No. _____

In The
Supreme Court of the United States

NICOLE WEBER,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Nicole Weber suffered severe damage to her eyesight and other injuries when an Allergan breast implant spewed silicone into her body. Nicole sued, asserting state-law, strict-product liability for a manufacturing defect. To prove that, she relied in part on res ipsa loquitur. But the Ninth Circuit approved the district court's grant of summary judgment against her because it concluded that:

(1) Nicole could not use the res ipsa loquitur doctrine to help prove a manufacturing defect. App. 9-10.

(2) Allergan's avowal in the breast-implant's labeling that over 99% of the gel would stay inside the implant did not constitute an FDA pre-market approval requirement. Thus, the right-breast implant's 2.8% silicone bleed supposedly violated no FDA requirement. App. 8, 10-13.

(3) The fact that Nicole's right-breast implant failed supposedly "does not show that Allergan failed to comply with the FDA's Current Good Manufacturing Practices." App. 14.

With that background, these are the questions for this Court:

(1) Can a plaintiff use the res ipsa loquitur doctrine as evidence that a Class III product had a manufacturing defect?

QUESTIONS PRESENTED—Continued

(2) Is a Class III product manufacturer's assertion of a percentage of reliability for its product in the product's labeling—which received FDA pre-market approval—an FDA requirement whose violation could support a product-liability claim?

(3) Can a manufacturing defect in a Class III product violate the FDA's Current Good Manufacturing Practices?

These are important questions of federal law that this Court has not settled, but should. Supreme Court Rule 10(c). On the third question, there is a 3-to-3 Circuit split whether the FDA's Current Good Manufacturing Practices can support a parallel state-law claim that will survive preemption. That split supports granting the petition. Supreme Court Rule 10(a).

PARTIES TO THE PROCEEDING

In accordance with Supreme Court Rule 14(b), all parties to the proceeding are named in the caption.

STATEMENT OF RELATED CASES

- *Weber v. Allergan, Inc.*, No. 2:12-cv-02388-SRB, U.S. District Court for the District of Arizona. Judgment entered January 25, 2018.
- *Weber v. Allergan, Inc.*, No. 18-15212, U.S. Court of Appeals for the Ninth Circuit. Judgment entered October 11, 2019.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

Page

TABLE OF APPENDICES

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES—Continued

STATUTES, REGULATIONS, AND RULES

TABLE OF AUTHORITIES—Continued

PETITION FOR A WRIT OF CERTIORARI

Petitioner Nicole Weber petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINION BELOW

The October 11, 2019 opinion of the United States Court of Appeals for the Ninth Circuit (App. 1-15) is reported as *Weber v. Allergan, Inc.*, 940 F.3d 1106 (9th Cir. 2019).

JURISDICTION

On October 11, 2019, the United States Court of Appeals for the Ninth Circuit filed its Opinion (App. 1-15) affirming the Judgment in a Civil Case that the United States District Court for the District of Arizona filed on January 25, 2018 (App. 25).

This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS

(a) Classes of devices

(1) There are established the following classes of devices intended for human use: . . .

> **(C) Class III, premarket approval**—A device which because . . . it . . .
>
> **(ii)(I)** is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
>
> **(II)** presents a potential unreasonable risk of illness or injury,
>
> is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360c(a)(1)(C)(ii)(I) & (II).

> **(d) Action on application for premarket approval**
>
> **(5)(A)(i)** A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 360j(f) of this title.

21 U.S.C. § 360e(d)(5)(A)(i).

> **(a) General rule**
>
> 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.

21 U.S.C. § 360k(a).

> Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications.

21 CFR § 820.70(a).

> Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria.

21 CFR § 820.80(d).

> Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

21 CFR § 820.90(a).

> Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action.

21 CFR § 820.100(a)

STATEMENT OF THE CASE

1. Introduction.

This case is about the interaction of federal preemption principles and state product-liability law when a Class III medical product—here, a breast implant whose contents profusely leaked into the patient's body—fails because of a manufacturing defect.

2. Factual background.

The facts are largely undisputed. Because of breast cancer, Nicole Weber underwent a double mastectomy. On December 21, 2009, she had reconstructive surgery using Allergan silicone-gel breast implants. After the implantation, Nicole suffered severe adverse symptoms and had the implants removed. App. 16-17.

Dr. Lu-Jean Feng, the surgeon who performed the explanation, concluded that an implant's gel had bled into Nicole's body and caused the adverse symptoms. App. 17. When he removed the right-breast implant, Dr. Feng discovered that it had lost about 2.8% of its total gel volume. App. 17.

Nicole alleged that the 2.8% gel bleed from the right-breast implant was due to a manufacturing defect. App. 17.

Allergan's Natrelle Style 20 breast implant used in Nicole's reconstructive surgery was a Class III medical device that had received FDA premarket approval in November 2006. App. 17.

As part of that approval process, Allergan's product labeling unequivocally stated that, after testing, over 99% of the implant gel (consisting of silicones and platinum) stayed in the implant. App. 17. What might leak from an implant could be, according to Allergan, "of no clinical significance." App. 17.

The FDA inspected Allergan's manufacturing facility in November 2008, and concluded that "the procedures seem to be adequate and it seems like no significant change has been made to manufacturing." App. 17-18.

Allergan claims that the type of implant used in the surgical reconstruction of Nicole's right breast was labeled and manufactured according to FDA specifications. App. 18-19. Nicole countered that the gel bleed constituted evidence from which a reasonable trier of fact could conclude that the right-breast implant deviated from the manufacturing specifications. App. 19.

In plain words, the right-breast implant must have had a manufacturing defect or it would not have bled about 2.8% of its mass when the specifications and

labeling indicated that over 99% of the gel would remain inside the implant.

Dr. Feng, Nicole's expert, opined that the right-breast implant's bleed of more than two times the amount that Allergan has specified in its product labeling was a manufacturing defect. App. 19. The district court itself acknowledged that Dr. Feng was a highly experienced medical authority on breast implants. App. 19-20.

Nicole argued that "Dr. Feng's expert report regarding the extent of the gel bleed and its consequences for [Nicole] constitute sufficient evidence of a manufacturing defect to withstand summary judgment." App. 20. After all, Dr. Feng testified that the implant bled more than twice the expected amount of gel according to Allergan's own product labeling and caused medical harm to Nicole. App. 22.

The district court agreed that Dr. Feng's testimony might "indeed be sufficient to withstand summary judgment if [Nicole] was required to show only that her implant malfunctioned or was defective." App. 22.

But the district court granted summary judgment for Allergan because it concluded that "Dr. Feng's opinion that the implant was defective because it did not perform properly is simply not evidence that it was not manufactured according to premarket approval specifications." App. 23.

The district court added that "it is entirely possible that a Class III device could be manufactured

according to specifications and still cause injury or fail to function as expected." App. 23. "Evidence of a malfunction, without more," according to the district court, "is therefore insufficient to withstand summary judgment." App. 23.

The Ninth Circuit affirmed. App. 1-15. It reasoned that a plaintiff who asserts state-law claims against the manufacturer of a Class III medical device cannot simply demonstrate a defect or a malfunction to prove a manufacturing defect. App. 9. The plaintiff must instead "'make some showing that the medical device was not manufactured in accordance with the FDA standards.'" App. 9 (quoting *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), *aff'd*, 388 Fed. Appx. 169 (3d Cir. 2010)).

Thus, according to the Ninth Circuit, to survive preemption of state-law product liability claims, a plaintiff cannot demonstrate that a defect or malfunction occurred and rely on res ipsa loquitur as evidence that there was a manufacturing defect. App. 9-10.

The Ninth Circuit also held that Allergan's unequivocal statement in the breast-implant's labeling that over 99% of the gel remained in the implant was not a requirement for FDA premarket approval, and therefore the 2.8% bleed from the right-breast implant violated no FDA requirement. App. 8, 10-13.

Finally, the Ninth Circuit held that Nicole had shown no violation of the FDA's Current Good Manufacturing Practices because evidence that her right-breast implant failed "does not show that Allergan

failed to comply with the FDA's Current Good Manufacturing Practices." App. 14.

REASONS FOR GRANTING THE PETITION

1. Under Arizona law, the res ipsa loquitur doctrine and the consumer-expectation test apply in proving if a product has a manufacturing defect. Those doctrines can and should apply in federal cases involving a possible manufacturing defect in a Class III product.

The breast implants were a Class III medical device intended for human use and presenting a potential of an unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I) & (II). *See also* 21 U.S.C. § 360e(d)(5)(A)(i).

None of the relevant principles of the Arizona res ipsa loquitur doctrine and Arizona product-liability law are different from or are in addition to requirements applicable to the breast implants under federal law or relate to the safety or effectiveness of the breast implants or to any requirement applicable to the breast implants under federal statutory or regulatory law. 21 U.S.C. § 360k(a).

The district court and the Ninth Circuit rejected res ipsa loquitur as a proper method for proving that a Class III device might have a manufacturing defect. Perhaps that makes sense for some products. But a product manufactured to hold a substance within a patient's body and not let it leak into the patient's body

is defectively manufactured if, during its intended use, as here, the substance it was built to contain leaks into the patient's body.

Reasonable jurors could conclude that the manufacturer made the product with defective materials, or put the product together incorrectly, or perhaps did both. In any event, the manufacturer made the product so badly that, when a surgeon implanted it into the patient, the product had a manufacturing defect causing it to fail. In the absence of any proof that the patient misused the product and in the absence of any other explanation, reasonable jurors could apply the res ipsa loquitur doctrine and find liability for a manufacturing defect.

"Res ipsa loquitur may have predated current strict liability laws by 100 years, but the doctrine's inferential premise is equally well-suited to the negligence and strict liability fields." Matthew R. Johnson, *Rolling the "Barrel" a Little Further: Allowing Res Ipsa Loquitur to Assist in Proving Strict Liability in Tort Manufacturing Cases*, 38 Wm. & Mary L. Rev. 1197, 1254 (March 1997).

There is nothing revolutionary in the concept that res ipsa loquitur principles can provide circumstantial evidence supporting an inference of a product defect. The Third Restatement of Torts dealing with product liability, after all, concluded that: "It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the

incident that harmed the plaintiff: (a) was of a kind that ordinarily occurs as a result of a product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution." *Restatement (Third) of Torts: Products Liability* § 3 (1998).

In Arizona law, the doctrine of res ipsa loquitur can be used to prove that a product had a manufacturing defect. *McDonald v. Smitty's Super Valu, Inc.*, 157 Ariz. 316, 318-19 (App. 1988). In this diversity case, Arizona law controls the applicability of the res ipsa loquitur doctrine. The Ninth Circuit itself, after all, has held that, under the rule of *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), "it is settled that the doctrine of res ipsa loquitur sufficiently affects the outcome of the litigation to require the federal courts to follow state law." *United Air Lines, Inc. v. Wiener*, 335 F.2d 379, 391 (9th Cir. 1967). *See also Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1983) ("State doctrines of res ipsa loquitur are respected in federal court because the doctrine has assumed the status of a substantive rule of law, affecting [a] plaintiff's burden of proof or production of evidence.").

Res ipsa loquitur is a universally accepted rule of evidence in this Court, in Arizona, and in every American jurisdiction. *See*, *e.g.*, *Johnson v. United States*, 333 U.S. 46, 49 (1948) ("No act need be explicable only in terms of negligence in order for the rule of res ipsa loquitur to be invoked. The rule deals only with permissible inferences from unexplained events."). But this Court has never decided whether res ipsa

loquitur can apply when deciding if there is a manufacturing defect in a Class III medical product.

Of course, even after receiving a res ipsa loquitur instruction, a jury might decide that the right-breast implant had no manufacturing defect. A jury might do that despite the right-breast implant's spectacular failure and the absence of any other proof why a product made to be safe, non-leaking, and robust in the hostile environment of a human body failed so badly. On the other hand, a jury could find that a colossal product failure of this type was, in the absence of strong countervailing evidence, naturally and logically the result of a manufacturing defect.

In Arizona, and elsewhere for that matter, whether res ipsa loquitur is persuasive evidence is normally a question of fact upon which a trial court instructs the jury and which the jury—not the trial court or an appellate court—decides as a question of fact. "Res Ipsa," *Negligence* 7, RAJI (Civil) (6th ed. Dec. 2018).

In an Arizona strict-liability product case, the "malfunction may itself, in the absence of abnormal use and reasonable secondary causes, be sufficient evidence of a defect to make the existence of the defect a jury question." *Ruiz v. Otis Elevator*, 146 Ariz. 98, 102 (App. 1985) (proper to apply res ipsa loquitur in a strict product-liability case). And it does not matter that there may be a "conflicting expert opinion that there is a likely non-negligent explanation for the event," because the jury gets to resolve the conflict. *Lowrey v.*

Montgomery Kone, Inc., 202 Ariz. 190, 193 ¶ 1 (App. 2002).

Despite controlling Arizona law, the district court and the Ninth Circuit decided that the res ipsa loquitur doctrine did not apply. The applicability of the res ipsa loquitur doctrine in cases against Class III product manufacturers is an important question of federal law that this Court has never before addressed or settled, but should. Supreme Court Rule 10(c). That supports granting the petition for writ of certiorari.

Just as important, under Arizona law, a "product is defective and unreasonably dangerous because of a manufacturing defect if it contains a condition which the manufacturer did not intend and, as a result, it fails to perform as safely as an ordinary consumer would expect when the product is used in a reasonably foreseeable manner." "Defect and Unreasonable Danger Defined (Manufacturing Defect)," *Product Liability 2*, RAJI (Civil) (5th ed. Jul. 2013).

In Arizona cases "where a manufacturing defect is alleged, a 'consumer expectation' instruction should be given." *Boy v. I.R.R. Grinnell Corp.*, 150 Ariz. 526, 536 (App. 1986) (citing *Dart v. Wiebe Manufacturing, Inc.*, 147 Ariz. 242, 244 (1985)). In other words, Arizona law, which controls in this case, uses a consumer-expectation test to determine the existence of a manufacturing defect. "The consumer expectation test works well in manufacturing defect cases because consumers have developed safety expectations from using properly manufactured products of the same general

design." *Golonka v. General Motors Corp.*, 204 Ariz. 575, 581 ¶ 15 (App. 2003).

An ordinary consumer using a breast implant in a reasonably foreseeable way, as Nicole was using her right-breast implant, would not expect that the product would bleed its gel into her body at an extreme rate. That super-leakage condition was clearly not a condition Allergan intended or predicted. Thus, under Arizona law, the right-breast implant had a "manufacturing defect."

The Ninth Circuit erred by deciding that the facts of the present case could not support a manufacturing-defect product liability claim under controlling law—which was Arizona law. After all, a properly alleged claim of a manufacturing defect concerning a Class III medical product would not be preempted. *Jones v. Medtronic, Inc.*, 745 Fed. Appx. 714, 717 (9th Cir. 2018).

Whether a plaintiff may use the consumer-expectations test in federal court to prove a manufacturing defect in a Class III medical product presents an important question of federal law this Court has not yet addressed or decided, but should. That supports granting the petition for writ of certiorari. Supreme Court Rule 10(c).

2. A product performance standard that a Class III manufacturer makes part of its FDA-approved product labeling constitutes a binding FDA requirement.

As noted, the Ninth Circuit held that Allergan's unqualified statement in the breast-implant's labeling that over 99% of the gel remained in the implant was not a requirement for FDA premarket approval, and therefore the 2.8% bleed from the right-breast implant violated no FDA requirement. App. 8, 10-13.

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008), this Court stated that state tort suits are preempted only to the extent that they impose requirements "different from, or in addition to" the requirements imposed by federal law. *Riegel* created a two-step analysis to determine if state-law claims are preempted:

First, the reviewing court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Id*.

Second, the reviewing court must decide if the state-law claims are based on requirements "different from or in addition to" federal requirements relating to safety and effectiveness. *Id*. at 323.

Here, Nicole's lawsuit concerning the defective breast implant satisfies both steps. Through the FDA premarket-approval process, the federal government had established the requirements that applied to the Allergan breast implant. The Arizona state-law claim for a manufacturing defect is not substantively

different from or in addition to federal requirements that a Class III product should not have manufacturing defects of the leakage sort that occurred in the right-breast implant.

The requirement at issue is the one found in Allergan's product labeling, which the FDA approved in its premarket-approval process, and which stated that, after testing, over 99% of the implant gel (consisting of silicones and platinum) stayed in the implant. App. 17. The 2.8% actual leakage rate vastly exceeded that limit and caused deadly harm to Nicole.

The FDA would concur that the more than 99% figure was a specific FDA-imposed requirement. After all, in an amicus brief in a 2004 federal-circuit case, the FDA stated that "the agency's approval of this [Class III] device through the PMA process *does impose* specific requirements for its design, manufacturing, performance, labeling, and use." *Brief for the United States as Amicus Curiae* at 15, *Horn v. Thoratec Corp*., 376 F.3d 163 (3d Cir. 2004), 2004 WL 1143720 at 15 (emphasis added).

Indeed, the FDA acknowledged that, in the premarket-approval and review process, it "considers in great depth and detail the performance and design specifications, methods of manufacture, labeling, and indications for use of a proposed medical device." *Amicus Brief* at 16. The FDA emphasized that a premarket-approval order "is better conceptualized as an individual adjudication that imposes 'specific requirements' on the device." *Id*. at 24. That is consistent with this

Court's view that the premarket-approval process is "rigorous." *Riegel*, 552 U.S. at 317.

In other words, the FDA would—and this Court should—view Allergan's more than 99% non-leakage figure as a product requirement. It was a product requirement that the 2.8% actual leakage rate violated. The failure to meet the over 99% non-leakage requirement made the product defective under the FDA requirement. That is consistent with regarding the right-breast implant as defective under the Arizona consumer-expectation test for a manufacturing defect.

Whether a product-performance standard that a Class III manufacturer makes part of its FDA-approved product labeling is a binding FDA requirement presents an important question of federal law that this Court has not, but should, settle. That supports granting the petition for writ of certiorari. Supreme Court Rule 10(c).

3. FDA's evident manufacturing defect violated the FDA's Current Good Manufacturing Practices.

A manufacturing defect in a Class III product, without more, can constitute a violation of the FDA's Current Good Manufacturing Practices. After all, the manufacturing defect in the right-breast implant violates several of those practices. For instance:

21 CFR § 820.70(a) requires product manufacturers to conduct and control its production processes to ensure that a device conforms to its specifications. A defective right-breast implant that discharges harmful implant gel into a woman's body is not one where a product manufacturer has properly conducted and controlled its manufacturing processes.

21 CFR § 820.80(d) requires product manufacturers to establish and maintain procedures for finished device acceptance to ensure that each batch of the finished product meets acceptance criteria. A defective right-breast implant that releases harmful implant gel into a woman's body is not one where the product has met acceptance criteria.

21 CFR § 820.90(a) requires product manufacturers to establish and maintain procedures to control products that do not conform to specified requirements. A defective right-breast implant that leaks harmful implant gel into a woman's body is not one where a product manufacturer has properly established and maintained procedures to control non-conforming products.

21 CFR § 820.100(a) requires product manufacturers to establish and maintain procedures for implementing corrective and preventive action. A defective right-breast implant that disgorges harmful implant gel into a woman's body is not one where a product manufacturer has properly implemented corrective and preventive action.

Nicole's "manufacturing defect claims may proceed, because . . . to the extent they are premised on violations of FDA regulations, they are parallel claims that are not preempted." *Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012).

There is, however, a Circuit split whether the Current Good Manufacturing Practices will support a parallel state-law claim surviving express preemption.

The Eighth and Eleventh Circuits, and the Ninth Circuit in the present case, have held that a plaintiff cannot rely on the Current Good Manufacturing Practices, because they are supposedly too general to create specific federal requirements that can be enforced under state law. *See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206-07 (8th Cir. 2010); *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1113-14 (9th Cir. 2019); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011).

But the Fifth, Sixth, and Seventh Circuits have held that certain Current Good Manufacturing Practices are specific enough to create federal requirements a plaintiff can enforce through a parallel state-law tort action. *See Bass v. Stryker Corp.*, 669 F.3d 501, 511-13 (5th Cir. 2012); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436, 440 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 554-56 & 554 n.1 (7th Cir. 2010).

The split among the Circuits "is real, and the Supreme Court ought to bridge the divide" by holding that "a violation of a generally applicable requirement survives express preemption." Jarrett Sena, *The Contours*

of the Parallel Claim Exception: The Supreme Court's Opportunity to Define the Ill-Defined, 42 Fordham Urban L.J. 291, 339 (Nov. 2014).

The unresolved 3-to-3 Circuit split on this important issue supports granting the petition for writ of certiorari. Supreme Court Rule 10(a).

CONCLUSION

Petitioner asks the Court to grant her petition, to vacate the adverse Opinion of the United States Court of Appeals for the Ninth Circuit and the Judgment entered against them, and to remand this case for proceedings on its merits.

Respectfully submitted,

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