No. 98-1768

IN THE SUPREME COURT OF THE UNITED STATES

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

BRIEF FOR THE RESPONDENT

Filed October 23rd, 2000

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STATEMENT

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), this Court unanimously determined that the Medical Device Amendments to the Food, Drug and Cosmetic Act do not expressly foreclose state power to afford a private damage remedy for violations of the Act. This case presents the question of whether Congress nonetheless implicitly intended to preempt such claims.

A. THE REGULATORY BACKGROUND

Historically, the safety of drugs and medical devices has been a central concern of the common law. *See* Hayes, T.A., *Drug Labeling and Promotion: Evolution and Application of Regulatory Policy*, 51 FOOD & DRUG L.J. 57, 60 (1996). The damage remedy provided by the common law, however, did not prove to be a sufficient deterrent to assure that these products safely achieved the therapeutic uses claimed for them. Congress enacted the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, to address this threat. *Medtronic*, 518 U.S. at 475-78; *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 617-20 (1973).

The central tenet of the FDCA is that clinical trials, rather than the "beliefs" of physicians, are necessary to properly judge the safety and effectiveness of drug products. As this Court observed in *Weinberger*, 412 U.S. at 619:

> [The] strict and demanding standards [of the FDCA], barring anecdotal evidence indicating that doctors "believe" in the efficacy of a drug, are amply justified by the legislative history. The hearings underlying the 1962 Act [regarding the regulation of drugs] show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.[1]

[1] The danger of using drugs or devices based on clinical theory or the anecdotal experience of physicians was vividly illustrated in the 1980s when physicians began to prescribe the drug Flecainide, off label, to treat arrhythmias. The drug proved effective in controlling irregular

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Accordingly, the law provides that a new drug may not be introduced into commerce unless the FDA makes a determination based on the outcome of clinical trials, that there is a reasonable assurance that the drug is actually safe and effective in treating the particular maladies for which the drug is offered to physicians and their patients. 21 U.S.C. § 355.

The law, as originally enacted, required premarket approval for drugs but did not authorize control over the marketing of new medical devices. *See* S. REP. No. 93-670 at 1-2 (1974); H.R. REP. No. 94-853 at 6 (1976). This omission proved to be a mistake. For example, in 1970, A.H. Robbins began marketing the Dalkon Shield as a safe and effective contraceptive device without performing clinical trials to support these claims. *Medtronic*, 518 U.S. at 476. The widespread use of this untested device resulted in a significant number of pregnancies, serious infections, and deaths. *Id.*; *see also* H.R. REP. No. 94-853 at 8. This experience, along with a general recognition that existing law was inadequate to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used," led Congress to enact the Medical Device Amendments ("MDA") to the FDCA, 21 U.S.C. § 360, *et seq.* *See* S. Rep. No. 94-33 (1976); *Medtronic*, 518 U.S. at 475-76.

Under the Medical Device Amendments, the FDA is required to place medical devices into one of three regulatory categories that are subject to three corresponding levels of regulatory control. *See* 21 U.S.C. § 360c. Class III devices are those which "present[ ] a potential unreasonable risk of illness or injury." These devices are subject to premarket approval

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heartbeats. However, when clinical trials were finally conducted with respect to this "off-label treatment," it appeared that those who took the drug had a 2½-fold increase in mortality and that 3,000 to 10,000 patients per year had died as a consequence of this "treatment." *See Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998), *amended*, 36 F. Supp. 2d 16 (D.D.C. 1999).

("PMA") by the FDA. *See* 21 U.S.C. §§ 360c(a)(1)(C) & 360e. The FDA may not grant a premarket approval unless it determines that there is a "reasonable assurance" that the device is safe and effective based on an evaluation of data from controlled clinical trials. *See* 21 U.S.C. §§ 360e(c), 360e(d)(2)(A) & 360j(g); 21 C.F.R. §§ 812 & 814.20; *Medtronic*, 518 U.S. at 477. The premarket approval process "is a rigorous one" to which agency officials typically devote an average of 1,200 hours. *Medtronic*, 518 U.S. at 477.

All Class III devices, including those in commerce at the time the MDA was enacted, are subject to the premarket approval process. 21 U.S.C. §§ 360c(a)(1)(C) & 360e(a). New, post-enactment devices are automatically treated as Class III devices that can not be marketed without a PMA. 21 U.S.C. § 360c(f). Existing medical devices, however, could not be withdrawn from the market while the FDA completed the classification and PMA review processes for such devices. *Medtronic*, 518 U.S. at 477-78. Therefore, a "grandfathering" provision was included in the legislation. *Id.* It provides that all devices which were in commerce as of the date of the enactment could remain on the market pending the eventual completion of the classification and PMA processes for such devices. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). In order to avoid monopolies in grandfathered devices, Congress enacted an exception to the rule prohibiting the sale of new Class III devices. This exception permits the marketing of a new, post-enactment device if the FDA finds that it is "substantially equivalent" to a "predicate device." A predicate device is one that was lawfully on the market before the enactment of the MDA in 1976. 21 U.S.C. §§ 360c(f)(1)(A) & 360e(b)(1)(B); *Medtronic*, 518 U.S. at 478. "Substantial equivalence" is claimed and either accepted or rejected through a "premarket notification" submitted under § 510(k) of the FDCA, 21 U.S.C. § 360(k). This provision requires a first-time marketer to submit a notification to the FDA advising the agency of its intent to market a new medical device. *See* 21 U.S.C. § 360(k); 21 C.F.R. § 807.81, *et seq.* A device is not "substantially equivalent" unless

"the device has the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1)(A).

"Intended use" is at the heart of the FDCA regulatory scheme. *See* 21 U.S.C. §§ 321(g) & (h). It determines whether a product is a drug or device, the character of the product, the regulatory requirements to which it is subject, and the extent of those requirements. Thus, for example, a screw that is intended for use in constructing a car is not a medical device subject to regulation under the FDCA. The same screw, if intended for use in constructing crutches, would be a Class I medical device subject to minimal regulation. 21 C.F.R. § 890.3150. If that screw were intended for use in the human spine, it would be a Class III medical device subject to premarket approval. J.A. 105.

"Intended use" refers to the manner in which those responsible for the distribution of a drug or device characterize the product in the marketplace as demonstrated by "labeling claims, advertising matter, or oral or written statements by such persons" and other "circumstances surrounding the distribution of the article."[2]

[2] *See, e.g.*, 21 C.F.R. §§ 801.4, 814.20(b)(3)(ii) & 807.87(e); 63 Fed. Reg. 40025, 40038 (Jul. 27, 1998) ("the term 'intended use' is broadly defined and encompasses the manner in which a company characterizes its product in the marketplace."); 59 Fed. Reg. at 59821-25; *Church of Scientology of California v. Richardson*, 437 F.2d 214, 217 (9th Cir. 1971) (skin galvanometer used in religious practices of Scientology deemed "device" based on literature that "contain[ed] diagnostic and therapeutic claims"); *United States v. An Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734, 739, 742 (2d Cir. 1969) (a cosmetic, such as facial lotion, can be a drug regardless of its actual physical effects, when marketed as a "face lift without surgery"); *United States v. 250 Jars, etc.*, 344 F.2d 288, 289 (6th Cir. 1965) (honey classified as a drug when it is sold for therapeutic purposes); *United States v. Hohensee*, 243 F.2d 367, 370 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957) (ordinary food product, such as peppermint tea leaves, may be drug based on claims); *Alberty Food Products v. United States*, 194 F.2d 463, 464 (9th Cir. 1952) (intended use judged (Cont'd)

Given the primacy of intended use in making the substantial equivalence determination, FDA's regulations provide that a premarket notification must include "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." *See* 21 C.F.R. § 807.87(e). Congruent with the concept of intended use, "labels" and "labeling" are not limited to the package insert that physically accompanies an article, but also include all other written and graphic materials which are separately distributed as part of an integrated series of transactions designed to result in the sale or distribution of the product including, for example, manuals, brochures, catalogues, booklets, and video tapes.[3] In addition, a 510(k) submission must include "any additional information" requested by the FDA "that is necessary . . . to make a finding as to" substantial equivalence. *See* 21 C.F.R. § 807.87(h).

The statements made in a 510(k) notification must be truthful. Federal law generally outlaws fraudulent submissions to federal agencies. 18 U.S.C. § 1001. And, the FDCA specifically prohibits "[w]ith respect to any device, the submission of any report . . . that is false or misleading in any

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objectively by characterization in the market); *Bradley v. United States*, 264 F. 79, 82 (5th Cir. 1920) (mineral water a drug where label claimed that product cured or alleviated certain diseases); *United States v. One Unlabeled Unit . . .*, 885 F. Supp. 1025, 1028 (N.D. Ohio 1995) (vinyl-covered bed with audio speakers deemed "device" where brochure claimed that bed "improve[d] circulation and balance," "reduce[d] the need for insulin," and "reduce[d] cholesterol").

[3] *See, e.g.*, 21 U.S.C. § 321(m); 21 C.F.R. §§ 201.128 & 801.4; *Kordel v. United States*, 335 U.S. 345, 348-50 (1948) ("literature"); *United States v. Ballistrea*, 101 F.3d 827, 830 (2d Cir. 1996), *cert. denied*, 520 U.S. 1150 (1997) ("literature and audiotapes"); *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995) ("written literature consisting of a brochure, two University and Field Trial Results booklets, a pamphlet, and an advertisement"); *Nature Food Centres, Inc. v. United States*, 310 F.2d 67, 69 (1st Cir. 1962), *cert. denied*, 371 U.S. 968 (1963) (lectures and Class Notes on Health and Nutrition); *Hohensee*, 243 F.2d at 369-70 ("leaflets and advertising copy," "lecture," and "printed materials").

material respect." 21 U.S.C. § 331(q)(2). The FDA is peculiarly dependent on compliance with this fundamental obligation of candor in the 510(k) process, because this process is an abbreviated one, consuming only 20 hours of agency time, on average. *Medtronic*, 518 U.S. at 479. Accordingly, the FDA's practice has been to make determinations of substantial equivalence based on the assumption that the applicant has provided it with correct information concerning the intended use of the device and without making any independent determination as to the accuracy of those representations. *See* Pet'r. Br., 21; J.A. 85-87.

The FDA's action on a 510(k) notification does not amount to an approval. Rather, the agency simply determines whether the device is substantially equivalent to a legally-marketed predicate device. *See* 21 C.F.R. §§ 807.100(a)(1) & (2). If the product is found to be substantially equivalent, the device may be introduced into commerce for the intended use described in the 510(k) notification. However, because different intended uses for the same physical article give rise to different and distinct devices, an article which is determined to be substantially equivalent for one intended use may not be labeled, marketed, or promoted for a different use.[4]

B. Buckman's Fraudulent Conduct

This case involves medical devices intended for use in spinal fusion surgery. *See* J.A. 6. During such surgery, bone is harvested

[4] *See, e.g.*, 63 Fed. Reg. at 40038 ("If . . . statements or materials promote a use [for a device] that has not been approved by the agency, the device is misbranded [and] . . . [t]he device is also adulterated"); 59 Fed. Reg. at 59821 ("The listing of unapproved uses in the labeling or advertising of an approved device results in an adulterated medical device under section 501(f)(1)(B) of the act"); H.R. Rep. No. 94-853 at 14-15 ("It is the Committee's intention that each use may . . . be treated as constituting a different device for purposes of classification and other regulation"); *United States v. Storage Spaces Designated Nos. 8 & 49*, 777 F.2d 1363, 1366-67 (9th Cir. 1985); *United States v. Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 978 (S.D. Fla. 1979); *United States v. Evers*, 453 F. Supp. 1141, 1149 (M.D. Ala. 1978), *aff'd*, 643 F.2d 1043 (5th Cir. 1981); J.A. 92.

from the patient's hip or a cadaver and applied to the bones in the spine to cause them to fuse together. *Id.* Although spinal fusion can be used in treating fractures, it is typically used to treat a variety of other conditions such as a "slipped disc," curvature of the spine, and spinal tumors. *See* Vanden Brink, K.D. & Edmonson, A.S., 2 *Campbell's Operative Orthopaedics*, 1992-97 (6th ed. 1980). Sometimes spine surgeons augment the fusion by attaching instrumentation to the spine to stabilize it while the fusion process takes place. *Id.* at 1997-2002. Prior to 1984, however, no doctor in the United States ever used a fixation device that was attached to the spine by screws inserted into the spinal pedicles, the thin bony archways that surround the spinal cord and nerves. J.A. 10.

In 1983, Arthur Steffee, M.D., formed AcroMed Corporation to "[m]anufacture and sell . . . spinal implants and instrumentation." J.A. 39. The company, through Steffee, developed and applied for a patent on a device which came to be known as the Variable Screw Placement ("VSP") Spinal Plate Fixation System. J.A. 42. As described in the patent documents, the device was specifically designed for use as an adjunct to spinal fusion surgery, and consisted of plates which were to be affixed to the spine with pedicle screws. J.A. 42-44; *see also* J.A. 88-89.

In 1984, AcroMed retained petitioner, The Buckman Company ("Buckman"), to assist it in obtaining 510(k) "clearance" for the VSP device. On September 4, 1984, and again on September 20, 1985, Buckman filed premarket notifications for the "VSP Spinal Fixation Plating System." J.A. 45-46, 93-94 & 100-01. These notifications truthfully represented that the device was intended for use in spinal fusion surgery. *Id.* On both occasions, the FDA informed Buckman that it had determined that the device was not substantially equivalent to any legally-marketed predicate device. J.A. 101-06. Accordingly, the agency also advised Buckman that the device was a Class III device that could not be commercially distributed without receiving premarket approval.

Id. The agency explained that these determinations were based on the fact that Buckman had not demonstrated that there was "a pre-amendment device . . . with a design substantially equivalent to the VSP Spine Plate System" and on the fact that the device "pose[d] potential risks not exhibited by other spinal fixation systems," including "greater chance of neurological deficit due to imprecise screw placement or the event of screw failure" and "soft tissue damage or inadequate fusion due to bending or fracture of device components." J.A. 105.

On December 12, 1985, a meeting took place among representatives of Buckman, AcroMed, and the FDA. J.A. 94. At that meeting, AcroMed asked whether it could label and sell the components of the VSP system for use in repairing fractures in the long bones of the arms and legs. J.A. 95. The FDA responded that in order for AcroMed to do so "it would have to submit separate 510 (k) applications for these purposes and that the FDA would evaluate those applications individually." J.A. 95.

In late December, 1985, Buckman submitted two new premarket notifications for what it described as "Nested Bone Plates" and "Cancellous Bone Screws." J.A. 46-57. These plates and screws were, in reality, the components of the VSP system. J.A. 95, 107-08; Pet. App. 5a. Buckman's December, 1985, premarket notifications omitted all reference to use of the device components in the spine and claimed that plates and screws were substantially equivalent to pre-amendment Class II devices intended for use in the repair of arm and leg fractures. J.A. 46-57. The notifications did not include any proposed labeling or promotional materials which indicated that the plates and screws would be marketed as components of a spinal fixation construct. *Id.* The FDA then sought clarification from Buckman concerning the intended use of the plates and screws. *See* J.A. 95 & 107. In a letter dated January 10, 1986, Buckman responded to this inquiry. J.A. 57-58. In that letter, Buckman affirmatively represented to the FDA that these device components were "intended for use in appropriate fractures of

long bones of both the upper and lower extremity." J.A. 58 & 96.

Shortly thereafter, the FDA determined that AcroMed's plates and screws were substantially equivalent to pre-enactment devices for the repair of long bone fractures — the intended use claimed by Buckman. J.A. 59-62 & 96.

The representations made by Buckman to the FDA were false and misleading. J.A. 86, 96-97. Indeed, within days of Buckman's representations, AcroMed's president admitted that the characterization of the plates and screws as a long bone fixation device was "a labeling slight-of-hand" that "in no way changes the intended use of the plates and screws." J.A. 65. AcroMed's vice president and chief counsel admitted under oath that the only purpose of AcroMed's plates and screws was for spinal fixation. J.A. 108; *see also* J.A. 42 (VSP System "is a spine device"). AcroMed's vice president of operations admitted to FDA enforcement officials that the plates and screws were "always intended for use in the spine and [were] never distributed to parties who were not known to have the skills and training to implant [them] in the spine." J.A. 69. Dr. Steffee himself admitted under oath that the device was properly characterized as a spinal plate and screw rather than a long bone fixation device. J.A. 42; *see also* J.A. 88-89. In fact, it was physically impossible to use the plates and screws in long bone repair. Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, Concerning Proposed Rule Making ("PLC Comments"), FDA Dkt. No. 95N-0176, Tab 278 at 7-8 (Mar. 1, 1996).

In the marketplace, AcroMed consistently characterized its plates and screws as a spinal fixation device and marketed the device exclusively for that purpose. J.A. 12, 75-79, 97, 124-26. Contemporaneous with 510(k) clearance, AcroMed formed a medical advisory panel which consisted of a cadré of key spine surgeons who agreed to serve in exchange for lucrative options to purchase AcroMed stock. J.A. 97. The members of the medical advisory panel agreed to promote the use of AcroMed's plates and screws in spinal surgery and trained surgeons for

that use. PLC Comments, 42. AcroMed would not ship its plates and screws unless it was demonstrated that they were going to be used by a spine surgeon who had been trained by one of the members of the AcroMed medical advisory panel to implant the device in the spine. J.A. 67, 75. Accordingly, AcroMed sponsored and conducted training sessions for hundreds of spine surgeons in which the members of its medical advisory panel provided instruction in the spinal application of AcroMed's plates and screws. *See* J.A. 75 & 76. In addition, AcroMed furnished physicians with video tapes (J.A. 73, 78), a "technique manual" (J.A. 80-83 & 97), product catalogues (J.A. 97 & 113), price lists (J.A. 109-13), and patient booklets (*e.g.*, J.A. 115-18), all of which characterized the AcroMed plates and screws exclusively as a spinal fixation construct. None of these materials mentioned use of the plates and screws in repairing long bone fractures. Indeed, it appears that there was not a single instance where AcroMed or Buckman ever characterized the plates and screws as a long bone fixation device.

An FDA investigation into the conduct of AcroMed and Buckman concluded as of October 7, 1991 that the agency had been defrauded as to the intended use of the AcroMed plates and screws. J.A. 124. However, by the time the government reached this conclusion an entire "Pedicle Screw" industry had emerged. This created a regulatory conundrum for the spinal implant industry, for orthopaedic surgeons, and for the FDA. As stated in a memorandum summarizing a series of meetings among those interests in the winter of 1993, "[t]he FDA, industry, and orthopaedics are all caught between a rock and a hard place; [and] need to find a way out." PLC Comments, 76 & Tab 90.

This "way out" was provided by the so-called "Cohort Study." The Cohort Study was sponsored by an association of "spinal implant manufacturers," including AcroMed. 63 Fed. Reg. at 40030. The stated purpose of the study was to gather "scientific" evidence to support reclassification of pedicle screw devices by the FDA so that they could be sold without premarket approval. *Id.* at 40026.

The FDA audited the results of the Cohort Study. According to a July 30, 1996 memorandum from the FDA's Division of Bioresearch Monitoring (BIMO), "the audit findings seem to reveal a poorly executed study," and the study data were "unreliable in evaluating the treatment under consideration." *See* Rodgers, A.E., *FDA Pedicle Screw Cohort Study: Audit Findings*, FDA Dkt. No. 95N-0176 (Jul. 30, 1996). BIMO also recommended a criminal investigation of the study. *Id.* However, FDA officials admitted that in their approach to the downclassification of pedicle screw fixation devices, "neither the scientific soundness nor the results of the retrospective [Cohort Study] process [were] of great importance." PLC Comments, 98 & Tab 166. Accordingly, the scientifically-infirm Cohort Study became the basis for a regulation reclassifying pedicle screw fixation devices, which was promulgated on July 27, 1998. *See* 21 C.F.R. § 888.3070. Significantly, this regulation retained Class III status for pedicle screw fixation devices when used for all but seven specific indications. With respect to these seven indications, the devices were placed in regulatory Class II subject to four special controls which were (a) "[c]ompliance with materials standards"; (b) "compliance with mechanical testing standards of performance"; (c) "compliance with biocompatibility standards"; and (d) "adherence to labeling requirements." 63 Fed. Reg. at 40027. None of these special controls were in effect prior to the promulgation of the regulation.[5] While the FDA commentary accompanying the regulation stated that the "FDA does not believe that pedicle screw spinal systems present a substantial deception" (63 Fed. Reg. at 40035), the agency made it clear that it had made no determination concerning whether any person's prior

[5] The MDA provides that performance standards of the type required in the reclassification regulation must be promulgated by regulation. *See* 21 U.S.C. § 360d(b). Such performance standards have not yet been promulgated. In addition, the labeling requirements set forth in the reclassification regulation were not imposed formally by regulation or informally in connection with the 510(k) clearance of AcroMed's plates and screws.

conduct in introducing pedicle screw fixation devices into the marketplace was fraudulent or otherwise illegal and that the reclassification regulation should not be understood to validate prior unlawful conduct. *See* U.S. Br., Pet. Stage, 14.

C. The Proceedings Below

Many individuals were injured as a result of having AcroMed's hardware attached to their spines in proximity to the delicate nerves emanating from their spinal cords. The resulting lawsuits were largely filed in or removed to federal district courts and transferred by the Judicial Panel on Multidistrict Litigation to the Eastern District of Pennsylvania for coordinated pretrial proceedings (Transfer Order of JPMDL, Aug. 4, 1994), where the court appointed a Plaintiffs' Legal Committee ("PLC") to coordinate the litigation on behalf of the plaintiffs. *Orthopedic Bone Screws*, 1995 WL 925680 (Jan. 31, 1995).

In the early, prediscovery stages of the MDL proceedings, the court entered PTO 12 in which it ruled that to the extent plaintiffs sought to recover damages suffered by virtue of misrepresentations to the FDA, their claims were foreclosed by the express preemption section of the MDA, 21 U.S.C. § 360k. Pet. App., 48a-50a. Thus, there was no discovery directed to the FDA concerning the issue of Buckman's fraud on the agency.[6]

Approximately one year after the transferee court dismissed plaintiffs' fraud claims, this Court issued its decision in *Medtronic*. Contemporaneous with *Medtronic*, some of the MDL plaintiffs filed pleadings in which they named defendants

[6] Substantially later in the MDL proceedings, the district court permitted plaintiffs to direct discovery to the FDA in order to meet defenses which were affirmatively based on FDA actions during the period from 1993 to 1998. *See Orthopedic Bone Screws*, PTO 51 (Jun. 1, 1995); *Orthopedic Bone Screws*, 1995 WL 925670, PTO 87 (Aug. 10, 1995); *Orthopedic Bone Screws*, PTO 92 (Aug. 18, 1995); J.A. 36-37. However, consistent with the FDA's "housekeeping regulation," 21 C.F.R. § 20.1, plaintiffs were not permitted to depose full-time employees of the FDA. *Id.*

in addition to those who actually sold the products that injured them. *See, e.g.*, J.A. 5. Buckman was named as one of the non-seller defendants in these so called "Omni Complaints." *E.g.*, J.A. 5. The complaints against Buckman alleged that Buckman and AcroMed contrived and implemented a strategy to fraudulently obtain 510(k) clearance of AcroMed's plates and screws for use in repairing arm and leg fractures and to then market the device components solely for use in spinal fusion procedures. J.A. 13-21. Plaintiffs alleged that as a result of this scheme, AcroMed's pedicle screw devices unlawfully reached the market where they were implanted within the plaintiffs' spines, causing them to suffer the very same injuries that the FDA cited as device risks when it refused marketing clearance in the first instance. J.A. 21.

In October, 1996, the MDL parties submitted a stipulation to the district court in which they agreed that the question of whether plaintiffs' fraud claims were preempted in light of *Medtronic* would be presented to the district court in the form of a motion by AcroMed to reaffirm PTO 12, which had dismissed plaintiffs' fraud-on-the-FDA claims at the outset of the MDL litigation. *See* 3d Cir. Appendix in App. No. 97-1783, A40. While that motion was pending, the PLC reached a limited-fund class action settlement with AcroMed pursuant to Fed. R. Civ. P. 23(b)(1)(B). *Orthopedic Bone Screws*, 176 F.R.D. 158 (E.D. Pa. 1997).

With AcroMed's departure from the litigation, another manufacturer was treated as a moving party on the motion to reaffirm the district court's prior ruling concerning preemption of plaintiff's "fraud-on-the-FDA claims." Pet. App. 33a. On March 28, 1997, the district court granted this motion. In doing so, it explicitly recognized that plaintiffs' fraud claims were not preempted in light of *Medtronic*. Pet. App. 40a. However, the district court reasoned that allowing a fraud-on-the-FDA claim would create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion . . . any grant of an implied private right of action would be contrary to the letter and spirit of the statute."

Pet. App. 37a. Based on this ruling, the district court granted a separate Rule 12 motion to dismiss, which was filed by Buckman. Pet. App. 45a. The dismissal of this claim against Buckman was certified as a final order subject to immediate appellate review under FED. R. CIV. P. 54(b). Pet. App. 54a-56a.

In a two-to-one decision, the Court of Appeals reversed, holding that no principle of federal law prevented plaintiffs from proceeding with state-law claims that were predicated upon Buckman's alleged misrepresentations to the FDA. Pet. App. 1a. The Court of Appeals' reasoning was straightforward.

First, the Court of Appeals held that "[a]bsent preemption by federal law . . . a district court . . . cannot decline to enforce liability imposed by the relevant state common law." Pet. App. 14a. Second, it recognized that preemption is a matter of legislative intent and "where Congress has expressed itself on preemption in a statute, Congress' [preemptive] intent primarily is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it." Pet. App. 15a. Third, the court recognized that the MDA contains an express preemption provision, 21 U.S.C. § 360k, which was definitively construed by this Court in *Medtronic*. As the Court of Appeals read that decision, the MDA only preempts state law to the extent that there is a federal requirement "with respect to" the specific device that caused the injuries for which plaintiffs seek to recover under state law. Pet. App. 18a. Because there were no device-specific regulatory requirements relating to AcroMed's plates and screws, the court found, there was no preempting federal requirement to displace the application of state law. Pet. App. 13a. Fourth, the Court of Appeals observed that § 360k was unanimously construed by this Court in *Medtronic* as manifesting a Congressional intent to allow states to provide "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Pet. App. 16a. Because plaintiffs' claims were based on a common-law duty to refrain from making misrepresentations, which is identical to the duty imposed by federal law, the court concluded that "the state common law

relied upon does not impose any obligation on Buckman inconsistent with federal law" and was not preempted. Pet. App. 13a. Finally, while the Court of Appeals did not "rule out the possibility that there may be some areas of preemption outside the scope of § 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA," it found "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." Pet. App. 18a. Thus, implied preemption was not appropriate.

SUMMARY OF THE ARGUMENT

In *Medtronic*, this Court unanimously ruled that the express preemption language of the MDA did not foreclose state power to provide a private damage remedy for violation of the requirements imposed by federal medical device law. The Court reached this conclusion notwithstanding its explicit recognition that the FDCA sets forth a comprehensive regulatory scheme for enforcing the requirements of the MDA, which does not include a private, federal right to damage relief. In the present matter, the plaintiffs seek damages under conventional concepts of state tort law for personal injuries they received as a result of the petitioner's violation of federal requirements governing truthful disclosure of information in the 510(k) process. Under *Medtronic*, the claim is not subject to express preemption.

In the context of examining Congress' expressed intent regarding MDA preemption, *Medtronic* rejected the principal arguments made to support implied "conflict" preemption here. Rejection of these arguments is no less compelling in the context of implied preemption. First, there is no reason to believe that Congress intended a broader preemption with respect to state-law claims based on MDA violations than that which it expressed in section 360k. Second, under the Court's jurisprudence, permitting a private damage remedy to redress the wholly private interest in freedom from bodily harm, does not create a preempting conflict with the federal remedial scheme, even where the plaintiff seeks damages as a result of a

violation of federal law. Third, it is inconsistent with basic notions of federalism to imply preemption based on the fact that a state tribunal may be called upon to interpret and apply federal regulatory law in a private damage action. State tribunals are presumptively competent to do so. Fourth, allowing a non-federal remedy for violation of a federal requirement provides incentives for compliance with federal mandates and, thus, generally advances rather than conflicts with federal interests. Finally, as demonstrated by the *Silkwood* decision, the Court has been loathe to invoke implied preemption to preclude the award of damages even where, unlike the present matter, the substantive area at issue is one that is subject to exclusive federal regulatory control.

ARGUMENT

I. Respondent's Fraud Claims Are Not Expressly Preempted

A.

The Medical Device Amendments contain a specific provision expressing Congress' intent with respect to the preemptive reach of the legislation, 21 U.S.C. § 360k. It provides that "no State . . . may establish or continue in effect with respect to a device . . . any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device. . . ." This express provision was definitively construed by the Court in *Medtronic*.

In *Medtronic*, the plaintiffs sought to recover damages for an injury allegedly caused by a Class III medical device that reached the market through the 510(k) substantial equivalence process. 518 U.S. at 480-83. Recovery was premised on multiple theories including design defect, "violat[ion of] FDA regulations," labeling inadequacy and manufacturing deficiencies. *Id.* at 481, 495. The manufacturer of the device, Medtronic, advanced numerous arguments in support of its contention that these claims were preempted. Each argument was rejected.

First, Medtronic made an argument similar to that advanced by petitioner here: "that any common-law cause of action is a

'requirement' which alters incentives and imposes duties 'different from, or in addition to,' the generic federal standards that the FDA has promulgated in response to mandates under the MDA" and that, therefore, "the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." *Id.* at 486.

The Court unanimously rejected this argument, holding that the language of the statute did not justify such a sweeping preemptive effect. If Congress intended such an effect, the Court reasoned, it could have achieved that result by precluding "any 'remedy' under state law relating to medical devices" rather than limiting preemption to state requirements. *Id.* at 487. Moreover, the legislative history did not justify the conclusion that the breadth of the federal regulatory scheme displaced the ability of state law to provide a damage remedy to persons harmed by medical devices. The legislators who enacted the MDA were "acutely aware of ongoing product liability litigation" involving medical devices, yet there was absolutely nothing in the legislative history "suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices." *Id.* at 491. Moreover, the legislation was intended to provide greater protections with respect to the dangers posed by unsafe medical devices than those that existed prior to enactment of the law. *Id.* at 487. Given that "there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action," the Court found, "Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity . . . 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' . . . ." *Id.* at 487. Harking to the principle established by this Court's *Silkwood* opinion, the Court refused to accept that Congress intended such an outcome. *Id.* at 487, *citing Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Next, the Court unanimously concluded that an essential prerequisite to statutory pre-emption under section 360k was the existence of a federal requirement having the same subject matter as (and thus subject to potential conflict with) the state "requirements" which formed the basis for the plaintiff's tort claim. *Id.* at 492-94; *see also id.* at 513 (O'Connor, J., concurring in part). While "the FDA may well examine 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device," *id.* at 493, the 510(k) substantial equivalency process "places no 'requirements' on a device," *id.* at 513 (O'Connor, J.). Therefore, all of the members of the Court agreed that a 510(k) clearance determination by the FDA does not preempt design defect claims. *Id.* at 493-94 & 513.

The Court's decision was unanimous in one other respect. The complaint at issue in *Medtronic* "include[d] claims that Medtronic has, to the extent that they exist, violated FDA regulations." *Id.* at 495. In asserting that these claims were preempted, Medtronic made exactly the same argument that petitioner makes here. Like Buckman, Medtronic argued that the FDCA's lack of an "express private right of action" and 21 U.S.C. § 337 signified Congressional intent to bar state-law claims based upon federal duties. *See* Br. for Cross-Respondent Medtronic in *Medtronic*, Nos. 95-754 & 95-886 at 43 (U.S., Mar. 29, 1996). As Medtronic put it "Congress's omission of a private right of action reflects an intent to reserve enforcement of federal requirements exclusively to the federal government." *Id.*

In a ruling which could not be any more direct (and any more devastating to Buckman's position here), the Court rejected Medtronic's argument. Under a section of the opinion entitled "Identity of Requirements," the Court held that damage claims based on FDCA violations "can be maintained without being pre-empted by § 360k." *Medtronic*, 518 U.S. at 495. Because the MDA preempts only state-law requirements that are "different from or in addition to" federal requirements and because allowing a remedy for unlawful conduct does not

amount to the imposition of a "requirement," the MDA, does not preempt state-law claims to the extent that they seek damages for alleged violations of federal requirements. "Nothing in § 360k denies [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* In other words, a claim of negligence *per se* or some other state-law claim premised on a violation of federal law is not barred by the FDCA. Indeed, rather than being inconsistent with the FDCA, a state-law damages remedy to enforce MDA standards "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.* Justice O'Connor summarized this point as follows:

> To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal law], but the requirements imposed on them under state and federal law do not differ. [The MDA] does not preclude States from imposing different or additional remedies, but only different or additional requirements.

Id. at 513.

Finally, the Court grappled with the proper construction of section 360k insofar as it limited preemption to state requirements that are "different from or in addition to" a federal requirement "applicable to the device." A majority of the Court accepted the interpretation contained in the FDA's preemption regulation, 21 C.F.R. § 808.1(d), ruling that a federal requirement is not potentially preemptive unless it is "specific" to a "particular device." *Medtronic*, 518 U.S. at 500. The FDA's Good Manufacturing Practices and labeling regulations are not device-specific and thus do not preempt common-law labeling or manufacturing defect claims. *Id.* at 497-500. While those federal regulations "reflect important but entirely generic concerns about device regulation," they do not evince "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 (plurality); *see also id.* at 507 (Breyer, J., concurring).

Under *Medtronic*, section 360k does not preempt the claims made by plaintiffs here.

To begin with, during the time at issue, there were no device-specific regulations that related to pedicle screw fixation devices, to orthopedic instrumentation or to any other matter germane to the plaintiffs' deceit claims. Certainly, the agency's generic 510(k) regulations and the statutes governing truthful disclosures to the FDA applied to Buckman's conduct, but these requirements are no more specific than the Good Manufacturing Practices and labeling regulations, which *Medtronic* judged insufficient to displace potentially conflicting duties under state tort law. Indeed, they are less so. *Compare* 21 C.F.R. § 801.1, *et seq.* & § 820.1, *et seq.*, *with* 21 C.F.R. § 807.81, *et seq.*

Moreover, the agency's application of its generic 510(k) regulations to the AcroMed devices does not give rise to potentially preemptive, device-specific mandates. Just as there is nothing in the statute or regulations regarding the 510(k) notification process which requires the FDA to come to a specific conclusion regarding device safety in terms of the design, labeling or manufacture of devices, there is nothing which requires the agency to evaluate the truthfulness of a 510(k) submission with respect to intended use or any other matter. *See* 21 U.S.C. §§ 360c(f)(1) & 360c(i)(1)(A); 21 C.F.R. § 807.100(b). In fact, the FDA does not do so as a matter of routine practice. *See* Pet'r. Br., 21. Therefore, an FDA determination of substantial equivalence pursuant to a 510(k) notification no more represents a preempting "requirement" with respect to the representations made in such a notification than it represented a preempting requirement with regard to the design, labeling or manufacture of the device in *Medtronic*.

Finally, federal statutory law expressly prohibits the making of fraudulent statements to the FDA. *See* 21 U.S.C. § 331(q)(2); 18 U.S.C. § 1001; 21 C.F.R. § 807.87(k). Here, the basis for plaintiffs' fraud claim is that Buckman deceived the FDA by making false statements to the agency concerning an issue of

paramount regulatory concern — the intended use of AcroMed orthopedic plates and screws. Thus, plaintiffs seek recovery for Buckman's "violation of federal requirements." If *Medtronic* was clear about anything, it was clear that such claims are not preempted by section 360k.

B.

Petitioner seeks to avoid these conclusions on four grounds. First, it argues that the holding in *Medtronic* only applies in actions where the theory of recovery is a "traditional" one. Second, Buckman claims that the ruling in *Medtronic* is limited to those cases that do not require a judge or jury to make any determination concerning the existence and breach of a duty under federal medical device law. Third, it argues, *sotto voce*, for reconsideration of the decision in *Medtronic* on the ground that recognition of a state-law right to recover damages for violation of FDCA requirements is at odds with Congress' determination not to recognize a federal private cause of action. Fourth, it claims that its conduct did not actually amount to a violation of federal requirements.

1. With respect to the first argument, demanding a "traditional" theory of recovery as a condition to avoiding preemption, Buckman parses the dialect of *Medtronic* in a way which neither the Court's language nor its reasoning justify. The focus of the Court's preemption analysis in the "Identity of Requirements" section of the decision was not on the heritage of state-law theories of liability which allow recovery for conduct that violates a federal statutory requirement. Indeed, given the range of potential causes of action which are recognized by state law, the variety of elements that must be proven to establish the breach of duty component for each such cause of action and the inherently plastic nature of the common-law process, it probably would be impossible for Congress to establish meaningful rules of preemption based on a determination of whether and to what extent a state-law theory of recovery was "traditional." Rather, the Court's focus in *Medtronic* was on the statutory language which allowed the assertion of a state-law claim for "violation of federal

requirements" or "to enforce an FDCA requirement," because section 360k "does not preclude States from imposing different or additional remedies, but only different or additional requirements." *Medtronic*, 518 U.S. at 495-97 & 513.

Moreover, the theory of recovery advanced by the plaintiffs here is, in fact, squarely within the common law tradition. A longstanding principle of common law holds that where one sustains injuries as a result of another's justifiable reliance on a fraudulent misrepresentation, he or she may recover damages for such injuries from the maker of the misrepresentation.[7] In a special application of this general rule, the law holds that where a statute or regulation requires information to be furnished, filed, or recorded with a government agency for the protection of a particular class of persons, one who makes a fraudulent misrepresentation in meeting such requirements is liable for the harm caused by his or her deceptive conduct.[8]

In addition, one of the most fundamental and long-standing tenets of our tort jurisprudence is that liability is established "per se" if an actor's conduct violates a statute, ordinance or regulation which is intended to protect individuals in the position of the plaintiff from harm caused by the kind of conduct at issue, regardless of whether there is an express or implied

[7] *See, e.g., Michael v. Shiley*, 46 F.3d 1316, 1334-35 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995); *Ostano Commerzanstalt v. Telewide Systems, Inc.*, 794 F.2d 763, 765-66 (2d Cir. 1986); *Haberman v. Washington Public Power Supply System*, 744 P.2d 1032 (Wash. 1987), *amended*, 750 P.2d 254, *app. dism'd*, 488 U.S. 805 (1988); *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 791 n.5, 34 Cal. Rptr. 2d 852, 858 n.5 (1994); *Woodward v. Dietrich*, 548 A.2d 301 (Pa. Super. 1988); *Albertson v. Richardson-Merrell, Inc.*, 441 So. 2d 1146 (Fla. App. 4th Dist. 1983), *pet. for review denied*, 451 So. 2d 850 (Fla. 1984); RESTATEMENT (SECOND) OF TORTS §§ 531, 533, 536 & 557A.

[8] *See, e.g.*, RESTATEMENT (SECOND) OF TORTS §§ 536 & 557A; *Learjet Corp. v. Spenlinhauer*, 901 F.2d 198, 199-201 (1st Cir. 1990); *Hawkins v. Upjohn Co.*, 890 F. Supp. 609, 611-12 (E.D. Tex. 1994); *Handy v. Beck*, 581 P.2d 68, 73-74 (Or. 1978).

statutory right of action for violation of the governmental requirement.[9]

The 510(k) notification procedure is an integral part of a regulatory scheme which is designed to protect members of the unsuspecting public from being exposed to drugs and devices that are "harmful *in potentia*" because their safety and efficacy has not been demonstrated in well-controlled scientific investigations. *See* pp. 1-4, *supra*. While 510(k) clearance does not itself adjudicate safety in device-specific terms, it is, in effect, the legal checkpoint to determine whether a device is a new Class III device that presents potential unreasonable risks of illness or injury and therefore must be evaluated through clinical trials and the PMA process before being allowed into the marketplace. *Id.* Thus, it is clear that the 510(k) notification procedure directly implicates public safety concerns. Accordingly, misrepresentations made in that process affect safety and are actionable under the traditional tort doctrines described above.

Thus, even though preemption does not depend on a determination of the extent to which plaintiff's cause of action is a "traditional one," it is clear that the present claim is squarely within the common law pedigree.

2. Buckman's second argument is equally unavailing. Under *Medtronic*, preemption turns, in part, on whether plaintiffs' state-law claim is premised on "common law duties [which] parallel federal requirements" or "seeks to enforce an FDCA requirement" through a damage action. Therefore, in order to determine if the claims are preempted, a judge will necessarily have to determine in the first instance what the federal law "requires" and a jury will, *per force*, have to determine whether those requirements have been violated. In other words, under *Medtronic*, § 360k necessarily contemplates that judges and juries will construe and apply

[9] *See, e.g.*, RESTATEMENT (SECOND) OF TORTS §§ 285(b), cmt. c & 286, cmt. c; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4; W. Page Keeton, *Prosser and Keeton on the Law of Torts*, § 36 at 220 (5th ed. 1984) (citing cases); *Stanton by Brooks v. Astra Pharmaceuticals Products, Inc.*, 718 F.2d 553, 563-65 (3d Cir. 1983).

federal requirements as the permitted foundation for state-law damage actions qualified to avoid preemption. This is consistent with the historic principle of federalism, which accepts "the constitutional obligation of the state courts to uphold federal law" and affirms emphatically this Court's "confidence in their ability to do so." *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 275 (1997); *Allen v. McCurry*, 449 U.S. 90, 105 (1980). "When pre-emption of state law is at issue, [courts] must respect the 'principles [that] are fundamental to a system of federalism in which the state courts share responsibility for the application and enforcement of federal law.' " *Johnson v. Fankell*, 520 U.S. 911, 922 (1997).

3. Buckman's third argument comes to this Court with little grace. Overruling *Medtronic* is inconsistent with the "cardinal and guiding principle" of *stare decisis* which has "special force in the area of statutory interpretation." *California v. FERC*, 495 U.S. 490, 499 (1990).[10] It is particularly inappropriate considering the fact that the Court was unanimous on the "Identity of Requirements" issue.

On the merits, Buckman is simply wrong in suggesting that there is an inconsistency between refusing to recognize an implied private federal right to recover damages for conduct that violates federal law and permitting states to recognize a right to a damage remedy for such conduct.

First, from the vantage point of Congressional intent, the legislative history of the FDCA demonstrates that there is no

[10] In addition to its *de facto* suggestion that the Court overrule the "Identity of Requirements" holding in *Medtronic*, petitioner explicitly suggests that the Court should also overrule *Medtronic* to the extent that it requires a device-specific federal regulation as a predicate to express preemption under § 360k. That would be inappropriate because of the principle of *stare decisis*, cited above, because the rationale for requiring device specificity expressed by the majority in *Medtronic* is sound and because the MDA was "written so that the benefit of the doubt is always given to the consumer [because] after all, it is the consumer who pays with his health and his life for device malfunctions." 121 CONG. REC. S. 6140 (Apr. 17, 1975).

conflict between recognizing state-law damage claims for violation of FDCA requirements and Congress' omission to provide a private right of recovery under the Act. *Medtronic*, 518 U.S. at 487-91. Indeed, in 1938, when Congress was considering the legislation that ultimately became the FDCA, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act, on the ground that such a right of action already existed under state common law. *See, e.g.*, Hearings before a Subcom. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d CONG., 2d Sess. 400, 403 (1933); *see also* Adler, R. & Mann, R., *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n.130 (1994) ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages because 'a common law right of action (already) exists'").

Moreover, the federal "implication doctrine" does not justify Buckman's position. That doctrine determines the circumstances under which federal law will recognize a private right of relief enforceable in a federal court as a federal cause of action where a federal statute imposes substantive obligations, but is silent regarding the availability of individual relief. *See, e.g., California v. Sierra Club*, 451 U.S. 287, 293 (1981); *Cannon v. University of Chicago*, 441 U.S. 677, 687-709 (1979); *Cort v. Ash*, 422 U.S. 66, 78 (1975). By its own terms, it is not concerned with the separate question of foreclosing relief under state law. *Id*; *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 805, 810 & 814 (1986). Indeed, the federal implication doctrine expressly defers to the viability of state law by providing that courts should be reluctant to "imply" the existence of a federal remedy for conduct in violation of a federal statute where the "cause of action is a subject traditionally relegated to state law." *See Merrell Dow*, 478 U.S. at 811, *citing Sierra Club*, 451 U.S. at 293 and *Cort*, 422 U.S. at 78.

Further, under the common law, a court does not "imply" a remedy for violation of a statute. *E.g., Lowe v. General Motors Corp.*, 624 F.2d 1373, 1379 (5th Cir. 1980); *Pratico v. Portland*

Terminal Co., 783 F.2d 255, 265 (1st Cir. 1985). In the case of liability *per se*, it merely uses a federal requirement to define an existing duty under state law when state law already recognizes a private right to relief. *Id.* In the case of a misrepresentation to a regulatory body, it simply applies state law concerning actionable misrepresentation where a federal regulatory body, by circumstance, is the causal intermediary between the deceptive conduct of the defendant and the harm suffered by plaintiff. *See* fns. 7, 8 & 9, and accompanying text, *supra*.

Finally, because states are free to create a cause of action with respect to virtually any matter relating to public health and safety, they should certainly be free, under basic notions of state-federal comity, to use federal law as a standard of conduct and impose liability for damages caused by a breach of that standard in the absence of a clear and unequivocal expression by Congress of a contrary intent. *See, e.g., Medtronic*, 518 U.S. at 495-97 & 513; *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 668 (1993); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 101-02 (1983).

4. Petitioner's final argument is that plaintiffs' common-law theory imposes a requirement that is different from the applicable federal requirement because, under federal law, "intended use" supposedly refers to the "objective" use set forth in the proposed product labeling submitted in the 510(k) notification, while plaintiffs' common-law theory purportedly equates intended use to a manufacturer's subjectively-desired off-label uses. In effect, petitioner contends that for purposes of a 510(k) notification, "intended use" is whatever the manufacturer says it is and is not legally susceptible to misrepresentation as a matter of law. These contentions misconstrue the applicable federal standards and the allegations in the complaints here.

If Congress expected that the FDA was to make substantial equivalence determinations based solely on whether the proposed labeling in a 510(k) notification described a type of device that was on the market prior to 1976, it would have been

simple enough to say that. However, the statute says that a device is not substantially equivalent to a pre-enactment device unless it actually has the same intended use as that predicate device. *See* 21 U.S.C. § 360c(i)(1)(A). "Intended use" is a well-established statutory concept that refers to the manner in which a device will actually be characterized by sellers in the marketplace — not only in the "package insert" that physically accompanies the device, but also through other materials such as catalogs, manuals, brochures, price lists, and other circumstances and expressions surrounding the distribution of the product. *See* fns. 2 & 3 and accompanying text, *supra*.

The agency's 510(k) regulations also make this explicit. These regulations do not simply direct a 510(k) applicant to submit the proposed "package insert" for a new device. Rather, the applicant is required to submit "[p]roposed labels, labeling, and advertisements sufficient to describe the device [and] its intended use." 21 C.F.R. § 807.87(e). In this regard, "labeling" is a well-understood statutory concept which includes all written and graphic materials that are to be employed in bringing the product to physicians and their patients. *See* fn. 3, *supra*.

Because "intended use" describes the manner in which a device is characterized in the market by those responsible for its sale, it is frequently said that the statutory phrase refers to the seller's "objective" intent. *See* 21 C.F.R. § 801.4. This objective approach to the definition of "intended use" and the related definition of "labeling" was developed by the law to effectuate the legislative intent of protecting consumers from the dangers of medical products which are physically labeled for one purpose but actually marketed for more dangerous uses. *See* fns. 2 & 3, *supra*. Therefore, the characterization of "intended use" as "objective" should not be twisted to negate the application of the concept in the all important premarket situation. In this context, "intended use" necessarily refers to the manner in which the proposed seller intends to characterize the device. The concept remains objective because it refers to the actual, objective marketing of the device rather than the seller's hopes or expectations as to how the device will be used.

The recent amendments to the MDA, which purportedly codify the FDA's prior practice of accepting a 510(k) applicant's representations concerning intended use, do not alter this conclusion. *See* 21 U.S.C. § 360c(i)(1)(E)(i); *see also* S. REP. No. 105-43 at 27 (1997). As the government itself says, while these amendments may relieve the FDA of an administrative burden, they do not relieve the applicant of the obligation to accurately inform the FDA of the actual use intended for the product. *See* U.S. Br., 15, n.2. Indeed, if the rule were otherwise, the MDA would have virtually no effect. Through the simple expedient of submitting a proposed label reflecting a pretextual use which matched a pre-enactment use, a new device could reach the market without regulatory constraint. *See* U.S. Br., 15.

This does not mean that one cannot request 510(k) clearance for a device with the hope or even the expectation that it will be used "off label," nor does it mean that a 510(k) clearance must list every potential use of a device. However, it does mean that if someone requests marketing clearance under section 510(k), they must, at a minimum, truthfully describe the manner in which they expect that the device will be characterized by its sellers and distributors — the "objective" intended use of the product.

It is this simple regulatory requirement which lies at the heart of the plaintiffs' claims. Plaintiffs do not allege that Buckman merely submitted a 510(k) notification to the FDA with the subjective hope, knowledge or expectation that the device at issue would be used "off label" for spinal fixation and failed to disclose this to the FDA. Rather, plaintiffs have alleged and proven that Buckman affirmatively told the FDA that the device at issue was intended for use in repairing arm and leg fractures when it had no expectation that the device would actually be described that way by anyone and specifically intended that the device would be characterized in the market and used solely as a spinal fixation device. Whether judged objectively, subjectively, or any other way, Buckman flat out lied to the FDA. It is hard to imagine a violation of federal law

which is any plainer than this. And it is hard to imagine a situation in which *Medtronic* applies any more forcefully to permit states to provide a private damage remedy.

II. RESPONDENT'S FRAUD CLAIM IS NOT SUBJECT TO IMPLIED PREEMPTION

A.

Preemption does not flow exclusively from explicit statements of Congressional intent. The petition here raises a question of implied "obstacle" preemption — does the award of damages under state law to victims injured as a consequence of a fraudulent submissions to the FDA "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"? *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *See also Freightliner Corp. v. Myrick*, 514 U.S. 280, 281 (1995); *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990).

Several important principles serve as guideposts in making this determination.

1. The preemptive consequences of the distinction between "requirements" and "remedies" articulated in *Medtronic* with respect to express preemption is equally significant in the area of implied preemption. While the Court has not been reticent to find implied preemption to the extent that state-law claims are based on liability requirements which would impose different or additional substantive duties under state-law than those which exist under federal law, *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1925 (2000), the Court has refrained from finding implied preemption of private remedies for breach of substantive duties which do not differ from federal requirements. This is true for a number of reasons.

To begin with, the federal government's regulatory interests are usually vindicated through a fairly prolix amalgam of remedies such as warnings, fines, penalties, injunctions, cease-and-desist orders and the like, which the federal regulators are given discretion to invoke as they believe necessary to advance the statutory goals entrusted to them. *See, e.g.*, 21 U.S.C. §§ 331-335c, 336, 337(a), 360(h). Allowing private litigants to

employ a remedy not entrusted to the quiver of regulatory enforcement mechanisms in order to vindicate private interests is inherently *de hors* the regulatory scheme. In and of itself, it does not impliedly "conflict" with federal law. Where "only the rights of private litigants are at issue," providing a remedy for the violation of a federal requirement will, by definition, affect only the litigants and will not have the kind of direct impact on the United States, which preemption is designed to protect from undue incursion. *Miree v. DeKalb County, Ga.*, 433 U.S. 25, 30-32 (1977); *Askew v. American Waterways Operators, Inc.*, 411 U.S. 325, 336 (1973).

In *Miree*, for example, private parties sued a municipality for breach of an agreement between the municipality and the Federal Aviation Administration on the theory that the private parties were third-party beneficiaries of the federal contract. The contract required the municipality to "restrict the use of land adjacent to or near the airport to activities compatible with normal aircraft operations, including landings and takeoffs." *Miree*, 433 U.S. at 25. The municipality allegedly operated a garbage dump adjacent to an airport, in violation of the FAA contract, which attracted a swarm of birds that caused a plane crash. Although federal common law undoubtedly would have controlled in any suit by or against the federal government to enforce the contract, and although "[t]he operations of the United States in connection with FAA grants . . . are undoubtedly of considerable magnitude," and although "the United States has a substantial interest in regulating aircraft travel and promoting air travel safety," the state-law claim was not preempted. *Id.* at 30-31. Preemption was inappropriate because "only the rights of private litigants are at issue here," because the claim against the municipality "will have no direct effect upon the United States," *id.* at 29-30, and because the suit did not seek to "impose upon the person contracting with the Government a duty contrary to the duty imposed by the Government contract." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 508-09 (1988) (explaining *Miree*).

Moreover, in our system of federalism, "Federal and state law 'together form one system of jurisprudence.' " *Coeur d'Alene*, 521 U.S. at 276. Therefore, it is fundamental that "state courts share responsibility for the application and enforcement of federal law." *Howlett v. Rose*, 496 U.S. 356, 372-73 (1990). This Court consistently has expressed its "emphatic reaffirmation . . . of the constitutional obligation of the state courts to uphold federal law, and [its] expression of confidence in their ability to do so." *Coeur d'Alene*, 521 U.S. at 275, *quoting Allen v. McCurry*, 449 U.S. at 105. Accordingly, any "doctrine based on the inherent inadequacy of state forums would run counter to basic principles of federalism." *Id.*

Consistent with this fundamental constitutional scheme, it would be inappropriate to "imply" preemption based on the fact that a state tribunal may be called upon to interpret and apply a federal requirement in a suit seeking relief for conduct which violates that requirement. "When pre-emption of state law is at issue, we must respect the 'principles [that] are fundamental to a system of federalism in which the state courts share responsibility for the application and enforcement of federal law.' " *Johnson v. Fankell*, 520 U.S. at 922. Federalism and comity recoil at any notion that the states are divested of power to interpret federal law and to provide state remedies that are "consistent with pertinent federal laws." *DeCanas v. Bica,* 424 U.S. 351, 357 (1976).

And, the Court repeatedly has recognized that allowing a non-federal remedy for violation of a federal requirement can not, by definition, serve to impose the kind of conflicting substantive duties under state law, which have triggered implied preemption in cases such as *Geier*. Rather, the availability of a state damage remedy for conduct which violates federal requirements provides an additional incentive for compliance with the federal mandate and thus generally serves to advance rather than impair federal interests for purposes of implied preemption analysis. *E.g.*, *Medtronic*, 518 U.S. at 495-97; *CSX Transp.*, 507 U.S. at 668; *Shaw*, 463 U.S. at 101-02; *California v. Zook*, 336 U.S. 725, 736 (1949).

Given the above, it is singularly inappropriate to imply preemption of a private state-law remedy for conduct which violates a federal requirement on the ground that the state cause of action "impose[s] liability over and above that authorized by federal law." *English*, 496 U.S. at 89; *California v. ARC America Corp.*, 490 U.S. 93, 105 (1989); *Zook*, 336 U.S. at 736. Unless Congress expressly provides that federal law is to be the exclusive source of law with respect to private remedies in a particular area, either directly or through "field preemption,"[11] the states are free to apply their own law of remedies in private actions arising from conduct that violates federal law. *Id.*; *CSX Transp.*, 507 U.S. at 668; *Shaw*, 463 U.S. at 101-02.

2. In addition, this Court consistently has refused to accept the notion that allowing a state-law damage remedy for injuries caused by conduct in an area subject to federal regulation, would "conflict with" the federal regulatory scheme even where that scheme does not itself afford damage relief. Implied preemption is peculiarly inappropriate in such situations. The Court's opinion in *Silkwood* vividly illustrates this principle. In *Silkwood*, the issue presented to the Court was whether the plaintiff could recover punitive damages under state law on account of the escape of plutonium from a federally-licensed nuclear facility in violation of a federal regulation imposing a duty on the facility to "maintain the release of radiation 'as low as reasonably achievable.' " *Silkwood*, 464 U.S. at 241 & 245. This Court held that the claim survived implied preemption, notwithstanding the fact that the Court had previously ruled that "states are precluded from regulating the safety aspects of nuclear energy" and notwithstanding the fact that the Nuclear Regulatory Commission had determined that the defendant "complied with most federal regulations." *Id.* at 240-41 & 244. The Court emphasized that even though Congress intended to divest the states of authority to regulate the safety aspects of nuclear power plants, the legislative history of the federal nuclear

[11] *See, e.g., San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959).

power legislation provided no indication that Congress even considered precluding the use of "state-law remedies" for individuals injured as a result of untoward conduct in the operation of nuclear power plants. *Id.* at 251. This, coupled with the fact that Congress provided no "federal remedy for persons injured by such conduct," made the Court loathe to imply that Congress had preempted such damage remedies, because it was "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Id.* at 251.

In reaching this conclusion, the Court rejected the position of the United States, as amicus curiae, that the award of punitive damages to plaintiff was implicitly preempted because it was at odds with the "federal remedial scheme" which allowed the Nuclear Regulatory Commission "to impose civil penalties . . . when federal standards have been violated." *Id.* at 257. Preemption, the Court ruled,

> should not be judged on the basis that the Federal Government has so completely occupied the field of safety that state remedies are foreclosed, but on whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of the federal law.

Id. at 239. The Court found "no such conflict or frustration in the circumstances of th[e] case." *Id.* at 256.

Although petitioner and the government would confine the operation of *Silkwood*'s "presumption" against implied preemption remedy to those instances in which preemption would leave an injured victim completely without compensation from any source,[12] the decision will not bear such a restrictive gloss. As the insolvency of AcroMed demonstrates here, the

[12] The government also argues that the presumption against preemption does not apply here because plaintiffs' claims "focus on an entity's obligations to truthfully disclose information to a federal regulatory agency," "an area of preeminent federal concern." (Cont'd)

existence of a viable defendant outside the realm of a potential preemption defense in a given case is too ephemeral and unrelated to legislative intent to serve as a touchstone for implied preemption. Significantly, the opinion in *Silkwood* focused on the legislature's preemptive intent in terms of whether Congress considered the foreclosure of damage remedies in general and not in terms of the availability of damage relief to plaintiff from sources other than a given defendant. *Id.* at 250-51 & 256-58. Moreover, the issue in *Silkwood* was not whether the plaintiff could recover compensatory damages. *Id.* at 241, 245-46. All of the members of the Court appeared to accept that the plaintiff could recover such damages under state law consistent with implied preemption principles. *Id.* (majority); 464 U.S. at 276 n.3 (Powell, J. dissenting). Rather, the issue before the Court was whether the plaintiff could recover punitive damages which are, by definition, not intended to compensate but to perform the public policy functions of deterrence and punishment, functions arguably committed to the exclusive jurisdiction of the federal government. It is clear, then, that the Court's *Silkwood* holding creates a virtually irrefutable presumption against implied preemption of private damage remedies predicated on an alleged conflict with a federal remedial scheme.

(Cont'd)
See U.S. Br., at 9-10. However, the presumption against preemption is predicated on respect for the traditional role of the states in affording a damage remedy for invasion of the personal safety interests of its citizens. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518, 523 (1992). *Medtronic* makes it clear that the presumption is not displaced, simply because the injuries at issue result from a violation of the defendant's federal regulatory obligations, notwithstanding the government's obvious "concern" for compliance with federal regulations. *See Medtronic*, 518 U.S. at 44-45 & 495-97; *see also Hillsborough Cty., Fla. v. Automated Medical Labs.*, 471 U.S. 707, 719 (1985) (the fact that regulatory powers are entrusted to FDA pursuant to a complex regulatory scheme reflecting a matter of "national concern" does not justify departure from presumption against preemption). Since the plaintiffs' claims here focus on recovery of damages for the injuries sustained by them, and not on regulatory compliance as an end in itself, application of the presumption is appropriate.

B.

Application of these principles defeats any assertion that the FDCA impliedly preempts plaintiffs' right to recover damages under state law for the harms which they sustained as a result of Buckman's fraud.

Petitioner and the United States attempt to portray this claim as one which focuses on the relationship between the federal government and the entities it regulates and which presents a "novel" claim that has "no existence that is independent of the federal statutes . . . that require regulated entities to make certain disclosures to those federal agencies." *See* U.S. Br., 18. In this setting, they urge, allowing a private party to recover damages caused by fraud on the FDA "conflicts with" the supposedly unique federal interest in allowing the FDA to determine if it has been defrauded and its "exclusive" authority to resort to the remedies available to it under the FDCA. Pet'r. Br., 34-39; U.S. Br., 17-24.

When viewed through the lens of this Court's precedents, however, this portrait is inaccurate. This litigation involves a private dispute between Buckman and individuals who allege that they were physically harmed because Buckman's conduct was part of a scheme which led to the implantation of dangerous, untested devices within their spines.

Thus, unlike the case in a government enforcement action, the plaintiffs do not seek to establish fraud in order to redeem the public interest underlying truthful disclosure to federal regulators, but seek to vindicate their own individual interests in being free from bodily injury. Unlike the case in a government enforcement action, the plaintiffs' theory does not depend principally on the existence of a federal requirement, but relies on traditional theories of tort law which happen to be applicable because the defendant used the government, rather than another route, as the causal intermediary through which injury was produced. Unlike the case in a government enforcement action, plaintiffs do not seek any remedy committed to the prosecutorial discretion of the FDA. Instead, they seek a damage remedy — a remedy not provided by federal law, a remedy which has

traditionally been committed to the realm of state tort law and one which Congress never even "considered precluding" when it enacted the FDCA or the MDA. *See Medtronic*, 518 U.S. 490-92.

Because plaintiffs' claim is based on conduct that violates a federal requirement, there is no "irreconcilable conflict" between federal standards and the "state standards" which form the predicate for liability. Because the remedy requested is wholly private damage relief outside the ken of federal regulation, the claim does not conflict with any unique federal interest in enforcing an otherwise comprehensive regulatory scheme.

Indeed, if the claim for punitive damages survived implied preemption in *Silkwood*, despite the fact that the regulatory scheme there preempted all safety regulation by the states, despite the fact that the punitive damage remedy at issue was one which had penal ramifications beyond the private interests of the parties, and despite the fact that the federal regulators in that case actually determined that the defendant had complied with most of its obligations under federal law, then the damage claim here should certainly survive where this Court has held (in *Medtronic*) that there is no "field preemption," where compensatory damages are involved and where at least some federal regulators have determined that Buckman violated a federal law designed to protect persons in the position of plaintiffs from the kind of injury which they sustained. J.A. 124-26.

C.

The conclusion that plaintiffs' fraud claims are not impliedly preempted by federal medical device law ineluctably follows from the application of yet another principle of preemption jurisprudence. " 'The purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic*, 518 U.S. at 485, *quoting Retail Clerks Intern. Ass'n Local 1625, AFL-CIO v. Schermerhorn*, 375 U.S. 96, 103 (1963). Unless Congress intends preemption, there is none. Accordingly, where Congress has expressed itself on preemption in a statute, "Congress' intent

. . . 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 Solid Wastes Management Assn.*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring).

It follows from this that where a Congressional enactment includes an express, unambiguous provision regarding the preemption of specific areas of state law, a court should seldom imply a preemptive intent with respect to those areas, which is broader than that expressed by the legislature itself. *Cipollone,* 505 U.S. at 517; *Freightliner*, 514 U.S. at 288; *CSX Transp.*, 507 U.S. at 664. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

Section 360k of the MDA expresses Congress' preemptive intent with respect to medical devices. *Medtronic*, 518 U.S. at 484. Although ambiguous in some respects, the statute unambiguously provides that federal law does not preempt the states' ability to provide a remedy for conduct that violates the FDCA. *Id.* at 495-97 (plurality) & 513 (O'Connor, J.). The legislative intent in this regard is so lucid that this Court had little trouble reaching the unanimous conclusion that a state-law damage claim based on a "violation of federal regulations" is not preempted by section 360k, notwithstanding its explicit recognition of the FDA's exclusive prosecutorial discretion with respect to FDCA remedies and the absence of a federal damage remedy for conduct which violates FDCA requirements. *Id.* at 495 & 513. Therefore, in enacting the MDA, Congress necessarily determined that there was no implicit preempting "conflict" between allowing injured claimants to obtain a damage recovery under state law for MDA violations, and affording the FDA the right to employ the various public enforcement mechanisms given by the statute. To hold otherwise would result in a legal oxymoron — a ruling that the legislature clearly expressed an intent not to preempt state power to provide a damage remedy for violation of MDA requirements, but nonetheless "implicitly" intended to do so. Surely, that is not sensible.

In order to harmonize the obvious conflict between the "Identity of Requirements" holding in *Medtronic* and the position which it takes regarding implied preemption here, petitioner must postulate a distinction between claims arising from violations of FDCA requirements that involve disclosure to the FDA and claims arising from the remaining miscellany of regulatory directives. Under this preemptive calculus, the deceit claims would be impliedly preempted, while the other claims would survive preemption under *Medtronic*. Such a distinction is artificial.

To begin with, there is simply no difference between a state-law claim based on fraudulent disclosure to the FDA and a claim based on the violation of other types of FDCA requirements in terms of the regulatory "conflicts" which are claimed to require implied preemption. The regulatory enforcement responsibilities of the FDA and the remedies available to it are the same regardless of whether an FDCA violation occurs through deceit, culpable nondisclosure or through some other means. *See, e.g.*, 21 U.S.C. §§ 331-335c & 360(h). Accordingly, allowing a state-law damage claim for violation of federal disclosure requirements does not present any greater risk of "distorting the penalty scheme established by the FDCA," "interfering with the FDA's prosecutorial discretion," agency burden, or "conflicting adjudication," than allowing a damage claim for violation of other federal requirements such as unlawful promotion and mislabeling. Indeed, given the protective strictures which most jurisdictions attach to the litigation of fraud claims — the requirement that fraud be pleaded with particularity based on an adequate pre-complaint investigation and be proven by clear and convincing evidence[13] — these proffered "risks" are even more attenuated for deceit claims than for claims rooted in federal requirements not involving regulatory disclosures.

[13] *See, e.g.*, FED. R. CIV. P. 9(b); FED. R. CIV. P. 11; Pa. R. CIV. P. 1019(b); *Humana, Inc. v. Forsyth*, 525 U.S. 299, 301 (1999); *Trans Penn Wax Corp. v. McCandless*, 50 F.3d 217, 232 (3d Cir. 1995).

Second, insofar as Congress, in enacting section 360k, recognized the states' power to afford private remedies for violation of FDCA requirements in order to provide manufacturers with additional incentives to comply with their federal regulatory obligations, preemption of claims based on misrepresentations to the FDA is peculiarly inappropriate. *See Medtronic*, 518 U.S. at 495 ("The presence of a [state-law] damages remedy . . . provides another reason for manufacturers to comply with . . . 'requirements' under federal law") & 513 (O'Connor, J.) ("the threat of a [state-law] damages remedy will give manufacturers an additional cause to comply").

The FDA's determination of whether to approve the marketing of a drug, device or biologic is completely dependent on the information reported to it by the approval applicant. *See* Merrill, R.A., *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 17 n.59 (1973). Therefore, the fulfillment of the agency's fundamental regulatory task depends entirely on full and truthful compliance with the FDA's disclosure requirements and "truthful responses to inquiries by the FDA." Green, M.D., *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J. LAW REFORM 461, 481 (1997); Garber, S., *Product Liability and the Economics of Pharmaceuticals and Medical Devices*, 127-28 (Rand 1993). Unfortunately, the history of the pharmaceutical-device industry is "littered with instances" of non-compliance in the form of intentional misrepresentations to the FDA or negligent failures to make required disclosures to the agency. Green, M.D., *Safety As An Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U.L.J. 163, 173 (1998). Indeed, in 1992, the Auditor General found so much fraud in the 510(k) process that the FDA amended its regulations to compel applicants to affirmatively state that their 510(k) notifications were truthful and not misleading. 57 Fed. Reg. 18062, 18064 (Apr. 28, 1992). And while the FDA has theoretical regulatory power to address such fraud, it is generally recognized that the agency does not have the resources to meet

this mandate in an effective way.[14] Accordingly, as one commentator put it, "[w]ithout regulatory resources to monitor and ensure universal compliance of this large, technologically complex, and informationally massive industry, we should expect that the tort system, rather than the FDA itself, will uncover instances of noncompliance with FDA [disclosure] standards." Green, 42 ST. LOUIS U.L.J. at 175.

If tort actions based on violations of FDCA requirements survive preemption under section 360k because of their perceived potential to secure compliance with such requirements, then deceit actions such as the present one should have a priority in avoiding the impediment of implied preemption.

D.

There is yet another reason why plaintiffs' fraud-on-the-FDA claims are not subject to implied preemption. In determining whether to imply preemption in a given instance, "the proper approach is to reconcile 'the operation of [the state and federal] schemes with one another. . . .' " *DeCanas*, 424 U.S. at 358. *See also CSX Transp.*, 507 U.S. at 668 (viewing state scheme as a "complement" to federal scheme); *Askew*, 411 U.S. at 332 (construction of federal statute as "one which allows . . . co-operation of the federal regime with a state regime"). Recognition of the states' power to make liability

[14] *See, e.g.*, Inspector General of the Department of Health and Human Services (HHS/IG), Report, *Investigative Devices: Four Case Studies*, OEI-05-94-00100 (Apr. 1995); General Accounting Office, *Medical Devices — FDA's 510(k) Operations Could be Improved*, GAO/PEMD-88-14 (Aug. 1988); HHS/IG, Report, *Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process*, A-15-89-00065 (Jul. 1990); H. R. Report by the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, *Less Than the Sum of its Parts — Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, GPO PRINT No. 103-N (May 1993); *Fogal v. Steinfeld*, 620 N.Y.S.2d 875, 882-83, n.5 (N.Y. Sup. 1994) (citing and collecting articles and studies); Green, 30 U. MICH. J. LAW REFORM at 476-77.

determinations based on whether there has been fraud on the FDA is necessary to preserve an appropriate reconciliation between state tort law and federal regulatory law insofar as drugs and devices are concerned.

The tort law throughout the nation has not evolved without accommodating to the fact that there is a federal scheme which regulates the market entry of drugs and devices based on an informed risk-benefit analysis by the FDA. *E.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6, cmt. b (1998). Given the thorough vetting of safety issues by the FDA, which takes place in connection with premarket approval of drugs and devices, emerging principles of state law would significantly constrict tort liability where the drug or device at issue has received premarket approval from the FDA. American Law Institute, *Enterprise Responsibility for Personal Injury*, Reporters' Study (Vol. II) at 95-101 (Weiler, ed. 1991); Green, M.D., *Statutory Compliance*, 30 U. MICH. J. LAW REFORM 461; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 & cmt. e.

However, the law also recognizes that an FDA evaluation of safety is only as good as the information on which it is based and that it is the manufacturer, not the FDA, who supplies the information upon which the agency makes its approval determinations. *Id.* Accordingly, a manufacturer cannot avoid tort liability based on an FDA regulatory approval if the plaintiff demonstrates that the approval process "was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency. . . ." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4, cmt. e.

The principal model of tort reform in the area of drug and device liability codifies the emerging common law approach. These statutes either foreclose tort liability altogether or preclude an award of punitive damages if the drug or device at issue received premarket approval from the FDA, except where the plaintiff shows that the defendant "knowingly withheld or misrepresented information required to be submitted to the FDA under its regulations." This model has been enacted as law in at

least six states[15] and proposed in the U.S. Congress (with the zealous support of the drug and device industry) during virtually every session from 1986 though the present.[16]

Permitting the award of damages based upon fraud on the FDA accommodates the primacy of federal regulation in protecting the public from unreasonably dangerous drugs and devices while assuring that individuals receive compensation when the proper operation of the federal regulatory system has been sabotaged by fraud as it was here. To hold that state courts lack the power to determine if the regulatory process was compromised by fraud because of "implied preemption" would undermine that accommodation. Ironically, it would also dismantle the principal tenet of tort reform espoused by the proponents of broad preemption in the field of drugs and devices.

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[15] *See* Mich. Comp. Laws Ann. § 600.2946(5); N.J. Stat. Ann. § 2A:58C-5; Ohio Rev. Code Ann. § 2307.80c; Or. Rev. Stat. § 30.927; Utah Code Ann. § 78-18-2; Arizona Rev. Stat. Ann. § 12-701.

[16] *See, e.g.*, S. 2760 (Product Liability Reform Act), 99th CONG., 2d SESS., § 303(c)(1)(B) (set forth in 132 CONG. REC. S12071-01) (Sept. 8, 1986) (amending original markup draft of S. 1999); S. 640 (Product Liability Fairness Act), 102d CONG., 2d SESS., § 303(c)(1)(B) (set forth in 138 CONG. REC. S13115-02 at S13117) (Sept. 9, 1992) (explained in S. REP. 102-215 (1991)); S. 687 (Product Liability Fairness Act), 103d CONG., 2d SESS., § 203(b)(2) (set forth in 139 CONG. REC. S4112-03 at S4149) (Mar. 31, 1993) (proposed amendments set forth in 140 CONG. REC. S7790-01 at S7754, S7793 & S7817) (Jun. 28, 1994); H.R. 956 (Common Sense Product Liability and Legal Reform Act of 1995), 104th CONG., 1st SESS., § 201(f) (reprinted and debated in 141 Cong. Rec. H2941-H2948) (Mar. 9, 1995) (passed, 141 CONG. REC. H3027 (Mar. 10, 1995)) ; H.R. 2425 (Medicare Preservation Act), 104th CONG., 1st SESS., § 15312 (set forth in 141 CONG. REC. H10147 at H10172) (Oct. 17, 1995); H.R. 2015 (Balanced Budget Act of 1997), 105th CONG., 1st SESS., § 4812(d)(B)(i) (set forth in 143 CONG. REG. H4416-01 at H4476) (Jun. 25, 1997); H.R. 2723 (BiPartisan Consensus Managed Care Improvement Act of 1999), 106th CONG., 1st SESS., § 412(b)(4) (set forth in 145 Cong. Rec. H9523-01 at H9554 (Oct. 7, 1999)).

E.

Petitioner and the government posit a rule of implied preemption akin to res judicata and collateral estoppel — that any determination necessary to sustain a cause of action cannot "conflict" with an express determination by a federal agency. *See* U.S. Br., 25-27; Pet'r. Br., 33-34. From this postulate, they argue that recognition of plaintiffs' fraud claim against Buckman is preempted because it would fail to effectuate the FDA's express determination to "grant[] market clearance for AcroMed's pedicle screws." *See* U.S. Br., 26-27.

There is substantial question as to whether the rule of preemption proffered by petitioner and the government applies where the allegedly preempting agency determination was based on fraud or other "affirmative misconduct." *See Arkansas La. Gas Co. v. Hall*, 453 U.S. 571, 583 (1981) (*Arkla*) (questioning the application of the "filed rate doctrine" where there is unadjudicated deceit).

There is also reason to question whether this rule could apply, consistent with the requirements of due process, to any agency determination that occurs outside of an APA rulemaking, adjudicative, or similar process. *See Davis v. Dep't of Labor and Industries of Wash.*, 317 U.S. 249, 256-57 (1942) (conditioning preclusive effect of agency determination on findings that result from adjudicatory process); *United States v. Utah Constr. and Mining Co.*, 384 U.S. 394, 421 (1966) (same).

Whatever the doctrinal limitations of this principle, one thing is clear. At a minimum, there must be a determination by a federal agency which is inconsistent with the plaintiffs' theory of liability. That minimum requirement is lacking in the present case.

Petitioner admits that in granting 510(k) clearance for AcroMed's plates and screws, the FDA made no determination with regard to the truthfulness of Buckman's representation that these components were intended for use in long bone fixation. *See* Pet'r. Br., 21. After the 510(k) clearance, representatives of the agency determined that they had been deceived concerning the intended use of the device components. J.A. 124. Accordingly, to the extent that plaintiffs assert that Buckman

defrauded the FDA, their claim does not conflict with any FDA determination.

Second, the relevant FDA determinations here are not at odds with the plaintiffs' cause of action. In seeking to establish a preempting conflict between the FDA's 510(k) determination and the plaintiffs' claims, the government twice says that "FDA granted market clearance for AcroMed's pedicle screws." *See* U.S. Br., 26. But these statements are wrong. The government's error in this regard actually demonstrates why the 510(k) determinations do not create a preempting conflict, even under the government's theory of implied preemption.

The fact is that the FDA specifically refused to grant 510(k) clearance "for AcroMed's pedicle screws." J.A. 101-06. In fact, the agency expressly told Buckman that AcroMed's pedicle screws could not be introduced into the market. *Id.*

Plaintiffs' claim is that Buckman subsequently deceived the FDA, and that as a result of this deception, devices intended for use in spine surgery — "pedicle screw fixation devices" — unlawfully entered the market where they were implanted in plaintiffs' spines causing serious injury. Nothing about that claim requires a finder of fact to determine that the FDA's determinations were "wrong" or otherwise "fails to give effect to" any FDA determination. In fact, recognition of the plaintiffs' claim actually serves to enforce the express determination made by the FDA that AcroMed's pedicle screw fixation devices should not be introduced into commerce because they posed serious risks that had not been adequately evaluated by accepted methods of science.

The principal cases cited by the government in support of implied preemption, *Arkla* and *Kalo Brick*, require that courts enforce pertinent agency determinations in private damage actions. *See Arkla*, 453 U.S. 571; *Chicago and N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). In seeking to recover damages caused by a fraudulent scheme to market pedicle screw fixation devices in violation of an express government prohibition, that is exactly what the plaintiffs have asked the courts to do here.

F.

It has also been argued that plaintiffs' fraud claims are subject to implied preemption because permitting the litigation of those claims would pose an incidental burden on FDA resources. The adherents to this unique view of preemption describe two forms of agency burden which, in their view, justify depriving damage relief to persons injured by fraud. First, they claim that allowing litigation predicated upon the interactions between the FDA and those whom it regulates will inevitably result in discovery requests requiring the agency to produce thousands of documents and subject its employees to an obligation to provide testimony. Second, they hypothesize that recognition of a private civil damage claim based on false disclosures to the FDA will create an incentive to deluge the agency with unnecessary documents which will further contribute to the regulatory mire.

This theory of implied preemption is a unique one which is unsupported by a single authority. The reasons for this are obvious.

First, federal law reflects differential policies towards agency disclosure of information. Importantly, there is a strong federal policy supporting full public disclosure of documents used, created and relied upon in the FDA regulatory process. This is reflected in the Freedom of Information Act and in the regulations promulgated by the FDA. *See, e.g.*, 5 U.S.C. § 552; 21 C.F.R. § 20.1, *et seq.* Therefore, preemption of a state cause of action based on the document production burden imposed on the government would actually be contrary to Congressional intent. It is, therefore, inconsistent with the requirement that implied preemption be employed only where state law presents an obstacle to accomplishing the objectives of Congress.

Of course, there are principles of federal law such as the "deliberative process privilege" and the "*Touhy*" doctrine, which are based on defined federal interests in limiting the availability of testimony or document disclosure by agency officials under certain discreet circumstances. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) (agency's power to promulgate

"housekeeping" regulations restricting employees from testifying in order to conserve agency resources); 21 C.F.R. § 20.1 (FDA's "*Touhy*" regulation); *Redland Soccer Club, Inc. v. Dep't of Army of U.S.*, 55 F.3d 827, 853 (3d Cir. 1995), *cert. denied*, 516 U.S. 1071 (1996) (deliberative process privilege). However, it is certainly more sensible to protect these limited governmental interests through a direct, and appropriately targeted application of these well-developed principles of federal law than through a broad preemption blunderbuss.

Second, the "discovery burden" theory of implied preemption which is espoused by our opponents is impossible to cabin. Irrespective of fraud claims, the typical pharmaceutical-device products liability litigation inevitably generates requests for the FDA to produce an enormous volume of documents and testimony concerning the interactions between the defendant and the agency.[17] This is not because plaintiffs usually claim that the agency was defrauded, but because the regulatory background is always a central factor underlying both the prosecution and defense of litigation of this sort. If the "burden" on the government created by such discovery requests was preemptive of the underlying liability claims, then all pharmaceutical-device claims would be preempted. Indeed, given the important role of federal regulation in everything from automotive safety to zoology, the potential production burden on the government could preempt nearly all civil litigation. The absurdity of this potential result counsels rejection of this type of "burden" as a basis for implied preemption. *E.g.*, *Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs, U.S. Dept. of Labor*, 519 U.S. 248, 261 (1997) (presumption that legislature does not intend an absurd result); *United States v. Rodgers*, 466 U.S. 475, 484 (1984) (same).

[17] Thus, for example, in the recent "FenPhen" Diet Drug Litigation, the plaintiffs did not make any substantive claim of fraud on the FDA. Nevertheless, in that litigation, the FDA produced 35,000 pages of agency records in response to a federal court subpoena and offered to make several of its employees available for testimony. *See* U.S. Mem. of Law in Opp. to PMC's Motion to Compel, Dkt. No. 201402, MDL 1203 (E.D. Pa.); *see also In Re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, MDL 1203, PTO 1461 (Oct. 12, 2000).

Finally, the argument that allowing damage liability for violation of FDA disclosure requirements will cause manufacturers to deluge the agency with irrelevant information which they otherwise would have withheld is based on complete speculation. What evidence is there to suggest that the possibility of paying damages to plaintiffs in an individual case will create a materially higher incentive to irrelevant disclosure than the possibility of criminal sanctions, fines, penalties, and product recalls which the FDA has the power to mete out? There is none. There is no legal principle which would allow a reed of speculation so slender to usurp the states' ability to afford damage relief.

G.

There remain three miscellaneous arguments which have been advanced in support of implied preemption. However, they do not merit extensive treatment.

1. First, it is claimed that the promulgation of the FDA's 1998 regulation reclassifying pedicle screws conflicts with plaintiffs' fraud claims. It is hard to see how. The government itself concedes that in promulgating that regulation, the FDA did not make any adjudication concerning the lawfulness of past conduct. U.S. Br., Pet. Stage, 14. The government concedes that the promulgation of that regulation in 1998 was prospective and could not validate unlawful behavior which preceded the regulation. *Id.* Finally, the regulation does not support a claim that Buckman's fraud was inconsequential on the grounds that it represents a regulatory determination that pedicle screw devices are properly subject to less regulation than that afforded to them at the time of Buckman's fraud in the mid-1980s. *See* Pet'r. Br., 39-40. The 1998 reclassification regulation allows Class II treatment of pedicle screw devices for a narrow range of indications subject to numerous special controls as to design, testing, material composition, biocompatability and labeling, which provide protections that the plaintiffs never received.

21 C.F.R. § 888.3070. If anything, the regulation demonstrates the risks that plaintiffs were exposed to because of Buckman's fraudulent evasion of the FDA's determination that pedicle screws should not reach the market without additional testing and controls. Consequently, as the government itself concedes, the reclassification regulation creates no preempting conflict with plaintiffs' claims. *See* U.S. Br., Pet. Stage, 14.

2. It is also claimed that permitting the assertion of plaintiffs' fraud claims will undercut a supposed federal policy to promote the development of "off-label" uses — those uses that have not been subject to FDA approval or clearance. However, the policy reflected in the FDCA is that such untested uses are "treacherous."[18] Thus, while recent amendments to the FDCA permit manufacturers to provide limited "educational materials" regarding "off-label use" under very narrow circumstances, the promotion and clinical development[19] of "off-label uses" without FDA approval or clearance is generally illegal. *See* pp. 1-2 & 6, *supra*; *see generally*, Weeks, E., *Is It Worth the Trouble? The New Policy On Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645 (1999). Accordingly, to the extent that recognition of plaintiffs' cause of action creates incentives to comply with federal law concerning the unlawful development, testing, marketing and promotion of unapproved uses, it is in harmony — not conflict — with the relevant objectives of federal law. Indeed, this is a reason not to imply preemption.

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[18] *See* pp. 1-2, *supra*. To the extent that the law allows physicians to use drugs or devices "off label," it does so as a consequence of the fact that the FDCA is limited to regulation of the distribution of drugs, devices and biologics and does not reach the "practice of medicine" by physicians. Nightingale, S.L. *Unlabeled Use of Approved Drugs*, DRUG INFORMATION JOURNAL, 26:141-47 (1992).

[19] If a manufacturer wishes to develop clinical evidence to support approval or clearance of an "off-label" use, it may only do so pursuant to an investigational device exemption from the FDA. *See* 21 U.S.C. § 360j(g); 21 C.F.R. § 812, *et seq.*

3. Finally, petitioner and its industry supporters invoke preemption as a specie of tort reform, urging that if the present fraud claims are not preempted, plaintiffs will routinely seek to avoid the effect of an FDA approval or clearance by making specious claims of fraud. This argument is a political one not properly conjured in aid of a judicial finding of implied preemption. *Geier*, 120 S. Ct. at 1932 (Stevens, J., dissenting). Even as a political argument it fails. The argument assumes that because an individual is a plaintiff, he or she will automatically file a baseless claim. Certainly, there is no evidence for this. The states of Michigan, Ohio, New Jersey, Oregon, Utah and Arizona have, for some period of time, had a scheme that allows plaintiffs to recover punitive damages in pharmaceutical-device cases only where they prove fraud on the FDA. *See* fn. 15, *supra*. Is there any evidence that plaintiffs have abused this scheme? It appears that there is not, particularly given that these statutes are touted as a model of tort reform.

Also, claims of fraud are attended by procedural safeguards, not attached to other causes of action, which provide substantial protection against specious assertions. These include the requirement that fraud be pleaded with particularity based on an adequate pre-complaint investigation and that fraud be demonstrated by clear and convincing evidence. *See* fn. 13, and accompanying text, *supra*.

In those rare occasions where there is abuse, sanctions or damage liability are available and afford appropriate remedies. *See, e.g.*, FED. R. CIV. P. 11; 28 U.S.C. § 1927; *Alyeska Pipeline Service Co. v. Wilderness Society*, 421 U.S. 240, 248-59 (1975); RESTATEMENT (SECOND) OF TORTS § 674. However, it would be ironic, indeed, if the courts retained the power to award damages for the injuries caused by fraudulent litigation, but were ousted of that power where the injuries at issue were caused by fraudulent regulatory submissions.

CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the Third Circuit should be affirmed.

Respectfully submitted,

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