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 OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

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

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

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a Washington, D.C.-based nonprofit public interest law firm with supporters in all 50 states.[1] WLF devotes a significant portion of its resources to promoting economic liberty, free

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[1] Pursuant to S. Ct. R. 37.6, WLF hereby affirms that no counsel for either party authored any part of this brief, and that no person or entity, other than WLF, its supporters, and its counsel, made a monetary contribution to the preparation or submission of this brief.

enterprise principles, and a limited and accountable government.

To that end, WLF has appeared before this and other state and federal courts in cases involving preemption issues, seeking to point out the economic inefficiencies created when multiple levels of government seek simultaneously to regulate the same business activity. *See, e.g., Geier v. American Honda Motor Co.*, 120 S. Ct. 1913 (2000); *United States v. Locke*, 120 S. Ct. 1135 (2000); *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996). WLF is particularly concerned that the American economy suffers, and public safety or health can be jeopardized, when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that obstructs or frustrates the objectives or operation of specific federal regulatory regimes, such as the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA") at issue here.

WLF also believes that medical consumers are best served by the widest possible dissemination of truthful information about FDA-approved product, even when that truthful information relates to off-label uses of the products. WLF successfully challenged, on First Amendment grounds, FDA efforts to suppress dissemination of such information. *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF is concerned that if suits such as Respondent's are determined not to be preempted by federal law, manufacturers will be reluctant to employ methods permissible under federal law for disseminating such information.

WLF fully concurs with Petitioner's argument that Respondent's claims are impliedly preempted. WLF is filing separately in order to focus on arguments that those claims are also expressly preempted by virtue of 21 U.S.C. § 360k(a). In particular, WLF's brief focuses on the type of federal "requirement" that must be present in order for § 360k(a) preemption to apply.

WLF submits this brief in support of Petitioner with the written consent of all parties. Letters providing blanket consent to all *amicus curiae* briefs are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement contained in Petitioner's Brief.

In brief, this case involves state-law personal injury suits filed by numerous plaintiffs who claim to have suffered injury after having orthopedic bone screws implanted into the pedicles of their spines. Those suits were consolidated for pre-trial proceedings pursuant to the multi-district litigation statute, 28 U.S.C. § 1407. Many of the suits claim that one defendant, Petitioner Buckman Company ("Buckman"), induced the Food and Drug Administration ("FDA") to permit the marketing of the bone screws by means of a series of fraudulent misrepresentations. The suits claim that had Buckman not defrauded FDA, the bone screws never would have been marketed in this country, doctors would not have been able to use the bone screws in their surgery, and thus the plaintiffs never would have been injured.

Buckman is a regulatory consultant to medical device manufacturers; it was retained by AcroMed Corporation to act as its liaison with FDA in its attempt to secure marketing clearance for its orthopedic bone screw device, known as VSP, for which AcroMed sought approval for use in back surgery. Buckman initially was unsuccessful in its efforts to secure marketing clearance under the "§ 510(k)" process -- which permits marketing of medical devices shown to be substantially equivalent to a device already on the market when the MDA was adopted in 1976. In December 1985, Buckman altered its approach. It split the VSP into two components and filed a separate § 510(k) application for each component. In each application, a new "intended use" was specified: the applications sought approval for use of the two components in the long bones of the arms and legs rather than in the pedicles of the spine. Respondent Plaintiffs' Legal Committee, representing all plaintiffs in the multi-district litigation, claims that the December 1985 applications were fraudulent because Buckman and AcroMed intended that the two components be used *solely* in the pedicles of the spine. FDA approved the applications; Respondent contends that FDA would not have done so had it been aware of Buckman and AcroMed's actual intended use.

Buckman and other defendants sought judgment on the pleadings on all such "fraud on the FDA" claims on the ground that those claims were expressly preempted by § 521(a) of the MDA, 21 U.S.C. § 360k(a), which prohibits States from imposing "any requirement" "with respect to" a medical device which is "different from, or in addition to, any requirement applicable under [the FDCA] to the device." The district court granted the motion on March 2, 1995. Petition Appendix ("Pet. App.") 46a-53a. The court

held that "fraud on the FDA" claims were both expressly preempted by § 360k(a) and impliedly preempted by the entire federal enforcement scheme, which vests in FDA exclusive authority to prosecute violations of the MDA. *Id.* at 48a-50a.

The following year, this Court rendered its decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which addressed the scope of § 360k(a). Respondent thereafter asked the district court to reconsider its March 2, 1995 dismissal order in light of *Medtronic*. On March 28, 1997, the district court reaffirmed the dismissal. Pet. App. 33a-44a. While acknowledging that *Medtronic* had undercut a portion of its analysis, the court adhered to its view that "fraud on the FDA" claims had been impliedly precluded by Congress when it decided not to provide for a private right of action to enforce the MDA. *Id.* at 40a. Because the "fraud on the FDA" claim was Respondent's only claim against Buckman, the district court entered final judgment for Buckman, and Respondent appealed therefrom.

The Third Circuit reversed by a 2-1 vote. Pet. App. 1a-32a. The appeals court held that § 360k(a) was inapplicable to "fraud on the FDA" claims because the § 510(k) approval process to which the AcroMed bone screws were subjected established no federal "requirement" "applicable to a device" and because Respondent's suit did not seek to impose a State "requirement" "with respect to" the bone screws. *Id.* at 13a. The appeals court also rejected Buckman's implied preemption claims, stating, "We see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA and preserving the right of people in the plaintiffs' position to bring common law fraudulent misrepresentation claims." *Id.* at 18a.

Judge Cowen dissented. *Id.* at 25a-32a. He noted that Respondent's claim was not dependent on a showing that the information Buckman or AcroMed submitted in order to demonstrate that the products were entitled to § 510(k) "long bone" marketing approval was false, or that they ever actually marketed bone screws for use in back surgery. *Id.* at 25a-26a. He stated that, under the majority's holding, the only basis for finding that Buckman/AcroMed committed fraud on the FDA was that they allegedly intended (*after* obtaining § 510(k) clearance) to violate FDA prohibitions on off-label promotion. *Id.* at 27a-28a. He charged that such a holding was equivalent to creating a private right of action to enforce those regulations -- even though Congress clearly did not intend to create such a right of action. *Id.* He also stated that the decision was likely to prevent doctors from obtaining valuable and potentially life-saving information about off-label uses of FDA-approved products. *Id.* at 28a-32a.

SUMMARY OF ARGUMENT

Respondent's "fraud on the FDA" claim is expressly preempted by § 360k(a). By its terms, § 360k(a) is applicable where: (1) there exists an applicable *federal* "requirement" of the type contemplated by § 360k(a)(1); (2) there exists a *State* "requirement" of the type contemplated by § 360k(a); and (3) the State "requirement" is "different from or in addition to" the applicable federal requirement. Buckman has demonstrated that all three of those conditions exist.

The Third Circuit's findings to the contrary were based on a misreading of *Medtronic*. The Third Circuit interpreted *Medtronic* as *mandating* that those three findings go against

Buckman. In fact, *Medtronic* took a much more nuanced approach and carefully considered the effect of § 360k(a) on each of the claims at issue there. Respondent's "fraud on the FDA" claim was not one of the causes of action in *Medtronic*. If one applies the approach taken in *Medtronic* to this case, one is compelled to conclude that the "fraud on the FDA" claim is expressively preempted by § 360k(a). Perhaps of greatest significance is that Respondent's cause of action, far from simply providing a parallel mechanism for disciplining those guilty of fraud, undermines the federal government's significant interest in the finality of its own administrative determinations.

Finally, WLF wishes to call the Court's attention to the history of FDA enforcement of § 360k(a). That history provides an explanation regarding how the "specific counterpart regulations" language worked its way into 21 C.F.R. § 808.1(d), an FDA regulation that purports to explain §360k(a). The history suggests that the Court gave § 808.1(d) an overly restrictive reading in *Medtronic*; the Court should take this opportunity to clear up any misunderstanding and to explain that § 808.1(d) does *not* impose strict limits on the types of federal "requirements" that can give rise to § 360k(a) preemption.

ARGUMENT

I. PREEMPTION OF STATE TORT LAW IS ULTIMATELY AN ISSUE OF CONGRESSIONAL INTENT, AND CONGRESS EXPRESSED AN INTENT TO PREEMPT STATE TORT LAW WHEN IT ADOPTED § 360k(a)

Whether the federal government has preempted an assertion of regulatory authority by state or local governments in a given instance is ultimately an issue of the intent of Congress and the operation of the Supremacy Clause. As the Court has repeatedly emphasized, "Pre-emption fundamentally is a question of congressional intent . . . ." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990). *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis") (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486-87 (1996) ("any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose.*'") (emphasis in original) (quoting *Cipollone*, 505 U.S. at 530 n.27 (opinion of Stevens, J.)).

In other words, it is the role of Congress, not a court, to define how broad or narrow a federal statute's preemptive reach should be. Of course, the courts look to a variety of sources[2] and employ a variety of interpretive techniques in

[2] "Congress' intent, or course, primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." *Medtronic*, 518 U.S. at 486 (quoting *Gade v. Nat'l* (continued...)

attempting to discern what Congress intended.[3] But once Congress's preemptive intent has been identified, it is not the role of the courts to construe preemption provisions broadly or narrowly. A court's "task in all pre-emption cases is to enforce the 'clear and manifest purpose of Congress.'" *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in the judgment) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Congress's intent to preempt state and local law may be explicitly stated in its statutory language or implicitly contained in the statute's structure or purpose. *Cipollone*, 505 U.S. at 516. State law is impliedly preempted if: (1) it actually conflicts with federal law; or (2) federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the

[2](...continued)
Solid Wastes Management Ass'n, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)).

[3] When the challenged State action is in a field that the States have traditionally occupied, such as "the historic police powers of the States," the Court generally has begun its analysis of congressional intent with the "assumption" that Congress would not seek to supplant the exercise of such traditional powers "unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485. That "presumption against preemption" has no place in this case, because States have not historically sought to regulate the relationship between the business community and federal regulatory agencies generally, or FDA in particular; that relationship has generally been governed principally or exclusively by federal law. *See United States v. Locke*, 120 S. Ct. 1135, 1147 (2000) ("an 'assumption' of nonpreemption is not triggered when the State regulates in an area where there has been a history of significant federal presence.").

States to supplement it." *Id.* (citations omitted). State law "actually conflicts" with federal law "*either* because compliance with both federal law and state regulations is a physical impossibility, *or* because the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California Fed. Sav. and Loan Ass'n v. Guerra,* 479 U.S. 272, 281 (1987) (emphasis added and internal quotations omitted).

WLF fully supports Buckman's argument that Respondent's "fraud on the FDA" claim is impliedly preempted because it stands as an obstacle to the accomplishment of the full purposes and objectives of Congress. WLF will not repeat those arguments here but will instead focus on Buckman's other argument: that the "fraud on the FDA" claim is expressly preempted under 21 U.S.C. § 360k(a).

II. THE COURT OF APPEALS' NARROW CONSTRUCTION OF § 360k(a) IS NOT WARRANTED BY EITHER THE STATUTORY LANGUAGE OR THIS COURT'S DECISION IN *MEDTRONIC*

The MDA contains the following preemption provision:

> **(a) General rule.** Except as provided in subsection (b), no 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 [the FDCA] 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 [the FDCA].
>
> **(b) Exempt Requirements.** Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if [certain conditions are met].

21 U.S.C. § 360k.

Purporting to follow *Medtronic*, the Third Circuit gave an extremely narrow reading to the preemption statute. By its terms, § 360k(a) is applicable only where: (1) there exists an applicable *federal* "requirement" of the type contemplated by § 360k(a)(1); (2) there exists a *State* "requirement" of the type contemplated by § 360k(a); and (3) the State "requirement" is "different from or in addition to" the applicable federal "requirement." Without even bothering to canvass the various candidates for an applicable federal "requirement," the appeals court dismissed out of hand Buckman's claim that § 360k(a) expressly preempted the "fraud on the FDA" claim:

> Based on [*Medtronic*], it is apparent that, within the meaning of § 360k, there is no federal "requirement" "applicable to the device" at issue here; nor is there a state "requirement" "with respect to" that device. Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001

makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful.

Pet. App. 13a.

The Third Circuit's analysis is unfaithful to the language of § 360k(a), to FDA's interpretation of that language, and to the holding of *Medtronic*. Even accepting fully every statement contained in *Medtronic* regarding the meaning of § 360k(a),[4] the Third Circuit misapplied each of the three principal elements of the preemption statute.[5]

A. There Exist Applicable Federal "Requirements" of the Type Contemplated by § 360k(a)(1)

The Third Circuit did not dispute that numerous federal anti-fraud requirements applied to Buckman's December 1985 § 510(k) submission to FDA or to any other § 510(k) submission. As set forth by the United States in its brief

[4] WLF respectfully suggests, as argued more fully below, that while *Medtronic* was correctly decided on its facts, some of the Court's language was based on an incomplete understanding of FDA's interpretation and historical application of § 360k(a).

[5] Section 360k(a)(2) also requires that the State requirement "relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." The Third Circuit did not contend that Buckman had failed to demonstrate that this requirement had been met, however, and Respondent did not raise the issue in its opposition to the certiorari petition.

supporting the grant of Buckman's certiorari petition, those requirements included:

- 18 U.S.C. § 1001 (prohibiting false or fraudulent statements on any matter within the jurisdiction of a federal agency);

- 21 C.F.R. 807.87(h) (1985) (requiring, during the period relevant here, that parties making § 510(k) submissions must provide FDA with "[a]ny additional information regarding the device requested by the Commissioner that is necessary for 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(k) (promulgated in 1992) (requiring each person submitting premarket notification to state that, "to the best of his or knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted").

U.S. Br. (June 7, 2000) at 12-13 n.5.[6]

The Third Circuit held, however, that those anti-fraud requirements were not federal "requirements" of the type contemplated by § 360k(a). Pet. App. 13a. It stated that that finding was compelled by *Medtronic*, which the appeals court interpreted as holding categorically that "[t]he § 510(k)

[6] Federal law also imposes detailed requirements regarding the required contents of a § 510(k) submission. *See, e.g.*, 21 U.S.C. § 360(k), 360e(b); 21 C.F.R. §§ 807.87 - 807.93.

process thus established no federal requirement 'applicable to a device' within the meaning of the MDA." *Id.* at 12a.

Medtronic held no such thing. *Medtronic* considered a manufacturer's assertion that § 360k(a) preempted defective design, defective manufacture, and defective labeling claims with respect to its medical device, which was being marketed pursuant to § 510(k) approval. The Court did *not* indicate that *no* medical devices being marketed pursuant to § 510(k) approval were subject to federal "requirements" of the type contemplated by § 360k(a). Rather, the Court carefully considered each of the plaintiff's claims in turn. *Medtronic*, Part V, 518 U.S. at 492-502.

With respect to defective design claims, the Court held that none of the § 510(k) requirements relied on by the manufacturer imposed any sort of minimum design safety standards. *Id.* at 492-93. While those requirements ensured that § 510(k) devices were substantially equivalent to (and no more dangerous than) pre-1976 devices, they did not (the Court held) provide assurance that the § 510(k) devices were actually safely designed because there is no statutory mechanism designed to assure that all pre-1976 FDA devices are safely designed. *Id.*

With respect to defective manufacture and labeling claims, the Court held that the requirements relied on by the manufacturer were too general in nature to qualify as federal "requirements" under § 360k(a). *Id.* at 497-502. The Court explained:

> The generality of those [federal manufacturing and labeling requirements] make this quite unlike 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 *in a particular case* or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 501 (emphasis added).[7]

Medtronic did not consider a "fraud on the FDA" claim of the type at issue here. Nonetheless, *Medtronic*'s rationale supports a finding that the anti-fraud requirements imposed on all § 510(k) applicants are federal "requirements" of the type contemplated by § 360k(a). Those requirements most definitely *are* intended to ensure nonfraudulent submissions -- unlike the design requirements at issue in *Medtronic*, which were intended to ensure equivalency, not design safety. Moreover, this is not a case in which FDA announced generally applicable requirements but never *specifically* applied them to the medical devices at issue (as was true of the manufacturing and labeling requirements at issue in *Medtronic*). Rather, FDA specifically examined Buckman's § 510(k) submissions and made a specific determination that the submission met FDA requirements (including FDA's anti-fraud requirements).

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[7] The Court was careful to add that it did "not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements." *Id.* at 500.

Surely, that is the type of FDA application of federal requirements to specific devices that § 360k(a) was "designed to protect from potentially contradictory state requirements." *Medtronic*, 518 U.S. at 501.

B. There Exist State "Requirement[s]" of the Type Contemplated by § 360k(a)

The Third Circuit did not dispute that State common-law suits in general, and suits alleging fraud in particular, can result in requirements being imposed on medical device manufacturers subject to such suits. The court concluded, however, that *Medtronic* mandated the conclusion that such suits never qualify as State "requirement[s]" within the contemplation of § 360k(a):

> "These state requirements [imposed by State common law] therefore escape preemption not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be `with respect to' specific devices such as pacemakers." [*Medtronic*, 518 U.S. at 502.] . . . Based on [*Medtronic*], it is apparent that, within the meaning of § 360k, there is no . . . state 'requirement' with respect to [the AcroMed] device.

Pet. App. 12a-13a.

The Third Circuit's conclusion that State common-law suits never qualify as State "requirements" within the meaning of § 360k(a) is a total misreading of *Medtronic*. To the contrary, five of the nine Justices stated explicitly that such suits would so qualify in a not-insignificant number of

cases. *Medtronic*, 518 U.S. at 510-11 (O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 503 (Breyer, J., concurring in part and concurring in the judgment) ("[T]he MDA will sometimes pre-empt a state-law tort suit. I basically agree with Justice O'CONNOR's discussion of this point and her conclusion.") The Court did not reach its no-preemption finding because State common-law suits never amount to State "requirements" within the meaning of § 360k(a), but because they were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.* at 501.

Any doubt on that score was laid to rest by the Court's recent decision in *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913 (2000). *Geier* held that State common- law suits challenging car makers' decisions not to install airbags in automobiles manufactured in the 1980s were impliedly preempted by the National Traffic and Motor Vehicle Safety Act of 1966 and regulations issued thereunder, even though such suits are merely a specific application of a generally applicable common-law duty not to sell defective products. *Id.* at 1928. Indeed, the Court on several occasions has invoked federal preemption statutes to find that State common-law suits do indeed impose "requirements" and thus are *expressly* preempted. *See, e.g., Cipollone,* 505 U.S. at 521, 522 (plurality); *id.* at 548-49 (Scalia, J., concurring in judgment in part and dissenting in part); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

In sum, the Third Circuit's holding that State common-law suits do not, because of their general applicability, constitute State "requirement[s]" within the meaning of

§ 360k(a) finds no support in any decision of this Court. To the contrary, there is simply no reason to distinguish between two State requirements having identical effects based solely on the method by which the requirements are imposed; to do so would have the "anomalous consequence[]" of "grant[ing] greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). It is telling that Respondent, in its brief opposing certiorari, made no effort to defend this portion of the Third Circuit's decision.

C. The State "Requirement" Is "Different from or in Addition to" the Applicable Federal "Requirement"

The Third Circuit also relied on *Medtronic* to find that any State requirements imposed on Buckman by virtue of these lawsuits are not "different from, or in addition to" (within the meaning of § 360k(a)) any federal requirements imposed on Buckman in connection with the § 510(k) submission. The appeals court quoted *Medtronic*'s holding that:

> "Nothing in § 360k denies [a State] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. . . . The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."

Pet. App. 12a (quoting *Medtronic*, 518 U.S. at 495). From that holding, the Third Circuit derived its finding that § 360k(a)'s "different from, or in addition to" requirement had not been satisfied, stating:

> Moreover, the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law. As plaintiffs stress, 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every premarket notification to contain a statement that the information contained therein is believed to be true.

Pet. App. 13a.

The Third Circuit's assertion that Respondent's suits are somehow consistent with FDA's approval of Buckman's § 510(k) submissions requires little refutation. In approving the § 510(k) submissions, FDA determined that the submissions complied with all federal regulatory requirements -- including the requirement prohibiting fraud on the agency. By filing a suit that challenges the propriety of the submissions, Respondent is also challenging the propriety of FDA's approval of those submissions. Of course, Respondent does not assert that FDA erred consciously; rather, Respondent alleges that FDA was hoodwinked by Buckman's fraud and would not have granted approval but for Buckman's deviousness. Respondent contends that it is only trying to impose, by means of State law, the very same result that FDA would have imposed had it not been the victim of fraud. But there is no avoiding the

reality that this suit seeks to impose a State "requirement" that is inconsistent with FDA's 1986 approval of the § 510(k) submissions, an approval that FDA has not seen fit to rescind despite repeated entreaties from Respondent.

As the United States recognizes:

> [T]he premise of respondent['s] state-law cause of action is that particular agency action should not and would not have been taken by a federal agency, and that damages should be awarded as if the conduct of [Buckman] that the FDA had *cleared* under the FDCA -- introducing the product onto the market -- was unlawful under the FDCA. A state court may not decline to give effect to an FDA decision that has not been rescinded by the FDA or set aside by a court. Cf. *Nantahala Power & Light Co. v. Thornburg*, 476 U.S. 953 (1986); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). The federal government has a significant interest in the finality of its own administrative determinations, and under the Supremacy Clause those determinations should generally be questioned or set aside, if at all, only by the federal government itself.

U.S. Br. (June 7, 2000) at 16. It is inescapable that a State "requirement" that undermines the federal government's "significant interest" in the finality of its own administrative determinations must be deemed "different from, or in addition to" federal regulation of those subject to the federal administrative determinations.

III. PORTIONS OF *MEDTRONIC*'S DISCUSSION OF § 360k(a) WERE BASED ON AN INCOMPLETE UNDERSTANDING OF FDA'S INTERPRETATION AND HISTORICAL APPLICATION OF THE STATUTE

WLF has demonstrated above that the Third Circuit's decision is inconsistent with this Court's case law and that, when properly analyzed, *Medtronic* supports Buckman's contention that Respondent's claims are preempted by § 360k(a). WLF nonetheless respectfully suggests that the Court should use the occasion to re-examine some of the statements included within *Medtronic* in light of new evidence regarding FDA's interpretation and historical application of § 360k(a). WLF does not suggest that *Medtronic* was improperly decided, only that some statements in the decision are not historically accurate.

In attempting to discern the types of federal "requirements" that can give rise to § 360k(a) preemption, the Court in *Medtronic* substantially deferred to FDA regulations that attempt to give substance to the preemption provision. The Court explained that deference as follows:

> Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone,* for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that FDA has promulgated a relevant federal "requirement."

Medtronic, 518 U.S. at 495-96.

The Court heavily relied on one FDA regulation -- 21 C.F.R. § 808.1(d) -- in its analysis of the types of federal "requirements" that can give rise to preemption. That regulation provides, in pertinent part:

> 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 particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). The Court picked up on FDA's use of the word "specific" (as in "specific counterpart regulations"), a word that does not appear in § 360k(a). *Medtronic,* 518 U.S. at 499-501; *id.* at 507 (Breyer, J., concurring in part and concurring in the judgment) ("[T]he regulation's word 'specific' does narrow the universe of federal requirements that the agency intends to displace at least some state law. Although the Court was unclear on this point, there is at least a suggestion from the Court that (based on the regulation's language) a federal "requirement" can not be deemed "specific," and thus can never have preemptive effect, unless the "requirement" applies to one specific medical device named therein or to a very small class of devices. *See, e.g., id.* at 500-01.

With all due respect, WLF believes that both the *Medtronic* plurality and Justice Breyer may have read too much into § 808.1(d) use of the word "specific." The historical record suggests that FDA used the word "specific" merely to indicate that a counterpart federal requirement

must be in existence before State requirements are preempted -- not in an effort to limit severely the universe of federal requirements that potentially could preempt state requirements. In other words, the relevant FDA statements in § 808.1(d) were aimed at ensuring 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 FDA took any regulatory action pursuant to the MDA).

Section 808.1(d) was adopted in 1978. Both the 1977 Federal Register notice proposing federal regulations relating to § 360k(a) (42 Fed. Reg. 30383 (June 14, 1977)) and the 1978 Federal Register notice adopting those regulations in final form (43 Fed. Reg. 18661 (May 2, 1978) confirm that FDA did not intend the restrictive definition of "specific" ascribed to it by the *Medtronic*. Rather, those notices confirm that FDA used the word "specific" to express the agency's view that some counterpart federal requirement must be in existence before state requirements can be preempted by § 360k(a). For example, in its 1977 preamble to the proposed regulations, FDA explained:

> Consistent with his understanding of the intent of Congress, the Commissioner has narrowly construed the preemption provision so that [§ 360k(a)] . . . preempts State and local requirements only when *a particular Federal requirement becomes applicable to a particular device by operation of the act.* This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State and local requirements were considered preempted prior to the time FDA implemented Federal

> requirements. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. at 30383 (emphasis added).

Statements made by FDA at the time its regulations became final in 1978 were to the same effect. For example, in rejecting arguments of commenters who argued that *all* State and local medical device requirements were preempted as of the date of the MDA's enactment in 1976, FDA explained:

> The Commissioner believes that both the language of [§ 360k(a)] and the legislative history of the [MDA] support the interpretation expressed in the proposal. . . Thus from a plain reading of [§ 360k(a)] . . . it is clear that the scope of preemption is limited to instances where there are *specific FDA requirements applicable to a particular device or class of devices.*

43 Fed. Reg. at 18662 (emphasis added).

As is apparent from context, the reference to "specific FDA requirements applicable to a particular device or class of devices" was not intended as a limitation on the type of federal requirements that would trigger preemption. By indicating that there must be "specific FDA requirements" in place before preemption occurs, the agency was saying nothing more than that some relevant federal requirement must actually be in place (not merely capable of being put in place) before counterpart state requirements are preempted.

In sum, WLF respectfully requests that the Court correct any confusion created by *Medtronic* and make clear that § 808.1(d)'s "specific counterpart regulations" language does not limit the universe of federal regulations capable of having preemptive effect to those regulations that reference by name a specific medical device or class of devices. Rather, the Court should explain that federal preemption is triggered so long as there are federal requirements in place that ensure that preemption does not lead to a regulatory vacuum. WLF notes that it a strong aversion to such regulatory vacuums that has caused the Court in the past to reject broad preemption arguments. *See, e.g., Medtronic,* 518 U.S. at 487 (plurality) ("Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices"). Because recognition of Buckman's preemption claim would leave in place powerful federal provisions designed to guard against fraud by medical device manufacturers, there is no danger that reversal of the decision below would create any sort of regulatory vacuum.

CONCLUSION

WLF respectfully requests that the Court reverse the decision of the U.S. Court of Appeals for the Third Circuit.

Respectfully submitted,

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