No. 06-179

IN THE
Supreme Court of the United States

DONNA S. RIEGEL, Individually and as Administrator of the Estate of Charles R. Riegel,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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This brief is filed on behalf of the Product Liability Advisory Council, Inc. as *amicus curiae* in support of Respondent, with the written consent of the parties.[1]

INTEREST OF *AMICUS CURIAE*

Amicus Curiae Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit association with more than 120 corporate members representing a broad cross-section of American and international product manufacturers.[2] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective derives from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Several hundred of the leading product liability defense attorneys in the country are also sustaining (nonvoting) members of PLAC. Since 1983, PLAC has filed more than 800 briefs as *amicus curiae* in both state and federal courts, including at least 69 briefs in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

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[1] Copies of those consents have been filed with the Clerk of the Court. No counsel for a party in this case authored this brief in whole or in part, and no person or entity other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

[2] A list of PLAC's current corporate membership is included as Appendix A to this brief.

PLAC is well situated to address the issues in this case. Its members often have confronted the interplay between the duties imposed by federal regulatory authorities and the common law standards applied in product liability cases. PLAC therefore can offer a more in-depth and broader perspective on preemption than the parties may provide.

SUMMARY OF ARGUMENT

In the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c, *et seq.*, Congress expressly preempted requirements imposed under state law that differ from or add to federal requirements applicable to a medical device. *See* 21 U.S.C. § 360k(a). For devices subject to the Pre-market Approval ("PMA") process, the Food and Drug Administration ("FDA") requires the manufacturer to do certain things, for example, to follow a specific design and to use particular language in the labeling. Petitioner argues that state law may impose a duty on the manufacturer – a requirement in the plainest sense of the word – to do or say something different. That position clashes with the clear language of the MDA.

Petitioner and her *amici* nonetheless seek refuge in the "presumption against preemption." But if applicable at all, a canon of construction is at most an aid in discerning the intent of Congress, not an avenue around it. Where the Congressional will is plain, this Court's task is to effectuate it. Here, based on the ordinary meaning of the words Congress used, the PMA process for medical devices imposes federal requirements specifically applicable to each approved device. The PMA

process entails close collaboration between the Food and Drug Administration and the applicant seeking approval. That collaboration, specifically mandated by statute, involves active give and take between FDA and the applicant. Through this process, FDA shapes the application, takes a hand in interpreting the relevant studies, specifies aspects of the design of the product, and often dictates the language of the label. In other words, even before approving the application, FDA imposes requirements applicable to the device. Moreover, once FDA does approve the application, the PMA imposes binding, highly particularized requirements applicable to the device. An applicant may not materially change the device, or its labeling, or the process by which the device is manufactured without FDA's concurrence. Petitioner's argument that the PMA process does not impose "specific substantive requirements" bears no relationship to reality.

On the other side of the ledger, state lawsuits under common law or consumer protection statutes likewise impose requirements applicable to medical devices. Indeed, this Court has repeatedly recognized, as recently as in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), that state common law imposes "requirements" for purposes of the express preemption provisions. *See id.* at 443 ("[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."). Nonetheless, Petitioner argues that her common law causes of action somehow transcend preemption because they are of general applicability, while preemption under the MDA is confined to product-specific regulations or statutes. The language of the MDA is not limited to

product-specific statutes and regulations. The preemption provision applies to *"any"* requirement imposed under state law that is different from or in addition to a federal requirement. *See* 21 U.S.C. § 360k(a). The word "any" is easily understood. It is encompassing. Moreover, the common law duties at issue here are not ones, for example, governing the commercial transaction in which the device is sold. Petitioner seeks to regulate the design and labeling of the device itself. Just as the overarching FDA requirement that a device be safe and effective for its intended use, *see* 21 U.S.C. § 360e(d), translates to particularized requirements applicable to a specific device through a PMA, a common law duty translates to particularized requirements applicable to a specific device through a lawsuit.

In enacting the express preemption provision in the MDA, Congress determined that imposition of state requirements in addition to or different from federal regulation would undermine public health. That judgment was correct. As FDA has stated in this Court, in Courts of Appeals, and in the preamble to regulations, allowing state judges and juries to second-guess the FDA's approval of PMAs, or to dictate different requirements than FDA has imposed, impedes FDA's ability to fulfill its mandate in furtherance of public health. This Court, therefore, should uphold the nearly unanimous conclusion of the Courts of Appeal that the Medical Device Amendments preempt state lawsuits challenging PMA-approved devices.

ARGUMENT

I. THE PRE-MARKET APPROVAL PROCESS IMPOSES FEDERAL REQUIREMENTS THAT PREEMPT STATE LAWS UNDER SECTION 360k OF THE MDA.

A. The Court Should Implement the Plain Language and Evident Intent of the Express Preemption Provision in the MDA.

This case requires a straightforward exercise in statutory construction. As this Court has stated, analysis of preemption begins "with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Morales v. Trans World Airlines Inc.*, 504 U.S. 374, 383 (1992). In the MDA, Congress included a provision expressly preempting state law. With regard to medical devices used in human patients, that provision bars states from "establish[ing] or continu[ing] in effect . . . any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a).

Petitioner contrives numerous reasons why this language does not mean what it pointedly says – that states cannot impose *any* requirement that differs from or adds to a requirement the MDA imposes on a device. In particular, Petitioner suggests that courts so disfavor preemption that Congress must proclaim its intention to preempt with a clarity seemingly beyond what the English language could muster. Congress bears a heavy burden in legislating to preempt state law, Petitioner

asserts, and this Court accedes to such an effort only in the most compelling circumstances. *See* Pet. Br. 17-19. If Petitioner means to imply that this Court should do anything other than divine and implement the Congressional intent embodied in a statutory provision expressly preempting state legal requirements, that is not the role this Court has set for itself. To be sure, Congress ought to speak clearly when preempting state laws. But where, as here, it has done so, the Court has long recognized that the job of the Judiciary is to interpret the statute as Congress intended – not to override Congress or to impose the Court's own preferences. *See Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30-31 (1996) ("This question is basically one of congressional intent. . . . Sometimes courts, when facing the pre-emption question, find language in the federal statute that reveals an explicit congressional intent to pre-empt state law."); *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) ("[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one.").

A presumption, if applicable at all, is no more than a tool for resolution of doubt. It operates at the margins of decision-making, where the Court must choose between equally plausible interpretations of a Congressional enactment – akin to the sandlot rule that a tie goes to the runner. If the call is that close, the Court might fairly presume that Congress would not cavalierly override state laws. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). But at least where the language of the statute is clear, or where the legislative purpose is discernible even though the statutory language is imprecise, the proper role for an Article III court is to

effectuate that congressional purpose, not to penalize Congress for imprecise or inelegant draftsmanship. As the Court has explained:

> "[A]nalysis of the scope of [a] statute's pre-emption is guided by [the] oft-repeated comment, initially made in *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 . . . (1963), that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case. . . . As a result, any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose*.'"

Id. at 485-86 (internal citations omitted); *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 151 (2001) ("There is indeed a presumption against pre-emption in areas of traditional state regulation such as family law. . . . But that presumption can be overcome where, as here, Congress has made clear its desire for pre-emption."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542 (2001) ("Our analysis begins with the language of the statute."). Thus, a presumption against preemption cannot justify reading the word "any" in Section 360k as "some," or inserting the word "specific" when Congress did not use it, or determining contrary to ordinary understanding that a state law "duty" or a compulsory PMA specification is not a "requirement." No presumption for purposes of statutory construction can supersede either the words or the intent of Congress.

Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005), is entirely in accord. The Court found there that the Federal Insecticide, Fungicide, and Rodenticide Act

("FIFRA") did not preempt certain state law causes of action and potentially preempted others. In making that determination, the Court did not marshal a presumption to trump the language of the statute. Indeed, the Court found that the language of the statute compelled the result as it was "the *only one* that makes sense of each phrase in" the preemption provision. *Id.* at 449 (emphasis supplied).

In sum, this Court should not take the detour Petitioner urges from the plain wording of this statute.

B. Irrespective of Any Presumption, the Pre-Market Approval Process Imposes Requirements that Preempt State Law.

In *Medtronic v. Lohr*, a majority of this Court held that the 510(k) pre-market notification process did not impose federal requirements within the meaning of the MDA's preemption provision. 518 U.S. at 493-94. But Justice Stevens's opinion for the majority on this issue carefully distinguished the pre-market *notification* process from the pre-market *approval* process. *Id.* at 478-80 ("The § 510(k) notification process is by no means comparable to the PMA process. . . ."). Under the 510(k) pre-market notification procedure, a device may be marketed if it is "substantially equivalent" to a pre-existing device, even where the pre-existing device was not approved through the PMA process. Thus, in the Court's view, FDA "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before

1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 493-94.

By contrast, the PMA process is all about imposing design, manufacturing, labeling, and other requirements on a particular device. Petitioner's argument to the contrary defies both logic and practical reality. For one, Petitioner concedes that a regulation dictating a particular design for a device would impose a specific requirement capable of preempting a different or additional state requirement. *See* Pet. Br. 25-26. Thus, if the FDA had adopted a regulation requiring that the balloon component of the device at issue here, a balloon catheter, be yellow, that would in Petitioner's view qualify as a federal requirement within the meaning of 21 U.S.C. § 360k(a). But – on Petitioner's reasoning – if FDA dictated that same condition during the PMA process, it would not be a requirement. Either Petitioner is elevating form over substance – defying logic – or she is maintaining that FDA does not impose such conditions in the PMA process – denying reality.

That regulations generally applicable to Class III devices set the boundaries of the PMA process does not mean that FDA refrains from imposing any specific requirements within those boundaries on devices undergoing review. The controlling standard, requiring that the PMA application demonstrate a reasonable assurance of safety and effectiveness, is formidable. As the Court recognized in *Lohr*, "Despite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance' . . . is a rigorous one." 518 U.S. at 477. In particular, those rigors of the PMA process include numerous, intricate, burdensome requirements.

The parties have addressed that process and the requirements it imposes, but certain aspects merit emphasis.

The MDA and the implementing regulations require manufacturers to submit, before a new Class III device can be marketed, a detailed application that describes the device, its functional components, principles of operation, manufacturing processes, clinical and non-clinical laboratory studies, and proposed labeling. 21 U.S.C. § 360e(c); 21 C.F.R. § 814.20. But it would be wrong to assume, as *amicus* AARP does, that because the manufacturer submits the application and draft labeling to FDA, the Agency is merely a passive receptacle, accepting or rejecting what the applicant proposes. In fact, the PMA process engenders active give and take between FDA and the applicant – or more aptly, a cycle of demands by FDA and compliance by the applicant – starting well before the PMA is filed. Through that process, FDA imposes requirements early and often.

FDA's specific requirements commence essentially upon conception of a new device. The Agency requires that most PMAs include data from investigations in humans – that is, "clinical investigations" – to establish the safety and effectiveness of the device. *See* 21 C.F.R. § 814.20(b)(6)(ii). Because it is otherwise illegal to distribute an unapproved medical device in interstate commerce, a person seeking to initiate a clinical investigation of an unapproved device must first seek FDA permission in an application for an Investigational Device Exemption ("IDE"). 21 C.F.R. § 812.1. Each IDE application must include a complete report of prior

investigations of the device, a description of the manufacturing procedures and quality controls used in producing the device, copies of all labeling for the device, and detailed information on the proposed clinical investigations. 21 C.F.R. §§ 812.27. To avoid rejections of IDE applications, FDA has procedures that communicate requirements to sponsors before the studies begin. These include a "pre-IDE" meeting, which "increase[s] the sponsor's understanding of various FDA requirements, regulations, and guidance documents and thus lead[s] to more complete original IDE applications." Food and Drug Administration, "Goals and Initiatives for the IDE Program," 1995 WL 17210906 (Jul. 12, 1995).

Even before submission of the actual IDE, FDA "encourages" sponsors to submit a "pre-IDE application" with preliminary information for FDA to review. *Id.* This submission allows FDA staff to "provide informal guidance to the industry on troublesome parts of the IDE application before the official submission is made." *Id.* Since FDA is the decider on the application, its "informal guidance" is more than just suggestive. Further, FDA has frequent communication with IDE sponsors during its review, so that "deficient information can be addressed within fewer review cycles." *Id*. Thus, both the pre-IDE and IDE review processes are interactive. FDA communicates its detailed requirements to sponsors from the outset, well before any PMA application is prepared. The sponsors attempt to meet them. The results of these interactions shape the product's design and labeling, which FDA ultimately must approve before any PMA device can be marketed.

Much of this was the case even before *Medtronic v. Lohr*. And since 1997, Section 513(a)(3)(D) of the Food Drug and Cosmetic Act, 21 U.S.C. § 360c(a)(3)(D), has dictated an additional process for "early collaboration" meetings between FDA and potential PMA applicants. As described in an FDA guidance document for industry and FDA staff, "Early Collaboration Meetings Under the FDA Modernization Act," those meetings occur after the pre-IDE meeting but before the applicant submits the PMA. *See* Food and Drug Administration, "Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff," 2001 WL 34768220 (Feb. 28, 2001). The purpose is "to facilitate interaction between FDA and applicants and provide clear *direction* for testing and development of those devices requiring clinical investigations to support marketing." *Id.* (emphasis supplied). To request an early collaboration meeting – again before the PMA is even filed – the applicant must include a detailed description of the device and the proposed conditions of use, information regarding the expected performance of the device, and a proposed plan for the clinical evaluation of the device, including a detailed clinical protocol. *See id.* The goal of the meeting is to reach consensus on exactly what FDA will require in a specific PMA. *See id.* In other words, it is another opportunity for FDA informally to impose device-specific requirements. If the applicant does not comply, the Agency will not accept the PMA for filing.

Once the applicant overcomes the preliminary hurdles, complies with FDA's required conditions, and submits a PMA that the Agency accepts for filing, FDA reviews the submission at length. *See* 21 C.F.R. § 814.42.

The review often involves an assessment by an advisory committee of outside experts, which typically holds a public meeting before providing its recommendations to FDA on the approvability of the PMA. *See* 21 U.S.C. §§ 360c(b), 360e(c)(2); 21 C.F.R. § 814.44. During this review, the interaction continues between FDA and the applicant to ensure that the applicant satisfies FDA's terms and conditions. For example, the FDA and the applicant will meet no later than one hundred days after the filing of the PMA to review the status of, and any deficiencies in, the PMA. 21 U.S.C. § 360e(d)(3). FDA can and does use this opportunity to impose additional requirements applicable to the device. *See* Mark Heller, 1 Guide to Medical Device Regulation ¶ 732 (1999) (applicant and FDA may develop an action plan at the hundredth day meeting or discuss options "related to premarket versus postmarket requirements").

At the conclusion of its review, FDA decides whether to approve the device for marketing. 21 U.S.C. § 360e(d)(1)(A); 21 C.F.R. § 814.45. Again, contrary to the suggestion of Petitioner's *amici*, the Agency is not confined to a "take it or leave it" choice – to accept or reject without alteration whatever the applicant proposes. Instead, the FDA may opt to impose still more requirements before approving the PMA. First, the Agency can request a manufacturer to amend its application "with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement." 21 C.F.R. § 814.37(b). If, for example, FDA concludes that a particular change in the design or labeling of the device is appropriate, it can use these

"requests" to make that change a requirement for approval of the PMA. *See id.*

Second, instead of approving or rejecting an application outright, FDA can issue an "approvable letter" when "the agency believes it can approve the application if specific additional information is submitted or *specific conditions* are agreed to by the applicant." 21 C.F.R. § 814.44(e) (emphasis supplied); *see also* Heller, *supra*, ¶ 740 ("The FDA may impose post-approval requirements on a device whose premarket approval (PMA) application it approves; in fact, the FDA Modernization Act of 1997 directed the Agency to balance premarket requirements with postmarket controls."). The approvable letter details the information the manufacturer must submit or the conditions it must satisfy. 21 C.F.R. § 814.44(e)(1).

Third, the Agency can also issue a "not approvable" letter requiring specific changes. This letter describes the deficiencies in the application, and "where practical, will identify measures *required* to place the PMA in approvable form." 21 C.F.R. § 814.44(f) (emphasis supplied). Thus, as the overseer of the PMA process, FDA has the power not only to say "yes" or "no," but also to say "yes, but" and "no, but," thereby imposing additional requirements that may subsequently lead to pre-market approval.

Even if FDA did not impose specific requirements by shaping the PMA process in this manner, once the PMA is approved, its specifications become requirements from which the manufacturer cannot deviate without FDA's concurrence. The applicant is

required to comply with the design specified in FDA's PMA. *See* 21 C.F.R. § 814.39. The applicant is *required* to adhere strictly to the labeling specified in the PMA. And the applicant is *required* to follow the manufacturing and other procedures specified in the PMA. 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). Any changes require detailed documentation, reporting, *and*, most importantly, further FDA approval. 21 C.F.R. § 814.39.

If the manufacturer fails to comply with these requirements, or if the device proves to be unsafe, FDA has a wide range of remedies. It can:

- Revoke or suspend the approval of the device. 21 U.S.C. § 360e(e); 21 C.F.R. § 814.46.

- Order the manufacturer to recall, repair, or replace the device. 21 U.S.C. § 360h(b), (e); 21 C.F.R. Part 810.

- Order the manufacturer to refund the purchase price of the device to customers. 21 U.S.C. § 360h(b)(2)(C).

- Require the manufacturer to issue a notice to all health professionals who prescribe or use the device and any other person, including device users, when necessary to eliminate an unreasonable risk of harm posed by a device. 21 U.S.C. § 360h(a); 21 C.F.R. Part 810.

- Seize the device. 21 U.S.C. § 334.
- Obtain a court injunction prohibiting the manufacture or marketing of the device. 21 U.S.C. § 332.
- Impose civil money penalties on the manufacturer. 21 U.S.C. § 333(g); 21 C.F.R. Part 17.
- Recommend criminal prosecution of the manufacturer or its executives. 21 U.S.C. § 335.

It is misleading to suggest that, because FDA does not invoke these powers as frequently as Petitioner's *amici* might wish, the remedies are toothless and the Agency is incapable of imposing requirements on manufacturers. Given FDA's authority and the regulatory tools in its arsenal, its whisper is as commanding as a shout by others. For example, FDA needs only to "ask" a manufacturer to conduct a recall. A refusal, necessitating a recall order by the Agency, is highly unusual. *See* Food and Drug Administration, "Learn about Medical Device Recalls," www.fda.gov/cdrh/recalls/learn.html ("Legally, FDA can require a company to recall a device. . . . However, in practice, FDA has rarely needed to require a medical device recall.").

In sum, the PMA process is an extended, iterative dialogue that both derives from and results in a highly particularized set of requirements for Class III devices.[3]

[3] These detailed requirements distinguish this case from *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). In *Bates*, (Cont'd)

Manufacturers must abide by these requirements or risk severe sanctions. Under the plain language of the statute, these customized requirements preempt any additional or different requirements under state law.

C. Irrespective of Any Presumption, State Product Liability Claims Are Different or Additional State Requirements Within the Meaning of 21 U.S.C. § 360k(a).

The plain language of Section 360k, barring states from imposing "any requirement" different from or in addition to those under the MDA, encompasses "requirements" imposed by state common law. As Medtronic's brief shows, a majority of this Court agreed in *Lohr* – and in subsequent cases.

The argument of Petitioner and her *amici* that tort suits do not impose requirements because they merely result in the payment of damages is illogical, inconsistent with this Court's decisions, and a reprise of arguments

(Cont'd)
the plaintiffs alleged that their use of Dow's EPA-registered pesticide in acidic soil resulted in damage to their crops and that Dow had failed to warn of this prospect. Dow argued that FIFRA preempted the claims because EPA had not required statements about efficacy in the labeling. The Court, in finding that preemption did not apply to a number of the plaintiffs' claims, stated that, in accordance with EPA's practice after 1972, "the EPA never passed on the accuracy of the statement in Strongarm's original label recommending the product's use 'in all areas where peanuts are grown.'" *Id.* at 440. By contrast, the FDA meticulously reviews and approves each specific claim in the labeling of a medical device approved through the PMA process.

that the Court has repeatedly rejected. The predicate to paying damages is a breach of a duty – or requirement – under state law. This Court has explained, as recently as *Bates*, that "requirements" included state common-law duties. *See* 544 U.S. at 443 ("[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.").

Petitioner and her *amici* argue further that Congress could not have intended to preempt tort lawsuits because it did not mention them in the legislative history. Inferences from legislative silence are perilous indeed, and the asserted inference is particularly unwarranted here, where the preemption extends to only devices subject to PMA approval – a tiny minority of the devices subject to FDA regulation[4] – and then only when state law imposes requirements different from or in addition to state requirements. In *Bates,* the Court noted that the legislative history of FIFRA contained no discussion of preempting state tort suits. *See* 544 U.S. at 452 n.26. Nonetheless, the Court held that, by its express terms, FIFRA preempts state law

[4] *See Lohr*, 518 U.S. at 477 ("Not all, nor even most, Class III devices on the market today have received premarket approval . . . ."). For example, in fiscal year 2005, FDA received just 43 original PMA applications, but received 3130 § 510(k) notifications. *See* FDA Office of Device Evaluation, Annual Report Fiscal Year 2005.

claims for fraud and failure to warn – both liability theories of general applicability to products of any kind – insofar as the claims would impose labeling or packaging requirements that differ from, or add to, the labeling and packaging requirements of FIFRA itself. *Id.* at 452-54.

In any event, the argument of Petitioner and her *amici* accords more importance to what was *not* said in committee reports or in debate than what *was* said in the statute itself. As all the Justices agreed in *Lohr*, Section 360k shows that Congress clearly intended to preempt state law. Congress expressed its intent as to the scope of preemption in the language of the statute. In specifying which state law was preempted, Congress picked two key words: "any" and "requirements." It could hardly have chosen broader terms.

This case illustrates precisely how state tort suits result in particularized state-law "requirements" within the meaning of Section 360k. Petitioner claims that the Medtronic device used in Mr. Riegel's angioplasty procedure was defectively and negligently designed and tested because the balloon burst during the operation. Pet. App. 4a. To prevail on these claims, as well as their claim regarding inadequate labeling, Plaintiffs would have to show that what Medtronic did in designing and labeling the device violated the company's duties under state law. In other words, Petitioner must establish that Medtronic should have, but failed to, design the device to withstand pressures higher than the 10 atmospheres ("atm") to which Mr. Riegel's surgeon inflated the balloon, *id.* at 4a-5a, and alter the product labeling to strengthen further the existing warning that the balloon

"should not be inflated beyond the 'rated burst pressure' of eight atmospheres," *id.* at 4a. Such proposed state law requirements are specific. They also are different from the design and labeling requirements that FDA imposed in the PMA process. The MDA therefore prevents the state from imposing these proposed requirements, whether by statute, regulation, or common-law.

II. A FINDING THAT THE PMA PROCESS PREEMPTS STATE PRODUCT LIABILITY CLAIMS WOULD PROMOTE THE PURPOSES OF THE MDA.

The overarching purpose of the Medical Device Amendments is to protect the public health. The MDA's preemption of product liability claims against devices approved through the PMA process serves that objective. A manufacturer facing tort liability for a medical device that has run the PMA gauntlet in theory would have several possible choices. First, the manufacturer could continue to market the device as approved by the FDA in the PMA process and shoulder the costs and burdens of litigation. Because the requirements in the PMA are just that, "requirements," this is usually the only choice for manufacturers, but it is neither a practical nor a tolerable one. The cost of litigation is staggering, particularly in cases involving medical devices, which, like pharmaceutical cases, often involve a "predominance of factual issues – design defect, warning inadequacy, and causation – that generally preclude the resolution of disputes on motion for summary judgment." Note, *A Question of Competence: The Judicial Role in the Regulation of*

Pharmaceuticals, 103 Harv. L. Rev. 773, 782 (1990). Losing one significant case is likely to trigger "an avalanche" of others. David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 463 (1999). The risk of multiple damage awards, plus the cost and disruption of massive, intrusive, and interminable litigation create a "hydraulic pressure" to settle. *Newton* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001). Whether the companies settle or litigate, the costs are necessarily are reflected in the price of the device – and other products they make. *Cf.* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203, 227 (1997) (finding "a substantial premium exists in the U.S. pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in Canadian prices"). That would further raise the escalating cost of health care and perhaps limit access to medical technology that FDA has found beneficial to the public health. *See, e.g.*, W. Kip Viscusi, Reforming Products Liability (1991). Congress did not intend that result, and Section 360k cannot be interpreted to permit it.

Petitioner premises her argument on the availability of a second option for a manufacturer – changing the device or its labeling as demanded by the plaintiffs. That alternative, however, would not necessarily avoid liability in the initial cases against the manufacturer or in subsequent cases seeking some different modification. And the manufacturer still would have to pay judgments and bear the burdens of litigation, despite full compliance with FDA requirements. Moreover, FDA might not approve the changes under the PMA supplement

process. *See* 21 C.F.R. § 814.39. If the Agency did not do so, the manufacturer would be unable to fulfill its state law duty while also complying with FDA regulations.

In such a conflict, Congress has stipulated that FDA requirements prevail, for good reason. The judge, the jury, and the plaintiff in an individual case focus only on the particular matter before the court. In litigation, each lawyer's obligation is solely to represent his or her client zealously. The adversary system, whatever its many virtues, is not designed to regulate the field of medical devices in the interest of the public health. It can be counted on even less to do so in any individual case. FDA, not lawyers for individual litigants, has the job of protecting the public health.

Thus, FDA has recognized in the context of prescription drugs that state lawsuits challenging approved labeling "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products ("Preamble"), 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006). In FDA's judgment, "State-law attempts to impose additional warnings lead to labeling that does not accurately portray a product's risks" and threaten "FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." *Id.* These principles apply with no less force to FDA regulation of medical devices.

Even supposing one jury could provide manufacturers with proper incentives to make their

products safer, would every jury? Manufacturers have been and likely will continue to be subject to multiple suits in varied jurisdictions. If the PMA process does not preempt state product liability suits imposing requirements at odds with the approved PMA, then juries in every state will influence device regulation, in numerous and often conflicting ways. *See, e.g.*, *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001) (en banc) ("[N]ational uniformity in product regulation [is] one of the explicit goals of the MDA."). Inconsistent jury determinations would "create chaos for both the regulated industry and FDA." *Horn v. Thoratec,* 376 F.3d 163, 178 (3d Cir. 2004) (quoting Statement of Interest of the United States, *Murphree v. Pacesetter et al.*, Civ. No. CT-005429-00-3, at 8 (Cir. Ct. Tenn., 13th Jud. Dist., filed Dec. 12, 2003)). Such disarray is the "antithesis of the orderly scheme Congress put in place and charged the FDA with implementing." *Id.* Unless products liability claims such as Petitioner's are preempted, FDA's expert determinations will be supplanted by a myriad of common law regulators, each one less likely than FDA to reach a right result.

Petitioner and her *amici* suggest that supplanting FDA's determinations is salutary because the Agency's regulation is inadequate. That argument, however, is not properly addressed to an Article III court. In fact, Congress recently bolstered FDA's regulation in this area, authorizing additional funding of $39,232,000 over the next five years for post-market surveillance of medical devices. Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007), § 215. No case has intimated that preemption turns on whether the Court thinks the Agency is doing

a good job. But even if the reports Petitioner cites were correct that FDA is understaffed and ineffectual, the solution would not be to allow state tort suits that, by FDA's own assessment, obstruct the Agency in performing its statutorily mandated role. Indeed, nothing in the cited reports suggests that state tort litigation is a solution to FDA's problems. In attempting to supply that missing link and to characterize litigation as an alternative or supplement to FDA regulation, Petitioner and her *amici* seek not only to intrude where FDA has disinvited them, but also to use means that are unsuited for the stated purpose.

A third option for a company facing liability involving an approved medical device is to withdraw it from the market. Depriving patients of medical products that the FDA has found safe and effective does not promote the public health. Yet that may well occur if the Court does not effectuate Congress's intent as expressed in Section 360k of the MDA.

In short, in the circumstances presented here, preemption of state tort claims both advances the public health and enforces congressional intent. Petitioner's argument amounts to a plea that this Court decline to apply the law as written, because doing so may leave some injured patients without the ability to sue, and because the FDA is supposedly ineffective. The argument is addressed to the wrong branch of government.

CONCLUSION

For the foregoing reasons, the Court should affirm the Court of Appeals judgment that the Medical Device Amendments preempt Petitioner's claims.

Respectfully submitted,

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APPENDIX A — CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS OF 8/6/2007

3M

A.O. Smith Corporation

Altec Industries

Altria Corporate Services, Inc.

American Suzuki Motor Corporation

Andersen Corporation

Anheuser-Busch Companies

Appleton Papers, Inc.

Arai Helmet, Ltd.

Astec Industries

BASF Corporation

Bayer Corporation

Bell Sports

Beretta U.S.A Corp.

BIC Corporation

Biro Manufacturing Company, Inc.

Black & Decker (U.S.) Inc.

BMW of North America, LLC

Boeing Company

Bombardier Recreational Products

BP America Inc.

Appendix A

Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
Chevron Corporation
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
The Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Freightliner LLC

Appendix A

Genentech, Inc.
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Koch Industries
Kolcraft Enterprises, Inc.
Komatsu America Corp.

Appendix A

Kraft Foods North America, Inc.
Lincoln Electric Company
Magna International Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Nokia Inc.
Novartis Consumer Health, Inc.
Novartis Pharmaceuticals Corporation
Occidental Petroleum Corporation
PACCAR Inc.
Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.

Appendix A

Purdue Pharma L.P.
Putsch GmbH & Co. KG
The Raymond Corporation
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Sanofi-Aventis
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.

Appendix A

TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.