No. 12-1351

In The
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

RICHARD STENGEL, *et ux.*,

Respondents.

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

BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED[1]

The Petition presents the question whether a state-law claim alleging that a medical device manufacturer violated a duty under the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") by failing to report adverse event information to the FDA is expressly or impliedly preempted.

PLAC will address two questions central to properly defining the scope of preemption under the MDA:

1. Can a state-law tort claim for negligence or a product defect escape preemption under 21 U.S.C. section 360k(A) as a "parallel claim" by alleging violation of a generic federal requirement applicable to all medical devices, such as the general duty to report adverse event information to the FDA?

The lower courts have struggled to determine the defining principles that determine whether a state liability theory will be considered "different from, or in addition to," a federal obligation under the MDA, or conversely, whether the theory qualifies as a parallel claim. Among other things, they disagree over whether a generic device regulation applicable to all medical devices is sufficiently "device-specific" to support a parallel claim. The

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[1] Counsel for a party did not author this brief in whole or in part. Such counsel or a party did not make a monetary contribution and did not intend to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made such a monetary contribution.

Ninth Circuit opinion here (*Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. En Banc 2013)) concluded that an Arizona common law duty to provide adequate warnings to a product user or their physician is identical to, and therefore parallel to, the generic federal requirement that device manufacturers report to the FDA the receipt of adverse event information. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496-497 (1996) (state- and federal-law duties are parallel when they are "equal" or "substantially identical").

2. Is the implied preemption arising from 21 U.S.C. section 337(a) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) limited to those state-law claims predicated on defrauding the FDA in disclosures seeking to obtain Pre-Market Approval?

Under section 337(a), only the United States can bring an action to enforce a provision of the MDA. *Buckman* therefore held that state tort law claims are preempted when the MDA supplies a critical element of the claim, thereby frustrating Congress' desire to vest enforcement authority exclusively in the FDA, or otherwise pose a risk of disrupting the balance in the regulatory framework. Subsequent decisions have varied widely in how broadly or narrowly they applied *Buckman*'s rationale.

The Ninth Circuit opinion adopts a narrow interpretation of *Buckman*, limiting implied preemption to claims for fraud in obtaining premarket approval. The lack of consistency to the

lower courts' applications of *Buckman* is problematic, since the MDA and this Court's decision in *Buckman* were intended to promote uniformity in the regulation of medical devices.

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INTEREST OF AMICUS CURIAE[2]

PLAC is a nonprofit corporation with 104 corporate members, including manufacturers and sellers, representing a broad cross-section of American industry. A list of PLAC's current corporate membership is attached as an Appendix. Several hundred of the leading product liability defense attorneys in the country are sustaining (i.e., non-voting) members of PLAC.

PLAC's primary purpose is to file *amicus curiae* briefs in cases presenting issues that affect the development of product liability law and impact PLAC's members. Since 1983, PLAC has submitted over 1000 such briefs in state and federal courts, including many briefs in this Court.

PLAC's interest in this action arises from the profound impact of state law claims seeking to impose obligations on manufacturers regulated by the FDA. As this Court has noted, in instances where manufacturers are subject to the detailed requirements of the FDA and are not protected by preemption, they may be required to do business under the daunting specter of the varied requirements of 50 states' tort laws. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349-51 (2001). Consequences might include subjecting manufacturers to broader obligations than Congress intended and inducing manufacturers to over-

[2] Pursuant to Rule 37(2)(a), counsel for PLAC notified the parties of PLAC's intent to file this brief more than ten days before it was due, and received written consent of all parties to file this brief.

disclose out of an over-abundance of caution fueled by concerns over imposition of liability under state law. *Id.* Better defining what is and is not preempted under the federal regulatory scheme is a matter of keen interest to device manufacturers. This case implicates the "delicate balance" of the FDA's regulatory scheme. *Id.* at 348. PLAC is interested in obtaining clear guidance for its members on the reach of state law and its relationship to federal obligations.

SUMMARY OF ARGUMENT

There is a pressing need for further guidance from this Court as to both the scope of the "parallel claims" limitation on express preemption under 21 U.S.C. section 360k(a) and the scope of implied preemption under 21 U.S.C. section 337(a) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Although articulated in this Court's decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the "parallel claims" limitation has never been applied or interpreted by this Court. Within this vacuum, the lower federal courts have struggled to define its contours and have reached varying conclusions in its application, with the courts particularly divided as to whether a *generic* federal requirement can support a parallel claim. Indeed, although created as a contradistinction to describe a species of claims that might *not* propose requirements "different from, or in addition to" device-specific federal requirements (§ 360k(a)(1)), in the lower courts it has taken on a life of its own. The Ninth Circuit decision is a particularly broad and disembodied interpretation and is particularly destructive of the Act's preemptive intent. This Court should end the prevailing uncertainty by clarifying what types of state-law tort claims qualify as parallel claims and avoid express preemption.

This case presents a synergistic opportunity for clarification of device preemption law, because the Ninth Circuit decision also adds to widespread

disarray in application of implied device preemption. Some courts have faithfully applied *Buckman*'s rationale and reasoning in adjudicating implied preemption; others have not, and consequently limit *Buckman*'s operation in various ways. The Ninth Circuit held that *Buckman* applies only to claims for fraud in obtaining premarket approval. A separate concurring opinion shrunk *Buckman* even further by denying preemption if the claim can be fit loosely into a *category* of traditional state tort law, such as the duty to exercise reasonable care or to avoid selling a defective or inadequately labeled product. So interpreted, *Buckman* offers little protection for the federal interests underlying section 337(a) and the MDA.

Thus, this case presents two highly unsettled issues critically important to the allocation of power between the FDA and the states in regulating the safety and effectiveness of life-saving medical devices. The Petition should be granted to provide sorely needed guidance and to resolve the conflicts and confusion among the lower courts, and to produce the preemption balance this Court sought to calibrate in *Riegel* and *Buckman*.

ARGUMENT

I. The MDA and This Court's Device Preemption Trilogy

The essence of federal preemption is the protection of federal goals and objectives arising from the statutory scheme. Congress has made policy-based decisions that call for allocation of power between federal authorities and the states. In deciding preemption issues, the courts are tasked with interpreting and enforcing the jurisdictional lines intended by Congress. *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990).

The goals of the MDA are to strengthen the safety and effectiveness of medical devices, to maximize their availability, and to encourage scientific innovation and medical progress through the development of new device technologies, all in the interest of promoting the public health. To do so, Congress increased federal oversight of the devices and their manufacturers, promoting predictability in their regulation and uniformity in their liability standards, and streamlining the premarketing approval and post-marketing surveillance processes. *See Riegel*, 552 U.S. at 326; *Buckman*, 531 U.S. at 348-351.

Congress decided that the goals of the MDA and the tools used to achieve them would be optimized by strictly limiting the influence of state regulatory and tort law in regulating the safety and effectiveness of devices and the requirements imposed upon manufacturers. *See Buckman*, 531

U.S. at 350. Accordingly, it enacted section 360k(a), which expressly bars states from imposing any requirements on devices that are not identical to the federal requirements—prohibiting any requirement related to the safety and effectiveness of a device that is "different from, or in addition to" the device-specific requirements generated by federal law. *Riegel*, 552 U.S. at 324-325. And it enacted section 337(a), which vests authority to enforce the provisions of the MDA exclusively in the federal government, prohibiting any private right of action based on violations of the MDA. *See Buckman*, 531 U.S. at 349 n.4, 352.

These limitations on the reach of state law have been honed by the FDA and by this Court. *See Lohr*, 518 U.S. at 496-497, 498-500. For example, both the FDA and this Court have interpreted "requirements" in the context of section 360k(a) to mean "device-specific requirements"—only those obligations applicable to a particular device, rather than any generally applicable requirements imposed by law, such as the Current Good Manufacturing Practices standards or the general obligation to report to FDA information concerning the occurrence of adverse device-related events. *Id.* at 498, 500-501. In a trilogy of decisions, this Court has attempted to provide further guidance to the lower courts as to the interpretation and application of both express and implied preemption arising from the MDA.

Lohr, 518 U.S. 470, limited the scope of express preemption under the MDA, holding that approval of Class III devices through the less rigorous "substantial equivalence" process does not

create sufficiently device-specific federal requirements to oust state regulation. *Id.* at 500-501. The Court read section 360k(a)'s preemption of state-imposed obligations "different from, or in addition to" device-specific federal requirements to preserve "parallel claims"—claims based on duties equivalent or substantially identical to the requirements imposed by federal law. *Id.* at 494-497.

Buckman, 531 U.S. 341, clarified the scope of implied preemption under the MDA. It held that state tort claims that threaten to disrupt the statutory and regulatory scheme of the MDA or inherently federal regulatory relationships, or that are rooted in federally created requirements, cannot be maintained. *Id.* at 349-351, 353. And in *Riegel*, the Court confirmed that approval of a Class III device through the rigorous premarket approval process establishes device-specific federal requirements, 552 U.S. at 322-323, and that state tort law theories of liability that seek to impose non-identical requirements applicable to the device are expressly preempted. *Id.* at 323, 330. In each of these decisions, this Court sought to clarify the permissible reach of state tort law in the regulation of the safety and effectiveness of medical devices.

II. Further Guidance Is Needed to Educate the Lower Courts and Restore the Balance of Power Intended by Congress

Notwithstanding these device preemption decisions, the present state of preemption jurisprudence in the lower courts demonstrates that

there is more work to be done. The MDA goals of federal predominance, predictability, and uniformity that Congress sought to pursue and that this Court sought to enforce remain elusive. In particular, the lower courts have struggled to interpret the scope of the "parallel claims" limitation to express preemption, i.e., to identify when a state-law claim seeks to impose requirements equal to or substantially identical to specific federal requirements, and have reached conflicting conclusions as to what types of MDA requirements can support a parallel claim. *Compare*, *e.g.*, *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010) ("*Sprint Fidelis*") (not a parallel claim because the federal requirements at issue were not device specific) *with Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769-771 (5th Cir. 2011) (finding claim parallel to generic federal adverse reporting requirements) and *Bausch v. Stryker Corp.*, 630 F.2d 546, 554-556 (7th Cir. 2010) (finding claim parallel to generic federal current Good Manufacturing Practices regulations).

The lower courts are also at odds over how to apply *Buckman* in various contexts. Some have sharply limited its impact by restricting it to a prohibition on affirmative tort claims for "fraud-on-the-FDA." *See*, *e.g.*, *Desiano v. Warner-Lambert & Co.*, 967 F.3d 85 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co. LLC v. Kent*, 552 U.S. 440 (2008). Some (including the Ninth Circuit here) have restricted implied preemption to state-law claims involving liability for inadequate disclosures in seeking premarket approval. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. En

Banc 2013). And the concurring majority in *Stengel* adopted an even more limiting reading—there is no implied preemption where the claim is categorically related to a general, traditional common law cause of action such as the duty of a manufacturer to exercise due care and refrain from marketing a defective product. *Id.* at 1235 (Watford, J., concurring). Other courts, in contrast, have gauged the scope of implied preemption based in part on a practical analysis of the degree to which the state law threatens to impair the federal interests that section 337(a) and *Buckman* seek to protect. *E.g.*, *Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1165-1166 (9th Cir. 2012), *rev'd*, 704 F.3d 1224 (9th Cir. En Banc 2013); *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012). And this Court most recently described *Buckman* as "holding that federal drug and medical device laws pre-empted a state tort-law claim based on failure to properly communicate with the FDA." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011).

On both issues, this Court's intervention is once again required to resolve these divergent approaches and to clarify the scope of express and implied preemption under the MDA.

A. There Is Disagreement and Confusion in the Lower Courts over the Meaning and Scope of the Parallel Claims Limitation on Express Preemption Under Section 360k(a)

The parallel claims limitation arose out of some relatively abstract discussion in the *Lohr* opinion explaining a type of state law requirement that would not be "different from, or in addition to" device-specific federal requirements, and therefore would void preemption under section 360k(a). *See* 518 U.S. at 495 ("The Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations."). *See also id.* at 496-497. *Riegel*, too, noted that these types of "parallel claims" are not necessarily preempted, but there again, the Court has had no opportunity to apply the limitation to any concrete claims. *See* 552 U.S. at 330.

An illustration of the concept appears as a hypothetical in Justice Breyer's *Lohr* concurrence. *See* 518 U.S. at 504 (discussing why state jury findings as to breaches of common law duties of care create specific state requirements subject to preemption). If federal law arising from an approved Premarket Approval application requires the device to have a 2-inch wire, and the jury is asked to impose liability under state law for failing to use a 1-inch wire, the requirements are different and the claim would be preempted. But if the jury is asked to impose liability under state law for failing to use a

2-inch wire, this would be a "parallel claim" because it is identical to the federal requirement.

Notwithstanding this seeming simplicity, as discussed above, lower court decisions applying the parallel claims concept to various different types of substantive claims have reached radically inconsistent results and have expanded the parallel claim concept, divorcing it from its roots.

One major disagreement among the courts is whether the federal requirement which the state-law claim parallels needs to be device-specific, or conversely, whether a parallel claim can rest on a generic federal requirement. Several courts have permitted claims to escape preemption as "parallel" even though they are parallel to generic MDA provisions that apply to all medical devices.

For example, the courts differ regarding whether parallel claims can be based on current Good Manufacturing Practices regulations broadly applicable to devices. *Compare Sprint Fidelis*, 623 F.3d at 1208 (preempted) with *Bausch v. Stryker Corp.*, 630 F.3d 546, 555-556 (7th Cir. 2010) and *Bass v. Stryker Corp.*, 669 F.3d 501, 512-513 (5th Cir. 2012) (not preempted).

The en banc Ninth Circuit panel erroneously sustained the Stengels' claim under Arizona law for negligent failure to comply with the generic reporting requirements of the MDA. On the state requirement end, the Arizona common-law duty to warn users or their physicians is too general to be "parallel" to a specific federal requirement; and the

federal requirement plaintiffs invoke to support their claim of parallelism is too general to qualify as a device-specific "federal requirement" within the meaning of section 360k(a). *See Riegel*, 552 U.S. at 322-323 (requiring device-specific federal requirements); *Lohr*, 518 U.S. at 500 (same). To ignore the requirement of device-specificity in applying the parallel claims limitation, while requiring it otherwise under section 360k(a), creates an anomalous asymmetry in the operation of the statute. *See Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495-497 (W.D. Pa. 2012).

Moreover, the federal and state requirements identified by plaintiffs are not parallel because they are not substantially identical. Arizona tort law imposes a duty on the manufacturer to warn *users and physicians* of risks actually caused by use of a product, including a medical device. In contrast, the federal reporting provisions require manufacturers to report *to the FDA* any "information" suggesting that its device "may have caused or contributed to a death or serious injury" or malfunctioned in a dangerous manner. These duties are simply not equal or substantially identical.

The strained interpretation adopted by the Ninth Circuit decision in this case highlights the need for more specific guidance as to how the parallel claim limitation operates.

B. There Is Disagreement and Confusion in the Lower Courts over the Meaning and Scope of Implied Preemption Under 21 U.S.C. Section 337(a) and *Buckman*

The Ninth Circuit opinion also reflects confusion over the scope of implied preemption of state claims that seek to enforce provisions of the MDA. As recognized in *Buckman*, section 337(a) reflects Congress' intent that only the federal government be permitted to enforce the MDA; allowing private litigants to pursue state law claims based on MDA requirements can frustrate that intent. Accordingly, preemption was required because the private claim effectively sought to enforce the MDA requirements, since those requirements were "a critical element" of the claim. 531 U.S. at 353. And preemption also applies where, in practical effect, the state claim threatens to disrupt the delicate balance maintained by FDA in administering the MDA and its regulatory relationships with manufacturers. *Id.* at 348-350, 353.

In *Buckman*, plaintiffs alleged "fraud-on-the-FDA" claims under state law following the FDA's § 510(k) approval of bone screws. Plaintiffs alleged an agent of the manufacturer fraudulently represented to the FDA that the screws would be used on arm and leg bones, but intended the screws for off-label use in the spine. As characterized by this Court, plaintiffs' state-law tort claims were based on the premise: "Had the representations not been made, the FDA would not have approved the

devices, and plaintiffs would not have been injured." 531 U.S. at 343.

The Court noted that the relationship between the FDA and the companies it regulates "is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"—the MDA. *Id.* at 347. Accordingly, there could be "no presumption of preemption," as the states have never occupied the field of "policing fraud against federal agencies." *Id.* at 347-48. The Court catalogued the litany of powers the FDA has at its disposal for "detecting, deterring, and punishing false statements" made to the FDA (*id.* at 349), concluding that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency … to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348; *see also id.* at 349 ("The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency."); *id.* (finding the FDA's enforcement "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives."). The Court held that allowing state law claims based on deceiving the FDA could disrupt or "skew" this balance by, for example: (i) increasing burdens on prospective applicants who may over-disclose and over-submit for fear of future civil liability; (ii) taxing or overwhelming the resources of the FDA due to unnecessarily voluminous approval applications; (iii) delaying the processing of applications and approval of new devices; and (iv) deterring off-label uses (which are nonetheless

common and generally accepted medical practices) by allowing claims premised on FDA disclosure requirements. *Id.* at 348, 350-51; *see also id.* at 350 (concluding that "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives.").

The Court distinguished two cases relied on by the plaintiff-respondent, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Lohr*, 518 U.S. 470. Both involved claims based "on traditional state tort law principles"; in *Silkwood*, the duty owed by an employer to its employee, and in *Lohr*, basic product liability duties to manufacture a product with reasonable care. *Buckman*, 531 U.S. at 352-353. In contrast, "the fraud claims [in *Buckman*] exist solely by virtue of the FDCA disclosure requirements" because the existence of these federal enactments was "a critical element in their case." *Id.* at 353. The Court concluded that "this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Id.*

Subsequent decisions of the lower courts reach inconsistent results on implied preemption, based on how narrowly or broadly they read the Court's rationale. *Compare*, *e.g.*, *Hughes*, 631 F.3d at 775-776 *with Lofton*, 672 F.3d at 380. Indeed, this outcome-determinative dichotomy is illustrated by the original panel opinion and the en banc opinion in this case. The initial panel concluded that state law failure-to-warn claims premised on a manufacturer's violation of FDA reporting requirements, like those

alleged by the Stengels, are legally indistinguishable from the alleged deceptive conduct claims found preempted in *Buckman*:

> The Stengels' theory is that if Medtronic had acted with reasonable care in complying with the regulations that required it to provide information to the FDA, the FDA would have required Medtronic to warn physicians about the danger of inflammation connected to its pump and Stengel could have avoided the injury caused by the pump. *See* 21 U.S.C. § 360k(a). This is precisely the same theory that was rejected in *Buckman*.

676 F.3d at 1164.

The en banc panel adopted a different view. The court mischaracterized the Stengels' claim as based on "traditional state tort law," the "settled Arizona law that protects safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers," including a cause of action for failure to warn. *Stengel*, 704 F.3d at 1233. It further found that the duty to warn could exist post-sale, and "contemplates a warning to a third party such as the

FDA." *Id.*[3] It then concluded that the claim that Medtronic had failed to properly report adverse events to the FDA was not impliedly preempted by *Buckman* because "[i]t is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*." Thus, the court narrowly interpreted *Buckman*, to preempt state law claims only when they arise from the premarket approval process.[4] *Buckman* is not so limited. *See PLIVA*, 131 S. Ct. at 2578 (*Buckman* preempts claims "based on failure to properly communicate with the FDA.").

The concurring opinion joined by a majority of the en banc panel elaborated. The state-law claim was not impliedly preempted because the Arizona cause of action for failure to adequately warn is "a traditional category of state law failure-to-warn

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[3] The court's reading of Arizona law was questionable. The cited case, *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719 (D. Ariz. 1992), *aff'd* 44 F.3d 806 (9th Cir. 1995) did not recognize a duty to warn third parties; it merely recognized that under certain circumstances a raw material supplier's duty to warn could be satisfied by a warning provided to a third-party intermediary, such as the completed product manufacturer. *Id.* at 723. But it certainly did not recognize a duty to warn *the FDA*—that obligation was and remains entirely foreign to Arizona law.

[4] The court's reading of *Buckman* as being based entirely on the MDA and having alleged no state-law claim was an obvious error. *See* 704 F.3d at 1230. This mirrored and propagated a similar error in *Hughes*, 631 F.3d at 775. But the court's overall reasoning, including the seven judge concurrence, suggests this mistake played little role in its decision. The court also plainly misread *Sprint Fidelis*, 623 F.3d 1200, as being "not inconsistent" with the 5th and 7th Circuit decisions in *Hughes* and *Bausch*. *See Stengel*, 704 F.3d at 1232.

claims that predated the federal enactments in question, and therefore does not exist solely by virtue of those enactments." *Id.* at 1235 (Watford, J., concurring). The opinion rejected the defense argument that the claim was not grounded in traditional state tort law because Arizona law had never required adverse event reports to be supplied to the FDA. "That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption." *Id.*

The several opinions below therefore illustrate the acute need for this Court's further guidance on how to apply *Buckman* and present a worthy vehicle for that education. Like some courts, the lead en banc opinion characterizes the state-law claim at a high level of generality (the duty of reasonable care, or manufacturer's duty to warn) and limits *Buckman* solely to claims based on misrepresentations in seeking premarket approval; the concurring majority similarly sets its lens at a high level of generality,

the manufacturer's duty to warn. [5] Both consequently conclude that the Stengels' claim is based on traditional state tort law and does not exist solely because of the MDA. 704 F.3d at 1233, 1235. The original panel opinion, on the other hand, found the claim sufficiently analogous to *Buckman* because it alleged that Medtronic had tacitly or overtly misinformed the FDA. It specifically found that the detailed obligations to report adverse events to the FDA as set forth in the MDA regulations "are not tied to th[e] general duty to warn consumers under Arizona law." "Thus, the Stengels' failure-to-warn claims … exist solely by virtue of the FDCA disclosure requirements and are, therefore, impliedly preempted." 676 F.3d at 1164-1165. The Eighth Circuit in *Sprint Fidelis*, 623 F.3d at 1205, similarly concluded that an alleged violation of federal adverse event reporting requirements was an impermissible private attempt to enforce the MDA.

Another distinctive difference between the original panel and the en banc panel, also seen in the divergent lower court applications of *Buckman*,

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[5] *See* 704 F.3d at 1235 (Watford, J., concurring):

> That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption. It is sufficient here that, in contrast to *Buckman*, the Stengels' claim is grounded in a traditional category of state tort law failure-to-warn claims that predated the federal enactments in question, and that the claim therefore does not exist solely by virtue of those enactments.

is the varying degree of meaningful consideration of the effect of the state-law claim on the statutory and regulatory regime under the MDA. The original panel found it significant that "the policing of such conduct in both instances [*Stengel* and *Buckman*] is committed exclusively to the federal government, and recognizing a state cause of action based on such conduct would conflict with the statutory scheme established by Congress." 676 F.3d at 1164. *See also id.* at 1165 ("the enforcement of a duty to report is an element of the federal scheme that is committed solely to the federal government."). And later in the opinion, the court further rejected a narrow reading of *Buckman* by observing that the Supreme Court majority opinion, unlike Justice Stevens' concurring opinion, was based not only on "a desire to avoid jurors second-guessing the FDA's decision making; it was also based on the idea that state fraud-on-the-FDA claims would 'exert an extraneous pull on the scheme established by Congress,' in which the FDA was supposed to enforce the FDCA's disclosure requirements." *Id.* at 1166 (quoting *Buckman*, 531 U.S. at 353). The court concluded that this rationale in *Buckman* applied to bar the Stengels' claim. *Id.*

No such consideration of the statutory intent appears in the two en banc opinions.

Consistent with this analytical pattern, courts finding that *Buckman* has preemptive effect beyond an affirmative state-law tort claim for "fraud-on-the-FDA" in the premarket approval process do so by

crediting the policy rationale of *Buckman*,[6] while those denying preemption tend to ignore the systemic policy concerns.[7]

The policy discussion was a critical part of this Court's reasoning in *Buckman*; it should play a significant role in decisions applying *Buckman* to determine the scope of implied preemption under the MDA. But in cases denying preemption it often is completely or virtually absent. The extent of the role these policies should play in the preemption analysis is an issue which has divided the lower courts. The issue is worthy of resolution.

III. For the Same Policy Reasons Discussed in *Buckman*, the Proper Allocation of MDA Enforcement Authority Is Critical to Rational and Consistent Public Health Policy and the Operation of the Medical Device Industry

Determination of the proper scope of preemption under the MDA is a matter of great significance to device manufacturers and to overall public health policy. This Court recognized as much by taking up the *Lohr*, *Buckman*, and *Riegel* cases to delineate the scope of MDA preemption for the guidance of the lower courts. Addressing the uncertainties arising from the preemption decisions of the lower courts is similarly important and necessary.

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[6] *E.g.*, *Lofton*, 672 F.3d at 380; *Guenther v. Novartis Corp.*, 2013 WL 1225391, *3-4 (M.D. Fla. Mar. 27, 2013).

[7] *E.g.*, *Hughes*, 631 F.3d at 775-776.

As discussed in *Buckman*, the MDA imposes a detailed scheme of federal oversight of device manufacturers designed to improve the overall safety and effectiveness of medical devices while simultaneously limiting obstacles to investment in research and development. These are matters of life and death. Congress sought to define the allocation of power between the FDA and the states in the MDA because the delicate balance among these objectives requires development and execution of a coordinated, nuanced, centralized, and uniform health policy.

Pursuant to section 360k(a) and section 337(a), the FDA must be free to carry out this mission unimpeded by the more single-minded and balkanized influence of numerous, inevitably conflicting applications of state-law by juries in individual personal injury lawsuits. Thus, the FDA—not various juries applying the laws of the various states in various different courtrooms adjudicating various different lawsuits—should have exclusive authority to determine what the law requires of devices and their manufacturers, as Congress intended.

For example, the FDA, not juries, should decide whether a manufacturer has adequately complied with FDA requirements for adverse reporting; if not, whether the violation warrants some type of punishment; and if so, what type and what level of severity. In other words, the FDA should be the entity exercising informed, policy-based prosecutorial discretion.

In addition to the FDA's superior expertise, resources, and vantage point, it is clear that a jury applying tort law in the context of a personal injury suit is a particularly blunt regulatory instrument. It sees only what the Rules of Evidence and the strategies of counsel allow it to see. Its decisions are narrowly guided by the phraseology of jury instructions, the arguments of counsel, and, inescapably, the passions, prejudices, and sympathies inherent in the human drama of a personal injury trial. Only the FDA is properly equipped to formulate and execute dispassionate, scientifically sound, and policy-based public health strategies. Only the FDA can employ the long run and see the big picture.

Accordingly, as Congress intended, enforcement decisions should be the exclusive province of the agency responsible for advancing the nuanced and often competing goals of public health on a case-by-case basis. *See Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4th 910, 935 (2004) (finding certain state law warnings preempted because FDA warning decisions further nuanced goals and conflict with a jury's "more single-minded goal of informing the consumer of risks"); *Riegel*, 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

Ignoring these factors, the Ninth Circuit decision misreads *Buckman* by failing to heed its primary concern over the "extraneous pull" of state-law claims adjudicated by juries, their unpredictable

and variable influence on the resource allocation decisions that the regulated device manufacturers tackle constantly. Only the FDA can be counted on to make adequately informed decisions reasonably calculated to promote overall health policy.

The ability of the FDA to regulate its own relationship with manufacturers and to interpret and enforce its own regulations offers a flexibility that "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. Narrow construction of *Buckman*, such as that applied by the Ninth Circuit here, improperly and unwisely compromises the FDA's exclusive control over the regulatory relationship, and exclusive authority to enforce the MDA. *Id.* at 350-51; *see also Lofton*, 672 F.3d at 380 (same).

CONCLUSION

For the foregoing reasons, as well as the reasons stated in the Petition, PLAC respectfully requests that the Court grant Petitioner Medtronic's Petition for a Writ of Certiorari and reinforce the allocation of authority enacted by Congress and reinforced in *Buckman* and *Riegel* by reversing the decision of the Court of Appeals.

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APPENDIX

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Corporate Members of the
Product Liability Advisory Council
as of 5/24/2013

Total: 104

3M
Altec, Inc.
Altria Client Services Inc.
Anadarko Petroleum Corporation
AngioDynamics
Ansell Healthcare Products LLC
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boehringer Ingelheim Corporation
The Boeing Company
Bombardier Recreational Products, Inc.
Bridgestone Americas, Inc.
Brown-Forman Corporation
Caterpillar Inc.
CC Industries, Inc.
Celgene Corporation
Chrysler Group LLC
Cirrus Design Corporation
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Crane Co.
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
Delphi Automotive Systems

Discount Tire
The Dow Chemical Company
E.I. duPont de Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, LLC
Exxon Mobil Corporation
Ford Motor Company
General Electric Company
General Motors LLC
Georgia-Pacific Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
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Hyundai Motor America
Illinois Tool Works Inc.
Isuzu North America Corporation
Jaguar Land Rover North America, LLC
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Kolcraft Enterprises, Inc.
Lincoln Electric Company
Lorillard Tobacco Co.
Magna International Inc.
Marucci Sports, L.L.C.
Mazak Corporation
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Medtronic, Inc.
Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.

Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Mueller Water Products
Mutual Pharmaceutical Company, Inc.
Navistar, Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
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Panasonic Corporation of North America
Peabody Energy
Pella Corporation
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The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.

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Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.