No. 98-

In the Supreme Court of the United States

OCTOBER TERM, 1998

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that approval was obtained though a "fraud on the agency" is expressly or impliedly preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

2. Whether the Medical Device Amendments, which expressly preempt "any" state requirement that "relates to the safety or effectiveness" of a device and is "different from, or in addition to" a federal requirement (21 U.S.C. § 360k(a)), exclude state requirements that are imposed through tort laws of general applicability.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent companies or nonwholly owned subsidiaries.

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OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-32a) is reported at 159 F.3d 817. The opinion of the district court (App., *infra*, 33a-44a), which was incorporated in the order granting petitioner's motion for dismissal (App., *infra*, 45a), is unreported. The original opinion of the district court (App., *infra*, 46a-53a) is unreported.

JURISDICTION

The court of appeals' judgment was entered on November 19, 1998. A timely petition for rehearing was denied on February 3, 1999 (App., *infra*, 57a-58a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution provides in relevant part: "[T]he Laws of the United States * * * shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

The relevant provision of the Medical Device Amendments, 21 U.S.C. § 360k, is reproduced at App., *infra*, 59a.

STATEMENT

This case raises important, recurring questions relating to the preemptive scope of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k(a), the meaning of this Court's fractured decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and the validity of efforts by litigants to circumvent Congress's express preemption commands through state tort claims asserting that federal administrative determinations should be disregarded because they were the product of "fraud on the agency."

In 1976, Congress greatly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices, such as heart pacemakers and orthopedic bone screws, by enacting the MDA. To protect the uniformity of the federal regulatory scheme, the MDA provides that no State may impose any requirement relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a). In *Medtronic*, this Court interpreted the MDA's preemption provision, but that opinion has engendered widespread conflict and confusion in the lower courts, as reflected in the decision below.

The first conflict, which the court below expressly recognized, concerns whether the MDA preempts a state tort claim that a manufacturer "defrauded" the FDA by making misrepresentations during the regulatory approval process. In contrast to the Seventh and Eleventh Circuits, the Third Circuit has held that so-called "fraud on the agency" claims are not prohibited attempts under state law to second-guess the determinations of a federal agency. If permitted, "fraud on the agency" claims would allow state judges and lay jurors to create havoc with the federal regulatory scheme by deciding that an administrative agency's decision should be ignored even where the agency itself, in full possession of the relevant facts, does not believe that any fraud was committed. As Judge Cowen stated in dissent (App., *infra*, 32a), "[i]t seems very unlikely that Congress intended a state cause of action to intrude so much both in the enforcement of the FDCA's regulatory scheme and in the severity of the penalties attached to a violation."

The second conflict concerns an even more fundamental question raised but not settled by *Medtronic*: whether the MDA can ever preempt a state tort claim of general applicability. The Third Circuit, like the Tenth Circuit, has held that the MDA was not meant to preempt such claims, but the Fourth, Sixth, Seventh and Ninth

Circuits have reached the opposite conclusion. Both of these issues merit further review.

A. The Regulatory Structure of the Medical Device Amendments

The MDA divides medical devices into three classifications based on the possible risks of harm. Devices such as tongue depressors, which present little likelihood of illness or injury, are designated as Class I and subjected only to minimal regulation, or "general controls." 21 U.S.C. § 360c(a)(1)(A). Potentially more dangerous devices, such as tampons, which are classified as Class II, face increased regulation but can still be marketed without FDA approval. *Id.* § 360c(a)(1)(B). The FDA designates as Class III those devices that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). All post-1976 devices, including the orthopedic bone screws at issue here,[1] are initially automatically considered Class III devices and cannot be marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Manufacturers may obtain permission to market Class III devices in either of two ways. First, the FDA may grant approval after a thorough premarket approval (PMA) process, in which the manufacturer must present the FDA with "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e. Second, to allow competition with "grandfathered" devices that were on the market in 1976 when the MDA took effect, the FDA may permit marketing of a new device if the manufacturer submits a "premarket notification" showing that the device is "substantially equivalent" to

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[1] After these suits were filed, many of the bone screws challenged by plaintiffs were reclassified as Class II devices as part of pedicle screw systems. 63 Fed. Reg. 40025, 40027 (1998).

a pre-1976 device. *Id.* §§ 360e(b)(1)(B), 360(k), 360c(f)(1)(B). The "premarket notification" route is often referred to as the "510(k)" process, after the section number in the original act. See *Medtronic*, 518 U.S. at 478.

The FDA has established detailed requirements for manufacturers' Section 510(k) notifications. See 21 C.F.R. § 807.87 (1986).[2] Manufacturers must submit "[p]roposed labels, labeling, and advertisement sufficient to describe the device, its intended use, and the directions for its use"; supporting information; comparisons with currently distributed devices; and data showing the effect on safety and effectiveness of any significant changes from the pre-1976 device. *Ibid.*

Once a device has been approved for marketing under Section 510(k), the manufacturer may not market or promote it for uses other than those specified in the FDA clearance.[3] However, physicians remain free under federal law to employ the device for any purpose, including so-called "off-label uses." See *Ortho Pharm. Corp.* v. *Cosprophar, Inc.*, 32 F.3d 690, 692 (2d Cir. 1994). Not only has the FDA recognized the existence of off-label uses (which, as part of the practice of medicine, it cannot regulate, see 21 U.S.C. § 396); it has also acknowledged that "'unapproved' or, more precisely, 'un-labeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches * * * that have been extensively reported in medical literature."

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[2] These requirements were expanded by the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990), to require more detailed descriptions of the design, materials, properties, functioning, and scientific basis of the device. See 21 C.F.R. §§ 807.87, 807.92, 807.93 (1998).

[3] What constitutes marketing or promotion remains uncertain. See *Washington Legal Found.* v. *Friedman*, 36 F. Supp. 2d 16, 19 (D.D.C. 1999).

FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Off-label uses of devices have "traditionally been regulated by the hospitals in which the physicians practice and not by the FDA." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 77 (1998)).

B. The FDA's Clearance of the Bone Screws

Petitioner The Buckman Company (Buckman) is a regulatory consultant for medical device manufacturers, helping them navigate FDA procedures, plan regulatory strategy, and monitor clinical trials. In 1984, AcroMed Corporation hired Buckman as its liaison with the FDA to attempt to obtain marketing clearance for its devices. See App., *infra*, 4a-5a.

In September 1984, Buckman, on behalf of AcroMed, applied for Section 510(k) marketing clearance for an orthopedic bone screw device, the Variable Screw Placement Spinal Plate Fixation System (VSP).[4] This application stated that AcroMed intended to market the VSP as a pedicle screw for use in spinal surgery. App., *infra*, 5a. The FDA rejected the application, finding that the VSP was a Class III device not substantially equivalent to any pre-1976 devices. A year later, AcroMed, through Buckman, submitted a second Section 510(k) application for the VSP, again indicating that the device would be labeled as a pedicle screw. The FDA rejected this application as well. *Ibid.*

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[4] Also at issue is AcroMed's ISOLA Spine Fixation System, for which Buckman obtained Section 510(k) clearance in 1986. Like the Third Circuit, "our discussion of the VSP system applies with equal force to the ISOLA system." App., *infra*, 5a n.2.

In December 1985, following a meeting with FDA officials, AcroMed and Buckman separated the VSP into its component parts — the screw and the plate — and sought Section 510(k) approval for each. App., *infra*, 5a. These applications specified that the devices were intended to be used in the arm and leg long bones, rather than in the spine. The FDA determined that the screw and plate individually were substantially similar to pre-1976 devices and granted the applications in February 1986. *Id*. at 5a.

Despite the limited nature of the FDA clearance, "[i]n practice, surgeons often use[d] orthopedic screws which FDA ha[d] cleared for other purposes * * * as pedicle screws." FOOD & DRUG ADMIN., UPDATE ON PEDICLE SCREWS (1993) (quoted in Beck & Azari, 53 FOOD & DRUG L.J., at 77). Indeed, the FDA observed in 1995 that, since at least 1992, pedicle fixation with screws has been "considered to be the standard of care by the surgical community." 60 Fed. Reg. 51946, 51947 (1995). These uses, though widespread, were all off-label, because the FDA did not approve the marketing of bone screws for use in spinal surgery until January 1995. *Id*. at 51947-48.

C. The Orthopedic Bone Screw Product Liability Litigation

As just noted, after AcroMed placed its bone screws on the market, orthopedic surgeons used them, as well as bone screws produced by other manufacturers, as spinal fixation devices. After a national television program ran a story on alleged harm caused by this use of the bone screws, thousands of plaintiffs filed state-law suits against doctors, hospitals, universities, bone screw manufacturers, and regulatory consultants such as Buckman, alleging product defects and fraud in the manufacturers' representations to the FDA. The federal suits — approximately 2,300 civil cases involving 5,041 plaintiffs and 334 defendants — were consolidated in this multidistrict litigation. App., *infra*, 55a.

Plaintiffs did not contend that, in applying for Section 510(k) clearances, Buckman or AcroMed had misrepresented any objective fact, such as the size, shape, or technical characteristics of the screws or their equivalence to pre-1976 devices. Rather, plaintiffs claimed that Buckman and AcroMed deceived the FDA as to the "intended uses" of the devices, representing that they would be labeled for long bones while planning to market them for use in the spine. App., *infra*, 6a. In plaintiffs' view, the Section 510(k) clearances were the product of fraud under state law and, but for such fraud, the devices would never have been on the market and would not have been used in their pedicle surgery.

On March 2, 1995, the district court, relying on *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 516 U.S. 815 (1995), granted judgment on the pleadings on all "fraud on the agency" claims, holding that they were preempted both expressly by the MDA and impliedly by the federal scheme, which vests in the FDA exclusive authority to prosecute violations of the MDA. App., *infra*, 46a-53a. The MDA's express preemption provision, the district court explained, simply "does not permit courts to 'perform the same functions initially entrusted to the FDA.'" *Id*. at 49a (quoting *Michael*, 46 F.3d at 1329). Moreover, "[b]ecause the FDA possesses the proper authority to regulate this field, courts are prohibited from conducting 'a searching state inquiry into the inner workings of FDA procedures.'" *Ibid*. (quoting *Michael*, 46 F.3d at 1329); see also *id*. at 50a (reasoning that, "given the FDA's central role in reviewing and approving devices * * * [the agency] is in the best position to decide whether [a manufacturer] withheld material from the agency and, if so, the appropriate sanction"). Finally, the court reasoned that permitting "fraud on the agency" claims would be inconsistent with Congress's failure to authorize a private right of action under the Food, Drug and Cosmetic Act. *Ibid.*

Following this Court's *Medtronic* decision in 1996, plaintiffs sought to revive their "fraud on the FDA" claims and various defendants (including Buckman) moved the district court to reaffirm its prior decision. App., *infra*, 7a, 33a. On March 28, 1997, the district court reaffirmed its ruling. *Id.* at 33a-44a. The court agreed with plaintiffs' argument that *Medtronic* had undercut portions of its previous analysis, but concluded that "fraud on the agency" claims were still precluded because they were inconsistent with Congress's decision not to include a private right of action under federal law. *Id.* at 36a. Such claims, the district court reasoned, are simply "not interchangeable" with the claims at issue in *Medtronic*, which involved no allegation of fraudulent procurement of agency approval and therefore did not amount to a collateral attack on any agency decision. *Id.* at 40a.

Because "fraud on the FDA" was the sole claim against Buckman, the district court granted Buckman's motion for dismissal for failure to state a claim on which relief could be granted (App., *infra*, 45a) and certified the dismissal as a final order under Rule 54(b) of the Federal Rules of Civil Procedure. *Id.* at 54a-56a.

D. The Court of Appeals' Decision

A divided panel of the court of appeals reversed, over a "vehement[]" (App., *infra*, 32a) dissent by Judge Cowen. The majority concluded that *Medtronic*'s construction of the MDA's express preemption clause undermined the holding in *Michael* that state law "fraud on the FDA" claims are expressly and impliedly preempted. *Id.* at 13a-17a. The Third Circuit acknowledged that this holding was in direct conflict with the Seventh Circuit's decision in *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (1997), cert. denied, 118 S. Ct. 1300 (1998), which held that "fraud on the FDA" claims remain preempted after *Medtronic*. App., *infra*, 17a n.5.

The court of appeals rejected Buckman's express and implied preemption arguments. In the majority's view, the MDA does not expressly preempt "fraud on the FDA" claims because the Section

510(k) process does not establish *any* "federal 'requirement'" that is "'applicable to the device' at issue here." App., *infra*, 13a. In equally sweeping fashion, the majority — adopting the position of a distinct minority of circuit courts — broadly declared that plaintiffs' common law claims do not impose *any* "state 'requirements' 'with respect to' that device." *Ibid*.

The Third Circuit also rejected the argument that "fraud on the agency" claims are impliedly preempted. App., *infra*, 16a. The majority recognized that "Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA." *Id*. at 13a. But it "s[aw] no inconsistency" between Congress's decision to give the FDA the "exclusive prerogative" and discretion to enforce the requirements of federal law and allowing individuals to "bring common law fraudulent misrepresentation claims" to "enforce the FDCA." *Id*. at 18a.

Judge Cowen dissented. Unlike the majority, he was greatly troubled by permitting judges and juries hearing "fraud on the FDA" claims "to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing." App., *infra*, 32a. Judge Cowen observed that "[t]he majority endorses a claim of 'fraud on the FDA' under circumstances that will expose manufacturers to fraud liability for seeking desirable innovations in a product's use, distort the penalty scheme established by the FDCA and its regulations, and generate substantial liability when manufacturers respond to doctors' widely accepted practice of purchasing medical products for off-label uses." *Id*. at 25a.

REASONS FOR GRANTING THE PETITION

The decision below creates one circuit conflict and extends another as to vitally important and frequently recurring issues of federal law: (1) whether "fraud on the agency" claims brought under state law are expressly or impliedly preempted by a comprehensive

federal regulatory regime administered by an expert administrative agency; and (2) whether this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), exempts from both express and implied preemption *all* state requirements that happen to be imposed through state tort laws of general applicability.

The Third Circuit is the first federal court of appeals to allow plaintiffs to bring tort actions under state law challenging FDA decisions as fraudulently obtained. Prior to *Medtronic*, every circuit to address the issue had held that such claims were preempted by federal law. As the court below acknowledged, its decision also squarely conflicts with a post-*Medtronic* decision of the Seventh Circuit. App., *infra*, 17a n.5. This intercircuit conflict impairs the stability and uniformity of the FDA's decisionmaking process.

Moreover, the circuit split over preemption of "fraud on the agency" claims extends beyond the MDA to cases involving similar regulatory schemes. See *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) (Boat Safety Act preempts "fraud on the agency" claim), cert. dismissed, 118 S. Ct. 1793 (1998); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) "does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), cert. denied, 118 S. Ct. 1839 (1998). Thus, if permitted to stand, the decision below will allow litigants in the Third Circuit to circumvent express preemption provisions in a number of federal statutes.

Review of this case would also allow the Court to resolve widespread uncertainty over the meaning of *Medtronic*. In the wake of *Medtronic*, lower courts have disagreed over whether the MDA preempts only state "requirements" that apply exclusively to medical devices or whether it also preempts some state requirements

imposed through laws of general applicability. See *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1371 n.7 (11th Cir. 1999) (acknowledging conflict). The court below, like the Tenth Circuit, interpreted *Medtronic* as exempting state tort requirements from preemption simply because of their generality, while the Fourth, Sixth, Seventh and Ninth Circuits have rejected that view. Compare *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997), with *Mitchell* v. *Collagen*, 126 F.3d 902, 912 (7th Cir. 1997) (*Mitchell II*), cert. denied, 118 S. Ct. 1300 (1998); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), cert. denied, 118 S. Ct. 166 (1997); *Martin* v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097-98 (6th Cir. 1997), cert. denied, 118 S. Ct. 850 (1998); and *Duvall* v. *Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996). Because these disputes are attributable to ambiguities in the *Medtronic* decision itself, only this Court can bring clarity to this important area of federal law.

I. The Circuits Are Divided Over Whether "Fraud on the Agency" Claims Are Preempted By Federal Law

A. This Case Squarely Presents the Conflict

The decision below creates a conflict in the circuits over whether "fraud on the agency" claims are preempted under the MDA and other federal statutes containing analogous express preemption clauses. In contrast to the Third Circuit, the Seventh and Eleventh Circuits have held that collateral attacks on agency rulings through private tort actions are expressly and impliedly preempted. See *Mitchell II*, 126 F.3d at 913-14 (MDA preempts "fraud on the FDA" claims); *Lewis*, 107 F.3d at 1502; see also *Kuiper*, 131 F.3d at 666. This split is the result of disagreements over the meaning of *Medtronic*, as a brief review of its development demonstrates.

1. Prior to *Medtronic*, the lower courts were in general agreement that state law claims alleging fraud on the FDA either were expressly preempted by 21 U.S.C. § 360k(a) or were impliedly preempted both because they would interfere with the

FDA's exclusive authority over the regulatory regime for medical devices and because the MDA contains no private cause of action.[5]

Courts reasoned that "fraud on the FDA" claims were expressly preempted because they would impose require-ments under state law that were "different from, or in addition to" (21 U.S.C. §

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[5] See *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), cert. dismissed, 517 U.S. 1230 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995) (*Mitchell I*), vacated, 518 U.S. 1030 (1996); *Michael*, 46 F.3d at 1328-29; *Reeves* v. *AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), cert. denied, 515 U.S. 1104 (1995); *Mears* v. *Marshall*, 905 P.2d 1154 (Or. Ct. App. 1995), vacated, 921 P.2d 966 (Or. 1996); see also *Scott* v. *CIBA Vision Corp.*, 38 Cal. App. 4th 307 (1995) (preemption of claim of negligence per se for failure to follow FDA regulations). But see *Evraets* v. *Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779 (1994) (no preemption).

Courts had also rejected "fraud on the agency" claims in other regulatory contexts. See *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.) (FIFRA), cert. denied, 510 U.S. 913 (1993); *Oeffler* v. *Miles, Inc.*, 642 N.Y.S.2d 761, 765 (N.Y. Sup. Ct. 1996) (same); see also *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995) (FIFRA preempts claims that would "allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling require-ments of its own regulations"); *Worm* v. *American Cyanimid Co.*, 5 F.3d 744, 748 (4th Cir. 1993) (FIFRA preempts state law claim that manufacturer should have "voluntarily [made] additional disclosures and representations" and sought permission from the EPA to modify its label); *Wegoland Ltd.* v. *Nynex Corp.*, 27 F.3d 17, 21 (2d Cir. 1994) (filed-rate preemption doctrine bars claims of fraud on a rate-setting agency); *Taffert* v. *The Southern Co.*, 967 F.2d 1483, 1488-95 (11th Cir. 1992) (en banc) (same); *H.J., Inc.* v. *Northwestern Bell Tel. Co.*, 954 F.2d 485, 491-92 (8th Cir. 1992) (same).

360k(a)) the FDA's clearance requirements under the MDA. See, *e.g.*, *Reeves*, 44 F.3d at 307 ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."); *Michael*, 46 F.3d at 1329 ("Under § 360k, states may not * * * reach a different conclusion than the FDA."); *Mitchell I*, 67 F.3d at 1283 ("[I]f the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a [different or additional] state requirement."). State liability predicated on a manufacturer's failure to make certain disclosures to the FDA also raised the specter that a "manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity." *Talbott*, 63 F.3d at 29.

In addition to express preemption, courts found that state law "fraud on the FDA" claims were impliedly preempted because they would "'stand[] as an obstacle to the accom-plishment and execution of the full purposes and objectives of Congress.'" *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995). Such claims would frustrate Congress's desire to create a unitary device marketing clearance system, enforced by the FDA, and would conflict with Congress's determination not to include a private cause of action under the MDA. See *Michael*, 46 F.3d at 1329 ("[P]ermitting a fraud claim based on false representation to the FDA would conflict with our precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act."); *Talbott*, 63 F.3d 29-30 ("Congress * * * has not provided for [private policing of the MDA], choosing instead to place sole enforcement authority in the hands of the FDA.").

2. There matters stood at the time of the Court's decision in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996). In *Medtronic*, a 4-1-4 decision, the Court addressed negligence and strict liability claims brought against the manufacturer of an allegedly defective pace-

maker that had received the FDA's Section 510(k) marketing clearance. Although the Court held that those claims were not expressly preempted, its fractured decision failed to articulate a single interpretation of the MDA preemption provision.

Both the plurality and Justice Breyer, who concurred in part and concurred in the judgment, rejected the argument that Section 360k(a) preempts *all* state law product liability claims relating to a medical device. See 518 U.S. at 487-89 (plurality); *id*. at 503-05 (Breyer, J. concurring). They also agreed that, to preempt state law, the manufacturing, design, and warning requirements imposed on a device by federal law must be "specific." See *id*. at 500; see also *id.* at 506-07 (Breyer, J.). Because the Section 510(k) process did not impose specific design requirements, and because the FDA's regulations did not impose specific warning and manufacturing requirements, the Lohrs' tort claims were not preempted. *Id.* at 493, 501; *id.* at 508 (Breyer, J.). Finally, the Court held unanimously, in dicta, that state law claims seeking to impose identical requirements are not "different from, or in addition to" federal requirements and are thus not preempted. *Id*. at 495 (majority); *id.* at 513 (opinion of O'Connor, J.).

3. Although *Medtronic* did not involve a "fraud on the agency" claim, and the Court's analysis was not broad enough to cover such claims, the unclear opinions have been a source of confusion for lower courts.

After *Medtronic*, the Third Circuit overruled its decision in *Michael* and held that "fraud on the agency" claims are not preempted. App., *infra*, 16a-17a; see also *Mears* v. *Marshall*, 944 P.2d 984, 992 (Or. Ct. App. 1997) (allowing "fraud on the agency"

claims on remand after *Medtronic*). The Seventh Circuit, in contrast, reaffirmed its decision in *Mitchell I* and held that *Medtronic* does not save "fraud on the agency" claims from preemption. See *Mitchell II*, 126 F.3d at 913-14. The division is also reflected in other courts. See *Carey* v. *Shiley, Inc.*, 32 F. Supp. 2d 1093, 1108 (S.D. Iowa 1998) (finding preemption); *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996) (finding no preemption); *Green* v. *Dolsky*, 685 A.2d 110, 117 n.7 (Pa. 1996) (same), cert. denied, 520 U.S. 1168 (1997); *Dutton* v. *AcroMed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997) (same).

Courts finding no preemption have interpreted *Medtronic* as holding that the Section 510(k) process imposes no federal requirements, as opposed to merely no federal *design* requirements (App., *infra*, 13a), and that state law requirements that a manufacturer not defraud the FDA are identical to MDA requirements. See *Mears*, 944 P.2d at 992 n.4; *Connelly*, 927 S.W.2d at 855; *Green*, 685 A.2d at 414 n.7; *Dutton*, 691 N.E.2d at 742. See also *Goodlin*, 167 F.3d at 1375. Courts finding preemption, on the other hand, have held that the MDA approval process imposes federal disclosure requirements and that allegations of "liability under state law despite [the defendant's] conformity to the [FDA] requirements * * * must be considered preempted. Permitting such claims would add requirements that are 'different from, or in addition to,' those established" by the MDA. *Mitchell II*, 126 F.3d at 913-14; see *Carey*, 32 F. Supp. 2d at 1108.

This post-*Medtronic* conflict, moreover, has not been confined to the MDA, but extends to similar regulatory contexts. Compare *Lewis*, 107 F.3d at 1505 ("fraud on the Coast Guard" claim preempted under Federal Boat Safety Act), and *Kuiper*, 131 F.3d at 666 ("FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself."), with *Hoelck* v. *ICI Americas, Inc.*, 584 N.W.2d 52, 61 (Neb. Ct. App.) (FIFRA does not preempt claim "based upon * * * failure to disclose relevant information to the EPA"),

review denied (Oct. 28, 1998).

In contrast to the Seventh and Eleventh Circuits, the court below misunderstood the limited effect of *Medtronic* on the previously uniform rejection of "fraud on the agency" claims. Without resolution of the conflict by this Court, lower courts will continue to disagree over whether state juries can sit as "super-[agency] review boards that could question the adequacy of the [agency's] determination of whether a * * * registrant successfully complied with * * * [the agency's] regulations." *Kuiper*, 131 F.3d at 666 (quoting *Welchert* v. *American Cyanamid Inc.*, 59 F.3d 69, 73 (8th Cir. 1995)).

B. The Issue Presented by the Conflict is Recurring and of Great Practical Importance

The conflict in the circuits over "fraud on the agency" claims is particularly significant because of its far-reaching legal and practical effects. To begin with, because the Third Circuit's decision arises out of a multidistrict litigation proceeding involving literally thousands of cases, to which the decision below has already been applied, the opinion obviously has a far more substantial impact than the typical appellate decision in an ordinary product liability case.

Furthermore, "fraud on the agency" claims are not con-fined to the medical device context but have the potential to undermine a broad range of federal regulatory schemes.[6] "Virtually any federal agency decision that stood in the way of a lawsuit could be chal-

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[6] Numerous federal regulatory statutes contain preemption provisions with operative language virtually identical to the MDA. See, *e.g.*, FIFRA, 7 U.S.C. § 136v(b); Flammable Fabrics Act, 15 U.S.C. § 1203(a); Federal Hazardous Substances Act, *id.* § 1261 note (b)(1)(A); National Traffic and Motor Vehicle Safety Act, *id.* § 1392(d); Poison Prevention Packaging Act, *id*. § 1476(a); Consumer Product Safety Act, *id.* § 2075(a); Electronic Product Radiation Control Act, 21 U.S.C. § 360ss; Federal Boat Safety Act, 46 U.S.C. § 4306.

lenged indirectly by a claim that the industry involved had misrepresented the relevant data or had otherwise managed to skew the regulatory result." *Lewis*, 107 F.3d at 1505. Under the MDA and analogous federal statutes, "fraud on the agency" claims thus provide a ready means to circumvent almost any preemptive federal requirement.[7] "Congress could not have intended for the process it so carefully put in place" by passing such statutes "to be so easily and thoroughly undermined." *Ibid.*

Even as limited to the MDA, the decision below will have an enormous impact on the medical device industry and on the public health. Allegations of fraud, even if unsubstantiated, may trigger burdensome, intrusive, and expensive discovery into product development files, often covering multi-year periods and evolving scientific evaluations of complex formulas and patient reactions.[8] In the highly competitive medical device industry, companies could bring such claims against manufacturers of successful devices,

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[7] Indeed, such claims may be brought under state law even where, as here, the agency itself does not believe it was "defrauded." Despite the fact that plaintiffs filed comments with the FDA detailing the allegations of fraud that form the basis of their claims, the FDA granted permission for the bone screws at issue to be labeled for use in spinal fixation. See *In re Orthopedic Bone Screw Prods Liab. Litig.*, 1995 WL 764580, at *5-*6 (E.D. Pa. Dec. 14, 1995); 63 Fed. Reg. 40025 (1998).

[8] These discovery proceedings could embroil the agency in time-consuming and disruptive private litigation, as litigants seek to obtain the best evidence about whether the agency was defrauded and, if so, what the agency would have done in the absence of the fraud. This case provides a compelling example. Petitioner and other defendants submitted strong evidence that the "fraud" alleged by plaintiffs — the submission of separate Section 510(k) applications for the component plates and screws of the AcroMed system — was in fact *suggested by FDA personnel*. See Pet. C.A. Br. at 15-18; Pet. C.A. App. Tab 2, Exhs. 1-2.

asserting that FDA actions were obtained through fraud. The FDA, not the courts, is the appropriate forum for considering such claims, through the agency's established procedures. See, *e.g.*, 21 C.F.R. §§ 10.25, 10.30, 10.33, and 10.35.

What is more, because "fraud on the agency" claims would subject medical device manufacturers to a duty to comply with the shifting and uncertain requirements imposed by juries applying the common law of the 50 states, manufacturers could never be certain that their submissions to the FDA were adequate. They would be compelled to inundate the agency with unnecessary data and speculative impressions in order to foreclose future state law claims that they procured the FDA's clearance through fraudulent concealment. At the same time, manufacturers would be far more reluctant to respond in valid, nonpromotional ways (such as by sending reprints of scientific articles) to physician inquiries concerning off-label uses of their products, for fear that such communications would be taken as evidence of the manufacturer's "true" "intended use" for the device and "fraud on the agency."

Armed with less information, many physicians would make less informed treatment decisions and might also be discouraged from engaging in off-label uses. But, as noted above, the practice of using drugs and medical devices for purposes other than those designated by the manufacturers during the FDA approval process is both extremely common and largely beneficial to patients. See PHYSICIANS' DESK REFERENCE COMPANION GUIDE 1623-54 (1998) (listing common off-label uses for nearly 1000 medical conditions). Indeed, the FDA is well aware of the prevalence and public benefits of such off-label uses. See FDA DRUG BULL. 12:4-5 (1982) (quoted in 59 Fed. Reg. 59820, 59821 (1994)). Given the widespread use of devices for off-label purposes, it is inevitable that manufacturers' submissions to the FDA will vary from the drugs' or devices' eventual uses — a circumstance that renders manufacturers particularly susceptible to the claim that they "defrauded" the federal agency.

Finally, "fraud on the FDA" claims, such as this one, that allege fraud in an "intended use" statement (made before any marketing has taken place) could lead to liability absent proof of *any* actual marketing violations. As a practical matter, however, such claims would "throw[] into the jury box" the difficult, policy-laden question of if and "when unacceptable 'marketing' has taken place" (App., *infra*, 29a (Cowen, J., dissenting)). Congress and the FDA have developed complex statutes and regulations explaining when manufacturers may disseminate information on off-label uses. See 21 U.S.C. §§ 360aaa to 360aaa-6; 63 Fed. Reg. 64556 (1998). If "fraud on the agency" claims are allowed to proceed, "[t]he penalties attached to a violation of the FDA's regulations will often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." App., *infra*, 28a (Cowen, J., dissenting). In sum, as Judge Cowen correctly noted, "when juries are permitted to displace the FDA's judgment about whether a manufacturer has engaged in improper marketing, they will fail to provide a consistent standard, inhibit valuable exchange of information on off-label uses, and needlessly raise the price of drugs and medical devices." *Id.* at 32a.

II. The Decision Below Reflects Widespread Uncertainty Over the Meaning of *Medtronic* v. *Lohr*, Which This Court Alone Can Dispel

Wholly apart from its impact on "fraud on the agency" claims, the decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has engendered a sharp conflict in the circuits on a fundamental question of immense importance to the scope of MDA preemption: whether the MDA was intended to preempt state laws of general applicability. See *Goodlin*, 167 F.3d at 1371 n.7 (noting circuit split); *Mitchell II*, 126 F.3d at 913 n.4 (same). Just over a year ago, the Solicitor General acknowledged "the division among the lower courts" on "questions concerning Section 360k's preemption of state common or statutory law applied in tort suits" and recommended that the Court "grant review and definitively resolve the conflict" in

an appropriate case. No. 96-1405 U.S. Br. at 18, *Smiths Indus. Med. Sys.* v. *Kernats*.

The confusion in the lower courts is traceable to Justice Breyer's tie-breaking vote in *Medtronic* (see *Mitchell II*, 126 F.3d at 912; *Papike*, 107 F.3d at 742) and to the effect of an FDA regulation interpreting the MDA's express preemption provision, 21 U.S.C. § 360k(a) (preempting state requirements "*with respect to a device*" that are "different from, or in addition to" federal requirements) (emphasis added).[9] The FDA has construed the highlighted language to mean that state requirements are not preempted if they are "requirements of general applicability." See 21 C.F.R. § 808.1(d)(1) (no preemption of "State or local requirements of general applicability where the purpose of the requirements relates either to other

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[9] The lower courts are in dispute over whether deference is owed to an administrative agency's interpretation of an express preemption clause. See *Commonwealth Edison Co.* v. *Vega*, 1999 WL 212210, at *5 (7th Cir. April 13, 1999) (noting circuit conflict); see also *Massachusetts* v. *United States Dep't of Transp.*, 93 F.3d 890, 894 (D.C. Cir. 1996) (stating that "[n]either the Supreme Court nor this one has ever definitively decided" this issue). Compare *Brannan* v. *United Student Aid Funds*, 94 F.3d 1260, 1263 (9th Cir. 1996) (deferring to agency interpretation), cert. denied, 521 U.S. 1106 (1997), *Gustafson* v. *City of Lake Angelus*, 76 F.3d 778, 786 (6th Cir. 1996) (same), *Time Warner Cable* v. *Doyle*, 66 F.3d 867, 876 (7th Cir. 1995) (same), and *Elizabeth Blackwell Health Ctr. for Women* v. *Knoll*, 61 F.3d 170, 182 (3d Cir. 1995) (same), with *Grunbeck* v. *Dime Svg. Bank*, 74 F.3d 331, 341 (1st Cir. 1996) (refusing to defer to agency interpretation of "bare statutory language" of preemption provision); *Teper* v. *Miller*, 82 F.3d 989, 998 (11th Cir. 1996) (opinion of Kravitch, J.) ("it is not at all clear" that a court should defer to agency views on preemption); *Brannan*, 94 F.3d at 1268 (Fletcher, J., dissenting) (no deference to agency preemption interpretations), *Knoll*, 61 F.3d at 185 (Nygaard, J., dissenting) (same), and *Colorado Public Utilities Comm'n* v. *Harmon*, 951 F.2d 1571, 1579 (10th Cir. 1991) (same).

products in addition to devices * * * or to unfair trade practices in which the requirements are not limited to devices").

The Court's opinion in *Medtronic*, which Justice Breyer joined, agreed that under the FDA's interpretation of the MDA preemption provision, only state requirements that are "specific" are subject to preemption. See 518 U.S. at 500; see also *id.* at 506-07 (Breyer, J.). But the Court also stated: "[W]e do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted * * * ." *Id.* at 500; see also *id*. at 514 (opinion of O'Connor, J.) (noting that "the statutory language does not indicate that a requirement must be specific, either to preempt or to be preempted"). The majority nevertheless held that the tort claims involved in that case "escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." *Id.* at 501 (plurality); *id.* at 508 (Breyer, J.).

In his separate opinion, however, Justice Breyer agreed with the four dissenting Justices who had rejected reliance on the FDA preemption regulation. See 518 U.S. at 503 ("I basically agree with Justice O'Connor's discussion of [whether the MDA will ever preempt a state law tort action] and with her conclusion."); *id.* at 511 (opinion of O'Connor, J.) (concluding that state common law damages actions can be preempted). Justice Breyer also indicated that he disagreed with the plurality "that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare[.]'" *Id*. at 508. And Justice Breyer explained that the state requirements that can be preempted include "a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05. In fact, Justice Breyer

gave a lengthy explanation of how a state negligence claim, perhaps the paradigmatic general state common law requirement, can be a preempted state "requirement." *Id.* at 504.

Medtronic's inconsistency over whether generalized state tort claims can be preempted under the MDA has played itself out in the circuit courts. The court below and the Tenth Circuit have held that *Medtronic* bars preemption of state law claims of general applicability, citing the part of the plurality opinion that Justice Breyer joined but ignoring the reasoning of his separate concurrence.[10]

On the other hand, the Fourth, Sixth, Seventh and Ninth Circuits have held that the MDA can preempt general common law tort claims.[11] Focusing on the language of Justice Breyer's concurring

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[10] See App., *infra*, 12a (general common law "state requirements * * * escape pre-emption * * * because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices") (quoting *Medtronic*, 518 U.S. at 501); *id*. at 13a (the state tort claim of "fraud on the agency" presented no "state 'requirement' 'with respect to'" the bone screws at issue); *Oja*, 111 F.3d at 789 ("Like the * * * claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent * * * claim were not specifically developed 'with respect to' medical devices. * * * Instead, Oja's * * * claim is predicated upon a general duty applicable to every manufacturer * * *.") (citing *Medtronic*, 518 U.S. 501-02).

[11] See *Mitchell II*, 126 F.3d at 912 ("[I]n order to determine whether a common law cause of action is preempted * * * it is necessary * * * to determine whether the *final judgment* of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.") (emphasis added); *Papike*, 107 F.3d at 742 (finding preemption even though "generally applicable state law principles are involved"); *Martin*, 105 F.3d at 1099 (holding that a "generally applicable" negligent manufacturing claim was preempted); *Duvall*, 103 F.3d at 330 (holding that "common-law causes of action" may be preempted by the MDA).

opinion, these courts have concluded that

> it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law 'requirements' which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted * * *.

Mitchell II, 126 F.3d at 912 (quoting *Papike*, 107 F.3d at 742). The D.C., First and Eighth Circuits have adopted a similar interpretation of Justice Breyer's *Medtronic* concurrence in cases involving other regulatory statutes.[12]

This disarray is also reflected in the federal district and state courts.[13] Indeed, the conflict is all the more troubling because in

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[12] See *Geier* v. *American Honda Motor Co.*, 166 F.3d 1236, 1240 & n.10 (D.C. Cir. 1999); *Symens* v. *SmithKline Beecham Corp.*, 152 F.3d 1050, 1055 (8th Cir. 1998); *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 554 (1st Cir. 1996), cert. denied, 519 U.S. 1149 (1997).

[13] Compare, *e.g.*, *Easterling* v. *Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 370 (E.D. La. 1997) (allowing preemption of state general common law claims); *Lake* v. *TPLC*, 1 F. Supp. 2d 84, 87 (D. Mass. 1998) (same); *Chmielewski* v. *Stryker Sales Corp.*, 966 F. Supp. 839, 842-43 (D. Minn. 1997) (same); *Richman* v. *W.L. Gore & Assoc.*, 988 F. Supp. 753, 757 (S.D.N.Y. 1997) (same); *Berish* v. *Richards Med. Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (same); *Steele* v. *Collagen Corp.*, 54 Cal. App.4th 1474, 1486-87 (1998) (same); *Hernandez* v. *Coopervision, Inc.*, 691 So.2d 639 (Fla. Dist. Ct. App. 1997) (same); *Weiland* v. *Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854, 861 (Ill. App. Ct. 1998) (same), appeal allowed (Ill. Mar. 31, 1999) (Table, No. 86903); *Connelly*, 927 S.W.2d at 854-55 (same); *Sowell* v. *Bausch & Lomb, Inc.*, 230 A.D.2d 77, 83-4 (N.Y. App. Div. 1997) (same); *Green*, 685 A.2d 110 (same); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511 (R.I.) (same), cert. denied, 118

eight states (California, Kentucky, Illinois, Michigan, Ohio, Oregon, Pennsylvania, and Washington), state appellate court decisions on MDA preemption of tort claims directly contradict those of the relevant federal court of appeals.[14] Resolution of such conflicts is

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S. Ct. 374 (1997); *Worthy* v. *Collagen*, 967 S.W.2d 360, 371 (Tex. 1998) (same); with *Lakie* v. *SmithKline Beecham*, 965 F. Supp. 49, 53-54 (D.D.C. 1997) (general common law claims not preempted because of generality); *Armstrong* v. *Optical Radiation Corp.*, 50 Cal. App.4th 580 (1996) (same); *Kernats* v. *Smiths Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct. 1996) (same), cert. denied, 118 S. Ct. 684 (1998); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 822-23 (Ky. 1997) (same), cert. denied, 118 S. Ct. 1187 (1998); *Walker* v. *Johnson & Johnson Vision Prods, Inc.*, 552 N.W.2d 679, 686 (Mich. Ct. App. 1996) (same); *Baird* v. *American Med. Optics*, 713 A.2d 1019, 1029-30 (N.J. 1998) (same); *Dutton*, 691 N.E.2d at 741-42 (same); *Mears*, 944 P.2d at 990 (same); *Wutzke* v. *Schwaegler*, 940 P.2d 1386, 1389-90 (Wash. Ct. App. 1997) (same), review denied, 953 P.2d 96 (Wash. 1998).

[14] Compare App., *infra*, 12a-13a (3d Cir.) (not allowing preemption), with *Green*, 685 A.2d 110 (Pa.) (allowing preemption); *Papike*, 107 F.3d at 741 (9th Cir.) (allowing preemption), with *Mears*, 944 P.2d at 990 (Ore.) (not allowing preemption), 50 Cal. App.4th 580 (Cal. Ct. App) (same), and *Wutzke*, 940 P.2d at 1389-1390 (Was. Ct. App.) (same); *Mitchell II*, 126 F.3d at 913 (7th Cir.) (allowing preemption) with *Kernats*, 669 N.W.2d 1300 (Ill. App. Ct.) (not allowing preemption); *Martin*, 105 F.3d at 1997-98 (6th Cir.) (allowing preemption), with *Walker*, 552 N.W.2d at 686 (Mich. Ct. App.) (not allowing preemption), *Niehoff*, 950 S.W.2d at 822-23 (Ky.) (same), and *Dutton*, 691 N.E.2d at 741-42 (Ohio Ct. App.) (same).

essential to prevent forum shopping. See *Baldwin* v. *Alabama*, 472 U.S. 372, 374 (1985).

Because the scope of preemption varies widely among the circuits, medical device manufacturers, which do business in all 50 states, confront dramatic differences in liability exposure from state to state for the identical products. And because the conflict stems from ambiguities in this Court's decision in *Medtronic*, additional litigation in the lower courts is most unlikely to lead to further clarity. Without a definitive resolution, the MDA, designed to promote uniform regulation of life-saving medical devices, will instead continue to spawn inconsistent rulings.

III. The Decision Below Is Incorrect

A. The Court Below Erred In Concluding That "Fraud on the Agency" Claims Are Not Subject To Preemption Under *Medtronic*

There is no sound reason to suffer the harms discussed above because the Third Circuit's decision is incorrect. The court below arrived at the counterintuitive conclusion that the MDA does not preempt "fraud on the agency" claims by repeatedly misconstruing this Court's precedents.

1. *Medtronic* restated the general principles of an express preemption inquiry: courts should consider whether the case falls "in a field which the States have traditionally occupied," 518 U.S. at 485, as well as the "purpose of Congress" and the "structure and purpose of the statute as a whole." *Id.* at 485-86. The Third Circuit applied none of these factors, all of which counsel in favor of preemption of "fraud on the agency" claims. For example, unlike the product liability suit at issue in *Medtronic*, this case involves the accuracy of submissions *to a federal agency*, a field that the states have *never* occupied. Similarly, unlike the product liability suit in *Medtronic*, preempting plaintiffs' claims would not have the "effect of granting complete immunity from design defect liability to an entire

industry." *Id.* at 487. To the contrary, plaintiffs would still be able to bring personal injury suits against the manufacturers, as well as fraud claims for representations made to them or their physicians. Put another way, preemption here would not eliminate any claim that plaintiffs would have had under state law if the MDA had not been enacted.

Finally, the "structure and purpose of the statute as a whole" suggest preemption. The MDA and its accompanying regulations contemplate a unified federal approach to marketing clearance of medical devices, giving the FDA discretionary power both to require additional information from applicants (21 C.F.R. §§ 807.87(*l*)), 807.92(d)) and to punish false statements in applications through rescinding approval, requiring corrective actions, or ordering a recall (see, *e.g.*, 21 U.S.C. §§ 331q(2), 336, 337(a); *Talbott*, 63 F.3d at 29; 56 Fed. Reg. 46191, 46200 (1991)).

2. Even when it understood *Medtronic*'s approach to MDA express preemption, the Third Circuit misapplied those principles. In particular, the court below erroneously applied the holding of five Justices in *Medtronic* that only "specific" federal requirements can preempt state laws that impose requirements "different from" or "in addition to" the federal requirements. See 518 U.S. at 500 (plurality); *id*. at 506-07 (Breyer, J.).

The Third Circuit transformed this Court's determination that the Section 510(k) process imposes *no federal design requirements* into a holding that the Section 510(k) process imposes *no federal "requirements" at all*. Compare 518 U.S. at 493-94 (rejecting preemption of design claim because the Section 510(k) process did not "'require' Medtronic's pacemaker to take any particular form for any particular reason") with App., *infra*, 12a ("The § 510(k) process * * * established no federal requirement 'applicable to a device' within the meaning of the MDA."). Given the detailed and

specific regulatory requirements of the Section 510(k) approval process (see 21 C.F.R. § 807.87), this leap of logic is simply indefensible.[15] In essence, the Third Circuit attempted to deny the existence of the very federal requirements that plaintiffs accused Buckman of violating.

The final misstep in the Third Circuit's express preemption analysis was its holding that "fraud on the agency" claims are not "different from, or in addition to" the Section 510(k) requirements. But to prevail on their fraud claim, plaintiffs would have to prove that Buckman was required to disclose its plans to violate wholly separate FDA marketing regulations in its Section 510(k) application. Federal law imposes no such disclosure requirements. Under the MDA, "intended use" is determined by "the objective intent of the persons legally responsible for the labeling of devices" (21 C.F.R. § 801.4); see also 21 U.S.C. § 360c(i)(1)(E)(i); 21 C.F.R. § 807.87(e)), not by the applicant's subjective expectations. As Judge Cowen observed, the majority "stretches the 'intended use' statement" into both a statement of subjective intent and "an all purpose guarantee that an applicant will not violate other FDA rules." App., *infra*, 27a. State law claims that would impose liability for failing to disclose information that the FDA itself does not require are certainly "different from" and "in addition to" the federal requirements and are preempted by Section 360k(a).

3. All else aside, it should be clear that *Medtronic* had no effect on implied preemption principles. This Court was explicit that even common law claims can still be "preempted under conflict pre-

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[15] For example, the Section 510(k) process requires that devices be "substantially equivalent" to pre-1976 devices in order to obtain marketing clearance. See 21 U.S.C. § 360e(b)(1)(B). Surely a state law that instead required a medical device to be "exactly identical" to a pre-1976 device would be preempted.

emption analysis." 518 U.S. at 503; see also *id.* at 507-08 (Breyer, J.). For this reason alone, the Third Circuit erred in holding that *Medtronic* undermined prior decisions holding that "fraud on the agency" claims were impliedly preempted.

As previously explained, plaintiffs' suit would require juries applying state law to determine what information should have been submitted to the FDA and whether the agency, if it had received that information, would have reached a different result on AcroMed's Section 510(k) application. Claims such as this would plainly frustrate the MDA's purpose of having uniform federal submission requirements and vesting all authority over medical device marketing in the FDA. See *Michael*, 46 F.3d at 1329; *Mitchell I*, 67 F.3d at 1283. As the Eleventh Circuit explained, "[r]egulatory fraud claims" are

> impliedly preempted for fundamental, systemic reasons. Permitting such claims would allow juries to second-guess federal agency regulators * * *. If that were permitted, federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts.

Lewis, 107 F.3d at 1505.

Indeed, the conflict between "fraud on the agency" claims and the FDA's regulatory procedures is most stark in cases, such as this one, where the FDA has been presented with the very same evidence of "fraud" and determined that the device is properly on the market. See note 7, *supra*. Plaintiffs' claim, pure and simple, is that the FDA should not have granted Section 510(k) approval to the bone screws and should instead have required the more exacting premarket approval process. But the FDA, fully aware of plaintiffs' position, has only recently reiterated that "premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness." 63 Fed. Reg. 40025, 40032 (1998). The FDA

has gone so far as to reclassify the bone screws, deciding that pedicle fixation should be a labeled use for many of the devices and spinal conditions involved in this litigation. *Ibid.*

The essence of plaintiffs' state law claim is that the medical devices at issue "had no lawful access to the market for any purpose." App., *infra*, 23a. Yet, the FDA, applying federal law, has repeatedly concluded that the devices should be on the market. Plaintiffs' suit would "stand[] as an obstacle" to the accomplishment of that federal purpose. *Freightliner*, 514 U.S. at 287.

B. The Court Below Erred In Holding That State Tort Claims Are Not Preempted Because of Their Generality

The Third Circuit's conclusion that state tort law requirements are not preempted because of their generality contradicts the holding in *Medtronic*, the text of the preemption provision, and common sense.

As the Fourth, Sixth, Seventh and Ninth Circuits have recognized, common law tort claims can be preempted under the MDA. See pages 19-23, *supra*. This also was the view of five Justices in *Medtronic*, who stated that the MDA can preempt "a standard of care or behavior imposed by a state-law tort action." 518 U.S. at 504-05 (Breyer, J.); see also *id.* at 510-12 (opinion of O'Connor, J.).

Indeed, in *Medtronic*, the FDA's own lawyer — the Solicitor General — rejected the proposition on which the Third Circuit rested its holding: the phrase "with respect to" in Section 360k(a) means that common law claims are never preempted. The Solicitor General stated (Br. 17): "The Lohrs argue that the 'with respect to' phrase limits the scope of the provision to state requirements that *specifically refer or relate to medical devices*, and therefore excludes *general* common-law duties. *That argument is strained as a grammatical matter.*" (citation omitted and emphasis added).

In fact, the Solicitor General maintained, exactly the opposite is true: "[T]he 'with respect to' clause *suggests that such a 'requirement' may be one of general applicability.*" *Id*. at 18 (emphasis added). The Solicitor General went on to argue that common law duties qualified as "requirements" within the meaning of Section 360k(a). *Id*. at 15-19, 25 n.20.

The Third Circuit's position lacks any support in the text of the MDA. The language of Section 360k(a) broadly preempts "any" state requirement that affects "a device intended for human use," is "different from, or in addition to" any federal requirement, and "relates to" either "the safety or effectiveness of the device" or "any other matter included in a requirement applicable to the device under [the MDA]." 21 U.S.C. § 360k(a). Only a strained interpretation of these deliberately broad phrases can sustain the Third Circuit's determination that Section 360k(a) bars preemption of generally applicable tort requirements even when they are applied in the specific context of medical devices.

Finally, a blanket exclusion of generally applicable state tort claims would be nonsensical. There is no reason to believe that Congress cared about the form, as opposed to the content, of state requirements applicable to medical devices or intended to allow the states to avoid preemption through creative legislative drafting. As this Court has recognized in other preemption settings, recognition of a broad exception for "generally applicable" state requirements would create "an utterly irrational loophole." *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992); accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959). The same is true here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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