No. 12-1351

In the Supreme Court of the United States

MEDTRONIC INCORPORATED, PETITIONERS

v.

RICHARD STENGEL AND MARY LOUIS STENGEL, RESPONDENTS

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

BRIEF FOR *AMICUS CURIAE* DRI—THE VOICE OF THE DEFENSE BAR IN SUPPORT OF PETITION FOR CERTIORARI

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae DRI—The Voice of the Defense Bar ("DRI") is an international organization with approximately 22,000 member attorneys who defend businesses and individuals in civil litigation. 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 one, which raises an issue of importance to DRI's members and to the judicial system.

DRI members represent federally-regulated businesses and industries in tort litigation in both state and federal courts. DRI members are regularly called upon to inform and advise clients about the potential liability that they face for making business decisions based upon state tort

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[1] Pursuant to this Court's Rule 37.6, amicus curiae states that no counsel for any party authored this brief in whole or in part, and that no person or entity other than amicus curiae or their counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for all parties were notified timely of the intent to file. The parties have consented to the filing of this brief, and letters evidencing such consent are being filed herewith, pursuant to this Court's Rule 37.3.

law. DRI members are asked to offer counsel regarding the sometimes conflicting obligations imposed under federal and state statutory and regulatory law. DRI members are well-positioned to offer this Court practical insight based on first-hand experience with the impact of state tort claims on federally-regulated businesses and industries.

Product manufacturers and distributors, along with many other businesses, and their employees and consumers, have benefitted from a regime in which an expert federal regulatory agency makes informed and comprehensive decisions about design, construction, materials, services, and products. DRI has a strong interest in assuring that this Court continues to apply federal preemption in a manner consistent with its history and purpose. The law must afford consistency and clarity to potential civil litigants. The issue of federal preemption is of great importance to DRI. DRI frequently participates as amicus curiae in cases addressing federal preemption and other matters. *See, e.g.*, *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314; *Kurns v. R.R. Friction Prod. Corp.*, No. 10-879; *see also Oxford Health Plans LLC v. Sutter*, No. 12-135.

INTRODUCTION

Congress's enactment of the Medical Device Amendments ("MDA") created a scheme of federal safety oversight that broadly preempts state laws relating to medical products. This case brings before the Court once again questions concerning

the scope of both express and implied preemption under the MDA. The issues presented have widespread implications: (1) what constitutes a "parallel claim" under state law that would fit the narrow express preemption gap under *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and (2) whether a state law claim founded on an alleged violation of the reporting requirements of the Food and Drug Administration ("FDA")—no matter how that claim is framed—fits within the scope of implied preemption under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

Congress's enactment of broad preemption for medical devices was based on the recognition 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. This Court has repeatedly acknowledged that strong policy.

Despite the Court's prior guidance, the Ninth Circuit held that Respondents' claims were not expressly or impliedly preempted because Respondents alleged Petitioner's failure to submit adverse-event reports to the FDA violated a general tort duty imposed by Arizona law. The effect of the Ninth Circuit's ruling is to allow state tort law to determine FDA reporting requirements for manufacturers. That result, if allowed to stand, would seriously undermine the FDA's policing authority, inserting state law requirements into the

regulatory scheme. The decision also conflates the FDA's role in the federal regulatory scheme with the role of a downstream manufacturer in state tort law, a fatal flaw in the legal analysis and an invalid basis for finding an exception to established preemption principles.

SUMMARY OF ARGUMENT

This Court should grant the Petition for Certiorari filed by Medtronic. It is painfully clear that *Lohr, Buckman*, *Riegel* and *Mensing* have not settled the law to the extent necessary to avoid repeated litigation over the scope and reach of federal preemption in the area of a manufacturer's reporting requirements to the FDA. This case represents another attempt to find interstices in this Court's prior pronouncements into which tort claims may be forced. The Ninth Circuit's reasoning is at best highly questionable, and presents a clear divergence from other circuit decisions.

The decision below imposes an additional requirement on medical device manufacturers not found in the MDA—that they act "reasonably" in submitting adverse-event reports. That is a requirement different from, and in addition to, the requirements of the MDA, and a claim based on that requirement is expressly preempted.

In addition, negligence claims based on the conduct of a manufacturer in reporting to the FDA will necessarily intrude upon and conflict with the FDA's regulatory function. Such claims are, as a result, impliedly preempted.

Finally, allowing negligence claims based on failure to report to the FDA will, in effect, create a private cause of action for violation of the MDA reporting requirements, contrary to established law.

This case presents an excellent vehicle to clarify the extent to which federal regulatory law—not state tort law—controls whether and how a manufacturer must comply with federal law. Certiorari should be granted in order to conclusively answer whether a state law claim founded on an alleged reporting violation to the FDA—no matter how it is framed—is expressly preempted, or fits within the scope of implied preemption.

ARGUMENT

I. THE NINTH CIRCUIT'S DECISION MISCONSTRUES THIS COURT'S PREEMPTION CASES.

A. To Escape Express Preemption, State Law "Parallel Claims" Must Be Identical To Federal Requirements, And The Claim In This Case Is Not.

As the petition explains, respondents' claim is expressly preempted under the parallel-duty analysis in *Lohr* and *Riegel*. Pet. at 29–32. *Lohr* held that state law may provide a damages remedy for violations of common-law duties when those duties parallel, rather than differ from or add to, federal requirements. 518 U.S. at 495. *Riegel* held

that, notwithstanding *Lohr,* the MDA bars common-law claims that are "different from or in addition to" the FDA's requirements for any device that received premarket approval from the FDA. 552 U.S. at 330. *Riegel* confirmed that Congress intended broad preemption to govern state claims regarding such devices in order to ensure that the FDA can effectively review and evaluate medical devices and weigh risks and benefits before and after approval. Many traditionally pled state tort law duties do not meet the strict requirements for a parallel claim. *Riegel*, 552 U.S. at 329–30 (citing *Lohr*, 518 U.S. at 495).

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 "*genuinely* equivalent." *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (emphasis in original). "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." *McMullen v. Medtronic, Inc.,* 421 F.3d 482, 489 (7th Cir. 2005) (citing *Bates*, 544 U.S. at 454). 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)).

Medical device manufacturers have relied on *Lohr*, *Riegel*, and cases applying preemption and the narrow exceptions to preemption, understanding that they do not need to comply with any duties additional to or different from those required by the FDA.

The Ninth Circuit's decision injects tremendous uncertainty into what should be settled law. In this case, the Ninth Circuit held that the MDA does not preempt a state-law claim predicated on a manufacturer's general duty to use reasonable care in providing warnings, when those warnings would consist of reporting adverse events to the FDA. 704 F.3d at 1232–33. Yet reasonable care is found nowhere in the MDA reporting requirements and the FDA has no duty to warn end users.

Under the MDA, the FDA reviews and evaluates reports of adverse incidents involving previously approved products. The FDA takes action not based on whether the manufacturer has acted reasonably or unreasonably, but rather based on what the evidence shows. The insertion of a "reasonableness" requirement into the reporting process clearly adds a requirement that is different from and in addition to any requirements found in the MDA.

The decision below produces a dramatic and unsupportable paradox: even if the FDA might have concluded that a manufacturer's reporting was adequate under federal law, a jury could still decide that the manufacturer's reporting was

negligent as a matter of state law. That is clearly impermissible under the principles of express preemption articulated by this Court, and results in serious harm to the federal regulatory scheme. As a result, it should be expressly preempted.

On first examination, this argument may seem in tension with *Lohr*'s holding that a state-law claim may satisfy the parallel-duty exception to express preemption even if it requires the plaintiff to prove a negligent violation of federal requirements, as the addition of a negligence element "would make the state requirements narrower, not broader, than the federal requirement." 518 U.S. at 495. Any tension is illusory, though. The claim permitted in *Lohr* did not require that a jury decide whether the FDA might have taken corrective action thereby preventing harm to a plaintiff. But the claim permitted by the decision below requires a jury to decide whether the FDA would have taken action sufficient to prevent harm to a plaintiff. *Stengel v. Medtronic*, 704 F.3d 1224, 1233 (9th Cir. 2013); *see also id.* at 1234 (Watford, J. concurring) ("To prevail, they will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries."). The decision below thus creates tort liability even where the FDA took no action or would have taken no action. In those situations, states' tort laws impose requirements different from and in addition to the MDA's requirements.

The Court has expressly recognized that the state tort system can "disrupt[ ] the federal scheme no less than state regulatory law to the same effect," and possibly more so:

> 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).

State-law claims that are not parallel to federal requirements 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.

Under the Ninth Circuit's holding, a jury decides if a manufacturer's reporting is reasonable, and if not, makes a finding of negligence. But negligence is irrelevant to the FDA's inquiry, and in this context is clearly different from and in addition to the requirements of the MDA. This Court should grant certiorari to address the significant limitation on the doctrine of express preemption created by the Ninth Circuit.

B. The Ninth Circuit Incorrectly Applied Implied Preemption And The Controlling Precedent Of *Buckman*.

Under *Buckman*, 531 U.S. at 343, "fraud-on-the-FDA" claims are impliedly preempted, because they impermissibly intrude on the FDA's regulatory prerogative. To side-step this prohibition, Respondents cast their claims as state-law products liability theories premised on Medtronic's claimed common law reporting duties to the FDA. Respondents assert that under Arizona common law, Medtronic had a duty to warn a third party (the FDA), which in turn also had a duty to warn plaintiffs of dangers in the product, completing the chain of causation. This theory fails for a number of reasons.

1. No Duty Exists For The FDA To Act, And None Can Be Imposed By State Law.

The Ninth Circuit premised its decision on a lower federal court decision holding that a component manufacturer might have a duty under

Arizona law to warn the completed product manufacturer if the failure to warn was cause-in-fact and proximate cause of the injuries sustained by the plaintiffs. *Stengel*, 704 F.3d at 1233 (citing *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992), *aff'd*, 44 F.3d 806 (9th Cir. 1995)). Assuming, for the sake of argument, the above is a correct statement of Arizona law, it is either meaningless to the claim here, or squarely preempted.

Unlike the FDA, the manufacturer or distributor of a product generally has an obligation under state product liability law to warn the ultimate user or consumer of conditions of its product that pose a risk of harm. *E.g.*, *Anguiano*, 808 F. Supp. at 724–25 (citing *Suchomajcz v. Hummel Chem. Co.*, 524 F.2d 19, 26–27 (3d Cir. 1975)). Correspondingly then, there may be a duty on the part of a component part manufacturer or original manufacturer to warn the downstream entity of known dangers, so that entity can warn the ultimate user or consumer.

Here, there is absolutely no duty on the part of the FDA to convey to the user or consumer any information that it receives from manufacturers; the reports it receives may (or may not) be communicated to product users through FDA notices to their physicians depending on the judgment and discretion of the FDA. And there can be no liability for the FDA's failure to do so. Accordingly, the principle of Arizona law relied upon is simply inapposite. And if that is not the case, to the extent the claim is premised on a duty

imposed on the FDA, such a claim must be preempted, just like any claimed duty of reasonable care allegedly owed by Medtronic under state law, but not the MDA.

2. Inquiry Into Possible FDA Actions Will Impermissibly Intrude On The Regulatory Process.

To prevail on their claim, Respondents will also necessarily have to litigate the FDA decision-making process, and convince a jury that the FDA would have taken a particular course of action. The Ninth Circuit characterized this as a "causation issue." Plaintiffs will examine FDA policies, interview FDA regulators, and ask a jury to assume the role of those regulators. It is difficult to imagine a more intrusive inquiry into the regulatory process. For that reason, Respondents' claims are impliedly preempted as well.

The claim allowed by the Ninth Circuit contemplates, as a necessary element of proof by the plaintiffs, that if the FDA had been notified of adverse events, it would have done something. This element might have a place between upstream and downstream manufacturers, each of whom have a duty to warn a buyer. But the FDA has no duty to warn anyone. The causation chain that the Ninth Circuit laid out clearly embroils the FDA in state litigation—the issue is what would the FDA have done, and when would it have done it, if it had received the notices that plaintiffs claim should have been provided.

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579 (2011) does not allow state tort law's proximate-cause analysis to undo federal preemption:

> We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. Following Mensing and Demahy's argument to its logical conclusion, it is also *possible* that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments.

Id. If this chain of maybes were "suffic[ient] to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force." *Id.*

Even if state law of general application allows a tort claim based on a failure to report to the FDA (fraud by omission), the claim is, necessarily, dependent on proving that the FDA would take further action. Without proof of that element, there is no causation. In other words, the plaintiff must still establish to the satisfaction of a fact finder that the FDA would have acted to provide additional warnings. That is dramatically different from the state tort law upon which the Ninth Circuit relied, which as a matter of common law imposes affirmative duties serially on those in the chain of manufacture and distribution to provide warnings. And in proving that claim, the plaintiffs must, as a certainty, litigate the FDA decision-making process, an effort that impermissibly intrudes on the FDA's mission.

3. Inquiry Into Possible FDA Actions Will Impermissibly Interfere With The Regulatory Process.

Central to *Buckman*'s holding is the recognition 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 MDA's enactment, states oversaw these devices. *Id.* The MDA calibrated the amount of FDA oversight to the amount of risk presented by a

device. *Id.* at 316. 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." *Id.* at 318.

For these reasons, most courts have rejected the lower court's interpretation of *Buckman*, and have held that claims alleging that manufacturers withheld or misrepresented information to the FDA are impliedly preempted. *See* Gregory J. Wartman, *Life After Riegel: A Fresh Look at Medical Device Preemption One Year After Riegel v. Medtronic, Inc.*, 64 Food & Drug L.J. 291, 305 (2009).[2]

The Ninth Circuit's reliance on *Lohr*, also is misplaced. *See Stengel*, 704 F.3d at 1233. *Lohr* did not address implied preemption. *Buckman*, 531 U.S. at 352. Moreover, the claims in *Lohr* "arose from the manufacturer's alleged failure to use

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[2] Allowing a jury to supplant FDA regulatory judgment at the post-approval stage is no less intrusive than at the pre-approval stage, as lower courts have recognized. *See Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 379 (5th Cir. 2012) ("[D]isclosures to the FDA are 'uniquely federal' and thus beyond the states' traditional police power." (quoting *Buckman*, 531 U.S. at 347–48)); *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).

reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Id.* at 352. In contrast, the fraud claims in *Buckman*—like those here—were based solely on federal reporting requirements.

The Ninth Circuit's decision returns the law to a pre-*Buckman* world where a "failure to warn" state-law claim is not impliedly preempted, if the claim is based on established state law principles. That reasoning contradicts current law as it is understood by a majority of courts. *See* 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."). *See also* Pet. at 13–17.

Plaintiff's claims in this case inevitably conflict with the FDA's regulatory function, because the parties would be litigating future FDA action where none has occurred to date. In other words, state law would ask the jury to decide whether the FDA had an obligation to warn. But the decision to

take action upon receipt of adverse incident reports is within the discretion of the FDA.

C. The Ninth Circuit's Decision Incorrectly Allows State Courts To Enforce The Reporting Requirement of the MDA Through Private Actions.

In *Buckman*, the Court noted that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration," 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 Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration 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. For these reasons, the Court has 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)).

The rule of no private enforcement of the MDA falls into an abyss if a state duty to warn claim can be based on an alleged failure to report adverse incidents to the FDA. An otherwise forbidden private right of action under the MDA is thus allowed so long as it is given a label as a state tort claim.

The decision below treats the FDA as a manufacturer who has a duty to warn third parties. To avoid preemption, a state law claim must be independent of the duty imposed by the MDA. A general duty to warn must exist, but the Ninth Circuit cited no case under Arizona law that says there is a duty to tell a third party who *may* tell the plaintiff. Accordingly, the only source of the duty is failure to "reasonably comply" with the MDA. This is expressly preempted by the MDA's prohibition on private enforcement.

If it is true that a general duty of care under Arizona law imposes an obligation on the part of a manufacturer to provide information to a third party, and liability may be imposed for failure to do so even if that third party has no obligation to pass the information on, then there is no limit to private enforcement of the MDA; fraud-on-the-FDA claims become negligent failure-to-warn claims. A plaintiff has no reason to allege fraud when simple negligence is enough to avoid preemption. That is a result that cannot be allowed to stand.

Congress did not intend to force the FDA to operate in tandem with state tort laws. *See Buckman*, 531 U.S. at 350 ("[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA.").

II. EFFORTS TO CIRCUMVENT THIS COURT'S DECISIONS HAVE LED TO DIFFERING OPINIONS AMONG THE CIRCUITS AND SIGNIFICANT UNCERTAINTY AT THE TRIAL COURT LEVEL.

The claim allowed by the Ninth Circuit adds another patch to the already unsightly national quilt of conflicting approaches to implied and express preemption under the MDA. The lower courts, consumers, and manufacturers need specific direction on how to deal with these claims, which,

despite *Buckman*, *Riegel* and *Lohr*, return repeatedly.

If a cause of action can be based on state-law duties to act with "reasonable care" in providing warnings required under the MDA, then there is no limit to the claims that might be brought, while still avoiding preemption. A claim that was in substance a fraud-on-the-FDA can now proceed if it is described as negligence-on-the-FDA. In the Ninth Circuit, all the plaintiff must allege is that the manufacturer failed to reasonably advise the FDA. On the other hand, if conformity to federal law is the basis for the claim—that is, if state law provides a cause of action for non-compliance with federal law—then the state cause of action is merely a private vehicle to enforce the MDA. In either circumstance, preemption should bar the claim. But unless the Court grants this petition, failure-to-report claims will proceed in the Ninth and Fifth Circuits, but will be barred in the Eighth and Sixth Circuits. *Compare Stengel*, 704 F.3d at 1233, *and Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 765 (5th Cir. 2011), *with In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010), *and Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423–24 (6th Cir. 2005).

CONCLUSION

Despite the Court's several decisions on the subject, division and uncertainty continue in the lower courts on the proper application of preemption and its exceptions in the medical device context. This case presents an excellent opportunity for the Court to remove the existing uncertainty, and provide clearer guidance for manufacturers, consumers, counsel and the courts. The petition should be granted.

Respectfully submitted,

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