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 federal court of appeals to consider the question (except for the court below), have 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, slip op. 35-36 (Nov. 1, 2000).

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. Br. 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

[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 (Pl. Br. 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.

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.

Plaintiffs respond that there is no express preemption because the pertinent federal disclosure requirements are (1) identical to the disclosure requirements imposed under plaintiffs' "fraud on the agency" claim and (2) not sufficiently "specific" to come within 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 in the labeling) 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 U.S. Br. 14-15; Pl. Br. 27. 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 [the] device

exclusively for [that] use." U.S. Br. 15 (emphasis added); see also 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 plain language of the MDA, 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) (see App., *infra*, 2a).[2] As the accompanying Senate Report explained, this provision was added to make explicit Congress's 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). Accord H.R. REP. NO. 105-307, at 25 (1997). 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 this 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 equivalence determination." U.S. Br. 16 n.2. Since Buckman's "intended use"

[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).

representations were made in the context of just such a "substantial equivalence determination," the government's concession should end the debate on this point. The government maintains, however, that Section 360c(i)(1)(E)(i) "does not relieve manufacturers of their obligation * * * 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." U.S. Br. 15 n.2; see also Pl. Br. 26-29 (arguing that Section 801.4's definition of "intended use" applies to 510(k) submission). Under Section 801.4, "intended use" means the use that "will be revealed by all the manufacturer's 'expressions' and 'the circumstances surrounding' the device's 'distribution.'" U.S. Br. 15.

This argument is wrong. 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, "*[a]ny* determination by the [FDA] of the intended use of a device *shall be based* upon the proposed labeling submitted" (emphasis added). It also is refuted by the FDA regulation that applies specifically to "intended use" representations *in the context of 510(k) applications*. That regulation — 21 C.F.R. § 807.87(e) — requires applicants to submit "[p]roposed labels, labeling, and advertisements sufficient to describe the device, *its intended use*, and the directions for its use" (emphasis added) (see App., *infra*, 5a). This wording confirms that "intended use" is not a statement of the applicant's subjective intent or expectation but rather a representation in the *labeling* that serves to define the scope of marketing approval that is being requested. The "intended use" that must be identified under 21 C.F.R. § 807.87 is the "intended use" that must be the exclusive basis for the FDA's substantial equivalence determination under the statute.

It is telling that, rather than focus on the statutory or regulatory provisions that expressly govern "intended use" representations in the 510(k) context, plaintiffs and the government rely on a different "intended use" regulation, 21 C.F.R. § 801.4 (see App., *infra*, 4a). As explained in our opening brief (at 23 n.3), however,

Section 801.4 does not apply to 510(k) applications. It is part of the *general labeling* provisions (Title 21, Chapter 1, Subchapter A, Part 801), *not* the provisions 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, which governs "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." Moreover, while Section 801.4 requires warnings in certain circumstances, it does *not* provide that a foreseeable off-label use creates a new "intended use."

It is entirely sensible to require a device manufacturer to include warnings about foreseeable, but unapproved, uses in the labeling for a device following clearance of the device for marketing. As Section 801.4 itself acknowledges, a device's use "may change after it has been introduced into interstate commerce by its manufacturer." 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.[3]

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[3] 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 such off-label use "could cause harm." Like Section 801.4, this section merely authorizes the FDA to require a warning as part of the 510(k) clearance process if it has information regarding a potentially harmful off-label use. But an unclaimed use for which the agency may require a warning is still not an "intended use" for purposes of the substantially equivalence determination, and thus a manufacturer does not commit fraud by failing to mention it as

(continued...)

Finally, it is worth emphasizing that the FDA found that the screws, plates, rods and hooks involved in this case were in fact similar, in their physical characteristics, to devices that were commercially available prior to 1976. The FDA also determined that, when evaluated in light of the "intended use" 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 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 hope 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*.[4]

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[3] (...continued)
part of its 510(k) submission. See PhRMA Br. 18-19 & n.10.

[4] 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. § 807.87(f)) and the independent restrictions imposed by the FDA's "regulations prohibiting marketing for off-label uses." Pet. App. 28 (Cowen, J., dissenting).

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* (like 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 a single device or a single class of devices). 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 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*." *Ibid.* (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" enough because they "appl[y] to all devices that must undergo the Section 510k clearance process, *not just pedicle screw devices*." *Ibid.* (emphasis added).

1. The government's position is impossible to square with common sense or any rational congressional purpose underlying the MDA's express preemption clause. Under the government's view, if the disclosure requirements imposed by 21 C.F.R. § 807.87 applied *only* to "pedicle screw devices," then the requirements *would* trigger preemption under 21 U.S.C. § 360k(a). In other words, if the FDA took the *identical* disclosure requirements now covered by Section 807.87 and promulgated

thousands of identical versions of that regulation, each applicable to one type of device, then each of the regulations would trigger express preemption. But because the agency has chosen to issue a single regulation applicable to all 510(k) applications, state law may impose different or additional disclosure requirements on device manufacturers without running afoul of Section 360k(a). Why would Congress have intended such an bizarre result?[5]

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 requirement within Section 360k(a).[6] That 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

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[5] The statutory requirement of "substantial equivalence" applies to *all* devices that undergo the 510(k) clearance process, not just pedicle screw devices. 21 U.S.C. § 360(k). Therefore, under the plaintiffs' and the government's "specificity" rationale, a state law requiring that new pedicle screw devices be "identical," rather than "substantially equivalent," to pre-1976 devices would not be preempted by Section 360k(a).

[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. 12. The disclosure requirements do not apply to investigational devices or devices seeking premarket approval under Section 360e. 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*.

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 no plausible distinction between the federal disclosure requirements at issue in this case and the examples given by the government of federal requirements that concededly "appl[y] 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, ophthalmic eyeshields, irrigating syringes, surgical masks, tourniquets, water bottles, elastic binders, crutch pads and tips, intestinal splinting tubes, and in vitro 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 but the disclosure requirements at issue in this case do not.

2. There is a second, independent reason why the federal disclosure requirements 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 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 and the government argue that this comparison is invalid because the FDA is not required "to evaluate the truthfulness of a 510(k) submission with respect to intended use" (Pl. Br. 20) and "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 the existence or effect of the disclosure requirements imposed on Buckman is in no way dependent upon what the FDA did with the information after Buckman complied. Regardless of what the agency did, or what it was required to do, with the information, or whether it made an assessment of Buckman's compliance, the fact remains that Buckman was *required to make specific disclosures in the 510(k) submission for specific devices*. There is no difference between that process and what occurs when a common law claim "is made applicable to a device through application in" litigation. U.S. Br. 12-13 n.1. In any event, the fact that the FDA granted the 510(k) applications after prolonged scrutiny shows conclusively that the agency determined that the requirements had been met.

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. The

[7] The fraud duty underlying plaintiffs' claim 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 dispute this.

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)(i) (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 (U.S. Br. 12) 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), a manufacturer may seek an exemption or variance from certain performance standards applicable to devices containing electrode lead wires or patient cables, but must first disclose the device's "intended use(s)" by submitting "representative labeling." 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' CLAIM IS IMPLIEDLY PREEMPTED

Even if plaintiffs' "fraud on the agency" 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; conflict with the MDA statutory scheme; and interfere substantially with the operations of the federal agency. The Solicitor General 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 nullify 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 legislature itself." Pl. Br. 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). Just last Term in *Geier*, the Court held that an express preemption clause "does *not* bar the ordinary working of conflict pre-emption 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 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 preemption 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* v. *National Foreign Trade Council*, 120 S. Ct. 2288, 2302 (2000). 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 state law to penalize the manufacturer for not removing the device from the market.[8]

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

[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 Court's cases. See, *e.g.*, *Crosby*, 120 S. Ct. at 2298 ("[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 Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 246-247 (1959). See also U.S. Br. 20, 23-24.

requirement." Pl. Br. 31. But, contrary to plaintiffs' assumption, the states *cannot* provide a cause of action "for violation of FDCA requirements" (*id.* at 39; see also *id.* at 38, 40). 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). This suit seeks to make an end run around that congressional judgment by allowing plaintiffs, in effect, 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.

In addition, 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 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*,

[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 the 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 as this Court has frequently observed, "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy." *Garmon*, 359 U.S. at 247. See U.S. Br. 24.

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.

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 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 contracts." *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 responsibility of the federal government to enforce the MDA, including the consideration of 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" claim "implicates 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 Medtronic Sofamor Danek Br. 19-24; MDMA Br. 13-20; PhRMA Br. 20-27; PLAC Br. 15-20. In addition, if allowed to proceed, "fraud on the agency" claims could easily be used to circumvent a wide variety of federal administrative decisions on the ground that they were the product of "fraud." 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. 46. 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 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 n.10. But we

have not suggested that the Court reconsider *this* aspect of *Medtronic*, which, unlike the "specificity" gloss, has support in the statutory text 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," see 21 C.F.R. § 808.1(d)) before preemption may occur. See WLF Br. 21-25. *Stare decisis* should not prevent the Court from reconsidering a 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. *Khan*, 522 U.S. 3, 21-22 (1997); *Solorio* v. *United States*, 483 U.S. 435, 448 (1987).

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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 itself acknowledged in its *Medtronic* brief that "the 'with respect to' clause suggests" 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.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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NOVEMBER 2000

APPENDIX

21 U.S.C. § 360c(i):

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device —

> **(i)** has the same technological characteristics as the predicate device, or
>
> **(ii)** (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 360(k) of this title, the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D) Whenever the Secretary requests information to demonstrate that devices with differing technological

characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing —

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall —

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations

specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on November 21, 1997.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360j(l) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

21 C.F.R. § 801.4 (2000):

§ 801.4 Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 807.87 (2000):

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name

and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) 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. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety

and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.

(j) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(l) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make

a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.