No. 98-1768

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

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

BRIEF FOR PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company and that no publicly held company owns 10% or more of its stock.

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BRIEF FOR PETITIONER

OPINIONS BELOW

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

JURISDICTION

The judgment of the court of appeals was entered on November 19, 1998, and a timely petition for rehearing was denied on February 3, 1999 (Pet. App. 57a-58a). The petition for a writ of certiorari was filed on May 3, 1999, and was granted on June 29, 2000. This Court has jurisdiction 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 of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), is reproduced at Pet. App. 59a.

STATEMENT

This case raises important questions concerning the preemptive scope of the Medical Device Amendments (MDA), 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."

A. The Regulatory Structure Of The Medical Device Amendments

In 1976, Congress enacted the MDA, which vastly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. NO. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly 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).

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, are designated as Class II; they face increased regulation in the form of "special controls," such as performance standards, imposed by the FDA. *Id.* § 360c(a)(1)(B). The FDA designates as Class III those devices that either (1) 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 (2) "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). All post-1976 devices that are not "substantially equivalent" to a pre-1976 device initially are automatically consid-

ered Class III devices and cannot be marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Except for certain exempt devices, manufacturers must obtain permission to market post-1976 devices in one of two ways. First, for certain Class III devices, 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 both safe and effective. 21 U.S.C. § 360e. Second, for all other devices, 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 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' 510(k) notifications. See 21 C.F.R. § 807.87 (1999, 1986). 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.* Manufacturers are also required to provide "[a]ny additional information regarding the device requested by the Commissioner that is necessary * * * to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. § 807.87(*l*); *id.* § 807.87(h) (1986). Substantial equivalence under Section 510(k) requires that a device "ha[ve] the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A).

Once a device has been cleared for marketing under Section 510(k), the manufacturer may not market or promote it for uses

other than those specified in the FDA clearance. Physicians, however, 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 stated that off-label uses "may be appropriate and rational in certain circumstances, and may, in fact reflect approaches * * * that have been extensively reported in medical literature." *Use of Unapproved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4, 5 (April 1982). Indeed, FDA officials have acknowledged that in certain circumstances "prescribing for off-label uses may be the very best medical practice." Nightingale, *Unlabeled Uses of Approved Drugs*, 26 DRUG INFO. J. 141, 143 (1992) (FDA Assoc. Comm'r for Health Affairs). Off-label uses of medical 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).

B. The FDA's Clearance Of AcroMed's Devices

Petitioner The Buckman Company (Buckman) is a regulatory consultant for medical device manufacturers, helping them navigate FDA procedures, plan regulatory strategy, and monitor clinical investigations. In 1984, AcroMed Corporation hired Buckman as its liaison with the FDA in an effort to obtain marketing clearance for its devices. Pet. App. 4a-5a. Buckman assisted AcroMed in obtaining clearance for the components of two orthopedic bone screw systems: (1) the Variable Screw Placement Spinal Plate Fixation System (VSP), and (2) the ISOLA Spine Fixation System (ISOLA).

1. *The VSP System*. In September 1984, Buckman, on behalf of AcroMed, submitted a 510(k) clearance notification for the VSP System. The submission stated that AcroMed intended to market the VSP as a pedicle screw for use in spinal surgery. Pet. App. 5a.

The FDA rejected Buckman's submission, 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 510(k) notification for the VSP, again indicating that the device would be labeled as a pedicle screw. The FDA rejected this submission as well. *Ibid.*

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 510(k) clearance for each. Pet. App. 5a; J.A. 46-57. These submissions, and subsequent correspondence from Buckman, identified the devices' intended use as in the arm and leg long bones, rather than in the spine. J.A. 51, 57-58. The FDA determined that the screw and plate were each substantially similar to pre-1976 devices and cleared the products for marketing in February 1986. Pet. App. 5a; J.A. 59-62.[1]

2. *The ISOLA System.* AcroMed subsequently developed the ISOLA System, which uses screws in conjunction with rods and, in some circumstances, hooks. J.A. 17-18. In June 1988, Buckman, on behalf of AcroMed, applied to the FDA for permission to initiate clinical trials relating to use of the ISOLA in spinal applications (as it had done with the VSP, see note 1, *supra*). J.A. 18. Three months later, in September 1988, Buckman submitted three separate 510(k) notifications for the screws, rods, and hooks that made up the ISOLA System. *Ibid.* These submissions specified that the devices, like their pre-1976 equivalents, had an intended use in locations other than the pedicles of the spine. *Ibid.* In April and May 1989, the FDA determined that the rods, hooks, and screws were substantially equivalent to pre-1976 devices and cleared them for marketing. *Id.* at 19.

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[1] A month *before* the FDA granted these clearances, AcroMed applied to the agency for an investigational device exemption (IDE) in order to conduct clinical trials on spinal use of the VSP System. J.A. 63-64. The FDA granted the IDE. J.A. 12, 17-18.

In granting 510(k) clearance of the iliac screw used in the ISOLA System, the FDA informed AcroMed that the device could "not be labeled or promoted for pedicular attachment to, or fixation of, the spine." J.A. 19. The FDA also required "all labeling" of the device to "prominently state that the screws * * * are intended for sacral/iliac attachment only" as well as to include the following statement: "WARNING — THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION." *Ibid.*

Despite the limited nature of the FDA's clearances of AcroMed's devices and similar products, "[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. 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, although widespread, were all off-label, because the FDA did not clear the marketing of bone screws with a labeled indication for use in spinal surgery until January 1995. *Id*. at 51947-51948.

C. The Proceedings In The District Court

After a national television program ran a story on alleged harm caused by use of bone screws as spinal fixation devices, thousands of plaintiffs filed state-law suits against doctors, hospitals, universities, 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. Pet. App. 55a.

1. *Plaintiffs' "Fraud On The FDA" Allegations*. Plaintiffs did not contend that, in applying for 510(k) clearances, Buckman or AcroMed had misrepresented any objective fact, such as the size, shape, or technical characteristics of the screws, plates, rods or hooks, 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 or other non-spinal applications while planning to market them for use in the spine. Pet. App. 6a; J.A. 15-19. In plaintiffs' view, the 510(k) clearances were the product of fraud under state law and, but for such fraud, the devices would never have come onto the market or been used in their pedicle surgeries. J.A. 21.

In addition to the statements concerning "intended use" in the 510(k) submissions, plaintiffs premised their "fraud on the FDA" claim on a follow-up letter relating to the VSP bone plates that Buckman sent in January 1986. J.A. 15-16. The letter was submitted in response to a telephone call from an FDA official indicating that there was a "need for a more definitive statement covering the intended 'indications for use' of the AcroMed Nested Bone Plate." J.A. 58. As required by the FDA's regulation (21 C.F.R. § 807.87 (1986)), Buckman provided the agency with the information requested, stating (J.A. 58):

> The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for purposes of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

In their complaint, plaintiffs also cited other evidence purporting to show that Buckman and AcroMed possessed a subjective intent that the bone screws and plates would be used by doctors in spinal applications. J.A. 16-20.

In response to plaintiffs' "fraud on the FDA" allegations, Buckman contended that "intended use" is a term of art referring to the use for which the manufacturer seeks FDA clearance, as

determined by the indications for use claimed in the proposed labeling for the device, and does not encompass the manufacturer's subjective hopes, desires or expectations about how physicians, in the exercise of their independent medical judgment, might elect to use a device once it is on the market. Accordingly, Buckman argued that plaintiffs' state-law claim was preempted by the MDA, because it would impose disclosure requirements regarding a device's intended use that were "different from, or in addition to" (21 U.S.C. § 360k(a)) the disclosure requirements imposed by federal law.

Indeed, Buckman pointed out that it was *the FDA itself* that proposed, at the December 1985 meeting, that AcroMed separate the VSP into its component parts — the screw and the plate — and seek 510(k) clearance for each. Buckman submitted a memorandum written by FDA official Dan McGunagle, who had attended the meeting, in which McGunagle recalled:

> With the meeting at a stalemate I pointed out the FDA's long standing policy of evaluating (for not only substantial equivalence but safety and effectiveness) a device based on the labeling submitted for the device and the agreement between the labeling and the device's physical abilities to perform as the labeling claimed. I also pointed out that because of the physical and mechanical similarities between the plates and (the original design) screws of the system to ordinary bone plates and screws these devices, when labeled, indicated and promoted as simple bone screws and plates would, in fact, be substantially equivalent to pre-Amendment[] devices and could be shipped in interstate commerce. * * * I pointed to the oft stated FDA policy of not regulating the practice of medicine by individual physicians. I said that if individual practitioners, on their own without guidance from labeling or promotion by the manufac-

> turer, chose to use the plates and screws for spinal fixation that would fall under the practice of medicine and outside FDA's authority.

J.A. 136.

In addition, Buckman explained that there was no possibility that the FDA had been misled about AcroMed's subjective hopes or desires that the screws, plates, rods, and hooks in the VSP and ISOLA Systems would be used by physicians in spinal applications. With regard to the VSP System, AcroMed had twice sought FDA clearance for spinal use; spinal applications had been discussed again at the December 1985 meeting; and shortly before the component plates and screws of the VSP gained 510(k) authorization, the company had asked the FDA for permission to begin clinical trials on the VSP System for spinal application. J.A. 13-16, 135-137. As for the ISOLA System, AcroMed had requested FDA approval to begin clinical trials concerning spinal use even before filing 510(k) notifications for individual components of the System. J.A. 17-18. In clearing the iliac screw component, the FDA had specifically directed the company to warn that it had "NOT BEEN APPROVED FOR PEDICULAR APPLICATION." J.A. 19.

2. *The District Court's Decisions*. In March 1995, the district court granted judgment on the pleadings on the "fraud on the agency" claim, holding that it was preempted both expressly by the MDA and impliedly by the federal scheme. Pet. App. 46a-53a. The district court explained that the MDA's express preemption provision "does not permit courts to 'perform the same functions initially entrusted to the FDA.'" *Id*. at 49a (quoting *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), cert. denied, 516 U.S. 815 (1995)). 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 Pet. App. 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 information from the agency and, if so, the appropriate sanction" (citation and internal quotation marks omitted)). Finally, the court noted that permitting "fraud on the agency" claims would be inconsistent with Congress's decision not 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" claim. Pet. App. 7a, 33a. Among other things, plaintiffs argued that their claim was not expressly preempted under *Medtronic* because it was seeking to enforce state requirements that were "identical" to the federal requirements and because the pertinent state and federal requirements relating to intended use disclosures were "general" in nature and thus not eligible for express preemption. Buckman responded that *Medtronic* did not involve a "fraud on the agency" claim and thus did not alter prior law in the Third Circuit (and in other jurisdictions) holding that such claims are preempted.

In March 1997, the district court reaffirmed its ruling that plaintiffs' "fraud on the agency" claim was preempted. Pet. App. 33a-44a. The court agreed that *Medtronic* had undercut portions of its previous analysis but held that the claim was still precluded because it was inconsistent with Congress's decision not to include a private right of action under federal law. *Id*. at 36a-37a. The court added that plaintiffs' claim was "not interchangeable" with the claims at issue in *Medtronic*, which involved no allegation of fraudulent procurement of agency clearance 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 (Pet. App. 45a) and certified the dismissal as a final order under Rule 54(b) of the Federal Rules of Civil Procedure. Pet. App. 54a-56a.

D. The Court Of Appeals' Decision

A panel of the Third Circuit reversed, over a "vehement[]" (Pet. App. 32a) dissent by Judge Cowen. It concluded that *Medtronic* undermined the Third Circuit's previous holding in *Michael* that state "fraud on the FDA" claims are expressly and impliedly preempted. *Id.* at 13a-17a & n.5.

The court of appeals' reasons for rejecting express preemption were set forth in a single paragraph. According to the majority, the MDA did not expressly preempt "fraud on the FDA" claims because the 510(k) process does not establish *any* "federal 'requirement'" that is "'applicable to the device' at issue here." Pet. App. 13a. In equally sweeping fashion, the majority broadly declared that plaintiffs' common law fraud claim does not impose *any* "state 'requirement' 'with respect to' that device." *Ibid.* Finally, the majority reasoned that the state requirements plaintiffs sought to enforce do not "impose any obligation on Buckman [that is] inconsistent with federal law," because federal law prohibits making fraudulent statements to the FDA. *Ibid.*

The Third Circuit also rejected the argument that "fraud on the FDA" claims are impliedly preempted. Pet. App. 16a. The majority recognized that "Congress has not created an express or implied private cause of action for violations of the [Federal Food, Drug and Cosmetic Act (FDCA)] or the MDA." *Id.* at 13a. But it saw "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. The majority relied as well on the "presumption against preemption" and the absence of express preemption of plaintiffs' claim, reasoning that *Medtronic* "teaches that where Congress has expressed its intention with respect to preemption, we should look primarily to what it said." *Id.* at 16a.

Judge Cowen dissented. Unlike the majority, he was 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." Pet. App. 32a. Judge Cowen also predicted that the majority's approach "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.

E. The FDA's Reclassification Proceeding

Contemporaneous with these judicial proceedings, the FDA conducted a rulemaking in which it reclassified many of the bone screws challenged by plaintiffs from Class III to Class II when used to treat certain spinal conditions. See 60 Fed. Reg. 51946 (1995); 63 Fed. Reg. 40025 (1998). The FDA's decision, which followed an extensive review of the available medical data, was based upon its conclusion that special controls alone "would provide reasonable assurance of safety and effectiveness." 63 Fed. Reg. at 40025.

The plaintiffs in this case participated extensively in the FDA's reclassification proceeding. Plaintiffs' 231-page comments included the same "fraud on the agency" allegations that they advanced in the district court, accompanied by an 18-volume appendix consisting of more than 400 exhibits, many of which were drawn from discovery in this case. Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, FDA Dkt. No. 95N-0176, at 17, 31-39 (filed March 1, 1996). In adopting its final rule, the FDA declined to credit plaintiffs' allegations and expressly rejected the argument that bone screws should be banned based on "deception." 63 Fed. Reg. at 40035-40036.

SUMMARY OF ARGUMENT

I. Plaintiffs' "fraud on the FDA" claim is expressly preempted by 21 U.S.C. § 360k(a). If allowed to proceed, it would impose *state* disclosure requirements relating to the "intended use" of the AcroMed medical devices that are materially different from the *federal* disclosure requirements relating to "intended use" that apply to the very same devices. The essential premise of plaintiffs' claim is that Buckman should have informed the FDA of AcroMed's subjective hopes, desires and expectations concerning how the devices might be used by physicians once they were on the market. Federal law imposes no such disclosure requirement in the 510(k) process.

Moreover, the state and federal disclosure requirements at issue in this case are "specific" in every relevant sense. They arise from the particularized application of state and federal laws to individual devices (and no others); they impose obligations to make specific disclosures that concern each device's "intended use"; and they are the product, on the federal side, of active and particularized review and consideration by the FDA.

II. Plaintiffs' "fraud on the FDA" claim is also impliedly preempted. Unlike the traditional state tort requirements involved in *Medtronic*, the gravamen of plaintiffs' claim is that petitioner Buckman *defrauded a federal agency*. That claim amounts to a collateral attack on the FDA's decision to clear the relevant devices for marketing. To prevail on their state-law claim, plaintiffs would have to show that the AcroMed devices should not have been on the market. But, from the perspective of the federal government, these devices *were* properly on the market. It is difficult to imagine a starker conflict between state and federal law. What is more, plaintiffs' claim would require a judge or jury, applying state law, to decide (1) what disclosures should have been made to the FDA, (2) whether Buckman satisfied those federal disclosure requirements, (3) whether the FDA already knew the information that was not disclosed, and (4) what the FDA would have done if

Buckman had disclosed the required information. The potential for second-guessing the FDA's own determinations of these issues is obvious.

Plaintiffs' "fraud on the FDA" claim also would conflict with the FDA's substantial interest in valid, final and correct decision-making as well as with Congress's intent to vest exclusive enforcement authority in the FDA. The claim would undermine the uniformity of federal law. And it would interfere substantially with federal government operations, by subjecting agency personnel to intrusive discovery, creating serious distortions in the FDA's regulatory process, and constricting the flow of medical information concerning off-label uses.

III. If the Court concludes that plaintiffs' "fraud on the FDA" claim is not preempted under current law, then it should reexamine *Medtronic*'s conclusion that the MDA's express preemption clause encompasses only "*specific* requirements" imposed by state and federal law. The concept of "specificity" is contrary to the plain language of Section 360k(a); is inherently ambiguous; has spawned enormous confusion and conflict in the lower courts; and has led to uncertainty and serious practical difficulties for device manufacturers. It is also based on an erroneous view of the FDA's past regulatory practice. The Court should eliminate this "utterly irrational loophole" (*Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992)) from the law of MDA preemption.

ARGUMENT

In recent years, this Court has been called upon repeatedly to decide whether Congress, in enacting express preemption clauses aimed at safeguarding the exclusive authority of expert federal regulators and protecting interstate commerce from the burdens of excessive or divergent state regulation, meant to nullify state-law requirements that are imposed by judges or juries in private lawsuits. See, *e.g.*, *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913 (2000); *Medtronic*, 518 U.S. 470; *Cipollone* v. *Liggett Group,*

Inc., 505 U.S. 504 (1992). That question has proved to be most nettlesome where the consequence of a finding of preemption is to deprive injured people of traditional remedies that they would otherwise have under state law against the manufacturers of dangerous or defective products.

This case is entirely different. The gravamen of plaintiffs' state-law claim is that certain participants in a federal regulatory process *defrauded the federal agency*. According to the plaintiffs, petitioner should have made certain disclosures and statements (and should not have made others) to the Food and Drug Administration in the course of seeking regulatory clearance to market certain medical devices. But it is hardly a traditional role of state law to police whether parties to a federal regulatory process comply with disclosure requirements imposed by a federal agency. Although state law generally includes protections against fraud, plaintiffs do not claim that *they* were defrauded; they claim that *the FDA* was defrauded.

This case accordingly bears no resemblance to the product liability suit in *Medtronic*, which involved routine state-law claims of design and manufacturing defects. This case also differs from *Medtronic* because preempting plaintiffs' claim here would not have "the perverse effect of granting complete immunity from design defect liability to an entire industry." 518 U.S. at 487. To the contrary, plaintiffs would still be able to bring product liability suits against the manufacturers, as well as fraud claims for representations made to them or to 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*. Indeed, plaintiffs' claim *could not exist* if there were no federal regulatory process in place; it is entirely dependent upon, and derivative of, a federal regulatory proceeding.

Plaintiffs' "fraud on the agency" claim is even more unlike a traditional tort action because, at bottom, it amounts to a collateral attack on the FDA's clearance decision. To prevail on their claim,

plaintiffs must prove that, but for Buckman's "fraudulent" submissions to the FDA, AcroMed's bone screws *would never have been cleared by the FDA* and thus would never have been used in plaintiffs' operations. To resolve plaintiffs' claim, then, a judge or jury — applying state law — must decide 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 510(k) notifications. Traditional state-law product liability actions, in contrast, do not require judges and juries to step into the shoes and minds of federal regulators, interpret the scope of federal disclosure or other requirements, or second-guess decisions made by a federal agency.

For all of these reasons, plaintiffs' unorthodox claim is expressly as well as impliedly preempted by federal law. Plaintiffs' claim is expressly preempted because it imposes disclosure requirements with respect to medical devices that are plainly "different from, or in addition to" the disclosure requirements imposed by federal law. 21 U.S.C. § 360k(a). Plaintiffs' claim is impliedly preempted because it is a collateral attack on the marketing clearance decisions of expert federal regulators; it conflicts with Congress's decision to delegate to the FDA exclusive regulatory authority over the MDA (and Congress's corresponding decision *not* to create a private right of action under the MDA); it threatens the uniformity of federal law; and it creates distortions in the federal regulatory process, in the flow of information relating to off-label uses of devices, and in the agency's allocation of its own resources.

I. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS EXPRESSLY PREEMPTED BECAUSE IT IMPOSES STATE-LAW DISCLOSURE REQUIREMENTS RELATING TO "INTENDED USE" THAT ARE "DIFFERENT FROM, OR IN ADDITION TO" THE DISCLOSURE REQUIREMENTS IMPOSED BY FEDERAL LAW

In enacting the MDA, Congress sought to preserve the uniformity of the federal regulatory scheme and to protect innovations in device technology from being "stifled by unnecessary restrictions" by including a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 12, 45. That "general prohibition" was expressed in a broadly worded preemption clause:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement —
>
> (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The only exception to this sweeping command is for state requirements that the FDA elects to exempt from preemption pursuant to 21 U.S.C. § 360k(b).

Plaintiffs' "fraud on the agency" claim falls comfortably within the language of Section 360k(a). That claim rests entirely on the premise that state law required Buckman to make certain disclosures to the FDA about the "intended use" of the components of the VSP and ISOLA Systems. As discussed below, these state disclosure requirements are "different from, or in addition to," the disclosure requirements about "intended use" that are "applicable * * * to the device" under federal law. There is no dispute that the state requirements underlying plaintiffs' claim "relate[] to the

safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device"; plaintiffs have never suggested otherwise. Accordingly, this case presents a straightforward example of express preemption.

In *Medtronic,* a majority of this Court gave a limiting construction to the broad language of Section 360k(a). See 518 U.S. at 496-97. The majority relied, in turn, on a narrow interpretation of Section 360k(a) adopted by the FDA in setting forth the agency's procedures for considering exemptions from preemption. See 21 C.F.R. § 808.1(d). The Court also instructed that any inquiry into express preemption requires "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." 518 U.S. at 500. We accordingly explain, first, why the federal and state disclosure "requirements" involved in this case are different and, second, why those requirements fit within the ambit of Section 360k(a) as construed in *Medtronic.*

A. Plaintiffs Seek To Impose Disclosure "Requirements" That Are "Different From, Or In Addition To" The Disclosure "Requirements" Imposed By Federal Law

1. As an initial matter, we note that plaintiffs have never disputed that, at the time of the conduct giving rise to their claim, federal law imposed "requirements" on Buckman to make certain disclosures to the FDA in the 510(k) process involving the AcroMed devices. Indeed, plaintiffs have consistently maintained that Buckman violated the agency's disclosure requirements — an allegation that would make no sense if disclosure of the information specified in the agency regulations were *optional*. Although the parties vehemently disagree about what disclosures federal law

requires, there is no dispute that it *requires something*. This is not a case, then, where federal law imposes no requirement at all.[2]

Equally clear is the fact that plaintiffs' "fraud on the agency" claim, if allowed to proceed, would impose state-law "requirements" on Buckman concerning disclosures in FDA proceedings. In *Medtronic*, a majority of this Court held that state tort duties imposed through the common law constitute "requirements" within the meaning of Section 360k(a). See 518 U.S. at 509-511 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 504-505 (opinion of Breyer, J.). Indeed, Justice Breyer even gave as an example of a claim that would be preempted by the MDA "a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id.* at 504. Plaintiffs' "fraud on the agency" claim, which is similarly premised on state tort law, imposes "requirements" no less than does the state negligence or strict liability law in Justice Breyer's hypothetical.

2. These federal and state disclosure "requirements" are not "substantially identical." 21 C.F.R. § 808.1(d)(2). Plaintiffs' "fraud on the agency" claim is predicated on Buckman's purported

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[2] The Third Circuit apparently concluded otherwise, declaring that "[b]ased on *Lohr*, * * * there is *no* federal 'requirement' 'applicable to the device' at issue here." Pet. App. 13a (emphasis added). That rationale, however, indefensibly transforms this Court's determination in *Medtronic* that the 510(k) process imposes *no federal design "requirements"* into a holding that the 510(k) process imposes *no federal "requirements" at all*. See 518 U.S. at 493-494. The Third Circuit's logic also should be rejected because it would lead to ridiculous results. For example, Section 510(k) plainly 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). Yet if Section 510(k) imposes no requirements at all, then the MDA would not preempt a state law that instead required a medical device to be "exactly identical" to a pre-1976 device before it could be marketed.

obligation, under state law, to disclose to the FDA that AcroMed subjectively desired or hoped that the bone screws, plates, rods, and hooks of the VSP and ISOLA Systems — although labeled for use only in bones other than the spine — would be used by physicians for spinal fixation. According to plaintiffs, if Buckman had disclosed this "true" subjective intent as it was required to do, the FDA would have refused to clear the 510(k) submissions and the VSP and ISOLA devices would not have been permitted onto the market. J.A. 21.

Federal law, in contrast, does *not* impose any requirement that a 510(k) submission disclose how a manufacturer subjectively intends that a device will be used, because subjective intent is irrelevant under the MDA. The FDA's regulatory authority extends *only* to the labeling and marketing of devices in interstate commerce and not to the practice of medicine (including off-label uses of approved drugs and devices). See 21 U.S.C. §§ 331(a), 396; 37 Fed. Reg. 16503, 16503 (1972) (objective of FDCA is "is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof," and regulatory authority does not extend to physicians' off-label use); *Pedicle Screws*, 24 FED. MED. BULL. 10 (May 1994) (noting that "pedicle screws may not be marketed" for spinal fixation because that indication for the devices has not yet been cleared by the FDA). So long as a device's labeling and a manufacturer's marketing refer only to cleared uses, the manufacturer has complied with the federal statute even if it hopes (as would any rational manufacturer) that physicians engage in off-label uses. See Nightingale, 26 DRUG INFO. J. at 141-143 (FDA Assoc. Comm'r for Health Affairs).

Under the 510(k) clearance process, the manufacturer determines the "intended use" for which it seeks FDA authorization to label and market a device. *That* use — not the use or uses for which the manufacturer hopes that physicians will employ the device — is what must be disclosed to the FDA and evaluated for "substantial equivalence" under Section 510(k). By imposing liability for

Buckman's failure to tell the FDA about AcroMed's *subjective* intent regarding its devices' use, state law would establish a disclosure requirement materially "different from, and in addition to" the requirements of federal law.

a. The statutory text strongly confirms our understanding of the scope of the federal disclosure requirement. In its current form, the MDA expressly provides that the "intended use" of a device in the 510(k) context is the use designated by the manufacturer in its submission to the FDA. The statute provides that "[a]ny determination by the Secretary of the intended use of a device," for purposes of determining whether the device is "substantially equivalent" to a pre-1976 device, "shall be based upon the proposed labeling" in the 510(k) submission. 21 U.S.C. § 360c(i)(1)(E)(i); see also S. REP. NO. 105-43, at 27 (1997) ("For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use."). The FDA may require a warning statement on the device's label against foreseeable uses that are potentially harmful — just as it did here, in requiring the statement "WARNING — THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION" to be included on labeling of the iliac screw that was part of the ISOLA System, see J.A. 19 — but it may not require the manufacturer to list those uses in its 510(k) submissions. See 21 U.S.C. § 360c(i)(1)(E)(i); S. REP. NO. 105-43, at 27.

Although this express statutory limitation of "intended use" postdates Buckman's 510(k) submissions, both Congress and the FDA have made clear that it corresponds to the original intent of Congress about how Section 510(k) should be applied. The committee report accompanying the clarifying amendment explains that it conforms to Congress's understanding of statutory requirements in enacting the MDA in 1976. See S. REP. NO. 105-43, at 27. The FDA has similarly noted that the statutory requirement that "intended use" for Section 510(k) be determined by the use listed in proposed labeling "is not different from the manner in which 510(k)s have traditionally been reviewed." U.S. Dep't of Health &

Human Servs., Food & Drug Admin., Office of Device Evaluation, Center for Devices and Radiological Health, *Determination of Intended Use for 510(k) Devices — Guidance for Industry and CDRH Staff* 1 (Jan. 30, 1998); cf. 21 U.S.C. § 360c(a)(2)(B) ("safety and effectiveness of a device are to be determined * * * with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id.* § 355(d)(1).

b. Prior FDA pronouncements and applications of the statute are consistent with the principle that the intended use of a device for 510(k) purposes is determined by labeling claims rather than by the manufacturer's subjective intent. Thus, an FDA official explained in 1989 that determining whether the "intended use" of a device is substantially equivalent to that of a predicate device is established by asking whether the new device has the "Same Indication Statements" as the pre-1976 device. Callahan, *The Process of FDA Approval of a Spinal Implant: Governmental Perspective*, 2 J. SPINAL DISORDERS 288, 289 (1989); accord Center for Devices and Radiological Health, Food & Drug Admin., Premarket Notification Review Program, 510(k) Memorandum #86-3 (June 30, 1986) (reprinted at <http:/www.fda.gov/cdrh/k863.html>). "When the FDA approves products," the agency official noted, "it does so on a device-by-device basis *for specific intended uses* and not in general terms, e.g., pedicle spinal fixation systems." Callahan, 2 J. SPINAL DISORDERS at 290 (emphasis added); see also, *e.g.*, 57 Fed. Reg. 18062, 18063 (1992) ("[i]n determining whether the new device has the same intended use as a predicate device" under Section 510(k), FDA assesses "any differences in *indications for use* in terms of the safety and effectiveness questions they may raise" (emphasis added)); 63 Fed. Reg. 64556, 64560 (1998) (noting that new "intended use" is created when device previously marketed for general use is labeled for use on specific body part).

Indeed, the FDA regulation governing device labeling expressly provides that "intended use" "refer[s] to the *objective intent*

of the persons legally responsible for the labeling of devices," as manifested by "labeling claims, advertising matter, or oral or written statements." 21 C.F.R. § 801.4.[3] Although a manufacturer may be required to include warnings in its labeling informing customers of dangerous off-label uses, see *ibid.*, there is *no* FDA requirement that a manufacturer seek FDA clearance for all foreseeable uses by listing them in its 510(k) submission.

c. Determining substantial equivalence under 510(k) by reference to a manufacturer's subjective intent is also difficult to reconcile with the nature of the 510(k) process itself. The substantial equivalence inquiry under 510(k) is necessarily comparative in nature: the 510(k) device must "ha[ve] the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A); see also 21 C.F.R. § 807.100(b)(1). But the FDA would have no way of knowing how the manufacturer of a predicate device subjectively intended for it to be used prior to 1976 (or for that matter what the manufacturer's subjective intent is today, because the FDA does not require manufacturers to seek clearance of new off-label uses for devices that are already on the market).[4] Accordingly, the intended use of the predicate device must necessarily be judged by its *labeling claims*. Under plaintiffs' theory, the FDA would have to apply one standard of "intended use" to the predicate device and another,

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[3] By its terms, the definition of "intended use" in Section 801.4 does not apply to 510(k) premarket notifications. Compare 21 C.F.R. § 801.4 (defining "intended uses" and similar words "in §§ 801.5, 801.119, and 801.122"), with *id.* § 807.87 (governing information required in a premarket notification submission, including "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use"). Nonetheless, Section 801.4 confirms that "intended use" in the MDA does not refer to a manufacturer's subjective intent.

[4] The FDA's longstanding position has been that "the decision about whether or not, and when" to apply for approval of off-label uses is the manufacturer's alone to make. Nightingale, 26 DRUG. INFO. J. at 142.

quite different standard to the device for which 510(k) clearance is being sought. There is no basis for such an anomalous result.

d. Plaintiffs' subjective standard also undermines the basic purpose underlying Section 510(k), which is to ensure that pre-1976 devices are not insulated from competition by later market entrants. Plaintiffs' definition of intended use would mandate rejection of new devices based on vague notions of subjective intent. That, in turn, would have the effect of impeding competition even where the proposed 510(k) device has the same labeling claim as a predicate, pre-1976 device to which the proposed device is substantially equivalent. There is no reason to think that Congress meant to enhance competition only where manufacturers of 510(k) devices have no subjective hope, desire, or expectation that their devices, once cleared, might be used by physicians for some off-label use.

e. Finally, plaintiffs' definition of intended use would be wholly unworkable in practice. Plaintiffs have not explained, for example, *whose* subjective intent would have to be disclosed to the FDA. If a corporate director intended one use for a device, while the marketing director intended another, which would be subject to mandatory disclosure to the FDA and govern the substantial equivalence inquiry? Cf. 21 C.F.R. § 801.4 (defining intended use for labeling purposes as "objective intent of *persons* legally responsible for the labeling of devices" (emphasis added)). What if corporate officials intended primarily that the device would be used in a well-established manner, but hoped for eventual acceptance of a now-experimental methodology? Would it make any difference if the company's subjective intent changed between the time it filed the 510(k) notification and the FDA's clearance of the device for marketing? These questions demonstrate why 510(k) disclosure requirements focus on how a device will be labeled and do not extend to a manufacturer's subjective intent or hope about how a device might be used.

B. The State "Requirements" Underlying Plaintiffs' Claim Qualify For Express Preemption Under *Medtronic*

Section 360k(a) covers "any [state or local] requirement" that "relates" either "to the safety or effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device." There can be no doubt that the state requirements in this case "relate" to safety and effectiveness concerns. They also plainly relate to a "matter" that is "included in" a counterpart federal requirement — disclosures concerning the device's "intended use." See 21 C.F.R. § 807.87(e) (1986, 1999). The state "requirement" in this case accordingly comes within the plain language of the MDA's express preemption clause.

The FDA, however, has taken the position that Section 360k(a)'s broad reference to "*any* requirement" should be interpreted as meaning "any *specific* requirement." See 21 C.F.R. § 808.1(d). In *Medtronic*, a majority of this Court appeared to endorse the FDA's "specificity" gloss on the statutory text. Compare 518 U.S. at 500, 506-507, with *id*. at 512 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part) ("The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists."). Whether *Medtronic*'s *actual holding* turned on the absence of specificity in the *state* requirements involved in that case is not altogether clear for at least two reasons.

First, the same majority that appeared to endorse "specificity" in *Medtronic* elsewhere declared: "[W]e do not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted." 518 U.S. at 500. That statement, of course, reflects a *rejection* of the idea that requirements under Section 360k(a) are preempted or preemptive only if they are "specific."

Second, the overriding focus of Justice Breyer's tie-breaking opinion was almost exclusively on the pertinent *federal* (as opposed to the *state*) requirements. 518 U.S. at 507 (Breyer, J.) ("Insofar as there are any applicable *FDA requirements here,* those requirements, even if numerous, *are not 'specific' in any relevant sense*." (emphasis added)). Since Justice Breyer's resolution of the case turned on the character of the *federal* requirements at issue, which he concluded were too general to trigger preemption, he had no occasion to resolve whether express preemption under the MDA also requires specificity on the *state* side. Accord *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir.) ("Although Justice Breyer joined in Section V [of Justice Stevens' opinion], * * * it is clear enough that the Court found no preemption of the common-law claims largely because the pacemaker was not subject to any device-specific FDA regulations."), cert. denied, 522 U.S. 862 (1997).

In any event, the state requirements underlying plaintiffs' claim satisfy any "specificity" gloss that might apply. In sharp contrast to *Medtronic*, where "the precise contours of [plaintiffs'] theory of recovery" had "not yet been defined" (518 U.S. at 495), plaintiffs' "fraud on the agency" claim has been set forth in minute detail in their complaint (see J.A. 13-21), as required by Fed. R. Civ. P. 9(b). Plaintiffs allege that Buckman and AcroMed should have made specific disclosures to the FDA in connection with the 510(k) submissions they made for the components of the VSP device and ISOLA Systems. In particular, plaintiffs claim that Buckman was required to state precisely that AcroMed had a subjective desire or intent that each of these devices would be used by physicians in spinal applications. That claim is just as "specific" as Justice Breyer's example of a claim based on the manufacturer's failure to use a 1-inch wire. Indeed, a more precise formulation of the "liability-creating premises" of a plaintiff's "state-law tort suit" (518 U.S. at 508 (Breyer, J.)) is difficult to imagine. See *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998).

The state laws underlying plaintiffs' claim have also been applied with specificity to each of the AcroMed devices, thus satisfying the "specificity" concept expressed in the FDA's regulation, 21 C.F.R. § 808.1(d)(1). At some point in the course of litigation, the general duties that are the basis of a plaintiff's tort claim become applied with specificity to a particular product that is at issue in the lawsuit. As the United States recognized in its brief at the petition stage, when that occurs "a specific duty of care" is "made applicable to a device through a State's common law of torts," and that duty gives rise to a "requirement" within the meaning of the MDA's express preemption clause. U.S. Br. 10 n.4. That plainly has occurred in this case. Plaintiffs' claim thus imposes state-law requirements that are "specific" in every relevant sense.

The Third Circuit was accordingly wrong to conclude that "[b]ased on *Lohr* * * * there is no * * * state 'requirement' 'with respect to'" AcroMed's medical devices. Pet. App. 13a. To the extent that the court of appeals read *Medtronic* as shielding all common law claims "of general applicability" from express preemption, it simply misread the case.

C. The Counterpart Federal "Requirements" Involved In This Case Trigger Express Preemption Under *Medtronic*

The federal disclosure requirements at issue in this case are derived from FDA regulations in effect at the time Buckman submitted 510(k) notifications for the devices comprising the VSP and ISOLA Systems. Those regulations, which remain in force today, mandated the disclosure for proposed 510(k) devices of "the following information: * * * (e) Proposed labels, labeling, and advertisements s*ufficient to describe* the device, *its intended use*, and the directions for its use." 21 C.F.R. § 807.87(e) (1986, 1989) (emphasis added). The FDA's regulations also required regulated entities to supply "[a]ny additional information regarding the device requested by the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution." 21 C.F.R. § 807.87(h) (1986, 1989).

Buckman complied with the standard disclosure requirements by submitting detailed information about the screws, plates, hooks and rods of the VSP and ISOLA Systems (and the pre-1976 devices to which those devices were substantially equivalent) in its 510(k) submissions. See J.A. 48-51, 54-57. These submissions included information about each device's intended use. See J.A. 51, 57. Moreover, according to plaintiffs' own complaint, the FDA informed Buckman, following the submission of AcroMed's 510(k) notifications relating to the VSP System, that there was a "need for a more definitive statement covering the intended 'indications for use' of the AcroMed Nested Bone Plate." J.A. 15-16, 57-58. Buckman sent a letter in response to this agency demand for more information, stating (J.A. 58):

> The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for the purpose of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

It is beyond dispute that all of these disclosures were *required* by federal law.[5]

In addition, the federal disclosure requirements imposed on Buckman in this case were "specific" in every relevant sense. See

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[5] In its cursory comparison of the state and federal requirements at issue, the Third Circuit misidentified the pertinent federal requirements as those imposed by 18 U.S.C. § 1001 and 21 C.F.R. § 807.87(j), which "make[ ] it a crime to make a fraudulent statement to a federal agency and * * * require[ ] every premarket notification to contain a statement that the information contained therein is believed to be truthful." Pet. App. 13a. The Third Circuit's reliance on 21 C.F.R. § 807.87(j) is especially puzzling, because that provision did not even exist at the time that the pertinent 510(k) submissions were made in 1985 and 1988.

21 C.F.R. § 808.1(d). The FDA's regulation requiring disclosure of a device's intended use in any 510(k) submission (21 C.F.R. § 807.87(e) (1986, 1989)) was applied with particularity to each of the AcroMed devices. Moreover, the FDA regulation requiring the disclosure of information specifically requested by the agency (21 C.F.R. § 807.87(h) (1986)) was applied to the AcroMed Nested Bone Plate when the agency demanded more detailed disclosures about that device. These federal disclosure requirements narrowly and specifically focused upon "intended use" disclosures concerning *these particular devices*. And, in response to these federal requirements, Buckman and AcroMed made detailed and particularized statements about the intended use of the individual devices — again, disclosures *required* by federal law. The applicable federal requirements, in short, were "specific" in their content as well as in their application to *these* devices. See 21 C.F.R. § 808.1(d) ("State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other *specific* requirements applicable to *a particula*r device under the act * * *." (emphasis added)). They plainly trigger preemption under Section 360k(a).

This case presents an especially strong one for preemption because of the active role played by the FDA in requiring Buckman to make disclosures about the "intended use" of the AcroMed devices. It is undisputed that the FDA met with Buckman and AcroMed in December 1985 specifically to discuss the "intended use" of the VSP System. It is also undisputed that after Buckman submitted the 510(k) notifications for the VSP, the FDA reviewed those submissions and requested a more detailed disclosure, which was provided. With respect to the ISOLA System, moreover, plaintiffs allege that FDA officials engaged Buckman in discussions about whether the various 510(k) devices could be combined into a single 510(k) submission. J.A. 18. Plaintiffs also allege that the FDA, in authorizing the marketing of the iliac screw, imposed a specific warning requirement that plainly indicated an awareness of the possibility that some physicians might use the screw in pedicle applications. J.A. 19.

Thus, unlike in *Medtronic*, where the Court found that federal labeling and good manufacturing practices (GMP) requirements that applied generally to all medical devices did not trigger preemption, this is

> a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved * * *, and implemented that conclusion via a specific mandate on [the] manufacturer[].

518 U.S. at 501.[6]

In sum, through the 510(k) clearance process, FDA officials applied the "intended use" disclosure requirements with particularity to the *specific* AcroMed devices involved in this case in a manner that produced *specific* disclosures. Thus, even as construed in *Medtronic*, Section 360k(a) plainly preempts plaintiffs' "fraud on the agency" claim.

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[6] The federal labeling regulations at issue in *Medtronic* also are distinguishable because they apply, "with a few limited exceptions," to "every medical device." 518 U.S. at 497; see also *ibid*. (noting broad applicability of GMPs). In contrast, the FDA's disclosure requirements involved in this case are limited to devices for which 510(k) clearance is sought. The FDA has acknowledged that "specific FDA requirements applicable to a particular device *or class of devices*" trigger express preemption under the MDA. 43 Fed. Reg. 18661, 18662 (1978) (emphasis added); see also *id*. at 18664 (federal requirements that apply to PMA devices trigger express preemption); 45 Fed. Reg. 67321, 67322 (1980) (federal GMP regulations trigger preemption under the MDA).

II. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS IMPLIEDLY PREEMPTED BECAUSE IT IS FLATLY INCONSISTENT WITH THE FEDERAL REGULATORY SCHEME

The only basis for plaintiffs' claim against Buckman is that the FDA should not have cleared AcroMed's devices for sale under Section 510(k). Plaintiffs do not contend that Buckman is liable because the devices were defectively designed or manufactured; as a consultant to AcroMed, involved solely in the regulatory process, Buckman had nothing to do with device design or manufacture. Nor do plaintiffs contend that Buckman is liable because the devices were marketed for an unapproved use, undoubtedly because Buckman had no involvement in marketing. Plaintiffs assert, instead, that Buckman fraudulently misrepresented the intended use of AcroMed's devices in its submissions and statements to the FDA and that, but for this fraud, "the FDA would not have issued 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and [individual plaintiffs] would not have been exposed to the dangerous device[s] which [were] surgically implanted" in their spines. J.A. 21. Plaintiffs' injuries thus derive entirely from the FDA's decision to allow AcroMed's devices to be marketed; that is the sole error they challenge here.

Plaintiffs' attack on the FDA's decisional process intrudes on an area "so 'intimately blended and intertwined with responsibilities of the national government' that its nature alone raises an inference of exclusion" of state law. *Bethlehem Steel Co.* v. *New York State Labor Relations Bd.*, 330 U.S. 767, 772 (1947) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 66 (1941)); see also *United States* v. *Locke*, 120 S. Ct. 1135, 1147 (2000); *Boyle* v. *United Technologies Corp.*, 487 U.S. 500, 507 (1988). The basic premise of plaintiffs' claim is that the States must oversee (and occasionally override) federal agencies' decisions to ensure faithful execution of the agencies' duties. Yet the relationship between a federal agency and the entities it regulates is a matter solely of

federal concern, governed solely by federal law. The terms of the interaction between a federal agency and regulated entities — including what the entities must disclose to the agency and how those disclosures must be made — are determined entirely by agency-set and agency-enforced rules and requirements. And because it is interests protected by the federal agency that are at stake, the agency is best able to vindicate those interests when its rules and requirements are violated. See Pet. App. 50a (FDA "is in the best position to decide whether [a manufacturer] withheld material information from the agency and, if so, the appropriate sanction" (citation and quotation marks omitted)). The States have *no* role in policing this area.[7]

Predictably, then, state "fraud on the agency" claims would have substantial adverse effects on federal law and policy. If permitted, plaintiffs' claim would undermine the validity and finality of agency decisions and threaten the interests that underlie those decisions; conflict with Congress's intent that the MDA be administered exclusively by the FDA and with the FDA's own claim of primary jurisdiction over regulated matters; contravene the FDA's decision to permit AcroMed to market its devices notwithstanding plaintiffs' allegations of fraud; and interfere substantially with FDA operations by encouraging regulated entities to flood the agency with unwanted information and by embroiling the agency and its employees in private litigation. Thus, regardless of whether plaintiffs' "fraud on the agency" claim is expressly preempted, it is impliedly preempted because it would "actually conflict" with federal law (*Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982)) and would "stand[

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[7] The uniquely federal interests at stake render inapplicable the "presumption against preemption of areas traditionally occupied by state law," on which the court below relied. See Pet. App. 18a. There is *no* tradition of State oversight of compliance with federal regulations governing submissions to federal agencies (or, indeed, with any other regulations governing the relationship between federal agencies and regulated parties). In fact, plaintiffs' "fraud on the agency" claim *would not even exist* but for federal law.

as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995) (citation and quotation marks omitted); see *Geier*, 120 S. Ct. at 1922; *Boggs* v. *Boggs*, 520 U.S. 833, 841 (1997).

A. "Fraud On The Agency" Claims Conflict With Federal Agencies' Interest In Valid, Final, And Correct Decisionmaking

1. Our federalist system rests on the principle that "[a] state court may not decline to give effect" to a valid decision of the federal government. U.S. Br. 16 (petition stage). As the Solicitor General has observed, a federal agency's decisions "should generally be questioned or set aside, if at all, only by the federal government itself." *Ibid*.

"Fraud on the agency" claims contravene this basic principle. To prevail on their claim, plaintiffs must obtain a determination under *state law* that AcroMed's devices are illegally on the market, even though the FDA has conclusively determined, under *federal law*, that they should be on the market. States lack this "virtual power of review" over federal agency decisions. *Leslie Miller, Inc.* v. *Arkansas*, 352 U.S. 187, 190 (1956); see *Bethlehem Steel*, 330 U.S. at 775-776. It is difficult to imagine a greater conflict between state and federal law.

2. In addition to its interest in the validity of its own decisions, the federal government has a "significant interest in the[ir] *finality*." U.S. Br. 16 (petition stage) (emphasis added). If plaintiffs and similarly situated litigants were permitted to pursue "fraud on the agency" claims, "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* v. *Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), cert. dismissed, 523 U.S. 1113 (1998). Binding federal decisions should not be vulnerable to state-law collateral attacks brought years or even decades later.

3. "Fraud on the agency" claims require a judge or jury, applying state law, to decide (1) the scope of the federal duty involved; (2) whether that duty was met; and (3) if not, what the federal agency would have done had it been met. Permitting courts to engage in this inquiry under state law — in particular, determining what a federal agency would have done under different circumstances — creates an unacceptable potential for conflict with the agency's own assessment of federal interests.

A judge or jury asked to guess what an agency would have done in a particular factual scenario would have to speculate about the agency's likely rationale and the relative weight that would be given to different decisional factors — all without the benefit of agency expertise. In many cases, the jury would arrive at decisions at odds with the decision the agency itself would have reached. A jury applying state law might conclude, for example, that a particular device as to which certain disclosures were not made should not have been allowed on the market, whereas the FDA might have determined that the nondisclosures were not material or that, despite the violation, the public health required that the device be available. This unacceptable risk of conflict with federal interests is endemic to state-law claims based on speculation about what a federal agency would have done under different circumstances.

B. "Fraud On The Agency" Claims Conflict With The MDA Statutory Scheme

1. State second-guessing of FDA decisions is particularly troubling under the regulatory regime at issue in this case. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of *exclusive* authority to the FDA.

Permitting state review and nullification of FDA enforcement decisions runs roughshod over this carefully calibrated enforcement scheme.

The FDA is expressly charged with determining when and how to enforce the Food, Drug and Cosmetic Act, including the MDA. See 21 U.S.C. §§ 371(a), (h), 393; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). The FDA has exercised this authority by taking "primary jurisdiction" over all "issues within its statutory mandate," including the decision "whether a device that is marketed for the first time after May 28, 1976, is substantially equivalent to a previously marketed device." 21 C.F.R. § 10.25(b); 41 Fed. Reg. 37457, 37459 (1976); see also H.R. REP. NO. 94-853, at 13. The FDA's domain extends not only to the "initial determination" of these issues, but also to previous decisions that "the agency conclude[s] should be reconsidered." 21 C.F.R. § 10.25(b).

The FDA's enforcement authority is marked by "complete discretion" in responding to statutory or regulatory violations. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985); see also 21 U.S.C. § 336 (FDA need not seek sanctions for minor violations of FDCA where it "believes that the public interest will be adequately served by a suitable written notice or warning"). Although the FDA typically withdraws clearance of a device upon learning that it was obtained through fraud or misrepresentation, the agency may choose not to overturn its prior decision if, in its view, public health or other considerations support another course of action. See 56 Fed. Reg. 46191, 46192-46194, 46197 (1991); 55 Fed. Reg. 52323, 52324 (1990).

The broad enforcement discretion given to the FDA is combined with an express exclusion of other would-be litigants. Thus, unlike under the securities law, the antitrust laws, and many other federal regulatory schemes, there is no express or implied private right of action under the FDCA. See *Medtronic*, 518 U.S. at 487. To the contrary, "all * * * proceedings for the enforcement, or to restrain violations, of [Title 21, Chapter 9] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although States

are expressly permitted to enforce a small set of provisions (not including Section 510(k)), they may do so only after giving advance notice to the FDA so that the agency can decide whether to bring its own enforcement action or to intervene in the state proceedings. 21 U.S.C. § 337(b). The only mechanism for individual enforcement of the MDA is a citizen petition to the FDA. 21 C.F.R. §§ 10.25(a), 10.30(e).

Plaintiffs' "fraud on the FDA" claim cannot be reconciled with Congress's reservation of exclusive enforcement authority to the FDA or with the FDA's own claim of primary jurisdiction. As this Court recognized in *Merrell Dow Pharmaceuticals, Inc.* v. *Thompson*, 478 U.S. 804 (1986), in the absence of a private right of action to enforce a federal statute, it would "flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless * * * provide remedies for violations of that federal statute." *Id.* at 812. In fact, the effect of plaintiffs' "fraud on the agency" claim in this case "is exactly the same as it would be if a state court determined that an implied right of action was created by a federal statute." Sherman, *Use of Federal Statutes in State Negligence Per Se Actions*, 13 WHITTIER L. REV. 831, 890, 902 (1992).

By infringing on the FDA's exclusive authority to decide whether a device is substantially equivalent to a pre-1976 device and to respond to fraud or misrepresentation in the clearance process, and by asking a court to nullify an FDA decision under state law, plaintiffs' claim "interferes with the methods by which the [MDA] was designed" to be carry out Congress's goals. *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494-495 (1987); see also *Gade* v. *National Solid Wastes Management Ass'n*, 505 U.S. 88, 103-104 (1992) (plurality); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 211 (1985). The Supremacy Clause does not permit a court applying state law to "usurp[] a function that Congress has assigned to a federal regulatory body." *Arkansas-Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 580-582 (1981).

2. The Third Circuit recognized that there was no private right of action under the FDCA, but held that, under *Medtronic*, this

could not be a basis for implied preemption. See Pet. App. 15a. The court of appeals reasoned that the *Medtronic* plurality had "viewed Congress' failure to provide a federal remedy [under the FDCA] as persuasive evidence of an intent not to preempt common law liability for the same conduct." *Ibid.* Given the *Medtronic* plurality's conclusion that Section 360k(a) did not bar "'a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements,'" the court explained, "[r]efusing to entertain Buckman's fraudulent misrepresentation claim solely because the statutory scheme does not contain a private cause of action would be * * * contrary to [*Medtronic*'s] clear holding." Pet. App. 16a (quoting *Medtronic*, 518 U.S. at 495).

The Third Circuit's reasoning suffers from several fatal flaws. To begin with, the language quoted from *Medtronic* was concerned entirely with the applicability of *express* preemption of common law claims under 21 U.S.C. § 360k(a). This Court had no occasion in *Medtronic* to consider the consequences for *implied* preemption of Congress's decision to preclude a private right of action under the FDCA. Indeed, even the Justices who concluded that express preemption did not apply agreed that a common law claim might nonetheless be *impliedly* preempted because of its conflict with the federal regulatory scheme. 518 U.S. at 503, 508.

Moreover, and more important, *Medtronic* did not involve a "fraud on the agency" claim, which is qualitatively different from the routine product liability claims that were then before the Court. *Medtronic* upheld against preemption "a traditional damages remedy for violations of common-law duties," so long as those duties "parallel federal requirements." 518 U.S. at 495. Common law claims alleging liability for design defect or negligent manufacture — *i.e.*, claims like the ones in *Medtronic*, *id.* at 481 — are within the core of the State's police power. They rest on *state*-imposed duties of care, derived from *state* standards. They do not require a state judge or jury to evaluate the wisdom of the FDA's decision to grant marketing clearance under 510(k), and a judgment

in favor of the plaintiff would not reflect on the FDA's decisional process.

The claim at issue here is of a very different sort. It involves the FDA's enforcement of its requirements governing the federal regulatory process, an area of longstanding and exclusive *federal* authority. It seeks to impose liability for violation of a duty imposed by *federal*, not state, law. And the crux of the claim is a challenge to the propriety of an FDA clearance decision and the integrity of the FDA decisional process. In this sense, plaintiffs' "fraud on the agency" claim is similar to a claim challenging a device's 510(k) clearance on the grounds that the employee responsible for the decision was not hired in accord with FDA requirements. Like the FDA's compliance with its own internal hiring policies, Buckman's compliance with FDA regulatory requirements is an area of exclusively federal concern, properly policed by the agency itself and not by judges and juries applying the laws of the 50 States.

Congress's decision to centralize all FDCA enforcement authority in the FDA, and to preclude private rights of action to enforce the *federal statute*, might not be frustrated by allowing traditional *state law* claims, such as those involved in *Medtronic*, to proceed. But it is quite another matter to allow plaintiffs' "fraud on the agency" claim, which (while nominally based on state law) could not exist apart from the FDCA, which seeks to enforce requirements imposed by the FDCA, and which in essentially all respects is indistinguishable from a private cause of action under the FDCA.

3. The very purpose of the FDCA's exclusive enforcement scheme is to ensure consistency and uniformity of interpretation. As this case demonstrates, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner* v. *Teamsters Local Union No. 776*, 346 U.S. 485, 490-491 (1953). A judge or jury asked to reevaluate an FDA decision under state law may have to consider events going back years or even decades; with "regulatory and scientific approaches [changing]

over time," "[a]ctions or choices that may seem clear today may have been less obvious to the decision makers involved in the issues at the time decisions were being made." FOOD & DRUG ADMIN., REPORT OF THE HALCION TASK FORCE i (1996).

In this case, the potential inconsistency has become actual. Plaintiffs pursue a "fraud on the FDA" claim despite the fact that the FDA has already thoroughly considered their allegations of fraud *and concluded that AcroMed's devices should remain on the market*. As noted above (at 11-12), plaintiffs submitted lengthy comments in recent FDA proceedings to reclassify bone screws, in which plaintiffs raised each of their allegations of fraud against Buckman; after reviewing the evidence, the FDA nonetheless decided that — far from being removed from the market — bone screws should be subject to *less* regulation and labeled for use in the spine. "It is difficult to escape the conclusion that the [state] litigation [is] * * * an attempt by a disappointed [litigant] to gain from the [state] courts the relief it was denied by the [federal agency]," a result barred by the Supremacy Clause. *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324, 326-327 (1981); see also *Schneidewind* v. *ANR Pipeline Co.*, 485 U.S. 293, 310 (1988); *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953, 968-969 (1986).

4. The express preemption provision in the MDA, like those in many other statutes,[8] manifests Congress's intent to shield

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[8] Numerous federal regulatory statutes contain express preemption provisions similar or identical to Section 360k(a). *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.* § 1075(a); Electronic Product Radiation Control Act, 21 U.S.C. § 360ss; Federal Boat Safety Act, 46 U.S.C. § 4306. "Fraud on the agency" claims have been brought under many of these statutes as well. *E.g.*, *Lewis*, 107 F.3d at 1505; *Welchert* v. *American Cyanamid,* (continued...)

regulated entities against inconsistent state laws. Yet "[v]irtually any federal agency decision that stood in the way of a lawsuit could be challenged 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. "Congress could not have intended for the process it so carefully put in place" by adopting express preemption provisions "to be so easily and thoroughly undermined." *Ibid.*

Even unsuccessful claims of "fraud on the agency" impose tremendous burdens on regulated entities. Allegations of incomplete disclosure in the MDA context, for example, can trigger burdensome, intrusive, and expensive discovery into product development files, covering multi-year periods and evolving scientific evaluations of complex formulas and patient reactions. Often, such claims can be rejected only after a full trial. And of course, companies may be charged with "fraud on the agency" not just by disgruntled consumers but also by industry competitors. Suits such as these, which represent collateral attacks on agency decisions, cannot be reconciled with Congress's decision to preempt inconsistent state laws and to centralize all enforcement authority in the FDA.

C. "Fraud On The Agency" Claims Interfere Substantially With Federal Government Operations

Federal agencies are charged by statute with faithful execution of federal law — "getting the Government's work done." *Boyle*, 487 U.S. at 505. Permitting private litigants to pursue "fraud on the agency" claims would impede those agencies' ability to carry out their statutory and regulatory duties. Under the Supremacy Clause, States may not "interrupt the acts of the general government" in

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[8] (...continued)
Inc., 59 F.3d 69, 73 (8th Cir. 1995); *Papas* v. *Upjohn Co.*, 985 F.2d 516, 518-519 (11th Cir.), cert. denied, 510 U.S. 913 (1993).

this manner. *Johnson* v. *Maryland*, 254 U.S. 51, 55 (1920); see also *Mayo* v. *United States*, 319 U.S. 441, 445 (1943); *Arizona* v. *California*, 283 U.S. 423, 451 (1931); cf. *Howard* v. *Lyons*, 360 U.S. 593, 597 (1959) (refusing to apply state law that would interfere with the "effective functioning of the Federal Government"); *Hancock* v. *Train*, 426 U.S. 167, 178 (1976) (same).

In some instances, federal safety requirements might reasonably be viewed as "minimum" or "baseline" standards, to be supplemented by additional, more stringent requirements under state law. It is inconceivable, however, that Congress intended federal requirements governing interaction with a federal agency — such as requirements about what information must be submitted in a 510(k) application — to function as a "minimum" to be supplemented by state law. To the contrary, state "supplementation" under these circumstances is a recipe for chaos.

1. If courts applying state law, in the guise of deciding "fraud on the agency" claims, were permitted to interpret federal requirements governing 510(k) submissions, it is inevitable that they would disagree with the FDA and each other about what those requirements entail. Rather than run the risk of liability for "defrauding" the FDA by not submitting information that a court or jury might subsequently find material, manufacturers would seek to comply with the most expansive interpretation.

Thus, manufacturers would inundate the FDA with documentation that the agency itself does not require. Faced with this overload of information, neither the FDA nor consumers would be able to separate wheat from chaff, thus defeating the entire point of the regulatory scheme. And the deluge of paper would not stop with 510(k) clearance, because manufacturers would approach post-clearance reporting obligations[9] with the same incentive to flood the agency with information of uncertain and attenuated relevance.

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[9] *E.g.*, 21 U.S.C. §§ 360i, 360l, 360ll, 360nn; 21 C.F.R. Parts 803, 804, 806, 820 Subpart M, and 821.

Section 510(k) submissions, intended to be a quick and simple means to FDA clearance, would turn into mini-premarket approvals, and the FDA would be drowned in backlogged submissions.[10] The FDA, not state law, should control how much information is provided to the agency.

The threat of state-law liability for "fraud on the FDA" would have negative effects extending beyond this immediate context. As Judge Cowen noted in dissent (Pet. App. 29a-31a), manufacturers might well be reluctant to research and develop new off-label uses, since each such use would be potential evidence of a new "intended use" that, under plaintiffs' theory, should have been disclosed to the FDA and placed on the device's labeling regardless of its safety or efficacy. Even where off-label uses were known, device manufacturers would be loathe to disseminate information about them (by sending reprints of scientific articles in response to physician inquiries or otherwise), for fear that such communications would be taken as evidence of the manufacturer's "true" "intended use" for the device. As a result, physicians would make less informed treatment decisions or simply shy away from off-label uses. This outcome would not only impair the public health — for, as the FDA has recognized, off-label use of devices and drugs can be beneficial to patients, see page 4, *supra* — it would also thrust judges and juries into regulation of medical practice (*i.e.*, off-label use of devices) under the guise of "protecting" the FDA, even though the FDA itself is prohibited from regulating in this area. See 21 U.S.C. § 396; *More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 82 (1996) (William B. Schultz,

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[10] This outcome would not only burden the FDA, but also interfere with Congress's clear intent to streamline the regulatory process. In 1997 amendments to the MDA, Congress provided that manufacturers should be permitted to establish "substantial equivalence" under Section 510(k) by the "least burdensome means" possible. See 21 U.S.C. § 360c(i)(1)(D). The FDA has recently implemented regulatory reforms for the specific purpose of expediting clearance decisions. See 65 Fed. Reg. 44540 (2000).

FDA Deputy Comm'r); cf. *Arkansas-Louisiana Gas Co.*, 453 U.S. at 580 (holding that federal law preempts state breach-of-contract claim that "permit[s] a state court to do * * * what the [federal agency] itself may not do").

2. As noted above (at 33), "fraud on the agency" claims require proof of an agency's regulatory requirements, the applicant's failure to satisfy those requirements, and the way in which the agency would have acted differently in the absence of wrongdoing. In every case, the best source of evidence as to these factors — indeed, often the *only* source of credible evidence — would be the agency itself. Accordingly, if these claims were allowed to go forward, private litigants would routinely seek discovery from federal agencies and agency officials to shed light on these crucial issues.

Even if the discovery attempts were unsuccessful,[11] they would drain agency resources. The agency would be obliged to contest discovery requests and to litigate ensuing efforts to obtain compliance. And if the FDA ultimately were not required to provide the critical evidence, the result would be flawed decisionmaking and enormous harm to defendants charged unfairly with having defrauded the agency.

In at least some instances, moreover, discovery attempts would succeed, and federal agencies would become embroiled in private litigation. Government employees would be burdened with having to testify; relevant agency documents would have to be produced; internal deliberations and discussions would have to be revealed;

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[11] The Department of Justice has taken the position that federal employees cannot be forced to testify or produce records in private lawsuits with respect to their official duties. See, *e.g.*, 21 C.F.R. §§ 20.1, 20.2; see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951). Some courts have rejected this claim of blanket privilege to resist third-party discovery. *E.g.*, *Exxon Shipping Co.* v. *U.S. Dep't of Interior*, 34 F.3d 774, 778 (9th Cir. 1994); see also 26A C. WRIGHT & K. GRAHAM, FEDERAL PRACTICE & PROCEDURE § 5682, at 206 (1992).

and the agency's ability to obtain expert scientific and technical advice from private advisors would be diminished. See J.A. 31-33. As the Solicitor General observed at the petition stage, "[t]he prospect of such intrusive inquiries" would "pose a significant potential * * * for distorting [the agency's] decision-making processes." U.S. Br. 17.

This case presents a telling example of the way in which federal agencies would be burdened by private litigants pursuing "fraud on the agency" claims. Plaintiffs sought documents from the FDA covering 28 separate topics, including all premarket notifications submitted for spinal use of pedicle screws from January 1, 1993 onward; "[a]ll documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon"; "[a]ll documents reflecting, relating or referring to each 'predicate device' for which substantial equivalence was claimed in each of the relevant premarket notifications"; and "[a]ll documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications." J.A. 25-30. Plaintiffs also sought testimony from 14 FDA employees, including five "special" employees who comprised an advisory committee that reviewed pedicle screw systems. J.A. 25-26. The federal government sought a protective order, submitting evidence that special employees would be "hesitant to serve" on advisory panels if they could be subjected to depositions in private lawsuits. J.A. 25, 33, 34-35. Nonetheless, the district court allowed discovery to go forward against all but a single government employee. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at ¶ 2 (E.D. Pa. Aug. 21, 1995) (PTO 92).

The FDA's regulatory decisions about pedicle screws also fell subject to judicial monitoring and supervision as a result of this litigation. At the request of the district court, the FDA extended the period for filing public comments on the FDA's proposal to reclassify pedicle screws. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 1 (E.D. Pa. Jan. 2, 1996) (PTO 188). The FDA was ordered to turn over to plaintiffs its internal

files on an FDA-monitored study on pedicle screw safety, see *In re Orthopedic Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 2 (E.D. Pa. Oct. 16, 1995) (PTO 147), and ultimately to disclose information about the study sufficient to allow identification of participating physicians in breach of the agency's promise of confidentiality. See Pl. Mem. in Support of Pl. Mtn. for Order Requiring Disclosure of Additional Confidential Info. at 4-6, 18-24, Docket No. 1184, *In re Orthopedic Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. filed Dec. 6, 1995).

The interference that this litigation has caused with FDA operations is not aberrational. If state "fraud on the agency" claims were permitted to go forward, their predictable effect would be to swamp federal agencies with information they do not want and have not requested, and generally to interfere with agencies' abilities to carry out their mandated duties. The States have no power, under the Supremacy Clause, to impose these harmful effects on the federal regulatory process.

III. THE COURT SHOULD RECONSIDER ASPECTS OF *MEDTRONIC* THAT ERRONEOUSLY RESTRICT THE SCOPE OF EXPRESS PREEMPTION UNDER THE MDA

As we have explained, plaintiffs' "fraud on the FDA" claim is expressly preempted under Section 360k(a) and this Court's decision in *Medtronic*, as well as impliedly preempted by federal law. But if the Court disagrees with our preemption arguments under current law, it should take this opportunity to revisit and reconsider its conclusion in *Medtronic* that express preemption under Section 360k(a) applies only to "specific" requirements. See page 24, *supra*. With all due respect, the four dissenting Justices in *Medtronic* were correct when they observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (opinion of O'Connor, J.).

1. *Stare decisis* "is a principle of policy rather than an inexorable command." *Hohn* v. *United States*, 524 U.S. 236, 251 (1998) (citation and quotation marks omitted). Although the doctrine has more force in statutory cases, this Court has not hesitated to revise its construction of a statute when "a precedent may be a positive detriment to coherence and consistency in the law * * * because of inherent confusion created by an unworkable decision." *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 173 (1989); see also *Monell* v. *New York City Dep't of Soc. Servs.*, 436 U.S. 658, 695 (1978).

Experience has proven this Court's fractured decision in *Medtronic* to be just such a case. As demonstrated in the petition (at 14-16, 19-25), the lower courts have had tremendous difficulty understanding what the decision means and how it should be applied. See also *Wilson* v. *Bradlees of New England, Inc.*, 96 F.3d 552, 559 (1st Cir. 1996) (per Boudin, J.) (this Court's "divisions" in *Medtronic* "make even more general forecasts shaky"), cert. denied, 519 U.S. 1149 (1997). In this respect as well, the *Medtronic* dissenters have turned out to be correct. See 518 U.S. at 509 (opinion of O'Connor, J.) (describing majority's analysis as "bewildering").

The problem lies not just in understanding how the three separate opinions interact to dispose of the issues before the Court (although that has been difficult enough for the lower courts). See Pet. 19-25. It also lies in the hopelessly ambiguous concept of "specificity" itself, which could refer either to the *content* of a requirement (as in Justice Breyer's 2-inch wire, which is "specific" when compared to a more generalized duty to use care in the design of a product) or to a requirement's *applicability* to more than a single device, a single class of devices, or to products in addition to medical devices. As the United States acknowledged at the petition stage (U.S. Br. 10 n.4), even a requirement that is general in content or that applies broadly to products other than medical devices can (and usually does) become "specific" over the course of litigation as the plaintiff develops his precise theory of

liability and as general duties are applied to the individual device at issue.

2. This aspect of *Medtronic* should also be revisited because it rests on an erroneous premise. In adopting the "specificity" requirement as a gloss on Section 360k(a), the majority reasoned that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability." 518 U.S. at 499-500. In fact, the FDA has repeatedly treated state requirements that are *not* "specific" — because they are not limited to a single medical device, class of medical devices or even to medical devices in general, or because they are general in content — as eligible for exemption from express preemption. Perhaps the best example of the former is California's Sherman Food, Drug and Cosmetic Law, which contains numerous provisions that are couched in general terms and/or pertain to drugs as well as to medical devices — provisions that the FDA has considered for exemption under Section 360k(b). See 44 Fed. Reg. 19440 (1979); 21 C.F.R. § 808.55(b)(1).[12]

In addition, as noted above (see note 6, *supra*), the FDA has taken the position in regulatory notices, as well as in its brief in *Medtronic* (Nos. 95-754 and 95-886 U.S. Br. 24-25 & nn.19-20), that the federal GMP requirements trigger express preemption and that state GMP regulations are susceptible to express preemption. Indeed, the FDA has indicated that if California — which in passing the Sherman Law "adopt[ed] the FDA GMP regulations as its own" — either "interprets or applies the GMP regulations in

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[12] For example, the FDA has determined that Section 360k(a) preempts a California provision that makes it unlawful "for any person to *advertise* any *drug or* device *represented to have any effect* in any of the following conditions, disorders, or diseases: * * * (m) [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." 21 CAL. HEALTH & SAFETY CODE § 26463(m) (1984) (emphasis added). According to the FDA, this provision is preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); 45 Fed. Reg. at 67322.

such a way as to make them different from or in addition to the Federal regulations, then the California requirements *will be preempted to that extent*." 45 Fed. Reg. 67321, 67322 (1980) (emphasis added). That plainly indicates that state and federal "requirements" that are expressed generally and that apply to a wide array of medical devices as well as other products fall within the scope of Section 360k(a).

It is no small irony, then, that a majority in *Medtronic* — relying principally on deference to the FDA — held that the federal GMPs do not impose "requirements" that are sufficiently "specific" to trigger express preemption. 518 U.S. at 501. That holding is in fact contrary to the FDA's own longstanding position. For that reason as well, *Medtronic*'s endorsement of the specificity concept should be reconsidered. Deference, in other words, required the opposite result.

In fact, a close examination of the regulatory record indicates that the FDA's "specificity" concept never was intended to be a limitation on the type of *federal* requirements that trigger express preemption under Section 360k(a). Language in the pertinent regulation (21 C.F.R. § 808.1(d)) that was interpreted in *Medtronic* as recognizing a "specificity" limit merely stated that a *counterpart* federal requirement *must be in existence* before state requirements are preempted. See 43 Fed. Reg. 18661, 18662, 18664 (1978); 42 Fed. Reg. 30383, 30383-30384 (1977). In other words, the relevant FDA regulation, read against the backdrop of its regulatory history, was designed to ensure that there would not be a regulatory vacuum immediately after the MDA was passed, in which all state requirements relating to medical devices would be preempted (even before the FDA took any regulatory action to implement the MDA).

3. The final reason why the Court should abandon the "specificity" gloss is that it makes no sense. On the state side, why would Congress have meant to preempt "different" or "additional" state requirements imposed by laws that apply exclusively to medical devices, but to preserve the *very same requirements* if imposed by

laws that apply to other products as well? In either case, the impact on uniformity and the harm to the federal scheme is exactly the same. On the federal side, why would Congress have meant to disable the FDA from issuing a preemptive requirement in regulations that are applicable to all or many devices, but to allow the agency to preempt state law if it imposed exactly the same requirement in a thousand separate regulations, each applicable to a single device? There is simply no reason to attribute to Congress such an absurd design, which would empower States to avoid preemption through skillful drafting and would place formalistic restrictions on the FDA's power to issue preemptive requirements. And if "specificity" relates to the *content* (as opposed to the *applicability*) of state and federal requirements covered by Section 360k(a), how would a court determine when a requirement is "specific" enough to come within Section 360k(a)?

Not surprisingly, this Court has repeatedly rejected invitations to read similar limitations into other express preemption provisions. Illustrative is *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), which involved a provision of the Airline Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws specifically addressed to the airline industry are pre-empted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. [13] Such an interpretation, this Court noted,

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[13] Accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common law tort and contract causes of action); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed

(continued...)

would create "an *utterly irrational loophole*." *Ibid.* (emphasis added). That criticism applies with equal force to the interpretation of Section 360k(a). The Court should take this opportunity to eliminate this "utterly irrational loophole" from the law of express preemption under the MDA.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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[13] (...continued)
towards the governance of industrial relations.")