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 THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED), DRI, MEDMARC, AND THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA) AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTERESTS OF *AMICI CURIAE*[1]

Amici, whose members are active participants in the medical device regulatory, insurance and litigation process, are uniquely situated to alert the Court to two practical issues of significance to its decision here.

First, notwithstanding petitioner and her *amici*'s view that current federal oversight is lean and in need of all-encompassing state-law augmentation, in actuality—as *amici* here are well-aware and illustrate in detail below—the United States Food and Drug Administration ("FDA") comprehensively regulates medical devices, both before and after their launch on the United States market through the Premarket Approval ("PMA") process.

Second, *amici* are well-acquainted with numerous harmful effects of state-law liability risks in this sensitive context, in which Congress has charged an expert federal agency, FDA, with striking a careful balance of public health objectives. These harmful effects include: (i) forgoing innovation, discouraging device development, and exacerbating a growing "pipeline problem"; (ii) decreasing the availability of potentially beneficial medical treatments in the United States, particularly those relating to women's health; (iii) increasing medical costs; and (iv) encouraging "defensive labeling" that interferes with rational prescribing decisions by physicians.

The Advanced Medical Technology Association ("AdvaMed"), formerly known as the Health Industry Manufacturers Association, is the largest medical technology

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[1] Petitioner and respondent have consented to the filing of this *amicus* brief in letters on file with the Clerk's office. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and their counsel made a monetary contribution to its preparation or submission. This brief is filed in compliance with the Court's May 2, 2005 rules. *See* Sup. Ct. R. 48.3 (2007).

association in the world. It represents more than 1,200 medical device, diagnostic, and health information system manufacturers. AdvaMed's members manufacture 90 percent of the $75 billion of health care technology purchased annually in the United States and more than 50 percent of the $175 billion purchased around the world annually.

AdvaMed's members are innovators of technologies that save lives and increase the quality of life for hundreds of thousands of patients every year. For example, technological breakthroughs such as coronary stents, implantable defibrillators, and minimally invasive bypass surgery have helped reduce the death rate from heart disease by 40 percent since 1980. AdvaMed's members spend an enormous amount of money—roughly $9 billion annually—on the research and development of these innovations. On a percentage of sales basis, this investment constitutes more than four times the average spent on research and development by non-pharmaceutical manufacturers in other industries.

One of the inevitable consequences of innovation in health care technology is that a small percentage of patients suffer injuries that they allege were caused by these highly specialized products. AdvaMed and its members therefore have a significant interest in the outcome of this litigation. Nearly all of AdvaMed's members do now or will in the future face the prospect of tort litigation concerning the medical devices they manufacture, and related costs in the form of self-insurance or insurance premiums to cover the potential risks of alleged device-related injury.

DRI is an international organization that includes more than 22,000 attorneys involved in the defense of civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys. Because of this commitment, DRI seeks to address issues germane to defense attorneys and the civil justice system, to promote the role of the defense attorney, and to improve the civil justice system. DRI has long been a voice in the ongoing effort to make the

civil justice system more fair, efficient, and—where national issues are involved—consistent. To promote these objectives, DRI participates as *amicus curiae* in cases that raise issues of importance to its membership and to the judicial system.

Here, to extend unbounded state tort liability to companies that have successfully brought to market the most cutting-edge medical devices pursuant to the PMA process, as petitioner urges, would threaten the efficient and fair administration of justice. Allowing states to serve as secondary regulatory bodies able to impose different or additional requirements on device manufacturers despite the express preemption provision implicated here would override Congress's intentions with respect to the PMA process and obstruct FDA from fulfilling its regulatory charge. Not only would device manufacturers be subjected to costly and uncertain litigation nationwide, but the overall economy and public health would suffer as a result of the decreased innovation triggered by the threat of liability.

The issues in this case are, accordingly, of substantial concern to DRI. Because DRI's members have first-hand experience with medical device litigation and FDA's regulatory role, DRI is well-suited to address the grave consequences of the unpredictable patchwork of state liability that petitioner's position would create.

Medmarc Insurance Group (Medmarc) is a specialty insurer, owned by the life science industry, which provides product liability coverage for medical device and life science manufacturers. Owned and controlled by its member policyholders in the life science industry, Medmarc was founded in 1979 by that industry in response to volatile conditions in the commercial insurance market for product liability protection. Medmarc's membership includes approximately 700 manufacturers and distributors of medical devices, biotech, generic pharmaceutical, and diagnostic products.

The Medical Device Manufacturers Association (MDMA) is a national trade association representing innovative and entrepreneurial medical device designers and manufacturers. Its membership includes over 150 makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

SUMMARY OF ARGUMENT

Amici will not repeat the legal arguments that are well developed by respondent and other *amici*. Instead, *amici* focus the Court's attention on two key issues.

First, in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Court observed that the § 510(k)-clearance process described in that case was "by no means comparable" to the more "rigorous" PMA process. *Id.* at 477-79. Yet petitioner and her *amici* understate the robust, device-specific pre- and post-marketing review FDA exercises in the PMA context. If anything, this oversight has increased since *Lohr*. For example, FDA has recently further enhanced its "long history of effective medical device safety as a result of both its premarket review process and its postmarket surveillance and enforcement activities" with new initiatives to enhance efforts to "identify safety signals at any point in a product's lifecycle and take timely action." Daniel G. Schultz, M.D., Director, FDA Center for Devices and Radiological Health ("CDRH"), *Medical Device Safety, FDA's Postmarket Transformation Initiative*, 62 Food & Drug L.J. 593, 593 (2007). One such initiative is the Medical Device Safety Network or "MedSun." MedSun, which has been in effect for approximately five years, supplements FDA's existing, mandatory post-marketing surveillance mechanisms with additional "valuable data on how devices are used in the real world of clinical practice," *id.* at 594, such as identifying

"close calls" and engaging in other "proactive prevention" collaboratively with clinicians and manufacturers. MedSun, About MedSun, www.medsun.net/about2.asp.

Second, the state tort liability urged by petitioner and her *amici* threatens to undermine the balance of safety, effectiveness, and innovation Congress has charged FDA with calibrating and would threaten numerous harmful effects. By enacting the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and creating the PMA process, Congress charged FDA with striking a sensitive balance between important, and often competing, public health objectives. On the one hand, Congress sought to ensure that cutting-edge and oftentimes high-risk medical devices would offer, in the agency's expert judgment, a reasonable assurance of safety and effectiveness based on valid scientific evidence before reaching the United States market. On the other hand, Congress focused on fostering a regulatory and legal environment that promotes device innovation that is imperative to preserving and advancing important and life-saving patient treatments.

Enhanced state-law liability poses a challenge to this balance and threatens to, among other things: (i) harm the device development and innovation that Congress and FDA have endeavored to foster; (ii) undermine the availability of medically beneficial devices already on the market; (iii) raise prices for important and life-saving medical devices; and (iv) fuel the proliferation of defensive "over-warning" that undermines rational prescribing decisions, based on risks the expert agency determines to be scientifically justified, and discourages use of beneficial therapies.

ARGUMENT

I. ENHANCED STATE-LAW LIABILITY WOULD INTERFERE WITH FDA'S EXTENSIVE PRE- AND POST-MARKETING OVERSIGHT OF MEDICAL DEVICES, NOT FILL A REGULATORY "GAP."

In *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Court held that state-law claims were not preempted by the MDA's *different* Section 510(k) "substantial equivalence" process which—unlike the comprehensive PMA process at issue here—"requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly," in an average of only 20 hours. *Id.* at 477-79 (internal quotation omitted). The *Lohr* opinion observed that "the 510(k) process is focused on *equivalence* [to another approved product], not safety" and "[a]s a result, substantial equivalence determinations provide little protection to the public." *Id.* at 493 (internal quotation omitted).

In contrast, the Court juxtaposed the "rigorous" PMA process in which FDA spends "an average of 1,200 hours on each submission." *Id.* at 477. The Court underscored that "[t]he § 510(k) notification process is by no means comparable to the PMA process," *id.* at 478-79, and

> *quite unlike* a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. [*Id.* at 501 (emphasis added).]

In keeping with this analysis, nearly every Circuit to have considered the issue (including the Second Circuit below) has

concluded that most state-law claims with respect to PMA-approved medical devices are preempted.[2]

Petitioner and her *amici* seek to undermine the force of this analysis by suggesting that PMA devices actually receive little oversight by FDA. See, *e.g.*, Pet. Br. 4-6, 24-31; Br. *Amici Curiae* Am. Ass'n for Justice et al. 22-27. They then advance the position that state law can properly serve as "a complement" to the PMA process and is "congenial to" Congress's charge and FDA's regulation of PMA devices. Br. *Amicus Curiae* Consumers Union 11. Their view is mistaken.

As recognized in the *Lohr* decision, the PMA process involves robust federal regulation affecting every stage of the development and marketing of a medical device, both before and after FDA permits it to reach the United States market. If anything, this review—and the case for preemption—has become even stronger since the time of *Lohr*.

A. FDA Exercises Substantial Pre-Marketing Oversight Of Medical Devices.

Even before the PMA process begins, manufacturers typically must satisfy extensive FDA requirements to gain a so-called Investigational Device Exemption ("IDE") to authorize clinical investigations involving human subjects. To obtain an IDE, the manufacturer must make detailed submissions to FDA regarding every aspect of the device and clinical investigation. See 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812.1-812.150 (regulations applicable to IDEs). During the IDE process, FDA reviews voluminous materials and

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[2] *See, e.g.*, Pet. App. 2a; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), *cert. denied*, 547 U.S. 1003 (2006); *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir.), *cert. denied*, 546 U.S. 935 (2005); *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *but see Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

evaluates whether "the anticipated benefits to the subjects and the importance of the knowledge to be gained" from such trials outweighs the estimated "risks to the subjects," and further ensures that the informed consent provisions are adequate, the investigation is scientifically sound, and there is no reason to believe the device will be ineffective. 21 C.F.R. § 812.30; see *Martin* v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095-96 (6th Cir. 1997) (describing IDE process and related preemption issues). Clinical investigations generally require prior approval from an Institutional Review Board ("IRB")—an independent scientific reviewing body acting under the auspices of the National Institutes of Health. See 21 C.F.R. §§ 56.101-56.124 (IRB regulations); 45 C.F.R. §§ 46, *et seq*. (Health and Human Services regulations regarding protection of human subjects and pertaining to IRBs); see also, *e.g.*, 21 C.F.R. §§ 812.35(b), 812.40-812.47, 812.60-812.66, 812.150(a)-(b) (imposing IDE-specific IRB requirements).

Before FDA can determine that a device is safe and effective through the PMA process, 21 U.S.C. §§ 360c(a)(1)(C)(i), 360e(d)(2), it reviews exhaustive submissions. A PMA application must include: (1) full reports of all safety and efficacy investigations; (2) a full statement of the device's components, ingredients, properties, and principles of operation; (3) a complete description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing or installation of the device; (4) information demonstrating compliance with statutory performance standards; (5) samples of the device, if requested by the FDA; (6) specimens of proposed labeling; and (7) any other information FDA requires. See 21 U.S.C. § 360e(c)(1); *id.* § 360e(f)(3); 21 C.F.R. § 814.20 (requiring statements of indications for use, device description, alternative practices and procedures, marketing history, summary of studies, and study conclusions).

These submissions typically include "'thousands of pages of documentation'" to which FDA must apply its expert analysis to determine whether there is a reasonable assurance of safety and efficacy. *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 172 (3d Cir. 2004) (quoting *amicus curiae* brief of the United States); see *Rattay* v. *Medtronic, Inc*., 482 F. Supp. 2d 746, 748 (N.D.W. Va. 2007) (PMA application exceeded 1,700 pages); *Steele* v. *DePuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 444 (D.N.J. 2003) (PMA application 2,000 pages before supplements).

During this review, FDA informs the manufacturer if there are any "major" or "minor" deficiencies that must be satisfactorily addressed before the PMA application can move forward. See generally FDA, CDRH, *Review Process* June 11, 2003), www.fda.gov/cdrh/devadvice/pma/review_process.html. For example, "[o]ne of the most important aspects of the device approval process is the development of a meaningful and accurate product label" and the agency "works closely with the manufacturer to create this label." I. Muni et al., *Challenges in Regulating Breakthrough Medical Devices*, 60 Food & Drug L.J. 137, 138 (2005). If FDA determines that the application is deficient in any respect (*e.g*., labeling, manufacturing, design specifications), it may take a manufacturer months, if not years, to cure the deficiency. See, *e.g.*, *Horn*, 376 F.3d at 169-70 (PMA process began in 1975, PMA application submitted to FDA in 1992, and device approved in 1994); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000) (four years between IDE approval and PMA approval).[3]

During this process, the agency draws on its unique vantage point. Indeed, FDA "holds the only broad, cross-cutting knowledge" and "experience with the totality of other

[3] Such back-and-forth would not be necessary, of course, if FDA determines the PMA application fully answers its questions in the first instance and no remaining issues need to be addressed.

applications," and also utilizes its knowledge of "the latest science." FDA, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* 13 (Mar. 2004), *available at* www.fda.gov/oc/initiatives/criticalpath/whitepaper.html. To the extent an application does not meet FDA's standards or the agency has questions, there may need to be substantial back-and-forth between the manufacturer and agency. In *Horn*, for example, after the manufacturer submitted its PMA application to FDA it "supplemented it in the ensuing three years with a substantial amount of amendments and responses to FDA questions." *Horn*, 376 F.3d at 170.

Even after a manufacturer satisfies any deficiencies flagged by FDA, the agency generally refers the application to an independent committee of experts, which holds a public meeting to review the device and prepares a report and recommendation to FDA on whether a device is safe and effective. See 21 U.S.C. § 360e(c)(2); 21 C.F.R. pt. 14; *id.* §§ 814.42, 814.44; FDA, *Review Process*, *supra*. After the committee issues its recommendation, FDA considers that information along with the other submissions to determine whether the device's "safety and effectiveness" has been demonstrated through "valid scientific evidence." 21 C.F.R. § 860.7; FDA, *Review Process*, *supra* (recognizing that even after a committee recommendation, FDA may require additional submissions from the manufacturer).[4]

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[4] Since *Lohr*, FDA also has increased its scrutiny of a limited set of § 510(k) devices. In FDAMA, Congress augmented the § 510(k) process by allowing manufacturers an option of gaining clearance by utilizing conformance with FDA recognized standards to demonstrate safety and efficacy equivalent to a predicate device. *See* 21 U.S.C. § 360d(c)(1); *id.* § 360c(i)(1)(A)(ii); FDA, CDRH, *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff* (June 20, 2001), *available at* www.fda.gov/cdrh/ost/guidance/321.html ("In the case of 510(k)s, information on conformance with recognized consensus standards may help establish the substantial equivalence" and "can be

If FDA determines that a manufacturer has provided reasonable assurance that the device is safe and effective for its intended use, the agency then issues a letter order incorporating by reference the submissions pertaining to this regulatory process and permitting the manufacturer to market the device in the United States. It does so after a manufacturer demonstrates that the manufacturing and processing methods and facilities conform to FDA requirements, and that the proposed labeling is not false or misleading. *See* 21 U.S.C. § 360e(d)(2); 21 C.F.R. § 814.45. Thereafter, as described below, the manufacturer may not alter design, labeling, or manufacturing process in any way that would affect the safety or effectiveness of the device or "is inconsistent with any conditions to approval specified in the PMA approval order for the device" without FDA approval. *Id.* § 814.80.

B. FDA Exercises Substantial Post-Marketing Oversight Of Medical Devices.

After a PMA application is approved, FDA's comprehensive oversight continues—and has been enhanced further in recent years. See, *e.g.*, 21 C.F.R. § 814.44; FDA, *Review Process*, *supra*. For instance, the manufacturer may have to satisfy further conditions of approval for the device to remain on the market. 21 C.F.R. § 814.82(a). As noted, a manufacturer may not change the approved product design, labeling, or manufacturing process in any manner that would affect the safety or effectiveness of the device without FDA approval. *Id.* § 814.80; *id.* § 814.39 (requiring prior FDA approval for most modifications). The manufacturer is subject to audit and inspection by FDA. See 21 U.S.C. §§ 360h, 360i, 360j; 21 C.F.R. §§ 814.80, 814.82, 814.84.

FDA's oversight of safety issues continues post-marketing, as the device moves from the realm of clinical study to

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used to show that the new device is as safe and effective as the predicate in the areas covered by the standards.").

broader, real-world clinical use. As the FDA Deputy Commissioner has explained, "even for a product that is rigorously tested preapproval, some risks will become apparent only after approval, when the product is used in tens of thousands or even millions of patients in the general population." Scott Gottlieb, *Latest Trends in FDA Practice*, 878 PLI/Pat 525, 536 (2006). This can occur, for example, with respect to rare side effects. See Muni, *supra*, at 138-39.

As the American Medical Association has long recognized, FDA's "post marketing surveillance outside of formal studies constitutes a vital activity in ensuring the safety of drugs and devices." Am. Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 Food & Drug L.J. 359, 360 (1994). Of course, if Congress instead had enacted a different regulatory system that effectively "forbid marketing of a [device] until all long-term consequences and interactions are identified through formal research[, it] would impose unacceptable costs in the form of untreated or inadequately treated illness." *Id.*

FDA has a continuing role in notifying healthcare professionals (and affected individuals) of risks presented by medical devices, see 21 U.S.C. § 360h(a), requiring manufacturers to repair or replace defective devices, *id.* § 360h(b), instituting recall campaigns, *id.* § 360h(e),[5] overseeing required recordkeeping and reports of adverse reactions and injuries associated with devices, *id.* § 360i, and requiring post-market surveillance of devices, *id.* § 360j. In

[5] FDA has different classes of "recall," most of which do not involve a product's removal from the market, and which range from addressing potentially serious issues (Class I) to simply correcting matters that "are unlikely to cause any adverse health reaction" (Class III). FDA, *FDA Recall Policies* (June 2002) *available at* www.cfsan.fda.gov/~lrd/recall2.html; *accord* FDA, CDRH, *FY 2006 Highlights* 30 (2006); *see* 21 C.F.R. § 7.3(g)-(h); Muni, *supra*, at 141 (stating there are approximately 1,000 "recalls" per year yet only 10-20 per year are designated as Class I).

addition, FDA may revoke PMA approval if it subsequently determines, *inter alia*, that a device is no longer safe and effective or that the manufacturer has not satisfied postapproval requirements. See *id.* § 360e(e); 21 C.F.R. § 814.46. Furthermore, FDA can invoke injunctive relief, seizure, criminal, and civil monetary penalty options for non-compliance. See 21 U.S.C. §§ 332, 333.

Moreover, since *Lohr* was decided, FDA has enhanced post-approval oversight. See generally Daniel G. Schultz, M.D., Director of FDA's CDRH, *Medical Device Safety: FDA's Postmarket Transformation Initiative*, 62 Food & Drug L.J. 593, 593 (2007) ("[W]e have instituted significant changes over the past few years in our approach to postmarket medical device issues."); *id.* at 595 (stating that the measures rely on "expert[ise]" in all aspects of medical device development and regulation to "manage device-related public health issues" including "comprehensive review of medical device performance through a product's lifecycle"); Muni, *supra*, at 139 (discussing enhancements since 2002).

Among other initiatives, FDA has (i) issued guidance regarding how post-approval studies are to be conducted, see, *e.g.*, FDA, *Guidance for Industry and FDA Staff - Procedures for Handling Post-Approval Studies Imposed by PMA Order* (Aug. 1, 2007); (ii) utilized Public Health Notifications and the "FDA Patient Safety News" program to disseminate information about device-related risk, see Muni, *supra*, at 141; and (iii) supplemented the existing post-marketing Medical Device Reporting ("MDR") system, 21 C.F.R. §§ 803.30, 803.50, with the Medical Device Safety Network or "MedSun." Schultz, *supra*, at 594; Muni, *supra*, at 139.

Launched in 2002, MedSun draws on active reporting from practitioners in healthcare facilities across the United States "of problems like close calls or the rejection of a device over safety concerns." MedSun, About MedSun, www.medsun.net/about2.asp. As an interactive surveillance and compliance program, when an issue is raised, "MedSun researchers

work with each facility's representatives to clarify the situation and fully understand the problem. Reports are later shared without facility identification so that clinicians can take necessary preventative actions." *Id.*

FDA has been active in responding to potential "safety signals" emitted by the reporting systems, as well as engaging in compliance and enforcement where appropriate. See Schultz, *supra*, at 593 ("over the past five years, we have seen an increase in the number of adverse event reports received"). For instance, FDA recently reported that in the last quarter of fiscal year 2006 alone its "safety analysts identified over 100 new and ongoing medical device safety issues" and "responded to over 100 consult requests related to information in the reports database." FDA, CDRH, *FY 2006 Highlights* 28 (2006); see also *id.* at 29 (discussing fiscal year 2006 actions including ordering postmarket surveillance studies, continuing ongoing surveillance, and issuing warning letters for postmarket surveillance violations). During 2006, CDRH took at least 55 enforcement actions, including four seizures and an injunction, and initiated hundreds of correction actions. *Id.* at 30.

During this process, collaboration between the agency and the manufacturer is integral to ensuring patient safety:

> [T]his cooperation between FDA and its regulated industries has been demonstrated to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of industry, as well as FDA, to get unsafe and defective products out of the hands of clinicians and patients as soon as possible. [Muni, *supra*, at 140.]

Furthermore, FDA has the expert perspective necessary to ensure that the correct measure of oversight is employed. See *id.* at 141 (noting that, in some cases, inspections may be

necessary whereas, in others, spot checks alone might be sufficient to cure the identified problem).

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Given FDA's continuing pre-approval scrutiny of PMA devices, see *Lohr*, 518 U.S. at 477, and the increase in post-approval oversight, the potential for state-law interference has grown since this Court last considered the MDA in *Lohr*. In this light, the case for preemption in the PMA context is even stronger than this Court previously suggested. Cf. *id.* at 478-79 (contrasting § 510(k) review with PMA).

State-law tort actions, in contrast, cannot promise the swiftness with which FDA can act; fail to account for the safety-efficacy-innovation balance both Congress and FDA have sought to strike; and lack the expert perspective central to fulfilling the multiple objectives of Congress. Expansive state tort liability not only provides a form of additional regulation, but would "regulate" in a manner completely untethered to the designs of the MDA and PMA process such that it undoes their purposes.[6] Moreover, lay juries are not institutionally well-equipped to make the kinds of nuanced risk-benefit calculations and scientific judgments Congress

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[6] Petitioner's *amici*, including the American Association for Justice and Public Justice, admit that tort liability functions as a form of regulation. Br. *Amici Curiae* Am. Ass'n for Justice et al. 18-19. Although they posit that the enhanced state-law liability they seek "promot[es] optimal deterrence," they do not (and cannot) reconcile their position with the deterrence balance already reached by FDA, which is charged by Congress with balancing considerations of safety, efficacy, and innovation. *Id.* at 18 (internal quotation omitted). To have state tort liability promote "optimal deterrence" that hinges on "minimiz[ing] the sum of accident costs" would necessarily unravel the PMA regime, which purposely allows—and encourages—devices with the greatest degree of risk to come to market under the expert agency's close oversight. In the end, petitioner and her *amici* seek to have state law second-guess and supplant the public health balance struck by Congress and the individual balancing determinations reached by FDA as to particular devices.

has charged FDA—as the expert federal agency—with making. For example, mock jury studies explain that lay jurors tend to overestimate the level of risk of low probability events, overreact to risks posed by new technology, and punish defendants for undertaking risk-benefit analyses. See Reid Hastie & W. Kip Viscusi, *What Juries Can't Do Well: The Jury's Performance As a Risk Manager*, 40 Ariz. L. Rev. 901, 909-11 (1998).[7]

II. EXTENDING STATE-LAW LIABILITY WOULD UNDERMINE THE BALANCE OF PUBLIC HEALTH OBJECTIVES REFLECTED IN THE MDA.

The enhanced state-law liability petitioner seeks would threaten the calibrated public health balance at the heart of the MDA. On the one hand, the MDA seeks to protect patients by ensuring that medical devices are marketed in the United States only after FDA determines that they meet the requisite threshold of safety and effectiveness based on valid scientific evidence. See, *e.g.*, 21 U.S.C. §§ 360c(a)(1), 360e(d)(2); 21 C.F.R. § 860.7; FDA, FDA's Mission Statement, www.fda.gov/opacom/morechoices/mission.html (FDA's mission includes "protecting the public health by assuring the safety, efficacy, and security of . . . medical devices").

On the other hand, the MDA recognizes that device development, innovation, and availability are essential to improving public health. Indeed, Congress expressly sought to foster innovation in medical device technology and "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for

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[7] *See, e.g.*, W. Kip Viscusi, *Jurors, Judges, and the Mistreatment of Risk By the Courts*, 30 J. Legal Stud. 107, 111-14 (2001) (finding mock jurors misapplied cost-benefit analyses particularly in low-probability, large-loss cases); W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 588 (2000) (jury awards and attitudes skeptical of risk-benefit analyses).

human use." 21 U.S.C. § 360j(g)(1). As the Senate Committee Report explains:

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development. [S. Rep. No. 94-33, at 2 (1975).]

Such innovation leads to more effective, safer, and more affordable treatments. See *id.*

The express preemption provision at issue here arose in this context of balancing important public health objectives.[8] Addressing the propriety of the express preemption provision in light of the importance of device development, the House Report counseled that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the federal government, interstate commerce will be unduly burdened," and preemption will be necessary to ensure that "innovations in medical device technology are not stifled by unnecessary regulation." H.R. Rep. No. 94-853, at 12, 45 (1976); see *id.* at 10 (protecting the public from unsafe devices is "counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field"); *id.* at 12 (stating that MDA "reflects the need to develop innovative new devices"); *Hearings on H.R. 5545, H.R. 974 & S. 510 Before the Subcomm. on Health & the Environment of the H. Comm. on Interstate & Foreign Commerce*, 94th

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[8] The express preemption provision appears at 21 U.S.C. § 360k(a). The briefs of respondent and its other *amici*, as well as the Second Circuit's decision below ably detail the application of this provision to the PMA context. We will not burden the Court by repeating that analysis here.

Cong. 201 (1975) (Statement of Rep. Fred Rooney) (urging passage of the MDA to replace the "piecemeal" and "after the fact" approach typified by then-existing judicial remedies).

In 1990, Congress reaffirmed that its goals included encouraging medical device development to flourish when it amended the MDA. See Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 ("SMDA"). "Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices." S. Rep. No. 101-513, at 13 (1990).[9]

Following *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), Congress again sought to encourage innovation through the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). There, Congress further refined FDA's mission, requiring the agency, *inter alia*, to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Indeed, "[a] central purpose of the [FDAMA] is 'to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development.'" FDA, *The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concepts &*

[9] Statements by a cross-section of members of Congress echo these objectives. *See, e.g.*, 136 Cong. Rec. S15205, S15211 (daily ed. Oct. 12, 1990) (statement of Sen. Kennedy) (objectives include "encourag[ing] technological innovation"); *id.* at S12493 (daily ed. Aug. 4, 1990) (statement of Sen. Dodd) (MDA "is structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products"); *id.* at S17459 (daily ed. Oct. 27, 1990) (statement of Sen. Hatch) (legislation "balance[s] the need for regulation with the benefits of innovation").

Principles; Final Guidance for FDA & Industry (Oct. 4, 2002) (quoting S. Rep. No. 105-43 (1997)) ("Congress'[s] goal was to streamline the regulatory process (i.e., reduce burden) to improve patient access to breakthrough technologies."), *available at* www.fda.gov/cdrh/ode/guidance/1332.html.

The state-law liability petitioner seeks to impose would trigger, or exacerbate, harmful effects contrary to these congressional purposes. These effects include discouraged innovation, diminished availability, increased costs, and defensive labeling—each of which would undermine public health.[10]

A. State Tort Liability Stifles Innovation Of Important And Life-Saving Medical Devices.

The state tort liability for which petitioner advocates would stifle medical device innovation, thereby exacerbating an already serious "pipeline problem" in the development of important medical devices. Robust research and development is the catalyst for safer devices and new devices that may address previously untreatable or poorly controlled conditions. Indeed, the Medtronic catheter at issue here, like all Class III medical devices, is so-classified because it is used "in supporting or sustaining human life." 21 U.S.C. § 360c(a)(1)(C)(ii)(I). Congress subjected these devices to the stringent federal regulatory oversight of the PMA process because they intrinsically "present[] a potential unreasonable

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[10] Although not presented in this appeal, this is not to suggest that all state tort claims with respect to a PMA-approved medical device necessarily would be preempted. It may be the case that certain manufacturing flaw claims—those premised not on a challenge to the overall FDA-approved manufacturing process but on the specific device the patient received containing a manufacturing flaw reflecting a deviation from the FDA-approved design and manufacturing process—would survive a preemption analysis. *See, e.g.*, Pet. App. 35a (addressing manufacturing flaw claim that otherwise failed to survive summary judgment).

risk of illness and injury." *Id.* § 360c(a)(1)(C)(ii)(II); see *Lohr*, 518 U.S. at 477 (juxtaposing § 510(k) review and explaining that FDA takes, on average, 1,200 hours to review a PMA application). Yet Congress freed such devices from additional state regulatory requirements, thereby facilitating continued innovation.

AdvaMed's members alone spend roughly $9 billion annually on research and development to facilitate device innovations. Even a decade ago, this trajectory was evident: In 1995, the average research and development expense underlying a PMA-approved device was approximately $75 million, a three-fold increase from 1990. See William W. George, *Medical Technology and Competitiveness in the World Market: Reinventing the Environment for Innovation*, 50 Food & Drug L.J. 477, 480 (1995). In addition to threshold research and development costs, the PMA application itself imposes significant costs. The United States Government Accountability Office found that user fees charged by FDA for PMA review of a device averaged over $239,000 per device in 2005. GAO-06-62, *Medicare Durable Medical Equipment: Class III Devices Do Not Warrant a Distinct Annual Payment Update* 3 (Mar. 1, 2006). And, over ten years ago, FDA estimated that PMA applications and supplements cost the industry approximately $35 million per year. See 62 Fed. Reg. 51112, 51113 (Sept. 30, 1997).

These costs, and the length of PMA approval, contribute to a background "pipeline problem" in bringing new and innovative medical products to market that is further exacerbated by state tort liability risks. See generally FDA, *Innovation or Stagnation*, *supra*, at 1 (recognizing a "growing crisis in moving basic discoveries to the market where they can be made available to patients"); *id.* (noting the decrease in the number of device applications). FDA recently expressed its "growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for

patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly." *Id.*

The American Medical Association has observed that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." Am. Med. Ass'n Bd. of Trs., *Impact of Product Liability on the Development of New Medical Technologies* 1 (1988). It remains difficult to properly insure against state tort risks.[11]

"[M]edical equipment companies are increasingly reluctant to innovate because of concern about suits with larger numbers of claimants and extraordinary awards." Lawrence Tancredi & Dorothy Nelkin, *Medical Malpractice and Its Effect on Innovation* 251, 260, *in The Liability Maze* (P.W. Huber & R.E. Litan eds., 1991). "The threat of . . . enormous awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Browning Ferris Indus. of Vt., Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part).

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[11] *See, e.g.*, David Dial et al., *Tort Excess 2005*: *The Necessity for Reform from a Policy, Legal and Risk Management Perspective* 9-10 (2005) ("[t]he unpredictable and catastrophic nature of U.S. tort exposures . . . has made insuring large-scale liability risks substantially more challenging" in recent years, and "the scarcity of coverage" for pharmaceuticals "has reached critical proportions"); Scott E. Harrington, *Tort Liability, Insurance Rates, and the Insurance Cycle*, *Brookings-Wharton Papers on Financial Services* (2004) ("An expanding tort liability system that entails substantial uncertainty about the cost of future claims will inevitably lead to increasingly expensive [insurance] coverage.").

Numerous commentators have remarked on this phenomenon.[12] For example, Professor Michael E. Porter of the Harvard Business School has explained that in the United States "product liability is so extreme and uncertain as to *retard innovation*" because "the legal and regulatory climate places firms in constant jeopardy of costly and, as importantly, lengthy product liability suits" and "goes beyond any reasonable need to protect consumers." Michael E. Porter, *The Competitive Advantage of Nations* 649 (1990) (emphasis added). State tort exposure's "profound negative impact on the development of new medical technologies," AMA, Bd. of Trs., *supra*, at 1, unfortunately reflects a reasoned response by manufacturers to pull back in the face of unreasonable and unpredictable liability.

Similarly, the threat of liability skews device-development incentives in a manner that can undermine public health. For example, FDA has recognized that rising costs create incentives for manufacturers to focus on low risk, high profit products. See generally FDA, *Innovation or Stagnation* ("Because of rising costs, innovators often concentrate their efforts on products with potentially high market return."). At the same time, manufacturers are discouraged from

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[12] *See, e.g.*, Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development in The Liability Maze* 34, 337, *supra* ("concern about liability has led to serious delays in product development and to increased liability insurance costs"); W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability & Innovation in The Liability Maze* 81, 83, 94-96, *supra* (recognizing that product liability can cause lags in drug development and that losses exceeded premiums for insurers of pharmaceutical companies throughout the 1980s); W. Kip Viscusi, et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most innovative industries in the economy, has been particularly hard hit by the surge in liability costs."); *id.* at 1419 (recognizing that a National Academy of Science panel also found that increased liability costs had discouraged innovation in the pharmaceutical industry).

developing medical treatments which, despite potentially life-saving benefits, also pose heightened risks. See *id.* ("For very innovative and unproven technologies, the probability of an individual product's success is highly uncertain, and the risks are perceived as extremely high."); see also *id.* ("[i]nventors of candidate artificial organs, bioengineered tissues, and other novel devices face serious challenges and uncertainties").

B. State Tort Liability Threatens The Availability Of Significant Medical Treatments.

The specter of state liability threatens the availability of important medical treatments and can have a chilling effect on marketing treatments in the United States that are available abroad. Historically, this phenomenon has been particularly acute in the area of women's health.

Bendectin, the only prescription medication approved by FDA for treating significant morning sickness during pregnancy, provides a classic example of this dynamic. See Lasagna, *supra*, at 337-41. Extreme morning sickness can have a devastating medical impact both on the pregnant woman and on the developing child and requires medical treatment. Although no scientifically reliable study ever found a causal relationship between the medication and birth defects, and FDA repeatedly found the product to be safe and effective, the manufacturer faced nearly 2,000 tort suits seeking to recover for alleged birth defects. See generally Dep't of Health & Human Servs., FDA, Determination That Bendectin Was Not Withdrawn From Sale For Reasons Of Safety Or Effectiveness, 64 Fed. Reg. 43190 (Aug. 9, 1999). And even though its manufacturer was successful in defending the litigation on the merits, Bendectin was withdrawn from the market in 1983, in light of $18 million per year insurance and legal costs, as compared to only $20 million in annual sales. See, *e.g.*, Marvin E. Jaffe, *Regulation, Litigation and Innovation in the Pharmaceutical Industry: An Equation for Safety*, *in Product Liability & Innovation: Managing Risk in an Uncertain Environment*

120, 126 (J.R. Hunziker & T.O. Jones eds., 1994); Lasagna, *supra*, at 338 ("[Bendectin's] doom was traceable to the flood of legal actions that followed assertions in the scientific literature that Bendectin could produce congenital defects in both animals and humans.").

This experience has had a ripple effect in discouraging the future development of morning sickness treatments in the United States. See Lasagna, *supra*, at 341 (stating that after the Bendectin experience "[i]t seems safe to predict" that no manufacturer will seek FDA approval for a morning sickness drug). In the absence of a viable treatment such as Bendectin, "treatment for severe nausea during pregnancy" accounted for "nearly $40 million of the nation's annual hospital bill" in 1994 alone, and "[i]t is unlikely that any new drug will be developed to close this therapeutic gap." Jaffe, *supra*, at 126. Moreover, since the withdrawal of Bendectin from the United States market, hospitalizations due to severe morning sickness have increased three-fold in the United States, while such hospitalizations have declined, for example, in Canada, where the drug has remained available under the name "Diclectin." FDA/NIH Conference, *Clinical Pharmacology During Pregnancy Addressing Clinical Needs Through Science* (Dec. 4, 2000), *available at* www.fda.gov/cder/present/clinpharm2000/1204preg.txt; see C. Ineke Neutel, *Variation In Rates of Hospitalization for Excessive Vomiting In Pregnancy By Bendectin/Diclectin Use in Canada*, *available at* www.nvp-volumes.org/p1_9.htm ("What is then the impact of the withdrawal of Bendectin? The increase of hospitalization for [excessive vomiting in pregnancy] for thousands of women for more than a decade led to increased cost and hardship to the women and their families, as well as to the healthcare system.").

The withdrawal of Norplant from the United States market also illustrates the point. Norplant, a set of implanted rods that release a hormone to inhibit ovulation, was acclaimed upon introduction to the market in 1991 and had

approximately one million users by 1995. See Linda A. Johnson, *Wyeth Won't Resume Norplant Sales*, Associated Press Online, July 26, 2002; Albert George Thomas Jr. & Stephanie M. LeMelle, *The Norplant System: Where Are We in 1995*, 40 J. Fam. Prac. 125, 125 (1995). FDA repeatedly found Norplant to be an effective method of birth control. See, *e.g.*, Johnson, *supra*; Sylvia A. Law, *Sex Discrimination & Insurance for Contraception*, 73 Wash. L. Rev. 363, 371 (1998) ("Norplant has been subject to extensive testing and appears to be highly effective and safe."). Yet Norplant was withdrawn from the United States market in August 2000, amidst allegations that certain individual lots might not be effective. See Johnson, *supra*.

Despite positive public health findings by FDA, the World Health Organization, and the American Society of Reproductive Medicine, commentators have observed that Norplant was "'killed off,'" as lawsuits based on "untru[ths]" and "misperceptions" hurt sales, and Norplant's manufacturer made a "business decision" to no longer market the product. Johnson, *supra*; Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. Times, May 28, 1995, at C1.[13] Even the company's "'legal success has come at a steep price because lawsuits are time consuming, expensive and have a chilling effect on research.'" Morrow, *supra* (quoting manufacturer's North American President).

In the end, litigation stifled a medical treatment that was beneficial to many women, leaving in its wake a poor climate for future development of contraceptive devices. As Dr. Felicia Stewart, then-deputy assistant for population affairs at

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[13] Over the course of Norplant litigation, more than 50,000 plaintiffs purportedly sued the company. *See Contraceptive Maker Wins Woman's Suit Over Side Effects*, N.Y. Times, Sept. 5, 1998. No plaintiff won a jury verdict and the manufacturer won multiple trials, numerous summary judgment motions, and had tens of thousands of cases dismissed. David J. Morrow, *Maker of Norplant Offers a Settlement in Suit Over Effects*, N.Y. Times, Aug. 27, 1999.

the Department of Health and Human Services, recognized "'[i]t's clear watching what happened with Norplant why a company thinking about marketing a new contraceptive product might say it isn't worth making an investment.'" Kolata, *supra*; see, *e.g.*, Johnson, *supra* (noting that the manufacturer also declined to introduce a successor device to the United States market although it had done so abroad); Anna Biernbaum, Note, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. Cal. Rev. L. & Women's Stud. 411, 412-13 (2001) ("Due to the bad publicity Norplant received, few women are using this safe and effective form of birth control. . . . [T]here is no longer an incentive for drug companies to research and market new birth control devices, since the threat of litigation is something that they are keenly aware of in the wake of Norplant."). Under the rule for which petitioner and her *amici* advocate, there is no reason to believe that the threats to innovation will be any less severe with respect to PMA-approved medical devices.

C. State Tort Liability Increases Price And Undermines The Affordability Of Medical Treatments.

State tort liability increases the price of medical therapies. See, *e.g.*, Barbara Marsh, *The Product Liability Morass; Complications Set In; Big Suppliers Pulling Out of Medical Market*, L.A. Times, May 6, 1995, at A1. For example, manufacturers of certain catheters, heart valves and other devices were forced to withdraw from the market when silicone prices increased to $100 per pound from $6 per pound due to product liability litigation. *Id.* Vaccines provide another example of the point. Between 1980 and 1989, the wholesale price of most vaccines doubled or tripled; in contrast, the price of two vaccines with a higher perceived liability potential increased by factors of 40 and seven in the same period. Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J. L. & Econ. 247, 254-57, 273 (1994) (describing, respectively, the

increased price of the diphtheria, pertussism and tetanus (DPT) vaccine and the oral polio vaccine).

In setting the price of medical therapies, not only must a manufacturer recoup its research, development, and production costs through device sales—a goal managers of publicly held companies may have a fiduciary duty to pursue—but it also must insure against litigation risks. As described above, companies "often have to self-insure" against the prospect of large tort awards in a climate of "present and future risks that are almost impossible to quantify but that may be potentially large enough to include financial catastrophe for the manufacturer." Lasagna, *supra*, at 337. Moreover, endeavoring to comply with 50-plus divergent state standards governing the marketing, design, and labeling of a device—rather than a single federal standard—would pose considerable incremental costs that would be reflected in increased price.

D. State Tort Liability Encourages Defensive Labeling And Overwarning That Undermine Rational Prescribing By Physicians.

FDA has cautioned that state common-law tort actions which "encourage, and in fact require, lay judges and juries to second-guess" FDA's balancing of the benefits and risks of a specific device, create pressures for "'defensive labeling' . . . resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments." Br. *Amicus Curiae* of the United States at *25-26, *Horn*, *available at* 2004 WL 1143720 (filed 3d Cir. May 14, 2004) (recognizing potential harm to public health); cf. 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("[A]dditional [state-law] requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.").

In an attempt to avoid state liability where plaintiffs allege they were not adequately warned of a particular risk, manufacturers have an inappropriate incentive to disregard FDA's expert judgment about the proper balance of risk information and instead warn of each and every conceivable risk of using the product, no matter how remote. This creates a serious danger that manufacturers include warnings with respect to medical devices that are not scientifically substantiated and overemphasize warnings as to marginal risks—thereby inappropriately de-emphasizing more serious risks.

Defensive labeling is far from benign. A physician's prescription decision is rational only when he or she has an accurate understanding of the risks and benefits of the prescription device under consideration and can compare those risks and benefits to those associated with other treatment alternatives. A fog of unmanaged warnings, unfiltered by FDA's expert judgment, impairs the ability of prescribing physicians to properly assess whether the potential benefits of the therapy for a particular patient outweigh its potential risks. Defensive labeling may cause physicians to prescribe a treatment that is riskier than they realize because serious risks are obscured in a blur of low risks, and may ultimately dissuade physicians from prescribing (and patients from undergoing) therapies that have more potential good than harm for a given patient because of unsubstantiated fears.[14]

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[14] *See*, *e.g.*, Horn *Amicus* Br., *supra*, at 25-26; *Brooks*, 273 F.3d at 797; W. Kip Viscusi, *Individual Rationality, Hazard Warnings, and the Foundations of Tort Law*, 48 Rutgers L. Rev. 625, 665-66 (1996) ("Excessive warnings are not innocuous. If warnings indicate a high relative risk when there is none, they will distort relative product comparisons, thus compromising credibility. Similarly, if warnings are included for inconsequential risks, they will serve to further dilute the warnings for the real hazards that should be identified to consumers."); Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know"*

Inappropriate incentives with respect to defensive warnings are particularly acute given that "[t]ime and again, one sees how an avalanche of lawsuits can be set loose by a tiny hiccup of error in scientific research." Peter Huber, *Junk Science in the Courtroom*, Forbes, July 8, 1991, at 68. The following example illustrates the point:

> [L]awyers won a spectacular $5.1 million verdict . . . largely on the strength of a single study that had very tentatively suggested that spermicides might cause birth defects. Not quite two years after the verdict, however, the several authors of that study spoke out again. One acknowledged that their work "was not corroborated by subsequent studies," and that their "study's definition of exposure to spermicide near the time of conception was grossly inaccurate." Another conceded: "I believe our article should never have been published. In our present litigious environment, the reservations and qualifications written into a published report are often ignored, and the article is used as 'proof' of a causal relationship." [*Id.*[15]]

Tort risks such as these encourage "defensive labeling."

From the "Need to Know" About Consumer Product Hazards, 11 Yale J. on Reg. 293, 380 (1994) (discussing dangers of overwarning and recognizing that FDA "generally frowns upon and will not approve defensive labeling").

[15] A similar research "blip" occurred recently with respect to drug-coated heart stents—stents with a drug coating to help minimize re-narrowing of heart structures following surgery. Last year, researchers presented preliminary data at academic conferences "that suggest[ed] a small but significant increased risk of stent thrombosis [*i.e.*, blood clots] in patients who have drug-eluting stents" as opposed to bare-metal stents FDA, *FDA Statement on Coronary Drug-Eluting Stents* (Sept. 14, 2006). FDA concluded that the drug-coated stents remained safe and effective, and pledged further study. *See id.* Soon thereafter, the same researchers concluded (after completing an additional year of study) that there was *no* statistically significant difference in the risk posed by drug-coated stents. *See* Maria Cheng, *New Study: Drug-Coated Stents Not So Bad*, Associated Press Online, Sept. 2, 2007.

CONCLUSION

For these reasons, as well as those set forth in respondent's brief, the decision below should be affirmed.

Respectfully submitted,

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