No. 15-1102

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

DONNA CISSON AND DAN CISSON,
Plaintiffs-Appellees,

v.

C. R. BARD, INC.,
Defendant-Appellant,

On Appeal from the United States District Court for the Southern District of West Virginia (Charleston), No. 2:11-cv-195, Judge Joseph R. Goodwin

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND CHAMBER OF COMMERCE OF THE UNITED STATES AS *AMICI CURIAE* IN SUPPORT OF APPELLANT

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Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, the Product Liability Advisory Council, Inc., as *amicus curiae*, makes the following disclosures:

1. Is party/amicus a publicly held corporation or other publicly held entity? No.
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6. Does this case arise out of a bankruptcy proceeding? No.

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4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))? No.
5. Is party a trade association? (*Amici curiae* do not complete this question.) N/A
6. Does this case arise out of a bankruptcy proceeding? No.

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

STATEMENT OF INTEREST[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with over 100 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to the improvement and reform of the law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers. Since 1983, PLAC has filed more than 1,000 briefs as *amicus curiae* in both state and federal courts, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability. A list of PLAC's corporate members is attached as Appendix A.

The Chamber of Commerce of the United States ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million U.S. businesses and professional organizations of every size, in every industry, and from every region of the country. A principal function of the Chamber

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[1] The parties have consented to the filing of this brief. No counsel for any party authored this brief in whole or part; no party or counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amici curiae* made such a contribution.

is to represent its members' interests by filing *amicus curiae* briefs in cases involving issues of vital concern to the nation's business community.

PLAC and the Chamber are deeply troubled by the district court's decision, in this product-liability case, to exclude evidence of the manufacturer's compliance with federal laws and regulations applicable to its products. Many of PLAC's and the Chamber's members are national or multi-national businesses that are subject to a shifting and unpredictable patchwork of regulation through common-law decisionmaking by courts and juries. *Amici* therefore have an interest in mitigating the disruptive and burdensome effects of that patchwork by ensuring that defendants are permitted to inform juries, in accordance with state law, of their compliance with applicable federal standards.

INTRODUCTION AND SUMMARY OF ARGUMENT

I. In common-law tort actions alleging that a medical device is defective, the State of Georgia, like many other States, has chosen to make the device manufacturer's compliance with federal law a relevant consideration for the jury—both in determining liability and in assessing punitive damages, if any. Georgia's choice is a sensible one, as it promotes

fairness to defendants, federal-state comity, and uniform development of the law.

II. Evidence of § 510(k) clearance is relevant under Georgia law and easily passes muster under Federal Rule of Evidence 401, as it bears on the safety, efficacy, and reasonableness of the product's design. The district court erred in concluding that the § 510(k) process is not concerned with a device's safety or effectiveness. On the contrary, to obtain clearance to market a new device under § 510(k), a manufacturer must show that the device is "as safe and effective" as a preexisting, legally marketed product—in this case, a product for which FDA had found "reasonable assurance of . . . safety and effectiveness" under the existing federal regulatory structure. 21 U.S.C. § 360c(a)(1)(A)–(B), (f)(1)(A), (i)(1)(A). FDA itself recently stressed that a clearance decision under § 510(k) "reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'" FDA, THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET

NOTIFICATIONS: GUIDANCE FOR INDUSTRY AND FDA STAFF 7 (July 28, 2014) (hereinafter "FDA 510(K) GUIDANCE").[2]

III. There is no basis for excluding § 510(k) evidence under Rule 403 as unduly prejudicial. As an initial matter, the district court here could not conduct a meaningful Rule 403 balancing because it incorrectly believed that § 510(k) evidence lacked any probative value at all. In any event, there is no cognizable prejudice from admitting this evidence, as Georgia law entrusts juries with evaluating such evidence of regulatory compliance and provides appropriate pattern instructions to ensure that they do not give it undue weight. Excluding this evidence, on the other hand, is extremely prejudicial to defendants. It prevents them from satisfying jurors' understandable expectation that a medical-device case will include a regulatory narrative, and it hamstrings their ability to combat the jury's hindsight bias by introducing evidence to show why the manufacturer believed its choices were reasonable at the time.

IV. The Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), does not prevent a State from allowing juries to consider

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[2] *Available at* http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.

evidence pertaining to a device's clearance under § 510(k). The Court held only that the § 510(k) process did not impose federal-law "requirements" on the design of a medical device that could preempt state-law claims entirely. It did not hold, and could not rationally have held, that § 510(k) clearance is irrelevant to the safety, efficacy, and reasonableness of a device's design. Moreover, because the Court in *Lohr* dealt with a product cleared by FDA in 1982, it did not consider the many significant changes to the § 510(k) process that have taken place over the last three decades and have clarified that that process is centrally concerned with a device's safety and efficacy. Far from supporting the district court's decision, *Lohr* emphasized federalism concerns that support honoring Georgia's decision to let juries weigh evidence of regulatory compliance.

ARGUMENT

I. Under Georgia Law, a Manufacturer's Compliance with Federal Law Is a Relevant Consideration for the Jury.

In *Medtronic v. Lohr*, the Supreme Court emphasized the historic primacy of state law in matters of health and safety. 518 U.S. at 475, 485. Here, Georgia—like many other States—has sensibly chosen to make a manufacturer's compliance with federal regulations a relevant (though not dispositive) consideration for juries tasked with determining whether

a product is defective and, especially, whether to impose punitive damages on the product's manufacturer.

First, Georgia makes a broad inquiry into "reasonableness" the touchstone for deciding whether the manufacturer is liable at all. Georgia law provides that in order to determine whether a product is defective, a jury must conduct a flexible "risk-utility analysis" that ultimately asks "whether the manufacturer acted reasonably" in marketing the product as designed. *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673 (Ga. 1994). And Georgia law treats "compliance with federal standards or regulations" as one "factor for the jury to consider in deciding the question of reasonableness." *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997). Such compliance is not a "shield from liability," but one "significant . . . piece of the evidentiary puzzle." *Id.*; *see also Volkswagen of Am., Inc. v. Gentry*, 564 S.E.2d 733, 738 (Ga. Ct. App. 2002); *Pinney v. Nokia, Inc.*, 402 F.3d 430, 446 (4th Cir. 2005) (applying Georgia law). Georgia's law on this point is reflected in its pattern jury instructions, which list thirteen non-exclusive "factors" for the jury to consider in determining "whether the manufacturer acted reasonably," including "the manufacturer's compliance with . . . governmental

regulations." Ga. Suggested Pattern Jury Instruction No. 62.650 (5th ed. 2015).

Second, Georgia law makes compliance with federal regulations an even more important factor in a jury's consideration of punitive damages. The Georgia Supreme Court has explained that regulatory compliance "tend[s] to show that there is no clear and convincing evidence of . . . the type of behavior which supports an award" under Georgia's punitive-damages statute, namely, "'willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.'" *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (quoting Ga. Code Ann. § 51-12-5.1(b)); *see also Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998). Georgia law does not preclude a jury from imposing punitive damages where, although the defendant complied with relevant regulations, there is "other evidence showing culpable behavior." *Gen. Motors Corp. v. Moseley*, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994), *abrogated on other grounds*, *Webster v. Boyett*, 496 S.E.2d 459 (Ga. 1998). But the Georgia Supreme Court has concluded that regulatory compliance makes punitive damages, "as a general rule, improper." *Stone Man*, 435 S.E.2d at 206.

The rule adopted by Georgia and many other States—under which a defendant accused of violating a nebulous common-law duty is permitted to show the jury that it complied with federal regulations—deserves the federal courts' respect and encouragement. Under these States' approach, national and multi-national businesses unable to invoke federal preemption can at least explain to a jury how federal standards reasonably informed their decisionmaking process and argue that those standards should serve as guideposts for the jury's application of the State's common law. Allowing juries to consider such evidence thus helps to promote fairness to defendants, federal-state comity, and uniform development of the law. Federal courts surely should not make themselves into stumbling blocks to the wider adoption and implementation of this sensible approach.

To be sure, for a manufacturer's compliance with federal law to be relevant to a design-defect claim, the federal standards at issue must be generally concerned with promoting safety, efficacy, and reasonableness in the design and marketing of products. That a manufacturer paid its federal taxes on time and complied with wage-and-hour laws is not relevant to whether its product's design was reasonable. But as explained

below, § 510(k) review of new medical devices is a critical part of the scheme by which Congress and FDA seek to ensure that such devices are reasonably safe and effective. Bard's receipt of § 510(k) clearance was therefore relevant under Georgia law.

II. Evidence Regarding § 510(k) Clearance Is Relevant Under Rule 401 and Georgia Law.

Notwithstanding Georgia's policy of admitting evidence of compliance with federal regulations, the district court held that evidence related to FDA's clearance for Bard to market its pelvic mesh pursuant to § 510(k) was irrelevant and thus inadmissible. The court based that holding on its belief that "the § 510(k) process does not go to whether the product is safe and effective." Dkt. 486, at 5. In so ruling, the court failed to appreciate § 510(k)'s central role in the federal regulatory scheme for ensuring the safety and efficacy of medical devices that are sold to the public.[3]

The basic standard of relevance under Rule 401 is "typically a low bar to the admissibility of evidence." *Jones v. Ford Motor Co.*, 204 F.

[3] As Bard's brief points out (at 36–38 & n.20), the district court compounded its error by extending its § 510(k) ruling to exclude evidence of Bard's compliance with other federal regulations that were indisputably relevant to the safety and effectiveness of Bard's product.

App'x 280, 283 (4th Cir. 2006). And the bar may be lowered even further by state substantive law that broadly defines relevant considerations for the jury in a particular type of case. *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 767–68 (7th Cir. 2013). Evidence that Bard complied with § 510(k) in bringing its product to market easily cleared that bar. Contrary to the district court's flawed understanding, the § 510(k) process is directly related to ensuring that a medical device is reasonably safe and effective. More to the point for purposes of Georgia law, the § 510(k) process is directed toward ensuring that the device is designed in such a way that, in the judgment of the federal government, it can reasonably be sold to the public.

The most pertinent provisions of the federal regulatory scheme for medical devices are straightforward. A manufacturer seeking to market a new medical device like Bard's pelvic mesh must first submit a "premarket notification" report under § 510(k) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 360(k). FDA will clear the new device for sale to the public if the manufacturer demonstrates that the device is "substantially equivalent" to a preexisting, legally marketed device, typically called a predicate device. 21 U.S.C. § 360c(f)(1)(A). The

predicate device can be either (i) a device that was already on the market when Congress enacted § 510(k) in 1976, or (ii) a post-1976 device that FDA has categorized as "Class I" or "Class II" under the Act, meaning it has determined that the "general" or "special" regulatory controls available under the Act are capable of providing "reasonable assurance of the safety and effectiveness of the device." *Id.* § 360c(a)(1)(A)–(B), (f)(1)(A).

The statute and its accompanying regulations leave no doubt that the § 510(k) process is concerned with the device's safety and efficacy. To demonstrate substantial equivalence, the manufacturer must submit data establishing that, insofar as the new device is different from the predicate device, it is "as safe and effective as," and "does not raise different questions of safety and effectiveness than," the predicate device. *Id.* § 360c(i)(1)(A); *see also* 21 C.F.R. § 807.100(b)(2) (reiterating this standard). Legislative history confirms that Congress considered the substantial-equivalence inquiry relevant to safety and effectiveness: "The term 'substantially equivalent' . . . should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device

do not relate to safety and effectiveness." H.R. Rep. No. 94-853, at 36 (1976).

FDA, too, has stressed that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." FDA 510(K) GUIDANCE 6. According to the agency:

> Although the 510(k) process involves a comparison of a new device to a predicate device rather than an independent demonstration of the new device's safety and effectiveness, as is required for [premarket approval under a different statutory provision], in both cases FDA's review decision reflects a determination of the level of control necessary to provide a "reasonable assurance of safety and effectiveness."

Id. at 7; *see also id.* ("Safety and effectiveness factor into both parts of the FDA's [§ 510(k)] review."). Indeed, one of FDA's core statutory missions is "protect[ing] the public health by ensuring . . . the safety and effectiveness of [medical] devices." 21 U.S.C. § 393(b)(2)(C). Since the overwhelming majority of new medical devices are brought to market through § 510(k), the district court's assertion that FDA's § 510(k) review has nothing to do with the safety and effectiveness of those devices wrongly implies that FDA is shirking its duty to the public on a massive scale.

As the foregoing explanation makes plain, clearance to market a new medical device under § 510(k) embodies a judgment by the federal

government, after due consideration of the device's safety and efficacy, that the device can reasonably be sold to the public. By enacting the § 510(k) process into law, Congress and the President resolved that it is in the public interest to allow the introduction of new medical devices that FDA determines are essentially the same, in terms of their safety and effectiveness, as preexisting, legally marketed devices. That judgment by two branches of the federal government at least suggests that a manufacturer's decision to market, with clearance from FDA, a "substantially equivalent" device is reasonable—and certainly that such a decision is not so willfully malicious as to warrant punitive damages.

Section 510(k) clearance thus is relevant even when FDA cleared the medical device at issue by comparing it to a *pre-1976* predicate device that was never specifically reviewed by FDA, since the statute reflects Congress's judgment that it is reasonable for such devices—whose safety and effectiveness can be evaluated based on long experience—to remain on the market. But the relevance of § 510(k) clearance is even more obvious where, as here, FDA cleared the device at issue by comparing it to a *post-1976* predicate device covered by an affirmative agency finding that available regulatory controls reasonably assure its safety and

effectiveness. In such a case, clearance under § 510(k) denotes FDA's conclusion that the new device is "as safe and effective" as a device for which there is "reasonable assurance of . . . safety and effectiveness." 21 U.S.C. § 360c(a)(1)(A)–(B), (f)(1)(A), (i)(1)(A). The notion that § 510(k) clearance under these circumstances does not relate to the safety and efficacy of the device, and therefore to the reasonableness or culpability of marketing it, is untenable.

The district court nonetheless treated Bard's attempt to introduce § 510(k) evidence as if Bard had tried to offer evidence of its compliance with federal tax or wage-and-hour laws having nothing whatsoever to do with the safety, efficacy, and reasonableness of its product's design. That was error. "The § 510(k) process requires [FDA to exercise] judgment regarding . . . how well [the] evidence demonstrates safety and efficacy" and to "balanc[e] . . . values such as safety and cost." *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 264 F.3d 344, 364 (3d Cir. 2001), *cert. denied sub nom. Bradley v. United States*, 535 U.S. 1095 (2002). That is precisely the sort of balancing that Georgia law required the jury to perform under the broad "risk-utility" analysis. Nor was the district court's error confined to this case. Instead, the court has treated its ruling

that the § 510(k) process is not related to safety and effectiveness as barring admission of § 510(k) evidence in *every* case without the need for further inquiry. *See, e.g.*, Dkt. 486, at 7 ("I have applied this ruling in each subsequent MDL trial.").[4]

Under Supreme Court precedent, to be sure, FDA's determination through the § 510(k) process that it was appropriate for Bard to market

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[4] For the reasons set forth above, § 510(k) evidence is inherently relevant to design-defect claims, regardless of the particulars of FDA's review and clearance of the device at issue. At a minimum, however, the district court's one-size-fits-all approach to excluding such evidence is inappropriate. For example, in some cases, the aspect of the device that the plaintiff alleges is unreasonably dangerous may be one of the specific differences between the device at issue and a predicate device that FDA's § 510(k) review considered and found not to "pose[] a significant safety or effectiveness concern for the new device." FDA 510(K) GUIDANCE 20. In other cases, FDA may have granted § 510(k) clearance to the device at issue because it was "as safe and effective" as a predicate device that FDA had expressly determined to be safe and effective, including (though not limited to) a device that was subject to the rigorous new-drug-approval process that governed some medical devices before 1976. *Compare Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 255 (E.D.N.Y. 2014) (design-defect claim was preempted to extent it was based on use of FDA-approved component), *with Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014) (district court below) (FDA approval of component was "irrelevant" and did not even render § 510(k) evidence admissible); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 746 (S.D. W. Va. 2014) (district court below) (adhering to holding of *Lewis* in case involving FDA-approved component) (Rule 50(b) motion pending).

its pelvic mesh, and that federal law reasonably assured the mesh's safety, did not *preempt* the jury from deciding that Bard violated state law. But by the same token, the district court had no warrant to frustrate Georgia's sensible policy of allowing juries to *consider* Congress's and FDA's judgment as one factor bearing on the reasonableness or culpability of Bard's conduct.[5]

III. Evidence Regarding § 510(k) Clearance Is Not Unduly Prejudicial to Plaintiffs, and Excluding Such Evidence Is Highly Prejudicial to Defendants.

In addition to holding that evidence pertaining to a device's § 510(k) clearance was irrelevant and thus inadmissible under Rules 401 and 402, the district court declared that the probative value of such evidence was

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[5] As a substantive matter, evidence of § 510(k) clearance will generally, if not always, be relevant to a design-defect claim, whether or not the State whose law governs has affirmatively declared that regulatory compliance is a factor for the jury to consider. The fact that the expert federal agency reviewed a premarket notification for a device and determined that its design was "as safe and effective" as a predicate device for which there was "reasonable assurance of . . . safety and effectiveness," 21 U.S.C. § 360c(a)(1)(A)–(B), (f)(1)(A), (i)(1)(A), at the very least tends to show that the design was, in fact, reasonable rather than defective—and that the manufacturer's conduct was reasonable rather than so culpable as to warrant punitive damages. Georgia's explicit case law discussed in the text, and its promulgation of a pattern jury instruction on point, simply make the district court's error all the more clear.

outweighed by its tendency to confuse and mislead the jury, making the evidence inadmissible under Rule 403. *See* Dkt. 486, at 8–9. That, too, was error.

To begin, the district court's Rule 403 analysis never got out of the starting blocks because the court's mistaken belief that § 510(k) clearance was irrelevant, and thus had no probative value *at all*, made it impossible for the court to meaningfully conduct the balancing of probative value and prejudicial effect that Rule 403 requires. In other words, the court's invocation of Rule 403 did not represent an independent, alternative ground for its ruling that § 510(k) evidence is inadmissible, but was inextricably and fatally intertwined with its erroneous ruling on relevance.

More fundamentally, however, when state law makes compliance with federal regulations a relevant jury consideration in product-liability cases, a federal court may not exclude such evidence under Rule 403 on the ground that, as the district court here worried, the jury might incorrectly view such evidence as "dispositive." *Id.* at 8. Excluding regulatory-compliance evidence on that basis would conflict with Georgia's policy of giving juries flexibility in the weighing of such evidence. Any

risk that the jury might wrongly think the evidence dispositive is easily addressed through an appropriate limiting instruction; indeed, Georgia provides just such an instruction. *See* Ga. Suggested Pattern Jury Instruction No. 62.670 ("Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable . . . . However, a product may comply with such standards or regulations and still contain a design defect."). The district court's view that jurors cannot be trusted to evaluate § 510(k) evidence within a broader framework is thus contrary to Georgia law.

The district court's baseless fears notwithstanding, the reality is that a jury is far more likely to be confused and prejudiced by exclusion of the regulatory narrative associated with a medical device than by an honest explanation of the § 510(k) process. It is common knowledge that medical drugs and devices are heavily regulated by the federal government and often cannot be sold without FDA's permission. There is, consequently, a high likelihood that in a case where a manufacturer is accused of marketing an allegedly defective medical device, at least some members of the jury will expect to hear about whether the defendant complied with federal law. As the Supreme Court has recognized, jurors

"bring with them to the courthouse" certain "expectations as to what evidence ought to be presented by a party, and may well hold the absence of that evidence against the party." *Old Chief v. United States*, 519 U.S. 172, 188 & n.9 (1997).

The risk that jurors will draw a negative inference from the absence of evidence that a defendant complied with federal law is present in every drug or device case. That risk, however, is made even more acute by the Georgia pattern jury instruction given by the district court in this case, which expressly told the jury that it should consider "the manufacturer's compliance with . . . governmental regulations." Dkt. 399, at 13. So instructed, and having heard nothing at all about Bard's compliance with federal regulations as a result of the court's erroneous evidentiary rulings, the jury could hardly help but infer that Bard had *not* acted in accordance with federal law.

In addition, withholding evidence of regulatory compliance exacerbates a jury's susceptibility to hindsight bias. An ever-present danger in product liability cases, hindsight bias occurs when a juror's evaluation of the *ex-ante* reasonableness of a manufacturer's conduct is distorted by her *ex-post* knowledge that an injury occurred. This natural

cognitive bias can lead jurors to "treat tort defendants unfairly" by "mak[ing] bad outcomes seem more predictable in hindsight than they were" when the defendant acted. Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 937 (2002). To combat hindsight bias, it is vital that the defendant be allowed to offer evidence that will help the jury understand "why the defendant felt [its] choice was reasonable at the time." *Id.* at 941. Excluding evidence of the defendant's compliance with federal law makes it far more difficult for the defendant to keep the jury from falling prey to hindsight bias. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

IV. *Medtronic v. Lohr* Does Not Support the Exclusion of § 510(k) Evidence.

Given the importance of safety and efficacy in the statutes and regulations governing the § 510(k) process, and given FDA's frequent characterizations of that process as one of the means by which it ensures that new devices are safe and effective, it would be remarkable if the Supreme Court had concluded—as the district court believed it had—that

§ 510(k) has nothing whatsoever to do with safety and effectiveness. Not surprisingly, the Court has said no such thing.

In *Medtronic v. Lohr*, the Court did not decide whether § 510(k) clearance relates to safety and effectiveness. Rather, it decided a far narrower question: whether § 510(k) clearance imposed a federal-law "requirement" on the pacemaker at issue, which would have preempted additional or different state-law "requirements." 518 U.S. at 492; *see* 21 U.S.C. § 360k(a) (barring States from supplementing any federal "requirement" for a medical device). All nine Justices agreed with the plaintiffs that preemption was not triggered because "the § 510(k) premarket notification process imposes no 'requirement' on the design of Medtronic's pacemaker." 518 U.S. at 492; *see id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (agreeing that plaintiffs' defective-design claims were not preempted because § 510(k) "places no 'requirements' on a device"). That narrow holding has no bearing on the distinct question of whether a jury applying Georgia law is entitled to consider the fact that the manufacturer obtained § 510(k) clearance as one factor in determining whether the manufacturer acted reasonably and, if

not, whether its conduct was so willfully malicious as to warrant punitive damages.

In concluding otherwise, the district court focused on a single dictum from *Lohr* taken out of context: the Court's offhand observation, borrowed from the Eleventh Circuit, that "'the 510(k) process is focused on *equivalence*, not safety.'" *Id.* at 492. That is a false dichotomy; as explained above, safety considerations are central to FDA's substantial-equivalence inquiry, and requiring equivalence is how FDA ensures reasonable safety and efficacy. But more importantly, the Court did not hold or even suggest that safety is *irrelevant* in the § 510(k) process. On the contrary, it acknowledged that "FDA may well examine § 510(k) applications . . . with a concern for the safety and effectiveness of the device." *Id.* at 493. And five years later, the Court confirmed that § 510(k) review is one of the methods by which FDA seeks "to ensure . . . that medical devices are reasonably safe and effective." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349–50 (2001).

The district court's reliance on *Lohr* was also misplaced for another reason. The Court there dealt with a pacemaker that FDA had cleared in 1982, just six years after § 510(k)'s enactment. 518 U.S. at 480. The

Court thus had no occasion to consider the many subsequent statutory and regulatory changes that have rendered § 510(k) review even more robust:

> In 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. It is not uncommon for applicants to present significant laboratory, animal, and/or clinical data running to thousands of pages. . . . [I]t is typical [for FDA to request] specific additional data and information (including potentially clinical data) required to find a proposed device substantially equivalent.

Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 FOOD & DRUG L.J. 365, 382 (2014); *see* FDA, 510(K) WORKING GROUP: PRELIMINARY REPORT AND RECOMMENDATIONS 34 (Aug. 2010) ("[O]ver time, [the § 510(k) program] has become a multifaceted premarket review process that is expected to assure that cleared devices . . . provide reasonable assurance of safety and effectiveness.").[6] Most notably, the Court in *Lohr* cited neither the safety-and-effectiveness-focused statutory standards for § 510(k) review that were introduced by the Safe Medical Devices Act of 1990 nor FDA's

[6] *Available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf.

regulations implementing those standards. *See* Pub. L. No. 101-629, § 12(a), 104 Stat. 4511, 4523 (1990) (enacting 21 U.S.C. § 360c(i)); 57 Fed. Reg. 58,400, 58,403 (Dec. 10, 1992) (promulgating 21 C.F.R. § 807.100); *see supra* at 11–12. The Court did, however, cite a 1987 estimate that "the § 510(k) review is completed in an average of only 20 hours," 518 U.S. at 479—a figure that "no longer reflects reality and should be considered mythical." Shapiro, 69 FOOD & DRUG L.J. at 382 n.106.

Finally, the Court in *Lohr* placed significant reliance on "federalism concerns and the historic primacy of state regulation of matters of health and safety," which led the Court to interpret the Act's preemption clause narrowly. 518 U.S. at 485; *see also id.* at 475. Here, however, those same federalism concerns point toward respecting Georgia's decision to make a manufacturer's compliance with federal law a matter to be weighed by the jury. Indeed, allowing a State that chooses to do so the option of making regulatory compliance a relevant consideration for juries fosters comity between state and federal drug-and-device regulation. Where preemption does not apply, informing jurors about the federal standards that the defendant complied with helps the jury to make an intelligent decision

about whether the imposition of additional or different standards under state law is truly warranted.

CONCLUSION

The Court should reverse the judgment below.

Respectfully submitted,

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Dated: April 20, 2015

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, I hereby certify:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,102 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Century Schoolbook font.

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

CERTIFICATE OF SERVICE

Pursuant to Rule 25 of the Federal Rules of Appellate Procedure, I hereby certify that I have this 20th day of April 2015, served a copy of the foregoing document electronically through the Court's CM/ECF system on all registered counsel.

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APPENDIX: CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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Product Liability Advisory Council, Inc. as the
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CERTIFICATE OF SERVICE

I certify that on April 20, 2015 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

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