

Opinion of the Court

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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 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 1960’s and 1970’s, 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 pregnan-

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cies. 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.*,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 the FDA to exempt some state and local requirements from

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

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pre-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 Court’s 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 MDA’s 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 de-

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vice exempt from premarket approval. §360c(f)(1)(A). The agency’s 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 device’s safety and effectiveness that have been published or should reasonably be known to the applicant; a “full statement” of the device’s “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 device’s “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 none-

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theless 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 device's 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 FDA 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,

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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 conditions in its labeling. §360e(e)(1); see also §360h(e) (recall authority).

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. Riegel's doctor inserted the Evergreen Balloon Catheter into his patient's coronary artery in an attempt to dilate the artery, although the device's labeling stated that use was contraindicated for patients with diffuse or calcified stenoses. The label also

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warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres. Riegel's 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 bypass surgery.

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 Medtronic's 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 Riegel's 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 Riegel's claim for loss of consortium to the extent it was derivative of the pre-empted claims. *Id.*, at 68a; see also *id.*, at 75a.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

²The 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 Riegel's derivative consortium claim. *Ibid.* The Court of Appeals affirmed these determinations, and they are not before us.

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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.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 Medtronic’s 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 MDA’s 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 com-

³Charles Riegel having died, Donna Riegel is now petitioner on her own behalf and as administrator of her husband’s estate. 552 U. S. ___ (2007). For simplicity’s 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.

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mon-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 manufacturer’s 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 (O’Connor, 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

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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 York’s 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 O’Connor, 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 preempting 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

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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 preempted 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 State’s “requirements” includes its common-law duties. As the plurality opinion said in *Cipollone*, common-law liability is “premiered 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 manufacturer’s 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

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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,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

⁴The 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.

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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 Congress’s 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.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 agency’s 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 agency’s 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 agency’s 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 agency’s 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

⁵Contrary 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.

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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 O’Connor, J., joined by Rehnquist, C. J., and SCALIA and THOMAS, JJ).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

⁶The 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 MDA’s] statutory and regulatory language necessarily precludes . . . ‘general’ state requirements from ever being pre-empted . . .” *Medtronic, Inc. v. Lohr*, 518 U. S. 470, 500 (1996).

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upon New York’s “continu[ing] in effect” general tort duties “with respect to” Medtronic’s 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 MDA’s 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 MDA’s pre-emptive scope, it does not provide unambiguous support for the Riegels’ position. The agency’s reading of its own rule is entitled to substantial deference, see *Auer v. Robbins*, 519 U. S. 452, 461 (1997), and the FDA’s 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 agency’s explanation less than compelling, since the same could be said of general requirements imposed by electrical codes, the Uniform Commercial Code, or unfair-trade-practice law, which the regulation specifically excludes

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from pre-emption.

Other portions of 21 CFR §808.1, however, support the agency’s 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 FDA’s 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 regulation’s 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 statute’s meaning; and neither accepting nor rejecting the FDA’s 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

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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 (O’Connor, 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 Medtronic’s device violated state tort law notwithstanding compliance with the relevant federal requirements, see *id.*, at 68a. Although the Riegels now argue that their lawsuit raises parallel claims, they made no such contention 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.