

Opinion of STEVENS, J.

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 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 GINSBURG’s 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 MDA’s 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 Admini-

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stration-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.”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

¹The 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 jury’s 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 Court’s opinion.

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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,”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 Court’s 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 Court’s judgment and all of its opinion except for Parts III–A and III–B.

²See *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 petitioner’s 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).