No. 06-179

IN THE
Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

REPLY BRIEF FOR PETITIONERS

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TABLE OF AUTHORITIES

STATUTES AND REGULATIONS

REPLY BRIEF FOR PETITIONERS

The parties agree on two points. First, the lower courts are in conflict over the question whether 21 U.S.C. § 360k(a) preempts medical devices marketed under the FDA's premarket approval ("PMA") process. Second, this question has been presented in prior petitions filed in this Court, which the Court has denied. These points of agreement are related because, in response to the prior petitions, respondent has argued that the conflict would disappear without this Court's assistance.[1] Yet today, nearly a decade after the conflict arose, it remains in place on both the federal and state sides of the preemption analysis outlined by the Court in *Medtronic v. Lohr*, 518 U.S. 470 (1996).

1. Medtronic says that its inability to find recent damages cases involving PMA devices and addressing preemption in some of the jurisdictions that have held that section 360k(a) does not preempt damages claims suggests that those holdings are not strong precedent in those jurisdictions. Opp. 19 & n.11. Logically, it means the opposite. That the Eleventh Circuit has not had cause to revisit *Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999), for example, means not that *Goodlin* was "anomalous," Opp. 19, but that it is respected as the law of the Circuit. In fact, in a district court case in Florida, Medtronic made arguments similar to those it makes here—that *Goodlin* need not be followed because some other courts disagreed with its holding and because the FDA had since reversed its view to favor preemption. The Court responded: "Not only does the court 'feel bound' by the *Goodlin* decision, it *is* bound by the decision . . . ." *Jimenez v. Medtronic*, No. 05-1088 (M.D. Fla. Oct. 18, 2005) (order

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[1] *See* Br. for Resp. in *Knisley v. Medtronic*, No. 05-22 (filed Sept. 6, 2005), Br. for Resp. in *Martin v. Medtronic*, No. 01-441 (filed Nov. 14, 2001), and Br. for Resp. in *Kemp v. Medtronic*, No. 00-1766 (filed July 23, 2001).

denying motion for protective order). Likewise, the Illinois Supreme Court has twice had the opportunity to consider whether section 360k(a) preempts damages claims with respect to PMA devices, including once after several appellate courts had held that such claims are preempted. *See*, *e.g.*, *Mitchell v. Collagen Corp*., 126 F.3d 902 (7th Cir. 1997); *Worthy v. Collagen Corp*., 967 S.W.2d 360 (Tex. 1998). The Illinois court nonetheless held that section 360k(a) does not preempt damages claims. *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E. 1149 (Ill. 1999); *see also Smith Indus. Med. Sys. v. Kernats*, 675 N.E.2d 634 (Ill. 1996) (denying review of appellate court decision holding no preemption).

2. The question presented here is what the language of section 360k(a) means. In two briefs filed in this Court, the FDA has argued that the plain language of section 360k(a) does not preempt state-law damages claims, including claims arising from PMA devices. *See* Br. of U.S. as Amicus Curiae in *Smith Indus. Medical Sys. v. Kernats*, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997) (regarding PMA device); Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 1996) (regarding § 510(k) device).

In 2004, the FDA reversed itself. In a Third Circuit amicus brief, the FDA acknowledged its prior position that section 360k(a) does not preempt damages claims but made an about-face to argue that section 360k(a) does preempt such claims. Br. of U.S. as Amicus Curiae in *Horn v. Thoratec*, 3d Cir. No. 02-4597, 2004 WL 1443720 (filed May 14, 2004).

Now, Medtronic suggests that the FDA's 2004 brief will cause the conflicts among the lower courts to disappear. This suggestion is unfounded. To begin with, the conflict existed before 2004, even in the face of an FDA brief clearly stating the agency's view that damages claims involving PMA devices were generally not preempted. *See* Br. of U.S. as Amicus

Curiae in *Smith Indus. Med. Sys.*, *supra* p. 2. The number of courts that, between 1997 and 2004, held that claims involving PMA devices are preempted shows that the lower courts simply do not give FDA amicus briefs on this question much weight.

Now that the FDA has reversed its position, its amicus briefs are entitled to even less consideration by the courts. As Judge Pooler noted below, an agency's claims that an express preemption provision extends to damages claims are "particularly dubious" where, until relatively recently, the regulating agency did not think that such claims are preempted. Pet. App. 46a (quoting *Bates v. Dow AgroSciences*, 544 U.S. 431, 449 (2005)).

Thus, not surprisingly, the FDA's 2004 brief has done nothing to minimize the undeniable disagreement about the scope of section 360k(a). Rather, although both federal courts of appeals to have considered the issue since the FDA filed its brief have found preemption, one court paid little attention to the FDA's brief, *see* Pet. App. 14a, 37a-38a, and both decisions provoked strong dissents. *See id.* 46a-47a (Pooler, J., dissenting); *Horn v. Thoratec*, 376 F.3d 163, 182 n.29 (3d Cir. 2004) (Fuentes, J., dissenting) (noting that arguments advanced in agency amicus briefs "are entitled to 'near indifference,' and are only as persuasive as their merits dictate") (quoting defendant).

Moreover, as the dissent noted in *Horn*, "the *Lohr* court gave deference to the FDA's regulations in particular, not to an amicus brief." *Id*. Because the relevant FDA regulation (21 C.F.R. § 808.1) has not changed in nearly 30 years and the FDA's 2004 brief did not tie its argument to that regulation, the FDA's amicus brief should not affect the views of the courts on either side of the conflict.

3. If there is a development that should affect the lower courts' approaches to interpreting the scope of section 360k(a),

it is not the seesawing views of the FDA; it is this Court's developing preemption jurisprudence. Over the past decade, the Court has consistently reversed lower court decisions broadly construing express preemption provisions to preempt damages claims. *See* Pet. 18 (citing cases). Most recently, the Court in *Bates* resolved a conflict far more lopsided than the one at issue here by rejecting a pesticide company's preemption argument based on a statutory provision "similarly worded" to section 360k(a). 544 U.S. at 447.

Many lower courts have failed to heed the Court's direction with respect to construction of express preemption provisions. Medtronic's brief in opposition reflects this same shortcoming. For example, Medtronic twice cites *Bates* for the proposition that a statutory provision that preempts "requirements" may encompass damages claims. Opp. 18 & 27 n.5 (citing *Bates*, 544 U.S. at 443); but Medtronic never acknowledges that *Bates rejected* the broad preemption holdings of nine federal courts of appeals. Much of what the Court stated in *Bates* with respect to claims against pesticide manufacturers is equally true here: "The long history of tort litigation against manufacturers . . . adds force to the basic presumption against pre-emption," 544 U.S. at 449, and "[w]e have been pointed to no evidence that such tort suits led to a 'crazy-quilt' of [federal] standards or otherwise created any real hardship for manufacturers or for [the agency]. Indeed, for much of this period [the agency] appears to have welcomed these tort suits." *Id*. at 451-52.

4. Unable to deny the conflict among the lower courts, Medtronic argues that the conflict may diminish in light of two implied preemption cases—*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). Medtronic's speculation has no basis, and, in any event, time has already proven it wrong.

First, Medtronic's focus on *Buckman* is a distraction, for that case does not address the question presented here. Accordingly, although four years have passed since the Court decided *Buckman*, the split in authority is as deep as ever.

That *Buckman* has not affected cases construing section 360k(a) is not surprising. In holding that a fraud-on-the-FDA claim is impliedly preempted, *Buckman* explicitly distinguished that claim from claims "relying on traditional state tort law which had predated the federal [medical device] enactments in question." 531 U.S. at 353. Moreover, *Buckman* involved neither a PMA device nor preemption under section 360k(a). *Buckman*'s only discussion of PMA appears in a description of the medical device regulatory scheme. *Id*. at 344. That description is taken wholly from FDA regulations and from *Lohr*, and thus has always been available to the courts on both sides of the post-*Lohr* conflict on which the petition is based. Aside from that background discussion, *Buckman* mentions PMA only in passing. *Id*. at 348, 349.

Second, Medtronic repeatedly suggests that the Court's 2000 decision in *Geier* will cause courts to reconsider decisions finding no preemption. *Geier* involved the National Highway Traffic Safety Act. The Court found no express preemption but held that the plaintiff's damages claims were impliedly preempted because they would frustrate the agency's objective with regard to a specific motor vehicle safety standard. 529 U.S. at 867, 874-75. *Geier* has had no effect on the development of case law involving preemption under section 360k(a). Perhaps for this reason, Medtronic never discusses *Geier*'s facts or holding or explains why it repeatedly refers to it.

5. Medtronic tries to minimize the importance of the question presented here by emphasizing that PMA devices comprise only one percent of the devices that enter the market. Opp. 28. Whatever the validity of that statistic, PMA is

required for life-sustaining devices and those that present the greatest risk of causing injury, 21 U.S.C. § 360c(a)(C), which not surprisingly tends to lead to a disproportionate number of injuries and lawsuits. The number of reported cases involving PMA devices, some of which are cited in the petition and opposition, speaks to the frequency of injuries and litigation attributable to PMA devices. Indeed, one of Medtronic's own PMA devices recently sparked so many cases as to warrant coordination in multidistrict litigation. *See In re Medtronic Implantable Defibrillators*, MDL No. 1726 (D. Minn.) (pending). Another Medtronic PMA device led to dozens of individual lawsuits and reported decisions from three different federal courts of appeals. *See Martin v. Medtronic*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000); *Goodlin*, 167 F.3d 1367. Of course, Medtronic is not the only medical device manufacturer to have marketed a device that caused injuries and deaths and that led to significant litigation. *See*, *e.g.*, *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (settlement of class action arising from injuries to approximately 55,000 patients implanted with defective PMA heart valve); *In re: Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 912-13 (S.D. Ohio 2003) (more than 3,880 patients required extra surgeries due to two defective PMA devices; more than 1,300 lawsuits filed); *Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 398 F.Supp.2d 1371 (D. Minn. 2005) (order creating MDL for cases involving PMA cardiac devices).

Thus, the relative number of PMA devices as compared to section 510(k) devices says little if anything about the number of injuries caused by PMAs and the number of patients who will go without any means of redress if the decision below stands.

6. Attempting to minimize the disarray in the lower courts, Medtronic focuses on a few of the cases cited in the

petition and argues that the cases were wrongly decided. Medtronic's descriptions of these cases consistently mischaracterize the courts' analyses.

First, Medtronic misrepresents the reasoning of *Goodlin*, omitting key aspects of the opinion and selectively quoting from two pages of a 10-page analysis. Opp. 17. In *Goodlin*, as here, Medtronic relied on the rigor of PMA review. The Eleventh Circuit understood, however, that the PMA process does not result in any device-specific requirement, but only in a finding that the company has demonstrated reasonable assurance of a device's safety and effectiveness. 167 F.3d at 1375. The court explained that "while a PMA review is considerably more rigorous and detailed than the premarket review notification [section 510(k)] process at issue in [*Lohr*], it is, in fact, no more 'specific a requirement.'" *Id*. at 1376 (quoting *Sowell v. Bausch & Lomb, Inc*., 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997)).

Next, Medtronic turns to *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, which also holds that PMA does not preempt damages claims. Citing 21 C.F.R. § 814.80, the generally applicable regulation prohibiting manufacturers from altering the manufacturing or labeling of a PMA device in ways inconsistent with the conditions of approval, Medtronic disputes *Weiland*'s statement that PMA imposes no substantive requirements on the design or manufacture of the device. Opp. 15. To begin with, the relevant FDA regulations regarding section 510(k) devices, which were at issue in *Lohr*, are very similar to the PMA regulation cited as an example by Medtronic. *See* 21 C.F.R. § 807.81(a)(3) (prohibiting significant design or manufacturing changes prior to new section 510(k) submission); *see also id*. § 801.109 (prescription device labeling regulations applicable to both PMA and section 510(k) devices). Nonetheless, *Lohr* held that section 510(k) regulation does not trigger section 360k(a).

Furthermore, in the portion of *Weiland* cited by Medtronic, Opp. 14-15, the court is simply explaining that the design of the device originated with the company, and that the FDA had the authority to impose specific design standards but had not done so. 721 N.E.2d at 1152-53. Although it is true that PMA imposes various requirements on a manufacturer, both *Lohr*, 518 U.S. at 500, and the relevant FDA regulation, 21 C.F.R. § 808.1, instruct courts to consider whether those requirements are device-specific and whether state-law damages claims are counterparts to specific requirements. Notably, Medtronic never undertakes that analysis. That is, Medtronic never identifies what requirement a state-law damages claim would impose on the company, much less how that requirement would be different from or in addition to a device-specific federal requirement imposed through PMA. *See also Bates*, 544 U.S. at 443 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.").

Turning to cases that hold that state-law damages claims are too general to fall within the preemptive scope of section 360k(a), Medtronic ignores many of the state-court decisions cited in the petition and focuses almost exclusively on *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997). While conceding that *Oja* conflicts with the decision below, Medtronic faults *Oja* for "never directly consider[ing] whether a finding of liability under a state common law duty would 'have the effect of establishing a substantive requirement for a specific device.'" Opp. 17 (quoting *Oja*, 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500)). In reality, the Tenth Circuit "directly considered" that possibility and expressly found that "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device.'" 111 F.3d at 789. Medtronic also criticizes *Oja* for purportedly failing to recognize that, in *Lohr*, five

members of this Court would have held that state-law damages claims can, in some circumstances, impose requirements preempted by section 360k(a). Opp. 17. But *Oja* is fully consistent with that approach. The opinion applies *Lohr* at every step, *see generally* 111 F.3d at 788-89, and holds that the common-law claims at issue were based on generally applicable duties that did not relate specifically to devices.[2]

Medtronic also argues with the petition's citation to *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997), which held that, under *Lohr*, state laws of general applicability that apply to all products fall outside the preemptive scope of section 360k(a). Medtronic (at 15 n.6) responds that *Niehoff* involved an investigational device, not a PMA device. That statement is correct, as the petition itself states, *see* Pet. 16 n.4, but irrelevant. *Niehoff*'s holding that generally applicable state-law claims are not preempted concerns the state-law side of the section 360k(a) preemption analysis and, therefore, applies with equal force to claims involving all types of devices, including PMA devices. Medtronic's claim (at 16 n.8) that *Niehoff* did not so hold is belied by the decision itself, *see* 950 S.W.2d at 822, and by a subsequent decision of the Kentucky Court of Appeals, which reads *Niehoff* precisely as Petitioners do. *See Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799, 802-03 (Ky. App. 1998).

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[2]Medtronic (at 17 n.9) also derides *Oja* for finding that a specific federal requirement applied to the section 510(k) device at issue there, given that *Lohr* found no device-specific requirements applicable to the Medtronic section 510(k) device in that case. However, *Oja* involved injury caused by a device for which the FDA had imposed a device-specific labeling requirement. 111 F.3d at 789. Medtronic misrepresents *Oja* by suggesting that the Tenth Circuit held that the section 510(k) process itself imposed that requirement.

Similarly, *State ex rel. Miller v. New Womyn, Inc*., 679 N.W.2d 593, 596 (Iowa 2004), addressed preemption under section 360k(a) and the FDA's preemption regulation, 21 C.F.R. § 808.1(d)(1), and held that the state law at issue was not preempted because it was a law of general applicability. Medtronic (at 16 n.8) dismisses this case on the ground that it did not involve a PMA device or a damages claim. Again, the factual assertions are correct but irrelevant. The Iowa Supreme Court's reading of *Lohr* and the applicable FDA regulation conflicts with the decisions in damages cases involving PMA devices, such as *Mitchell*, 126 F.3d at 912, and *Horn*, 376 F.3d at 174-75, that hold that section 360k(a) can preempt state-law claims of general applicability.

7. In Petitioners' view, the decision below is inconsistent with the text and purpose of the Medical Device Amendments, FDA regulations, and *Lohr*. Medtronic disagrees. The petition and opposition reveal the parties' drastically different understandings of the law and the significance of PMA. If the Court grants the petition, there will be time enough to respond to Medtronic's merits arguments in detail. For present purposes, the depth of the parties' disagreement on the merits only mirrors the depth of the disagreement among the lower courts and underscores the need for review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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