No. 98-1768

In the Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Plaintiffs represent that they "seek damages under conventional concepts of state tort law" (Pl. Br. 15). But there is nothing "conventional" about plaintiffs' claim. A judge or jury, applying *state* law, would have to decide what the FDA actually knew about the medical devices at issue, whether the FDA believed that the information allegedly withheld was material, and what regulatory actions the FDA would have taken if certain disclosures had been made. And in order for plaintiffs to prevail, a judge or jury, applying *state* law, would have to find that the medical devices at issue should not have been on the market, even though the FDA has conclusively determined, as a matter of *federal* law, that the devices were at all times properly on the market.

It is difficult to imagine a state tort claim that has a greater potential to conflict with federal law. For this reason, the Solicitor General, as well as every court of appeals to consider the question (except for the court below), has concluded that "fraud on the agency" claims are preempted by federal law. Indeed, just three weeks ago the Sixth Circuit held that such claims are preempted because "actions for fraud on the FDA would allow individual juries to undertake a counterfactual FDA review, and conclude that the FDA would not have approved the device," and because "a fraud claim premised on false representations to the FDA * * * would conflict with well-established precedent that no implied private action exists under the FDCA." *Kemp* v. *Medtronic, Inc.*, No. 99-3720 (Nov. 1, 2000), slip op. 35-36.

In our opening brief, we explained why plaintiffs' "fraud on the FDA" claim is both expressly and impliedly preempted by federal law. In response, plaintiffs do not dispute that their fraud claim imposes *state* requirements that are subject to express preemption under 21 U.S.C. § 360k(a). They contend, however, that the *federal* disclosure requirements applicable to the devices were not "specific" or "different" enough from the state requirements to qualify for express preemption. As for implied preemption, plaintiffs make no effort to address the many ways in which

their fraud claim would conflict with and frustrate federal law. Instead, they rely almost entirely on catchwords such as the "presumption against preemption," "basic notions of federalism," and "incentives for compliance with federal mandates." Pl. 15-16, 33. In the end, much of plaintiffs' brief is devoted to addressing arguments that were never made and to describing facts that are largely irrelevant to the issues presented in this case.[1]

I. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS EXPRESSLY PREEMPTED

We explained in our opening brief (at 17-24) that plaintiffs' claim is expressly preempted under the plain language of 21 U.S.C. § 360k(a) because, if allowed to proceed, it would impose *state* disclosure "requirements" relating to the "intended use" of the AcroMed medical devices that are "different from, or in addition to" the *federal* disclosure requirements relating to intended use that apply to the very same devices. We further demonstrated (at 25-30) that the state and federal disclosure requirements at issue in this case are "specific" in every relevant sense: they arise from the particularized application of state and federal laws to individual devices (and no others); they impose obligations to make specific disclosures that concern each device's "intended use"; and they are the product, on the federal side, of active and particularized review and consideration by the FDA.

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[1] Plaintiffs' brief is replete with factual assertions that are incorrect, drawn from portions of plaintiffs' affidavits that were controverted by other evidence, or dependent exclusively upon extrarecord materials. For example, plaintiffs incorrectly state that the FDA concluded that it had been defrauded by Buckman. See Pl. Br. 10 (citing J.A. 124, an FDA letter to *AcroMed* that does not mention Buckman or say that the agency was defrauded). Plaintiffs also assert (at 9) that "it was physically impossible" to use the AcroMed "plates and screws in long bone repair," but their only support for that "fact" is an affidavit that was attached to plaintiffs' own comments in an FDA proceeding (which are not part of the record of this case). Moreover, plaintiffs' lengthy description of Buckman's supposed "fraud" (Pl. Br. 9-12) focuses largely if not entirely on (a) post-clearance conduct (b) by AcroMed (c) that had nothing to do with Buckman and is properly addressed through enforcement of the FDA's rules against unlawful marketing practices.

Plaintiffs respond that there is no express preemption because the pertinent federal disclosure requirements (1) are identical to the disclosure requirements imposed under plaintiffs' "fraud on the agency" claim and (2) are not sufficiently "specific" to come with Section 360k(a). Neither argument is correct.

A. The State And Federal Requirements Are Different

In our opening brief (at 19-24), we showed that plaintiffs' "fraud on the agency" claim is predicated on Buckman's purported obligation, under state law, to disclose to the FDA that AcroMed subjectively desired, hoped, or expected that the bone screws, plates, rods, and hooks of the VSP and ISOLA Systems — although labeled for use only in bones other than the spine — would be used by physicians for spinal fixation. We further demonstrated that federal law, in contrast, does *not* impose any requirement that a 510(k) submission disclose how a manufacturer subjectively intends that a device will be used, because subjective intent is irrelevant under the MDA. The "intended use" that must be disclosed in a 510(k) submission is the use (as listed on the label) for which FDA marketing clearance is sought. See also PhRMA Br. 16-20; MDMA Br. 5-13.

Both plaintiffs and the government concede that under federal law "a manufacturer is *not* required to disclose *every* foreseeable use of a device that it secretly desires." U.S. Br. 15 (emphasis added); see also Pl. Br. 28 (acknowledging that 510(k) submission need not "list every potential use of a device"). They also concede that the concept of "intended use" under federal law is "objective" rather than "subjective." See Pl. Br. 27; U.S. Br. 14-15. Yet the government contends (as do plaintiffs) that Buckman was required to disclose the foreseeable and subjectively intended use of spinal fixation because, according to the allegations in plaintiffs' complaint, "at the time of the [510(k)] application, [the] manufacturer plan[ned] to promote and distribute a device *exclusively* for [that] use." U.S. Br. 15; see also Pl. Br. 28. While the government refuses to shed any further light on what else would constitute an "intended use" that must be disclosed in a 510(k) submission, see

U.S. Br. 15, plaintiffs take the position that an applicant must disclose every use that it expects will be a part of "the manner in which * * * the device will be characterized by its sellers and distributors." Pl. Br. 28.

The argument that the "intended use" that must be disclosed in a 510(k) application extends beyond labeling claims cannot be reconciled with the statutory text, which defines "substantial equivalence" as consisting of situations where the proposed device "has the same intended use as the predicate device" (21 U.S.C. § 360c(i)(1)(A)) and which unequivocally provides:

> *Any* determination by the [FDA] of the *intended use* of a device *shall be based upon the proposed labeling* submitted in a report for the device under [Section 510(k)].

Id. § 360c(i)(1)(E)(i) (emphasis added).[2] As the accompanying Senate Report explained, this provision was added to make explicit Congress's original intent in passing the MDA "that device * * * approval decisions be made based on the *intended use of devices as described in the labeling*. * * * No considerations outside of the proposed labeling for the § 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device." S. REP. NO. 105-43, at 27 (1997) (emphasis added). The statutory text and legislative history thus firmly establish that "intended use" means the use *identified in the device's labeling*. See also PhRMA Br. 17-20; MDMA Br. 7-12.

In light of the statutory language, the government is forced to concede that, under Section 360c(i)(1)(E)(i), "the FDA is required to confine its inquiry to the intended use identified in the proposed labeling when it makes a substantial equivalency determination." U.S. Br. 16 n.2. Since Buckman's disclosures were made in the context of just such a "substantial equivalency determination," it

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[2] Although this statutory language was added after the 510(k) submissions at issue here were made, the amendment corresponds to Congress's original intent and thus "do[es] not alter the analysis" (U.S. Br. 15 n.2).

is difficult to see why the government's concession does not end the debate on this point. The government maintains, however, that Section 360c(i)(1)(E)(i) "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[s]' regulation, 21 C.F.R. 801.4." U.S. Br. 15 n.2. See also Pl. Br. 26-29 (arguing that Section 801.4's definition of "intended uses" applies to 510(k) submission). If we understand the government's position correctly, an applicant seeking clearance of a 510(k) device must identify and disclose the device's "intended use" in two distinct senses: (1) the "intended use" as set forth in the labeling, which will serve as the basis (and the only basis) for the "substantial equivalence" determination; and (2) the "intended use" in some broader sense, presumably as that term is defined in 21 C.F.R.§ 801.4.

This argument is flawed at every turn. To begin with, it is refuted by the plain language of 21 U.S.C. § 360c(i)(1)(E)(i), which specifically provides that, for purposes of 510(k) submissions and substantial equivalence determinations, "*any* determination by the [FDA] of the intended use of a device *shall be based* upon the proposed labeling submitted" (emphasis added). The breadth of that command is highlighted by the more limited scope of the sentence that immediately follows it: "However, *when determining that a device can be found substantially equivalent* to a legally marketed device, the [FDA] * * * may require a statement in labeling that provides appropriate information regarding a *use of a device not identified in the proposed labeling* * * * ." *Ibid.* (emphasis added).

Moreover, the 510(k) process does not impose any "obligation" upon an applicant for clearance to disclose "a device's 'intended use' *as that term is defined in* FDA's 'intended use[s]' regulation, 21 C.F.R. 801.4." U.S. Br. 15 n.2 (emphasis added). As explained in our opening brief (at 23 n.3), 21 C.F.R. § 801.4 *does not apply to 21 C.F.R. 807.87(e) or to 510(k) applications*. Section 801.4 is part of the procedures governing *labeling* (Title 21,

Chapter I, Subchapter H, Part 801), *not* the procedures governing *premarket notifications* (Title 21, Chapter 1, Subchapter H, Part 807, Subpart E). By its plain terms, Section 801.4 applies *only* to three regulations, none of which is at issue here: 21 C.F.R. § 801.5, which governs "adequate directions for use"; 21 C.F.R. § 801.119, "In vitro diagnostic products"; and 21 C.F.R. § 801.122, which governs medical devices "intended for processing, repacking, or use in the manufacture of another drug or device."[3]

Nor is there anything else in the pertinent 510(k) disclosure regulations — including 21 C.F.R. § 807.87(e) — that supports the broad disclosure "obligation" claimed by the government. Those regulations require applicants to submit "[p]roposed labels, *labeling*, and advertisement *sufficient to describe* the device, *its intended use*, and the directions for its use." 21 C.F.R. § 807.87 (1999, 1986) (emphasis added). That wording confirms that "intended use" is not a representation of the applicant's subjective intent or expectation but rather a *labeling claim* that serves to define the scope of marketing approval that is being requested. Plainly, the "intended use" that must be identified under 21 C.F.R. § 807.87 is precisely the "intended use" that must be the exclusive basis of the FDA's substantial equivalence determination.

This is not to say, of course, that the definition set forth in 21

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[3] Even if Section 801.4 defined the "intended use" that must be identified in a 510(k) submission, it would not support the distinctions offered by the government and the plaintiffs between (1) all foreseeable uses (which need not be disclosed under their theory), and (2) foreseeable uses that the manufacturer plans to promote exclusively or that the applicant expects will be mentioned by sellers and distributors (which must be disclosed). See pages 3-4, *supra*. To the contrary, the regulation appears to envision that *foreseeability* alone is enough to turn an off-label use into an "intended use," and it focuses on foreseeability of *use* rather than of *marketing efforts*. See 21 C.F.R. § 801.4 (stating that "if a manufacturer knows, or has knowledge of facts that would give him notice that a device * * * is to be used for" an off-label use, then "he is required to provide adequate labeling for such other uses"). Plaintiffs' and the government's need to disregard the plain language of the regulation they cite, in order to avoid the breadth of its apparent scope, merely highlights the absurdity of applying that definition of "intended uses" in the very different context of a 510(k) application.

C.F.R. § 801.4 does not apply to the situations it specifically mentions. It is entirely sensible to require a device manufacturer to include warnings against foreseeable, but unapproved, uses in the labeling for a device *following* clearance of the device for marketing. Notably Section 801.4 itself suggests that it applies post-marketing by acknowledging that a device's intended use "may change after it has been introduced into interstate commerce by the manufacturer." 21 C.F.R. § 801.4. In the context of a 510(k) submission, however, equating "intended use" with "foreseeable use," "subjectively intended use," or even use that an applicant expects will be "a part of the manner in which * * * the device will be characterized by its sellers and distributors" (Pl. Br. 28) would be wholly unworkable, as we showed in our opening brief (at 24) and as plaintiffs and the government do not dispute.[4]

Finally, it is worth emphasizing that plaintiffs do not deny that the screws, plates, rods and hooks involved in this case were in fact similar, in their physical or technological characteristics, to devices that were commercially available prior to 1976. See note 5, *supra*. They also do not deny that, when evaluated in light of the "intended uses" identified in the pertinent 510(k) submissions, the devices qualified as "substantially equivalent" to pre-1976 devices for long bone use. That means that screws and plates just like

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[4] As the government points out (Br. 15-16 n.2), FDA has the authority under 21 U.S.C. § 360c(i)(1)(E)(i) to require a warning with respect to a "use of a device not identified in the proposed labeling" if the agency 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." See also 21 U.S.C. § 360c(i)(1)(E)(ii). "That statutory authority," the government contends, "confirms that a device's intended use may be determined from evidence other than a device's proposed labeling." U.S. Br. 16 n.2 (emphasis added). But the additional language cited by the government — like the definition of "intended uses" in 21 C.F.R. § 801.4 — does not define "intended use" in the context of premarket review by the FDA. Instead, it refers to the agency's authority to require additional warnings *once marketing clearance has been granted*. Thus, although the FDA can require a warning about dangerous off-label uses, a manufacturer is under no obligation to submit that information in a Section 510(k) submission, and thus the failure to do so is not fraudulent.

AcroMed's, presumably marketed for long bone use, were already on the market in 1985. And, of course, there was no reason why those plates and screws could not lawfully have been used by surgeons for spinal applications. In light of these facts, and the basic purpose of Section 510(k) to allow competition with grandfathered devices, it was perfectly consistent with the statutory scheme for AcroMed to seek market clearance for its devices, labeled for long bones, in the hopes that surgeons would similarly use their products for spinal surgery. Of course, AcroMed could not *market* the devices for that use; but that is a matter addressed through the FDA's *marketing* regulations, not its regulations governing disclosures of intended use *prior to marketing*.[5]

B. The Federal Disclosure Requirements Are "Specific"

As noted in our opening brief (at 28-29, 46-47, 49), the "specificity" concept has at least two possible meanings. A requirement can be "specific" in its *content* (as in Justice Breyer's 2-inch wire requirement, which is specific when compared to a more generalized duty to use reasonable care in the design of a product). Alternatively, a requirement can be "specific" in its *applicability* (as where it applies to more than a single device, a single class of devices, or to products other than medical devices — each of which is a potential meaning of "device-specificity"). The federal disclosure requirements at issue in this case are "specific" in both content and applicability.

In arguing otherwise, plaintiffs pointedly avoid explaining which of the various meanings of "specificity" they endorse or

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[5] Plaintiffs assert that, if the "intended use" determination for purposes of 510(k) were limited to the labeled use, the MDA "would have virtually no effect" because a manufacturer could "reach the market without regulatory constraint" through "the simple expedient of submitting a proposed label reflecting a pretextual use which matched a pre-enactment use." Pl. Br. 28. But Congress itself has mandated this definition of "intended use." In any event, plaintiffs' argument ignores both the applicant's duty to show that the proposed device has the same technological characteristics as the predicate device (see 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 907.87(f)) and the severe restrictions imposed by the FDA's *marketing* regulations (see 21).

why. See Pl. Br. 20-21. The government, in contrast, acknowledges the fundamental ambiguity but explains that under the FDA's exemption regulation, a federal requirement that is specific *either in content or in applicability* will trigger preemption under Section 360k(a). See U.S. Br. 12. On the issue of what is meant by "specificity" in a requirement's "applicability," the government suggests that federal requirements qualify if they apply "to a specific device *or set of devices*." U.S. Br. 12 (emphasis added). Thus, the government concedes that a federal requirement may satisfy the "specificity" test even if it applies to more than a single medical device. At the same time, however, the government takes the position that the disclosure requirements involved here are not "specific" because they "appl[y] to all devices that must undergo the 510k clearance process, *not just to pedicle screw devices*." *Ibid.* (emphasis added).

1. To begin with, the government's position is impossible to justify on the basis of logic or any rational congressional purpose underlying the MDA's express preemption clause. Under the government's view, if 21 C.F.R. § 807.87 applied only to "pedicle screw devices," then its disclosure requirements *would* trigger preemption under 21 U.S.C. § 360k(a). Indeed, the FDA could impose *identical* disclosure requirements on *all the very same devices now covered by Section 807.87* — but with the opposite result in terms of triggering express preemption — so long as the agency promulgated thousands of identical versions of Section 807.87, each applicable to one type of device. Given the purpose of Section 360k(a), why would Congress have intended such an absurd result?

The government also offers no plausible reason why a federal requirement's applicability to a "set of devices" that consists of a single *regulatory* class is not enough to bring the requirements within the FDA's definition set forth in 21 C.F.R. § 808.1(d).[6] That

[6] As explained in our opening brief (at 30 n.6), the federal disclosure requirements at issue in this case apply only to a single regulatory class of medical devices: those for which 510(k) clearance is sought. Accord U.S. Br. (continued...)

position is inconsistent with the FDA's past regulatory interpretation and practice as well as with congressional intent. As noted in our opening brief (at 30 n.6), the FDA has acknowledged that federal requirements that apply to the regulatory class of PMA devices trigger express preemption. See 43 Fed. Reg. 18661, 18664 (1978). In addition, the House Report accompanying the MDA gave as an example of state laws that should be granted an exemption from preemption under 21 U.S.C. § 360k(b) a California law that required "premarket approval of all medical devices." H.R. Rep. No. 94-853, at 45-46 (1976). There would have been no need for an exemption if federal PMA requirements did not trigger express preemption in the first place. If federal requirements that target the regulatory class of PMA devices are "specific" enough to trigger preemption, so too must be requirements targeting 510(k) devices.

Moreover, there is simply no rational distinction between the federal disclosure requirements at issue in this case and the examples given by the government of federal requirements that concededly "apply to a specific device or set of devices" (U.S. Br. 12) and thus trigger express preemption. Those examples include, for example, federal requirements that apply to (1) all medical devices that contain natural rubber (21 C.F.R. § 801.437) and (2) all medical devices containing any patient cable or electrode lead wire (21 C.F.R. § 898). But according to the FDA itself, the "natural rubber" regulation applies to *43 different categories* of medical devices, including catheters, latex gloves, tracheal tubes, balloons, orthodontic headgear and bands, condoms, enema kits, elastic bandages, opthalmic eyeshields, irrigating syringes, surgical masks, tourniquets, water bottles, elastic binders, pistonsyringes, crutch pads and tips, intestinal splinting tubes, and in vitro

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[6] (...continued)

12. The disclosure requirements do not apply to investigational devices or devices for which premarket approval is sought. For that reason, plaintiffs are wrong when they say (Pl. Br. 20) that the federal requirements at issue in this case "are no more specific than the Good Manufacturing Practices and labeling regulations" at issue in *Medtronic*.

diagnostic devices. 63 Fed. Reg. 50660, 50673-50676 (1998). Moreover, FDA has estimated that these 43 categories comprise "approximately 17,600" different models of medical devices. *Id.* at 50676. The government offers no explanation why such broadly applicable requirements trigger express preemption whereas the disclosure requirements at issue in this case do not.

2. There is a second, independent reason why the federal disclosure requirements here are sufficiently specific *in applicability* to trigger preemption under 21 C.F.R. § 808.1(d): they have been *specifically applied* to the *particular* medical devices at issue in this case. Contrary to the government's suggestion, there is no analytical difference between (1) the process by which a generally applicable state tort-law "duty of care * * * is made applicable to a device through application in specific litigation," which the government admits can lead to "specific" requirements (U.S. Br. 12-13 n.1), and (2) the process of specific application of federal requirements to individual devices that occurred in this case.[7]

Plaintiffs assert that this analogy breaks down because "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." Pl. Br. 20 (emphasis added). That argument is beside the point; the fact remains that specific federal disclosure requirements were imposed on Buckman. Similarly, the government is wrong to suggest that the comparison is inapposite because "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." U.S. Br. 13 n.1. But again, whether the disclosure requirements were in fact *applied* to particular devices in this case is unaffected by what federal law requires the FDA to do with the information once it was provided by Buckman (or by whether the FDA applied its own regulations

[7] The fraud duty underlying plaintiffs' claim obviously applies, potentially, to products other than medical devices. Yet as demonstrated in our opening brief (at 26-27), that state-law duty has been applied with great specificity in this litigation, as set forth in the detailed allegations of plaintiffs' complaint. Neither plaintiffs nor the government disputes this.

correctly). In any event, the fact that the FDA granted the 510(k) applications after lengthy scrutiny shows conclusively that the agency determined that the requirements had been met (and distinguishes this situation from *Medtronic*)..

3. The federal disclosure requirements are also "specific" in their *content* and, according to the government's position, thus trigger preemption on this alternative basis under 21 C.F.R. § 808.1(d)(1). The federal disclosure requirements narrowly and specifically focused upon "intended use" disclosures concerning *these particular devices*. And, in response to these federal requirements, Buckman and AcroMed made detailed and particularized statements about the intended use of the individual devices — again, disclosures *required* by federal law. Indeed, the disclosure requirements here are at least as specific *in content* as other requirements that the government concedes would trigger express preemption because they are "stated with specificity." U.S. Br. 12. See, *e.g.*, 21 C.F.R. § 801.420(c)(6) (requiring statements in user instruction brochures for hearing aid devices not to be "false and misleading"); *id.* § 801.437(c) (requiring certain statements in the labeling of devices containing natural rubber to be "prominently and legibly displayed").

Indeed, one of the regulations identified by the government as being "stated with specificity," 21 C.F.R. § 898, contains a disclosure requirement concerning "intended uses" that is indistinguishable in content from that involved in this case. Under 21 C.F.R. § 898.14, a manufacturer may seek an exemption or variance from certain requirements imposed on performance standards for devices containing electrode lead wires or patient cables, but must first disclose the device's "intended use(s)" by submitting "representative labeling." *Id.* § 898.14(a). If the representations required of Buckman in the 510(k) process had been made in an application for an exemption under Section 898.14(a), there would be no question, under the government's own admission, that the federal disclosure requirement would trigger preemption under Section 360k(a). There is no rational basis for a different conclusion here.

II. PLAINTIFFS' "FRAUD ON THE FDA" CLAIM IS IMPLIEDLY PREEMPTED

Even if plaintiffs' claim is not expressly preempted by the MDA, it is impliedly preempted. As explained in our opening brief (at 31-45), plaintiffs' claim, if permitted to proceed, would frustrate the FDA's interest in valid, final, and correct decisionmaking; would conflict with the MDA statutory scheme; and would interfere substantially with the operations of the federal agency. The United States agrees that plaintiffs' claim is impliedly preempted, explaining that if allowed to go forward, it would intrude upon an area of preeminent federal concern, conflict with important federal interests in permitting the FDA to decide for itself whether it was defrauded (and, if so, what remedy to seek), and conflict with the FDA's decision to clear the relevant devices for marketing. U.S. Br. 16-30.

Plaintiffs have now abandoned the argument, which they pressed below and which was the basis for the Third Circuit's decision, that this Court's decision in *Medtronic* resolved the implied preemption issue in their favor. As the Sixth Circuit recently explained, in disagreeing with the decision below, "nothing in [*Medtronic*]" undercuts a finding of implied preemption because the plaintiffs in that case "did not present a 'fraud on the FDA' claim'" and because such claims simply cannot be equated with "'parallel' state law requirements as contemplated by" *Medtronic*. *Kemp*, slip op. 33-34.

Although plaintiffs decline to defend the basis for the lower court's ruling, they do advance a variety of arguments aimed at incorporating the MDA-specific limits on express preemption recognized in *Medtronic* into the law of implied preemption. Those efforts, and plaintiffs' other responses to our implied preemption arguments, are wholly unpersuasive.

1. Plaintiffs first assert that where Congress has enacted an express preemption provision, "a court should seldom imply a preemptive intent * * * which is broader than that expressed by the statute itself." *Id.* at 37. In making this argument, plaintiffs rely on

a serious misreading of *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992), without acknowledging that their contention has been repudiated by subsequent decisions of this Court. See *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913, 1919-1920 (2000); *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287-289 (1995). Plaintiffs also ignore the Court's holding just last Term in *Geier* that an express preemption clause "does *not* bar the ordinary working of conflict preemption principles." 120 S. Ct. at 1919.

Equally incorrect is plaintiffs' suggestion that *Medtronic*'s framework for analyzing express preemption under the MDA — and in particular the distinction between "requirements" and "remedies" (Pl. Br. 29-30) — should be superimposed in whole or in part on the implied preemption analysis in this case. No issue of implied preemption was raised or resolved in *Medtronic*, and in fact the Court emphasized that common law claims that are not subject to express preemption can still be "preempted under conflict pre-emption analysis." 518 U.S. at 503; see also *id.* at 507-08 (Breyer, J.). Congress presumably takes the trouble to enact an express preemption clause only where it wishes to *supplement* the displacement of state law that occurs by virtue of the Supremacy Clause and through the ordinary workings of implied preemption principles. See *Crosby*, 120 S. Ct. at 2302. And plaintiffs are simply wrong to suggest that state remedies are incapable of conflicting with federal remedies as long as they purport to enforce the same "requirement." If, for example, the FDA were to find that an applicant made misrepresentations in a 510(k) request but that, for public health reasons, the medical device should remain on the market, it surely would conflict with federal policies for a state court to determine that the device should be removed from the market.[8]

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[8] Plaintiffs assert that "the Court has refrained from finding implied preemption of private remedies for breach of substantive duties which do not differ from federal requirements." Pl. Br. 29. But they cite no case that supports the far-reaching principle that "allowing a non-federal remedy for violation of a federal requirement can not, by definition" result in implied preemption. *Id.* at 31. In fact, that proposition is squarely at odds with this

(continued...)

2. Plaintiffs next argue that it would offend "our system of federalism" 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." Pl. Br. 31; see also *id.* at 38. Contrary to the assumption underlying this argument, plaintiffs' lawsuit does not "apply" or "enforce" a "federal" requirement. As we explained in our opening brief (at 34-37), Congress chose not to make the FDCA enforceable in a private right of action and instead vested exclusive enforcement authority in the FDA. 21 U.S.C. § 337(a). Accordingly, this lawsuit seeks to make an end run around that congressional policy by allowing plaintiffs to enforce the same FDCA requirements under the pretense of applying state law. The cases cited by plaintiffs (at 31) acknowledging the responsibility of state courts to enforce rather than disregard federal law are thus entirely beside the point.

What is more, plaintiffs overlook the more serious problem here, which is not the mere possibility of divergent interpretations. Instead, it is the fact that plaintiffs' "fraud on the FDA" claim amounts to a collateral attack on the FDA's clearance decision. To resolve plaintiffs' claim, a state judge or jury would have to guess whether the FDA relied on Buckman's disclosures and, if so, how the agency would have exercised its discretion if different disclosures had been made. And, to rule in plaintiffs' favor, a state judge or jury would have to nullify the FDA's decision that the devices at issue were properly on the market. As the Solicitor General has observed, "FDA's clearance decision is entitled to respect under the Supremacy Clause, and no State may provide a common law

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[8] (...continued)
Court's cases. See, *e.g.*, *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 * * *.") (citations and internal quotations omitted); *Pennsylvania* v. *Nelson*, 350 U.S. 497, 499-510 (1956) (Pennsylvania law criminalizing sedition against the United States is impliedly preempted by Smith Act, which proscribes the same conduct); *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236, 246-247 (1959). See also U.S. Br. 20, 23-24.

cause of action that fails to give effect to that decision." U.S. Br. 27. Plaintiffs have no response.[9]

3. Plaintiffs rely heavily (Br. 30, 32-34) on *Silkwood* v. *Kerr McGee Corp.*, 464 U.S. 238 (1984), and *Miree* v. *DeKalb County*, 433 U.S. 25 (1977), but those cases are easily distinguishable. The Court's rejection of implied preemption in *Silkwood* turned largely on affirmative evidence — conspicuously absent here — that "Congress * * * intended to tolerate whatever tension there was" between the Nuclear Regulatory Commission's "exclusive authority to regulate safety matters" under the Atomic Energy Act and the availability of punitive damages awards under state tort law. 464 U.S. at 256. In particular, the Court interpreted the Price Anderson Act, which establishes an indemnification scheme for nuclear operators held liable under state tort law, as constituting affirmative evidence of Congress's acceptance of state tort actions. See *id.* at 251-256. There is nothing comparable in this case; indeed, 21 U.S.C. §§ 336 and 337 are strong evidence of a contrary congressional intent. Moreover, the Atomic Energy Act contains no preemption provision and in fact explicitly preserves significant authority for the states (e.g., 42 U.S.C. §§ 2018, 2021(b), 2021(k)). Here, in contrast, Congress has included an express preemption clause in the MDA which, as this Court held in *Medtronic*, preempts tort actions brought under state law.

The relevance of *Miree* is even more mysterious. That case involved the narrow question whether federal common law or state law governed the right of passengers in a plane crash and others to bring suit as third party beneficiaries against the Georgia county that ran the airport under contracts with the FAA. 433 U.S. at 28-29. Noting that the resolution of this issue "raises no question

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[9] Plaintiffs suggest that their collateral attack on the FDA's decision does not conflict with any federal interest because their subjective motivation is "recovery of damages for injuries sustained by them, and not * * * regulatory compliance as an end in itself." Pl. Br. 34 n.12; see also *id.* at 35-36. But whether state law conflicts with, or frustrates the purposes of, federal law is not dependent upon the subjective motivation of the person or entity who initiates a state proceeding.

concerning the liability of the United States or the responsibility of the United States under the contracts," the Court held that state law should control. The Court explained that the federal government's operations would not "be burdened or subjected to uncertainty by variant state-law interpretations regarding whether those with whom the United States contracts might be sued by third-party beneficiaries to the contract." *Id.* at 30. Indeed, so slight was the federal interest that the United States waived its right to file a brief on the ground that its interests "would not be directly affected" by the outcome. *Id.* at 29-30.

Here, in contrast, plaintiffs' claim *does* raise a question directly implicating the exclusive responsibilities of the federal government to regulate and enforce the MDA, including submissions that regulated entities must make in federal regulatory proceedings and the enforcement actions, if any, that the FDA will take in response to alleged violations of agency disclosure requirements. Moreover, unlike in *Miree* plaintiffs' "fraud on the agency" claims "implicate an area of paramount federal concern" — namely, the "need of federal regulatory agencies to receive accurate information from entities they regulate" and, more generally, "the relationship between the federal government and the entities it regulates." U.S. Br. 18-19.

4. Unable to explain away the clear conflict with federal interests, plaintiffs next resort (at 33-34 & n.12) to the "presumption against preemption" to defeat implied preemption here. As both we (at 32 n.7) and the government (at 17-21) have explained, however, that presumption has no application in this case because plaintiffs' "fraud on the FDA" claim does not represent a traditional state remedy and because "the relationship between the federal government and the entities it regulates" — including what disclosures must be made to a federal agency in a federal proceeding — involve "an area where there has been a history of significant federal presence." *United States* v. *Locke*, 120 S. Ct. 1135, 1147 (2000). See also PLAC Br. 20-24. It is worth repeating that plaintiffs' state law claim would not even exist were it not for the existence of the federal regulatory scheme.

5. In our opening brief (at 40-45), we explained that plaintiffs' claim, if allowed to proceed, would substantially interfere with the operations of the federal government in a variety of ways, including by sapping agency resources and embroiling agency personnel in litigation and by adversely affecting the regulatory process. See also PhRMA Br. 20-27; PLAC Br. 15-20; MDMA Br. 13-20. In addition, if allowed to proceed "fraud on the agency" claims could be used to easily circumvent a wide variety of express preemption schemes created by Congress. The government agrees that a host of "undesirable practical consequences" would flow from a finding of no preemption in this case, including the real prospect of "highly intrusive inquiries into FDA's internal deliberations," "distort[ions]" in "the behavior of regulated entities," and a "real danger of making it more difficult for FDA to perform its central function of protecting the public health." U.S. Br. 28-30.

Plaintiffs simply ignore most of these adverse consequences. The only problem they address (Pl. Br. 45-47) is embroiling agency personnel in litigation. In essence, plaintiffs suggest that the appropriate response to this problem is to bar discovery from FDA officials. Pl. Br. 47. But that would be manifestly unfair to litigants such as petitioner, whose liability under plaintiffs' theory turns on what agency personnel knew and what they would have done if other information had been provided. Moreover, as the government points out, it would also "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," because a jury deprived of such evidence "could only speculate about the crucial issues in the case." U.S. Br. 29.

III. THE COURT SHOULD RECONSIDER THE "SPECIFICITY" GLOSS ON 21 U.S.C. § 360K(A)

If the Court rejects our arguments for express and implied preemption under current law, then it should take this opportunity to reconsider the conclusion — endorsed by a majority in *Medtronic* over the dissent of four Justices — that express preemption under the MDA is limited to "specific" requirements. Plaintiffs do not dispute that, as we have shown (Pet. 14-16, 19-

25), and as the Sixth Circuit recently confirmed, "[t]he various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with [*Medtronic*'s] language in the effort to discern its holding." *Kemp*, slip op. 13. Nor do plaintiffs deny that the concept of "specificity" is inherently ambiguous; they make no attempt to show that the "specificity" gloss has any statutory support or can be reconciled with this Court's decisions rejecting this "utterly irrational loophole" in other express preemption settings.

Other than an appeal to *stare decisis*, plaintiffs' only response is to address an argument we never made. They urge this Court to reject our "*de facto* suggestion that the Court overrule the 'Identity of Requirements' holding in *Medtronic*." Pl. Br. 24. But we have not suggested that the Court overrule *this* aspect of *Medtronic*, which, unlike the "specificity" gloss, has support in the statutory language and has created no confusion in the lower courts.[10]

For the reasons stated above and in our opening brief, the federal disclosure requirements at issue in this case should satisfy any sensible interpretation of the "specificity" concept. But if the Court disagrees, then we urge it to revisit the question whether Section 360k(a) requires federal requirements to be "specific"(as opposed to being "counterpart") before preemption may occur. *Stare decisis* should not prevent the Court from reconsidering a

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[10] The "identity of requirements" holding in *Medtronic* finds textual support in the phrase "different from, or in addition to" in 21 U.S.C. § 360k(a). In contrast, as the four dissenters in *Medtronic* observed, "[t]he statute makes no mention of a requirement of specificity" (518 U.S. at 512 (O'Connor, J.)). The "specificity" gloss would have to be based on the statutory phrase "with respect to a device." But the FDA acknowledged in its *Medtronic* brief that "the 'with respect to' clause suggests," in fact, that the state requirements covered by Section 360k(a) "may be of * * * *general* applicability." Nos. 95-754 and 95-886 U.S. Br. 18 (emphasis added). And, as explained in our opening brief (at 47-48), the FDA's *Medtronic* brief and its regulatory notices took the position that the federal GMP requirements — which are general in content and applicability — triggered preemption under Section 360k(a). Thus, deference to the FDA's views and past exemption practice should have led the majority to *reject* importing the notion of specificity into the statute.

narrowly divided issue decided only four years ago that was premised upon a misunderstanding of past agency practice and that has proven to be completely unworkable. See *Hohn* v. *United States*, 524 U.S. 236, 251 (1998); *State Oil* v. *Kahn*, 522 U.S. 3 (1997); *Solorio* v. *United States*, 483 U.S. 435, 448 (1987).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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