NO. 05-22

IN THE
Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

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

REPLY BRIEF FOR PETITIONERS

LOUIS F. GILLIGAN
GREGORY M. UTTER
JOSEPH M. CALLOW, JR.
JASON M. COHEN
KEATING, MUETHING & KLEKAMP, P.L.L.
One East Fourth Street
Cincinnati, Ohio 45202
(513) 579-6400

ALLISON M. ZIEVE
Counsel of Record
BRIAN WOLFMAN
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Petitioners
M. R. Knisley, *et al.*

September 2005

TABLE OF AUTHORITIES

STATUTES AND REGULATIONS

REPLY BRIEF FOR PETITIONERS

Respondent Medtronic, Inc. concedes the conflict among the lower federal and state courts on the question presented. It offers two arguments why the petition should nonetheless be denied. First, Medtronic contends that the courts on the no-preemption side of the conflict are going to reverse themselves. However, Medtronic made the same prediction in opposition to two petitions for certiorari filed four years ago, and time has proven the prediction to be wrong. Second, Medtronic argues that decisions finding no preemption are incorrect. Petitioners of course believe those decisions to be correct. Yet whichever group of cases has properly construed 21 U.S.C. § 360k(a) and *Medtronic v. Lohr*, 518 U.S. 470 (1996), the continuing conflict will not be resolved without the Court's intervention.

1. Medtronic does not deny that the lower courts are in conflict over the question presented in this case: whether the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval ("PMA"). Indeed, Medtronic does not dispute the existence of a conflict on either side of the preemption analysis: Medtronic (at 17) agrees that a conflict exists over whether premarket approval establishes a preemptive requirement on the federal side of the analysis. *Compare Goodlin v. Medtronic*, 167 F.3d 1367, 1373-77 (11th Cir. 1999) (PMA not a device-specific requirement for purposes of preemption under § 360k(a)), *and Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (PMA preempts damages claims), *and Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) (same). And Medtronic acknowledges (at 19) that the courts disagree over whether state-law damages claims, such as those at issue here, are too general to trigger

preemption under the Court's analysis in *Lohr* and the FDA's long-standing preemption regulation, 21 C.F.R. § 808.1. *Compare Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (failure-to-warn claim predicated upon general duties applicable to every manufacturer not preempted), *and Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (same), *with Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (state-law damages claims preempted by § 360k(a)), *and Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (same).

2. 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)—and an amicus brief in *Horn*, in which the United States reversed its position on the preemptive effect of PMA. Medtronic's speculation is unfounded.

First, Medtronic's focus on *Buckman* is a distraction, for that case does not address the question presented here. In fact, Medtronic made the same argument—that courts would revisit and reverse their no-preemption rulings in light of *Buckman*—in opposing the petitions for certiorari in *Kemp v. Medtronic*, No. 00-1766, and in *Martin v. Medtronic*, No. 01-441. Yet although four years have passed since *Buckman* was decided, 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 claims that "rely[] on traditional state tort law which had predated the federal [MDA] 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.

Likewise, Medtronic twice suggests (at 1, 15) without explanation that the Court's 2000 decision in *Geier* will affect the long-standing conflict on the question presented. *Geier* involved preemption under 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. *Geier* has had no effect on the development of case law involving preemption under section 360k(a), and Medtronic does not cite any case suggesting otherwise.

Last, Medtronic points to an amicus brief filed by the United States in *Horn*, 376 F.3d 163, a Third Circuit case in which the government argued that PMA preempts damages claims. That brief also will not spur the lower courts to alter their prior holdings. Generally, statements contained in amicus briefs do not have the requisite formality to warrant deference or other significant weight. *See United States v. Mead Corp*., 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in this Court arguing against preemption, but then disavowed its own arguments and filed an amicus brief in *Horn* taking the opposite position. *Compare* Br. of U.S. as Amicus Curiae in *Smith Industries*

Medical Systems v. Kernats, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997), *and* Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996), *with* Br. of U.S. as Amicus Curiae in *Horn v. Thoratec, Corp*., 3d Cir. No. 02-4597, 2004 WL 1443720 (filed May 14, 2004). Thus, in *Bates v. Dow Agrosciences*, where the United States filed an amicus brief arguing a position directly opposite to the position it took in an earlier brief, the Court gave the later brief little attention and no weight. *See generally* 125 S. Ct. 1788 (2005); *see also id.* at 1801 (rejecting argument that provision unambiguously preempts tort claims as "particularly dubious" given that the United States earlier advocated the contrary position).

Not only does the government's position in the *Horn* amicus brief contradict the arguments it made twice before this Court, it contradicts the FDA's previous construction of its own regulation, 21 C.F.R. § 808.1(d), to which *Lohr* gave substantial weight. *See* 518 U.S. at 496-97, 498-99; *id.* at 505-06 (Breyer, J., concurring). Thus, the amicus brief deserves no deference from the courts. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see Mead Corp*., 533 U.S. at 228 (degree of deference due to government depends on, among other things, consistency and formality of government's position); *cf. Maislin Indus. v. Primary Steel, Inc.,* 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning."). In these circumstances, far from diminishing the confusion, the *Horn* amicus brief adds to it.

Last Term in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings

of a majority of the circuit courts, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. *Bates* represents the latest in a series of cases in which the Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. *See Sprietsma v. Mercury Marine,* 537 U.S. 51, 63-64 (2002); *Geier*, 529 U.S. at 867-68; *Lohr*, 518 U.S. at 492-502; *see also Cipollone v. Liggett Group, Inc.,* 505 U.S. 504 (1992). The lower courts' responses to the Court's recent preemption jurisprudence demonstrates, not that time will resolve the conflicts, but that the Court's guidance with respect to the specific question presented here is urgently needed.

3. 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 and "unlikely to survive." Opp. 17. However, Medtronic does not cite a single case from any of the relevant federal circuits or state courts, or from the trial courts within those jurisdictions, that suggests that these appellate decisions will be revisited.

Medtronic's descriptions of the opinions it selects for discussion consistently mischaracterize the courts' analyses. First, Medtronic misrepresents the reasoning of *Goodlin v. Medtronic*, 167 F.3d 1367, omitting key aspects of the opinion and selectively quoting from two pages of a 10-page analysis. Opp. 17. Just as Medtronic does here, in *Goodlin*, Medtronic relied on the rigor of the PMA review. The Eleventh Circuit correctly understood, however, that the PMA process does not result in any regulation or substantive statement, 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 [510(k)] process at issue in [*Lohr v.*] *Medtronic*, 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 sets its sights on *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. 18. To begin with, the relevant FDA regulations regarding 510(k) devices 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 510(k) submission); *see also* 21 C.F.R. § 820.1 (good manufacturing practices regulations applicable to both PMA and 510(k) devices); *id.* § 801.109 (prescription device labeling regulations applicable to both PMA and 510(k) devices). Nonetheless, the Court in *Lohr* held that section 510(k) regulation did not trigger section 360k(a).

Furthermore, in the portion of *Weiland* cited by Medtronic, 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 just 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 particular federal requirement imposed through the PMA process. *See also Bates*, 125 S. Ct. at 1799 ("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. 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. 20 (quoting *Oja*, 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500)). In fact, the Tenth Circuit did "directly consider" 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.'" *Oja*, 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). But *Oja* is fully consistent with that approach. The opinion applies *Lohr* at every step, *see generally id.* 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.

In addition to *Oja* and other cases, the petition cites *Niehoff v. Surgidev*, 950 S.W.2d at 822, as a case holding that, under *Lohr*, state laws of general applicability that apply to all products fall outside the preemptive scope of section 360k(a). Medtronic (at 19 n.11) responds that *Niehoff* involved an investigational device, not a PMA device. That statement is correct, as the petition itself states, *see* Pet. 17 n.6, 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 PMA devices. Medtronic's claim 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).

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 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.

4. In Petitioners' view, the decision below is inconsistent with the text and purpose of the MDA, with FDA regulations, and with this Court's decision in *Lohr*. Medtronic

disagrees. The petition and opposition reveal the parties' drastically different understandings of the law and the significance of the facts concerning the FDA approval of the 4004M pacemaker lead. For instance, Petitioners maintain that design specifications originate with the manufacturer and therefore are not specific federal requirements with preemptive force under section 360k(a), while Medtronic argues that PMA transforms the manufacturer's specifications into preemptive federal requirements. And although Medtronic cites various Federal Register notices and congressional reports, Petitioners believe that each supports their view when read in context.

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 disagreement on the merits only underscores the need for review. The parties' submissions make clear that courts have come down on both sides of the question presented, creating conflicts as to both aspects of the two-pronged analysis outlined in *Lohr*. In addition, as discussed in the petition (at 23-24), some courts have effectively ignored that analysis, disregarding, in particular, the Court's majority opinion with respect to the state-law side of the inquiry, which rejects preemption of generally applicable state law, such as the common-law duties on which Petitioners rely here. The conflicting decisions on the question presented, like the parties' positions, are irreconcilable and can be resolved only by this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Louis F. Gilligan
Gregory M. Utter
Joseph M. Callow, Jr.
Jason M. Cohen
KEATING, MUETHING & KLEKAMP, P.L.L.
One East Fourth Street
Cincinnati, Ohio 45202
(513) 579-6400

Allison M. Zieve
Counsel of Record
Brian Wolfman
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Petitioners
M. R. Knisley, *et al.*

September 2005