No. 20-1822

In The
Supreme Court of the United States

AMBER BROOKS AND JAMIE GALE,

Petitioners,

v.

MENTOR WORLDWIDE LLC,

Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Do the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and this Court's opinions in *Buckman* and *Riegel* support Rule 12(b)(6) dismissal of state common law claims for failure to warn (based on bare allegations of inaccurate adverse event reporting to FDA) and manufacturing defect regarding an FDA-approved medical device?

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

1. Mentor Worldwide LLC ("Mentor") is a Delaware limited liability company.

2. Ethicon, Inc., is Mentor's parent company and owns 100% of the membership interests of Mentor. Ethicon, Inc., is a wholly-owned subsidiary of Johnson & Johnson.

3. Johnson & Johnson has no parent corporation, and no publicly held company owns 10% or more of Johnson & Johnson's stock.

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BRIEF IN OPPOSITION

INTRODUCTION

Plaintiffs-Petitioners argue that this Court should accept review because the Tenth Circuit's opinion "reflects a conflict between circuits" on the question presented here and the Tenth Circuit erred by failing to side with the Ninth Circuit. Pet. 3, 21. The alleged conflict, however, is illusory, and this case is a poor vehicle to address the question presented.

Petitioners sued Mentor Worldwide LLC ("Mentor") alleging injuries as a result of their MemoryGel Silicone Gel Breast Implants ("MemoryGel Implant")—a Class III medical device approved by the U.S. Food and Drug Administration ("FDA") as safe and effective through the premarket approval ("PMA") process. The District Court dismissed Petitioners' failure to warn claims as impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Petitioners also failed to plead a manufacturing defect claim that survived express preemption under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). A unanimous panel of the Tenth Circuit affirmed, following *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015) (Gorsuch, J.), *cert. denied*, 577 U.S. 1062 (2016).

The Tenth Circuit created no conflict among the circuits by doing so. The supposed conflict rests on a misreading of *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013), which discerned a duty under Arizona law to provide post-sale warnings through reporting adverse events to FDA. The Tenth Circuit

found no such duty exists under Kansas law. Petitioners identify no other circuits that depart from the Tenth Circuit's holding that a duty to warn claim is impliedly preempted when no state law duty to comply with FDA post-approval requirements exists. In other words, the outcomes differ because the underlying state law applied by the panels differed, not because of a conflicting application of federal preemption principles.

To reach the question presented, then, this Court would have to disagree with the Tenth Circuit on the content of Kansas law. But this Court typically defers to lower federal courts on the application of state law, and Petitioners cite no case that conflicts with the Tenth Circuit's holding that Kansas state law imposes no duty to report adverse events to FDA. As a result, this case is an inappropriate vehicle for addressing the question presented.

Petitioners' arguments over the dismissal of their manufacturing defect claims are not properly before this Court. First, Petitioners now argue that district courts should not be permitted to grant motions to dismiss based on preemption because it is an affirmative defense; this argument was not pressed or passed upon below. Second, Petitioners' question presented does not challenge the Tenth Circuit application of the pleading standard articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). For both reasons, these arguments have been forfeited and are not appropriate for review.

Accordingly, this Court should deny the Petition.

STATUTES INVOLVED

In addition to the provisions contained in the Petition, this case involves 21 U.S.C. § 337(a).

> **(a)** Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

STATEMENT

A. History of Breast Implant Litigation

Breast implant litigation dates to the 1990s. Plaintiffs filed thousands of cases alleging local injuries, including pain from capsular contracture, rupture, leakage, infection, and temporary or permanent disfigurement, as well as systemic illnesses, including autoimmune and connective tissue disorders. *See*, *e.g.*, *In re Breast Implant Cases*, 942 F. Supp. 958, 959 (S.D.N.Y. 1996). The Honorable Jack Weinstein—one of the judges who presided over those cases—characterized the litigation as "[a] legal and economic mini-disaster caused by lack of robust application of science in the courts." Jack B. Weinstein, *Preliminary Reflections*

on Administration of Complex Litigations, 2009 CARDOZO L. REV. DE NOVO 1, 4 (2009). According to Judge Weinstein, "[t]he breast implant litigation was largely based on a litigation fraud" perpetrated by "medical charlatans." *Id.* at 14. Had they maintained control over scientific evidence, courts overseeing the litigation could have avoided a judicial "fiasco" that led to "[h]uge unwarranted recoveries with resulting bankruptcies." *Id.* at 15.

During this first wave of litigation, a consensus developed in the scientific community that there was no connection between breast implants and an increased likelihood of any disease. *See Pozefsky v. Baxter Healthcare Corp.*, No. 92CV0314LEKRWS, 2001 WL 967608, at *3–5 (N.D.N.Y. Aug. 16, 2001) (unpublished). Indeed, dozens of epidemiological studies concluded that silicone breast implants do not cause disease. *See id.* at *4 (referring to "nearly thirty published epidemiological studies that conclude that breast implants do not cause any typical or atypical diseases"); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1227 (D. Colo. 1998) (explaining that "[e]very controlled epidemiological study concludes that silicone breast implants do not double the risk of any known disease").

B. Statutory and Regulatory Background

Introduction of new medical devices into the market was historically regulated at the state level. *Riegel*, 552 U.S. at 315 (citing *Medtronic, Inc. v. Lohr*, 518 U.S.

470, 475–76 (1996)). As more complex medical devices emerged, Congress passed the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, "which swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. To ensure FDA oversight of medical devices was not controverted by state law, Congress included an express preemption provision:

> Except as provided in subsection (b), no 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 this chapter 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 this chapter.

§ 360k(a). Subsection (b) allows FDA, under certain circumstances, to exempt certain state and local requirements from federal preemption. *Riegel*, 552 U.S. at 316. No such exemption is at issue here.

The MDA established three levels of oversight for medical devices based on the level of risk they present. *See Riegel*, 552 U.S. at 316–17. Class I devices, such as elastic bandages and examination gloves, present the lowest level of risk and require only "general controls." *Id.* at 316 (citing § 360c(a)(1)(A)). Class II devices, such as powered wheelchairs and surgical drapes, are subject to additional "special controls." *Id.* at 316–17. Class III devices, which include replacement heart valves,

implanted cerebella stimulators, and pacemaker pulse generators, are subject to the most stringent regulatory controls. *Id.* Breast implants are Class III devices that must receive PMA before they can be sold in the United States. 21 C.F.R. § 878.3530.

As this Court has recognized, PMA is a "rigorous" process. *Riegel*, 552 U.S. at 317 (citing *Lohr*, 518 U.S. at 477). To obtain PMA, a "manufacturer must submit what is typically a multivolume application" containing specific information and data about the safety and efficacy the Class III device, which is then scrutinized by FDA. *Id.* at 317–18. The required information includes the design specifications, manufacturing processes, and labeling proposed by a manufacturer. *Id*. FDA spends an average of 1,200 hours reviewing each PMA application, *id.* at 318 (citing *Lohr* 518 U.S. at 477), and only grants PMA upon a showing of "reasonable assurance" of the device's "safety and efficacy," § 360e(d). Following approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). FDA can also require post-approval studies as a condition of approval. 21 C.F.R. § 814.82(a)(2). After approval, the device must be manufactured in line with the specifications in its approval application because FDA has determined that the approved form provides reasonable assurance of safety and efficacy. *Riegel*, 552 U.S. at 323. FDA also

must approve product labeling and can impose device-specific restrictions. § 360j(e)(1).

FDA regulation does not end upon PMA. Afterwards, devices are subject to ongoing FDA regulation, including reporting requirements. § 360i. Manufacturers are obligated to inform FDA of new clinical investigations and scientific studies, 21 C.F.R. § 814.84(b)(2), and "to report incidents where the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred," *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 803.50(a)). FDA also retains the power to withdraw a device's PMA based on any newly-reported data or existing information and "***must*** withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Id.* at 319–20 (emphasis added) (citing § 360e(e)(1); § 360h(e) (recall authority)).

C. Preemption Under the FDCA

1. Express Preemption Under *Riegel*

In *Riegel*, this Court analyzed the MDA's express preemption provision's effect on traditional state tort law claims involving a Class III, PMA device. The Court adopted a two-step inquiry: First, a court must decide whether FDA has established "requirements" applicable to the device at issue. *See* 552 U.S. at 321. Second, if FDA has established requirements, the court must determine whether the state law claims impose

requirements related to safety and efficacy that are "different from, or in addition to" the federal requirements. *Id.* at 322 (citing § 360k(a)).

Riegel held that the PMA process involves device-specific requirements that constitute a federal safety review. 552 U.S. at 322–23. This Court then held that the common law claims at issue clearly related to safety and efficacy and that the common law negligence and strict liability claims imposed state-law requirements preempted by the device-specific federal requirements. *Id.* at 323–24. But the Court left open the possibility that a state could maintain a remedy for acts that violated FDA regulations, explaining that § 360k(a) does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330.

2. Implied Preemption Under *Buckman*

Buckman confirms that the ultimate source of the remedy must be state law. The FDCA states that all actions to enforce or restrain violations of the Act "shall be by and in the name of the United States," 21 U.S.C. § 337(a), and *Buckman* held that this directive does not authorize private litigants to sue "for noncompliance with the medical device provisions." 531 U.S. at 349 n.4. Thus, any state law claim that exists "solely by virtue of the FDCA," including a duty to disclose information to FDA, is impliedly preempted. *Id.* at 348,

353 (holding "fraud-on-the-FDA" claims are impliedly preempted because they "exist solely by virtue of the FDCA disclosure requirements"). To state a viable state law claim involving a PMA medical device, a plaintiff must rely on traditional state tort law that predates the FDCA and MDA. *Id.* at 353 (holding claims impliedly preempted where "the existence of these federal enactments is a critical element in their case").

3. The Narrow Gap Between Express and Implied Preemption

Together, *Buckman* and *Riegel* create a "narrow gap" through which a state-law claim "must fit" to escape both express and implied preemption: a plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009); *see also Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). Stated another way, a claim does not survive preemption unless it is "premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 411 (D. Del. 2014).

4. Mentor's MemoryGel Implants Are Class III Medical Devices Approved Through FDA's PMA Process.

The MemoryGel Breast Implants at issue in this case are Class III medical devices. (C.A. Aplt. App. Vol. 1 at 15, ¶ 29.) FDA approved MemoryGel Implants through its PMA process in November 2006, finding them to be safe and effective as designed, manufactured, and labeled. (C.A. Aplt. App. Vol. 1 at 19, ¶ 54.)[1] Thereafter, they only could be sold to healthcare professionals in accordance with the design, manufacturing, and labeling specifications approved by FDA. *Id.*; *see also* 21 C.F.R. § 801.109. Although FDA is empowered to withdraw premarket approval if a manufacturer fails to comply with any post-approval requirements, 21 C.F.R. § 814.82, the approval for the MemoryGel Breast Implants remains in effect.

5. Claims Involving Breast Implants Are Routinely Dismissed as Preempted.

Based on these preemption principles, and as Petitioners readily acknowledge, Pet. 31–33, courts across the country routinely hold that failure-to-warn

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[1] *See also* PMA Approval Order and Summary of Safety and Effectiveness for P030053 (Nov. 17, 2006), available at https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030053a.pdf (last visited Sept. 27, 2021); 72 Fed. Reg. 15,855, 15,886 (Apr. 9, 2007) Notices, TABLE 1: List of Safety and Effectiveness Summaries for Approved PMAs Made Available from October 1, 2006 to December 31, 2006, available at https://www.govinfo.gov/content/pkg/FR-2007-04-03/pdf/E7-6166.pdf (last visited Sept. 27, 2021).

and manufacturing-defect claims involving Mentor's breast implants are preempted. *See*, *e.g.*, *Billetts v. Mentor Worldwide LLC*, No. ED CV 19-01026-AB (PLAx), 2019 WL 4038218 (C.D. Cal. Aug. 27, 2019), *aff'd*, 847 Fed. Appx. 377 (9th Cir. Feb. 5, 2021), *petition for cert. filed* (U.S. July 6, 2021) (No. 21-26); *Sewell v. Mentor Worldwide LLC*, No. SA CV 19-01126-AB (PLAx), 2019 WL 4038219 (C.D. Cal. Aug. 27, 2019), *aff'd*, 847 Fed. Appx. 380 (9th Cir. Feb. 5, 2021), *petition for cert. filed* (U.S. July 6, 2021) (No. 21-26); *T. Jacob v. Mentor Worldwide LLC*, 393 F. Supp. 3d 912 (C.D. Cal. 2019), *aff'd*, 847 Fed. Appx. 373 (9th Cir. Feb. 5, 2021), *petition for cert. filed* (U.S. July 6, 2021) (No. 21-26); *Vieira v. Mentor Worldwide LLC*, 392 F. Supp. 3d 1117 (C.D. Cal. 2019), *aff'd*, 845 Fed. Appx. 503 (9th Cir. Feb. 5, 2021), *petition for cert. filed* (U.S. July 6, 2021) (No. 21-26); *Ebrahimi v. Mentor Worldwide LLC*, No. CV 16-7316-DMG (KSx), 2018 WL 6829122 (C.D. Cal. Dec. 27, 2018) ("*Ebrahimi III*"), *aff'd*, 804 Fed. Appx. 871 (9th Cir. May 15, 2020); *Laux v. Mentor Worldwide LLC*, 786 Fed. Appx. 84 (Nov. 26, 2019), *cert. denied*, 141 S. Ct. 455 (2020); *D'Addario v. Johnson & Johnson*, No. 19-15627 (MAS) (TJB), 2021 WL 1214896 (D.N.J. Mar. 31, 2021) ("*D'Addario II*"); *Kline v. Mentor Worldwide LLC*, No. 2:19-cv-02387-MCE-KJN, No. 2:19-cv-02391-MCE-KJN, 2021 WL 1173279 (E.D. Cal. Mar. 29, 2021); *D'Addario v. Johnson & Johnson*, No. 19-15627 (MAS) (TJB), 2020 WL 3546750, at *2 (D.N.J. June 30, 2020) ("*D'Addario I*"); *Diodato v. Mentor Worldwide LLC*, No. JKB-20-762, 2020 WL 3402296 (June 19, 2020); *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550 (N.D.N.Y. 2020); *L. Jacob v. Mentor Worldwide LLC*,

389 F. Supp. 3d 1024 (M.D. Fla. 2019) ("*L. Jacob I*"); *Tinkler v. Mentor Worldwide LLC*, No. 1:19-cv-23373-UU, 2019 WL 7291239 (S.D. Fla. Dec. 30, 2019); *L. Jacob v. Mentor Worldwide LLC*, No. 8:19-cv-229-T-35SPF, 2019 WL 6766574 (M.D. Fla. Dec. 10, 2019) ("*L. Jacob II*"); *Cashen v. Johnson & Johnson*, No. MID-L-002442-18, 2018 WL 6809093 (N.J. Super. L. Dec. 24, 2018); *Shelp v. Mentor Worldwide LLC*, No. C18-1427-JCC, 2018 WL 6694287 (W.D. Wash. Dec. 20, 2018); *Ebrahimi v. Mentor Worldwide LLC*, No. CV 16-7316-DMG (KSx), 2018 WL 2448095 (C.D. Cal. May 25, 2018) ("*Ebrahimi II*"), *aff'd*, 804 Fed. Appx. 871 (9th Cir. May 15 2020); *Ebrahimi v. Mentor Worldwide LLC*, No. CV 16-7316-DMG (KSx), 2017 WL 4128976 (C.D. Cal. Sept 15, 2017) ("*Ebrahimi I*"), *aff'd*, 804 Fed. Appx. 871 (9th Cir. May 15, 2020); *Malonzo v. Mentor Worldwide LLC*, No. C 14-01144 JSW, 2014 WL 2212235 (N.D. Cal. May 28, 2014).

D. Procedural History

Petitioners brought suit against Mentor in 2019, asserting claims for negligence, negligence *per se*, and strict products liability based on failure to warn and manufacturing defect theories. (C.A. Aplt. App. Vol. 1 at 9–46.) Mentor moved to dismiss based on express and implied preemption under the FDCA, and the District Court granted Mentor's motion. Pet. App. 19a–37a. The District Court noted Petitioners' allegations were unclear but appeared to assert two overarching theories: (1) failure to warn based on negligence, negligence

per se,[2] and strict products liability; and (2) manufacturing defect based on negligence, negligence *per se*, and strict products liability. Pet. App. 29a.

Addressing the failure to warn claims, the District Court held that under the learned intermediary doctrine Mentor had no state law duty to warn Petitioners directly. Pet. App. 30a. Petitioners claim that Mentor had a duty to warn FDA by conducting clinical studies and reporting adverse events was impliedly preempted under *Buckman* because Petitioners were attempting private enforcement of FDA regulations. Pet. App. 30a–31a. Petitioners also argued Mentor had a duty under state law to provide different warnings to physicians through label updates and adverse event reporting to FDA. The District Court rejected these arguments because no parallel duty existed under federal law. Pet. App. 31a–32a. A state tort law requirement to change the MemoryGel Implant label thus would have imposed a requirement beyond those imposed by federal law, which the MDA expressly preempts. Pet. App. 31a–32a.

The District Court next turned to Petitioners' arguments that Mentor had a duty to indirectly warn physicians through reporting negative study results to FDA. Pet. App. 32a–34a. Petitioners in effect argued that if Mentor had reported data it allegedly withheld, FDA would have included this data in a publicly-accessible database—something FDA was not required to do. *Id.* Petitioners' theory would also require the court to

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[2] Petitioners are not challenging the dismissal of their negligence *per se* claims. Pet. 18 n.11.

assume Petitioners' physicians would have accessed this data and altered their treatment decisions in reliance on the data. *Id*. The court found these allegations "far too speculative" to meet *Twombly* and *Iqbal*'s plausibility standard and held that, even if they could survive that standard, the claim would be impliedly preempted because Petitioners identified no state law duty that required Mentor to report adverse events to FDA. Pet. App. 33a–34a.

The District Court then turned to Petitioners' manufacturing defect claims. To the extent those claims merely sought to enforce federal manufacturing requirements, they were impliedly preempted under *Buckman*. Pet. App. 35a (citing *Buckman*, 531 U.S. at 353). Petitioners' remaining allegations consisted of conclusory statements that Mentor failed to follow good manufacturing practices, negligently included materials that "could not stand up to normal usage and/or which differed from those which were commercially reasonable," failed to exercise reasonable care in product testing and inspection, and failed to exercise reasonable care regarding "manufacturing, quality control and quality assurance processes." Pet. App. 36a. The court held these bare conclusory statements were insufficient to survive a motion to dismiss under *Twombly* and *Iqbal*. *Id.* Petitioners' strict liability–manufacturing defect claims failed for the same reasons. Pet. App. 36a–37a.

Petitioners appealed to the Tenth Circuit, which affirmed. Petitioners' claim that Mentor had a duty to warn FDA by conducting clinical studies and reporting adverse events was impliedly preempted because

Petitioners identified no Kansas state law duty to comply with FDA post-approval requirements. Pet. App. 12a. The Tenth Circuit then held that Petitioners' manufacturing defect allegations were too vague and conclusory to state a claim for relief under *Twombly* and *Iqbal*. *Id.* at 14–15. While Petitioners alleged a host of historical facts about Mentor studies and adverse result reporting, they alleged no facts tying this historical information to an alleged flaw in the manufacturing of Petitioners' implants, despite a 38-page, 201-paragraph Complaint. *Id.* Last, the Tenth Circuit affirmed dismissal without leave to amend because Petitioners failed to follow the local rule for seeking leave to amend. *Id.* at 15–18.

ARGUMENT

A. The Circuit Split Alleged by Petitioners Is Illusory.

Petitioners concede the narrow gap between express and implied preemption is by Congressional design. Pet. 20. While Petitioners may find it "'difficult to believe that Congress would'" preempt state law tort claims by consumers alleging injury from "FDA-approved devices . . . this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326 (majority opinion, quoting Ginsburg, J., dissenting). As the *Riegel* majority explained, the preemptive effect of the MDA was a congressional policy choice based on "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. It is no surprise after *Buckman* and *Riegel* that plaintiffs have had difficulty bringing claims over PMA devices. That was the natural and intended result of federal preemption: some patients' claims alleging injuries due to medical devices would be wholly preempted based on the safety/efficacy balancing performed by FDA, as directed by Congress. In short, Petitioners fail to explain why this Court's intervention is needed here "to clarify the law." *City & Cty. of San Francisco v. Sheehan*, 575 U.S. 600, 610 (2015).

1. There Is no Circuit Split on Preemption of a Duty to Warn Claim When no State Law Duty to Comply With FDA Post-Approval Requirements Exists.

To begin with, Petitioners identify no conflict among the circuits. Petitioners first suggest the decision below conflicts with *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013), which discerned a duty under *Arizona law* to provide post-sale warnings through reporting adverse events to FDA. Pet. 21–22. But there is no outcome-dispositive conflict between *Stengel* and the decision below, which held that no such duty to report exists under *Kansas law*. Pet. App. 12a–13a ("But Plaintiffs have not identified a state-law duty to comply with FDA-imposed post-approval requirements such as testing and reporting.").

Indeed, Petitioners admit no case recognizes a duty to report under Kansas law. Pet. 22. They instead point to a host of decisions from other jurisdictions addressing far different situations. *See* Pet. 22–23.[3] Because no Kansas state law duty exists that could implicate an issue of federal law decided in *Stengel*, there is no outcome-dispositive conflict between *Stengel* and the decision below.

Worse still, Petitioners fail to acknowledge later Arizona authority repudiating *Stengel*'s prediction of the tort duty Arizona law would recognize. The Arizona

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[3] *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002) (securities case involving bank's affirmative representations under Rule 10b-5); *Lau v. Opera Ltd.*, No. 20-cv-674 (JGK), 2021 WL 964642, *6 (S.D.N.Y. 2021) (securities case involving misstatements in a company's initial public offering prospectus); *Trahan v. Interactive Intel. Grp., Inc.*, 308 F. Supp. 3d 977, 991 (S.D. Ind. 2018) (securities case where shareholder alleged company made misstatements of fact in its business projections); *Thimjon Farms P'ship v. First Int'l Bank & Tr.*, 2013 ND 160, 837 N.W.2d 327, 339 (N.D. 2013) (debtor alleged creditor made false statements under North Dakota's Unlawful Sales or Advertising Practices Act); *New Milford Sav. Bank v. Zandy*, No. CV990078766S, 2001 WL 79830, *2 (Conn. Super. Ct. 2001) (foreclosure case involving fiduciary relationship where bank allegedly failed to disclose information in mortgage transaction); *United States v. Singh*, No. 19-CR-3623 BLM (DMS), 2020 WL 5500232, *6 (S.D. Cal. 2020) (criminal case involving statements made by immigrants on visa application where certain government employees had duty to report); *Chester Cty. Employees' Ret. Fund v. KCG Holdings, Inc.*, No. 2017-0421-Kjm, 2019 WL 2564093, *11 (Del. Ch. 2019) (case involving misstatements by directors in disclosures prior to shareholder vote); *Owens v. Nationwide Prop. & Cas. Ins. Co.*, No. 7:13-cv-00832, 2014 WL 4258084, *6 (N.D. Ala. 2014) (insurance case where plaintiffs alleged insurance company failed to disclose conflict of interest).

Supreme Court addressed and squarely rejected *Stengel* on this point in *Conklin v. Medtronic, Inc.*, 245 Ariz. 501, 508, 431 P.3d 571, 579 (2018), holding that "*Stengel* incorrectly recited and applied Arizona law." *Conklin* explained that only federal law, not Arizona law, imposed a duty to submit adverse event reports to FDA. *Id.* at 507. Any claim based on a failure to report thus was an attempt to enforce federal law and impliedly preempted. *Id.* at 508.

Petitioners identify no other circuits that depart from the Tenth Circuit's holding that a duty to warn claim is impliedly preempted when no state law duty to comply with FDA post-approval requirements exists. Pet. 23–24. They try to do so indirectly by citing *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 213 (E.D.N.Y. 2017), but the authorities *Babayev* cites reveal no outcome-determinative conflict. *Babayev* quotes *Funk v. Stryker Corp.*, 631 F.3d 777, 779 (5th Cir. 2011), but in context the Fifth Circuit's reference to "state law claims that are based on federal regulations" as "parallel" refers to a traditional state law claim that "parallels" a federal requirement and is thus permissible under *Riegel*.

Equally unhelpful is *Babayev*'s mention of *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586–87 (6th Cir. 2013). While *Fulgenzi* discusses implied preemption, it does so for illustration purposes in the context of a generic drug product liability case related to a failure to update labeling claim. *See id.* at 586–87 & n.4 (no need to "define the precise contours" of implied preemption because plaintiff's claim "comfortably conforms with

the 'parallel'-claim principle identified in *Lohr* and *Riegel*"). And *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 2555, 206 L. Ed. 2d 489 (2020), spoke to an "intercircuit disagreement" on a different issue—"whether a parallel claim demands that the federal 'requirement' must be 'device-specific' . . . or may be a general FDA regulation applicable to all medical devices"—not implicated here. *Id.*

In sum, Petitioners identify no circuit split that warrants this Court's review of the dismissal of their duty to warn claim.

2. Petitioners Forfeited any Argument That Preemption Cannot Support a Rule 12(b)(6) Dismissal, and no Circuit Split Exists on This Issue.

Petitioners next insist—for the first time in this case—that dismissal of their manufacturing defect claim is "premature," because preemption is an affirmative defense that cannot justify dismissal under Fed. R. Civ. P. 12(b)(6), citing *Bausch v. Stryker*, 630 F.3d 546 (7th Cir. 2010). Pet. 25–27. But Petitioners forfeited this argument and, in any event, there is no conflict among the circuits on whether *Iqbal* and *Twombly* apply to negligent manufacturing claims.

First, Petitioners never raised this argument in the briefing before either the District Court or Court of Appeals and, not surprisingly, neither lower court addressed it. This Court has stressed that it "ordinarily

will not decide questions not raised or litigated in the lower courts." *City of Springfield v. Kibbe*, 480 U.S. 257, 259 (1987) (per curiam) (dismissing writ as improvidently granted). There is no reason to depart from that practice here.

Second, *Bausch* creates no conflict among circuits on whether *Iqbal* and *Twombly* apply to negligent manufacturing claims. In *Bausch*, the plaintiff alleged receiving a hip implant six days after FDA informed the manufacturer that a component of the implant was "adulterated" and that the company's manufacturing "failed to comply with federal standards." *Id.* at 549. She also alleged that an implant component bearing the same catalogue number as the one the plaintiff received was later recalled; that FDA issued a letter warning that the device was "adulterated due to manufacturing methods" and "not in conformity with industry and regulatory standards"; and that she received a device with the same catalogue number as the device not in compliance with regulations. *Id.* at 559. These and other allegations of federal regulatory enforcement linked to the actual hip implant plaintiff received that she claimed caused her injuries, the Seventh Circuit held, stated a claim for relief that was "plausible on its face" under *Iqbal* and *Twombly*. *Id.*

This plausibility standard aligns with the standard applied by the court below when it held that Petitioners' manufacturing defect allegations were too vague and conclusory to state a claim for relief under *Twombly* and *Iqbal*. Pet. App. 13a–15a. To be sure, *Bausch* contains dicta on whether a plaintiff should be allowed

discovery before having her complaint dismissed. *See id.* at 558. But the plaintiff there, unlike Petitioners here, was able to plead specific facts supporting her claims even without the benefit of discovery. *See id.* at 561.

In short, Petitioners fail to identify any conflict warranting this Court's review.

B. The Decision Below Is Correct.

1. The Tenth Circuit Properly Dismissed Petitioners' Failure to Warn Claims.

Petitioners' argument that this Court should grant certiorari to review the propriety of the Tenth Circuit's granting dismissal over Petitioners' failure to warn claim can be rejected at the outset because it is clear that no Kansas state law duty required Mentor to submit adverse events to FDA. *See* Pet. 22 (arguing that even "in the absence of Kansas decisions addressing this precise issue, there is no reason to believe Kansas law does not recognize the same duty"), Pet. App. 12a ("But Plaintiffs have not identified a state-law duty to comply with FDA-imposed post-approval requirements such as testing and reporting."). Despite the lack of a relevant state law duty, Petitioners ask this Court to grant certiorari, determine in the first instance that such a state law duty exists, and then consider Petitioners' federal law arguments that *Buckman* does not apply to post-sale conduct and that in mandating the submission of adverse event reports, FDA is acting similar to a library making the reports available

for others to rely on through an indirect, attenuated warning system. Pet. 33–37. Beyond the fact that Petitioners' failure to warn claims failed under Kansas state law, neither of the federal law arguments they present to this Court are correct.

Taking the second argument first, Petitioners argue that FDA requires adverse event reporting so the reports can be made available for reliance by others, analogizing FDA to a public library. Pet. 33. But FDA regulations do not require FDA to make adverse event reports available to the public at all. 21 C.F.R. § 803.9(a); *see Connelly v. St. Jude Med., Inc.*, No. 17-2006-EJD, 2018 WL 732734, at *1 n.1 (N.D. Cal. Feb. 6, 2018) (FDA "may disclose" adverse-event reports in database, but is not required to do so); *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013) (adverse event reports are not automatically made public and decision to release them is within FDA discretion).[4] Petitioners' analogy thus falls flat.

[4] Petitioners' argument on this point is also inconsistent with their admissions before the Tenth Circuit that FDA does not make all adverse event reports public. *See* Aplts.' C.A. Opening Br. 9 n.5 ("Manufacturers were authorized by 21 [C.F.R. §]803.19(c) addressing 'exemptions, variances, or alternative forms of adverse event reporting' to report serious injuries and well-known or expected malfunctions in quarterly Postmarket Spreadsheet Reports ('PSR') as an alternative to individual MDR reports. PSR reports are not included in the MAUDE database." (internal citations omitted), 15 n.9 ("The FDA provided an alternative reporting method through the Alternative Summary Reporting Program ('ASRP') from 1999 through April 2019 which were not available in MAUDE. . . . To participate in the program, manufacturers such as Mentor would request an exemption, variance or reporting alternative under 21 [C.F.R.

Warstler v. Medtronic, Inc., 238 F. Supp. 3d 978, 989 (N.D. Ohio 2017) ("[A]dverse event reports 'are not automatically made public.'" (citing *Pinsonneault*, 953 F. Supp. 2d at 1016; *Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1286 (N.D. Ga. 2014)); 21 C.F.R. § 803.9 ("[FDA] *may* disclose to the public any report . . . submitted under this part." (emphasis added))).

Nor is it true that *Buckman* only applies to pre-approval activity. After all, FDA regulation of medical devices does not end at premarket approval; FDA's adverse event reporting requirement aids FDA's ongoing oversight. § 360i; *Riegel*, 552 U.S. at 319 (citing 21 C.F.R. § 803.50(a)). This oversight includes the power to withdraw a device's premarket approval based on any newly reported data or existing information. *Riegel*, 552 U.S. at 319–20 (citing § 360e(e)(1); § 360h(e) (recall authority)). Therefore, just as pre-approval submissions determine whether a device may be marketed, post-approval submissions determine whether a device may continue to be marketed. And as Petitioners concede, FDA has utilized adverse event reporting in its continuous monitoring of the safety of breast implants. Pet. 37–40.[5]

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§]803.19]." (citing U.S. Food & Drug Administration, MDR Data Files, https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files)).

[5] Before the Tenth Circuit, Petitioners acknowledged FDA's use of and reliance on information, including adverse event reports, submitted by Mentor post-approval. Aplts.' C.A. Opening Br. 11–12 ("Indeed, the FDA relied on the data to publish its

It follows that the same FDA regulatory concerns expressed in *Buckman* apply equally after approval. The relationship between FDA and the regulated entity is still inherently federal, because it is governed by federal law. *See Buckman*, 531 U.S. at 347. Allowing a plaintiff to argue fraudulent, federally-mandated submissions to FDA harmed her without FDA regulatory action on the same point would skew the balance sought by FDA in punishing and deterring fraud against the agency. *Id.* And Congress did not distinguish between pre- and post-approval enforcement when conferring exclusive authority to enforce the MDA on the Federal Government. 21 U.S.C. § 337(a).

Here, since Kansas does not recognize a state law duty to submit adverse events to FDA, Petitioners' failure to warn "claims exist solely by virtue of the FDCA disclosure requirements" and fall comfortably within implied preemption under *Buckman*. 531 U.S. at 353. Petitioners' citation of *Stengel* again misses the mark, Pet. 36–37, because *Stengel* predicted (incorrectly) that Arizona would recognize such a state law tort duty. *See* pp. 17–18, *supra*. And, far from helping Petitioners, *Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461 (S.D. Ohio 2020), actually held that the plaintiff's failure to report claim failed as a matter of law. *See* 494 F. Supp. 3d at 476 (holding plaintiff's failure to report

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'Update on the Safety of Silicone Gel-Filled Breast Implants' in June 2011 to provide preliminary data from post-approval studies, summarize and analyze adverse events reported since approval, and review and analyze clinical publications about the safety and effectiveness of silicone gel-filled implants.").

claim failed because no such duty existed under Ohio law and that even if such a duty did exist under Ohio law, it "would still be preempted under the MDA" according to *Buckman*).

2. The Tenth Circuit Properly Dismissed Petitioners' Manufacturing Defect Claims, and Petitioners Forfeited any Claim of Error on This Point.

The Tenth Circuit correctly dismissed Petitioners' manufacturing defect claims as inadequately pleaded, and Petitioners forfeited any argument that it erred in doing so. As discussed above, the issue Petitioners raise here—that dismissal of their manufacturing defect claims is "premature" because preemption is an affirmative defense—was never raised below and therefore is not properly before this Court. *See* pp. 19–20, *supra*; *see Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995) (issue must be raised or "passed upon" below). What is more, Petitioners' question presented does not encompass a challenge to the *Twombly*/*Iqbal* pleading standard relied on by the courts below in dismissing their manufacturing defect claims. *Compare* Pet. 20 & Pet. App. 13a–15a, *with* Pet. i (Question Presented); *see also* Rule 14(1)(a) ("The statement of any question presented is deemed to comprise every subsidiary question fairly included therein. Only the questions set out in the petition, or fairly included therein, will be considered by the Court."); *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 533–38 (1992). Petitioners

have therefore forfeited any claim of error in the dismissal of their manufacturing defect claims.

Even if not forfeited, Petitioners' claim of error is meritless. Petitioners argue that a special exception to *Twombly* and *Iqbal* should be carved out here, because plaintiffs in medical device cases do not have adequate access to information they need to properly plead a viable complaint. No such exception is warranted.

Petitioners' argument relies mainly on the *Bausch* dicta. Pet. 26–27; *see also* 630 F.3d at 558 (explaining a court "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law [so f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim"). But none of the concerns identified in *Bausch* are unique to the medical device context.

Twombly, for instance, considered whether a complaint adequately alleged incumbent telecommunications providers entered into an illegal agreement not to compete in violation of the Sherman Act. 550 U.S. at 550–51. This Court held that "[a]sking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage; it simply calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of illegal agreement." *Id.* at 556. And this Court identified a couple considerations that supported applying a plausibility standard to such a claim. *Id.* at 557–58. For one thing,

without it, a largely groundless claim could "'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.'" *Id.* at 558. For another, discovery can be expensive, and "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Id.* (internal quotation marks omitted).

The same concerns apply here. Scores of threadbare lawsuits are filed against pharmaceutical and medical device manufactures on a regular basis, evoking the same concern with *in terrorem* settlement demands that applies to antitrust claims. Discovery will be no less expensive for pharmaceutical and medical device manufactures if claims of this sort are allowed to proceed past the pleading stage. *Cf. Marion v. Smith & Nephew, Inc.*, No. 1:15-cv-00096-JNP-BCW, 2015 WL 7756063, at *2 (D. Utah 2015) (holding "the difficulty of crafting a complaint" sufficient to avoid preemption under "§ 360k(a) is not a proper legal basis for allowing a plaintiff to proceed to discovery," but merely justified leave to amend). And although the issue was not raised or discussed, the claims in *Buckman* reached this Court on a motion to dismiss. *See In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d 817, 818–19 (3rd Cir. 1998), *rev'd sub nom. Buckman*, 531 U.S. 341, 347.

Indeed, Petitioners eventually acknowledge that district courts can grant a motion to dismiss based on an affirmative defense when it is apparent from the face of the complaint that the pleading is barred as a matter of law. Pet. 29; *see also Caplinger*, 784 F.3d at

1341 ("a district court may grant judgment as a matter of law under Federal Rule of Civil Procedure 12(b)(6) on the basis of an affirmative defense like preemption when the law compels that result"); 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 2004 & Supp. 2014) (collecting cases). Under Petitioners' own rule, then, preemption is an affirmative defense that can be raised in a motion to dismiss.

A motion to dismiss based on preemption aligns with Petitioners' own rule because the fact that a Class III medical device went through PMA is not in dispute, and the fact of FDA's PMA subject to judicial notice. *See supra* n.1. At that point, coupled with this Court's holding in *Riegel*, a medical device manufacturer does not need to establish any facts to prevail on preemption. Rather, it becomes incumbent upon the plaintiff to allege a violation of federal law that runs parallel to her state law claims. In other words, a plaintiff must provide factual support for her parallel claim to satisfy Rule 8(a)(2)'s requirement of "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the claim is and the grounds upon which it rests.'" *Twombly*, 550 U.S. at 555 (internal alteration marks omitted) (quoting Rule 8(a)(2); *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Petitioners cite no authority to the contrary. And a different rule would require the defendant to plead and prove affirmative compliance with a vast area of federal law (*Caplinger* noted "the FDA's medical device

regulations alone cover 592 pages of eight-point type," 784 F.3d at 1342), which would run afoul of *Twombly*'s instruction that the plaintiff must "provide the 'grounds' of his 'entitle[ment] to relief,'" *Twombly*, 550 U.S. at 555).

In short, there is nothing wrong with a "nationwide trend" of dismissing claims against pharmaceutical and medical device manufacturers "on a widespread basis" when, as here, those claims fail to plead enough facts to identify a plausible parallel manufacturing defect in the product at issue. Pet. 25, 31–33 (citing numerous Mentor preemption dismissals).

C. This Is a Poor Vehicle for Addressing the Question Presented.

Beyond all this, this case is a poor vehicle for this Court to address an alleged circuit split over how to apply this Court's guidance on preemption in *Buckman* and *Riegel* to the narrow gap of possible state tort claims. The Tenth Circuit discerned no duty to report adverse events under Kansas law, Pet. App. 10a–12a, and this Court "generally accord[s] great deference to the interpretation and application of state law by the courts of appeals." *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1149–50 (2017) (quoting *Pembaur v. Cincinnati*, 475 U.S. 469, 484 n.13 (1986)). Add to this Petitioners' concession that there is no Kansas case on point, Pet. 22, and this Court would have to differ with the Tenth Circuit, without any supporting

authority, just to reach the federal issue on the failure to warn claims.

This case fares no better as a vehicle for addressing Petitioners' concerns with the dismissal of their manufacturing defect claims. As discussed above, Petitioners forfeited any argument that the dismissal of their manufacturing defect claims is "premature" because preemption is an affirmative defense, and their question presented does not encompass a challenge to the pleading standard applied below. *See* pp. 19–20, 25–26, *supra*. So there is no issue on the dismissal of Petitioners' manufacturing defect claims that is properly before this Court.

Petitioners' argument that this case is of national importance is thus hyperbole. Even on its own terms, the argument fails. Petitioners cite FDA's continuing regulatory action on breast implants, including FDA's recognition of a link between breast implants and a rare form of cancer not alleged here, but all this cite shows is that the federal regulatory system functions as Congress prescribed. Through pharmacovigilance involving FDA's Adverse Event Reporting System, FDA recognized an association between BIA-ALCL and breast implants. FDA is also actively monitoring reports of "breast implant illness." "Currently, however, BII is not recognized as a formal medical diagnosis and there are no specific tests or recognized criteria to define or characterize it."[6]

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[6] FDA, Medical Device Reports for Systemic Symptoms in Women with Breast Implants (Aug. 20, 2020), available at

Despite Congress's amply empowering FDA to regulate the sale of medical devices in the United States, to the exclusion of conflicting state law, Petitioners suggest this Court should intervene and disregard Congress's mandate. The Court should not accept this invitation, particularly in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants (last visited Sept. 27, 2021).