of safety and effectiveness that underlie each 510(k) clearance.

AdvaMed is the world's largest medical technology association, with approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards. The innovations created by AdvaMed's members advance efficiency in health care through earlier disease detection and more effective treatments which, in turn, reduce the economic burden of disease and allow people to live longer, healthier, and more productive lives.

The Chamber is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the

Chamber is to represent the interests of its members in matters before the courts, Congress, and the Executive Branch. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.[1]

LEGAL ARGUMENT

The context for an FDA decision to clear a device for market is highly relevant for determining the product and corporate liability issues in this litigation. This evidence speaks directly to the safety and effectiveness of the mesh device and to the reasonableness of Defendant's conduct in

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

bringing this medical device to market. This evidence is also essential for ensuring that the court's liability and regulatory decisions are not unduly influenced by the injuries to any specific plaintiff or ignorant of the government's efforts to balance a device's risks with its benefits. New Jersey courts have recognized that juries are fully capable of considering evidence related to compliance with government standards, and there is no reason to exempt the 510(k) process for medical devices from this jurisprudence.

Congress and FDA have been purposeful in developing the 510(k) process for clearing medical devices since Congress enacted the Medical Device Amendments ("MDA") in 1976 to give FDA the authority to oversee the safety and effectiveness of medical devices. *See* 21 U.S.C. § 360, *et seq.* The 510(k) clearance process, which governs the vast majority of medical devices, gives FDA flexibility to determine the best way to give the public access to beneficial, incremental changes in device technology. Rather than require each new iteration of a device to go through the full premarket approval process, Congress decided it would be better for public health if FDA could clear such a device for use if it is "substantially equivalent" to an earlier, or predicate, device. Congress enacted the Safe Medical Devices Act in 1990 to make it abundantly clear that this substantial equivalence standard must include a determination

that the new device is at least "as safe and effective" as the predicate. The 510(k) clearance process has become a rigorous, substantial undertaking on safety and effectiveness.

Here, as Defendant has explained, FDA cleared its surgical mesh product after determining it was substantially equivalent to a predicate mesh device subject to six years of intensive study in the 1980s. This earlier process included three advisory panels; experts in general and plastic surgery devices, orthopedic devices and gastroenterology and urology devices; public comment; and a review of scientific literature. *See* 21 C.F.R. § 860.1, et seq.; 47 Fed. Reg. 2810 (Jan. 19, 1982); 53 Fed. Reg. 23856 (June 24, 1988); 21 C.F.R. § 878.3300. To prove substantial equivalence to this predicate device, Defendant in 2007 submitted an application that included clinical data, animal testing, biocompatibility results, and warnings including of the harms alleged here. *See* Def. Br. at 10-12. FDA, after a thorough review, concluded that Defendant's surgical mesh device was "substantially equivalent with respect to predicate surgical meshes for safety and effectiveness." *Id.* at 14.

Amici respectfully urge the Court to overturn the ruling below and acknowledge that the process Congress and FDA set up for clearing a medical device for use in the United States is relevant to the jury's assessment of whether this device is defective and Defendant acted appropriately in bringing the

device to market. Jurors cannot assess the nature and gravity of conduct if they are shielded from important aspects of that conduct. The Court should hold that this evidence is admissible and trust New Jersey juries to properly assess its significance.

I. CONGRESS AND FDA ESTABLISHED THE 510(K) PROCESS TO ENSURE THE SAFETY AND EFFECTIVENESS OF CLASS II MEDICAL DEVICES, WHICH INCLUDES THE MESH DEVICE IN THIS CASE.

A. FDA Rigorously Reviews Each Medical Device for Safety and Effectiveness Before It Can Be Cleared Under the 510(k) Process for Public Use.

Since 1976, Congress and FDA have thoughtfully developed a regulatory regime for approving and clearing medical devices to provide the public with "reasonable assurance of the safety and effectiveness of devices intended for human use." *See* 21 U.S.C. § 360c(a)(1). This regime is predicated on pre-market review and post-market controls. *See* 21 U.S.C. § 360c. To determine the level of review and controls needed for a particular device, Congress instructed FDA to categorize devices into three risk classes: Class I (lowest risk); Class II (intermediate risk); and Class III (highest risk). *See* 21 U.S.C. § 360c(a)(1). As the Supreme Court has appreciated, "[r]egardless of which category FDA chooses, there must be a 'reasonable assurance of the safety and effectiveness of the device.'" *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000).

1. FDA Assigns Each Device to the Appropriate Class.

FDA convenes panels of medical and scientific professionals to place each device into the proper risk classification. Class I medical devices are simple devices that present low risk, such as scalpels, bandages, tongue depressors, and medical gloves, and may be marketed if they satisfy certain "general controls." "General controls" include registration, good manufacturing practices, proper labeling, compliance with quality system regulations, and post-market reporting. *See* 21 U.S.C. § 360c(a)(1)(A). Although all devices are subject to such general controls, Class I devices, by definition, are those devices for which general controls are "sufficient to provide reasonable assurance of [] safety and effectiveness." *Id.*[2] Manufacturers do not need FDA authorization to market a Class I device. *Id.*

Devices placed in Class II, which FDA concluded was the appropriate class for surgical mesh, are devices for which these general controls are not sufficient to provide reasonable assurance of safety and effectiveness. Here, though, FDA has sufficient information based on studies and other materials to establish the necessary "special controls to provide such assurance." 21 U.S.C. § 360c(a)(1)(B). Special controls can

[2] Class I devices also include those devices which are not 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 do not "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A).

include requirements for clinical data, bench testing, satisfaction of certain standards, use of specific materials, patient registries, FDA recommendations and guidelines, and post-market surveillance.[3] *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). Other Class II devices include ultrasonic diagnostic equipment, x-ray machines, biopsy needles, syringes, sutures, insulin pumps, and prostheses. These devices are generally subject to the 510(k) clearance process.

Class III devices are high-risk devices for which general controls are inadequate to assure device safety and there is insufficient information to establish special controls to provide reasonable assurance of safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C). Examples of Class III devices are pacemakers, heart valves, and hemodialysis machines. They are subject to a different Pre-Market Approval process ("PMA").

2. FDA, Not the Manufacturer, Determines the Proper Level of Pre-Market Review.

FDA tailors the pre-market review process to the class and risk profile of each device. Both the 510(k) process, which is largely for Class II medical devices, and the PMA process, which is generally reserved for Class III devices, are integral to

[3] The predominant special control FDA employs today is the issuance of guidance documents for the content of 510(k) applications. *See* Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365, 369 (2014); *see also* 21 U.S.C. § 360c(a)(1)(B).

FDA's statutory and regulatory framework. Together, they provide FDA with the needed flexibility to "pursue[] difficult (and often competing) objectives" in allowing devices to be available for public use. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-50 (2001). Although the 510(k) process is less onerous than the PMA process, the U.S. Supreme Court has recognized that the 510(k) process is itself a "comprehensive scheme" that enables FDA to balance the key factors in determining whether the device is safe and effective for public use. *Id.* at 348-49.

To obtain 510(k) clearance, a manufacturer must demonstrate to FDA that the device is "substantially equivalent" to a legally marketed predicate device. *See* 21 U.S.C. § 360c(f)(1). "Substantial equivalence" means that the device has the same intended use as the predicate, and that any different characteristics from the predicate "do not raise different questions of safety and effectiveness." 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b). Thus, safety and effectiveness are integral to FDA's substantial equivalence determination. In fact, FDA cannot grant 510(k) clearance if the new device is not at least "as safe and effective" as the predicate. 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b).

Substantial equivalence has become a robust standard; FDA has "a 25 page checklist of requirements that must be met just

for a 510(k) notification to be administratively accepted for review." Shapiro, *supra*, at 382. Submissions must include:

- a statement of the device's intended use and an explanation as to why any difference in intended use from the predicate device does not affect safety and effectiveness;
- a description of the device, including its technological characteristics such as its materials, design, energy source, and other features, and a comparison of those characteristics to the predicate device; the proposed labeling for the device;
- "an adequate summary of any information respecting safety and effectiveness," including "detailed information regarding data concerning adverse health effects"; and
- any clinical or scientific data necessary to support a substantial equivalence finding.

21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.87; 21 C.F.R. § 807.92.

Also, non-clinical data can include: bench testing on mechanical, electrical, and biological engineering performance, such as fatigue, wear, tensile strength, compression, flowrate, and burst pressure; electromagnetic compatibility; sterility; stability/shelf life; and software validation, as well as non-clinical animal and/or biocompatibility studies. *See* FDA, *FDA Guidance, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* (July 28, 2014), at 22 (hereafter "2014 FDA 510(k) Guidance").[4] At this point, "[i]t is not uncommon for applicants to present significant laboratory,

[4] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

animal, and/or clinical data running to thousands of pages." Shapiro, *supra*, at 382.

FDA has many tools for evaluating these submissions to ensure devices conform to its performance and safety standards. It can request clinical data to determine that the new device is as safe and as effective as the predicate device, seek team or advisory panel reviews, and ask for additional information to clarify or strengthen a submission. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b). FDA often requires such additional information,[5] and regularly rejects inadequate applications. *See* FDA, *FDA Has Taken Steps to Strengthen The 510(k) Program* (Nov. 2018), at 5 (noting 30% of 510(k) submissions are not accepted for initial review due to deficiencies).[6] FDA typically takes six months to review a 510(k) application,[7] and denies clearance when it determines that the proper standards have not met.[8]

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[5] *See* FDA, Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance (Nov. 9, 2015), at 176-77, *available at* https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM472220.pdf (from 2000 to 2015, the percent of 510(k) submissions where FDA made Additional Information (AI) Requests in its first substantive review cycle ranged from 37% to 77%; the percent of 510(k) submissions where FDA made AI Requests in its second substantive review cycle ranged from 5% to 35% for that same time period).

[6] https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM626541.pdf.

[7] *See* Emergo Group, *How Long It Takes the US FDA to Clear Medical Devices Via the 510(k) Process* (Mar. 2017), at 5,

B. The Trial Court Mischaracterized the 510(k) Clearance Process in Determining This Evidence Was Inadmissible.

The trial court mischaracterized fundamentals of the 510(k) clearance process and its importance to the jury's charge in this case. It suggested the 510(k) process refers to substantial equivalence only to a pre-1976 device that never went through the FDA review and control process, which is not the situation here. It referred to the 510(k) process as an "exemption" from pre-market approval, which, as discussed below, has not been the situation since at least the 1990 Safe Medical Device Amendments that solidified the 510(k) process as its own safety and effectiveness review. And, it misconstrued the substantial equivalency concept as not being about safety and effectiveness at all, thereby improperly concluding the 510(k) process "is not a safety requirement." These assertions are all incorrect.

1. The Trial Court's View of the 510(k) Clearance Process Is Anachronistic, Dating to the 1980s.

The view that compliance with the 510(k) clearance process is not relevant to device safety emanates from a

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available at https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf. This recent information contrasts sharply with the much shorter timeframe quoted by the U.S. Supreme Court in its 1996 characterization of the process in *Lohr*, discussed below.

[8] *See* FDA, Initial Results of 510(k) Audit: Analysis of Not Substantially Equivalent (NSE) Determinations (June 15, 2011), at 2, *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM447401.pdf ("For FY 2010, 8 percent of 510(k) submissions resulted in an NSE determination.").

misunderstanding of the U.S. Supreme Court ruling in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). To be clear, the 510(k) process under review in *Lohr* differs entirely from the 510(k) process at issue here. Also, as discussed below, *Lohr* addressed a different question of law, and the defendant in *Lohr* was seeking to introduce the evidence for a different purpose.

In *Lohr*, the Supreme Court assessed whether an early use of the 510(k) process should receive the same preemptive effect as the PMA process. The device in *Lohr* was a Class III pacemaker cleared in 1982 based on a predicate device that existed before FDA started overseeing medical devices in 1976 and had not undergone FDA review. Congress decided to "grandfather" devices already on the market before the 1976 Act took effect, meaning that these older devices could stay on the market until FDA could classify them under the new regulatory regime, which would take years. However, Congress was concerned that manufacturers of these grandfathered devices would gain a monopoly if it required all new Class III devices to go through the PMA process. So, it initially allowed a post-1976 Class III device to be cleared through the 510(k) process as a temporary exemption to the PMA process if the new device was substantially equivalent to a pre-1976 grandfathered device. Thus, unlike here, the predicate device in *Lohr* never went through any pre-market classification or review. *See id.* at 477-78.

As the Court can appreciate, there are several differences between *Lohr* and the situation at bar. First, the 510(k) process at issue in that case was fundamentally different from that here; it was a short-term means for facilitating the marketing of new medical devices until FDA could classify all pre-existing devices. By contrast, the mesh device here was cleared in 2007 based on a post-1976 predicate device that was subject to a six-year pre-market review. Also, at the time at issue in *Lohr*, there were few special controls, guidance, or standards for the 510(k) process, and the types and quality of data required were not well defined. As scholars have observed, "[i]n the early days of the 510(k) program, a submission could be quite short and consist merely of a narrative description of the proposed device versus the predicate device. Those days are long gone." Shapiro, *supra*, at 382. Further, if FDA failed to respond in 90 days, the product could enter the market without clearance. This "grandfathered device" exemption is now largely obsolete. FDA, *FDA Has Taken Steps to Strengthen The 510(k) Program*, at 7.

The pivotal moment for the 510(k) clearance process and the substantial equivalence standard came in 1990, when Congress enacted the Safe Medical Device Act ("SMDA") to make 510(k) review a permanent and dominant system for evaluating post-1976 Class II devices. In the SMDA, Congress prohibited launch of any new device until FDA issued a written response to the submission

and made a determination to clear the product for use. It defined, for the first time, "substantial equivalence" in the 510(k) process as pertaining to whether the "device is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device." 21 U.S.C. § 360c(i)(1)(A).[9] It also introduced the concept of special controls for Class II devices.

As a result, 510(k) submissions became much more robust. *See* Jordan Bauman, *The "Déjà vu Effect:" Evaluation of United States Medical Device Legislation, Regulation, & the Food & Drug Administration's Contentious 510(k) Program*, 67 Food & Drug L.J. 337, 353 (2012) (reporting that from 1983 to 2008, the average number of pages per 510(k) increased from 50 to 369). FDA's review time doubled, with the average review now taking at least six months. *See* Emergo Group, *How Long It Takes the US FDA to Clear Medical Devices Via the 510(k) Process* (Mar. 2017), at 5.

Second, the admissibility of evidence that a company adhered to the 510(k) process and complied with FDA's request for information and conditions for clearance presents an entirely different question of law from preemption. In *Lohr*, the Supreme Court evaluated whether the 510(k) process preempted

[9] The legislative history states the "most significant" SMDA provision was a "clarified statutory basis for examining safety and effectiveness in making determinations that two devices are substantially equivalent." H. Rep. No. 101-108 (1990).

state torts and applied a presumption against preemption. *See* 518 U.S. at 485. The Court never suggested the 510(k) process was irrelevant to liability or device safety. *See Otero v. Zeltiq Aesthetics, Inc.*, No. CV173994DMGMRWX, 2018 WL 3012942, at *3 (C.D. Cal. June 11, 2018) ("Although [*Lohr*] observed that obtaining Section 510(k) clearance is not as onerous as the 'rigorous' PMA process, the Supreme Court did not find that the former has no bearing on a device's safety and effectiveness.").

Third, *Lohr* never touched on the relevance of 510(k) evidence for assessing a manufacturer's conduct in bringing a product to market, either under a reasonableness standard or for punitive damages. These are the inquiries here. As one federal court recently noted, *Lohr's* "preemption discussion" does not stand for the proposition that "[t]he 510(k) process does not address product safety and efficacy and therefore is not relevant to [a manufacturer's] obligations under [] state tort law." *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1048 n.2 (D. Ariz. 2018) (internal quotation marks and citations omitted).

Lohr, therefore, provides no guidance on the issues before this Court, namely the current use of the 510(k) process for devices FDA places in Class II based on the recommendation of medical and scientific panels, or the admissibility of such

evidence for assessing Defendant's conduct in bringing such a device to market.

2. FDA Has Repeatedly Affirmed that the 510(k) Process Is a Safety Standard, Which Deserves Deference.

The trial court's assertion that the 510(k) process "is not a safety requirement" has been repeatedly contradicted by FDA, which has affirmed on multiple occasions that "principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff* (July 29, 2014), at 6; FDA CDRH Preliminary Internal Evaluations – Vol. 1, 510(k) Working Group Preliminary Report and Recommendations (Aug. 2010), at 34 (calling the 510(k) program "a multifaceted premarket review process that is expected to assure that cleared devices, subject to general and applicable special controls, provide reasonable assurance of safety and effectiveness")[10]; 2014 FDA 510(k) Guidance, at 7 (stating for both PMA and 510(k) devices, "FDA's review decision reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'"). Indeed, FDA has never deviated from its position that post-SMDA 510(k)

[10] https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM220784.pdf.

review encompasses safety and effectiveness as a needed, statutorily mandated requirement.[11]

The U.S. Supreme Court has long recognized that such consistent "rulings, interpretations and opinions" of a federal agency "while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). Further, to the extent the trial court is asserting that the SMDA does not serve its stated purpose, it is rendering a policy judgment outside its purview. As the U.S. Supreme Court has cautioned, "courts are not at liberty to jettison Congress' judgment." *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 667 (2014); *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2414 (2015) ("[C]ourts must attend" to "the rule-of-law values . . . while leaving matters of public policy to Congress."); *United States v. Am. Trucking Ass'ns*, 310 U.S. 534, 542 (1940) ("[T]he function of the courts is . . . to construe the language so as to give effect to the intent of Congress.").

Thus, in developing the 510(k) clearance process, Congress gave FDA the responsibility, which FDA accepted, to determine

[11] FDA regularly eliminates 510(k)-cleared devices as predicates when they raise safety concerns. Indeed, it has eliminated 1,758 devices as predicates since 1976. *See* FDA, *FDA Has Taken Steps to Strengthen The 510(k) Program*, at 8.

the safety and effectiveness profile for each medical device and allow only devices that are sufficiently safe to enter the U.S. market. The Court is not required to determine that this process preempts state tort law, as was the issue in *Lohr*, but only whether conformance to this process, and a manufacturer's engagement with FDA throughout this process, is admissible as evidence in a case where a jury is being asked to assess these very issues.

II. Evidence of a Manufacturer's Conformance with FDA's Safety Standards for a Device Pursuant to the 510(k) Process Is Essential to a Fair Determination of Product Defect and Punitive Damages in This Case.

Several courts, recognizing the 510(k) process for this and other mesh products included a rigorous review for safety, have concluded that evidence of conformance with this process, while "not dispositive, is nonetheless relevant to . . . whether the company defectively designed" the device. *Bard IVC Filters*, 289 F. Supp. 3d at 1047; *see also Retractable Techs., Inc. v. Becton*, No. 2:08-CV-16-LED-RSP, 2013 WL 11322723, at *2 (E.D. Tex. Aug. 29, 2013) ("[I]t is relevant to put in context the relationship between the 510(k) process and the safety of a given device."); *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig.*, No. 114ML02570RLYTAB, 2018 WL 6617375, at *2 (S.D. Ind. Dec. 18, 2018) (same).

These courts have found that in order to ensure a fair trial, the manufacturer must be able to inform the jury of the regulatory framework that guided, informed, and dictated its design and safety decisions. Specifically, as here, where a plaintiff alleges it was unreasonable—even egregious—not to conduct premarket clinical trials, the jury must be allowed to know that FDA, after its review of the device's safety profile, chose not to require the manufacturer to undertake such trials. Plaintiffs may still argue the clinical trials should have been conducted, but the Court should not allow Rule 403 to strike Defendant's primary defense by eliminating any reference to FDA and the regulatory regime under which Defendant brought its device to market. Such information is critical to both the design defect and punitive damages questions before this jury.

A. The Standards and Tests for Product Defect, Generally and in this Case, Require Admissibility of this Evidence.

For medical devices and other products, when a jury determines that a product is defective, it essentially is making a regulatory decision that extends beyond any single person's allegations of injury. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("tort duties of care" under state law "directly regulate" a product). In most cases, this determination requires an assessment of the safety and effectiveness of the product itself, which is generally achieved through a risk-utility test.

This often considers government standards, the best available technology, and industry practice. *See, e,g., Kim v. Toyota Motor Corp.*, 424 P.3d 290, 296 (Cal. 2018).

Accordingly, New Jersey courts entrust juries to weigh conformance with government standards in determining liability in a wide variety of product cases. *See, e.g., Cepeda v. Cumberland Eng'g Co.*, Inc. 76 N.J. 152 (1978) ("[S]afety codes in existence when a machine is marketed are admissible, albeit not conclusive as to defectiveness vel non of an impugned machine."); *Jackson v. New Jersey Mfrs. Ins. Co.*, 166 N.J.Super. 448 (1979) ("The law is clear that compliance with a legislative enactment, administrative regulation or industrial safety code, while evidential, is not conclusive as to the nonnegligence of a manufacturer or the absence of a defect in a machine."); *Ladner v. Mercedes-Benz of North America, Inc.*, 266 N.J.Super. 481 (1993) (same for automobiles); *Covell v. Bell Sports, Inc.*, 651 F.3d 357 (3d Cir. 2011) (same for sports equipment); *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173 (2012) (same for prescription drugs). There is no rationale for treating medical devices differently, in this or other cases.

In fact, the value of this information is particularly strong here. The parties have agreed that this case is governed by North Carolina's product liability statute. This law states that the jury "shall" consider the "extent to which the design

or formulation conformed to any applicable government standard" in assessing whether "the manufacturer acted unreasonably in designing or formulating the product." N.C. Gen. Stat. § 99B-6(a),(b)(3); *accord Lee v. Certainteed Corp.*, 123 F. Supp. 3d 780, 802 (E.D.N.C. 2015).[12] Further, because this case involves a medical device, the issue is not mere conformance to pre-existing minimum standards, but safety standards FDA established for this specific type of device. Indeed, a federal district court has already determined that evidence of conformance with FDA's 510(k) clearance process is admissible under North Carolina law. *Winebarger v. Boston Scientific Corp.*, No. 3:15CV211-RLV, 2015 WL 5567578, at *6-7 (W.D.N.C. Sept. 22, 2015). Although not dispositive, that case reflects the view of a federal district court sitting in North Carolina of North Carolina law. The Court should find its ruling persuasive until a North Carolina state court determines the issue.

If medical device manufacturers are forced to re-design beneficial devices without a full airing of the considerations that went into the devices' design, the result will be harmful to the many people not before this Court that use the device. Similarly, if manufacturers withdraw from the market products

[12] New Jersey and North Carolina courts follow a statute's plain language where, as here, that language is clear. *See Marino v. Marino*, 200 N.J. 315 (2009); *Midrex Techs., Inc. v. N.C. Dep't of Revenue*, 794 S.E.2d 785 (N.C. 2016).

cleared through the 510(k) process, and are dissuaded from using the 510(k) process in the future, even when directed to do so by FDA, the public's access to this and other highly beneficial devices will be needlessly compromised. Such a result would undermine New Jersey's "profound public interest in developing new products" to address patient medical needs. *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 5 (1999). It also would run counter to Congress's directive in the FDA Modernization Act of 1997 that FDA "take a least burdensome approach to medical device premarket evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products." FDA, *FDA Guidance: The Least Burdensome Provisions: Concepts and Principles* (Feb. 2019), at 4.[13]

B. The N.J. Legislature Has Specified that Compliance with Government Regulations Is Integral to Punitive Damages.

Similarly, New Jersey's punitive damages law, which applies in this case, is clear that punitive damages are not to be awarded if a medical device is "generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations." N.J. Stat.

[13] https://www.fda.gov/media/73188/download; *see also* FDA, *Background on MDUFMA* (Dec. 5, 2017), at https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/background-mdufma (explaining that the Medical Device User Fee and Modernization Act of 2002 was intended to give FDA the resources it needed "to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time").

§ 2A:58C-5(c). For reasons given in Defendant's Opening Brief (pp. 46-57), this statute applies to devices cleared to market through the post-SMDA 510(k) process and should govern here.

In enacting this statute, the New Jersey legislature made a public policy decision that there can be no clear and convincing evidence of malice, willfulness, or wantonness when a manufacturer has properly complied with federal regulations in bringing its device to market. *See Kendall,* 209 N.J. at 194. Others have broadly agreed that "[t]he strongest case for a regulatory compliance defense arises when punitive damages are sought." American Law Inst., *Reporter's Study on Enterprise Responsibility for Personal Injury: Approaches to Legal and Institutional Change* (1991), at 101.[14] "If a defendant has fully complied with a regulatory requirement . . . it is hard to justify the jury's freedom to award punitive damages." *Id.*

Denying a defendant the ability to at least inform the jury of its conformance with FDA regulations specific to its product is, therefore, entirely inconsistent with New Jersey law and Rule 403. *Cf. Reed v. Tiffin Motor Homes, Inc.*, 697 F.2d 1192,

[14] *Accord Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (punitive damages improper given, *inter alia*, compliance with federal standards); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 578-80 (1996); *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 826 (Fla. 1986); *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993); *Malcolm v. Evenflo Co.*, 217 P.3d 514, 542 (Mont. 2009); *Phillips v. Cricket Lighters*, 883 A.2d 439, 447 (Pa. 2005).

1198 (4th Cir. 1982) (finding compliance with regulatory standards is "clearly" relevant to "wantonness, willfulness and maliciousness" required for punitive damages). Further, it is a violation of Defendant's due process rights to deny Defendant the ability to "present every available defense" when the state seeks to punish it through punitive damages. *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007). To be sure, there can be little doubt a manufacturer's failure to comply with FDA's 510(k) process would be used as evidence in support of punitive damages. Its compliance should be considered just as relevant. The Court should follow the New Jersey legislature's clear public policy, along with scholars and other courts, and allow the jury to assess Defendant's actions in full context.

C. Device Manufacturers Cannot Receive Fair Trials if Regulatory Compliance Evidence Is Inadmissible.

If the Court fails to overturn the trial court and affirms the exclusion of this evidence, medical device manufacturers, including Defendant, will continue to face undue prejudice and be denied their constitutional due process right to a fair trial. Removing "any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury." *Bard IVC Filters*, 289 F. Supp. 3d at 1049. New Jersey juries will be left to speculate about FDA's involvement

and could wrongly conclude that device manufacturers operate in a lawless space, without oversight or accountability.

To the extent there are any risks of prejudice to plaintiffs in allowing such evidence, these risks can be mitigated. *See id.* at 1048-49 (explaining such risks "can be adequately addressed without excluding relevant evidence to the detriment of Defendants"). Specifically, courts have found that proper jury instructions sufficiently alleviate any such concern. *See, e.g., Winebarger*, 2015 WL 5567578, at *7 (providing such an instruction); *Bard IVC Filters*, 289 F. Supp. 3d at 1049 (same); *Goulah v. Ford Motor Co.*, 118 F.3d 1478, 1487 (11th Cir. 1997) (instructing "that compliance [with regulations] did not exempt [manufacturer] from liability"); *Johnson by Johnson v. Gen. Motors Corp.*, 438 S.E.2d 28, 39 (W. Va. 1993) (approving instruction that regulatory compliance is relevant to, but "'not conclusive proof'" of, device safety); *Estep, v. Mike Ferrell Ford Lincoln-Mercury, Inc.*, 672 S.E.2d 345 (W. Va. 2008) (same); *Moehle v. Chrysler Motors Corp.*, 443 N.E.2d 575, 578 (Ill. 1982) ("With careful instructions . . . Festthe jury can properly evaluate the importance of the [regulatory] evidence.").

Further, regulatory compliance "mini-trial" can be avoided by limiting the witnesses and cumulative evidence. *See, e.g.*, *Bard IVC Filters*, 289 F. Supp. 3d at 1049 ("The Court is also

convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials.").

A manufacturer's conduct with respect to a device's development and the 510(k) process are so inextricably intertwined that one story cannot be told without the other. Juries must be able to hear why a manufacturer conducted some tests but not others, why a manufacturer did not conduct certain clinical trials, and why its device's warnings did or did not contain certain information. The 510(k) process informs these inquiries. Otherwise, plaintiffs will always be able to argue that an additional test would have prevented their harm, and there will be no context for why that test was not conducted.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court reverse the ruling below and allow 510(k) evidence to be admissible at trial.

Respectfully submitted,

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