No. 06-179

In the Supreme Court of the United States

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

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QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of that device.

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INTEREST OF THE UNITED STATES

This case presents the question whether the Food and Drug Administration's (FDA's) premarket approval of a medical device preempts state claims relating to the safety or efficacy of that device. FDA administers the premarket approval process for medical devices and monitors devices' safety after they are marketed. The decision in this case will affect that responsibility. At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. a. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, sort medical devices into three classes. See 21 U.S.C. 360c(a)(1). Class I and II devices are subject to regulatory controls or standards, but do not require pre-

market approval. See 21 U.S.C. 360c(a)(1)(A) and (B); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 476-477 (1996).

A device falls within Class III if (i) it "presents a potential unreasonable risk of illness or injury," or is purported to be used to sustain or support human life or to have substantial importance in preventing impairment of human health, and (ii) there is inadequate evidence for FDA to determine that controls or standards authorized for Class I or II devices would provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). In general, a Class III device requires premarket approval (PMA) by FDA unless it was marketed for use before the MDA's enactment or it is "substantially equivalent" to a device that is already lawfully on the market. 21 U.S.C. 360e(a) and (b)(1)(A) and (B), 360(k). Fewer than 1% of new devices require premarket approval. Pet. App. 13a.

FDA's PMA process for the relatively few devices that require it is "rigorous." *Lohr*, 518 U.S. at 477. A manufacturer must submit: full reports of all studies and investigations, including clinical investigations, of the device's safety and effectiveness; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in, and facilities and controls used for, the manufacture, processing, packing, and installation of the device; a reference to any performance standard that would apply if the device were a Class II device, and information showing that the device satisfies that standard or justifying any deviation from it; any sample of the device or its components requested by FDA; and the proposed labeling. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. FDA may request additional information from the manufacturer, and may also consult with a scientific advisory committee made up of outside experts. See 21 C.F.R. 814.44, 814.20(b)(13). The agency conducts an in-depth review of requests for premarket approval, devoting an average of 1,200 hours to each application. See *Lohr*, 518 U.S. at 477.

FDA may grant premarket approval for a Class III device only if it finds, among other things, that (i) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (ii) the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). In determining safety and effectiveness, FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B)(ii); 21 C.F.R. 814.82(a)(1), and it may also impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1).

Following FDA's premarket approval, a manufacturer must submit a supplemental application to FDA and receive its approval before making any changes to a device that affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. 814.39(a). The same process that applies to an original PMA application generally applies to a supplemental application. See 21 U.S.C. 360e(d)(6)(B); 21 C.F.R. 814.39(c). With only narrow exceptions, the manufacturer also must receive FDA's approval before making any changes to the labeling of a device. See 21 C.F.R. 814.39(a) and (d)(1).

Manufacturers are also required to collect and report to FDA information on certain adverse events related to the device after it has been approved. See 21 U.S.C. 360i(a); 21 C.F.R. Pt. 803. The manufacturer must report within 30 days any incident in which a device may have caused or contributed to a death or serious injury, or in which the device malfunctioned in a manner that would likely cause or contribute to serious injury if the malfunction recurred. See 21 C.F.R. 803.10(c)(1), 803.50(a)(1)-(2). The manufacturer must report such an incident within five days if remedial action is required "to prevent an unreasonable

risk of substantial harm to the public health." See 21 C.F.R. 803.10(c)(2)(i).

A device manufacturer is also required to provide annual reports to FDA. See 21 C.F.R. 803.55(b), 814.84. Among other things, an annual report must identify any reports in the scientific literature about the device, as well as any unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device about which the manufacturer knows or reasonably should know. See 21 C.F.R. 814.84(b)(2).

Based on new information reported to FDA or other information known to the agency, FDA may withdraw premarket approval of a Class III medical device if it finds, among other things, that the device no longer satisfies the standards for premarket approval. 21 U.S.C. 360e(e)(1).

b. The MDA's express preemption provision 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). FDA is authorized to exempt some state or local requirements from preemption. 21 U.S.C. 360k(b).

FDA's regulations implementing Section 360k provide that "State or local requirements are preempted only when [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d). The regulations further explain that state or local requirements potentially subject to preemption include those "having the force and effect of law (whether established by

statute, ordinance, regulation, or court decision)." 21 C.F.R. 808.1(b). Under the regulations, a general state prohibition against adulterated or misbranded devices may be preempted if it "has 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." 21 C.F.R. 808.1(d)(6)(ii).

2. The Evergreen Balloon Catheter is a Class III medical device used to open clogged arteries. Pet. App. 3a. FDA granted premarket approval for the device in 1994, and approved respondent's supplemental applications in 1995 and 1996. *Id.* at 3a-4a. Charles Riegel was injured after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. *Id.* at 4a. The physician used the device in contraindicated circumstances, and overinflated the device contrary to warnings on its label. *Ibid.*

Charles Riegel and his wife Donna Riegel brought this suit against respondent, alleging negligent design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. Pet. App. 4a-5a. The district court held that all of petitioners' claims except those for negligent manufacturing and breach of express warranty were preempted by Section 360k(a). See *id.* at 55a-74a. The court subsequently granted summary judgment to respondent on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a. In holding that the bulk of petitioners' claims were preempted, the court construed the term "requirement" in Section 360k to encompass the design and labeling for the device set forth in an approved PMA application. *Id.* at 26a-28a. The court explained that FDA may impose conditions on premarket approval in order to ensure that a device is safe and effective, and that federal law requires a manufacturer to comply with the specifications set forth in an approved PMA application. *Id.* at 9a.

The court of appeals determined that the imposition of tort liability based on the allegedly defective character of a device or label would subject the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. In contrast, the court determined that petitioners' negligent manufacturing claim is not preempted because it is premised on an alleged violation of federal requirements. *Id.* at 36a.

While characterizing the question as a "close" one, Judge Pooler would have held that none of petitioners' claims are preempted. Pet. App. 43a, 50a-54a.

SUMMARY OF ARGUMENT

The court of appeals correctly held that petitioners' claims are preempted to the extent that they seek to impose liability on respondent for not departing from an FDA-approved design or labeling requirement imposed in the premarket approval process. Section 360k generally preempts any state "requirement" that is "different from, or in addition to, any [federal] requirement" and that "relates to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." 21 U.S.C. 360k(a).

For a Class III device to obtain premarket approval, FDA must determine that there is reasonable assurance that the device is safe and effective and that its label is not false or misleading. FDA undertakes an exhaustive scientific review to determine whether those requirements are satisfied. In doing so, FDA does not merely police minimum standards of safety. Instead, FDA weighs potential health risks against benefits. If the agency grants approval, it does so for a specific design and label based on that weighing, and the manufacturer is then barred from changing the FDA-approved design or label without FDA approval (subject only to limited exceptions that do not appear to apply here). Thus, the premarket approval process imposes federal requirements with preemptive effect under Section 360k.

The state-law claims in dispute here would impose requirements that are different from, or in addition to, those federal requirements. As five Justices concluded in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), state common-law damages actions impose "requirements" subject to preemption under Section 360k. The claims at issue here are premised on the assertion that the Evergreen Balloon Catheter, in the form and with the label approved by FDA, is not safe and effective. Thus, the common-law duties on which those claims are based would impose additional or different requirements. Moreover, subjecting a manufacturer to liability for not departing from an FDA-approved design or label would interfere with FDA's ability to protect public health by balancing the risks and benefits of a particular design or label. For example, a state requirement that additional warnings must be included in the labeling for a device could dilute the effectiveness of more meaningful risk information, or deter beneficial uses of the device, contrary to FDA's judgment that the existing label appropriately balances the health risks and benefits.

Finally, preemption is not limited to state requirements that apply *exclusively* to medical devices intended for human use, as petitioners contend. State requirements are preempted "with respect to a device intended for human use." 21 U.S.C. 360k(a). That means that Section 360k(a) does not preempt the application of general state requirements to matters *other than* devices intended for human use; it does not mean that States can regulate such devices in any way they wish so long as they also regulate other things as well.

ARGUMENT

FDA'S PREMARKET APPROVAL OF A MEDICAL DEVICE PREEMPTS STATE TORT CLAIMS CHALLENGING THE DESIGN OR LABELING APPROVED BY FDA

Congress expressly preempted, with respect to devices intended for human use, any state "requirement" that is "different from, or in addition to, any [federal] requirement" and that "relates to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." 21 U.S.C. 360k(a). That provision precludes state tort suits to the extent that they seek to impose liability on a device manufacturer for *not* departing from an FDA-approved design or label.

A. FDA's Premarket Approval Process Imposes Specific Federal Requirements

The court of appeals correctly held that FDA's premarket approval of a Class III device imposes specific federal requirements applicable to the device, and thus has preemptive effect. Pet. App. 25a-29a.

1. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), establishes the analytical framework for this case. In *Lohr*, this Court held that FDA's determination under 21 U.S.C. 360(k) that a device is substantially equivalent to a legally marketed device does not impose any federal "requirements" that preempt state law. See *Lohr*, 518 U.S. at 493. The Court explained that the manufacturer's contrary position in that case "exaggerate[d] the importance of the [substantial-equivalence] process," in part because FDA had determined only whether the device was substantially equivalent to a legally marketed device, not (as here) whether it was safe or effective. *Id.* at 492-493. In doing so, the Court emphasized that FDA's substantial-equivalence determination "is by no means comparable to the PMA process." *Id*. at 478-479.

This Court also held in *Lohr* that FDA's "general federal regulations governing the labeling and manufacture of all medi-

cal devices" do not preempt state tort claims. 518 U.S. at 497. The Court explained that, under FDA's regulations concerning the preemptive scope of the MDA, "state requirements are preempted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.'" *Id.* at 498 (quoting 21 C.F.R. 808.1(d) (1995)). Those FDA preemption regulations are entitled to "substantial weight," in part because Congress delegated to FDA the authority to grant exemptions from preemption—an authority that requires FDA to assess the preemptive effect of the MDA and the agency's own actions on state laws. *Id.* at 496. Consistent with FDA's preemption regulations, the Court determined that the *general* federal mandates on which the manufacturer relied in *Lohr* "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation" that give rise to preemption. *Id.* at 501.

2. As this Court recognized in *Lohr*, a premarket approval is "by no means comparable" to a substantial-equivalance determination under Section 360(k). 518 U.S. at 478-479; see *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); Pet. App. 25a-27a. Unlike a substantial-equivalence determination, see *Lohr*, 518 U.S. at 493, FDA will grant premarket approval only if there is "reasonable assurance" that the device is safe and effective under the proposed conditions of use, and the proposed labeling is not "false or misleading in any particular," 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). As part of FDA's "rigorous" review of those questions (*Lohr*, 518 U.S. at 477), an applicant is required to submit extensive information, including scientific studies that generally must be undertaken pursuant to FDA's published standards. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20; p. 2, *supra*.

FDA encourages applicants to meet with it before submitting an application, so that FDA can "provide the applicant with the

agency's determination of the type of valid scientific evidence that will be necessary." FDA, *Device Advice—Premarket Approval* (Device Advice) (visited Oct. 19, 2007) <http://www.fda.gov/cdrh/devadvice/pma/printer.html>. After an application is filed, FDA may request any additional information needed to determine whether the device is safe and effective and properly labeled. See 21 U.S.C. 360e(d)(3)(A)(ii); 21 C.F.R. 814.37(b). FDA may also refer an application to a panel of experts, who provide FDA with a "report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation." 21 U.S.C. 360e(c)(2); see 21 C.F.R. 814.44(a) and (b). "In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation." Device Advice.

If the available information is ultimately insufficient to provide reasonable assurance of safety or effectiveness, FDA does not approve the application. 21 U.S.C. 360e(d)(2). Instead, FDA will informally determine whether a manufacturer will voluntarily provide additional information or make changes to a device's design or label that would permit approval. If those discussions are unsuccessful, FDA will either: (i) issue an "approvable letter" stating that the agency could approve the application if the applicant submitted specific additional information or agreed to conditions on approval, 21 C.F.R. 814.44(e); (ii) issue a "not approvable letter" describing the deficiencies in the application, 21 C.F.R. 814.44(f); or (iii) deny the application outright, 21 C.F.R. 814.45. FDA approves about 60% of PMA applications. See FDA, *Annual Report* 41 (2004) <http://www.fda.gov/cdrh/annual/fy2004/ode/2004.pdf>. The other applicants typically receive approvable or not approvable letters. See *ibid.*

FDA devotes approximately 1,200 hours to a typical PMA review. See *Lohr*, 518 U.S. at 477. While this Court found that substantial-equivalance determinations "provide little protection to the public," *id.* at 493, premarket approvals reflect FDA's

expert judgment, rendered after exhaustive analysis, that there is reasonable assurance that the devices are in fact safe and effective and properly labeled.

3. FDA's premarket approval imposes "specific requirements applicable to a particular device." *Lohr*, 518 U.S. at 498 (quoting 21 C.F.R. 808.1(d) (1995)). The MDA requires that a device be safe and effective, and that its label not be false or misleading. 21 U.S.C. 360e(d). FDA's premarket approval gives specific content to those general requirements as applied to a particular device. The agency approves a specific design and label based on the agency's expert balancing of the health risks and benefits, and the MDA generally requires the manufacturer not to make subsequent changes without FDA's approval.

a. Contrary to petitioners' contention (Br. 24) that FDA reviews devices only for "minimum standards" of safety and effectiveness, the MDA directs FDA to "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. 360c(a)(2)(C). Under that standard, FDA conducts a risk-benefit analysis to determine whether safety risks (whatever their magnitude) are warranted in light of the potential benefits. See, *e.g.*, H.R. Rep. No. 853, 94th Cong., 2d Sess. 16-17 (1976); Device Advice. FDA's risk-benefit balancing for devices is parallel to the risk-benefit balancing it undertakes pursuant to 21 U.S.C. 355(d) as part of the pre-market approval process for drugs. See *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.").

Applying that approach, FDA has, for example, approved cancer treatments that are highly toxic and thus not "safe" as that term is ordinarily used, but that are nonetheless safe in the relevant sense under the FDCA because the potential benefits to health outweigh the risks. 61 Fed. Reg. 44,413 (1996); see *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000).

FDA has likewise approved a ventricular assist device for use in children with failing hearts, even though the survival rate for children with the device is under 50%. The agency explained that the device's benefits outweighed its significant risks. FDA, *Summary of Safety and Probable Benefit* 20 (2004) (Summary) <http://www.fda.gov/cdrh/pdf3/H030003b.pdf>.

In determining whether benefits outweigh risks, FDA may also consider the availability of other drugs, devices, or courses of treatment, as well as their safety profiles. As then-FDA Commissioner David Kessler testified in 1996, FDA "must determine if each new drug or device is safe enough in view of its anticipated benefits and the comparative benefit of other available treatments." *Testimony Before the Senate Comm. on Labor and Human Resources* <http://www.hhs.gov/asl/testify/t960221a.html>. Thus, when FDA approved the ventricular assist device discussed above, it relied in part on "the risks and benefits associated with alternative methods of treatment," which had high mortality rates. See Summary 20.

If similar, safer products are on the market, the agency requires a heightened health benefit to justify the heightened risk. For example, FDA determined in 2005 that Bextra should be withdrawn from the market because it presented greater safety risks than other drugs with comparable efficacy, and the manufacturer withdrew it. See FDA, *Alert for Healthcare Professionals* (2005) <http://www.fda.gov/cder/drug/InfoSheets/HCP/valdecoxibHCP.pdf>; *FDA Memorandum* 17 (2005) <http://www.fda.gov/cder/drug/infopage/COX2/NSAIDdecisionMemo.pdf>.

FDA also weighs the overall health consequences of including particular warnings in the labeling. As FDA has explained, "[e]xaggeration of risk could discourage appropriate use of a beneficial drug." 71 Fed. Reg. 3935 (2006). The same is true for devices. Excessive warnings in the medical area risk deterring the use of critically important products. Thus, a warning label

must strike a balance between notifying users of potential dangers and not unnecessarily deterring beneficial uses. See *ibid.*

Moreover, the more warnings included in labeling, the less effective each constituent warning becomes. Warning of theoretical risks can cause more meaningful risk information to "lose its significance." 44 Fed. Reg. 37,447 (1979); accord 71 Fed. Reg. at 3935; 65 Fed. Reg. 81,083 (2000). Indeed, "[o]verwarning has the effect of not warning at all. The reader stops paying attention to excess warnings." FDA, *Write It Right* 7 (1993). Thus, there are "a number of sound reasons why the FDA may prefer to limit warnings on product labels." *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002).

In *Lohr*, this Court emphasized that FDA had *not* "weighed the competing interests relevant to the particular requirement in question" or "reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases." 518 U.S. at 501. Because FDA undertakes such a weighing as part of its premarket approval process, according preemptive effect to FDA's premarket approvals is fully consistent with *Lohr*.

b. Once FDA granted premarket approval for the Evergreen Balloon Catheter based on the agency's risk-benefit balancing, respondent could not have lawfully marketed a product that deviated from the approved version nor made any changes affecting the safety or efficacy of the device, including labeling changes, without first submitting a supplemental application to FDA. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39(a). The supplemental premarket approval process is similar to the initial PMA process. "All procedures and actions that apply to an [original application] * * * also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. 814.39(c).

While petitioners argue (Br. 31) that applicants may make some changes without prior FDA approval, that is true only in

very limited circumstances that do not appear to apply here. Some changes in labeling, quality controls, or manufacturing processes may go into effect before FDA review if they "enhance[] the safety of the device." 21 C.F.R. 814.39(d). As FDA recently explained in a draft guidance document, however, even those types of changes may be made without prior FDA approval only if "the manufacturer has newly acquired safety-related information" that "was not previously considered by the FDA." FDA, *Draft Guidance for Industry and FDA Staff, Modifications to Devices Subject to Premarket Approval (PMA)* 19 (Mar. 9, 2007) (Draft Guidance) <http://www.fda.gov/cdrh/ode/guidance/1584. pdf>. Unilateral changes based on information available at the time of FDA's approval could upset FDA's balance of health risks and benefits, and thus "undermine" the PMA process. *Ibid.* Indeed, it would make little if any sense to permit unilateral changes immediately following FDA's approval based on the same information that FDA had already considered.

Even if a manufacturer relies on new information to support a safety-enhancing change to a label, it still must obtain prior approval for any changes that affect both safety *and* efficacy. Draft Guidance 20. Though such a change would (in the manufacturer's view) improve a device's safety, it could also reduce health benefits, and thus affect the overall risk-benefit tradeoff. In this case, it appears that the exceptions to prior approval are beside the point, in part because petitioners' tort claims do not appear to be based on newly available information. And, in any event, the statute and regulations vest in FDA, not States or juries, the authority to accept or reject the changes, whether or not the manufacturer has put them into effect in the meantime.

c. Petitioners argue (Br. 27) that, although FDA can impose design requirements with preemptive effect by regulation, the PMA process does not impose such requirements because FDA merely approves the applicant's proposed design. That is incorrect. If FDA finds that a proposed device is not safe or effective,

it can condition its grant of premarket approval on the manufacturer's making specified changes to the device. 21 C.F.R. 814.44(e) and (f). In FDA's experience, manufacturers often agree to make such changes, even before FDA formally requires them as a condition of approval, in order to receive premarket approval. There is no meaningful basis for distinguishing between a specification imposed by regulation and the same specification imposed as a condition of premarket approval. In either case, a manufacturer could not deviate from the requirement without risking a violation of the MDA. Thus, FDA's regulations provide that federal "requirements" include not only "regulations," but also "other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d).

Similarly, it makes no difference whether the approved device is identical to the one initially submitted by the applicant for approval, or was modified in the course of FDA's review. As the court of appeals explained, it would be perverse to subject respondent to greater potential tort liability on the ground that, because the device was safe and effective in the form submitted to FDA, it did not require changes or additional safeguards as a condition of premarket approval. Pet. App. 27a-28a. Whether or not the specifications were modified in the approval process, the applicant is generally barred from making changes without FDA's prior approval. Once the premarket approval process is complete, the manufacturer, with exceptions not relevant here, cannot lawfully market a product that deviates from the approved version. The specifications, as to both product and label, developed in the approval process become the requirements for lawfully marketing the device.

B. Petitioners' Tort Claims Would Impose State-Law Requirements

Just as the premarket approval process imposes requirements, petitioners' state-law claims would impose requirements on the design and labeling of the device.

1. Petitioners argue at length (Br. 14-23) that *no* state common-law duties are "requirements" subject to preemption. As the court of appeals explained, this Court has already rejected that contention. See Pet. App. 30a-32a.

While a four-Justice plurality of the *Lohr* Court predicted that "few, if any, common-law duties have been pre-empted by this statute," 518 U.S. at 502, a majority of this Court disagreed. Writing for herself and three other Justices, Justice O'Connor "conclude[d] that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the [MDA]." *Id.* at 509. She explained that "state common-law damages actions operate to require manufacturers to comply with common-law duties." *Id.* at 510. "The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Ibid.* (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)).

Writing separately, Justice Breyer "basically agree[d] with Justice O'Connor's discussion of this point and with her conclusion." 518 U.S. at 503. Justice Breyer explained that distinguishing between a state agency regulation requiring a particular design and a jury verdict imposing liability for failure to use that design would produce the "anomalous result" of "grant[ing] 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." *Id.* at 504. Thus, Justice Breyer concluded that, "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-505.

The Court reached the same conclusion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Bates* v. *Dow Agro-*

sciences LLC, 544 U.S. 431 (2005). *Cippolone* held that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests *no distinction* between positive enactments and common law; to the contrary, those words *easily encompass* obligations that take the form of common-law rules." 505 U.S. at 521 (plurality opinion) (emphases added); accord *id.* at 548-549 (Scalia, J., concurring in the judgment in part and dissenting in part). In *Bates*, this Court again held that "requirements" "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." 544 U.S. at 443.[1]

Petitioners err in arguing (Br. 22) that "requirements" should be read to exclude common-law requirements because, at the time Congress enacted Section 360k, this Court had not yet construed a similar provision in any other statute to include common-law requirements. That rationale would have applied with equal force in *Cippolone*, because that was the first case in which this Court construed the term "requirement" in an express preemption clause. But the meaning of a statutory term stems from its ordinary usage and statutory context, not whether it has previously been construed by this Court. Cf. *Cippollone*, 505 U.S. at 521 (plurality opinion) (explaining that the term "requirements" "plainly" and "easily" includes common-law duties).

2. Petitioners argue (Br. 19-21) that the conclusion that common-law standards of care are "requirements" is inconsistent with the statutory structure. There is no inconsistency. Petitioners assert (Br. 13) that "requirements" cannot encompass state

[1] Petitioners rely (Br. 37) on *Bates*' statement that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 544 U.S. at 445. That passage does not address the question whether the substantive standard of care sought to be enforced in a common-law claim is a requirement (a question *Bates* answers in the affirmative, see *id.* at 443). Instead, it addresses the separate question whether requirements that do not directly apply to a product's label or packaging are nonetheless requirements "for labeling or packaging," as required by the statute at issue in *Bates*. See *id.* at 444-445. That question is not implicated here.

tort duties because Section 360k(b), which authorizes FDA to exempt from preemption a state or local "requirement" that satisfies certain conditions, "cannot workably be applied to damages claims." But nothing in the statute bars FDA from granting an exemption for a requirement developed at common law. FDA may grant an exemption if either (i) a state requirement is more stringent than the corresponding federal requirement, or (ii) a state requirement is "required by compelling local conditions" and compliance with the requirement would not cause the device to violate a federal requirement. 21 U.S.C. 360k(b)(1).

While it may be more difficult for a common-law requirement to satisfy the conditions for an exemption, that does not mean that FDA lacks authority to grant an exemption if a common-law requirement satisfies either of the statutory prongs. Common-law judges are not unable to impose clear requirements. Some common law rules are very clear. See, *e.g.*, *Ling* v. *Jan's Liquors*, 703 P.2d 731, 635 (Kan. 1985) (no liability at common law for furnishing liquor to intoxicated person). Common-law requirements can be clearly explained in opinions and are often clear enough for state legislators to replace a common-law requirement with one imposed by positive law. See, *e.g.*, N.Y. Gen. Oblig. § 11-101 (imposing liability for furnishing liquor in some circumstances). In any event, while petitioners assume that Congress intended to ensure the availability of an exemption for every type of "requirement" subject to preemption, that assumption does not follow from the statutory text. Even if the conditions for granting an exemption meant that some types of requirements were not eligible for exemptions, that does not mean that those requirements would somehow lose their status as requirements.[2]

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[2] FDA's regulations do not expressly identify judicial or common-law rules as a subject for exemption, but do not rule them out, either. See 21 C.F.R. 808.20(c)(1) (State or locality must identify the "statute, rule, regulation, or ordinance" for which it seeks an exemption).

Petitioners also rely (Br. 20) on 21 U.S.C. 360h(d), which provides that an FDA order requiring public notice that a device poses an unreasonable risk of substantial harm does "not relieve a person from liability under Federal or State law," including "damages for economic loss." While that provision contemplates that *some* state-law actions are not preempted, it nowhere suggests that *no* such actions are preempted. Nor does it shed light on *which* such actions are preempted, which is the question here.

The more telling contextual evidence comes from the statute's drafting history. The preemption provision in the bill initially passed by the Senate applied only to "a standard or regulation which prescribes any requirements as to" specified topics. S. Rep. No. 33, 94th Cong., 1st Sess. 72 (1975). By ultimately enacting the broader text of Section 360k(a)—which refers to "any requirement," not only a requirement prescribed by a standard or regulation—Congress rejected a provision that was limited to state positive law in favor of one that is not. Moreover, as the House Report explained, Congress's concern was that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. Rep. No. 853, *supra*, at 45. That concern does not turn on the form or source of a requirement.

C. The State-Law Requirements At Issue Here Are Different From, Or In Addition To, The Federal Requirements

The court of appeals correctly determined which of petitioners' state-law claims assert duties that are different from or in addition to federal requirements, and are therefore preempted. See Pet. App. 32a, 35a-36a.

1. Common-law claims are preempted insofar as they assert that a device in its FDA-approved form is not safe or effective for use as directed in the FDA-approved labeling

Petitioners' negligent-manufacturing claim is not preempted "to the extent it rest[s] on the allegation that the particular Evergreen Balloon catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. Such a claim would not impose an additional or different *requirement*; instead, it would provide a *remedy* for respondent's alleged failure to comply with a state law that parallels federal requirements. See 21 C.F.R. 808.1(d)(2); *Lohr*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

In contrast, the other claims at issue here are premised on the assertion that the device, "in its present PMA-approved form, is in some way defective and therefore requires modification." Pet. App. 32a. Any judgment in petitioners' favor on those claims would necessarily rest on a finding that respondent was required, under state law, to alter the FDA-approved product specifications or labeling. As such, those state-law claims would impose requirements that are different from, or in addition to, the federal requirements.[3]

2. The claims at issue here would interfere with FDA's expert balancing of health risks and benefits

The conclusion that the MDA preempts the claims at issue here is buttressed by the extent to which those claims would interfere with FDA's expert balancing of a device's health risks

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[3] Like petitioners' negligent-manufacture claim, their express-warranty claim is not preempted because it would merely provide a remedy for the violation of a state law that parallels a federal requirement. Pet. App. 72a. The district court entered summary judgment on the merits of that claim, however, and petitioners did not appeal that aspect of the judgment. *Id.* at 6a n.3.

and benefits. In *Lohr*, the Court looked to the statute's "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. Justice Breyer likewise concluded that "[i]t makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the pre-emption statute (and the pre-emption regulation) in light of * * * basic [conflict] pre-emption principles." *Id.* at 508.

a. Permitting a state jury to impose liability on the basis that a device FDA found to be safe and effective is *not* safe or effective would clearly interfere with the agency's ability to utilize the premarket approval process to balance the risks and benefits of Class III medical devices. The MDA is a "balanced" statute designed "to assure [both] that the public is protected from unsafe and ineffective medical devices" and "that innovations in medical technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12. In keeping with the latter concern, FDA balances a device's health risks against its benefits, and approves even devices that pose significant risks if their benefits outweigh the risks. See pp. 11-13, *supra*. Thus, premarket approval reflects FDA's expert determination that a device is on balance beneficial to human health, and therefore *should* be on the market. In such circumstances, a jury's imposition of liability based on a device's FDA-approved design or label would interfere with the balance struck by Congress in the MDA, and by FDA in approving the particular device.

Consider the example Justice Breyer used in *Lohr*. See 518 U.S. at 504. If FDA approves a hearing aid with a one-inch wire, a jury's imposition of liability on the theory that a two-inch wire should have been used would conflict with FDA's expert judgment. While petitioners assert (Br. 38) that the basis for a jury verdict is not always so clear, that hardly diminishes the concern. Imprecise standards can frustrate the federal regulatory balance as much as (if not more than) clear rules. What matters is not

the precision of the state law, but its conflict with federal policy. And in this example, the conflict is clear: FDA found that the device was safe and effective in a particular form, and the jury found that it was not.

Claims that challenge a device's FDA-approved label would similarly intrude upon FDA regulation. Over-warning poses serious health risks. See pp. 12-13, *supra*. As FDA has explained, "product liability and medical malpractice lawsuits, together with increasing litigation costs, ha[ve] caused manufacturers to become more cautious and include virtually all known adverse event information [in labels], regardless of its importance." 65 Fed. Reg. at 81,083. The consequence is "to limit physician appreciation of potentially far more significant" risks. 71 Fed. Reg. at 3935. The critical importance of providing appropriate warnings for medical devices—and, in particular, the most complex and highest-risk devices—further supports the conclusion that Congress intended FDA to use its expert judgment concerning the appropriate warnings for a particular medical device, and not to permit that judgment to be second guessed by lay juries.

b. Petitioners argue (Br. 40) that there is no conflict because "PMA does not preclude a later determination that the device is not safe and effective." Petitioners note in that regard (see Br. 40-41) that FDA has authority to change its mind and to withdraw its premarket approval of a device. That point only underscores, however, that Congress charged FDA, not state juries, with the responsibility to determine whether a device remains safe and effective and, thus, whether to withdraw the agency's approval.

Manufacturers must provide extensive information to FDA following approval of a medical device, including prompt reporting of adverse events that might be related to the device. See pp. 3-4, *supra*. FDA also conducts "routine postmarket inspections" of manufacturing facilities and other sites, and receives complaints from members of the public. FDA, *Ensuring the*

Safety of Marketed Medical Devices 11-13, 15 (2006) <http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf>. Based on all of those sources of information, FDA may withdraw premarket approval for a variety of reasons, including that the agency no longer believes that the device satisfies the requirements for premarket approval. 21 U.S.C. 360e(e)(1). When FDA has not taken that action, however, its premarket approval of the device—and the federal requirements that result from that approval—remain in effect.[4]

d. FDA's conclusion that state tort liability would undermine its ability to balance risks and benefits is similar to the agency policy judgment to which this Court deferred in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000). There, as here, the agency did not merely impose minimum safety standards. *Id.* at 874-875. Instead, it determined that public safety was best served by permitting manufacturers to install a variety of different passive restraint systems in their vehicles. *Id.* at 881. The Court held that a state suit seeking to impose liability for failure to use a particular type of restraint system would stand as an obstacle to the federal agency's decision. *Id.* at 881-883; see also, *e.g.*, *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 325, 327 (1981). So too here, imposing liability on a manufacturer for using an FDA-approved design or altering an FDA-approved label would conflict with FDA's determination that the design and label appropriately balance the health risks and benefits.

FDA's understanding of its premarket approval process, and its judgment respecting the extent to which state law would interfere with that process, are entitled to deference. As this

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[4] That does not mean that injured persons are necessarily without a remedy. Petitioners' express-warranty and negligent-manufacturing claims were not preempted. See Pet. App. 70a-72a. In any event, FDA's decision to grant and not withdraw premarket approval strongly suggests that a device is not defective.

Court explained in *Lohr*, "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495-496. It is FDA that makes a case-specific determination regarding the safety and effectiveness of a device, and it is FDA's approval of the design and labeling of the device that requires the manufacturer to adhere to those specifications in order to market the device. FDA's role in administering the MDA makes it "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Ibid.* (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)).

Petitioners argue (Br. 33-34) that FDA's judgment respecting the conflict between premarket approval and state tort duties is not entitled to deference because FDA changed its view on the matter in 2004, and its position is not set forth in a formal regulation. As explained in the government's petition-stage brief (at 16-17), however, the United States' earlier position was based in part on proposed regulations that FDA has since withdrawn, and its prior position is inconsistent with FDA's current understanding and application of the risk-management principles discussed above (*e.g.*, the need to prevent over-warning). Neither FDA's reasoned change in position, nor the absence of a formal agency regulation addressing the specific question presented here, negates deference. See, *e.g.*, *Auer* v. *Robbins*, 519 U.S. 452, 461-462 (1997) (deferring to agency view set forth in amicus brief); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983) (holding that agency's changed position is entitled to deference so long as the agency provides a reasoned explanation for the change).

3. The federal and state requirements at issue here are not equivalent

Petitioners argue (Br. 39) that their claims are not preempted because they are based on duties equivalent to federal statutory requirements for a Class III device, such as the prohi-

bition against misbranding and the requirement of reasonable assurance that a device is safe and effective when used in accordance with its labeling.

That claim was neither pressed nor passed upon in the court of appeals. Nor did petitioners raise it in their petition for a writ of certiorari. Thus, that claim is not properly before this Court. See, *e.g.*, *Adickes* v. *S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970). Indeed, it would make little sense for this Court to undertake, in the first instance, to determine the elements of petitioners' state-law causes of action and to compare them to federal statutory and regulatory requirements. Cf. *Bates*, 544 U.S. at 447 (remanding for the court of appeals to undertake that task).[5]

In any event, petitioners' argument is wrong. In *Lohr*, this Court held that common-law claims that allege violations of FDA regulations are not preempted. 518 U.S. at 495. The court explained that "a damages *remedy* does not amount to the additional or different '*requirement*' that is necessary under the statute." *Ibid.* (emphases added). Significantly, however, the only requirements at issue there were FDA's "general" regulations applicable to "every medical device." *Id.* at 497-498.

Here, in contrast, the relevant federal "requirements" are not merely the general standards for premarket approval (such as safety and effectiveness). Instead, as discussed above, they include the specific design and labeling requirements imposed as part of the PMA process. A state-law finding of liability for not modifying the FDA-approved design or label would conflict with those specific requirements, because it would be based on a determination that an FDA-approved design was not safe or effective, or an FDA-approved label was inadequate.

Bates is inapposite for similar reasons. In that case, this Court construed the preemption provision of the Federal Insecti-

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[5] The United States' petition-stage brief (at 14-15) pointed out that petitioners had not preserved a claim that the state and federal requirements were equivalent. In their supplemental brief, petitioners did not dispute that point.

cide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b). This Court held that FIFRA would not preempt the plaintiffs' state failure-to-warn claim if the elements of that claim were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. 544 U.S. at 447.

This case is fundamentally different from *Bates* because, under FIFRA, the Environmental Protection Agency (EPA) did not evaluate either the product's efficacy or the accuracy of statements about efficacy in the proposed labeling. *Bates*, 544 U.S. at 440. Because EPA had never "passed on the accuracy of" the relevant statements in the product's label, it had done nothing to "further refine [its] general [misbranding] standards in any way that [wa]s relevant to [the plaintiffs'] allegations" in *Bates*. *Id.* at 440, 453 n.27. Here, in contrast, FDA determined that there is reasonable assurance that the device is safe and effective in its current form, and that its labeling is accurate. Morever, FIFRA, unlike the MDA, does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Id.* at 450.

D. Preemption Does Not Turn On Whether State Requirements Also Apply To Matters Other Than Medical Devices Intended For Human Use

Petitioners argue (Br. 34-36) that the common-law duties on which they rely are not preempted because they apply to matters other than medical devices intended for human use. That contention is incorrect.

1. Section 360k(a) provides that "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 * * * which is different from, or in addition to, any requirement applicable under this chapter to the device" (emphasis added). Con-

trary to petitioners' assumption, the phrase "with respect to a device intended for human use" does not mean that only those requirements that apply *exclusively* to devices intended for human use are preempted. That phrase does not follow and modify the term "requirement." Instead, it follows and modifies the phrase "no State * * * may establish or continue in effect." Thus, it means that state requirements that apply both to devices intended for human use and to other matters are not preempted in their entirety, but instead are preempted only insofar as they apply "with respect to" devices intended for human use.

Petitioners' contrary reading is illogical. A state law's interference with federal requirements for devices intended for human use is in no way lessened by the state law's application to other matters. There is, for example, no reason that Congress would want to preempt a state statute that imposes design requirements on devices intended for human use, but to exempt altogether a state statute that imposes the same design requirements on devices intended for both human and animal use. In either case, Congress has an identical interest in preempting the statute with respect to medical devices intended for human use. The same is true of a common law duty that applies to, but is not limited to, medical devices intended for human use. Compare *Morales* v. *TWA*, 504 U.S. 374, 386 (1992).

FDA's regulations are consistent with that common-sense reading of the statutory text. They explain that the statute preempts state requirements "whether established by statute, ordinance, regulation, *or court decision*." 21 C.F.R. 808.1(b) (emphasis added). Petitioners rely (Br. 36) on a provision stating that the statute does not preempt "State 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 C.F.R.

808.1(d)(1). When FDA proposed that regulation, it explained that its intent was to exclude from preemption "requirements of general applicability that relate *only incidentally* to medical devices," such as "general fire and electrical codes." 42 Fed. Reg. 30,384 (1977) (emphasis added); see *ibid.* (same). Neither the regulatory text nor the preamble states that general tort duties of care fall outside the scope of preemption. Unlike fire codes or restrictions on unfair trade practices, such duties do not relate only incidentally to devices. Instead, they directly regulate every aspect of the device itself, including its very design.

The more relevant regulation is 21 C.F.R. 808.1(d)(6)(ii). Under that provision, "a State or local requirement prohibiting the manufacture of adulterated or misbranded devices" is "[g]enerally" not preempted, but is preempted when it "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement." As discussed, petitioners' tort claims would have precisely that effect because any imposition of liability would be based on a finding that the FDA-approved design or labeling is inadequate in some respect. Indeed, a jury verdict or common-law judge's opinion can be understood as taking a general legal rule and applying it in a way that establishes a substantive requirement for the specific device at issue.

A contrary reading of the statute or regulations would effectively exempt all common-law claims (and many positive-law claims) from preemption. Petitioners have identified no general common-law duties that apply only to medical devices intended for human use, and the United States is aware of none. Petitioners' position is thus difficult to square with the regulations' determination that requirements "established by * * * court decision," as well as general requirements that "ha[ve] the effect of establishing a substantive requirement for a specific device," are preempted. 21 C.F.R. 808.1(b) and (d)(6)(ii). In any event, FDA's interpretation of its regulations is entitled to deference. See, *e.g.*, *Auer*, 519 U.S. at 461-462.

2. Nor can petitioners' position be reconciled with this Court's decision in *Lohr*. Providing the decisive fifth vote, Justice Breyer rejected the *Lohr* plurality's view that "future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" 518 U.S. at 508. As Justice Breyer explained, it would make little sense to distinguish between a state agency regulation requiring a particular hearing-aid design and "a state-law tort action that premises liability upon the defendant manufacturer's failure to use [that design] (*say, an award by a jury persuaded by expert testimony that use of a [different design] is negligent*)." *Id.* at 504 (emphasis added). Under petitioners' position, however, that state-law negligence action would not be preempted, because the common-law tort of negligence is not limited to medical devices intended for human use.

Petitioners rely (Br. 35) on a portion of the *Lohr* majority opinion stating that "the general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," and therefore were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." 518 U.S. at 501. In context, that discussion cannot mean that no general common-law requirements are preempted. That conclusion would be inconsistent with Justice Breyer's decisive concurrence.

Instead, the relevant discussion is best read as reflecting the types of federal and state requirements at issue in *Lohr*. The Court was addressing whether "*general* federal regulations governing the labeling and manufacture of all medical devices" preempted *general* state tort duties. See 518 U.S. at 497 (emphasis added). Here, in contrast, the question is whether FDA's device-specific PMA preempts a State's application of its general tort duties to a specific device. Because this case involves a device-specific federal requirement, it is logical to consider the state requirements at the same level of specificity. Indeed, one must

do so in order to understand the extent to which the state requirements would interfere with the federal ones.

E. The Presumption Against Preemption Does Not Control This Case

Petitioners invoke (Br. 21) the presumption against preemption, asserting this the Court should refuse to find that state tort claims are preempted in the absence of clear evidence of congressional intent. As a majority of this Court recognized in *Lohr*, however, Congress manifested the requisite intent to preempt common-law tort duties that are different from, or in addition to, federal requirements. See p. 16, *supra*. And, as discussed above, the state claims at issue here would clearly interfere with the federal requirements imposed by the PMA process, as they seek to impose liability on respondent for using an FDA-approved design and label.

Moreover, Congress delegated to FDA the responsibility to administer Section 360k's express preemption provision. Accordingly, FDA's judgment that petitioners' claims are preempted is entitled to "substantial weight." *Lohr*, 518 U.S. at 496.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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