No. 10-17755

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RICHARD STENGEL and MARY LOU STENGEL,

Plaintiffs/Appellants,

v.

MEDTRONIC INCORPORATED, a foreign corporation,

Defendant/Appellee.

On Appeal from the United States District Court
for the District of Arizona
Raner C. Collins, District Judge
Case No. 4:10-cv-00318-RCC

BRIEF *AMICUS CURIAE* OF DRI – THE VOICE OF THE DEFENSE BAR IN SUPPORT OF DEFENDANT-APPELLEE MEDTRONIC ON REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, disclosure is hereby made by *amicus curiae* DRI – The Voice of the Defense Bar of the following corporate interests:

a. Parent companies of the corporation/association:

None.

b. Any publicly held company that owns ten percent (10%) or more of the corporation/association:

None.

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Interest of *Amicus Curiae*[1]

Amicus curiae DRI – The Voice of the Defense Bar ("DRI") is an international organization comprised of approximately 22,000 attorneys defending businesses and individuals in civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys around the globe. Therefore, DRI seeks to address issues germane to defense attorneys, to promote the role of the defense attorney, and to improve the civil justice system in America. DRI has long been a voice in the ongoing effort to make the civil justice system more fair, efficient, and – where national issues are involved – consistent. To promote these objectives, DRI participates as *amicus curiae* in cases such as this that raise issues of importance to its membership and to the judicial system.

DRI is particularly well-situated to provide the Court with context for the important issues raised by this case. DRI and its members have extensive experience in defending private lawsuits under the Food, Drug, and Cosmetics Act and related regulations and have an acute

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[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part and no person or entity, other than *amicus curiae* and its counsel, made a monetary contribution to its preparation or submission.

appreciation for the issues that prompted Congress to enact a broad federal scheme to place the authority for regulating medical devices with the federal agency tasked with doing so, foster consistent and uniform standards, and limit interference from conflicting state law tort claims.

Introduction

Congress's enactment of the Medical Device Amendments ("MDA") of 1976 created a scheme of federal safety oversight that broadly preempts state laws. This case raises issues concerning the scope of both express and implied preemption in light of the MDA, both of which have wide-spread implications: (1) what constitutes a "parallel claim" under state law that would fit through the narrow express preemption gap under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and (2) whether a state law claim founded on an alleged reporting violation to the Food and Drug Administration ("FDA") – no matter how it is framed – fits within the scope of implied preemption under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Underlying these questions is the important policy behind Congress's enactment of broad preemption for medical devices, which recognizes that preemption serves the important task of limiting the "extraneous pull" of state tort

claims on the FDA's execution of its statutory responsibilities to balance risks and benefits in regulating medical devices.

DRI respectfully contends that the majority opinion in this case properly applied the preemption analyses and reached the right conclusions. This e*n banc* court should reach similar conclusions.

Summary of the Argument

The majority panel opinion in this case correctly follows *Riegel* in holding that state law safety and effectiveness claims are squarely preempted by the MDA, as are Plaintiffs' attempts at adding a new safety requirement – an alleged state law duty to send medical device correction notices to physicians. Likewise, to the extent Plaintiffs' allegations fall within a "failure to warn" class of cases, they too are impliedly preempted under *Buckman.*

The dissent apparently laments this outcome, perhaps out of concern that the United States Supreme Court has left little room for conventional state tort theories to operate. But Congress has been fully aware of Supreme Court jurisprudence in the area of medical device preemption over the years, and has not sought to create additional exceptions to preemption. Instead, Congress recognizes that for the FDA to operate effectively – and for manufacturers to be able to create

and distribute medical devices that can offer important and even life-saving treatments – the federal government needs to dominate the field of legal duties imposed upon such manufacturers. There is nothing that calls for a sea change now in the application of *Riegel* and *Buckman*. Therefore, this *en banc* Court should, like the majority panel opinion, determine that both express and implied preemption preclude Plaintiffs' state law claims.

Legal Discussion

I. To Escape Preemption, State Law "Parallel Claims" Must Be Identical To Federal Requirements

Both the majority and dissent in the panel opinion for this case acknowledge the controlling precedent of *Riegel v. Medtronic*, 552 U.S. 312 (2008), in which the Supreme Court held that Class III medical devices approved pursuant to the FDA's rigorous pre-market approval ("PMA") process, such as the one involved in this case, are exempt from all common law claims that impose requirements different from or in addition to the FDA's requirements. *Riegel*, 552 U.S. at 330. *Riegel* stands for the proposition that Congress intended broad preemption to govern state claims regarding such devices to ensure that the FDA can effectively vet medical devices and weigh risks and benefits prior to approval. In *Riegel*, the Supreme Court suggested that the MDA

preemption clause does not expressly preempt parallel claims. *Id.* 21 U.S.C. section 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (citing *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996)).

Riegel's exception for "parallel claims" has been the focus of much litigation in recent years, and indeed, the majority and dissent in this case disagree about how the *Riegel* exception should be applied in this case. However, this Court need not wade into the dispute concerning the scope of the "parallel claims" exception in this case, as preemption can be determined based on a straightforward application of express preemption under Section 360k and *Riegel*.

Under *Riegel,* a court must first "determine whether the Federal Government has established requirements applicable [to the device at issue]." If so, the court "must then determine whether the [plaintiff's] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321-22 (citing § 360k(a)). In short, *Riegel* held that the

preemption provision of the MDA bars common law claims challenging the safety and effectiveness of PMA medical devices. *Id.* at 324.

The Supreme Court previously held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), that section 360k does not prevent a state from providing damages for violations of common law duties when those duties parallel, rather than add to, federal requirements. *Riegel* did not abandon that holding, but also left no doubt that many such duties as traditionally pled do not meet the strict requirements for a parallel claim. *Riegel*, 552 U.S. at 329-30 (citing *Lohr*, 518 U.S. at 495). *See also Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012) (plaintiff states a parallel claim if he "pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs [Current Good Manufacturing Practice] themselves and that this failure caused the injury"). A state law claim may, however, impose burdens on the plaintiff that are narrower than the applicable federal duties, such as requiring a showing of negligence. *Riegel*, 552 U.S. at 329-30. Medical device manufacturers have relied on *Lohr, Riegel* and cases applying both preemption and the narrow exceptions to preemption for their

understanding that they do not need to comply with any duties additional to or different from those required by the FDA.

The dissent's approach would seriously unsettle manufacturers' expectations about what should be at this point settled law. What the dissent in this case fails to recognize is that for a state law claim to be "parallel" so as to escape preemption, the claim's requirements must be *identical* to those imposed by federal law. Colloquially, "parallel" can mean "similar," "analogous," or "heading in the same direction." But for a claim to be parallel within the meaning of *Riegel*, the duties must be identical or at least "genuinely equivalent." *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (citing *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 454 (2005)). "State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Id.* Thus, to defeat express preemption, "'[p]laintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' …." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (quoting *In re Medtronic Inc.,* 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)).

The majority panel opinion in this case concluded that Plaintiffs' strict liability, negligence and warranty claims "generally challenged

the safety and effectiveness" of the medical device in question "without any hint of an allegation" that Medtronic violated FDA regulations. (Maj. Op. at 4092.) "Safety and effectiveness" claims are squarely preempted under *Riegel*. The majority also looked to Plaintiffs' proposed amended complaint, which claimed that Medtronic should have sent a medical device correction notice to physicians. Again, because such a claim is premised on an obligation not imposed by, but instead is additional to, those imposed by the FDA, any such claim also would be expressly preempted. *Id.; see also Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 842 (9th Cir. 2011) (holding class's state law claims were preempted because they sought to impose requirements regarding disinfectants in lens solutions that were in addition to federal requirements); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 578 (4th Cir. 2012) (holding that no parallel claim was asserted where plaintiff's claim sought to impose state law requirements more stringent than federal requirements).

The issue of what constitutes a "parallel" claim reaches far beyond the respective components of various state law claims. Implicit in the parallel claims analysis is a recognition that the state tort system can

"disrupt[] the federal scheme no less than state regulatory law to the same effect," and possibly more so:

> Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device [that], along with its greater effectiveness, brings a greater risk of harm? *A jury, on the other hand, 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.*

Riegel, 552 U.S. at 325 (emphasis added). Accordingly, state law claims that are not parallel to federal requirements necessarily do not account for the individuals who might benefit from higher risk medical treatments or devices that are available only because the FDA, based on a careful assessment, concluded that the potential benefits to many patients outweigh the potential risks to a few. In other words, the statute "suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id.* at 326.

In summary, the dissent erroneously ignores the rigors of what constitutes a "parallel" state claim. In contrast, the majority's approach

is faithful to *Riegel* and correctly applies *Riegel* as controlling Supreme Court precedent to hold that the Stengels are attempting to assert a non-parallel state claim. This Court acting *en banc* should hold the same.

II. The Majority Correctly Applies Implied Preemption And The Controlling Precedent Of *Buckman*

Another area of potential confusion in the area of preemption and medical devices is the holding of implied preemption in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001). The majority and dissent both recognize that under *Buckman*, any "fraud-on-the-FDA" claims are impliedly preempted, but disagree in this case over whether the Plaintiffs could re-cast their claims as an alleged violation of Medtronic's reporting duties to the FDA. As with express preemption under *Riegel,* implied preemption under *Buckman* actually is straightforward here, and the principles set forth in *Buckman* should be underscored by this Court acting *en banc*.

In *Buckman*, the Supreme Court held that state law fraud-on-the-FDA claims conflict with and are impliedly preempted by federal law. That case involved a group of plaintiffs who claimed injuries resulting from the use of orthopedic bone screws. *Buckman*, 531 U.S. at 343. The *Buckman* plaintiffs alleged that the defendant made fraudulent

representations to the FDA during the course of obtaining market approval. *Id.* In holding that the plaintiffs' claims were impliedly preempted, the Court noted that the defendant's "dealings with the FDA were prompted by the MDA, and the very subject matter of [its] statements were dictated by that statute's provisions." *Id.* at 347-48.

The Court noted that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency," and that the FDA uses this authority "to achieve a somewhat delicate balance of statutory objectives" that could be "skewed" by permitting related claims to be raised under state tort law. *Id.* at 348. State fraud-on-the-FDA tort claims conflict with the FDA's responsibility to police fraud and impose the burden of complying with "50 States' tort regimes." *Id.* at 350. Regulated entities would also not have the benefit of the certainty and consistency of their reporting obligations:

> [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Agency neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application. As a result, the comparatively speedy § 510(k) process could encounter delays, which would, in turn, impede competition among predicate devices

> and delay health care professionals' ability to prescribe appropriate off-label uses.

Id. at 351. The Court concluded that there is "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Id.* at 352 (citing 21 U.S.C. § 337(a)).

Buckman explicitly distinguished *Lohr*, rejecting an attempt to analogize the common law negligence action at issue in *Lohr* to a fraud-on-the-FDA claim, even if both claims arguably arose "from violations of FDCA requirements." *Id.* The Court held that the *Lohr* claims clearly stemmed from alleged negligence, "not solely from the violation of FDCA requirements." *Id.* In contrast, the claims in *Buckman* existed "solely by virtue of the FDCA disclosure requirements." *Id.* at 353. The Court soundly rejected the proposition that any violation of the Food, Drug and Cosmetic Act ("FDCA") will support a state law claim. *Id.*

The dissent here interprets *Buckman* and *Lohr* to contend that only a claim denoted "fraud-on-the-FDA" is impliedly preempted, and that similar state law tort claims are not. The dissent relies on *Lohr* for its conclusion that an Arizona "failure to warn" state law claim is not impliedly preempted, contending that *Buckman* did nothing to limit *Lohr*. But the only way to give effect to *Buckman* is to preempt state law claims that effectively seek to impose liability for failure to provide

information to the FDA. *See, e.g.,* James M. Beck, *The Food, Drug, and Cosmetic Act: Searching for the Crossroads of Safety and Innovation: Article: Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are And Where We Might Be Headed*, 32 Hamline L. Rev. 657, 704-705 (2009) ("A majority of courts have interpreted *Buckman* to extend preemption to fraud-on-the-FDA allegations where those allegations are asserted in support of some other, non-fraud cause of action. Rather, the FDA is viewed as the proper forum for such allegations. These courts concluded that agency fraud allegations pose the same burdens on the FDA's functioning whether or not stated as an independent cause of action."). Central to *Buckman's* holding is that state tort litigation can be disruptive, exert an "extraneous pull on the scheme established by Congress," and therefore is preempted by that scheme. *Buckman*, 531 U.S. at 353.

Riegel adhered to *Buckman's* observations in noting that the MDA created a scheme of federal oversight for medical devices and "swept back" state oversight schemes. *Riegel*, 552 U.S. at 316. Before the enactment of that legislation, states had been largely responsible for oversight of these devices. *Id.* The MDA calibrated the amount of FDA oversight to the amount of risk presented by a device, providing the

most oversight for Class III devices such as the one at issue here. *Id.* at 316. Devices are assigned to Class III if a less stringent classification would not provide reasonable assurance of safety and effectiveness, and they may present a potential unreasonable risk of illness or injury. *Id.* at 316 (citing § 360c(a)(1)(C)(ii)). It is the FDA's objective and duty to balance risk with benefit. The FDA may "thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318.

This Court has noted that *Buckman*'s implied preemption holding is consistent with the FDCA's prohibition on any private enforcement of the statute. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (discussing 21 U.S.C. § 337(a)). The *Buckman* court held that this "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4. Indeed, section 337(a) "limits the ability of a private plaintiff to pursue state law theories where such claims collide with the exclusive enforcement

power of the federal government." *PhotoMedex*, 601 F.3d at 924 (citing *Buckman*, 531 U.S. at 343, 349-50, 353).[2]

The majority correctly recognizes that the existence of an FDA warning letter does not change the holding of *Buckman.* The dissent appears to have adopted Plaintiffs' interpretation of *Buckman*, i.e., that the case only requires preemption where the FDA has not previously determined that the manufacturer violated federal reporting requirements However, as the majority notes, Plaintiffs would have this Circuit follow the concurrence in *Buckman* rather than the majority holding in that case. (Maj. Op. at 4097-4098.) Most courts have rejected this interpretation of *Buckman* to hold that claims alleging that manufacturers withheld or misrepresented information to the FDA are impliedly preempted. *See* Gregory J. Wartman, *Life After*

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[2] In *PhotoMedex*, the FDA corresponded with the defendant about potential issues in its clearance, but ultimately cleared the device, elected not to find a violation, and chose not to take any enforcement action. *Id.* at 930. The Court therefore did not address the question of whether the plaintiffs could have pursued a claim had the FDA taken affirmative enforcement action and found a violation. *Id.* at 930 n.6. In any event, warning letters such as those in *PhotoMedex* are not final agency actions and do not indicate that illegal activity has occurred. *See Summit Technology, Inc. v. High-Line Medical Instruments Co.*, 933 F. Supp. 918, 934 n.9 (C.D. Cal. 1996) (rejecting plaintiff's claim that warning letters indicated illegal conduct; "after further review, the FDA could ultimately decide . . . that [the conduct] is entirely legal").

Riegel: *A Fresh Look at Medical Device Preemption One Year After* Riegel v. Medtronic, Inc., 64 Food Drug L.J. 291, 305 (2009).

The dissent's reliance on *Lohr* also is misplaced. As the majority in this case recognized, *Lohr* did not address implied preemption at all. Maj. Op. at 4094, n.1 (citing *Buckman*, 531 U.S. at 352). Moreover, the *Lohr* claims "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352. In contrast, the fraud claims in *Buckman* were based solely on federal reporting requirements.

Finally, *Lohr* concerned the question whether a device approved through the substantial equivalent "510(k) process" was expressly preempted, and held that the general requirements set out in the 510(k) process were not preemptive requirements. But this holding is simply irrelevant here in light of the Court's later decision in *Riegel*, which is on all fours with the instant case. Both *Riegel* and the instant case concern devices that have undergone the more rigorous pre-market approval process, making much of the discussion in *Lohr* inapposite to this matter. The *Buckman* court recognized the potential for confusion in light of *Lohr,* and thus distinguished *Lohr* on the basis that its claims

"arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352. The dissent simply misapprehends *Buckman*, which did not abandon *Lohr* but limited its application by specifying that *Lohr*'s allowance for parallel claims does not extend to fraud-on-the-FDA and like claims that are not based on traditional common law duties.

In this case, Plaintiffs' claim is of the same type as that brought in *Buckman*. Plaintiffs' amended claim is not a traditional tort claim, but rather a fraud-on-the-FDA-style claim based on Medtronic's alleged withholding of information it was obligated to report to the FDA under federal law. Whether the alleged withholding of information occurs pre-market or post-market, the alleged violation is of the same kind. *See Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 379 (5th Cir. 2012) (citing *Buckman*, 531 U.S. at 347-48) (holding, "Disclosures to the FDA are 'uniquely federal' and thus beyond the states' traditional police power."); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (holding that an alleged failure to disclose all relevant information to the FDA "essentially equates" to a state law prohibition against fraudulent representations to the FDA).

Accordingly, the majority's straightforward application of *Buckman* should be followed by this Court *en banc*.

Conclusion

For the reasons stated above, this *en banc* Court should affirm the panel opinion in this case.

Dated: August 29, 2012

Respectfully submitted,

SNELL & WILMER L.L.P.

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Certificate of Compliance

Certificate of Compliance with Type-Volume Limitation, Typeface Requirements, and Type Style Requirements.

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 3,477 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B).

2. This brief complies with the type face requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using a Microsoft Word 2010 processing program in 14-point Century Schoolbook type style.

Dated: August 29, 2012

SNELL & WILMER L.L.P.

By: /s/ Mary-Christine Sungaila
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Statement of Related Cases

There are no known related cases pending in this Court.

Dated: August 29, 2012

SNELL & WILMER L.L.P.

By: /s/ Mary-Christine Sungaila
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing **BRIEF OF AMICUS CURIAE** with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on August 29, 2012. I further certify that all parties are registered users of the CM/ECF system.

Dated: August 29, 2012

/s/ Mary-Christine Sungaila
Mary-Christine Sungaila

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