# SUPREME COURT OF THE UNITED STATES

No. 06–179

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL, PETITIONER *v.* MEDTRONIC, INC.

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

[February 20, 2008]

JUSTICE GINSBURG, dissenting.

The Medical Device Amendments of 1976 (MDA or Act), 90 Stat. 539, as construed by the Court, cut deeply into a domain historically occupied by state law. The MDA's preemption clause, 21 U. S. C. §360k(a), the Court holds, spares medical device manufacturers from personal injury claims alleging flaws in a design or label once the application for the design or label has gained premarket approval from the Food and Drug Administration (FDA); a state damages remedy, the Court instructs, persists only for claims "premised on a violation of FDA regulations." *Ante*, at 17.[1] I dissent from today's constriction of state authority. Congress, in my view, did not intend §360k(a) to effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices.

Congress' reason for enacting §360k(a) is evident. Until 1976, the Federal Government did not engage in premarket regulation of medical devices. Some States acted to fill the void by adopting their own regulatory systems for

[1] The Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of §360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval.

medical devices. Section 360k(a) responded to that state regulation, and particularly to California's system of premarket approval for medical devices, by preempting State initiatives absent FDA permission. See §360k(b).

I

The "purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 516 (1992) (internal quotation marks omitted). Courts have "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 485 (1996).[2] Preemption analysis starts with the assumption that "the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947). "This assumption provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones* v. *Rath Packing Co.*, 430 U. S. 519, 525 (1977) (citation omitted).

The presumption against preemption is heightened "where federal law is said to bar state action in fields of traditional state regulation." *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U. S. 645, 655 (1995). Given the traditional "primacy of state regulation of matters of health and safety," *Lohr*, 518 U. S., at 485, courts assume "that state and local regulation related to [those] matters . . . can normally coexist with federal regulations," *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 718 (1985).

Federal laws containing a preemption clause do not

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[2] In part, *Lohr* spoke for the Court, and in part, for a plurality. Unless otherwise indicated, citations in this opinion refer to portions of *Lohr* conveying the opinion of the Court.

automatically escape the presumption against preemption. See *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431, 449 (2005); *Lohr*, 518 U. S., at 485. A preemption clause tells us that Congress intended to supersede or modify state law to some extent. In the absence of legislative precision, however, courts may face the task of determining the substance and scope of Congress' displacement of state law. Where the text of a preemption clause is open to more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." *Bates*, 544 U. S., at 449.

II

The MDA's preemption clause states:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> "(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 chapter." 21 U. S. C. §360k(a).

"Absent other indication," the Court states, "reference to a State's 'requirements' includes its common-law duties." *Ante*, at 11. Regarding the MDA, however, "other indication" is not "[a]bsent." Contextual examination of the Act convinces me that §360k(a)'s inclusion of the term "requirement" should not prompt a sweeping preemption of mine-run claims for relief under state tort law.[3]

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[3]The very next provision, §360k(b), allows States and their political subdivisions to apply for exemption from the requirements for medical devices set by the FDA when their own requirements are "more stringent" than federal standards or are necessitated by "compelling local

A

Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539 (preamble).[4] A series of high-profile medical device failures that caused extensive injuries and loss of life propelled adoption of the MDA.[5] Conspicuous among these failures was the Dalkon Shield intrauterine device, used by approximately 2.2 million women in the United States between 1970 and 1974. See *In re Northern Dist. of Cal., Dalkon Shield IUD Prods. Liability Litigation*, 693 F. 2d 847, 848 (CA9 1982); *ante*, at 1–2. Aggressively promoted as a safe and effective form of birth control, the Dalkon Shield had been linked to 16 deaths and 25 miscarriages by the middle of 1975. H. R. Rep. No. 94–853, p. 8 (1976). By early 1976, "more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million" had been filed. *Ibid.*[6] Given the pub-

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conditions." This prescription indicates solicitude for state concerns, as embodied in legislation or regulation. But no more than §360k(a) itself does §360k(b) show that Congress homed in on state common-law suits and meant to deny injured parties recourse to them.

[4] Introducing the bill in the Senate, its sponsor explained: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975) (remarks of Sen. Kennedy).

[5] See, *e.g.,* H. R. Rep. No. 94–853, p. 8 (1976) ("Significant defects in cardiac pacemakers have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972."); S. Rep. No. 94–33, p. 6 (1975) ("Some 10,000 injuries were recorded, of which 731 resulted in death. For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices."); 122 Cong. Rec. 5859 (1976) (remarks of Rep. Waxman) ("A 10-year FDA death-certificate search found over 850 deaths tied directly to medical devices."); 121 *id.,* at 10689–10690 (1975) (remarks of Sen. Nelson). See also *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 476 (1996).

[6] The Dalkon Shield was ultimately linked to "thousands of serious injuries to otherwise healthy women." Vladeck, Preemption and

licity attending the Dalkon Shield litigation and Congress' awareness of the suits at the time the MDA was under consideration, I find informative the absence of any sign of a legislative design to preempt state common-law tort actions.[7]

The Court recognizes that "§360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Ante*, at 17. That remedy, although important, does not help consumers injured by devices that receive FDA approval but nevertheless prove unsafe. The MDA's failure to create any federal compensatory remedy for such consumers further suggests that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements. It is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for large numbers of consumers injured by defective medical devices. *Silkwood* v. *Kerr-McGee Corp.*, 464 U. S. 238, 251 (1984).

The former chief counsel to the FDA explained:

"FDA's view is that FDA product approval and state

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Regulatory Failure, 33 Pepperdine L. Rev. 95, 103 (2005). By October 1984, the manufacturer had settled or litigated approximately 7,700 Dalkon Shield cases. R. Sobol, Bending the Law: The Story of the Dalkon Shield Bankruptcy 23 (1991).

[7] "[N]othing in the hearings, the Committee Reports, or the debates," the *Lohr* plurality noted, "suggest[ed] that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation." 518 U. S., at 491. See also Adler & Mann, Preemption and Medical Devices: The Courts Run Amok, 59 Mo. L. Rev. 895, 925 (1994) ("To the extent that Congress mentioned common law tort claims, it was not to criticize them or to suggest that they needed to be barred once a federal regulation was in place. Rather, it was to note how they demonstrated that *additional* protections for consumers were needed.").

> tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. 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 . . . ." Porter, The *Lohr* Decision: FDA Perspective and Position, 52 Food & Drug L. J. 7, 11 (1997).

Cf. Brief for United States as *Amicus Curiae* on Pet. for Cert. in *Smiths Industries Medical Systems, Inc.* v. *Kernats*, O. T. 1997, No. 96–1405, pp. 17–18; Dept. of Health and Human Services, Public Health Service, Advisory Opinion, Docket No. 83A–0140/AP, Letter from J. Hile, Associate Comm'r for Regulatory Affairs, to National Women's Health Network (Mar. 8, 1984).[8] The Court's

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[8]The FDA recently announced a new position in an *amicus* brief. See Brief for United States as *Amicus Curiae* 16–24. An *amicus* brief interpreting a statute is entitled, at most, to deference under *Skidmore* v. *Swift & Co.*, 323 U. S. 134 (1944). See *United States* v. *Mead Corp.*, 533 U. S. 218, 229–233 (2001). The weight accorded to an agency position under *Skidmore* "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." 323 U. S., at 140. See also *Mead*, 533 U. S., at 228 (courts consider, *inter alia*, the "consistency" and "persuasiveness" of an agency's position); *Good Samaritan Hospital* v. *Shalala*, 508 U. S. 402, 417 (1993) ("[T]he consistency of an agency's position is a factor in assessing the weight that position is due."). Because the FDA's long-held view on the limited preemptive effect of §360k(a) better comports with the presumption against preemption of state health and safety protections, as well as the purpose and history of the MDA, the FDA's new position is entitled to little weight.

construction of §360k(a) has the "perverse effect" of granting broad immunity "to an entire industry that, in the judgment of Congress, needed more stringent regulation," *Lohr*, 518 U. S., at 487 (plurality opinion), not exemption from liability in tort litigation.

The MDA does grant the FDA authority to order certain remedial action if, *inter alia*, it concludes that a device "presents an unreasonable risk of substantial harm to the public health" and that notice of the defect "would not by itself be sufficient to eliminate the unreasonable risk." 21 U. S. C. §360h(b)(1)(A). Thus the FDA may order the manufacturer to repair the device, replace it, refund the purchase price, cease distribution, or recall the device. §360h(b)(2), (e). The prospect of ameliorative action by the FDA, however, lends no support to the conclusion that Congress intended largely to preempt state common-law suits. Quite the opposite: Section 360h(d) states that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." That provision anticipates "[court-awarded] damages for economic loss" from which the value of any FDA-ordered remedy would be subtracted. *Ibid.*[9]

B

Congress enacted the MDA after decades of regulating drugs and food and color additives under the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq*. The FDCA contains no preemption clause, and thus the Court's interpretation of

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[9] The Court regards §360h(d) as unenlightening because it "could not possibly mean that *all* state-law claims are not pre-empted" and "provides no guidance as to which state-law claims are pre-empted and which are not." *Ante*, at 12, n. 4. Given the presumption against preemption operative even in construing a preemption clause, see *supra*, at 2–3, the perceived lack of "guidance" should cut against Medtronic, not in its favor.

§360k(a) has no bearing on tort suits involving drugs and additives. But §360k(a)'s confinement to medical devices hardly renders irrelevant to the proper construction of the MDA's preemption provision the long history of federal and state controls over drugs and additives in the interest of public health and welfare. Congress' experience regulating drugs and additives informed, and in part provided the model for, its regulation of medical devices. I therefore turn to an examination of that experience.

Starting in 1938, the FDCA required that new drugs undergo preclearance by the FDA before they could be marketed. See §505, 52 Stat. 1052. Nothing in the FDCA's text or legislative history suggested that FDA preclearance would immunize drug manufacturers from common-law tort suits.[10]

By the time Congress enacted the MDA in 1976, state common-law claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation.[11] Congress' inclusion of a preemption

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[10] To the contrary, the bill did not need to create a federal claim for damages, witnesses testified, because "[a] common-law right of action exist[ed]." Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 400 (1933) (statement of W. A. Hines). See also *id.*, at 403 (statement of J. A. Ladds) ("This act should not attempt to modify or restate the common law with respect to personal injuries.").

[11] Most defendants, it appears, raised no preemption defense to state tort suits involving FDA-approved drugs. See, *e.g., Salmon* v. *Parke, Davis & Co.*, 520 F. 2d 1359 (CA4 1975) (North Carolina law); *Reyes* v. *Wyeth Labs.*, 498 F. 2d 1264 (CA5 1974) (Texas law); *Hoffman* v. *Sterling Drug Inc.*, 485 F. 2d 132 (CA3 1973) (Pennsylvania law); *Singer* v. *Sterling Drug, Inc.*, 461 F. 2d 288 (CA7 1972) (Indiana law); *McCue* v. *Norwich Pharmacal Co.*, 453 F. 2d 1033 (CA1 1972) (New Hampshire law); *Basko* v. *Sterling Drug, Inc.*, 416 F. 2d 417 (CA2 1969) (Connecticut law); *Parke-Davis & Co.* v. *Stromsodt*, 411 F. 2d 1390 (CA8 1969) (North Dakota law); *Davis* v. *Wyeth Labs., Inc.*, 399 F. 2d 121 (CA9 1968) (Montana law); *Roginsky* v. *Richardson-Merrell, Inc.*, 378 F. 2d 832 (CA2 1967) (New York law); *Cunningham* v. *Charles*

clause in the MDA was not motivated by concern that similar state tort actions could be mounted regarding medical devices.[12] Rather, Congress included §360k(a) and (b) to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level. See *supra*, at 3, and n. 3; *infra*, at 10–11, and n. 14.

Between 1938 and 1976, Congress enacted a series of premarket approval requirements, first for drugs, then for additives. Premarket control, as already noted, commenced with drugs in 1938. In 1958, Congress required premarket approval for food additives. Food Additives Amendment, §3, 72 Stat. 1785, as amended, 21 U. S. C. §348. In 1960, it required premarket approval for color additives. Color Additive Amendments, §103(b), 74 Stat. 399, as amended, 21 U. S. C. §379e. In 1962, it expanded the premarket approval process for new drugs to include review for effectiveness. Drug Amendments, §101, 76 Stat. 781, as amended, 21 U. S. C. §321 *et seq*. And in

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*Pfizer & Co., Inc.*, 532 P. 2d 1377 (Okla. 1974); *Stevens* v. *Parke, Davis & Co.*, 9 Cal. 3d 51, 507 P. 2d 653 (1973); *Bine* v. *Sterling Drug, Inc.*, 422 S. W. 2d 623 (Mo. 1968) *(per curiam)*. In the few cases in which courts noted that defendants had interposed a preemption plea, the defense was unsuccessful. See, *e.g., Herman* v. *Smith, Kline & French Labs.*, 286 F. Supp. 695 (ED Wis. 1968). See also *infra*, at 12, n. 16 (decisions after 1976).

[12] See Leflar & Adler, The Preemption Pentad: Federal Preemption of Products Liability Claims After *Medtronic*, 64 Tenn. L. Rev. 691, 704, n. 71 (1997) ("Surely a furor would have been aroused by the very suggestion that . . . medical devices should receive an exemption from products liability litigation while new drugs, subject to similar regulatory scrutiny from the same agency, should remain under the standard tort law regime."); Porter, The *Lohr* Decision: FDA Perspective and Position, 52 Food & Drug L. J. 7, 11 (1997) (With preemption, the "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 . . . .").

1968, it required premarket approval for new animal drugs. Animal Drug Amendments, §101(b), 82 Stat. 343, as amended, 21 U. S. C. §360b. None of these Acts contained a preemption clause.

The measures just listed, like the MDA, were all enacted with common-law personal injury litigation over defective products a prominent part of the legal landscape.[13] At the time of each enactment, no state regulations required premarket approval of the drugs or additives in question, so no preemption clause was needed as a check against potentially conflicting state regulatory regimes. See Brief for Sen. Edward M. Kennedy et al. as *Amici Curiae* 10.

A different situation existed as to medical devices when Congress developed and passed the MDA. As the House Report observed:

> "In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California." H. R. Rep. No.

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[13] The Drug Amendments of 1962 reiterated Congress' intent not to preempt claims relying on state law: "Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." §202, 76 Stat. 793.

94–853, p. 45 (emphasis added).[14]

In sum, state premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA; no such clause figures in earlier federal laws regulating drugs and additives, for States had not installed comparable control regimes in those areas.

C

Congress' experience regulating drugs also casts doubt on Medtronic's policy arguments for reading §360k(a) to preempt state tort claims. Section 360k(a) must preempt state common-law suits, Medtronic contends, because Congress would not have wanted state juries to second-guess the FDA's finding that a medical device is safe and effective when used as directed. Brief for Respondent 42–49. The Court is similarly minded. *Ante*, at 11–12.

But the process for approving new drugs is at least as rigorous as the premarket approval process for medical devices.[15] Courts that have considered the question have

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[14] Congress featured California's regulatory system in its discussion of §360k(a), but it also identified California's system as a prime candidate for an exemption from preemption under §360k(b). "[R]equirements imposed under the California statute," the House Report noted, "serve as an example of requirements that the Secretary should authorize to be continued (provided any application submitted by a State meets requirements pursuant to the reported bill)." H. R. Rep. No. 94–853, p. 46. Thus Congress sought not to terminate all state premarket approval systems, but rather to place those systems under the controlling authority of the FDA.

[15] The process for approving a new drug begins with preclinical laboratory and animal testing. The sponsor of the new drug then submits an investigational new drug application seeking FDA approval to test the drug on humans. See 21 U. S. C. §355(i); 21 CFR §312.1 *et seq*. (2007). Clinical trials generally proceed in three phases involving successively larger groups of patients: 20 to 80 subjects in phase I; no more than several hundred subjects in phase II; and several hundred to several thousand subjects in phase III. 21 CFR §312.21. After complet-

overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits.[16] Decades of

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ing the clinical trials, the sponsor files a new drug application containing, *inter alia*, "full reports of investigations" showing whether the "drug is safe for use and . . . effective"; the drug's composition; a description of the drug's manufacturing, processing, and packaging; and the proposed labeling for the drug. 21 U. S. C. §355(b)(1).

[16] See, *e.g.*, *Tobin* v. *Astra Pharmaceutical Prods., Inc.*, 993 F. 2d 528, 537–538 (CA6 1993); *Hill* v. *Searle Labs.*, 884 F. 2d 1064, 1068 (CA8 1989); *In re Vioxx Prods. Liability Litigation*, 501 F. Supp. 2d 776, 788–789 (ED La. 2007); *In re Zyprexa Prods. Liability Litigation*, 489 F. Supp. 2d 230, 275–278 (EDNY 2007); *Weiss* v. *Fujisawa Pharmaceutical Co.*, 464 F. Supp. 2d 666, 676 (ED Ky. 2006); *Perry* v. *Novartis Pharma. Corp.*, 456 F. Supp. 2d 678, 685–687 (ED Pa. 2006); *McNellis ex rel. DeAngelis* v. *Pfizer, Inc.*, No. Civ. 05–1286 (JBS), 2006 WL 2819046, *5 (D. NJ, Sept. 26, 2006); *Jackson* v. *Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 (Neb. 2006); *Laisure-Radke* v. *Par Pharmaceutical, Inc.*, 426 F. Supp. 2d 1163, 1169 (WD Wash. 2006); *Witczak* v. *Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (Minn. 2005); *Zikis* v. *Pfizer, Inc.*, No. 04 C 8104, 2005 WL 1126909, *3 (ND Ill., May 9, 2005); *Cartwright* v. *Pfizer, Inc.*, 369 F. Supp. 2d 876, 885–886 (ED Tex. 2005); *Eve* v. *Sandoz Pharmaceutical Corp.,* No. IP 98–1429–C–Y/S, 2002 WL 181972, *1 (SD Ind., Jan. 28, 2002); *Caraker* v. *Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1044 (SD Ill. 2001); *Motus* v. *Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1087 (CD Cal. 2000); *Kociemba* v. *G. D. Searle & Co.*, 680 F. Supp. 1293, 1299–1300 (Minn. 1988). But see 71 Fed. Reg. 3933–3936 (2006) (preamble to labeling regulations discussing FDA's recently adopted view that federal drug labeling requirements preempt conflicting state laws); *In re Bextra & Celebrex Marketing Sales Practices & Prod. Liability Litigation*, No. M:05–1699 CRB, 2006 WL 2374742, *10 (ND Cal., Aug. 16, 2006); *Colacicco* v. *Apotex, Inc.*, 432 F. Supp. 2d 514, 537–538 (ED Pa. 2006); *Needleman* v. *Pfizer Inc.*, No. Civ. A. 3:03–CV–3074–N, 2004 WL 1773697, *5 (ND Tex., Aug. 6, 2004); *Dusek* v. *Pfizer Inc.*, No. Civ. A. H–02–3559, 2004 WL 2191804, *10 (SD Tex., Feb. 20, 2004). But cf. 73 Fed. Reg. 2853 (2008) (preamble to proposed rule).

This Court will soon address the issue in *Levine* v. *Wyeth*, No. 2004–384, 2006 WL 3041078 (Vt., Oct. 27, 2006), cert. granted, 552 U. S. ___ (2008). The question presented in that case is: "Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ('FDA') pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cos-

drug regulation thus indicate, contrary to Medtronic's argument, that Congress did not regard FDA regulation and state tort claims as mutually exclusive.

III

Refusing to read §360k(a) as an automatic bar to state common-law tort claims would hardly render the FDA's premarket approval of Medtronic's medical device application irrelevant to the instant suit. First, a "pre-emption provision, by itself, does not foreclose (through negative implication) any possibility of implied conflict preemption." *Geier* v. *American Honda Motor Co.*, 529 U. S. 861, 869 (2000) (brackets and internal quotation marks omitted). See also *Freightliner Corp.* v. *Myrick*, 514 U. S. 280, 288–289 (1995). Accordingly, a medical device manufacturer may have a dispositive defense if it can identify an actual conflict between the plaintiff's theory of the case and the FDA's premarket approval of the device in question. As currently postured, this case presents no occasion to take up this issue for Medtronic relies exclusively on §360k(a) and does not argue conflict preemption.

Second, a medical device manufacturer may be entitled to interpose a regulatory compliance defense based on the FDA's approval of the premarket application. Most States do not treat regulatory compliance as dispositive, but regard it as one factor to be taken into account by the jury. See Sharkey, Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts, 15 J. Law & Pol'y 1013, 1024 (2007). See also Restatement (Third) of Torts §16(a) (Proposed Final Draft No. 1, Apr. 6, 2005). In those States, a manufacturer could present the FDA's approval of its medical device as

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metic Act, 21 U. S. C. §301 *et seq*., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." Pet. for Cert. in *Wyeth* v. *Levine*, O. T. 2007, No. 06–1249, p. i.

evidence that it used due care in the design and labeling of the product.

The Court's broad reading of §360k(a) saves the manufacturer from any need to urge these defenses. Instead, regardless of the strength of a plaintiff's case, suits will be barred *ab initio*. The constriction of state authority ordered today was not mandated by Congress and is at odds with the MDA's central purpose: to protect consumer safety.

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For the reasons stated, I would hold that §360k(a) does not preempt Riegel's suit. I would therefore reverse the judgment of the Court of Appeals in relevant part.