No. 21-26

In The
Supreme Court of the United States

BRITTANY BILLETTS, ET AL.,

Petitioners,

v.

MENTOR WORLDWIDE LLC,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth 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Plaintiffs-Petitioners argue that this Court should accept review because four Ninth Circuit judgments—issued in unpublished, non-precedential memorandum opinions—"misapplied" this Court's holdings in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Pet. 4. Petitioners further argue these unpublished opinions "reflect[] a conflict between circuits" and "acknowledged state of confusion across the federal judiciary." *Id.* Beyond the fact that the opinions are non-precedential, Pet. App. 1, Petitioners do not point to any conflict between the Courts of Appeals on an issue upon which their cases were decided. Rather, Petitioners argue the panel below misapplied existing Ninth Circuit precedent, while ignoring that the Court of Appeals affirmed dismissal due to Petitioners' failure to adequately plead their claims under *Twombly* and *Iqbal*. This case is a poor vehicle to address the question presented.

Petitioners sued Mentor Worldwide LLC ("Mentor") in four separate state court actions alleging injuries from 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. After removal to the Central District of California, the District Court dismissed all four cases, and the Ninth Circuit

affirmed. The failure to warn claims were dismissed because Petitioners failed to allege actual adverse events that Mentor supposedly failed to report to FDA, thus rendering their conclusory allegations insufficient to state a claim under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To the extent Petitioners based their claims on allegations that Mentor failed to properly conduct post-approval studies, the claims were impliedly preempted under *Buckman* because Petitioners identified no state-law duty to conduct post-approval studies. The manufacturing defect claims were expressly preempted because Petitioners failed to allege the MemoryGel Implants they received deviated from a specific FDA requirement in a manner that caused their injuries. A unanimous panel of the Ninth Circuit affirmed dismissal in all four cases.

The dismissal of Petitioners' failure to warn and manufacturing defect claims is not properly before this Court because Petitioners' question presented does not challenge the Ninth Circuit's application of the pleading standard articulated in *Twombly*, and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), to both of those claims. In addition, Petitioners now argue their manufacturing defect claims were erroneously dismissed because 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. For both reasons, these arguments have been forfeited and are not appropriate for review.

Moreover, Petitioners do not point to any circuit split implicated in the Ninth Circuit's opinions.

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, *Riegel*, 552 U.S. 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 a device is unsafe or ineffective under the conditions of 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," § 337(a),[1] and *Buckman* held that this directive does not authorize private litigants to sue "for

[1] Unless otherwise indicated, all unqualified statutory citations reference sections of 21 U.S.C.

noncompliance with the medical device provisions." *Buckman*, 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 are Class III medical devices subject to PMA. *Billetts* Compl. ¶¶ 42–43. FDA approved Mentor's MemoryGel Implants through its PMA process in November 2006, finding them to be safe and effective as designed, manufactured, and labeled. *Id.* ¶¶ 66–67.[2] Thereafter, they only could be sold to healthcare professionals in accordance with the design, manufacturing, and labeling specifications approved by FDA. *See Riegel*, 552 U.S. at 316; *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.

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[2] *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. 19, 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. 19, 2021).

5. Claims involving breast implants are routinely dismissed as preempted.

Based on these preemption principles, and as Petitioners readily acknowledge, Pet. 20, 29–30, 35–38, courts across the country routinely hold that failure-to-warn and manufacturing-defect claims involving Class III, PMA devices, such as Mentor's breast implants, are preempted. *See, e.g.*, *Brooks v. Mentor Worldwide, LLC*, No. CV 19-2088-KHV, 2019 WL 4628264 (D. Kan. Sept. 23, 2019), *aff'd*, 985 F.3d 1272 (10th Cir. 2021), *petition for cert. filed* (U.S. June 25, 2021) (No. 20-1822); *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' former lawyers filed four multi-plaintiff lawsuits against Mentor in California state courts. Pet. 19. Mentor removed all four cases to the U.S. District Court for the Central District of California and moved to dismiss. *Id.* The District Court held that all of Petitioners' state-law claims were expressly and impliedly preempted under the MDA. Pet. 19; Pet. App. 18–19. After restating the standards for express and implied preemption, Pet. App. 19–22, the District Court held Petitioners' "merely conclusory" allegations regarding failure to report adverse events to FDA failed to satisfy the federal pleading burden, *id.* at 23. Petitioners failed to reference any specific adverse events that Mentor failed to report or specifically allege that Mentor's performance in post-approval

studies violated federal law. *Id.* Similarly, Petitioners' manufacturing defect claims failed because they did not allege facts demonstrating that Mentor's specifications were inconsistent with federal standards. *Id.* In addition, Petitioners did not allege any fact linking an alleged federal violation to their claimed injuries—*i.e.*, they did not allege *how* a purported federal violation was causally connected to their allege injuries. *Id.* The District Court also rejected Petitioners' assertion that discovery was necessary because "Plaintiffs cannot be permitted to engage in discovery when they have not met the most basic pleading standards. Nothing in Plaintiffs' allegations suggests discovery is needed to resolve this Motion." *Id.* at 23–24. Petitioners moved for reconsideration, which the District Court held oral argument on before denying the motion. Pet. 19. Petitioners then appealed to the Ninth Circuit.

The Ninth Circuit affirmed the District Court's judgment in all four cases. *Id.* Under existing Ninth Circuit precedent, claims governed by state law recognizing a duty to report information to FDA, such as California, could parallel federal requirements. Pet. App. 3–4. Here, however, Petitioners failed to allege any actual adverse events that Mentor failed to report to FDA. *Id.* at 4. Instead, Petitioners speculated that if Mentor had conducted its post-approval studies differently, Mentor would likely have identified and reported additional adverse events to FDA. *Id.* These "conclusory and speculative allegations [were] insufficient to state a parallel failure to warn claim." *Id.* (citing *Twombly*, 550 U.S. at 555). The Ninth Circuit also held

that to the extent Petitioners based their failure to warn claims not on a failure to report actual adverse events to FDA, but instead on an "alleged failure to properly conduct the post-approval studies, Plaintiffs' claims are impliedly pre-empted because Plaintiffs do not identify a parallel state law duty to conduct post-approval studies." *Id.* Further, to the extent Petitioners argued Mentor "failed to warn them or their doctors directly, such claims [were] preempted because there are no such federal requirements." *Id.* (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring)).

As to the manufacturing defect claims, the Ninth Circuit explained that "to survive express preemption under the MDA, Plaintiffs must allege that Defendants 'deviated from a particular premarket approval or other FDA requirement applicable to the Class III medical device.' " Pet. App. 4 (quoting *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019), *cert. denied*, 140 S. Ct. 2555 (2020)). The Court of Appeals held that Petitioners had failed to allege Mentor had violated any particular FDA requirement, but instead only vaguely alleged Mentor's MemoryGel Implants contained unidentified materials that somehow differed from those approved by FDA. *Id.* at 5.

ARGUMENT

A. Petitioners do not identify a circuit split regarding the application of *Twombly* and *Iqbal* to express and implied preemption of claims regarding medical devices.

Petitioners concede the narrow gap between express and implied preemption, which has been recognized "by the federal judiciary nearly 200 times" since 2009, is by Congressional design. Pet. 20–21 (noting the Tenth Circuit's observation "that the concept of federal preemption of state law claims in relation to medical devices first appeared when Congress enacted the MDA in 1976"). 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 & Cnty. of San Francisco v. Sheehan*, 575 U.S. 600, 610 (2015).

1. Petitioners forfeited any argument that preemption cannot support Rule 12(b)(6) dismissal of a manufacturing defect claim, and there is no circuit split on this issue.

Petitioners argue—for the first time in this case—that courts are inappropriately dismissing manufacturing defect claims because preemption is an affirmative defense that cannot justify dismissal under Rule 12(b)(6) and that a circuit split exists on this issue. Pet. 29. But Petitioners forfeited this argument by not raising it below, and, in any event, there is no conflict among the circuits on whether *Iqbal* and *Twombly* apply to manufacturing defect claims. Moreover, Petitioners acknowledge that the Ninth Circuit's holdings below are not evidence of a circuit split, but rather "indicative of" a "nationwide trend." Pet. 29–30. Instead, Petitioners argue dismissal of their manufacturing defect claims was "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. 31–34.

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 failed to allege violation of a specific FDA requirement and instead only "vaguely allege[d]" that Mentor's MemoryGel Implants "contained unidentified materials that differed from those approved by the

FDA." Pet. App. 5.[3] 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, was able to plead specific facts supporting her claims even without the benefit of discovery. *See id.* at 561.

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

2. Petitioners do not identify a controlling split in authority regarding the dismissal of their failure to warn claims under *Twombly* and *Iqbal*.

Petitioners argue the "Ninth Circuit erred in applying the Court's preemption decisions to post-sale conduct." Pet. 27. But the Ninth Circuit's opinion did not rest on whether implied preemption under *Buckman* can apply to post-sale conduct. Rather, the Court

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[3] Petitioners falsely state the "Ninth Circuit affirmed, without opinion," while citing to the Ninth Circuit's unpublished memorandum opinion in their Appendix. Pet. 30, Pet. App. 1–5. Petitioners then suggest the District Court's unreported opinion creates a circuit split warranting this Court's intervention, Pet. 30, even though the Ninth Circuit's memorandum opinion relied on the Ninth Circuit's recent published opinion in *Weber*, App. 4–5, from which this Court denied certiorari, *see* 140 S. Ct. 2555. And the "intercircuit disagreement" referenced in *Weber* spoke to an issue not presented by Petitioners here: "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." 940 F.3d at 1114.

of Appeals held that Petitioners "fail[ed] to allege actual adverse events that Mentor did not report to the FDA" and that Petitioners' "conclusory and speculative allegations are insufficient to state a parallel failure to warn claim." Pet. App. 4 (citing *Twombly*, 550 U.S. at 555). Petitioners' question presented does not encompass a challenge to the *Twombly/Iqbal* pleading standard relied on by the courts below in dismissing their failure to warn claims. *Compare* Pet. 23–26 & Pet. App. 4, *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 failure to warn claims.

In addition, Petitioners' argument on this point is not really that the Ninth Circuit's unpublished memorandum opinions created or manifest a circuit split, but that the Ninth Circuit "oversimplified the analysis" under its *own* precedent in *Stengel*." Pet. 25–26. Aside from the impropriety of seeking error correction from this Court based on a Court of Appeals' application of its own precedent in an unpublished memorandum opinion, *id.* at 26 (positing "one cannot determine why the Ninth Circuit limited its own prior analysis so narrowly"), Petitioners ignore that the Ninth Circuit affirmed dismissal because they failed to plead facts in support of their failure to warn claim. Petitioners

identify no circuit that departs from the Ninth Circuit's holding that a failure to warn claim unsupported by adequate factual allegations under *Twombly* and *Iqbal* is subject to dismissal.

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 state law. *See* 494 F. Supp. 3d at 476 (holding plaintiff's failure to report claim failed because no such duty existed under Ohio law). Petitioners' reliance on *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 213 (E.D.N.Y. 2017), is similarly misplaced. The cases *Babayev* cites reveal no outcome-determinative conflict, and in most instances do not even address implied preemption under *Buckman*. *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*. *Funk* does not cite *Buckman* or mention implied preemption. Nor does *Kallal v. CIBA Vision Corp.*, 779 F.3d 443 (7th Cir. 2015). And *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), was an appeal from summary judgment that did not turn on the adequacy of pleadings under *Twombly* and *Iqbal*. 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*").

The Ninth Circuit held Petitioners' claims were properly dismissed because Petitioners failed to adequately allege specific factual content to survive a motion to dismiss on their failure to report claim. Even if a circuit split exists as to whether a state may maintain a failure to warn claim based on failure to comply with FDA's reporting obligations in light of *Buckman*'s application of § 337, Petitioners' cases were not decided on this issue, making this petition a poor vehicle to address it.

B. The decisions below are correct.

1. The Ninth Circuit properly affirmed dismissal of Petitioners' failure to warn claims.

Petitioners argue *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. 23–29. Neither of these arguments are correct, and neither is implicated by the decision below, which dismissed Plaintiffs' failure to warn claims under *Twombly* and *Iqbal* for failure to adequately allege

that Mentor had failed in its reporting obligations to FDA. Pet. App. 4.

Turning to Petitioners' second argument first, they 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. 24. 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. *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*

[4] Petitioners' argument on this point is also inconsistent with their admissions before the Ninth Circuit that FDA does not make all adverse event reports public, including all of Mentor's adverse event reports during the relevant time period. 9th Cir. *Billetts* Reply 16 (admitting 21 C.F.R. § 803.19(b) permits manufacturers to "request an exception or variance from any or all of the reporting requirements," and that Mentor utilized FDA's alternative device reporting regulation until 2019 when FDA "ended the Alternative Summary Reporting Program that had been in effect since 1999") (citing FDA "Alternative Summary Report Data Since 1999 Available," https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files#asr (last visited Oct. 2, 2021)).

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 continues to be marketed. And as Petitioners concede, FDA has utilized adverse event reporting in its continuous monitoring of the safety of breast implants. Pet. 39–40.

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. 341, 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).

Because the Ninth Circuit affirmed dismissal based on a completely independent basis, neither of these arguments present an issue that warrants this Court's review.

2. The Ninth Circuit properly dismissed Petitioners' manufacturing defect claims, and Petitioners forfeited any claim of error on this point.

The Ninth 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 was "premature" because preemption is an affirmative defense—was never raised below and therefore is not properly before this Court. *See* pp. 16–17, *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. 29–30, Pet. App. 4–5, *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. 31–32; *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 under 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 facts 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.* 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.* at 558 (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 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 (3d 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. 34; *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015) (Gorsuch, J.) ("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 that FDA granted PMA is subject to judicial notice. *See supra* n.2; *see also Funk*, 631 F.3d at 782 (affirming dismissal of inadequately supported manufacturing defect claim and holding district court appropriately took "judicial notice, under Rule 12(b)(6), of the PMA the FDA granted" defendant to market device at issue). 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. 30, 37–38 (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 dismissal of Petitioners' failure to warn claims was affirmed not under *Buckman*, but under *Twombly* and *Iqbal*. Pet. App. 4.

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 dismissal was "premature" because preemption is an affirmative defense, and their question presented does not encompass a challenge to the pleading standard applied below. *See* pp. 16–19, *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."[5]

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[5] FDA, Medical Device Reports for Systemic Symptoms in Women with Breast Implants (Aug. 20, 2020), available at https://www.fda.gov/news-events/press-announcements/fda-updates-analysis-medical-device-reports-breast-implant-illness-and-breast-implant-associated (last visited Sept. 22, 2021).

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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