No. 98-1768

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

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

REPLY BRIEF FOR PETITIONER

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In their brief in opposition, plaintiffs either concede outright or make no serious effort to dispute all of the essential reasons why review should be granted: there are sharp divisions among the circuits on both questions presented; the issues raised are recurring and of immense practical significance; and the conflicts in the lower courts stem from ambiguities in this Court's decision in *Medtronic Inc.* v. *Lohr*, 518 U.S. 470 (1996), which the lower courts are incapable of resolving. Although plaintiffs attempt to defeat review by insisting that this case is nonjusticiable or a poor vehicle, or by nibbling away at the edges of our submissions, their arguments are unconvincing. Further review is plainly warranted.

1. *The Issues Presented Are Important And Recurring*. Plaintiffs do not (and could not) dispute that the petition presents issues of enormous practical importance. See Pet. 16-19, 25 (explaining impact of decision below on thousands of cases involved in this multidistrict litigation, on the availability of the preemption defense under a wide range of statutes, and on the medical device industry and the public health).

The broad significance of the "fraud on the agency" issue is strongly confirmed by all three national organizations that have filed *amicus* briefs urging this Court to grant review. See Br. of Product Liability Advisory Council, Inc. ("PLAC Br.") 5, 9-13 (discussing adverse effect on federal policies and purposes, on regulatory processes, and on agency resources); Br. of Medical Device Manufacturers' Ass'n ("MDMA Br.") 2-14 (discussing likely disruption of agency processes and personnel, delay in approval of new therapies, inhibition on flow of information concerning beneficial off-label uses, and negative impact on manufacturer incentives); Br. of Pharmaceutical Research and Manufacturers' Ass'n ("PhRMA Br.") 2-3, 6, 18-19 (describing adverse effect on availability of new medications, on research into off-label uses, and on public health). Moreover, the question whether federal law preempts "fraud on the

agency" claims has arisen not only under the MDA but also under a host of other federal statutes. Pet. 10-12, 15-16 & nn.5-6; PLAC Br. 4-5.

The second issue presented — whether the MDA preempts state requirements that are imposed through tort laws of general applicability — is also important because it arises with great regularity in tort actions involving medical devices. Indeed, as plaintiffs themselves take pains to point out (Br. in Opp. 24-25), this issue is not limited to cases involving medical devices cleared through the 510(k) process. It also frequently arises in cases involving investigational and premarket-approved devices. In addition, the issue (and the precise meaning of the Court's treatment of it in *Medtronic*) has arisen in cases involving other statutory preemption provisions. Pet. 23 & n.12. The importance of the second question presented thus extends beyond the MDA.

2. *This Case Is A Good Vehicle For Resolving The Intercircuit Conflicts On Both Issues Presented*. Plaintiffs admit that, in conflict with the Third Circuit's decision in this case, "the Seventh Circuit ruled in *Mitchell II* that fraud-on-the-FDA claims were preempted." Br. in Opp. 22. They also acknowledge that, as we demonstrated in the petition (at 10-11, 22-23 & nn. 11-13), the lower courts are "divided" over the second question presented. Br. in Opp. 24 & n.18. And they make no effort to dispute our showing (Pet. 20 n.9) of substantial conflicts in the circuits, since *Medtronic*, over the underlying question whether *Chevron* deference is owed to an agency's interpretation of an express preemption clause.

Unable to deny the existence of these conflicts, plaintiffs fall back on a hodgepodge of arguments aimed at diminishing the extent or importance of the lower courts' confusion or persuading the Court that this case is a poor vehicle to resolve the issues presented. These efforts are unavailing.

a. Plaintiffs suggest that the conflict with the Seventh Circuit on whether the MDA preempts "fraud on the agency" claims is insubstantial because the Seventh Circuit's holding was "perfunctory" and rendered "only in passing, without expressing any legal reasons for this conclusion and without citing any authority to support it other than a pre-[*Medtronic*] decision by the Third Circuit which was subsequently found by that Court to have been overruled in [*Medtronic*]." Br. in Opp. 22-23 & n.16; see also *id*. at 1. This argument is flawed at every turn.

In holding that "fraud on the agency" claims are preempted, the Seventh Circuit declared:

> **We do not believe that our earlier decision that this ["fraud on the agency"] claim is preempted is altered by *Medtronic*.** We continue to believe that this issue was decided correctly by the Third Circuit in *Michael v. Shiley, Inc.*

Mitchell v. *Collagen Corp.*, 126 F.3d 912, 914 (7th Cir. 1997) (citation omitted; emphasis added), cert. denied, 118 S. Ct. 1300 (1998). Far from being a statement made only "in passing," the highlighted sentence is a direct and emphatic rejection of the rationale adopted by the Third Circuit in this case. Moreover, contrary to plaintiffs' contention, the Seventh Circuit expressly relied on its "earlier decision" in *Mitchell I* and not just on the Third Circuit's decision in *Michael*. As plaintiffs neglect to mention, *Mitchell I* contained an extended analysis of why "fraud on the FDA" claims are preempted (see *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995), vacated, 518 U.S. 1030 (1996)) — an analysis that relied not just on *Michael* but also on several First and Fifth Circuit decisions reaching the same conclusion. There was simply no reason for the Seventh Circuit to rehash all of this in rejecting the only new point before it: whether *Medtronic* had

affected the analysis in *Mitchell I*.[1]

In any event, it cannot be seriously disputed that district courts in the Seventh Circuit are bound to follow the holding of *Mitchell II*. Those courts are not at liberty to allow "fraud on the agency" claims to proceed, nor could they credit the argument (on which the decision below in this case rests) that *Medtronic* alters pre-*Medtronic* law on this score.[2]

b. In an effort to minimize the conflict on the first issue presented, plaintiffs assert that, with the exception of *Mitchell II*, "[a]ll of the other appellate courts that have considered the issue" of whether "fraud on the FDA" claims are preempted "have ruled, consistent with the Third Circuit here," that such claims are not preempted. Br. in Opp. 1-2. That assertion blithely ignores the substantial case law decided before *Medtronic*, which we identified in the petition (at 11-12 & n.5), and which remains in effect unless it was altered by *Medtronic* (an issue over which the lower courts have sharply disagreed). It also overlooks numerous pre- and post-*Medtronic* decisions involving preemption provisions that are analogous to 21 U.S.C. § 360k(a). See *id.* at 11 & n.5, 15-16; see also PLAC Br. 4-5.

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[1] Plaintiffs wishfully suggest that the Seventh Circuit "may well recede from its perfunctory ruling that 'fraud on the agency' claims are preempted if given an opportunity to do so." Br. in Opp. 23 n.16. Plaintiffs mistake for perfunctoriness the Seventh Circuit's emphatic rejection of an argument it regarded as meritless.

[2] Plaintiffs also suggest that *Mitchell* is "distinguishable" because it involved a device that "reached the market through premarket approval and not through the 510k clearance." Br. in Opp. 23 n.16. But a "fraud on the agency" claim is just as much of a collateral attack on the FDA's clearance decisions, whether those decisions are made in the 510(k) process or in the premarket approval process. See note 3, *infra*.

c. Plaintiffs devote several pages to arguing that the "fraud on the agency" question as stated in our petition "has nothing whatsoever to do with this case" and, accordingly, this case is "non-justiciable." Br. in Opp. 12-13. That is so, plaintiffs contend, because a "fraud on the agency" claim in no way "attacks" an FDA decision. *Ibid.* This argument boils down to a quibble with the phrasing of one of our questions presented.[3] Such a disagreement hardly renders the "fraud on the agency" issue non-justiciable. And since plaintiffs have failed to rephrase the first question presented in their opposing brief, any objection they might have to the question as phrased in our petition has been waived. S. Ct. Rule 15.2.

Plaintiffs also assert that we never argued below "that state-law claims based on agency fraud were preempted, either expressly or impliedly." Br. in Opp. 11. They are wrong again. We raised and argued both express and implied preemption below. See Pet. C.A. Br. 9-12 & n.5; Pet. for Reh'g 4-11.[4]

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[3] Our phrasing is entirely correct. Plaintiffs seek to have a jury impose penalties based on the FDA's decision to give marketing clearance to the bone screws at issue, which the FDA has continued explicitly to sustain. See Pet. 6, 17 n.7. It is difficult to see how this claim can be characterized as anything other than an "attack" on the FDA's decisions. See *Lewis* v. *Brunswick*, 107 F.3d 1494, 1505 (11th Cir. 1997) ("indirect[] "challenge[]"), cert. dismissed, 118 S. Ct. 1793 (1998); see also *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir.) ("collateral attack"), cert. denied, 515 U.S. 1104 (1995).

[4] Moreover, defendants Sofamor, S.N.C. and Danek Medical, Inc. submitted to the Third Circuit a joint brief as appellees, which set forth an extended argument for implied and express preemption. C.A. Br. of Appellees Sofamor & Danek 13-28; Pet. App. 8a n.3. The court determined that they lacked standing to appeal, but treated their submission as an *amicus* brief. Pet. App. 8a n.3.

Not surprisingly, plaintiffs do not contend that the express and implied preemption arguments advanced in the petition have been waived. That argument would be meritless, since under this Court's cases an issue is preserved for review if it was either *raised or decided* by the court below. See *United States* v. *Williams*, 504 U.S. 36, 40 (1992). There is no dispute that the Third Circuit rejected both implied and express preemption theories. Pet. 8-9. The "fraud on the agency" issue thus was both raised *and* decided below.

d. On the second question presented, we documented the existence of a 4-2 circuit split on whether the MDA can preempt state tort requirements of general applicability. Pet. 22-23 & nn. 11-12; see also MDMA Br. 15. Another three circuits, we explained, have endorsed the majority view by holding that tort requirements of general applicability are preempted by statutes analogous to the MDA. Pet. 23. And eight state appellate courts (including the Supreme Courts of Oregon, Pennsylvania, and Kentucky) have reached conclusions that are contrary to the federal circuits in which they are located. *Id.* at 24 & n.14. Multiple state and federal trial courts have reached conflicting results as well. *Id.* at 23 & n.13.

In response to this showing of disarray, plaintiffs say that "this division has not reached the point that Supreme Court intervention is required to clarify the law." Br. in Opp. 25. But plaintiffs provide no good reason why this Court should tolerate these serious and far-reaching conflicts until the Second, Fifth and Eleventh Circuits have addressed the issue. At most, if those circuits all side with the Third and Tenth Circuits, the position advocated by plaintiffs will still represent only a minority view in the federal courts of appeals. Moreover, the lower courts' confusion on this issue is traceable, in the end, to ambiguities in this Court's decision in *Medtronic*. See Pet. 20-23. Those ambiguities can be resolved by this Court alone, and they are not likely to be further illuminated by waiting for the

Second, Fifth and Eleventh Circuit to take sides in the debate.

In sum, the disagreements in the lower courts are substantial and recurring and plainly warrant this Court's intervention. As the Solicitor General recommended more than a year ago when the confusion was less extensive, this Court should "grant review and definitively resolve the conflict" in an appropriate case. No. 96-1405 U.S. Br. 18, *Smiths Indus. Med. Sys.* v. *Kernats*. This is that case.

Plaintiffs next argue that "this case does not present the real question engendered by the cited intercircuit conflict" because "this case only involves a 510k clearance." Br. in Opp. 25. Plaintiffs conflate two issues: (1) Which *federal* requirements trigger express preemption under the MDA? and (2) Which *state* requirements can be preempted by that statute? The conflict we identify in the petition is a conflict on how the second issue should be resolved. It is true (but completely irrelevant) that the lower courts have *also reached conflicting conclusions* about how the *first* issue should be resolved in light of *Medtronic*. Specifically, as plaintiffs note, the lower courts have disagreed over "whether an IDE or PMA can be preemptive." Br. in Opp. 25. That conflict, however, is not presented in this case — and we have never suggested otherwise.

Relatedly, plaintiffs maintain that this case is a poor vehicle for resolving the second question presented because even if the Third Circuit was wrong and state tort requirements of general applicability can be preempted, "there would still be no preemption of plaintiffs' claims against Buckman" because "fraud on the agency" claims are never preempted. Br. in Opp. 25. In essence, this amounts to an argument that the Court would not need to resolve the second question presented if it ruled in plaintiffs' favor on the first question. That argument puts the cart before the horse.

Even if plaintiffs are right that this Court is required to address

the two questions in a particular order, which is doubtful,[5] that would hardly make this case a poor vehicle. This Court frequently grants review in cases raising several issues, where a ruling on one issue may obviate the need to resolve the other question or questions presented. See, *e.g.*, *American Mfrs. Mut. Ins. Co.* v. *Sullivan*, 119 S. Ct. 977 (1999); *Heck* v. *Humphrey*, 512 U.S. 477 (1994). In addition, this Court is not prohibited from deciding both issues in such cases, when there is good reason to do so. *E.g.*, *Sullivan*, 119 S. Ct. at 989 (deciding due process issue even "[t]hough our resolution of the state action issue would be sufficient by itself to reverse the judgment of the Court of Appeals").

3. *The Decision Below Is Erroneous*. a. Plaintiffs devote most of their brief to arguments on the merits. They maintain that the Third Circuit's refusal to find the "fraud on the agency" claim preempted was a "straightforward application of a recent, unanimous ruling by this Court." Br. in Opp. 13; see also *id*. at 1, 13-20. In plaintiffs' view, if *Medtronic* "was clear about anything, it was clear that" claims of "fraud on the agency" are not preempted by the MDA. Br. in Opp. 18. Plaintiffs even go so far as to say that *Medtronic* "literally compelled the conclusion reached by the Court of Appeals here." *Ibid*.

All of this, of course, would come as news to the three-judge panel of the Seventh Circuit in *Mitchell II*, which unanimously and emphatically declared: "We do not believe that our earlier decision that this ["fraud on the agency"] claim is preempted is altered by *Medtronic*." 126 F.3d at 914. It would also come as news to Judge Cowen, who dissented from the panel's decision. And we

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[5] The Court might reasonably conclude that the second question identified in the petition is logically prior to the first question presented, because it concerns the threshold issue of whether *any* state law tort claims are preempted, as opposed to preemption of just "fraud on the agency" claims.

suspect that it would come as news to the various circuits that have ruled, since *Medtronic*, that "fraud on the agency" claims are preempted under analogous federal preemption schemes. See Pet. 10-11, 15.

Beyond that, plaintiffs' contention that *Medtronic* compels the result below is inherently implausible because *Medtronic* did not involve any "fraud on the agency" claim. As we explained in the petition (at 25-29), "fraud on the agency" claims are fundamentally different from the design defect claim held not to be preempted in *Medtronic*. See also PLAC Br. 16-18; Br. of Danek Medical, Inc. ("Danek Br.") 10-13. A "fraud on the FDA" claim directly attacks the agency's clearance decision; it requires a lay jury to guess as to what the FDA would have done in the absence of the "fraud"; it focuses not on representations made to physicians or patients but on the accuracy of submissions made to the federal agency; it is dependent (in ways ordinary product liability claims are not) on the very existence of the federal regulatory scheme; and it threatens to interject state courts into the internal decisionmaking processes of federal agencies and sap agency resources. Plaintiffs do not deny these differences.

Moreover, as we explained in the petition (at 27-29), *Medtronic* did not decide any issue of *implied* preemption. The Court's analysis focused instead on the question of *express* preemption. Accordingly, *Medtronic* could not possibly have "compelled" (Br. in Opp. 18) the panel majority's conclusion that "fraud on the agency" claims are not impliedly preempted by federal law.

b. We explained in the petition (at 26-27) that plaintiffs' "fraud on the agency" claim is expressly preempted by the MDA because it imposes "different" requirements than are applicable under federal law to the pedicle screws at issue in this case. 21 U.S.C. § 360k(a). Specifically, plaintiffs' state law claims would threaten to impose liability for failing to disclose in the 510(k) process information that

the FDA itself does not require.

In response, plaintiffs contend that their "fraud on the agency" claims impose requirements that are identical to those imposed under federal statutes and regulations. Br. in Opp. 18. This argument overlooks the fact that the FDA imposes an *objective* standard for statements of "intended use," which it determines from the proposed labeling, whereas plaintiffs' claims are premised on a *subjective* standard of intended use. Pet. 27; PLAC Br. 15-16; PhRMA Br. 10 ("[J]udging 'intended use' based on subjective intent is directly contrary to the federal regulatory scheme"). Plaintiffs have no answer to this point, and there is none.

c. Equally unpersuasive are plaintiffs' efforts to explain why their "fraud on the agency" claims are not *impliedly* preempted by federal law. Br. in Opp. 19-20. Plaintiffs fail to address the implied preemption analysis set forth in the petition (at 27-29) or the many cases that have concluded that "fraud on the agency" claims are impliedly preempted. See Pet. 12 n.5, 15-16; see also PhRMA Br. 12-17 ("fraud on the agency" claims would interfere with Congress's intent, reflected in recent legislation, to expedite the device approval process). In essence, plaintiffs fall back on the argument (refuted above) that their claim is no different from the design claim involved in *Medtronic*. Br. in Opp. 19-20.[6]

CONCLUSION

The petition for a writ of certiorari should be granted.

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[6] Plaintiffs make no effort to defend the Third Circuit's holding that tort law requirements of general applicability are excluded from preemption under the MDA.

Respectfully submitted.

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