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Riegel Vs. Medtronic, Inc.

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Court : US Supreme Court

Decided On : Feb-20-2008

Appeal No. : 06-179

Appellant : Riegel

Respondent : Medtronic, Inc.

Judgement :

Riegel v. Medtronic, Inc. - 06-179 (2008)

SYLLABUS
OCTOBER TERM, 2007
RIEGEL V. MEDTRONIC, INC.

SUPREME COURT OF THE UNITED STATES

RIEGEL, individually and as administrator ofESTATE OF RIEGEL *v* . MEDTRONIC, INC.

certiorari to the united states court of appeals for the second circuit

No. 06-179.Argued December 4, 2007-Decided February 20, 2008

The Medical Device Amendments of 1976 (MDA) created a scheme of federal safety oversight for medical devices while sweeping back state oversight schemes. The statute provides that a State shall not 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 [federal law] 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 relevant federal law. 21 U. S. C. 360k(a). The MDA calls for federal oversight of medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the premarket approval process. These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness. Manufacturers may not make changes to such devices that would affect safety or effectiveness unless they first seek and obtain permission from the FDA.

Charles Riegel and his wife, petitioner Donna Riegel, brought suit against respondent Medtronic after a Medtronic catheter ruptured in Charles Riegels coronary artery during heart surgery. The catheter is a Class III device that received FDA premarket approval. The Riegels alleged that the device was designed, labeled, and manufactured in a manner that violated New York common law. The District Court held that the MDA pre-empted the Riegels claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter, and their claim of negligent manufacturing insofar as the claim was not premised on the theory that Medtronic had violated federal law. The Second Circuit affirmed.

Held: The MDAs pre-emption clause bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. Pp. 8-17.

(a) The Federal Government has established requirement[s] applicable to Medtronics catheter within 360k(a)(1)s meaning. In *Medtronic, Inc.* v. *Lohr* , 518 U. S. 470 , 495, 500-501, the Court interpreted the MDAs pre-emption provision in

a manner substantially informed by an FDA regulation, 21 CFR 808.1(d), which says that state requirements are pre-empted only when the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under federal law. Premarket approval imposes specific requirements applicable to a particular device. The FDA requires that a device that has received premarket approval be marketed without significant deviations from the specifications in the devices approval application, for the reason that the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness. Pp. 8-10.

(b) Petitioners common-law claims are pre-empted because they are based upon New York requirement[s] with respect to Medtronics catheter that are different from, or in addition to the federal ones, and that relate to safety and effectiveness, 360k(a). Pp. 10-17.

(i) Common-law negligence and strict-liability claims impose requirement[s] under the ordinary meaning of that term, see, *e.g., Lohr, supra,* at 503-505, 512, *Cipollone* v. *Liggett Group, Inc.* , 505 U. S. 504 , 521-523, 548-549. There is nothing in the MDA that contradicts this normal meaning. Pp. 10-12.

(ii) The Court rejects petitioners contention that the duties underlying her state-law tort claims are not pre-empted because general common-law duties are not requirements maintained with respect to devices. Petitioners suit depends upon New Yorks continu[ing] in effect general tort duties with respect to Medtronics catheter. Title 21 CFR 808.1(d)(1)-which states that MDA pre-emption does not extend to [s]tate or local requirements of general applicability [whose] purpose relates either to other products in addition to devices or to unfair trade practices in which the requirements are not limited to devices-does not alter the Courts interpretation. Pp. 14-17.

(c) The Court declines to address in the first instance petitioners argument that this lawsuit raises parallel claims that are not pre-empted by 360k under *Lohr, supra,* at 495, 513. P. 17.

451 F. 3d 104, affirmed.

Scalia, J., delivered the opinion of the Court, in which Roberts, C. J., and Kennedy, Souter, Thomas, Breyer, and Alito, JJ., joined, and in which Stevens, J., joined except for Parts III-A and III-B. Stevens, J., filed an opinion concurring in part and concurring in the judgment. Ginsburg, J., filed a dissenting opinion.

Riegel v. Medtronic, Inc. - 06-179 (2008)

OPINION OF THE COURT
RIEGEL V. MEDTRONIC, INC.
552 U. S. ____ (2008)

SUPREME COURT OF THE UNITED STATES
NO. 06-179

DONNA S. RIEGEL, individually and as administra-tor of the ESTATE OF CHARLES R. RIEGEL,PETITIONER *v.* MEDTRONIC, INC.

on writ of certiorari to the united states court ofappeals for the second circuit

[February 20, 2008]

Justice Scalia delivered the opinion of the Court.

We consider whether the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U. S. C. 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA).

I

A

The Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U. S. C. 301 *et seq.* , has long required FDA approval for the introduction of

new drugs into the market. Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit. See *Medtronic, Inc.* v. *Lohr* , 518 U. S. 470 , 475-476 (1996).

The regulatory landscape changed in the 1960s and 1970s, as complex devices proliferated and some failed. Most notably, the Dalkon Shield intrauterine device, introduced in 1970, was linked to serious infections and several deaths, not to mention a large number of pregnancies. Thousands of tort claims followed. R. Bacigal, The Limits of Litigation: The Dalkon Shield Controversy 3 (1990). In the view of many, the Dalkon Shield failure and its aftermath demonstrated the inability of the common-law tort system to manage the risks associated with dangerous devices. See, *e.g.,* S. Foote, Managing the Medical Arms Race 151-152 (1992). Several States adopted regulatory measures, including California, which in 1970 enacted a law requiring premarket approval of medical devices. 1970 Cal. Stats. ch. 1573, 26670-26693; see also Leflar & Adler, The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic, 64 Tenn. L. Rev. 691, 703, n. 66 (1997) (identifying 13 state statutes governing medical devices as of 1976).

Congress stepped in with passage of the Medical Device Amendments of 1976 (MDA), 21 U. S. C. 360c *et seq.* ,[Footnote 1] which swept back some state obligations and imposed a regime of detailed federal oversight. The MDA includes an express pre-emption provision that states:

Except as provided in subsection (b) of this section, 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 chapter 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 chapter. 360k(a).

The exception contained in subsection (b) permits theFDA to exempt some state and local requirements frompre-emption.

The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: general controls, such as labeling requirements. 360c(a)(1)(A); FDA, Device Advice: Device Classes, http://www.fda.gov/cdrh/devadvice/3132.html (all Internet materials as visited Feb. 14, 2008, and available in Clerk of Courts case file). Class II, which includes such devices as powered wheelchairs and surgical drapes, *ibid.* , is subject in addition to special controls such as performance standards and postmarket surveillance measures, 360c(a)(1)(B).

The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, FDA, Device Advice: Device Classes, *supra* . In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. 360c(a)(1)(C)(ii).

Although the MDA established a rigorous regime of premarket approval for new Class III devices, it grandfathered many that were already on the market. Devices sold before the MDAs effective date may remain on the market until the FDA promulgates, after notice and comment, a regulation requiring premarket approval. 360c(f)(1), 360e(b)(1). A related provision seeks to limit the competitive advantage grandfathered devices receive. A new device need not undergo premarket approval if the FDA finds it is substantially equivalent to another device exempt from premarket approval. 360c(f)(1)(A). The agencys review of devices for substantial equivalence is known as the 510(k) process, named after the section of the MDA describing the review. Most new Class III devices enter the market through 510(k). In 2005, for example, the FDA authorized the marketing of 3,148

devices under 510(k) and granted premarket approval to just 32 devices. P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007).

Premarket approval is a rigorous process. *Lohr* , 518 U. S., at 477. A manufacturer must submit what is typically a multivolume application. FDA, Device Advice-Premarket Approval (PMA) 18, http://www.fda.gov/cdrh/devadvice/pma/printer.html. It includes, among other things, full reports of all studies and investigations of the devices safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the devices components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR 814.44(a) (2007), and may request additional data from the manufacturer, 360e(c)(1)(G).

The FDA spends an average of 1,200 hours reviewing each application, *Lohr, supra,* at 477, and grants premarket approval only if it finds there is a reasonable assurance of the devices safety and effectiveness, 360e(d). The agency must weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent. FDA, Center for Devices and Radiological Health, Summary of Safety and Probable Benefit 20 (2004), online at http://www.fda.gov/cdrh/pdf3/H030003b.pdf.

The premarket approval process includes review of the devices proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, 360e(d)(1)(A).

After completing its review, the FDA may grant or deny premarket approval. 360e(d). It may also condition approval on adherence to performance standards, 21 CFR 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, 814.82. The agency is also free to impose device-specific restrictions by regulation. 360j(e)(1).

If the FDA is unable to approve a new device in its proposed form, it may send an approvable letter indicating that the device could be approved if the applicant submitted specified information or agreed to certain conditions or restrictions. 21 CFR 814.44(e). Alternatively, the agency may send a not approvable letter, listing the grounds that justify denial and, where practical, measures that the applicant could undertake to make the device approvable. 814.44(f).

Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. 360e(d)(6); 21 CFR 814.39(c).

After premarket approval, the devices are subject to reporting requirements. 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the condi-tions in its labeling. 360e(e)(1); see also 360h(e) (recallauthority).

B

Except as otherwise indicated, the facts set forth in this section appear in the opinion of the Court of Appeals. The device at issue is an Evergreen Balloon Catheter marketed by defendant-respondent Medtronic, Inc. It is a Class III device that received premarket approval from the FDA in 1994; changes to its label received supplemental approvals in 1995 and 1996.

Charles Riegel underwent coronary angioplasty in 1996, shortly after suffering a myocardial infarction. App. to Pet. for Cert. 56a. His right coronary artery was diffusely diseased and heavily calcified. Riegels doctor inserted the Evergreen Balloon Catheter into his patients coronary artery in an attempt to dilate the artery, although the devices labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. The label also warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres. Riegels doctor inflated the catheter five times, to a pressure of 10 atmospheres; on its fifth inflation, the catheter ruptured. Complaint 3. Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypasssurgery.

Riegel and his wife Donna brought this lawsuit in April 1999, in the United States District Court for the Northern District of New York. Their complaint alleged that Medtronics catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. The complaint raised a number of common-law claims. The District Court held that the MDA pre-empted Riegels claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. App. to Pet. for Cert. 68a; Complaint 3-4. It also held that the MDA pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law. App. to Pet. for Cert. 71a. Finally, the court concluded that the MDA pre-empted Donna Riegels claim for loss of consortium to the extent it was derivative of the pre-empted claims. *Id.,* at 68a; see also *id.,* at 75a.[Footnote 2]

The United States Court of Appeals for the Second Circuit affirmed these dismissals. 451 F. 3d 104 (2006). The court concluded that Medtronic was clearly

subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved premarket approval application. *Id.* , at 118. The Riegels claims were pre-empted because they would, if successful, impose state requirements that differed from, or added to the device-specific federal requirements. *Id.* , at 121. We granted certiorari.[Footnote 3] 551 U. S. ___ (2007).

II

Since the MDA expressly pre-empts only state requirements different from, or in addition to, any requirement applicable . . . to the device under federal law, 360k(a)(1), we must determine whether the Federal Government has established requirements applicable to Medtronics catheter. If so, we must then determine whether the Riegels common-law claims are based upon New York requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness. 360k(a).

We turn to the first question. In *Lohr* , a majority of this Court interpreted the MDAs pre-emption provision in a manner substantially informed by the FDA regulation set forth at 21 CFR 808.1(d). 518 U. S., at 495; see also *id.* , at 500-501. That regulation says that state requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device . . . . 21 CFR 808.1(d). Informed by the regulation, we concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr* . The federal requirements, we said, were not requirements specific to the device in question-they reflected entirely generic concerns about device regulation generally. 518 U. S., at 501. While we disclaimed a conclusion that general federal requirements could never pre-empt, or general state duties never be pre-empted, we held that no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue. *Id.* , at 500-501.

Even though substantial-equivalence review under 510(k) is device specific, *Lohr* also rejected the manufacturers contention that 510(k) approval imposed device-

specific requirements. We regarded the fact that products entering the market through 510(k) may be marketed only so long as they remain substantial equivalents of the relevant pre-1976 devices as a qualification for an exemption rather than a requirement. *Id.,* at 493-494; see also *id.,* at 513 (OConnor, J., concurring in part and dissenting in part).

Premarket approval, in contrast, imposes requirements under the MDA as we interpreted it in *Lohr* . Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review-it *is* federal safety review. Thus, the attributes that *Lohr* found lacking in 510(k) review are present here. While 510(k) is focused on *equivalence* , not safety, *id.,* at 493 (opinion of the Court), premarket approval is focused on safety, not equivalence. While devices that enter the market through 510(k) have never been formally reviewed under the MDA for safety or efficacy, *ibid.* , the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, 360e(d). And while the FDA does not require that a device allowed to enter the market as a substantial equivalent take any particular form for any particular reason, *ibid.,* at 493, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness.

III

We turn, then, to the second question: whether the Riegels common-law claims rely upon any requirement of New York law applicable to the catheter that is different from, or in addition to federal requirements and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device. 360k(a). Safety and effectiveness are the very subjects of the Riegels common-law claims, so the critical issue is whether New Yorks tort duties constitute requirements under the MDA.

A

In *Lohr,* five Justices concluded that common-law causes of action for negligence and strict liability do impose requirement[s] and would be pre-empted by federal requirements specific to a medical device. See 518 U. S., at 512 (opinion of OConnor, J., joined by Rehnquist, C. J., and Scalia and Thomas, JJ.); *id.,* at 503-505 (opinion of Breyer, J.). We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state requirements pre-empted common-law duties. *Bates* v. *Dow Agrosciences LLC* , 544 U. S. 431 (2005), found common-law actions to be pre-empted by a provision of the Federal Insecticide, Fungicide, and Rodenticide Act that said certain States shall not impose or continue in effect *any requirements* for labeling or packaging in addition to or different from those required under this subchapter. *Id.,* at 443 (discussing 7 U. S. C. 136v(b); emphasis added). *Cipollone* v. *Liggett Group, Inc.* , 505 U. S. 504 (1992), held common-law actions pre-empted by a provision of the Public Health Cigarette Smoking Act of 1969, 15 U. S. C. 1334(b), which said that [n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes whose packages were labeled in accordance with federal law. See 505 U. S., at 523 (plurality opinion); *id.* , at 548-549 (Scalia, J., concurring in judgment in part and dissenting in part).

Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a States requirements includes its common-law duties. As the plurality opinion said in *Cipollone,* common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. *Id* ., at 522. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy. *Id.,* at 521.

In the present case, there is nothing to contradict this normal meaning. To the contrary, in the context of this legislation excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturers catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law

to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court. As Justice Breyer explained in *Lohr* , it is implausible that the MDA was meant to grant greater power (to set state standards different from, or in addition to federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. 518 U. S., at 504. That perverse distinction is not required or even suggested by the broad language Congress chose in the MDA,[Footnote 4] and we will not turn somersaults to create it.

B

The dissent would narrow the pre-emptive scope of the term requirement on the grounds that it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for consumers injured by FDA-approved devices. *Post* , at 5 (opinion of Ginsburg, J.) (internal quotation marks omitted). But, as we have explained, this is exactly what a pre-emption clause for medical devices does by its terms. The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification. See, *e.g., Connecticut Nat. Bank* v. *Germain,* 503 U. S. 249 , 253-254 (1992). It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available- the text of the statute-suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congresss estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.[Footnote 5]

In the case before us, the FDA has supported the position taken by our opinion with regard to the meaning of the statute. We have found it unnecessary to rely

upon that agency view because we think the statute itself speaks clearly to the point at issue. If, however, we had found the statute ambiguous and had accorded the agencys current position deference, the dissent is correct, see *post,* at 6, n. 8, that-inasmuch as mere *Skidmore* deference would seemingly be at issue-the degree of deference might be reduced by the fact that the agencys earlier position was different. See *Skidmore* v. *Swift & Co.,* 323 U. S. 134 (1944); *United States* v. *Mead Corp.,* 533 U. S. 218 (2001); *Good Samaritan Hospital* v. *Shalala,* 508 U. S. 402 , 417 (1993). But of course the agencys earlier position (which the dissent describes at some length, *post,* at 5-6, and finds preferable) is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agencys position.

The dissent also describes at great length the experience under the FDCA with respect to drugs and food and color additives. *Post,* at 7-11. Two points render the conclusion the dissent seeks to draw from that experience-that the pre-emption clause permits tort suits-unreliable. (1) It has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA. (2) If, as the dissent believes, the pre-emption clause permits tort lawsuits for medical devices just as they are (by hypothesis) permitted for drugs and additives; and if, as the dissent believes, Congress wanted the two regimes to be alike; Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.

C

The Riegels contend that the duties underlying negligence, strict-liability, and implied-warranty claims are not pre-empted even if they impose requirements, because general common-law duties are not requirements maintained with respect to devices. Brief for Petitioner 34-36. Again, a majority of this Court suggested otherwise in *Lohr.* See 518 U. S., at 504-505 (opinion of Breyer, J.); *id.* , at 514 (opinion of OConnor, J., joined by Rehnquist, C. J., and Scalia and Thomas, JJ.).[Footnote 6] And with good reason. The language of the statute does not bear the Riegels reading. The MDA provides that no State may establish or continue in

effect *with respect to a device* *any requirement* relating to safety or effectiveness that is different from, or in addition to, federal requirements. 360k(a) (emphasis added). The Riegels suit depends upon New Yorks continu[ing] in effect general tort duties with respect to Medtronics catheter. Nothing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.

The Riegels argument to the contrary rests on the text of an FDA regulation which states that the MDAs pre-emption clause does not extend to certain duties, including [s]tate or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. 21 CFR 808.1(d)(1). Even assuming that this regulation could play a role in defining the MDAs pre-emptive scope, it does not provide unambiguous support for the Riegels position. The agencys reading of its own rule is entitled to substantial deference, see *Auer* v. *Robbins* , 519 U. S. 452 , 461 (1997), and the FDAs view put forward in this case is that the regulation does not refer to general tort duties of care, such as those underlying the claims in this case that a device was designed, labeled, or manufactured in an unsafe or ineffective manner. Brief for United States as *Amicus Curiae* 27-28. That is so, according to the FDA, because the regulation excludes from pre-emption requirements that relate only incidentally to medical devices, but not other requirements. General tort duties of care, unlike fire codes or restrictions on trade practices, directly regulate the device itself, including its design. *Id.,* at 28. We find the agencys explanation less than compelling, since the same couldbe said of general requirements imposed by electrical codes, the Uniform Commercial Code, or unfair-trade-practice law, which the regulation specifically excludes from pre-emption.

Other portions of 21 CFR 808.1, however, support the agencys view that 808.1(d)(1) has no application to this case (though still failing to explain why electrical codes, the Uniform Commercial Code or unfair-trade-practice requirements are different). Section 808.1(b) states that the MDA sets forth a

general rule pre-empting state duties having the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*) . (Emphasis added.) This sentence is far more comprehensible under the FDAs view that 808.1(d)(1) has no application here than under the Riegels view. We are aware of no duties established by court decision other than common-law duties, and we are aware of no common-law duties that relate solely to medical devices.

The Riegels reading is also in tension with the regulations statement that adulteration and misbranding claims are pre-empted when they ha[ve] the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement that is different from, or in addition to a federal requirement. 808.1(d)(6)(ii). Surely this means that the MDA would pre-empt a jury determination that the FDA-approved labeling for a pacemaker violated a state common-law requirement for additional warnings. The Riegels reading of 808.1(d)(1), however, would allow a claim for tortious mislabeling to escape pre-emption so long as such a claim could also be brought against objects other than medical devices.

All in all, we think that 808.1(d)(1) can add nothing to our analysis but confusion. Neither accepting nor rejecting the proposition that this regulation can properly be consulted to determine the statutes meaning; and neither accepting nor rejecting the FDAs distinction between general requirements that directly regulate and those that regulate only incidentally; the regulation fails to alter our interpretation of the text insofar as the outcome of this case is concerned.

IV

State requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements imposed by federal law. 360k(a)(1). Thus, 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements. *Lohr,* 518 U. S., at 495; see also *id.* , at 513 (OConnor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted, see App. to Pet. for Cert. 70a-71a, but it interpreted the claims here to

assert that Medtronics device violated state tort law notwithstanding compliancewith the relevant federal requirements, see *id.,* at68a. Although the Riegels now argue that their law-suit raises parallel claims, they made no such conten-tion in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari. We decline to address that argument in the first instance here.

***

For the foregoing reasons, the judgment of the Court of Appeals is

Affirmed.

Footnote 1
Unqualified 360 *et seq.* numbers hereinafter refer to sections of 21 U. S. C.

Footnote 2
The District Court later granted summary judgment to Medtronic on those claims of Riegel it had found not pre-empted, viz., that Medtronic breached an express warranty and was negligent in manufacturing because it did not comply with federal standards. App. to Pet. for Cert. 90a. It consequently granted summary judgment as well on Donna Riegels derivative consortium claim. *Ibid* . The Court of Appeals affirmed these determinations, and they are not before us.

Footnote 3
Charles Riegel having died, Donna Riegel is now petitioner on her own behalf and as administrator of her husbands estate. 552 U. S. ___ (2007). For simplicitys sake, the terminology of our opinion draws no distinction between Charles Riegel and the Estate of Charles Riegel and refers to the claims as belonging to the Riegels.

Footnote 4
The Riegels point to 360k(b), which authorizes the FDA to exempt state requirements from pre-emption under circumstances that would rarely be met for common-law duties. But a law that permits an agency to exempt certain requirements from pre-emption does not suggest that no other requirements exist.

The Riegels also invoke 360h(d), which provides that compliance with certain FDA orders shall not relieve any person from liability under Federal or State law. This indicates that some state-law claims are not pre-empted, as we held in *Lohr* . But it could not possibly mean that *all* state-law claims are not pre-empted, since that would deprive the MDA pre-emption clause of all content. And it provides no guidance as to which state-law claims are pre-empted and which are not.

Footnote 5

Contrary to Justice Stevens contention, *post,* at 2, we do not advance this argument. We merely suggest that if one were to speculate upon congressional purposes, the best evidence for that would be found in the statute.

Footnote 6

The opinions joined by these five Justices dispose of the Riegels assertion that *Lohr* held common-law duties were too general to qualify as duties with respect to a device. The majority opinion in *Lohr* also disavowed this conclusion, for it stated that the Court did not believe that [the MDAs] statutory and regulatory language necessarily precludes . . . general state requirements from ever being pre-empted . . . . *Medtronic, Inc.* v. *Lohr,* 518 U. S. 470 , 500 (1996).

Riegel v. Medtronic, Inc. - 06-179 (2008)

OPINION OF STEVENS, J.
RIEGEL V. MEDTRONIC, INC.
552 U. S. ____ (2008)
SUPREME COURT OF THE UNITED STATES
NO. 06-179

DONNA S. RIEGEL, individually and as administra-tor of the ESTATE OF CHARLES R. RIEGEL,PETITIONER *v.* MEDTRONIC, INC.

on writ of certiorari to the united states court ofappeals for the second circuit

[February 20, 2008]

Justice Stevens, concurring in part and concurring in the judgment.

The significance of the pre-emption provision in the Medical Device Amendments of 1976 (MDA), 21 U. S. C. 360k, was not fully appreciated until many years after it was enacted. It is an example of a statute whose text and general objective cover territory not actually envisioned by its authors. In such cases we have frequently concluded that it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed. *Oncale* v. *Sundowner Offshore Services, Inc.,* 523 U. S. 75 , 79-80 (1998). Accordingly, while I agree with Justice Ginsburgs description of the actual history and principal purpose of the pre-emption provision at issue in this case, *post,* at 4-11 (dissenting opinion), I am persuaded that its text does preempt state law requirements that differ. I therefore write separately to add these few words about the MDAs history and the meaning of requirements.

There is nothing in the preenactment history of the MDA suggesting that Congress thought state tort remedies had impeded the development of medical devices. Nor is there any evidence at all to suggest that Congress decided that the cost of injuries from Food and Drug Administration-approved medical devices was outweighed by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations. *Ante,* at 13 (opinion of the Court). That is a policy argument advanced by the Court, not by Congress. As Justice Ginsburg persuasively explains, the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections. It was the then-recent development of state premarket regulatory regimes that explained the need for a provision pre-empting conflicting administrative rules. See *Medtronic, Inc.* v. *Lohr* , 518 U. S. 470 , 489 (1996) (plurality opinion) ([W]hen Congress enacted 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions).

But the language of the provision reaches beyond such regulatory regimes to encompass other types of requirements. Because common-law rules administered

by judges, like statutes and regulations, create and define legal obligations, some of them unquestionably qualify as requirements.[Footnote 1] See *Cipollone* v. *Liggett Group, Inc.* , 505 U. S. 504 , 522 (1992) ([C]ommon-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose requirements or prohibitions. [I]t is the essence of the common law to enforce duties that are either affirmative *requirements* or negative *prohibitions* (plurality opinion) (emphasis added)). And although not all common-law rules qualify as requirements,[Footnote 2] the Court correctly points out that five Justices in *Lohr* concluded that the common-law causes of action for negligence and strict liability at issue in that case imposed requirements that were pre-empted by federal requirements specific to a medical device. Moreover, I agree with the Courts cogent explanation of why the Riegels claims are predicated on New York common-law duties that constitute requirements with respect to the device at issue that differ from federal requirements relating to safety and effectiveness. I therefore join the Courts judgment and all of its opinion except for Parts III-A and III-B.

Footnote 1

The verdicts of juries who obey those rules, however, are not requirements of that kind. Juries apply rules, but do not make them. And while a jurys finding of liability may induce a defendant to alter its device or its label, this does not render the finding a requirement within the meaning of the MDA. A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. *Bates* v. *Dow Agrosciences LLC* , 544 U. S. 431 , 445 (2005). It is for that reason that the MDA does not grant a single state jury any power whatsoever to set any standard that either conforms with or differs from a relevant federal standard. I do not agree with the colorful but inaccurate quotation on page 12 of the Courts opinion.

Footnote 2

See *Cipollone* v. *Liggett Group, Inc.,* 505 U. S., 504, 523 (1992) (plurality opinion) (explaining that the fact that the pre-emptive scope of 5(b) cannot be limited to positive enactments does not mean that that section pre-empts all common-law claims and proceeding to analyze each of petitioners common-law

claims to determine whether it is in fact pre-empted); *Bates* , 544 U. S., at 443-444 (noting that a finding that 136v(b) may pre-empt judge-made rules, as well as statutes and regulations, says nothing about the *scope* of that pre-emption, and proceeding to determine whether the particular common-law rules at issue in that case satisfied the conditions of pre-emption).

Riegel v. Medtronic, Inc. - 06-179 (2008)

GINSBURG, J., DISSENTING
RIEGEL V. MEDTRONIC, INC.
552 U. S. ____ (2008)
SUPREME COURT OF THE UNITED STATES
NO. 06-179

DONNA S. RIEGEL, individually and as administra-tor of the ESTATE OF CHARLES R. RIEGEL,PETITIONER *v.* MEDTRONIC, INC.

on writ of certiorari to the united states court ofappeals 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 MDAs 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.[Footnote 1] I dissent from todays 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 medical devices. Section 360k(a) responded to that state regulation, and particularly to Californias 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).[Footnote 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 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 MDAs 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-

(1) which is different from, or in addition to, any requirement applicable under this chapter 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 chapter. 21 U. S. C. 360k(a).

Absent other indication, the Court states, reference to a States 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.[Footnote 3]

A

Congress enacted the MDA to provide for the safety and effectiveness of medical devices intended for human use. 90 Stat. 539 (preamble).[Footnote 4] A series of high-profile medical device failures that caused extensive injuries and loss of life propelled adoption of the MDA.[Footnote 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.*[Footnote 6] Given the publicity 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.[Footnote 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 MDAs 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:

FDAs view is that FDA product approval and state 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 Commr for Regulatory Affairs, to National Womens Health Network (Mar. 8, 1984).[Footnote 8] The Courts 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.[Footnote 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 Courts interpretation of 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 MDAs 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 FDCAs text or legislative history suggested that FDA preclearance would immunize drug manufacturers from common-law tort suits.[Footnote 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.[Footnote 11] Congress inclusion of a preemption clause in the MDA was not motivated by concern that similar state tort actions could be mounted regarding medical devices.[Footnote 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 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.[Footnote 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*

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. 94-853, p. 45 (emphasis added).[Footnote 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 Medtronics 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 FDAs 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.[Footnote 15] Courts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits.[Footnote 16] Decades of drug regulation thus indicate, contrary to Medtronics 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 FDAs premarket approval of Medtronics 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 plaintiffs theory of the case and the FDAs 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 FDAs 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 & Poly 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 FDAs approval of its medical device as evidence that it used due care in the design and labeling of the product.

The Courts broad reading of 360k(a) saves the manufacturer from any need to urge these defenses. Instead, regardless of the strength of a plaintiffs 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 MDAs central purpose: to protect consumer safety.

***

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

Footnote 1

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

Footnote 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.

Footnote 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 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.

Footnote 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).

Footnote 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).

Footnote 6

The Dalkon Shield was ultimately linked to thousands of serious injuries to otherwise healthy women. Vladeck, Preemption and 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).

Footnote 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.).

Footnote 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 agencys position); *Good Samaritan Hospital* v. *Shalala* , 508 U. S. 402 , 417 (1993) ([T]he consistency of an agencys position is a factor in assessing the weight that position is due.). Because the FDAs 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 FDAs new position is entitled to little weight.

Footnote 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.

Footnote 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.).

Footnote 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 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).

Footnote 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 FDAs 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 .).

Footnote 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.

Footnote 14

Congress featured Californias regulatory system in its discussion of 360k(a), but it also identified Californias 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.

Footnote 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 completing 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 drugs composition; a description of the drugs manufacturing, processing, and packaging; and the proposed labeling for the drug. 21 U. S. C. 355(b)(1).

Footnote 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 FDAs 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 FDAs comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic 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.

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