No. 12-1351

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

RICHARD STENGEL AND MARY LOU STENGEL,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

SUPPLEMENTAL BRIEF FOR PETITIONER

MICHAEL K. BROWN
JAMES C. MARTIN
LISA M. BAIRD
REED SMITH LLP
355 South Grand Avenue
Suite 2900
Los Angeles, CA 90071
(213) 457-8000

MIGUEL A. ESTRADA
Counsel of Record
AMIR C. TAYRANI
JONATHAN C. BOND
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
mestrada@gibsondunn.com

Counsel for Petitioner

RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

SUPPLEMENTAL BRIEF FOR PETITIONER

The United States believes that this Court's guidance is *not* needed because nearly everyone to pass upon the preemption issues presented—the court below, other circuits, this Court, and previously the government itself—has lost their way. Both on implied and express preemption, the government's brief abandons the views that it has previously urged upon this Court to offer novel (but implausibly crabbed) views of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA").

The government asserts that its theory that every court is wrong is sufficient to deny review here. But the government's conclusion does not remotely follow from its premise. If every court to address the issues has erred, that only magnifies the need for review. In fact, it is the government that has gone astray, making the need for guidance all the more urgent.

Respondents concede that their failure-to-warn-the-FDA claim rests on an alleged violation of federal requirements. Opp. 5, 20. And the government admits (at 22) that that claim would interfere with the FDA's work like the fraud-on-the-FDA claim held preempted in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). It nevertheless insists (at 23) that respondents' failure-to-warn-the-FDA claim differs from those other circuits have held impliedly preempted because it rests on a supposedly "independent" state-law duty. But the government never attempts to justify why the duty is "independent." Its view, at bottom, is that respondents' failure-to-warn-the-FDA claim escapes preemption

simply because of its state-tort-law label. That view not only contravenes *Buckman*, providing a roadmap for wholesale evasion of 21 U.S.C. § 337(a), but also amounts to a repudiation of the government's position in *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (per curiam)—which it never even mentions.

The government admits that the circuits are also divided regarding the scope of the MDA's "parallel duty" exception to express preemption. Yet it opposes certiorari because (it says) every circuit to address the issue—including the Ninth Circuit below—has erred, interpreting the MDA's express-preemption provision too broadly. That assertion is a direct attack on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), disregards a recent, unanimous express-preemption decision, *National Meat Association v. Harris*, 132 S. Ct. 965 (2012), and distorts the government's own leading authority, *Wyeth v. Levine*, 555 U.S. 555 (2009). If accepted, the government's new view would render the MDA's express-preemption provision a dead letter. And the government again fails to mention that its new position contradicts what it successfully argued to this Court in *Riegel* itself.

Like the decision below, the government's position would eviscerate both *Buckman* and *Riegel*. If the government really seeks a wholesale remaking of preemption law, urging that review be *denied* here is a surpassingly odd way to accomplish it. Its unexplained abandonment of precedent and its own positions, and its rejection of every circuit's view, only underscore the pressing need for this Court's review.

I. THE GOVERNMENT'S IMPLIED-PREEMPTION ARGUMENT FAILS TO REFUTE THE CIRCUIT SPLIT AND CONTRADICTS BOTH *BUCKMAN* AND THE GOVERNMENT'S OWN PRIOR POSITION.

A. As the panel below acknowledged, Pet. App. 38a, the circuits are sharply split on whether failure-to-warn-the-FDA claims are impliedly preempted under Section 337(a) and *Buckman*. The Sixth and Eighth Circuits have held that failure-to-warn-the-FDA claims are impliedly preempted, while the Fifth and Ninth Circuits have held that they are not. Pet. 13-17.

The government barely attempts, and demonstrably fails, to refute this direct and acknowledged conflict. It asserts that the claims the Sixth and Eighth Circuits held preempted are "materially different from" the claims the Fifth and Ninth Circuits sustained because the latter claims alleged violations of "independent state-law dut[ies]." U.S. Br. 23. But the Sixth and Eighth Circuits addressed "state law causes of action," which they held preempted because they were ultimately based on federal-law duties owed to the FDA. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203, 1205-06 (8th Cir. 2010); *see Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005); Appellants Br. 9, *Cupek* (No. 04-3201). The claim here is no different. Respondents allege that "*because Medtronic failed to comply with its duty under federal law*, it breached its 'duty' . . . under [state] law." Pet. App. 19a (emphasis added); *see also Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 771, 775-76 (5th Cir. 2011).

In short, notwithstanding the state-law labels plaintiffs in these cases attached to their claims, none of the claims rests on obligations truly inde-

pendent of federal law. The precise issue that has divided the circuits is whether plaintiffs pursuing federal-law-dependent claims may evade *Buckman*—and enlist juries to circumvent the FDA's exclusive enforcement of federal duties under Section 337(a)—simply by disguising such claims in general state-law terms. Pet. 13-17, 22-29.

B. The government's view that respondents' claim escapes implied preemption because it is framed in traditional state-law terms is irreconcilable with this Court's precedent and the government's own prior position.

1. *Buckman* forecloses the government's submission that respondents' claim is not impliedly preempted because it supposedly rests on state law. The *Buckman* plaintiffs asserted claims "under state tort law," alleging that the defendant violated its duty of truthful disclosure to the FDA. 531 U.S. at 343, 346-48. These "state-law fraud-on-the-FDA claims conflict[ed] with, and [were] therefore impliedly preempted by," the MDA because alleged violations of the MDA's requirements were "a critical element" of the claims. *Id.* at 348, 352-53. Although the plaintiffs framed their claims "under state tort law," the Court recognized that the claims really "would not be relying on traditional state tort law," but on the MDA. *Id.* at 348, 353.

So, too, here. The MDA's requirements are unquestionably a "critical element" of respondents' claim that petitioner failed to make required disclosures to the FDA. *See* D.C. Dkt. #22-1, at 3-5, 8; Pet. App. 19a. Respondents themselves summarize their claim as alleging that, "*by violating the federal requirements*, [petitioner] breached its state-law duty." Opp. 5 (emphasis added).

2. The government rejoins that respondents' claim "seek[s] to enforce traditional tort law, not the FDCA itself," because it is "*apparently*" based on a "state-law duty to warn" that is "independent" of federal law—and therefore does not interfere with the FDA's exclusive authority to enforce the MDA. U.S. Br. 22-23 (emphasis added). But the government offers no basis for that noncommittal assertion. It never confronts respondents' own description of their claim as "based on [petitioner's] violation of FDA reporting requirements" and as alleging "violat[ions]" of those "federal requirements." Opp. 5, 20. Nor does it attempt to defend the Ninth Circuit's erroneous conclusion that Arizona law imposes a novel, independent duty to report adverse events to the FDA. *Cf.* Pet. 24-27. Indeed, if that supposed duty—derived from highly generalized tort-law principles in the Restatement (Second) of Torts, *id.* at 17—were sufficiently independent to escape preemption, States could freely circumvent Section 337(a) at will.

Because the government offers no explanation of its own, one must conclude that it agrees with the decision below that respondents' claim does not rest on federal law because it "is grounded in a traditional category of state law" tort claims. Pet. App. 25a (Watford, J., concurring). Yet the government itself has demonstrated the error in that reasoning before. In *Warner-Lambert*, it explained that, under *Buckman*, "whether a claim relies on a traditional-*sounding* duty," as opposed to "'a newly-concocted duty between a manufacturer and a federal agency,'" is irrelevant. U.S. *Amicus* Br. 25-26, *Warner-Lambert* (No. 06-1498) ("U.S. *Warner-Lambert* Br.") (citation omitted). "All that matters is that the state statute requires a determination" that the manufacturer has violated its duty of disclosure to the FDA

"as a predicate to liability, and therefore conflicts with federal law under *Buckman*." *Id.* at 31.

The government's position here directly contradicts its view in *Warner-Lambert* that plaintiffs cannot evade *Buckman* by camouflaging federal-law claims in state-law clothes—a fact it never mentions. Nothing but the "traditional-sounding" nature of respondents' claim suggests that it rests on state law. That, however, is exactly what the government explained in *Warner-Lambert* does not suffice. The Administration is entitled to reevaluate on occasion what will best serve the United States' interests. But its views deserve no deference when, as here, it fails even to acknowledge, much less explain, its departure from prior positions.

C. Respondents' claim "interferes with a federal prerogative" (U.S. *Warner-Lambert* Br. 26) no less than those in *Buckman*. As the government once recognized, "[p]ermitting lay juries to second-guess the adequacy of a manufacturer's submission to FDA, and to impose damages . . . based on their appraisal" of the manufacturer's actions, "would interfere with FDA's exercise of its expert judgment." *Id.* at 7. To be sure, unlike the *Buckman* plaintiffs, respondents assert omissions, not misrepresentations, in petitioner's disclosures to the FDA. But that only exacerbates the interference: Dictating what manufacturers must affirmatively disclose—and when—intrudes further into federal prerogatives than merely forbidding false submissions.

The government admits (at 22) that respondents' failure-to-warn-the-FDA claim would interfere with the FDA's work: "Allowing respondents' claim to proceed could influence the relationship between FDA and manufacturers." *Ibid.* It nevertheless dis-

misses this intrusion as "the product of lower courts' misplaced focus on an attenuated theory of causation," *id.* at 21—*i.e.*, respondents' claim "that if [petitioner] had properly reported the adverse events to the FDA," this "information would have reached [respondents'] doctors in time to prevent [their] injuries," Pet. App. 23a (Watford, J., concurring). This "tortuous theor[y] of causation," it says (at 19), is an obstacle of the court of appeals' own making; the court *should* have considered the "more natural theory of causation" based on petitioner's failure unilaterally to "updat[e] its device's labeling."

The court of appeals did not consider that theory, however, because it "would have been *expressly* preempted under 21 U.S.C. § 360k." Pet. App. 22a (Watford, J., concurring) (emphasis added). Such a claim would rest on a state-law duty "'different from'" and "'in addition to'" the MDA's labeling requirements. *Ibid.* (citation omitted). Respondents, indeed, did not plead a relabeling claim or "predicat[e] their failure-to-warn claim on a duty to warn doctors directly." *Ibid.* They "instead alleged that [petitioner] breached its duty of reasonable care" by "failing to report adverse events *to the FDA*." *Id.* at 22a-23a. If the decision below stands, this case will proceed to trial on that theory—not on the relabeling claim of the government's imagining.

II. THE GOVERNMENT'S CLAIM THAT EVERY CIRCUIT HAS ERRED IN ADDRESSING EXPRESS PREEMPTION IS WRONG, BUT EVEN IF CORRECT WOULD NOT JUSTIFY DENYING REVIEW.

The government's assertion that the Ninth Circuit's express-preemption holding also does not warrant review because every circuit to address the is-

sue has erred is illogical. Its premise, moreover, is false. The government's new express-preemption position contravenes *Riegel* and *National Meat Association*. And it distorts its own chief authority, *Wyeth*—which addressed only *conflict* preemption for regulation of drugs, sharply distinguishing *express* preemption for devices.

A. The government concedes that the circuits are split regarding the scope of the "parallel duty" exception to express preemption under 21 U.S.C. § 360k(a). It admits (at 17) that the Eighth and Eleventh Circuits "have found claims preempted where the counterpart to the state requirement would have been a general federal requirement," while the Fifth, Sixth, Seventh, and now Ninth Circuits "have held that a state requirement is saved from express preemption if it parallels a federal requirement of any kind, be it device-specific or general." *Cf.* Pet. 17-21.

The government (at 17) disparages the Eighth and Eleventh Circuits' rulings, but its attacks are unfounded. It says those decisions "rest[ed] on deficiencies in the plaintiffs' pleadings" and addressed only the claims "'*[a]s pleaded and argued*'" by the parties. *Ibid.* (citation omitted). But Article III courts are *supposed* to proceed in that fashion, adjudicating only the claims properly presented to them. The government also claims that the Eighth and Eleventh Circuits gave inadequate "explanation" for concluding that state laws "cannot escape preemption by being parallel to a general federal requirement." *Ibid.* But it never explains why that conclusion is incorrect. In any event, those rulings are binding precedents in two circuits.

Unable to refute this acknowledged split, the government declares it (at 17-18) "academic"—not because the issue is unimportant, but because the government thinks *every* court of appeals is *wrong*. Every circuit "begin[s] with the premise" that "Section 360k(a) preempts *all* state requirements with respect to [a] device that are not parallel to some federal requirement"—whether general or device-specific. *Id.* at 16. The government once shared the view that Section 360k(a) "generally preempts any state 'requirement' that is 'different from, or in addition to, any [federal] requirement,'" and that "pre-market approval" of a device "imposes specific federal requirements applicable to the device, and thus has preemptive effect." U.S. Merits *Amicus* Br. 6, 8, *Riegel* (No. 06-179) ("U.S. *Riegel* Br.") (alteration in original) (citation omitted).

Now, however—without acknowledging its prior view—the government jettisons it. "[D]isagree[ing] with" "every case since *Riegel*," it argues that Section 360k(a) preempts *only* state-law requirements that address the "same subject" as a particular federal requirement. U.S. Br. 11, 15-16. According to the government, this supposedly widespread confusion counsels *against* certiorari. *Id.* at 15-16. That assertion is difficult to fathom. Even if every circuit had erred, that would only increase the need for this Court's intervention.

B. The government's newly crabbed view of express preemption, moreover, is wrong. It cannot be squared with the statute, this Court's case law, or the government's own prior position.

1. Section 360k(a) nullifies "any" state-law "requirement" that "is different from, or in addition to, any [federal] requirement" and "relates to the safety

or effectiveness of the device." 21 U.S.C. § 360k(a). Thus, *only* state-law requirements that "'parallel,' rather than add to, federal requirements" escape express preemption. *Riegel*, 552 U.S. at 330. And because "[p]remarket approval . . . imposes 'requirements' under the MDA," States cannot impose their own requirements on devices subject to premarket approval beyond what the FDA has imposed. *Id.* at 322.

The government's view (at 11) that States *may* pile on other requirements that do not address the "same subject" as a corresponding federal requirement contravenes the statute and *Riegel*. Section 360k(a) contains no exception allowing additional state-law requirements that address different topics than federal requirements. Indeed, the government's view would read "in addition to" out of the statute and reduce an *express*-preemption provision to a superfluous recital of *conflict*-preemption principles.

The government elides the distinction between express and implied preemption, as its heavy reliance (at 7, 11-13) on *Wyeth* illustrates. *Wyeth* addressed claims concerning prescription drugs, to which only conflict-preemption principles applied. *See* 555 U.S. at 563-81. The Court specifically contrasted the drug and device contexts—stressing the absence of any provision applicable to drugs paralleling Section 360k(a). *Id.* at 566, 574. On the government's view, however, *Wyeth*'s conflict-preemption analysis would apply with equal force in the express-preemption setting.

2. The government's submissions that respondents' claim falls outside Section 360k(a)'s scope exacerbate its departure from its prior position and this Court's teaching. It argues (at 12) that respondents'

failure-to-warn-the-FDA claim "attack[s] petitioner's conduct *after* its device received premarket approval," and therefore does not add to federal requirements imposed at the time of approval. That view is untenable—as the government itself explained in *Riegel*, where it refuted the plaintiff's argument that her claim was not preempted because premarket approval "'does not preclude a later determination that the device is not safe and effective.'" U.S. *Riegel* Br. 22 (citation omitted). "Congress," the government explained, "charged FDA, not state juries, with the responsibility to determine whether a device remains safe and effective." *Ibid*. "When FDA has not taken that action, however, its premarket approval of the device—and the federal requirements that result from that approval—remain in effect." *Id.* at 23.

As the decision below recognized, the government's assertion (at 12-13) that Section 360k(a) does not preempt a claim that a manufacturer should have unilaterally altered a device's labeling is also meritless. Pet. App. 22a (Watford, J., concurring). That FDA regulations allow manufacturers to modify labels without agency approval in limited circumstances after receiving premarket approval (U.S. Br. 13) does not save a relabeling claim from preemption. Such a claim would allege that a manufacturer was not merely permitted, but *required* by state law, to change the label. *Ibid.* But state law "imposes additional or different requirements" if it makes mandatory what federal law merely permits. *Nat'l Meat Ass'n*, 132 S. Ct. at 969-71 (Federal Meat Inspection Act—which forbids state-law "'[r]equirements'" "'in addition to, or different than,'" federal requirements—"covers not just conflicting, but also different or *additional* state requirements," and bars States from "impos[ing] new rules" regarding "what a

slaughterhouse *must* do" (emphases added) (citation omitted)). The government's hypothesized relabeling claim thus would impermissibly "impos[e] an additional obligation." *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

C. This Court's intervention is therefore doubly needed—both because the circuits are divided on the scope of the parallel-duty exception, and because the agency charged with administering the MDA has misread it. But even if every circuit were wrong, that would only magnify the need for this Court's guidance.

The government rejoins (at 17-19) that the case's "procedural posture" precludes providing such guidance here: Respondents' failure to cross-petition on whether state-law requirements are preempted if no federal requirement addresses the "same subject," it says, would prevent this Court from ruling for respondents on that issue. Not so. If the Court were inclined to abrogate *Riegel* and relegate Section 360k(a) to redundancy, it could hold, on that basis, that respondents' failure-to-warn-the-FDA claim is not expressly preempted. And if the Court did so—and also wished to nullify *Buckman*—it could affirm the judgment below that allowed respondents' claim to proceed. Neither outcome would require a cross-petition. Both, however, would eviscerate the MDA's preemptive force, enable state-law juries to second-guess the FDA, and imperil the public health.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

MICHAEL K. BROWN
JAMES C. MARTIN
LISA M. BAIRD
REED SMITH LLP
355 South Grand Avenue
Suite 2900
Los Angeles, CA 90071
(213) 457-8000

MIGUEL A. ESTRADA
Counsel of Record
AMIR C. TAYRANI
JONATHAN C. BOND
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
mestrada@gibsondunn.com

Counsel for Petitioner

June 3, 2014