No. 12-1351

In the Supreme Court of the United States

MEDTRONIC, INC., PETITIONER

v.

RICHARD STENGEL AND MARY LOU STENGEL

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

Petitioner manufactures a medical device subject to premarket approval by the Food and Drug Administration (FDA) under the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq*. A patient using the device was paralyzed by an adverse event allegedly caused by the device. That patient and his wife (respondents in this Court) allege that after the device was approved by FDA, petitioner learned about adverse events associated with the device; that petitioner failed to make reports of those adverse events to the FDA as the MDA generally requires manufacturers to do; that such reports would have prompted changes to the device's approved labeling; and that those changes would have given physicians information that would have prevented or mitigated the patient's injury.

Respondents sued petitioner on various theories, the gravamen of which is that petitioner breached its duty under Arizona law to use reasonable care in warning of risks associated with its product. The questions presented are as follows:

1. Whether respondents' claim is expressly preempted by the MDA, 21 U.S.C. 360k(a).

2. Whether respondents' claim is impliedly preempted under the rationale of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, "impose[] a regime of detailed federal oversight" administered by the Food and Drug Administration (FDA) for medical devices. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Depending on the nature of the device and the risks it presents, that oversight ranges from "general federal regulations governing the labeling and manufacture of all medical devices," *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 497 (1996), to "a rigorous regime of premarket approval for [certain] devices," *Riegel*, 552 U.S. at 317.

FDA may grant premarket approval for a device only if it finds, among other things, that (a) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (b) the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). After premarket approval, a manufacturer generally must receive FDA's approval of a supplemental application before making any change to the device itself that would affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. 814.39(a). The same process that applies to an original PMA application generally applies to such a supplemental application. See 21 U.S.C. 360e(d)(6)(B); 21 C.F.R. 814.39(c).

Most changes to the labeling of a device after premarket approval likewise require FDA's prior approval, 21 C.F.R. 814.39(a)(2), but certain changes do not, 21 C.F.R. 814.39(d)(1). In particular, prior to receiving FDA approval, a manufacturer may place into effect "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction," "that add or strengthen an instruction that is intended to enhance the safe use of the device," or "that delete misleading, false, or unsupported indications." 21 C.F.R. 814.39(d)(2)(i)-(iii). Those standards, and the associated process for a manufacturer to notify FDA of "changes being effected" (CBE) to a device's labeling, mirror the CBE provisions applicable to the labeling of brand-name prescription drugs addressed by this Court in *Wyeth* v. *Levine*, 555 U.S. 555, 568-569 (2009) (discussing 21 C.F.R. 314.70(c)(6)(iii)(A) and (C)).

"[P]remarket approval is specific to individual devices," *Riegel*, 552 U.S. at 323, but such devices are also subject to the more general provisions of the MDA and

FDA's regulations, such as those discussed above that govern revision of the labeling of a device subject to premarket approval. In addition, a manufacturer is required to collect and report to FDA within certain timeframes information on certain adverse events associated with its device. See 21 U.S.C. 360i(a); 21 C.F.R. Pt. 803.

b. The MDA's express preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].

21 U.S.C. 360k(a). FDA may exempt state requirements from preemption under appropriate circumstances. 21 U.S.C. 360k(b). This Court has described Section 360k as "authorizing the FDA to determine the scope of [preemption under] the [MDA]." *Wyeth*, 555 U.S. at 576; but see *Riegel*, 552 U.S. at 326 (suggesting FDA's view may merit "mere *Skidmore* deference").

In implementing Section 360k, FDA has long recognized that Congress did not wish "State and local regulation of medical devices [to] be reduced or eliminated before compensating FDA regulations [are in] effect[]." 43 Fed. Reg. 18,663 (May 2, 1978). FDA's regulations implementing Section 360k accordingly provide that such "requirements are preempted only when [FDA] has established specific counterpart regulations or there are

other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d).

Even when preemptive federal requirements exist, a state requirement is preempted only if it is "different from, or in addition to," federal requirements. 21 U.S.C. 360k(a)(1). Through that qualification, Section 360k(a) permits a State to "provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. *Riegel* confirmed the availability of such "parallel claims." 552 U.S. at 330.

2. Petitioner manufactured the SynchroMed EL Infusion System, a medical device with FDA premarket approval that delivers analgesics through a catheter into the space surrounding the spinal cord. According to respondents' complaint (Doc. 1 Ex. A) (Compl.), in 2000, surgeons implanted the device in respondent Richard Stengel. Compl. ¶ 5. A granuloma, or inflammatory mass, developed at the tip of the catheter, eventually leading to Mr. Stengel's collapse and hospitalization in 2005. *Id.* ¶ 6. Surgeons removed the device and most of the granuloma, but respondent was rendered permanently paraplegic. *Id.* ¶¶ 7-9. We are informed by respondents' counsel that Mr. Stengel has since died from his injuries.

According to respondents' substitute proposed amended complaint (Doc. 22 Att. 1) (Proposed Compl.), at the time FDA granted premarket approval, the agency was not aware that the device could cause granulomas. Proposed Compl. ¶ 13. The proposed complaint further alleges, however, that after premarket approval petitioner became aware of adverse events that should have been reported to FDA and that should have led petitioner to revise its label to warn physicians as early

as 2002 about the risk of granuloma formation. *Id.* ¶¶ 13-18, 21. Petitioner eventually warned physicians in 2008, but, the proposed complaint continues, if petitioner had delivered those warnings sooner, Mr. Stengel's injuries could have been avoided. *Id.* ¶¶ 19, 24.

3. Respondents sued petitioner in Arizona state court on various theories, the gravamen of which is that petitioner breached its duty under Arizona law to use reasonable care in warning of risks associated with its product. Petitioner removed the case to federal court based on diversity of citizenship, and it moved to dismiss respondents' claim as expressly preempted by Section 360k(a) or impliedly preempted under the rationale of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The district court dismissed the claim as expressly preempted and denied respondents' motion for leave to amend, concluding that the claim in the proposed complaint would be impliedly preempted under *Buckman*. Pet. App. 52a-58a.

4. A divided panel of the court of appeals affirmed, Pet. App. 26a-51a, but on rehearing the en banc court unanimously reversed, *id.* at 1a-21a. The principal en banc opinion held that the proposed complaint escaped express preemption "insofar as the state-law duty parallels a federal duty under the MDA." *Id.* at 19a. In particular, the court noted that respondents allege that "[petitioner] failed to perform its duty under federal law" to "monitor the [device] after pre-market approval and to discover and report to the FDA any [adverse events]," and that "because [petitioner] failed to comply with its duty under federal law, it breached its duty to use reasonable care under Arizona negligence law." *Id.* at 18a-19a (internal quotation marks omitted). The court pointed to general Arizona tort law regarding the duty of a

manufacturer to provide adequate warnings, *id.* at 19a, and explained that "Arizona law contemplates [that this duty can be discharged via] a warning to a third party such as the FDA," *id.* at 20a.

As for implied preemption, the principal en banc opinion emphasized that the plaintiffs in *Buckman* "alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred" in the agency process that cleared the device in question for marketing. Pet. App. 12a. The court of appeals noted that this Court held that claim impliedly preempted in *Buckman* because it would interfere with the "somewhat delicate balance of statutory objectives" the FDA pursues in policing such fraud, and because "the fraud claims [in *Buckman*] exist[ed] solely by virtue of the FDCA" rather than "traditional state tort law." *Id.* 12a-13a (quoting *Buckman*, 531 U.S. at 348, 352-353). By contrast, the court of appeals reasoned, respondents' claim is not impliedly preempted because it is "independent of the FDA[] * * * process that was at issue in *Buckman*." *Id.* at 20a.

Judge Watford filed a concurring opinion joined by a majority of the en banc court. Pet. App. 22a-25a. He observed that "[t]he most direct way to state [respondents' failure-to-warn] claim would be to allege that under Arizona law [petitioner] owed a post-sale duty to warn doctors when it learned of adverse events." *Id.* at 22a. Judge Watford recognized that the CBE regulation permitted petitioner to do so, but he believed that the mandatory state duty would be preempted by Section 360k(a) because it is different from the merely permissive FDA regulation. *Ibid.* He thus understood respondents to have assumed "a causation hurdle that would not otherwise exist," *viz.*, "that [petitioner]

breached its duty of reasonable care under Arizona negligence law by failing to report adverse events *to the FDA*," and that if petitioner had made proper reports, "that information would have reached Mr. Stengel's doctors in time to prevent his injuries." *Id.* at 22a-23a. Judge Watford rejected petitioner's contention that this reformulation implicated *Buckman*; "[petitioner's] failure to report was more than a mere misrepresentation to the FDA [as in *Buckman*] because it simultaneously misled the device's * * * users, to whom [petitioner] owed an independent duty under state law." *Id.* at 24a.

DISCUSSION

Respondents' failure-to-warn claim is neither expressly nor impliedly preempted, but for reasons that differ from those given by the court below. Section 360k(a) does not preempt respondents' straightforward claim that petitioner should have brought new safety information to physicians' attention through a CBE revision to the device's labeling, because such a claim implicates no preemptive device-specific federal requirement. As for implied preemption, such a claim does not implicate *Buckman*; rather, it closely resembles the claim against the brand-name prescription drug manufacturer that *Wyeth* held was not impliedly preempted.

The court of appeals' misimpression that Section 360k(a) would preempt such a straightforward claim led it to analyze the express and implied preemption questions in the context of unnecessarily tortuous theories of causation. That misstep creates a host of problems for review in this Court at this time. Most prominently, the correct analysis of the express preemption question would not be available to this Court because it would result in a more favorable judgment for respondents than they obtained below, and they have not cross-

petitioned for certiorari. And the implied preemption question the court of appeals analyzed is largely academic because it arises only under the peculiar theory of causation that the court of appeals embraced out of a misperceived need to navigate around Section 360k(a). Even setting those problems aside, there are no clear circuit conflicts on the questions presented. Especially given the case's interlocutory posture, the Court should deny the petition.

I. The Court Of Appeals' Conclusion That Respondents' Failure-To-Warn Claim Is Not Expressly Preempted Does Not Warrant This Court's Review In The Present Posture Of This Case

The court of appeals' conclusion that respondents' failure-to-warn claim is not expressly preempted is correct, but for a different and more basic reason than the court identified: the federal requirements relevant to respondents' claim are not device-specific, and therefore they do not have preemptive effect under Section 360k(a). This case, however, is not in a suitable posture for correcting that error.

A. Respondents' failure-to-warn claim escapes express preemption for reasons the parties and lower courts apparently overlooked

1. The analytical framework for the express preemption question here comes from this Court's decisions in *Lohr* and *Riegel*, and from the FDA's MDA preemption regulation, 21 C.F.R. 808.1.

a. In *Lohr*, the Court held that federal "requirement[s]" are "applicable to the device" within the meaning of Section 360k(a)(1) only when they are "'applicable to the device' in question," 518 U.S. at 500, and, in accordance with FDA regulations, only when they are

"'specific counterpart regulations' or 'specific' to a 'particular device,'" *ibid.* (quoting 21 C.F.R. 808.1(d)). Federal requirements therefore can have preemptive force under Section 360k(a) when "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501. Federal requirements ordinarily do not have a preemptive effect under Section 360k(a), however, when they "reflect * * * entirely generic concerns about device regulation generally." *Ibid.*

Thus, as we have previously argued to this Court, FDA's regulations addressing particular medical devices (such as hearing aids, 21 C.F.R. 801.420 and .421) preempt counterpart state requirements that are different from, or in addition to, those device-specific federal requirements, while by contrast FDA's general manufacturing and labeling regulations do not have preemptive force. See U.S. Amicus Br. at 12, *Buckman*, *supra*, No. 98-1768 (U.S. *Buckman* Br.) (citing *Lohr*, 518 U.S. at 501). As we explained in our amicus brief in *Buckman*, which supported the defendant on its *implied* preemption defense, the plaintiffs' claim there—that they would not have been injured but for the defendant's fraud on the FDA when obtaining clearance for the device—was not *expressly* preempted: Because the FDA requirement regarding the submission of information "is stated in general terms, and it applies to all devices that must undergo the [relevant] clearance process," it was "not the kind of federal requirement that can have a preemptive effect under [Section 360k(a)]." *Ibid.*

Riegel reaffirmed that distinction between "manufacturing and labeling requirements applicable across the board to almost all medical devices" and "requirements specific to the device in question." 552 U.S. at 322. The Court held that "[p]remarket approval * * * imposes 'requirements' under the MDA," explaining that "[u]nlike general labeling duties, premarket approval is specific to individual devices." *Id.* at 322-323. On the understanding that the *Riegel* plaintiffs' "claims * * * assert[ed] that [the] device violated state tort law notwithstanding compliance with the relevant federal requirements" established by the device's premarket approval, the Court concluded those claims were expressly preempted. *Id.* at 330.

b. To have preemptive force under Section 360k(a), a federal requirement ordinarily must be not only device-specific, but also relevant to the asserted state claim. "[I]n most cases a state law will be pre-empted only *to the extent* that the FDA has promulgated a *relevant* federal 'requirement.'" *Lohr*, 518 U.S. at 496 (emphases added). As FDA explained in promulgating its preemption regulation shortly after Congress enacted the MDA, "the scope of preemption is limited to instances where there are specific FDA requirements"; for example, where FDA had regulated hearing-aid labeling and conditions for sale, "only [state or local] requirements relating to labeling and conditions for sale were preempted, not all [s]tate or local requirements regulating all facets of hearing-aid distribution." 43 Fed. Reg. 18,662 (May 2, 1978). Accordingly, FDA has provided by regulation that "[s]tate or local requirements are preempted only when [FDA] has established specific counterpart regulations or there are other specific re-

quirements applicable to a particular device under the [FDCA]." 21 C.F.R. 808.1(d).[1]

c. That framework reflects sound policy. The "overarching concern" of Section 360k is "that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Lohr*, 518 U.S. at 500. If a state requirement were preempted absent a specific federal requirement that reflects FDA's weighing of competing considerations on the same subject and specific to the device (or type of device), the MDA would have the ironic effect of "provid[ing] less public protection from unsafe and ineffective medical devices" than pre-MDA law. 43 Fed. Reg. at 18,663. At best, FDA would be put in the straitjacket of federalizing *all* requirements for a given device once it chose to adopt *any* requirement. But a regulator often "take[s] one step at a time, addressing itself to the phase of the problem which seems most acute." *Massachusetts* v. *EPA*, 549 U.S. 497, 524 (2007) (citation omitted). Moreover, as this Court recognized in the analogous context of prescription drug labeling, "[s]tate tort suits" can be an important complement to the FDCA's regulatory framework because they "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," and "also serve a distinct compensatory function that may motivate injured per-

[1] The references in 21 C.F.R. 808.1(d) to "specific counterpart regulations or * * * other specific requirements" recognize that FDA establishes preemptive requirements both by promulgating "regulations" (as in the hearing-aid context) and through other agency action carrying the force of law (as in granting premarket approval). See 42 Fed. Reg. 30,384 (June 14, 1977) (explaining that a federal requirement is an FDA "*regulatory* or *administrative* action involving the application of a particular requirement of the [FDCA] to a particular device") (emphases added).

sons to come forward with information." *Wyeth*, 555 U.S. at 579.[2]

2. The foregoing principles refute petitioner's contention that Section 360k(a) expressly preempts respondent's failure-to-warn claim. Under *Riegel*, FDA's premarket approval of petitioner's device established preemptive requirements with respect to the design, manufacturing, and labeling of the device. Those would preempt any claim alleging in substance that FDA should have conditioned its approval on adopting some other design, manufacturing specification, or labeling. Such were the nature of the claims at issue in *Riegel* (see U.S. Amicus Br. at 13-14, *Riegel*, *supra*, No. 06-179), and those claims were therefore preempted.

But here, respondents attack petitioner's conduct *after* its device received premarket approval (and after FDA approved any relevant supplemental application). That conduct, as alleged in the proposed complaint, would have been governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents' failure-to-warn claim—whether styled as arising from petitioner's failure to make adverse event reports to FDA or from its failure to make a CBE revision to the device's labeling—is not expressly preempted.

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[2] Of course, an "express pre-emption provision[] does *not* bar the ordinary working of conflict pre-emption principles." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869 (2000). In some situations, a state requirement may be impliedly preempted because it threatens to frustrate the general operation of the federal program.

Indeed, the nature of the labeling change respondents contend petitioner should have made underscores the conclusion that no device-specific federal requirement appears to be implicated here. That change apparently would have been one to "strengthen a * * * warning" or "add * * * information about an adverse reaction," 21 C.F.R. 814.39(d)(2)(i), and it would have been based on new safety information. Cf. *Wyeth*, 555 U.S. at 568-570 (discussing the "newly acquired information" available to the manufacturer there). The change therefore could have been placed into effect under the device CBE regulation prior to FDA approval, belying any claim on petitioner's part that FDA had specifically required it to maintain its existing labeling in the face of that new safety information.

B. The court of appeals' reasoning for why respondents' failure-to-warn claim escapes express preemption may also be correct

1. The court of appeals reasoned that, although Section 360k(a)'s conditions for express preemption were in its view otherwise met, respondents' failure-to-warn claim was saved from express preemption because the requirements of Arizona law respecting warnings about a product communicated through an intermediary are parallel to federal requirements regarding reporting adverse events to FDA. See Pet. App. 18a-20a.

That may reflect a reasonable result, if one accepts the mistaken premise that general federal requirements ordinarily *do* have preemptive effect under Section 360k(a). Both the FDCA (as implemented by FDA) and Arizona law (as the court of appeals understood it) require petitioner to deliver warnings regarding its device through an appropriate channel, *viz.*, the device's FDA-mediated labeling. That parallelism is reinforced by the

FDCA's command that either inadequate warnings (21 U.S.C. 352(f)(2)) or a failure to submit required adverse event reports to FDA (21 U.S.C. 352(r)(2), 360i(a)) will render a device misbranded, and therefore "prohibited [from] introduction or delivery for introduction into interstate commerce" (21 U.S.C. 331 and (a)). Cf. *Mutual Pharm. Co.* v. *Bartlett*, 133 S. Ct. 2466, 2477 n.4 (2013) (noting but "not address[ing] state design-defect claims that parallel the federal misbranding statute").

If respondents' claim indeed parallels a federal misbranding claim, it is not expressly preempted. But subtleties may exist in squaring the broad and generalized requirements on both the state and federal sides of that parallelism. Here, the respective requirements may be conceived as analogous responses to somewhat different problems: The state requirement may be primarily concerned with warnings to traditional intermediaries (such as physicians using a specialized device), while the federal requirement exists to provide *FDA* with information bearing on the execution of its regulatory responsibilities. If those different objectives mean manufacturers do not face "*genuinely* equivalent" obligations, *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (construing an express preemption provision similar to Section 360k(a)), then the state requirement would be preempted as "different from, or in addition to" the federal requirement. However that subtle question of parallelism is resolved, though, respondent has (for the reasons given above, pp. 8-13, *supra*) stated a claim that is not expressly preempted.

2. Petitioner asserts that the court of appeals erred because, in petitioner's view, (1) "[Section] 360k(a) expressly preempts state-law claims regarding medical devices that have received premarket approval, unless

they are based on state-law duties that 'parallel' federal requirements," but (2) that "parallel-duty exception is limited to device-specific federal duties, and does not extend to the generally applicable federal reporting duty on which respondents' negligence claim is based." Reply Br. 10 (citation omitted); see Pet. 29-32. As explained above, pp. 10-12, *supra*, that misreads this Court's precedents and gets things backwards where general federal requirements are concerned. Such general requirements do not have preemptive force at all under Section 360k(a) because they "reflect important but entirely generic concerns about device regulation generally." *Lohr*, 518 U.S. at 501.

C. The circuits take a consistent, albeit incorrect, approach to express preemption of claims involving medical devices subject to premarket approval, but this case is not an appropriate vehicle for announcing the correct approach

1. The courts of appeals, in every case since *Riegel* involving a device subject to premarket approval, have tacitly dispensed with the first step of a proper Section 360k(a) preemption analysis—*i.e.*, asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement. That practice in the circuits may reflect an erroneous assumption that the existence of *any* device-specific federal requirement has across-the-board preemptive effect, even on a state requirement addressed to a different subject. See, *e.g.*, *Hughes* v. *Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011) ("[W]e ask if the FDA has established requirements applicable to the * * * device."). But that would be contrary to *Lohr*'s reasoning and FDA's consistent interpretation in its regulations and briefs to this Court.

Alternatively, that judicial practice may reflect a mistaken belief that the act of premarket approval itself establishes device-specific requirements on all possible subjects, thus preempting additional or different state requirements whatever their subject. See, *e.g.*, *Bausch* v. *Stryker Corp.*, 630 F.3d 546, 563 (7th Cir. 2010) ("Section 360k provides immunity for manufacturers of [devices with premarket approval] to the extent that they comply with federal law."), cert. denied, 132 S. Ct. 498 (2011). That oversimplification would lead to correct results in cases, like *Riegel*, where a plaintiff's claim does indeed concern a subject specifically addressed by the FDA's premarket approval (for example, the safety and effectiveness of a device's design and labeling given the information submitted to FDA at the time of premarket approval). But that approach fails where a plaintiff's claim concerns a subject not addressed in device-specific terms by FDA's premarket approval of the device—here, a manufacturer's duties *after* premarket approval upon learning of new information bearing on the safety of its device.[3]

2. Petitioner contends (Pet. 17-21) that the circuits diverge in their application of Section 360k(a) in cases involving a device subject to premarket approval. No clear conflict exists. The courts in question all begin with the premise that in such cases, Section 360k(a) preempts *all* state requirements with respect to the device that are not parallel to some federal requirement. We disagree with that premise because it leads to express preemption of state requirements on subjects

[3] FDA can impose device-specific postmarketing requirements on a device as a condition of premarket approval, see 21 C.F.R. 814.82, but petitioner does not contend its device was subject to any such requirement of relevance here.

addressed only by general federal requirements. But accepting it as correct, the petition then presents the question of the proper analysis where the state requirement is parallel to a federal requirement, but the federal requirement is not device-specific.

Most courts (including, implicitly, the Ninth Circuit below) 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. See *Bass* v. *Stryker Corp.*, 669 F.3d 501, 511-513 (5th Cir. 2012); *Bausch*, 630 F.3d at 554-556; *Howard* v. *Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436, 440 (6th Cir. 2010). Other courts have found claims preempted where the counterpart to the state requirement would have been a general federal requirement. See *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-1302 (11th Cir. 2011); *In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206-1207 (8th Cir. 2010) (*Sprint Fidelis*). Although passing language in those decisions is consistent with petitioner's position that a state requirement cannot escape preemption by being parallel to a general federal requirement, the cases provide no explanation for why that would be so, and they appear ultimately to rest on deficiencies in the plaintiffs' pleadings. See *Wolicki-Gables*, 634 F.3d at 1301-1302 (discussing conclusory allegations of complaint); *Sprint Fidelis*, 623 F.3d at 1207 ("[*A*]*s pleaded and argued*, the manufacturing defect claims are not parallel.").

3. In all events, the procedural posture of this case makes it an inappropriate vehicle for resolving any conflict, either among lower courts or between the decision below and *Lohr* and *Riegel*. The circuit conflict petitioner posits is essentially academic because it concerns how extensive a preemptive effect Section 360k(a) gives to

general federal requirements, yet such requirements should ordinarily have *no* such preemptive effect under Section 360k(a). As explained below, it is doubtful that this Court could properly announce the latter holding in this case.

Under the court of appeals' judgment, respondents' claim escapes preemption only by "facing a causation hurdle that would not otherwise exist," namely, that Mr. Stengel's injury resulted from petitioner's "fail[ure] to report adverse events *to the FDA*," rather than from petitioner's failure to warn physicians directly. Pet. App. 22a-23a (Watford, J., concurring). The concurring judges (who represented a majority of the en banc court) stated that a claim predicated "on an alleged state law duty to warn doctors directly"—via a CBE revision of the device's labeling—"would have been expressly preempted." *Id.* at 22a. Although the proposed complaint alleges such a claim, respondents have not filed a cross-petition for a writ of certiorari challenging the holding of the court of appeals rejecting that claim. Yet a correct application of Section 360k(a) would not only sustain the court of appeals' holding favoring respondents, *but also reverse its holding unfavorable to respondents*.

That is problematic. As a leading treatise explains, this Court has held repeatedly that "[i]f the *rationale* of an argument would give the satisfied party [*i.e.*, respondents] more than the judgment below, even though the party is not asking for more," that argument "is not open to the respondent who fails to file a cross-petition." Stephen M. Shapiro et al., *Supreme Court Practice* ch. 6.35, at 493 (10th ed. 2013) (collecting cases). Because the Court apparently could not consider all possible approaches to the express preemption question—

including what we submit is the *correct* approach—it should deny review of that question in this case.

II. The Court Of Appeals' Conclusion That Respondents' Failure-To-Warn Claim Is Not Impliedly Preempted Does Not Warrant Review At This Time

Petitioner also contends that respondents' failure-to-warn claim is impliedly preempted under *Buckman*. The parties and court of appeals proceeded on the assumption that, "to avoid express preemption," respondents were obliged to assume "a causation hurdle that would not otherwise exist"—that petitioner should have reported adverse events to FDA, which in turn would have warned physicians. Pet. App. 22a-23a (Watford, J., concurring). That "causation hurdle" refers (at least in part) to the agency decisionmaking process, and therefore may implicate *Buckman*. But as explained above, pp. 8-13, *supra*, that assumption about express preemption is mistaken. Freed of that error, the proposed complaint's more natural theory of causation is that petitioner should have invoked the CBE provision to update its device's labeling in light of new safety information. Such a claim would not implicate *Buckman*, and would not appear to be otherwise impliedly preempted. Respondents' continued pursuit of an unnecessarily complex causation theory might impel this Court to confront difficult questions about *Buckman*'s reach, but in the case's interlocutory posture immediate review is unnecessary.

A. Tort claims based on a manufacturer's failure to update its product's labeling to account for new safety information ordinarily are not impliedly preempted

Respondents may properly proceed on the theory that petitioner should have invoked the CBE process to update its device's labeling to reflect new information

bearing on the safety of the device. Such a claim would mirror the failure-to-warn claim against the prescription drug manufacturer that this Court held was not impliedly preempted in *Wyeth*. There, as here, the plaintiff contended that the manufacturer could have appropriately invoked the CBE process for drugs (which is similar in relevant respects to the CBE process for devices) to communicate warnings without FDA's prior approval. 555 U.S. at 568-572. The Court agreed, and for that reason rejected the manufacturer's impossibility-preemption defense. *Ibid.* The Court acknowledged that "FDA retains authority to reject labeling changes made pursuant to the CBE regulation"—which is true for both drugs and devices—"[b]ut absent clear evidence that the FDA would not have approved a change * * * , [the Court would] not conclude that [the FDCA made compliance with state law] impossible for [the manufacturer]." *Id.* at 571.

The same analysis applies here because the proposed complaint alleges that Mr. Stengel's injuries could have been avoided if petitioner had revised its device's labeling based on new safety information of the sort that permits labeling revision through the CBE process. Indeed, it may be true in practice that *any* tort claim predicated on a failure to report adverse events to FDA can be cast—with no worse prospect of ultimate recovery and in far simpler terms—as a claim that the manufacturer should have discharged its state-law warning duties by invoking the CBE process to revise its labeling to reflect its new knowledge about adverse events. If so, the court of appeals' decision on implied preemption is of only academic interest because it analyzed a causation theory that a plaintiff should have no reason to advance. Moreover, *Buckman* is not implicated on a straightfor-

ward causation theory here any more than it was implicated in *Wyeth*, and petitioner has not argued otherwise.

B. No clear circuit conflict exists on implied preemption, and any tension between the decision below and *Buckman* arises from the court of appeals' unnecessary reliance on a tortuous theory of causation

Petitioner contends that the decision below misapplies *Buckman* and exacerbates a circuit split over implied preemption involving medical devices. Pet. 13-17, 22-29. No clear split exists. Although the decision below may raise difficult questions about *Buckman*'s precise scope, those are essentially the product of lower courts' misplaced focus on an attenuated theory of causation.

1. In *Buckman*, the plaintiffs allegedly suffered injuries from devices that had been cleared for sale by FDA through the defendant's efforts. Those efforts, the plaintiffs claimed, involved a fraud on the FDA, and "[h]ad [those fraudulent] representations not been made, the FDA would not have [cleared] the devices, and plaintiffs would not have been injured." 531 U.S. at 344.

This Court held those claims preempted, relying on several considerations. First, the putative state-law claims sought to police fraud on a federal agency by entities it regulates, a matter of exclusively federal character on which FDA possessed ample direct authority. *Buckman*, 531 U.S. at 347-350. Relatedly, state tort law "would exert an extraneous pull" (*id.* at 353) on the relationship between FDA and those it regulates. *Id.* at 350-351. Moreover, enforcement of the FDCA is by statute vested exclusively in the United States. *Id.* at 349 n.4, 352 (citing 21 U.S.C. 337(a)). Finally, the claims did not "rely[] on traditional state tort law" but rather a theory that "exist[s] solely by virtue of the FDCA." *Id.* at 353.

2. The decision below implicates some of the concerns recognized in *Buckman* because the court of appeals relied on a causation theory in which a decision by FDA is an essential element. Allowing respondents' claim to proceed could influence the relationship between FDA and manufacturers like petitioner. Moreover, the court of appeals' causation theory inevitably asks the finder of fact to speculate about the answers to questions of device regulation committed to FDA's discretion. And, absent the FDCA, the FDA would not exist as an intermediary for warnings.

But respondents' claim differs from the claim in *Buckman* in that the underlying state-law duty to warn here apparently exists even absent the FDCA; in that sense, respondents seek to enforce traditional tort law, not the FDCA itself. A claim against a device manufacturer is viable if the plaintiff is "suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [Section] 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis*, 623 F.3d at 1204 (citation omitted). Indeed, an overly expansive reading of *Buckman* would extinguish the very parallel claims that Section 360k(a) preserves—a result that both *Buckman* itself, 531 U.S. at 352-353, and *Riegel*, 552 U.S. at 330, disclaim.

3. Petitioner contends that the circuits are divided on whether claims like respondents'—if pursued under the causation theory on which the Ninth Circuit relied—are impliedly preempted under *Buckman*'s rationale. Pet. 13-17. No clear conflict exists. Consistent with the decision below, the Fifth Circuit has held similar claims not impliedly preempted. *Hughes*, 631 F.3d at 775-776.

Petitioner contends that the Eighth Circuit in *Sprint Fidelis*, 623 F.3d at 1205-1206, and the Sixth Circuit in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421, 423-424, cert. denied, 546 U.S. 935 (2005), held to the contrary. But the *Buckman*-preempted claims in those cases appear to have been materially different from respondents' claim. In neither of those cases did the plaintiffs allege that the manufacturer's conduct violated an independent state-law duty; their theory instead apparently was that they were entitled to recover based simply on the manufacturer's alleged violation of federal requirements. See Br. in Opp. 15 (discussing district court's order in *Cupek*); Am. Master Consol. Compl. for Individuals, *In re Medtronic, Inc.*, No. 08-1905 Doc. 250-1 (D. Minn. Feb. 27, 2009) (*Sprint Fidelis* complaint lacking allegations that the manufacturer's failure to timely report adverse events violated any common law duty (¶¶ 161-168), despite asserting other counts premised on "parallel common law" duties (¶¶ 127, 143, 154, 183, 191) or violations of Minnesota state law (¶¶ 238-264)). So understood, those claims are unquestionably the type that *Buckman* forbids, but they are distinct from the Arizona-law claim respondents make here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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