No. 06-179

IN THE

Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF SENATOR EDWARD M. KENNEDY AND REPRESENTATIVE HENRY A. WAXMAN, AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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August 2007

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INTEREST OF *AMICI CURIAE*[1]

Edward M. Kennedy has been a member of the United States Senate representing the State of Massachusetts since 1962. Senator Kennedy currently serves as Chairman of the Senate Committee on Health, Education, Labor and Pensions. In 1974-76, as the Chairman of the Subcommittee on Health, Labor and Public Welfare, Senator Kennedy held hearings on legislation to strengthen FDA's authority over medical devices and was the sole sponsor of the Senate bill (S. 510) that resulted in the passage of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360c, *et seq*.) ("MDA") to the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq*.

Representative Henry A. Waxman has been a member of the United States House of Representatives representing the 30th Congressional District of the State of California since 1974. Representative Waxman currently serves as Chairman of the House Government Reform and Oversight Committee, which has investigative authority over all government agencies and areas of federal policy. In 1976, Congressman Waxman served on the House Committee on Interstate and Foreign Commerce, which reported out the MDA legislation. Congressman Waxman supported the MDA and actively participated in the debates on the legislation.

Senator Kennedy and Congressman Waxman have dedicated their careers to working on public health issues, and over the past 30 years have sponsored numerous bills related to the Food and Drug Administration ("FDA") that have been

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[1] Petitioners and respondent have filed letters with the Clerk of the Court consenting to the submission of amicus curiae briefs in this action. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part. No person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of the brief.

enacted into law. They seek leave to file this brief because they believe that the decision of the United States Court of Appeals for the Second Circuit is contrary to the legislative purpose and intent of the MDA, and that it stands as a significant obstacle to the fulfillment of the important policy objectives that underscored the passage of that law.

HISTORY OF THE MEDICAL DEVICE AMENDMENTS OF 1976 AND ITS PREEMPTION PROVISION.

A. The Federal Food, Drug, and Cosmetic Act.

For over a century, the FDA has been responsible for protection of the public health with regard to the use of a wide range of medical and other consumer products. Its authorizing statute, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq*., has been frequently amended as emerging science and new technology have created a need for greater or evolving protections. Often, Congress has enacted these amendments in the wake of a public health crisis.

Enacted in 1938, the FFDCA itself was passed in the wake of the elixir sulfanilamide disaster.[2] Elixir sulfanilamide was an untested sulfa drug that caused the deaths of nearly 100 people, many of them children. The statute for the first time required pre-marketing approval for drugs, mandating that drug manufacturers demonstrate safety before a new drug could be marketed to the public. Congress, however, did not enact a corresponding pre-market approval requirement for medical devices.

In some instances where Congress has amended the FFDCA to address a public health crisis, product liability

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[2] The Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, was the first federal statute regulating pharmaceuticals. It did not require pre-market approval of drugs and focused on preventing the sale of misbranded and adulterated products.

lawsuits brought by the victims of defective products helped bring the problem to the attention of Congress, as was true when Congress adopted the MDA. Despite repeated references to such lawsuits in legislative history, however, Congress never has expressed any intention to preempt such litigation in any of the amendments to the Act. In fact, the MDA is the first time that Congress included a specific preemption provision in the FFDCA, and, as *amici* explain below, that provision was included to address a specific state legislative scheme for regulating medical devices and not to preempt product liability lawsuits against device manufacturers. At the time the MDA was enacted in 1976, the terminology used in the preemption provision was understood by Congress not to encompass product liability litigation.

While FDA had focused earlier on protecting the public from fraudulent claims made for bogus devices, around 1960 FDA began focusing on health hazards created by legitimate medical devices. H.R. Rep. No. 94-853 ("House Report") at 7. Emerging technology drove this effort: the creation of heart pacemakers, kidney dialysis machines, defibrillators, cardiac and renal catheters, surgical implants and other complicated diagnostic and therapeutic devices heightened the potential harm for consumers. *Id.* In 1969, the Secretary of Health, Education and Welfare convened a medical device study group, chaired by Theodore Cooper, M.D., then-director of the National Heart and Lung Institute ("the Cooper Committee"). *Id.* at 9.

The Cooper Committee held meetings with representatives of the medical profession, industry, consumers and government agencies, and it conducted an extensive literature search that identified 10,000 injuries from medical devices over a 10-year period, of which 751 resulted in death. *Id.* The Committee recommended that new legislation be targeted specifically to the device industry, because devices presented entirely different issues from drugs. It also suggested that different classifications for medical devices be

created, which would tailor the regulatory controls to the risks involved.

B. The 1976 Medical Device Amendments.

While the Cooper Committee's recommendations were being debated in Congress during 1972 and 1973, pacemaker failures became widely reported. Between 1972 and 1976, there were 34 voluntary recalls of pacemakers involving 23,000 units. *Id.* at 8. In 1975, Congress held hearings to investigate problems that had been reported with the Dalkon Shield intrauterine device.

As the House Report on the bill noted, the FFDCA's "inadequacy has become a matter of acute concern because of the rapid technological advances in the medical device field." *Id.* at 11. The Report also found that "[a]bsent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of such products." *Id.* at 12

The tragedy of the Dalkon Shield, which caused spontaneous abortions, uterine infections, and many deaths, played an important role in the events that led to the MDA of 1976 and is repeatedly cited in the legislative history. *Id.* at 8 (noting that there were over 500 lawsuits seeking damages at the time of the Report); S. Rep. 94-33, at 1 (1975) ("Senate Report") (submitted by Senator Kennedy). In light of the Dalkon Shield tragedy and other information received in hearings on the bill, the focus of the legislation was protecting consumers from unsafe products.

The MDA was designed "to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes." Pub. L. No. 94-295, 90 Stat. 539 (1976); *see also* House Report at 12 (MDA intended "to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary re-

strictions."). Throughout the legislative history of the Act are expressions of concern about "faulty devices" and their toll on Americans. *E.g.,* Hearing on H.R. 5545 Before the House Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 94th Cong. 1 (1975) (statement of Rep. Paul Rogers, Chairman of the House Subcommittee on Health and the Environment). As one of the *amici* declared on the floor of the Senate during debate on the bill: "The legislation is written so that the benefit of the doubt is always given to the consumer." 121 Cong. Rec. S6140 (Apr. 17, 1975) (Statement of Sen. Kennedy). Thus, recognizing that many of the harms caused by medical devices were preventable, Congress enacted the MDA.

Under the MDA, the term "device" includes a vast array of products, including tongue depressors, band-aids, tampons, bone screws, hip replacements, artificial heart valves, and pacemakers. *See* 21 U.S.C. § 321(h). Each medical device falls into one of three classes. Class I devices, for example tongue depressors, are those for which the MDA's "general controls" applicable to all devices, such as record-keeping and good manufacturing guidelines, are sufficient to provide reasonable assurance of safety and effectiveness. *See* 21 U.S.C. §§ 360i(a), 360j(f). Class II devices, for example tampons, are those for which special controls are necessary to protect the public health. Special controls include performance standards, special labeling requirements, and post-market surveillance. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 874.3300(b)(2).

Finally, Class III devices operate to sustain human life, are important in preventing impairment of human health, or pose potentially unreasonable risks to patients. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). Class III devices must undergo pre-market approval by the FDA, s*ee* 21 U.S.C. §§ 360e(b)(1); 360e(c)(1), unless the device qualifies for one of the statute's exceptions. The balloon catheter in-

volved in this case is an example of a Class III device that underwent pre-market approval.

C. The MDA's Preemption Provision.

When it considered the MDA, Congress was aware of various state programs requiring pre-market approval of medical devices, and the House Report specifically noted that in 1970 California had adopted the Sherman Food, Drug, and Cosmetic Law, which the Committee described as "comprehensive" in its regulation of medical devices. House Report at 45. Although it adopted a comprehensive federal regulatory system, Congress gave FDA the authority to preserve more stringent state provisions where they existed, finding them to be "a useful supplement to Federal regulation." *Id.*

In 21 U.S.C. § 360k(a), the MDA provided that States may not "establish or continue in effect with respect to a device . . . any requirement" that is "different from, or in addition to" certain federal device "requirement[s]" imposed under the MDA. 21 U.S.C. § 360k(a). However, Congress authorized FDA to grant state and local governments exemptions from preemption for their medical device laws in certain circumstances, including when the requirement is more stringent than the federal requirement. *See* 21 U.S.C. § 360k(b); House Report at 4. Congress noted that the more stringent program established by the state of California was an example of a program that should be allowed to continue to operate even after passage of federal legislation. House Report at 46. Since passage of the MDA, FDA has granted several such exemptions to States that have passed more stringent regulations regarding hearing aids. *See, e.g.,* 21 C.F.R. §§ 808.53; 808.55; 808.69. Thus, consistent with the focus on public safety in the MDA, Congress favored patient protection over nationwide uniformity.

D. The *Lohr* Decision.

In 1996, this Court considered the scope of preemption in section 360k(a) in *Medtronic, Inc. v. Lohr*, 518 U.S. 470

(1996). In *Lohr,* the Court held that a state product liability lawsuit was not preempted with respect to a medical device that had *not* undergone pre-market approval. Nevertheless, some members of the Court discussed the issue of whether section 360k(a) preempts *any* tort suits.

In the plurality opinion by Justice Stevens, four members of this Court found no preemption in the *Lohr* case, but left open the issue of whether there could ever be preemption. Four members of the Court joined an opinion by Justice O'Connor that concluded that section 360k(a) did preempt product liability cases and that the product liability lawsuit in *Lohr* was preempted. Justice O'Connor relied heavily on the Court's interpretation of the Public Health Cigarette Smoking Act of 1969's preemption provision that the Court construed in *Cipollone v. Liggett Group, Inc*., 505 U.S. 504 (1992). Justice Breyer, in a separate opinion, agreed with Justice Stevens that there was no preemption in the *Lohr* case, but he also stated that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Lohr*, 518 U.S. at 504. [3]

That "requirement" in the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified at 15 U.S.C. § 1331, *et seq*.) ("PHCSA"), as amended and codified, 15 U.S.C. §§ 1331-40, may include common law tort

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[3] In his opinion, Justice Breyer discussed the tension between an FDA regulation that hearing aids be designed with a two-inch wire and a product liability lawsuit alleging the manufacturer should have used a safer, one-inch wire. As explained below, in enacting the express preemption provision contained in section 360k(a), Congress did not intend to preempt state product liability actions. Nevertheless, conflicts between state and federal law may be addressed under principles of implied conflict preemption. In this brief, *amici* do not address the complex issue of whether a state court verdict might be subject to implied conflict preemption, which was neither raised in nor decided by the court of appeals.

claims does not mandate a conclusion that use of the same term in a very different statute with different goals means the same thing. *Amici* explain below that use of the term "requirement" in the MDA, the structure of the MDA, the motivation of Congress in enacting the MDA, and other legislative history demonstrate that the term "requirement" in the MDA does not encompass state tort action. As Professor Walter Wheeler Cook cautioned some 75 years ago, although the tendency to assume that the same word means the same thing in different contexts "has all the tenacity of original sin," it "must constantly be guarded against." Walter W. Cook, *"Substance" and "Procedure" in the Conflict of Laws*, 42 Yale L.J. 333, 337 (1933).

SUMMARY OF ARGUMENT

The language of section 360k and its legislative history demonstrate that Congress did not intend to preempt state tort suits. The legislative history demonstrates that Congress included section 360k in the MDA for one specific reason--to reconcile the new federal regulatory scheme with device regulatory schemes that states had adopted in the absence of federal regulation. There is no suggestion anywhere in the legislative history to suggest that Congress even considered preempting state tort suits, much less that it intended to preempt such suits.

Congress amended the FFDCA numerous times between 1938, when it enacted the FFDCA, and 1976, when it enacted the MDA, to increase the authority of the FDA, yet it never included a provision expressly preempting state positive law or state tort suits. Because there were no parallel state regulatory schemes, Congress had no occasion to preempt state positive law. A preemption provision would have been necessary had Congress been concerned about state tort actions against the manufacturers that it was regulating. It was not.

Section 360k(a) prohibits States from establishing a "requirement" that is different from a federal "requirement" ap-

plicable to a medical device. Thus, in order to trigger preemption, there must be both a federal and a state requirement. Federal requirements are established by the statute, agency regulations, and in some cases by an order applicable to a specific product. For example, FDA is authorized to promulgate performance standards applicable to medical devices. These standards may establish specific requirements for a device. A state regulation that imposed a different requirement would be preempted by section 360k(a). However, the structure of the MDA makes clear that the use of the word "requirement" in the context of federal action does not extend to a lawsuit. The logical and most plausible inference is that the reference to a state "requirement" in the same subsection of the MDA does not encompass state lawsuits.

Any doubt about the meaning of section 360k(a) is resolved by section 360k(b), which permits states to obtain an exemption from section 360k(a) for a state "requirement." Once again, the structure of the MDA reveals that Congress could not have intended "requirement" to encompass a lawsuit: there is no practical way for a state to seek an exemption for a lawsuit, either before or after a jury verdict. Since "requirement" in subsection (b) does not include tort lawsuits, the term "requirement" in subsection (a) also does not include such lawsuits.

ARGUMENT

THE LANGUAGE OF THE MDA AND ITS LEGISLATIVE HISTORY DEMONSTRATE THAT CONGRESS DID NOT INTEND TO PREEMPT STATE COMMON LAW TORT SUITS.

This Court repeatedly has stated that the touchstone for express preemption is the intent of Congress. *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983). The relevant intent must be discerned from the language of the statute, its structure, purpose, and subject matter. *Cipollone,* 505 U.S. at

545 (Scalia, J., concurring in the judgment in part and dissenting in part). In addition, there is a presumption against Congress's displacing state law, especially in an area of traditional state authority, such as tort law. *See id.* at 516*; see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

Since 1938, when Congress adopted the FFDCA, which required pre-market approval of "new drugs," it has amended the Act numerous times, in 1958 to require pre-market approval of food additives, in 1960 to require pre-market approval of color additives, in 1962 to require that human drugs be proven to be effective in the pre-market approval process, and in 1968 to require pre-market approval of new animal drugs.[4]

At the time that it adopted each of these provisions, insofar as *amici* are aware, there were no competing state regulatory schemes covering any of these product categories, and in each case Congress did not include a preemption provision in any of these laws. Insofar as *amici* are aware, there was no interest in Congress in preempting state product liability lawsuits, although such suits, especially involving pharmaceuticals, were an ever-present backdrop. *See, e.g.*, Paul D. Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 Cal. L. Rev. 116 (1968) (describing MER/29 litigation, the first drug-related mass tort case, which was emerging as Congress was considering the 1962 Amendments).

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[4] Food Additives Amendment of 1958, Pub. L. No. 85-829, 72 Stat. 1785 (1958) (codified as amended at 21 U.S.C. § 348); Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 399 (1960) (codified as amended at 21 U.S.C. § 376); Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 321, *et seq.*); Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 343 (1968) (codified as amended at 21 U.S.C. § 382).

As noted above, in 1976, when Congress enacted the MDA, the state of California had adopted a comprehensive regulatory system applicable to medical devices. This led Congress to include for the first time in the FFDCA a provision providing for preemption of certain state device regulatory requirements. The provision, section 521(a) of the FFDCA, added by the MDA, provides as follows:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* –
>
> (1) which is different from, or in addition to, any *requirement* applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement applicable to the device under this Act.*

21 U.S.C. § 360k(a) (emphasis supplied).

The purpose of section 360k(a) is clear on its face. First, preemption applies only when there is a "requirement applicable to the device under this Act." 21 U.S.C. § 360k(a)(1). For example, under section 360d, FDA may issue performance standards, which are mandatory requirements applicable to specific devices. *See, e.g.,* 21 C.F.R. § 801.410 (providing specific requirements for impact-resistant lenses in eyeglasses and sunglasses). Thus, if FDA mandates that eyeglass lenses must pass a specific test prior to being labeled as impact-resistant, then section 360k(a) would bar a state from adopting a standard that is "different from, or in addition to" the FDA requirement.

Similarly, under section 360j(e), FDA, by regulation, may restrict the sale, distribution or use of devices. For example, FDA can mandate that a device be used only by physicians with specific training relevant to a product's use.

Such a regulation also could preempt a state requirement applicable to the same device that addressed the same subject matter as the regulation. The statute gives FDA other authority to impose requirements. *See, e.g.*, 21 U.S.C. § 360i (authorizing FDA to require records and reports). Every requirement imposed on a medical device manufacturer by FDA is imposed by the statute, by regulation or by an order applicable to a specific device.[5] None is issued by a court or any other body. In other words, "requirement," the second and third time it is used in section 360k(a), means a requirement imposed by federal positive law.

Section 360k(a) applies to a state "requirement" that is "different from or in addition to" the federal "requirement." Just as the federal "requirement" must be a regulation or specific agency pronouncement under the Act, Congress intended for the term state "requirement" to apply to medical device requirements enacted by a legislature or promulgated by an administrative agency. The straightforward meaning of section 360k(a) is that the provision was intended to preempt state laws and regulations applicable to specific devices that are "different from, or in addition to" any federal "requirement."

The preemption of state requirements is not absolute. Congress provided that states could apply for an exemption as to statutes and regulations preempted by subsection (a). Thus, in subsection (b), it provided the states an opportunity to obtain an exemption to the general preemption rule. Section 360k(b) states:

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[5] For example, under section 360e(d)(1)(B)(ii), in its approval decision, FDA may by order impose the same restriction that it may impose under section 360j(e) by regulation for all devices (for example, mandating that a device be used only by physicians with specific training relevant to the product's use). Such an order would be a requirement under section 360k(a).

> (b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a *requirement* of such State or political subdivision applicable to a device intended for human use if –
>
> (1) the *requirement* is more stringent than a *requirement* under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the *requirement* –
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the *requirement* would not cause the device to be in violation of any applicable *requirement* under this Act.

21 U.S.C. § 360k(b) (emphasis supplied).

As discussed above, when Congress enacted section 360k(b), it was aware that California already had adopted a regulatory scheme for medical devices.[6] Accordingly, in section 360k(b)(i), Congress provided that a state could apply to FDA for an exemption from section 360k(a) if the state requirement is more stringent than the federal requirement. Section 360k(b)(2) permits exemption from section 360k(a) because of compelling local conditions. These exemptions plainly contemplated that states that had laws or regulations "different from or in addition to" FDA *requirements* could obtain an exemption from FDA. It is difficult to imagine

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[6] *See* 1970 Cal. Stat. 3270 (requiring new medical devices receive pre-marketing approval before they can be sold).

how such an exemption could apply to a products liability jury verdict, either in advance of or after such a verdict.

Yet, if section 360k(a) is read to preempt certain product liability claims, then section 360k(b) must be read to provide an opportunity for an exemption from such claims, since both provisions apply only to federal and state "requirements." As this Court explained in *Commissioner v. Lundy*, 516 U.S. 235, 249-50 (1996), there is "no reason to believe that Congress meant the term . . . to mean one thing" in the first part of section 360k(a) "but to mean something else altogether" the next two times it appears.[7] As the Court further explained, "the interrelationship and close proximity of these provisions . . . 'present[] a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.'" *Id.* at 250 (quoting *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (internal quotations and case citations omitted)); *see also, e.g.*, *United States Department of Treasury v. Fabe*, 508 U.S. 491, 515 (1993) (Kennedy, J., dissenting) (referring to foregoing principle as a "basic rule of statutory construction"). Thus, since "requirement" in section 360k(b) must be limited to state statutes and regulations,

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[7] *Amici* urge here that the word "requirement" when it appears multiple times in the same section of a statute should be understood to mean the same thing. By contrast, *amici* have argued that the use of the word "requirement" in a different statute, the PHCSA, should not be understood to mean the same thing as it does in the MDA. The PHCSA was enacted by a different Congress at a different time and had different purposes than the MDA, including an explicit purpose of avoiding inconsistent state requirements for the labeling on cigarette packaging and in advertising and promoting cigarettes, 15 U.S.C. § 1331 The PHCSA contained specific requirements for the language to be used on cigarette packages and in advertising and promotion, and did not contain other usages of "requirement" in the statutory language inconsistent with a meaning that includes state common law. Thus, the two contentions by *amici* about the appropriate interpretation of "requirement" are not inconsistent.

that same term in section 360k(a) must be limited in the same way. If Congress had meant there to be different meanings for the same word employed in the same subsection, one would have expected it to say so. *Gustafson v. Alloyd Co., Inc*., 513 U.S. 561, 573 (1995). Congress's silence on this matter speaks loudly about its intent. There is no room in the plain language of the statute for an interpretation that that term could also include "requirements" imposed by product liability tort suits.

There also is no indication in the Congressional hearings, the Committee Reports or the debates on the House or Senate floor that even a single member of the House or Senate believed that section 360k would bar state common law remedies against manufacturers. Of course, the existence of such remedies was at the forefront of the consideration of the MDA, since prior to adopting the amendments, Congress had heard extensive testimony about the Dalkon Shield tragedy.[8] There is no indication in the Congressional history of the MDA that Congress intended to prevent state tort actions, which is strong evidence that such preemption was not intended.[9] As Justice Stevens observed in *Lohr,* the absence of any hint of preempting common law claims in the entirety of the MDA legislative history is "spectacularly odd" if such preemption was intended by Congress. *Lohr*, 518 U.S. at 491; *see also Bates,* 544 U.S. at 449 (2005) ("The long his-

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[8] The MDA was enacted against a backdrop of a long history of tort suits involving medical devices. *See* Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments,* 18 DePaul L. Rev. 348, 358 (1969); R.D. Hursh, *Annotation*, *Liability of Manufacturer or Seller For Injury Caused By Medical and Health Supplies*, *Appliances, and Equipment*, 79 A.L.R.2d 401 (1961).

[9] "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok,* 59 Mo. L. Rev. 895, 923-24 n.128 (1994).

tory of tort litigation against manufacturers . . . adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); *Chisom v. Roemer*, 501 U.S. 380, 396 (1991) ("if Congress had such an intent, Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history.").

It is, thus, not surprising that public commentary following the enactment of the MDA also does not even suggest the *possibility* that the Medical Device Amendments could preempt state common law product liability actions. *See Lohr*, 518 U.S. at 491 n.13 (plurality opinion). Similarly, in 1977, when it proposed 21 C.F.R. § 808.1(b) to implement the MDA, FDA directed applicants for an exemption to inform it as to "whether the statute, rule, or regulation has been subject to judicial or administrative interpretations that give it legal meanings in the State or political subdivision that are not readily apparent from the face of the document"). 42 Fed. Reg. 30383, 30385 (June 14, 1977); *accord* 43 Fed. Reg. 18661, 18663 (May 2, 1978). It is also relevant that the FDA's regulations declare that a state "requirement" is not "eligible for exemption from preemption" unless it has been "issued in final form." 21 C.F.R. § 808.5(b)(2). Regulations, ordinances and similar enactments are "issued" in "final form." Product liability judgments are not "issued," and, although they do become final, they are not refined into a "final form." FDA understood that the preemption provision applied to a "statute, rule, or regulation," and not to product liability lawsuits.

Indeed, the first reported decision that *amici* can locate in which preemption under section 360k(a) was employed as a defense to a state tort suit is *Ignace v. International Playtex,*

Inc., No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. Aug. 14, 1987).[10] Thus, it did not occur to attorneys in the medical device industry and the nation's product liability attorneys, who are paid to identify defenses to litigation against their clients, that Congress intended in section 360k(a) to preempt common law tort claims until more than a decade after the statute was enacted. That they began to assert preemption is likely the result of the emergence, in the mid-1980s, of cases claiming preemption based on the Federal Cigarette Labeling and Advertising Act. *See, e.g.*, *Palmer v. Liggett Group, Inc.*, 633 F. Supp. 1171 (D. Mass. 1986); *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189 (E.D. Tenn.1985).

It was not until the decision in *Cipollone* in 1992 that Congress was aware that this Court might interpret the term "requirement" in a statutory preemption provision to include state product liability lawsuits. At this point, Congress began explicitly stating in statutes that the term "requirement" in preemption provisions did not preempt product liability actions. In two amendments to the FFDCA since 1992, in which Congress preempted state "requirements," Congress explicitly stated that product liability cases were not preempted. Thus, in § 751 of the FFDCA, 21 U.S.C. § 379r, which preempted certain "requirement[s]" applicable to nonprescription drugs, Congress added subsection (e) titled "No effect on product liability law." Subsection (e) states that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." If Congress had had any indication in 1976 when it enacted the MDA that a court

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[10] There is also a slightly earlier, unreported case: *Muzatko v. International Playtex, Inc.*, No. 85-C-1540, 1987 U.S. Dist. LEXIS 14281 (E.D. Wis. May 14, 1987), cited in *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987). Notably, in all of these cases, FDA had promulgated a regulation mandating certain information about tampon risks to be placed on the product's labeling. *See* 21 C.F.R. § 801.430.

would interpret the term "requirement" in section 360k to include state product liability law, then it would have included such a provision in the MDA.[11]

Permitting state design defect claims also is consistent with the Congressional purpose in enacting the MDA. Denying them is not. As noted previously, in the aftermath of the Dalkon Shield tragedy, Congress's primary focus was ensuring the safety of medical devices when it enacted the MDA. Modern design defect litigation frequently requires a plaintiff to identify an alternative design that would make the product safer. *See* Restatement (Third) of Torts: Products Liability § 2(b) (1998) (product has defective design when a "reasonable alternative design" would reduce the foreseeable risks of the product). Moreover, if design defect litigation for PMA devices is preempted, the incentive created by tort litigation to identify better designs in the wake of adverse events suffered by users of those devices will be lost. *See Bates,* 544 U.S. at 451 ("the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement") (citation omitted). Congress might have decided that preemption is appropriate if the FDA were deciding the optimal design of medical devices in the PMA process, but that is not the case.

With respect to devices subject to pre-market approval, the basic determination that the FDA makes is whether the device--designed in whatever fashion the manufacturer has determined--is safe and effective for use. *See* Brief of the United States as Amicus Curiae at 20-21, *Lohr v. Medtronics,*

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[11] In 1997, Congress also amended the FFDCA to include a provision preempting state and local requirements for the labeling or packaging of cosmetics, which is codified at 21 U.S.C. § 379s(a). Congress also included a savings clause for state product liability claims in section 379s(d).

Inc., *supra*. If the device meets this statutory standard, FDA has no authority to deny approval even if an alternative design might make the device safer than the design proposed by the applicant. In other words, the manufacturer – not the FDA – has control over the design of the device.

Moreover, clinical trials of medical devices will not identify all of the significant risks involved in the use of the device. Risks that are relatively rare but important will emerge only when a device is released into a larger and more heterogeneous population. *See* Institute of Medicine, *Safe Medical Devices for Children* 113 (2005) (explaining the importance of adverse event reporting and monitoring of medical devices to identify "serious problems" with devices in light of its post-approval use "with many more patients, with different patient populations (*e.g.*, children), in different ways (*e.g.*, involving ad hoc modifications for pediatric use), for different purposes, in new and possibly less well-equipped settings, over longer periods, and, sometimes, by less experienced or skilled clinicians and care teams"); *see also* General Accounting Office, *FDA Drug Review: Postapproval Risks 1976-85* at 52 (1990) (finding that over 50 percent of prescription drugs approved by the FDA had serious risks that went undetected during pre-marketing clinical testing); Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007) (explaining the difficulty of determining all drug risks during pre-market testing).

After a device has been approved, new information about design changes to the device that may improve safety or efficacy is largely in the control of the manufacturer. Moreover, the FDA has limited authority to force a manufacturer to make a design change even if it is aware that the change would improve the device. The FDA can initiate proceedings to withdraw the product from the market, but the agency must establish that the product no longer meets the statute's safety and efficacy requirements and, in any event, this can

be a time consuming process.[12] In this context, design defect litigation affords an opportunity to identify those newly emergent risks and to consider alternatives to the design that would further consumer safety–the focus of the MDA. *See* Mary Lyndon, *Tort Law and Technology*, 12 Yale J. on Reg. 137, 176 (1995) ("[T]ort law's signals contain necessary basic messages that are not delivered through any other medium . . . offer[ing] advantages that we need to account for before preempting tort law.").

The Chief Counsel of the FDA, in the wake of *Lohr*, trenchantly explained this concern:

> FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 was enacted.

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[12] *See, e.g.,* 21 U.S.C. § 360e(e)(1) (requiring notice, an opportunity for an informal hearing, and, where appropriate, convening an advisory committee) & 21 U.S.C. § 360e(e)(2) (providing for review of an order withdrawing approval).

Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997); *see also* David A. Vladeck*, Preemption and Regulatory Failure*, 33 Pepp. L Rev.95, 97 (2005) ("Since the founding of our Republic, tort liability has filled [regulatory gaps].").

CONCLUSION

Congress was fully aware of widespread tort law suits over medical devices, yet there is nothing in the legislative history to suggest an intent preempt such suits. At the time the MDA was enacted, Congress did not understand the term "requirement" to include state tort law verdicts. More recent FDA legislation has clarified that preemption of state requirements does not include tort lawsuits. If Congress had intended to preempt state tort law suits, it would have explicitly done so. Taking into account the plain language of the MDA preemption provision, the absence of any indication in the legislative history that Congress even considered the possibility that the provision would preempt state tort suits, the presumption against preemption, and the legislative purpose of the MDA, it is plain that the "requirements" preempted under the statute do not include state tort law suits.

Based upon the foregoing, the *amici* respectfully request that this Court reverse the decision of the Second Circuit and remand the case for trial.

Respectfully submitted,

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August 2007