No. 98-1768

In the Supreme Court of the United States

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

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

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INTEREST OF THE UNITED STATES

This case presents the question whether federal law expressly or impliedly preempts state-law tort claims alleging fraud on the Food and Drug Administration (FDA) during the process of obtaining premarket clearance for certain medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). The United States has a substantial interest in the resolution of that issue. FDA is responsible for administering the premarket-clearance process for medical devices, and the decision in this case will affect that responsibility. In addition, FDA has issued regulations (21 C.F.R. 808.1) that interpret the FDCA's express preemption provision, 21 U.S.C. 360k(a). At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage in this case, and that brief urged the Court to grant the petition for a writ of certiorari.

STATEMENT

Respondents are persons who claim that they suffered injuries when their physicians implanted orthopedic bone screws into the pedicles of their spines. They allege that

Buckman Company (petitioner) fraudulently obtained clearance from FDA for another company, AcroMed, to market the pedicle screws, and they seek to hold petitioner liable under state law for its alleged role in causing their injuries. The district court granted petitioner's motion to dismiss, holding that respondents' fraud-on-the-FDA claims are preempted by federal law. The court of appeals reversed, holding that such claims are not preempted.

1. a. The FDCA, 21 U.S.C. 301 *et seq.*, regulates food, drugs, cosmetics, and medical devices, and authorizes FDA to enforce its requirements. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplemented the FDCA's medical device requirements. The MDA classifies medical devices into three classes based on the risk they pose to the public and the controls necessary to provide a reasonable assurance of a device's safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. IV 1998). Class I devices present no unreasonable risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful. Such devices are also subject to general controls, but FDA in addition has authority to require that such devices comply with other requirements known as "special controls." 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II). All post-1976 devices are initially deemed Class III devices. 21 U.S.C. 360c(f)(1).

In general, before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" (PMA) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a), (c) and (d) (1994 & Supp. IV 1998); 21 C.F.R. Pt. 814. A "grandfathering" provision permits Class III devices that were on the market before the

MDA's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In the interest of fairness and to prevent "grandfathered" manufacturers from monopolizing the market, Congress also permitted other manufacturers to distribute similar devices by showing through a premarket notification process that they are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). That premarket notification process is known as the "Section 510(k) process," referring to the section of the FDCA codified at 21 U.S.C. 360(k). A device is "substantially equivalent" to a grandfathered device only if, *inter alia*, it has the same "intended use" as that device. 21 U.S.C. 360c(i)(1)(A) (1994 & Supp. IV 1998).

b. FDA regulations set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.F.R. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," 21 C.F.R. 807.87(*l*). The regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted." 21 C.F.R. 807.87(k).

Federal law generally prohibits persons from making false or fraudulent statements in submissions to federal agencies, see 18 U.S.C. 1001 (1994 & Supp. IV 1998), and the FDCA specifically prohibits, "[w]ith respect to any device, the

submission of any report that is required by or under this chapter that is false or misleading in any material respect." 21 U.S.C. 331(q)(2). FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a wide range of remedies and sanctions if it uncovers such fraud, see 21 U.S.C. 332 (injunctive relief); 21 U.S.C. 333(f)(1)(A) (civil money penalties); 21 U.S.C. 334(a)(2)(D) (seizure of the device); 21 U.S.C. 333(a) (criminal prosecution). FDA has established an enforcement policy concerning fraud in premarket submissions that details the kinds of remedies it is likely to pursue. See 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. All lawsuits to enforce the Act's provisions, however, "shall be by and in the name of the United States." 21 U.S.C. 337(a).

c. The MDA contains an express preemption provision, 21 U.S.C. 360k(a), which provides:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) authorizes the Secretary to grant exemptions to the preemption provision in certain circumstances. FDA has issued regulations that interpret the scope of Section 360k(a). Under FDA's interpretation, State or local require-

ments are preempted only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. 808.1(d).

This Court addressed Section 360k's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). The *Medtronic* plaintiffs filed state common law tort actions for injuries caused by a pacemaker that FDA had cleared for distribution under Section 510(k). Plaintiffs asserted causes of action based on defective design, negligent manufacturing, and negligent labeling. The Court first held that Medtronic's compliance with the Section 510(k) premarket clearance process did not preempt plaintiffs' defective design claims, because FDA's clearance did not "require" the pacemaker "to take any particular form for any particular reason." *Id.* at 493; accord *id.* at 513 (O'Connor, J. concurring in part and dissenting in part). The Court next held that Section 360k did not preempt state-law claims in which the duty of care paralleled FDA requirements. *Id.* at 495; accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court explained that common law duties that "parallel" federal requirements are not "different from, or in addition to," the federal requirements. *Ibid.*

Finally, the Court held that Section 360k did not preempt plaintiffs' state-law claims based on negligent manufacturing and labeling. 518 U.S. at 497-502. The Court recognized that FDA regulations impose general manufacturing and labeling requirements. The Court noted, however, that under Section 360k, "federal requirements must be 'applicable to the device' in question, and, according to [FDA] regulations [construing Section 360k], pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 500. The Court therefore concluded that the "entirely generic" federal manufacturing and labeling requirements did not preempt the *Medtronic* plaintiffs' negligent manufacturing and labeling claims. *Id.* at 501.

2. a. Petitioner, a regulatory consultant, was retained by the AcroMed Corporation to act as its liaison to FDA. Pet. App. 4a. In September 1984, petitioner, on behalf of AcroMed, made a Section 510(k) submission to FDA to obtain marketing clearance for an orthopedic bone screw device known as the Variable Screw Placement (VSP) Spinal Plate Fixation System. *Ibid.* Petitioner's submission stated that AcroMed intended to market the device for use in spinal surgery. *Id.* at 4a-5a. FDA denied the request, finding that the VSP device was a Class III device and was not substantially equivalent to any predicate device marketed before the MDA's enactment. *Id.* at 5a. In September 1985, petitioner filed a second submission for marketing clearance, again stating that the device was intended for use in spinal surgery. *Ibid.* FDA denied the submission on the same ground. *Ibid.*

In December 1985, petitioner and AcroMed made a different attempt to obtain marketing clearance. Pet. App. 5a. They split the VSP device into its two component parts, which they called "nested bone plates" and "cancellous bone screws," and they filed separate Section 510(k) submissions for each component. *Ibid.* Those submissions stated that the devices were intended to be used in long bones of the arms and legs. *Ibid.* In responding to an FDA request for additional information about the devices' intended use, petitioner stated that they "are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)." J.A. 16. In February 1986, FDA granted marketing clearance for AcroMed's bone plates and screws for that stated purpose. Pet. App. 5a.

b. Respondents are plaintiffs who filed lawsuits alleging that they were injured when their doctors inserted the assembled VSP device into their spines. Pet. App. 1a. More than 2300 individual lawsuits were brought against multiple defendants, and those suits were consolidated for pre-trial

proceedings in the Eastern District of Pennsylvania pursuant to the multi-district litigation statute, 28 U.S.C. 1407 (1994 & Supp. IV 1998). Pet. App. 1a. The only count against petitioner is one that respondents call "fraud on the FDA." *Id.* at 5a. That count asserts that petitioner intentionally and falsely represented to FDA that the devices for which it sought clearance were "intended for use" in the long bones, when, in fact, the devices were "intended exclusively for use in the spine." J.A. 15-16. Respondents further allege that FDA did not know that the devices were intended exclusively for use in the spine, and that if petitioner had not made false statements about their intended use, FDA would not have cleared the devices for marketing, the devices would not have been sold, and respondents would not have been injured. J.A. 21. Respondents' claim does not depend on any allegation that the device itself was defective under state law or had been manufactured or labeled in a manner that was negligent or illegal under state law.

c. The district court dismissed the fraud-on-the-FDA claims on the ground that they were expressly preempted under 21 U.S.C. 360k. Pet. App. 53a. The district court reasoned that the MDA "does not permit courts to 'perform the same function initially entrusted to the FDA,'" *id* at 49a, and that FDA is in the "best position" to decide whether a manufacturer has "withheld material information from the agency and, if so, [to determine] the appropriate sanction," *id.* at 50a. After this Court decided *Medtronic*, respondents asked the district court to reinstate their fraud-on-the-FDA claims. *Id.* at 7a. The district court concluded that *Medtronic* foreclosed a finding of express preemption. *Id.* at 40a. It nevertheless refused to reinstate respondents' claims on the ground that they constituted an impermissible attempt to assert a private right of action for a violation of the MDA. *Id.* at 36a-40a.

3. A divided panel of the court of appeals reversed. Pet. App. 1a-32a. The court first held that respondents' fraud-on-

the-FDA claims are not expressly preempted, because there is neither a "federal 'requirement' 'applicable to the device' at issue," nor "a state 'requirement' 'with respect to' that device." *Id.* at 13a. The court further held that the "state common law relied upon [by respondents] does not impose any obligation on [petitioner] inconsistent with federal law," because "18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful." *Ibid.* The court of appeals also rejected the district court's conclusion that fraud-on-the-FDA claims constitute an impermissible attempt to obtain a private right of action for violations of the MDA. *Id.* at 13a-17a. The court concluded that such reasoning is inconsistent with *Medtronic*. *Id.* at 16a.

The court of appeals also held that respondents' fraud-on-the-FDA claims are not impliedly preempted. Pet. App. 18a. The court saw "no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and "common law fraudulent misrepresentation claims." *Ibid.* Finally, the court rejected petitioner's contention that a statement of intended use refers to the use for which an applicant seeks market clearance. *Id.* at 22a-24a. The court held that a statement of intended use refers to an applicant's marketing intentions. *Id.* at 22a-23a. The court therefore concluded that, if AcroMed intended at the time of the application to market its device solely for use in the spine, petitioner's statement that the device was intended for use in the long bones would have constituted a material misrepresentation. *Id.* at 23a-24a.

Judge Cowen dissented. Pet. App. 25a-32a. Judge Cowen concluded that fraud-on-the-FDA claims conflict with federal law because they "greatly distort the penalty scheme established by the statute." *Id.* at 28a. In particular, the "penalties attached to a violation of the FDA's regulations will

often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." *Ibid.* Judge Cowen also concluded that fraud-on-the-FDA claims conflict with federal law because they permit juries to impose "[m]assive liability" when FDA "would not find any misconduct." *Id.* at 31a.

SUMMARY OF ARGUMENT

I. Respondents' fraud-on-the-FDA claims are not expressly preempted by FDA's Section 510(k) disclosure requirements. Under *Medtronic*, express preemption occurs only when (1) the federal requirement is specific, and (2) the counterpart state requirement is different from, or in addition to, that specific federal requirement. Neither of those prerequisites for express preemption is present here.

First, FDA's Section 510(k) disclosure requirements are not specific. They are stated in general terms, and they apply to all devices that must undergo the Section 510(k) clearance process, not just pedicle screw devices. Second, respondents' common law theory of liability does not impose a duty that is different from, or in addition to, the applicable federal requirements. Federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance. Respondents' claim that petitioner falsely represented to FDA that its devices were intended for use in the long bones, when, in fact, they were intended exclusively for use in the spine, does not impose any requirement that is different from an applicable federal requirement.

II. Respondents' fraud-on-the-FDA claims nonetheless are impliedly preempted by federal law. When Congress legislates in a field of traditional state concern, there is a presumption against preemption. That presumption applied to the defective design, negligent manufacturing, and failure to warn claims at issue in *Medtronic*. Respondents' claims, however, focus on an entity's obligations to truthfully dis-

close information to a federal regulatory agency. That field is not one that States have traditionally occupied; instead, it is one of preeminent federal concern. Under this Court's cases, when state law intrudes on an area of preeminent federal concern, the presumption against preemption disappears, and the danger of a fatal conflict significantly increases.

Applying the preemption analysis that is appropriate when state law intrudes on an area of preeminent federal concern, respondents' fraud-on-the-FDA claims conflict with federal law. In particular, they conflict with the important federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action.

Respondents' fraud-on-the-FDA claims also conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices. Respondents' claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA.

Fraud-on-the-FDA claims also invite highly intrusive discovery concerning federal agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. Such claims therefore pose a real danger of diverting FDA's resources from the important health mission that Congress

has assigned to it and of distorting FDA's internal decision-making process.

ARGUMENT

I. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE NOT EXPRESSLY PREEMPTED

Petitioner contends (Pet. 26-27) that respondents' fraud-on-the-FDA claims are expressly preempted. In particular, petitioner argues that the federal requirement that an applicant for Section 510(k) marketing clearance submit information concerning a device's "intended use" preempts respondents' fraud-on-the-FDA claims. Under the MDA, however, express preemption occurs only when there is (1) a federal "requirement applicable to the device," and (2) the state requirement is "is different from, or in addition to," that federal requirement. 21 U.S.C. 360k(a). Neither of those prerequisites for express preemption is present here.

A. FDA's Disclosure Requirements Are Not Specific

In *Medtronic*, the Court held that federal "requirement[s]" are "applicable to the device" within the meaning of the MDA's express preemption provision only when they are "'applicable to the device' in question," 518 U.S. at 500, and, in accordance with FDA regulations, only when they are "'specific counterpart regulations' or 'specific' to a 'particular device,'" *ibid.* (quoting 21 C.F.R. 808.1(d)). Federal requirements therefore can have preemptive force under Section 360k(a) when "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501. Federal requirements do not have a preemptive effect under Section 360k(a), however, when they "reflect important but entirely generic concerns about device regula-

tion generally." *Id.* at 501-502; see also *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment).

Medtronic establishes a sensible and administrable line for determining the kind of federal requirements that can have preemptive force under Section 360k(a). For example, FDA's requirements concerning hearing aids (21 C.F.R. 801.420, 801.421), cables and leads (21 C.F.R. 898), impact-resistant lenses (21 C.F.R. 801.410), and devices containing natural rubber (21 C.F.R. 801.437) preempt counterpart state requirements that are different from, or in addition to, those requirements. Those federal requirements are stated with specificity and apply to a specific device or set of devices. In contrast, as the Court explained in *Medtronic*, FDA's general manufacturing and labeling requirements do not have preemptive force. 518 U.S. at 501. Those requirements are stated at a high level of generality and apply to all devices.

Under the interpretation of the express preemption provision adopted in *Medtronic*, the requirement that an applicant submit information concerning a device's "intended use" does not have preemptive force. That requirement is stated in general terms, and it applies to all devices that must undergo the Section 510k clearance process, not just pedicle screw devices. See 21 C.F.R. 807.87(e). Thus, like the general manufacturing and labeling requirements at issue in *Medtronic*, the statement of intended use required of applicants in the Section 510k process is not a "'specific counterpart regulation[]' or 'specific' to a 'particular device.'" *Medtronic*, 518 U.S. at 500 (quoting 21 C.F.R. 808.1(d)). It is therefore not the kind of federal requirement that can have a preemptive effect under the MDA's express preemption provision.[1]

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[1] As we explain in our amicus brief at the petition stage (at 10-11 n.4), Section 360k(a) does preempt a specific duty of care that is made applica-

B. Respondents' Fraud-On-The-FDA Claims Parallel Federal Requirements

Even if the general duty to provide information to FDA about a product's "intended use" were the kind of federal requirement that could have a preemptive effect under Section 360k(a), respondents' fraud-on-the-FDA claims would still not be expressly preempted. As construed in *Medtronic*, Section 360k does not deny a State "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. Such common law duties are not "different from, or in addition to," federal requirements within the meaning of Section 360k. *Ibid.*

Respondents' sample complaint includes allegations that petitioner committed common law fraud when it falsely informed FDA that AcroMed's devices were intended for use in long bones when, in fact, they were intended exclusively for use in the spine. Pet. App. 8a-9a; J.A. 15-16. Since federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance (see 21 U.S.C. 331(q)(2); 18 U.S.C. 1001; 21

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ble to a device through application in litigation of a State's common law of torts, if that requirement is different from, or in addition to, a specific requirement imposed by FDA. It does not follow from the fact that a general *state* tort duty may be preempted as applied in a particular case that the existence of general *federal* standards have preemptive force. The Court rejected that contention in *Medtronic*. 518 U.S. at 501-502; *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment). Similarly, the fact that a device has been cleared by FDA through the Section 510(k) process does not mean that any general rules and duties governing that process have thereby been made "specific" to the device. At most, FDA would have determined only that any preexisting requirements governing the process (whether general or "specific") were satisfied. In any event, there is no indication in this case that FDA determined when it cleared the device under Section 510(k) that petitioner and AcroMed had satisfied all applicable duties of disclosure.

C.F.R. 807.87(e); 21 C.F.R. 807.87(k)), respondents' common law fraud theory parallels the applicable federal requirements. It is therefore not "different from, or in addition to," the applicable federal requirements within the meaning of Section 360k(a).

Petitioner argues (Pet. 27; Reply Br. Pet. Stage 9-10) that respondents' common law theory imposes a requirement that is different from the applicable federal requirement because, under federal law, "intended use" refers to the use set forth in the labeling, while respondents' common law theory equates intended use with a manufacturer's subjectively desired off-label uses. Petitioner's contention misreads both the applicable federal standards and the allegations in respondents' complaint.

Under FDA's regulations, the "intended use" of a medical device is defined by the "objective intent of the persons legally responsible for the labeling of [the] device[]," and objective intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." 21 C.F.R. 801.4. Because objective intent is determined in part by reference to a manufacturer's "expressions," a device's "labeling" is relevant in determining a device's intended use. 21 C.F.R. 801.4. But a device's labeling is not the exclusive source for determining intended use. Also relevant are, *inter alia*: (1) "advertising matter," (2) a manufacturer's "oral or written statements," (3) the manufacturer's "knowledge" that a product is "offered and used for a purpose for which it is neither labeled nor advertised," and (4) the manufacturer's "knowledge" of facts that would give him "notice" that a product "is to be used" for purposes other than those for which the manufacturer offered it. 21 C.F.R. 801.4. See also 21 C.F.R. 801.5 (discussing adequate directions for use of a device for its intended use).

Thus, when FDA seeks from an applicant a statement of a device's intended use, it is not simply asking for the use that

will appear on the labeling. It is asking for the intended use that will be revealed by all the manufacturer's "expressions" and "the circumstances surrounding" the device's "distribution." 21 C.F.R. 801.4. Under the regulations, a manufacturer is not required to disclose every foreseeable use of a device that it secretly desires. Physicians often use medical devices for purposes that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market. But whatever may be the full scope of a manufacturer's duty to disclose possible uses of the device beyond those stated in the labeling the manufacturer has submitted, when, at the time of the application, a manufacturer plans to promote and distribute a device exclusively for one use, it must disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be false and misleading. The intended use stated in the premarket notification must be a bona fide use; it cannot be a pretext calculated to clear the device for distribution for other uses.[2]

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[2] That conclusion is not affected by the 1997 amendments to the FDCA. Those amendments were not in effect at the time of petitioner's alleged misconduct. In any event, the amendments do not alter the analysis for devices subject to the Section 510(k) process after they were enacted. Under 21 U.S.C. 360c(i)(1)(A), as amended in 1990, a device can be found to be substantially equivalent to a pre-1976 device only if it "has the same intended use as the predicate device." The 1997 amendments provide only that (for a period of five years), in making a "substantial equivalence" determination, FDA's determination concerning a device's "intended use * * * shall be based upon the proposed labeling." 21 U.S.C. 360c(i)(1)(E)(i) (Supp. IV 1998). That provision does not relieve manufacturers of their obligation under 21 C.F.R. 807.87(e), 807.87(k) and 21 U.S.C. 331(q)(2) to truthfully inform FDA of a device's "intended use" as that term is defined in FDA's "intended use" regulation, 21 C.F.R. 801.4. The manufacturer must continue to furnish proposed labeling that accurately reflects the device's intended use, and FDA then determines

Respondents' sample complaint includes allegations that petitioner engaged in just such misleading conduct. Respondents do not claim that AcroMed intended to market its devices for use in the long bones, but secretly hoped that they would be used in spinal surgery as well. Rather, respondents claim that, while petitioner represented to FDA in its Section 510(k) submission that AcroMed's devices were intended to be used in the long bones, in fact, AcroMed planned to promote and distribute the devices exclusively for use in the spine. J.A. 15-16. That common law theory of liability does not rest on the imposition of a duty that is "different from" or "in addition to" federal requirements. Instead, that common law theory is consistent with the duties imposed by applicable federal requirements. It is therefore not expressly preempted.

II. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE IMPLIEDLY PREEMPTED

The absence of express preemption, however, does not exhaust the preemption inquiry. An express preemption provision "does not bar the ordinary working of conflict pre-

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substantial equivalence based on the proposed labeling. The amendments also authorize FDA to require a statement in a device's labeling concerning "a use of the device not identified in the labeling" if FDA determines "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling" and "such use could cause harm." 21 U.S.C. 360c(i)(1)(E)(i)(I) and (II) (Supp IV 1998). That statutory authority confirms that a device's intended use may be determined from evidence other than a device's proposed labeling and that FDA is required to confine its inquiry to the intended use identified in the proposed labeling only when it makes a substantial equivalence determination. That statutory authority concerning other potentially harmful intended uses also underscores why a manufacturer seeking Section 510(k) clearance for a device must disclose all intended uses of the device, not merely those set forth in whatever proposed labeling the manufacturer chooses to submit in the Section 510(k) clearance process.

emption principles." *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913, 1919 (2000). Those principles preclude respondents' fraud-on-the-FDA claims.

A. Fraud-On-The-FDA Claims Intrude On An Area Of Preeminent Federal Concern, And Are Therefore Subject To A More Stringent Conflict Preemption Analysis

1. When Congress legislates "in a field which the States have traditionally occupied," preemption analysis begins "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485. That assumption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Ibid.* The *Medtronic* plaintiffs' claims of defective design, negligent manufacturing, and negligent failure to warn all implicated core areas of traditional state concern. The Court therefore began its analysis in *Medtronic* with a "presumption" that Congress did not intend to preempt those claims. *Ibid.*

The situation here is fundamentally different. Respondents' fraud-on-the-FDA claims do not depend on any showing that the device had a defective design, was negligently manufactured, or did not bear adequate warnings under state law. Pet. App. 8a-9a. Instead, respondents simply contend that, but for petitioner's alleged misrepresentations to FDA, the agency would not have cleared the device for marketing, the device would not have been marketed, and they would not have been injured. *Ibid.* Respondents' claim therefore does not focus on the device itself, on the manner in which it was designed, produced, and distributed, or on a State's legitimate interest in those subjects. It focuses,

rather, on the relationship between the federal government and the entities it regulates.

The field involving an individual's obligations to the federal government, and, more particularly, an individual's obligation to provide accurate information to a federal regulatory agency, is not one "which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485. Unlike the traditional common law torts at issue in *Medtronic*, the newly fashioned state-law tort of committing fraud on a federal regulatory agency has no existence that is independent of the federal statutes that establish federal regulatory agencies and require regulated entities to make certain disclosures to those federal agencies. In this case, for example, a holding that fraud-on-the-FDA claims are preempted would not eliminate any claim that existed under state law before the MDA was enacted. Conversely, the field involving an individual's obligation to provide accurate information to a federal regulatory agency is one in which there is an overriding and longstanding federal interest. If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how to sanction those who fail to provide such information.

In enacting the 1934 amendment to 18 U.S.C. 1001, Congress recognized the paramount need of federal regulatory agencies to receive accurate information from entities they regulate. The 1918 version of Section 1001 had prohibited false statements to government officials made for the purpose of cheating the government out of property or money. That restricted scope "became a serious problem with the advent of the New Deal programs in the 1930s." *United States* v. *Yermian*, 468 U.S. 63, 80 (1984) (Rehnquist, J., dissenting). Because the new regulatory agencies relied heavily on the reports filed by regulated entities to ensure compliance, the filing of false reports could readily defeat the

agency's regulatory objectives. *United States* v. *Gilliland*, 312 U.S. 86, 92-93 (1941). To address that concern, Congress amended Section 1001 to prohibit the making of any false statement or the filing of any false writing or document on any matter within the jurisdiction of any department or agency of the United States. *Ibid.* That amendment confirms the importance that federal law places on a regulatory agency's ability to obtain accurate information from those it regulates.

2. Because respondents' fraud-on-the-FDA claims implicate an area of paramount federal interest, they are subject to a more stringent conflict preemption analysis. Under this Court's cases, when state law implicates an area of preeminent federal concern, the presumption against preemption disappears and the likelihood of a fatal conflict between state and federal law significantly increases.

For example, in *Boyle* v. *United Techs. Corp.*, 487 U.S. 500 (1988), the Court noted that, while "[i]n most fields of activity," the Court has "refused to find federal pre-emption of state law in the absence of either a clear statutory prescription * * * or a direct conflict between federal and state law," in areas involving "unique federal interests", the Court has more readily determined that state law is preempted. *Id.* at 504. The Court explained that the presence of a "unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *Id.* at 508. Applying that analysis, the Court held that design defect suits against government contractors implicate unique federal interests that require the displacement of state law. *Id.* at 511-512. In reaching that conclusion, the Court noted that such suits border on two areas that it had previously found to involve uniquely federal interests: the obligations and rights of the United States under its contracts, which are governed exclusively by federal law, and the civil liability of federal officers for actions taken in the course of their official duty, which in many contexts is con-

trolled by federal law. *Id.* at 505. Just as federal law presumptively defines the duties owed by federal employees and contractors to the federal government, so too here federal law presumptively defines the duties owed to the federal government by entities regulated by the federal government. Cf. *Hancock* v. *Train*, 426 U.S. 167, 178-179 (1976).

Moreover, in *Boyle*, the plaintiff sought to hold the manufacturer liable for injuries caused by a product that allegedly was defective—a field generally subject to state law—and that state law was displaced only to the extent necessary to give effect to the countervailing federal interests.[3] Here, by contrast, respondents' fraud-on-the-FDA count does not depend on any claim that the product itself was independently defective under state law or on any claim that the distribution of the product independently violated any duty owed under state law. The concerns about the displacement of state law in *Boyle* are therefore largely inapplicable here.

In *Pennsylvania* v. *Nelson*, 350 U.S. 497 (1956), the Court held that federal sedition laws preempt comparable state prohibitions. The Court reasoned that the federal sedition laws "touch a field in which the federal interest is so dominant that the federal system [must] be assumed to preclude enforcement of state laws on the same subject." *Id.* at 504. The Court further explained that "[s]edition against the United States is not a *local* offense. It is a crime against the *Nation*. * * * It is not only important but vital that such prosecutions should be exclusively within the control of the Federal Government." *Id.* at 505.

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[3] In fashioning the scope of the government-contractor defense to liability under state law in those circumstances, the Court in *Boyle* relied on the discretionary function exemption under the Federal Tort Claims Act, 28 U.S.C. 2680(a), which exempts the United States from liability for performing the discretionary function of selecting an appropriate design. The Court held that to subject a federal contractor to liability for a design that was selected by the federal agency would undermine that exemption. 487 U.S. at 511-512.

And, in *United States* v. *Locke*, 120 S. Ct. 1135, 1151-1152 (2000), the Court held that Coast Guard regulations concerning the reporting of marine casualties preempted a state regulation that imposed similar requirements. The Court reasoned that the "assumption" of non-preemption does not apply "in an area where there has been a history of significant federal presence," *id.* at 1147, that maritime commerce constitutes such an area, *id.* at 1148, and that, in an area of preeminent federal concern, even state laws that mirror federal requirements can conflict with the intent to create "a workable, uniform system," *id.* at 1151.

B. Fraud-On-The-FDA Claims Conflict With The Important Federal Interest In Permitting FDA To Decide For Itself Whether It Has Been Defrauded, And, If So, What Remedy To Seek

Applying the analysis that is appropriate in cases involving an area of preeminent federal concern, respondents fraud-on-the-FDA claims are preempted. The FDCA establishes a comprehensive scheme to regulate the information that an entity must submit to FDA, and respondents' fraud on the FDA claims conflict with the strong federal interest in uniform enforcement of that comprehensive scheme.

1. FDA has issued regulations that set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.R.F. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in com-

mercial distribution," 21 C.F.R. 807.87(*l*). FDA has issued guidance on how to supply the information required by its regulations. See *Premarket Notification 510(k): Regulatory Requirements for Medical Devices, http://www.fda.gov /cdrh/manual/510kprt1.html.* FDA's regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted," 21 C.F.R. 807.87(k), and the FDCA specifically prohibits, "[w]ith respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect," 21 U.S.C. 331(q)(2).

The FDCA also contains a comprehensive scheme for enforcing those obligations. FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a variety of remedies and sanctions if it uncovers such fraud, including injunctive relief, 21 U.S.C. 332, civil money penalties, 21 U.S.C. 333(f)(1)(A), seizure of the device, 21 U.S.C. 334(a)(2)(D), and criminal prosecution, 21 U.S.C. 333 (a), 18 U.S.C. 1001 (1994 & Supp. IV 1998). FDA has adopted an enforcement policy concerning fraud and untrue statements of material facts in premarket submissions. 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Under that policy, when FDA finds that a submission contains fraudulent and unreliable data, it may withdraw clearance of a device cleared for marketing under Section 510(k) and seek voluntary corrective action from the submitter, such as removal of the persons involved in the wrongdoing from substantive responsibility for matters under FDA's jurisdiction. *Ibid.* Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. But there is no private right of action to enforce the FDCA's prohibitions. *Medtronic*, 518 U.S. at 487. FDA and the United States have exclusive authority to determine

how the provisions of the Act should be enforced. See 21 U.S.C. 337(a).

2. Respondents' fraud-on-the-FDA claims conflict with that comprehensive federal scheme for regulating the information that a regulated entity must submit to FDA. In particular, they conflict with the strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what statutorily authorized remedy to seek. That conflict manifests itself in three ways.

First, fraud-on-the-FDA claims would permit juries in different States to reach judgments that differ from FDA's concerning whether an entity has actually committed fraud on the FDA. As Judge Cowen observed in his dissenting opinion in this case, juries could "impose massive liability," when FDA "would not find any misconduct." Pet. App. 31a. Even if juries in different States applied the same substantive standards as FDA, it would not eliminate that conflict. As this Court has explained, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953).

Second, allowing fraud-on-the-FDA claims would "distort the penalty scheme established by the statute." Pet. App. 28a (Cowens, J., dissenting). While the FDCA contains a wide range of possible remedies for fraud on the FDA, neither compensatory relief nor punitive damages is among them. "[S]ince remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy * * * which has been withheld from the [FDA], * * * accentuates the danger of conflict." *San Diego Bldg, Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959); see also *Crosby* v. *National Foreign Trade Council*, 120 S. Ct. 2288, 2298 (2000) ("[C]onflict is imminent when two separate remedies are brought to bear on the same activity.")

Third, if common law fraud-on-the-FDA claims are permitted, it would interfere with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue. The FDCA allows FDA to pursue the remedies that, in FDA's judgment, best fit the violation and the overall purposes of the Act. See *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). For example, FDA may decide in a particular case in which fraud has been identified that the established health benefits of the device concerned counsel against removing the device from the market or imposing a severe penalty, and that removing the persons involved in the wrongdoing from responsibility for submissions is a more appropriate sanction. If fraud-on-the-FDA claims may be brought, the juries in 50 States could substitute their judgments for FDA's as to the appropriate sanction. Since fraud on the FDA "is not a *local* offense," but an offense against the United States, it is "vital" that enforcement "should be exclusively within the control of the Federal Government." *Nelson*, 350 U.S. at 505.

3. Because there is a strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate, state regulation of fraud on the FDA is preempted. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That sharp conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action. See *Garmon*, 359 U.S. at 247 ("The obligation to pay compensation" is "a potent method of governing conduct and controlling policy."). On the contrary, permitting private prosecution of fraud on the FDA only exacerbates the conflict, since private parties have no obligation to take into account the public interest before filing suit. *Nelson*, 350 U.S. at 507-508.

C. Respondents' Fraud-On-The-FDA Claims Conflict With FDA's Market Clearance Decision

Respondents' fraud-on-the-FDA claims are preempted for another reason. They conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices.

1. Under basic principles grounded in the Supremacy Clause, a federal administrative decision that has neither been rescinded by the agency nor set aside by a federal court in accordance with the procedures for review established by Congress has a preemptive effect. A State may not provide a common law cause of action that fails to give effect to such a decision. *Arkansas La. Gas Co* v. *Hall*, 453 U.S. 571 (1981) (*Arkla*); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981).

Arkla and *Kalo Brick* illustrate the preemptive effect of federal administrative decisions on state common law causes of action. In *Arkla*, Hall contracted to sell natural gas to Arkla at a specified rate, but the contract provided that, if Arkla purchased natural gas from another party at a higher rate, Hall would be entitled to that rate. 453 U.S. at 573. Hall filed the agreed-upon rate with the Federal Power Commission, and the Commission authorized the sale of gas at that rate. *Id.* at 574. Some years later, Arkla purchased gas from another party at a higher rate, but did not inform Hall of that fact or increase its payments to Hall. When Hall learned of Arkla's higher payments to the other party, he filed a state court breach of contract action, and the Louisiana Supreme Court awarded as damages the difference between what Arkla paid Hall and what it paid to the third party. *Id.* at 574.

This Court reversed, holding that the state contract action was preempted by the Commission's approval of Hall's filed rate. *Arcla*, 453 U.S. at 578-579. The Court reasoned that the "filed rate doctrine" forbids a regulated entity to charge rates for its services other than those filed with the

appropriate federal regulatory agency, and that it would undermine the federal scheme to allow a state court to award as damages a rate never filed with the Commission and never found by the Commission to be reasonable. *Id.* at 578-579. The Louisiana Supreme Court's determination that the Commission would have approved the higher rate as reasonable had it known about the circumstances of the case did not eliminate the conflict, *id.* at 580-581, since "under the filed rate doctrine, the Commission alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged," *id.* at 581. By awarding damages based on an assumption about what the Commission might have done, the Louisiana Supreme Court had "usurped a function that Congress ha[d] assigned to a federal regulatory body." *Id.* at 582; see also *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953, 963-964 (1986).

In *Kalo Brick*, the Interstate Commerce Commission approved a rail carrier's request to abandon service on a particular rail line. 450 U.S. at 314-315. Rather than seeking judicial review of the Commission's decision, a shipper who used that line asserted a common law tort action against the rail carrier for damages resulting from the abandonment of service. *Id.* at 315. The Court held that the common law tort action was preempted by the Commission's decision. *Id.* 324-327. The Court rejected the argument that the state tort remedy merely complemented the federal abandonment remedy. *Id.* at 324. The Court reasoned that the Act grants "exclusive discretion" to the Commission to decide whether a carrier should be permitted to abandon service on a line, and that it would be contrary to that feature of the Act "to permit litigation challenging the lawfulness of the carrier's actions to go forward when the Commission has expressly found them to be reasonable." *Id.* at 326.

2. Under the principles applied in *Arkla* and *Kalo Brick*, respondents' fraud-on-the FDA claims are preempted. FDA granted market clearance for AcroMed's pedicle screws, and

that decision has not been rescinded by FDA or set aside by a federal court in accordance with the procedures for judicial review established by Congress. Accordingly, under *Arkla* and *Kalo Brick*, FDA's clearance decision is entitled to respect under the Supremacy Clause, and no State may provide a common law cause of action that fails to give effect to that decision.

Respondents' fraud-on-the-FDA claims, however, fail to give effect to FDA's market clearance decision. Those claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. C.A. App. A63. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA. Litigation "challenging the lawfulness" of petitioner's actions in obtaining market clearance for the devices under the FDCA cannot "go forward" when FDA has "expressly found" that the devices should be cleared for marketing under that Act. *Kalo Brick*, 450 U.S. at 326. Respondents' assertion that FDA would not have cleared the devices had it known that petitioner misrepresented their intended use, moreover, does nothing to avert the conflict. FDA "alone is empowered" to decide whether a device should be cleared for marketing under the FDCA, and, by seeking damages based on an assumption concerning what FDA "might have done," respondents seek to "usurp[] a function that Congress has assigned to a federal regulatory body." *Arkla*, 453 U.S. at 581-582.[4]

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[4] Respondents' claims do not conflict with FDA's 1998 decision to classify and reclassify pedicle screw spinal systems for certain uses as Class II devices. FDA's classification and reclassification decision occurred after the underlying events at issue here (see Pet. App. 5a), and it was not intended to legitimize conduct that was unlawful at the time it occurred. 63 Fed. Reg. 40,025, 40,037-40,038 (1998). We also note that FDA classified and reclassified pedicle screw spinal systems as Class II devices only

D. Fraud-On-The-FDA Claims Would Result In Undesirable Practical Consequences

A holding that fraud-on-the-FDA claims are not preempted would also produce undesirable practical consequences. Absent an applicable privilege, *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 150-151 (1975), such claims would invite highly intrusive inquiries into FDA's internal deliberations. For example, respondents assert, as necessary elements of liability, that FDA did not know about the true intended use of the device in question; that FDA relied on petitioner's misrepresentation about that intended use; and that FDA would not have cleared the device for marketing in the absence of petitioner's alleged fraud. Pet. App. 8a-9a.

In litigating those issues, the parties would very likely seek discovery from FDA concerning agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. It is the position of the United States that employees of the federal government are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's *Touhy* regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only in federal court and only under the "arbitrary" or "capricious" standard of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). The lower federal courts, however, have taken divergent views on issues concerning third-party subpoenas issued by a federal court to federal employees. Compare, *e.g.*, *Comsat Corp.* v. *National Science Foundation*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v.

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for certain spinal uses, and it imposed four "special controls" for those uses. *Id.* at 40,027, 40,034-40,038. The record in this case does not address whether the devices that AcroMed marketed satisfied those limitations.

United States Dep't of Interior, 34 F.3d 774, 778-780 (9th Cir. 1994) (agency must produce evidence in response to a federal court subpoena, subject only to court's discretion to limit discovery under Fed. R. Civ. P. 26 and 45). Regardless of how that issue is ultimately resolved, widespread litigation could be expected on whether testimony and other evidence could be secured from FDA. This multidistrict litigation alone involves thousands of plaintiffs in more than 2000 cases that could be tried in several dozen different judicial districts. The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting FDA's resources from the important health mission that Congress has assigned to it and for distorting FDA's internal decisionmaking processes.

Nor would the undesirable consequences of fraud-on-the-FDA claims abate if the courts ultimately accept the government's position on when its officials can be required to testify. Parties would still be free to challenge any refusal to testify under the Administrative Procedure Act, and would retain every incentive to do so. And, in cases in which a government claim of privilege is sustained, a jury could only speculate about the crucial issues in the case. Such speculation would increase the danger that the jury's decision would conflict with FDA's judgment concerning whether it was defrauded and, if so, what should be done.

Permitting state-law suits for fraud on a federal agency could also distort the behavior of regulated entities. Those entities base their behavior largely on their understanding of how federal law has been applied in the past and how it will likely be applied in the future. If a regulated entity knows that juries applying the tort law of any one of the 50 States will play a central role in interpreting the entity's duties to the federal government, that concern could cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme. For example, if, in order to avoid a risk

that a jury in one of 50 States might conclude that they have withheld relevant information, regulated entities began to flood FDA with information that FDA does not need, it could significantly complicate the clearance process.

Fraud-on-the-FDA claims therefore pose a real danger of making it more difficult for FDA to perform its central mission of protecting the public health. That consequence can be avoided by a holding that such claims are impliedly preempted.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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