No. 18-1140

IN THE

Supreme Court of the United States

AVCO CORPORATION,

Petitioner,

v.

JILL SIKKELEE, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF DAVID SIKKELEE,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Petitioner designed a defective aircraft engine, and then kept that design even though, for years, evidence mounted that the engine was prone to failure. In 2005, petitioner's defective engine caused a fatal plane crash. Respondent sued petitioner under state law theories of strict liability and negligence. It is established—and not disputed before this Court—that a reasonable jury could find that petitioner's defective engine design caused the crash.

Petitioner seeks summary judgment on the ground that changing its design is "impossible," and therefore gives rise to conflict preemption. Changing the design is not impossible. Indeed, it is undisputed that if petitioner had attempted to change the design to a safe alternative, the Federal Aviation Administration (FAA) would have approved. The FAA had expressed concern about the problem that caused the crash in this case, and it had previously approved—and in fact mandated—a safe alternative.

Nevertheless, petitioner argues that because the FAA would have had to approve a design change, the Court must find impossibility as a matter of law and relieve petitioner of all liability for its decision to adopt and keep the defective design.

The question presented is whether the need to seek FAA approval for an aviation design change results in impossibility preemption of state-law design defect claims—even when the FAA had noted the problem with the existing design, had urged the manufacturer to correct it, had previously approved a safe alternative, and undisputedly would have approved an application to make the change.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

BRIEF IN OPPOSITION

Petitioner AVCO Corporation asks this Court to immunize aviation manufacturers from state-law design defect claims. According to petitioner, any time a manufacturer must obtain the approval of the Federal Aviation Administration (FAA) before changing a defective design to a safe one, the change is "impossible" under this Court's preemption precedents, foreclosing state-law liability. Petitioner further argues that every design change, however minor, requires such approval.

The implications of petitioner's rule are striking. Since the early 1900s, air crash victims and their families have relied on state tort law to obtain redress against the manufacturers of defective aviation products. In all that time, *no court*, other than the district court in this case, has ruled for a defendant on conflict preemption grounds. Petitioner's rule would turn that status quo on its head. Indeed, it would foreclose manufacturer liability in each and every plane crash case we have seen—whether it involves a single-engine plane or a jumbo jet—and deny all redress to the victims.

This attempt to upend decades of settled practice in the aviation industry should fail. In the 1990s, aviation manufacturers tried something similar, urging Congress to enact sweeping tort reform to limit claims against them. Congress rebuffed the manufacturers. The legislature recognized that "[t]he liability of general aviation aircraft manufacturers is governed by tort law . . . While the specific contours have ebbed and flowed, the public's right to sue for damages is ultimately grounded in the experiences of

the legal system and values of the citizens of a particular State." H.R. Rep. No. 103-525, pt. 2, at 3-4 (1994) (House Report). Congress "chose[] to tread very carefully when considering proposals . . . that would preempt State liability law." *Id*. at 4. Thus, it rejected the manufacturers' pleas for broad tort reform. Instead, it gave them a single concession: an eighteen-year statute of repose. *See* General Aviation Revitalization Act of 1994 (GARA), Pub. L. No. 103-298, 108 Stat. 1552, *reprinted in* 49 U.S.C. § 40101 note. Congress was clear, however, that "where the statute of repose has not expired, State law will continue to govern fully, unfettered by Federal interference." House Report pt. 2, at 7. This result struck "a reasonable balance between the sometimes conflicting objectives of keeping the price of general aviation aircraft at an affordable level and awarding fair compensation to persons injured in general aviation accidents." *Id.* pt. 1, at 4.

The petition is a plea for this Court to rewrite the law. Petitioner does not assert a circuit split (because none exists). It did not attempt to develop a factual record supporting its preemption defense (because its sweeping legal rule applies regardless of the facts). It did not seek rehearing en banc in the Third Circuit (despite the panel dissent and petitioner's previous contentions that Third Circuit law supported its position). And it has never hesitated to admit that its position would result in broad immunity for aviation manufacturers—an outcome it attempts to justify principally with policy arguments best addressed to the legislature (which considered and rejected them).

Petitioner's position is staggeringly broad and plainly wrong. Petitioner wants this Court to hold that

it was "impossible" to change the design of its engine—even though: (1) aviation manufacturers frequently change their designs (petitioner changed the design of this very engine at least 59 times); (2) for years, the FAA urged petitioner to address the problem that caused the crash in this case; (3) the FAA had previously approved (indeed, mandated) an alternative safe design for this very engine; and (4) it is undisputed that if petitioner had sought the FAA's approval to change the design, approval would have been granted.

Under this Court's precedents and any reasonable understanding of the word "impossible," routine design changes do not qualify. Petitioner argues otherwise, contending that the need to ask the FAA's permission before making a change renders the change "impossible" as a matter of law. In support, petitioner draws a strained analogy to cases involving generic drug labeling. These cases are inapposite because the restrictions preventing generic drug manufacturers from altering their warning labels bear no resemblance to the design change procedures available to aviation manufacturers. To the extent these cases are instructive, they do not stand for the broad proposition that courts should ignore reality when, as here, a manufacturer can change its designs with ease. Moreover, even if the generic drug cases apply, petitioner would still lose this case because it could have changed the design at issue here without any prior FAA involvement whatsoever.

For these reasons and others explained more fully below, certiorari should be denied.

STATEMENT OF THE CASE

I. Legal Background

1. This case is about whether and to what degree the design approval provisions of the Federal Aviation Act of 1958, Pub. L. No. 85-726, 72 Stat. 731, preempt state-law design defect claims. The most relevant approval is a "type certificate," which is a prerequisite to mass producing any aircraft, engine, or propeller. The statute provides that the FAA "shall issue a type certificate for an aircraft, aircraft engine, or propeller" that "is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under" the statute. 49 U.S.C. § 44704(a)(1). That language resembles the predecessor Civil Aeronautics Act of 1938, ch. 601, 52 Stat. 973. *See* Pet. App. 165a. It never mentions preemption.

Type certificate holders can change their designs, and frequently do. Design changes are either "major" or "minor." 14 C.F.R. § 21.93(a). A "minor change" is one that has no "appreciable effect" on "characteristics affecting the airworthiness of the product." *Ibid*. A manufacturer is responsible for deciding, in the first instance, whether a change is "minor." *See* FAA Order 8110.37F, at 4-4 (2017). If the manufacturer decides to classify a change that way, then it can implement the change using "a method acceptable to the FAA." 14 C.F.R. § 21.95. There are "acceptable" methods that do not require any prior FAA input whatsoever. *See* FAA Order 8110.4C, at 87 (2007) (minor changes can be made by recording them in the descriptive data); 14 CFR Part 23 Reorganization Aviation Rulemaking Comm., FAA, *Recommendations for Increasing the*

Safety of Small General Aviation Airplanes Certificated to 14 CFR Part 23, at 119 (2013), https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/air/directorates_field/small_airplanes/media/P23_Reorg_ARCFINAL.pdf (proposing a best-practices minor change procedure that includes no FAA involvement); Pet. App. 205a n.21. The determination that a change was minor is subject to later FAA review.

Before the rules changed in 2005 (*see infra* pp.18-20), major changes typically required the FAA's prior approval. To make a major change, the manufacturer submits an application with data showing that the proposed design meets the applicable minimum standards. If it does, then the FAA approves the change. Such changes are commonplace. For example, the type certificate for the engine in this case shows that from 1953, when it was first approved, to July 2003, petitioner obtained FAA approval for 60 different variants of the engine.[1] Most changes were approved within a month. Some were approved in less than two weeks. There is no evidence in the record of an application for a change to this engine design being denied.

Both the certification and design change process depend heavily on manufacturers, who conduct essentially all of the relevant testing. The FAA, in turn, "spot check[s]" the manufacturer's work. *United States v. S.A. Empresa de Viacao Aerea Rio Grandense*

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[1] *See* FAA, Type Certificate Data Sheet No. E-274, at 3 (rev. 21 2009), http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgMakeModel.nsf/0/6235a06ff153fff28625760e0051f018/$FILE/E-274.pdf.

(Varig Airlines), 467 U.S. 797, 816-17 (1984). More specifically, the FAA relies on "designees," who are private individuals and organizations—employed or contracted by the manufacturer seeking certification—that exercise delegated authority on the FAA's behalf. These designees review and approve design and test data to ensure that designs meet federal standards, performing "more than 90 percent of FAA's certification activities." Gov't Accountability Office (GAO), GAO-05-40, *Aviation Safety: FAA Needs to Strengthen the Management of Its Designee Programs* 12 (2004).

2. This case also involves Parts Manufacturer Approvals (PMAs), which govern the design and production of aftermarket parts for use on type certificated products. The change procedures for PMA holders are similar to those for type certificate holders.

This case also involves a repair station. Repair stations cannot change the design of a part in general, but they can alter individual aircraft. *See* 14 C.F.R. § 1.1 (defining major alterations and minor alterations); 14 C.F.R. pt. 43 (setting forth regulations governing major and minor alterations). The only immediately relevant point about repair stations is that when a type certificate holder changes its design, a repair station can alter an individual aircraft to conform to the new design without additional FAA approval. *See* FAA Order 8300.16, at 3, 13-16 (2015).

3. When the Federal Aviation Act was enacted, it contained no preemptive language of any kind. On the contrary, it included a savings clause providing that "'nothing in this chapter shall in any way abridge or alter the remedies now existing at common law or by

statute.'" *Am. Airlines, Inc. v. Wolens*, 513 U.S. 219, 222 (1995) (alterations and citation omitted).[2]

The Airline Deregulation Act of 1978, Pub. L. No. 95-504, 92 Stat. 1705, introduced a preemption clause, which applies only to commercial air carriers—not manufacturers. *See* 49 U.S.C. § 41713. Then, in 1994, Congress enacted GARA—which does apply to product liability claims against aviation manufacturers. As explained in the introduction, *supra*, GARA created an eighteen-year statute of repose, and expressly preempts any longer state limitations period. When Congress enacted this statute, it was explicit that "in cases where the statute of repose has not expired, State law will continue to govern fully, unfettered by Federal interference." House Report pt. 2, at 7.

II. Factual and Procedural Background

1. Respondent Jill Sikkelee claims that petitioner designed and sold a defective aircraft engine (the O-320 engine; specifically the O-320-D2C variant). The engine is defective because the screws that hold the two halves of the carburetor together are secured using ineffective lock tab washers, alongside ineffective gasket materials. Normal engine vibration can cause the screws to loosen so that the carburetor halves separate, resulting in a loss of power. Pet. App. 5a-7a.

The carburetor was not always designed this way. Petitioner's previous design used safety wire to hold the screws in place—which worked well. Indeed,

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[2] The savings clause was amended to provide that "[a] remedy under this part is in addition to any other remedies provided by law." 49 U.S.C. § 40120(c).

starting in 1964, the FAA mandated safety wire on this carburetor. *See* 29 Fed. Reg. 16,317, 16,318 (Dec. 5, 1964). But the following year, petitioner and its carburetor supplier sought permission to use the current lock tab configuration, which was cheaper. Thus, they requested that the FAA stop requiring the use of safety wire, and changed their design. Pet. App. 4a-5a.

No later than 1971, petitioner knew that its design was defective. The FAA contacted petitioner as reports of malfunctions poured in from the field. In 1972, the FAA confirmed that such reports "are still being received" and that the "majority of the incidents occurred" on "Cessna 172 model aircraft." C.A. App. 557. The FAA urged petitioner to provide comments "as to any action you may propose that will help in alleviating this problem." *Ibid.*; Pet. App. 5a-6a.

Petitioner responded in 1973 by issuing a Service Bulletin (SB366), which advised readers to check the screws for looseness and reassemble the carburetor if fuel leakage was evident. Numerous experts testified that this bulletin was inadequate—and could aggravate the problem because the process of checking the screws could damage the washers. Pet. App. 6a-7a.

Problems continued. In 2004, petitioner's carburetor manufacturer, Precision Airmotive, requested that petitioner, "as the type certificate holder, review the [service difficulty report] information and the installation to determine if some action is required." C.A. App. 581. Precision urged petitioner to consider "the pros and cons of a different attachment system." *Id.* at 582-83. Petitioner did not change its design.

That same year (2004), the carburetor in this case was overhauled by Kelly Aerospace, Inc. and Kelly Aerospace Power Systems, Inc. (together, "Kelly"), a PMA holder and repair station. Kelly used some of its PMA parts, which have the same form, fit, and function as petitioner's original parts, as replacements on the carburetor. It assembled the carburetor using lock tab washers, pursuant to petitioner's service bulletin and maintenance instructions. Pet. App. 7a-8a.

The carburetor was part of an O-320 engine that was installed on a Cessna 172 aircraft. In July 2005, that engine lost power shortly after takeoff, causing a crash that killed respondent's husband. Investigation revealed evidence that the carburetor had come apart. Respondent sued on strict liability and negligence theories under Pennsylvania law. Pet. App. 8a.

2. This case has a long procedural history. As relevant here, the district court held in 2010 that federal law preempts the field, and thus required respondent's claims to be repleaded under federal standards of care. Pet. App. 275a-96a. Those claims—for defective design, failure to warn end users, failure to notify the FAA of known defects, and negligence—largely survived summary judgment in 2012. *See Sikkelee v. Precision Airmotive Corp.*, 876 F. Supp. 2d 479, 490, 492, 495 (M.D. Pa. 2012).

After that summary judgment ruling, the case was reassigned to a different judge. On the eve of trial, the district court determined that the federal regulations actually did not articulate cognizable standards of care at all. The court found it impossible to fashion jury instructions out of the regulations, and determined that the proper remedy was to grant

summary judgment to petitioner, holding that the issuance of a type certificate (a federal design approval) conclusively established petitioner's compliance with any applicable federal standard. *See* Pet. App. 9a.

On respondent's appeal, the Third Circuit held that federal law does not preempt the field with respect to general aviation design defects. The court explained:

> We are dealing with an area at the heart of state police powers, and we have no indication of congressional intent to preempt the entire field of aviation design and manufacture. We therefore decline the invitation to create a circuit split and to broaden the scope of . . . field preemption to design defects when the statute, the regulations, and relevant precedent militate against it.

Pet. App. 215a. The court thus permitted respondent's claims to proceed based on state standards of care.

The Third Circuit recognized, however, that federal regulations could give rise to conflict preemption. The court accepted the FAA's argument that conflict preemption arises when: (1) the challenged design feature was "expressly approved by the FAA as shown on the type certificate," or other materials "incorporated by reference" into that approval; and (2) federal law binds the manufacturer to manufacture its product in accord with that approval. Pet. App. 201a-02a. After opening the door to conflict preemption, the Third Circuit left further definition of the test to the district court on remand.

Petitioner sought certiorari on the field preemption holding, which was denied. *AVCO Corp. v. Sikkelee*, 137 S. Ct. 495 (2016) (No. 16-323).

On remand, petitioner filed motions for summary judgment on state law and conflict preemption grounds. With respect to preemption, petitioner did not introduce any evidence showing that it could not have attempted to change its design unilaterally, or that the FAA would have prohibited petitioner from changing its design. Respondent highlighted the lack of record evidence, suggesting that the district court consider reopening the record to take evidence germane to the preemption defense, and noting that otherwise petitioner's defense could not succeed. *See* Dist. Ct. Oral Arg. Tr. 200 (May 19, 2017). Petitioner did not join the suggestion to reopen the record and the district court did not accept it, and so the record remains devoid of facts supporting petitioner's preemption defense.

To get around the lack of evidence, petitioner advanced the broadest possible legal theory of conflict preemption: that because any design change, however minor, is subject to approval by the FAA, federal law preempts any claim alleging that an approved design is defective. Under this rule, manufacturers would be immune from all liability for design defect claims—even when their designs cause aircraft to crash, and even when they could easily change their designs to address the defects.

Petitioner needed to advance this sweeping rule because, as it would later concede, changing the carburetor design to a safe alternative was easy; indeed, petitioner itself believed that the change

would qualify as "minor" under the FAA regulations. Pet. App. 17a; C.A. Oral Arg. Audio at 32:22-32:34.[3]

The district court granted summary judgment to petitioner on both state law and conflict preemption grounds. It also held that respondent could not base a claim on petitioner's failure to warn the FAA of known design defects. Pet. App. 2a-3a.

The Third Circuit reversed in part, holding that a reasonable jury could conclude that petitioner's designs were defective and that it was negligent (but affirming the dismissal of the claim based on failure to warn the FAA), Pet. App. 25a-27a, and further holding that petitioner had failed to carry its burden to prove that it was impossible to change its design, *id*. at 22a-24a. The court explained that petitioner "has made numerous changes to the type certificate for its O-320 engine, which the FAA approved in short order." *Id*. at 20a. Considering the facts of this case, the Third Circuit held:

> There is no evidence in the record showing that the FAA would not have approved a change to the carburetor's screws or attachment system. To the contrary, viewing the record in the light most favorable to the nonmovant, it shows that the FAA likely would have approved a change, which also would have meant Kelly would not have used the same allegedly defective design when it

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[3] https://www2.ca3.uscourts.gov/oralargument/audio/17-3006_Sikkeleev.PrecisionAirmotive.mp3 (last visited May 22, 2019).

> overhauled and reinstalled the carburetor in 2004.

Id. at 22a. The court noted that "[t]he FAA was aware, as its correspondence with [petitioner] shows, that the carburetor's screws loosened in some cases and caused fuel to leak," that it "wanted [petitioner] to address" this problem, and "had previously required the use of safety wire, the very design change [respondent] alleges would have cured the defect." *Ibid*. Because "[b]ased on this record, the FAA likely would have approved a proposed change to the attachment system," it "was not 'impossible' for [petitioner] to change its allegedly defective design." *Id*. at 22a-23a. The court also held that "allowing state-law claims to proceed in this context complements, rather than conflicts with, the federal scheme," and that "immunizing aircraft and aviation component part manufacturers from liability for their defective product designs is inconsistent with the Federal Aviation Act and its goal of fostering aviation safety." *Id*. at 23a-24a (alterations and quotation marks omitted).

The Third Circuit thus accepted respondent's narrowest argument against preemption, holding only that petitioner had not carried its burden to prove impossibility because it had not introduced *any evidence* that the FAA would have disallowed *this specific design change*.

Even though the panel was not unanimous, petitioner did not seek rehearing on the preemption question. Now it asks this Court to become the first appellate court anywhere to reject an aviation design defect claim on conflict preemption grounds—by embracing a sweeping theory of preemption.

REASONS TO DENY THE WRIT

I. The Conflict Preemption Question Does Not Warrant Certiorari.

A. There Is No Circuit Split, and No Reason to Consider This Question Now.

1. The petition does not assert a circuit split about conflict preemption, and none exists. In fact, this issue is truly novel. Aviation torts have been litigated for over a century. *See* Pet. App. 178a-79a. Yet the Third Circuit is the only circuit court that has even addressed conflict preemption of design defect claims, and the first time it discussed the question was in 2016.

Before that decision, everybody—plaintiffs and defendants alike—understood that tort claims against aviation manufacturers were not preempted, and litigated these cases on state law grounds. Typically, manufacturers did not even assert conflict preemption. In the rare counterexamples, district courts uniformly rejected the defense. *See Davidson v. Fairchild Controls Corp.*, 2016 WL 5539982, at *8 (S.D. Tex. Sept. 29, 2016); *Monroe v. Cessna Aircraft Co.*, 417 F. Supp. 2d 824, 836 (E.D. Tex. 2006); *Holliday v. Bell Helicopters Textron, Inc.*, 747 F. Supp. 1396, 1401 (D. Haw. 1990).

Three years ago, the first panel in this case agreed with the FAA that a conflict preemption defense is available. In the second appeal, the panel below again acknowledged the availability of a conflict preemption defense, but rejected it based on the one-sided evidentiary record showing that a design change would have been approved.

Petitioner has not identified a single court of appeals that has adopted a conflicting legal analysis of a similar claim—let alone a court of appeals that would have granted its motion for summary judgment. Absent any such split, the question presented does not warrant this Court's review.

2. The lack of a split highlights a broader problem: there is no reason to take up this issue now. Contrary to petitioner's sky-is-falling narrative about the importance of this case, the Third Circuit's decision merely maintained the status quo that has worked well for a century, and that Congress endorsed when it enacted GARA. The decision below did nothing to undermine the uniformity of federal aviation regulation. Indeed, to the extent conflict preemption promotes uniformity, the Third Circuit's decisions have advanced that objective by opening the door to a defense that previously failed to gain *any* traction in the district courts.

Even aviation defense attorneys have explained that "the majority's opinion does not hinder the aviation industry" because it "is a narrow, fact-based decision leaving room for impossibility- and obstacle-preemption defenses in subsequent cases, both within and outside the Third Circuit." John D. Goetz et al., *Sikkelee Round Two: Federal Aviation Law vs. State Tort Law Rematch*, Lexology (Nov. 13, 2018), https://www.lexology.com/library/detail.aspx?g=1f06c949-c1c9-4a3c-bf6f-142ef51e4f1c.

Against that backdrop, petitioner's arguments about the need for this Court's immediate review ring hollow. For example, petitioner and its amici argue that if state courts adjudicate tort claims, manufacturers will face a patchwork of conflicting

state rules, making compliance impossible. But neither petitioner nor its amici identify even a *single real example* of two States adopting conflicting design requirements for the same component—even though state tort claims have been litigated since the dawn of civil aviation. The fact that petitioner and its amici must speculate exposes this argument as hyperbole.

For much the same reason, petitioner's concern that state tort law will displace the FAA and hinder safety is unfounded. Under the Third Circuit's rule, if the FAA would have rejected a design change that is required by state law, then the state law is preempted. Thus, the FAA retains primacy. Moreover, it is hard to understand how state tort law, which merely requires that aircraft be safe, is likely to conflict with federal standards, which likewise prioritize safety. This case provides a useful illustration: the FAA had already approved alternative designs of the O-320 engine that comply with state law. Thus, a judgment in respondent's favor would not undermine the FAA's role in regulating aviation safety; it would underscore it. And petitioner has conceded that the change would not make the engine less safe.

3. This is also the type of novel legal issue for which further percolation will yield benefits. First, percolation will allow other appellate courts to consider the nuances of the underlying federal regulations. Aviation is diverse: it includes small planes, jumbo jets, helicopters, balloons, drones, and original and aftermarket components for each of these. It also includes original equipment manufacturers, PMA holders, and repair stations. Different regulations and requirements apply to different players, and it would be difficult to lay a sensible

preemption rule atop this uneven regulatory landscape.

The diversity of petitioner's amici illustrates the point. The Experimental Aircraft Association, Garmin International (a manufacturer of avionics and sensors), and Airbus Americas (which makes commercial transport category aircraft) filed briefs supporting the petition. But the regulatory requirements for these products and articles are different than the requirements for the engine in this case. Moreover, the record of this case contains no information about how these manufacturers' designs are approved, nor about what constraints, if any, federal law imposes on these manufacturers' ability to change their designs. It would be far better to allow the lower courts to determine, after accounting for the regulations actually at issue in a given case, whether preemption applies.

In a similar vein, further percolation will reveal whether the facts in this case are representative or idiosyncratic. In respondent's view, this case presents the strongest possible record against preemption because petitioner has effectively conceded that the FAA would permit a safe alternative design of the engine in question. Moreover, the factual record does not establish that petitioner would have been unable to make that change unilaterally. Other cases will have different facts—and those factual differences may be outcome determinative. Once those cases are decided, the Court will have a much clearer sense for the importance of the legal question and the practical consequences of adopting any given rule.

Relatedly, further percolation will reveal currently unknown facts that are critical to the legal

question. For example, it would be helpful to know how often manufacturers attempt to implement design changes unilaterally, and how often the FAA prevents them from doing so. Additionally, it would be good to know how often the FAA approves or rejects manufacturers' applications for major design changes. None of those facts are in the record, but they are undeniably important. As parties litigate cases with preemption in mind, the answers to these and other relevant questions will emerge.

Finally, percolation will allow the Third Circuit's own preemption jurisprudence to evolve. The Third Circuit's views about aviation conflict preemption are nascent, and there is no clear consensus on that court. Petitioner argued below that the first panel decision in this case supports its view of preemption, and a judge on the second panel dissented from the majority's preemption holding. It is shocking that petitioner chose to run straight here instead of seeking rehearing en banc. But in future cases, it is possible, and perhaps likely, that the Third Circuit's views regarding conflict preemption will change—either clarifying the need for this Court's review, or eliminating it.

4. There is another compelling reason to wait: the underlying regulations are in flux. There has already been one sea change in the FAA's regulations since the events in this case took place. In October 2005 (several months after the crash), the FAA issued regulations creating the Organization Designation Authorization (ODA) program, a form of enhanced delegation that gives the industry greater autonomy to approve its own design changes. *See* FAA, Delegated Organizations, https://www.faa.gov/other_visit/aviation_industry/designees_delegations/delegated_organizations/ (last

visited May 22, 2019). By November 2009, the ODA program was the only kind of organizational delegation available, and it had considerably reduced the reliance on individual designees at manufacturers that had received ODAs.

But the program has not always run smoothly, and it has evolved in reaction to criticism from both the Department of Transportation's Inspector General and the GAO. *See generally* Office of Inspector Gen., AV-2016-001, *Audit Report: FAA Lacks an Effective Staffing Model and Risk-Based Oversight Process for Organization Designation Authorization* (2015); Office of Inspector Gen., AV-2011-136, *Audit Report: FAA Needs to Strengthen Its Risk Assessment and Oversight Approach for Organization Designation Authorization and Risk-Based Resource Targeting Programs* (2011); GAO, GAO-14-829T, *Aviation Manufacturing: Status of FAA's Efforts to Improve Certification and Regulatory Consistency* (2014); GAO, GAO-11-14, *Aviation Safety: Certification and Approval Processes Are Generally Viewed as Working Well, but Better Evaluative Information Needed to Improve Efficiency* (2010).

Congress recently took interest in the FAA's certification programs after fatal crashes of the Boeing 737 MAX jet. Participants at congressional hearings stated that changes to the certification process are coming. The Transportation Department Inspector General testified that "FAA plans to introduce a new process that represents a significant change in its

oversight approach" by the end of July.[4] And Senator Richard Blumenthal indicated that he was planning to introduce legislation requiring greater FAA oversight of designees.[5]

When, as here, the law is changing, it would make little sense for this Court to enter the fray. It is entirely possible that anything the Court says will soon be obsolete. It is also possible—and perhaps likely—that if this Court announces a new preemption rule, that announcement would unnecessarily complicate the ongoing legislative effort to reform the certification process and enhance aviation safety. After all, nobody at recent congressional hearings suggested that manufacturers need less accountability or less liability when their designs cause accidents. But of course, that is exactly what petitioner seeks.

B. The Decision Below Is Correct.

Certiorari should also be denied because the decision below is correct on its own terms, and the result is supported by alternative justifications.

1. The Third Circuit held that when an aviation manufacturer can change its designs to comply with state law, it cannot seek refuge in the argument that it would be "impossible" to change its designs. That

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[4] Office of Inspector Gen., Dep't of Transp., *Perspectives on Overseeing the Safety of the U.S. Air Transportation System*, https://www.commerce.senate.gov/public/_cache/files/1c1fad9d-c836-43a6-a54f-839c7c9dd879/9770138BA3D435783B1B13779D28B324.inspector-general-scovel-testimony-1-.pdf.

[5] *See* C-SPAN, Commercial Airline Safety (Mar. 27, 2019), https://www.c-span.org/video/?459047-1/faa-ntsb-officials-testify-airline-safety-wake-boeing-737-crashes&start=5483 (video of Senate committee hearing, statement at 1:22:55).

makes sense because achievable outcomes are not ordinarily regarded as impossible.

Petitioner's argument to the contrary is that impossibility arises whenever a manufacturer must ask permission from the government before implementing a design change. Under petitioner's rule, it does not matter that the FAA had previously noted problems with the O-320 engine and urged petitioner to solve them. It does not matter that if petitioner had requested the FAA's permission to change the design, the FAA undisputedly would have approved. It does not even matter that the FAA had previously approved an alternate design, and the only reason the unsafe design was in use is that petitioner took the proactive step of seeking the FAA's permission to change the design for cost reasons.

Petitioner has no logical explanation for why it makes sense to ignore these facts when assessing impossibility. So it relies on a strained analogy to this Court's generic drug labeling precedents, which involved entirely different facts. Petitioner argues that this case resembles *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), which found product liability claims against generic drug manufacturers preempted. The Third Circuit rejected that argument, holding that the case more closely resembles *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Court held that similar claims against a brand-name drug manufacturer were not preempted because the manufacturer did not provide clear evidence that the Food and Drug Administration (FDA) would have rejected a proposed labeling change.

The Third Circuit correctly held that—to the extent drug labeling cases apply—this case is more like *Wyeth* than *PLIVA*. In *Wyeth* and *PLIVA*, the question was whether a drug manufacturer could be liable, under state law, for the contents of its warning label. In *Wyeth*, the Court held that the answer was "yes" for several reasons. First, the Court noted that when Congress empowered the FDA to regulate drugs and their labels in the 1960s, it "took care to preserve state law" by including a savings clause, and not including an express preemption clause in the statute. 555 U.S. at 567. Second, the Court noted that it was "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Id*. at 570-71. Third, an FDA regulation, called the "changes being effected," or "CBE" regulation, "permits a manufacturer to make certain changes to its label," including the addition of warnings, "before receiving the agency's approval" to make the change, as long as it had also submitted an application to make the change. *Id*. at 568. The Court acknowledged that "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation." *Id*. at 571. But it held that "absent clear evidence that the FDA would not have approved a change . . . we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Ibid*.

Contrast those facts with *PLIVA*. In *PLIVA*, the Court observed that while "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," a generic drug manufacturer "is responsible for ensuring that its warning label is the same as the

brand name's." 564 U.S. at 613. This "ongoing federal duty of 'sameness'" prevented generic manufacturers from changing their labels unless brand-name manufacturers first changed theirs. *Ibid*. Specifically, the generic manufacturers were not permitted to apply for a label change, or to use the CBE regulation to add warnings while those applications were pending. *See id.* at 614. The most the generic manufacturers could have done is notify the FDA of the need for additional warnings. Had they "done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label." *Id*. at 619. But there was "no evidence of any generic drug manufacturer ever acting" in this manner. *Id*. at 617. The Court held that this speculative chain of events was insufficient to defeat a conflict preemption defense. After all, if the availability of preemption turns on what the federal government *might* do in some hypothetical circumstance, that would "render[] conflict pre-emption all but meaningless" because a court could "often imagine" a circumstance in which the government *might* do something. *Id*. at 620-21.

The following paragraph from *PLIVA* is important:

> To be sure, whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the Manufacturers could satisfy state law, the FDA—a federal

> agency—had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

564 U.S. at 623-24.

Aviation manufacturers far more closely resemble brand-name drug manufacturers than they do generic drug manufacturers. Like brand-name manufacturers, aviation manufacturers have a duty to ensure the safety of their products (not a duty of sameness that prevents them from doing so). Like brand-name manufacturers, aviation manufacturers have significant independence, including the ability to implement certain design changes unilaterally, subject to the government's later veto. For other changes, aviation manufacturers have the unilateral ability to decide which design changes to make, and to apply directly to make those changes. Indeed, they frequently do (unlike generic manufacturers, who cannot do so and had never attempted to do so). Also unlike the generic manufacturers, there is no need to speculate about whether an aviation manufacturer's attempt to change its design *might* be approved; the evidence in the record shows that such changes are overwhelmingly approved (60 variants of the O-320 engine alone, and 32 more that are fuel-injected, with no evidence that a change application was ever denied).

Putting the issue in terms of *PLIVA*'s holding, petitioner did not show that it needs "the Federal Government's special permission and assistance" to change its engine design—and it certainly did not need a federal agency to "undertake special effort" or "exercise . . . judgment." 564 U.S. at 623-24. The aviation design change process is not "special"; it is routine. Moreover, all the heavy lifting to change the design would have been undertaken by petitioner's own employees. To the extent the FAA would have been involved (and it is not clear that it would have been), its only role would have been to spot-check petitioner's conclusion that its proposed design complied with federal minimum requirements. The FAA would not have had to negotiate with any other entity, or make any tricky judgment calls balancing the benefits of one design versus another. In short order, the change would have been approved.

For all these reasons, the Third Circuit was correct to hold that this case is more like *Wyeth*. And petitioner does not even attempt to argue that it could win under *Wyeth*.

Respondent has alternative arguments as well, which she would raise in support of the Third Circuit's judgment if certiorari is granted.

2. Even if *PLIVA*, and not *Wyeth*, provides the relevant framework, such that the question is whether petitioner could have acted unilaterally, respondent should still win. First, petitioner made a unilateral choice to adopt this defective design in the first instance; federal law did not compel that choice, and so it cannot protect petitioner's decision to make it. Second, petitioner has already received FAA approval for variants of the O-320 engine that do not include

this design defect; federal law thus does not compel it to maintain the defective O-320-D2C variant. Third, petitioner has not carried its burden to show that it could not have changed the O-320-D2C variant unilaterally using the minor change procedure. Indeed, petitioner conceded at oral argument that the design change would qualify as "minor," Pet. App. 17a, and petitioner did not develop the record to show what restrictions, if any, federal law imposes on petitioner's ability to unilaterally implement a minor change. Fourth, petitioner has not shown that it would have to consult an actual FAA employee, as opposed to one of its own employee designees, to change the O-320-D2C design. If petitioner does not need input from an FAA employee to make the change, that ought to be sufficiently "unilateral" to defeat impossibility preemption even under *PLIVA*. Finally, when the FAA proposed a conflict preemption defense, it reserved that defense for instances in which the relevant design feature was "expressly approved by the FAA as shown on the type certificate" or other comparable approval. *Id.* at 201a (quotation marks omitted). Petitioner's lock tab washer design was not expressly approved, and so does not trigger preemption at all.

3. More broadly, type certification should not give rise to conflict preemption at all. There is no indication in the statutory text that Congress intended for the Federal Aviation Act to preempt claims like this one. Indeed, all evidence is to the contrary.

"'[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Wyeth*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)) (alteration omitted). "'The case for federal pre-emption is particularly weak where

Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" *CTS Corp. v. Waldburger*, 573 U.S. 1, 18 (2014) (quoting *Wyeth*, 555 U.S. at 575) (alteration in original). That is exactly what Congress did when it enacted GARA: it acknowledged that "[t]he liability of general aviation aircraft manufacturers is governed by tort law," limited tort claims by enacting a statute of repose, and specified that "in cases where the statute of repose has not expired, State law will continue to govern fully, unfettered by Federal interference." House Report pt. 2, at 3-4, 7.

GARA sits alongside other features of the statutory scheme indicating that Congress did not intend preemption. For example, Congress refused to create a federal cause of action to recover for aviation accidents—indicating that Congress knew that state law would provide redress, and was counting on it to do so. Indeed, the statute includes a savings clause that preserves such remedies. 49 U.S.C. § 40120(c). Congress has also signaled that it knows how to preempt state law aviation claims when it wants to. In addition to GARA, which preempts stale products liability claims, Congress enacted the Airline Deregulation Act, which preempts claims relating to commercial carriers' rates, routes, and services. 49 U.S.C. § 41713.

In contrast with these provisions, the Federal Aviation Act does not include any language even suggesting intent to give preemptive effect to design approvals. Instead, type certification merely requires manufacturers to show that their designs meet the

"minimum standards" prescribed under the Federal Aviation Act. 49 U.S.C. § 44704(a)(1). In cases involving "minimum standards," this Court has recognized that States are free to set safety standards above the federal floor. *See, e.g.*, *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 335 (2011); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000). It is only when Congress intends to set both a ceiling and a floor that preemption may be appropriate. *See Geier*, 529 U.S. at 874-75. Petitioner has not identified any evidence that Congress regards type certification as a safety ceiling, as opposed to a floor.

Such a conclusion would be especially uncalled for considering of the well-documented problems with the type certification process, many of which are spelled out in the Inspector General and GAO reports cited *supra*, and many of which have been thrown into sharp relief by the 737 MAX debacle. Put succinctly, the certification process is demonstrably unable to ensure that aviation designs are safe, and it would be a terrible idea to give certification decisions preemptive effect—which is why Congress never did so.

4. Finally, consider the other side of the coin. If petitioner prevails, aviation manufacturers will have broad immunity from liability for design defects. In petitioner's view, all design changes require FAA approval, and thus trigger conflict preemption. That rule would have foreclosed liability in every other design defect case that we know about, denying all redress to the victims of manufacturers' negligence and undermining incentives to make designs safer. It would also render GARA a nullity. All available evidence shows that Congress rejected that result.

There also is no reason to think that petitioner's rule would stay cabined to design defect claims. In the next case, a defendant surely would argue that the issuance of an airworthiness certificate precludes liability for manufacturing defects; or that FAA approval of training procedures precludes liability for negligent training. Indeed, in every other federally regulated industry, defendants would demand expanded preemption—disrupting the balance of federalism and imposing unnecessary additional costs on accident victims.

For these reasons and others, the Third Circuit's judgment was correct, and certiorari should be denied.

C. This Case Is a Poor Vehicle.

Assuming *arguendo* that the Court wants to decide the question presented at some point, this case is a bad vehicle.

1. Contrary to petitioner's representation, the question presented is not case-dispositive for two reasons. First, even if petitioner is correct about the legal rule—*i.e.*, even if a manufacturer is entitled to preemption unless it can unilaterally change its design—it would still lose because petitioner has not shown that federal law prohibited it from acting unilaterally. *See* Part I.B.2, *supra*. Here, petitioner conceded that a design change would be "minor"—which means it could be implemented unilaterally using a "method acceptable to the FAA," making the dispute about the legal rule irrelevant to the outcome of this case.

Second, the question presented is limited to design defect claims, and petitioner conceded below that its defense does not reach failure-to-warn claims.

Dist. Ct. Oral Arg. Tr. 132 (May 19, 2017). Respondent asserted claims for failure to warn end users *and* failure to notify the FAA. *See* Resp. C.A. Br. 18, 45-46, 53; C.A. Reply Br. 16. The Third Circuit affirmed summary judgment on the claim for failure to notify the FAA, but not on the claim for failure to warn end users. That claim is based on petitioner's failure to provide appropriate warnings, and on petitioner's service instructions, including SB366, which risked aggravating the problem. That claim will go on.

2. This case is also a bad vehicle because the underlying facts are concededly idiosyncratic. In addition to being a case in which a design change is concededly minor, this case involves an aftermarket part manufactured by a PMA holder and installed by a repair station (Kelly), which will cloud any discussion about the preemptive import of type certification. Indeed, petitioner's argument is not actually a preemption argument at all; it is a causation argument that turns on whether, as a factual matter, Kelly could or would follow suit if petitioner changed its design. Kelly is subject to a different set of regulations from petitioner—the regulations governing PMA manufacturers (with respect to its designs) and repair stations (with respect to its ability to alter individual aircraft). And Kelly has now settled out of this case—so it would not be available to present its perspective. Indeed, petitioner's own counsel described the facts here as an "oddity" in the Third Circuit. C.A. Oral Arg. Audio at 23:35.

3. This case is also too old to be a good vehicle to consider preemption generally. The crash occurred in July 2005, before the creation of the ODA program, which has been described as a "radical shift" in the

FAA's approach to design approvals. Dominic Gates & Mike Baker, *Engineers Say Boeing Pushed to Limit Safety Testing in Race to Certify Planes, Including 737 MAX*, Seattle Times (May 5, 2019), https://www.seattletimes.com/business/boeing-aerospace/engineers-say-boeing-pushed-to-limit-safety-testing-in-race-to-certify-planes-including-737-max/. It would make little sense to grant certiorari to consider the import of a regulatory regime that has been displaced in significant part. The better approach would be to wait for a case that arises under today's regulations (or, in light of the ongoing revisions in this area, perhaps tomorrow's regulations).

4. Finally, while preemption is a legal question, the underdeveloped record in this case will lead to stilted arguments. Petitioner can only win if the Court adopts an extremely broad rule—and so petitioner will press such a rule. More reasonable alternatives will remain underdeveloped, increasing the risk of judicial error.

II. The Field Preemption Question Still Does Not Warrant Certiorari.

Petitioner argues (at 23-31) that in addition to conflict preemption, field preemption applies. Petitioner unsuccessfully sought certiorari on this precise question in this very case. For a detailed response, respondent respectfully requests that the Court consult her previous brief in opposition (cited herein as "16-323 BIO"). The key points are summarized here.

A. There Still Is No Circuit Split.

No court of appeals has held that field preemption extends to product liability claims against general

aviation manufacturers. In its 2016 decision, the Third Circuit recognized that ruling in petitioner's favor would have created a circuit split on this question, and it expressly declined to do so. Pet. App. 215a.

Petitioner cites two cases that it asserts "cannot be reconciled with" the decision below. Pet. 26. But *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318 (10th Cir. 2010), was not a products liability case; it was about alcohol service on a commercial flight. And *Goodspeed Airport LLC v. East Haddam Inland Wetlands & Watercourses Commission*, 634 F.3d 206 (2d Cir. 2011), was about tree removal near an airport. Every case that has considered field preemption in the context of products liability agrees with the Third Circuit. *See Martin ex rel. Heckman v. Midwest Express Holdings, Inc.*, 555 F.3d 806, 812 (9th Cir. 2009); *Pub. Health Trust of Dade Cty. v. Lake Aircraft, Inc.*, 992 F.2d 291, 294-95 (11th Cir. 1993); *Cleveland ex rel. Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438, 1447 (10th Cir. 1993); *see also* 16-323 BIO 18-20 (debunking split).

B. This Question Is Not Important.

Petitioner claims that this issue is important because of the need for uniformity in federal aviation regulation. But for the reasons explained in Part I.A.2, *supra*, these concerns are overblown. The Third Circuit's decision maintained the longstanding status quo, and petitioner has not identified any concrete problems arising from an alleged lack of uniformity.

Moreover, petitioner has not even explained what the applicable federal standards of care are, or how they differ from the state standards that currently govern this case. This is a major problem for petitioner

for a few reasons. First, if petitioner cannot show that the standards are materially different, it cannot explain why this issue matters or why this case is a suitable vehicle to decide it. In respondent's view, one fact—which the petition does not dispute—has overriding importance: the factual cause of the plane crash in this case was a flaw in petitioner's engine design. To the best of respondent's knowledge, no standard of care permits petitioner to design an engine that causes plane crashes. Whether the standard is given by federal or state law, petitioner will be liable here—and so will every other defendant in a case involving a plane crash. *See* 16-323 BIO 32-35.

Second, if petitioner cannot identify standards of care that govern respondent's design-defect and failure-to-warn claims in this case, that inability itself disproves the argument for field preemption, which arises only when federal regulation comprehensively displaces state law. If there is no applicable federal standard of care governing this type of claim, then there can be no field preemption. *See* 16-323 BIO 34.

Third, the inability to identify administrable federal standards of care will inevitably create practical problems. It has already done so in this case and others. This case ended up in appeals because on the eve of trial, the district court determined that it simply was not possible to translate the federal regulations into workable jury instructions. Other courts have experienced the same difficulty. *See Pease v. Lycoming Engines*, 2011 WL 6339833, at *22 (M.D. Pa. Dec. 19, 2011). On appeal, the Third Circuit recognized the issue: the FAA itself was unable "to specifically identify or articulate the proposed federal standard of care"; and the regulations themselves

were "in the nature of discrete, technical specifications" that are "exceedingly difficult to translate into a standard of care that could be applied to a tort claim." Pet. App. 185a, 187a.

Creating these practical problems may actually be petitioner's objective—because the district court was predisposed to hold that if there is no applicable federal standard of care, then there is no liability even if a design flaw causes a plane crash. But to the extent this field preemption argument is a back-door route to escaping liability altogether, it is clearly not about creating uniform standards for aircraft. It is about obtaining a windfall that Congress was manifestly unwilling to give, under the guise of implementing congressional intent.

C. The Decision Below Is Correct.

Given the lack of evidence that Congress intended type certification to have any preemptive effect, and given the other indications in the Federal Aviation Act that Congress contemplated that the victims of crashes would be able to obtain redress via state tort claims, the Third Circuit was correct to find that the Federal Aviation Act does not preempt the field of aviation design defect claims. *See* 16-323 BIO 20-31.

III. This Court's Recent Decision in *Merck Sharp & Dohme Corp. v. Albrecht* Does Not Warrant a GVR.

On May 20, 2019, this Court decided *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, holding that *Wyeth*'s "clear evidence" standard should be adjudicated by judges (not juries), and that in order to prove impossibility, a manufacturer must show that it

"fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." Slip op. 1-2.

If petitioner seeks a GVR on the basis of *Merck*, the Court should refuse. *Merck* does not suggest that *PLIVA*, rather than *Wyeth*, controls here; it does not speak to that question at all. And it does not suggest that the panel below misapplied *Wyeth*: the Third Circuit treated the preemption question as a matter of law to be reviewed de novo (Pet. App. 11a), and there is no doubt that under *Merck*'s articulation of the *Wyeth* standard, petitioner's preemption defense fails because petitioner never informed the FAA of the justifications for changing its engine design, and the FAA never informed petitioner that a change would be rejected. Moreover, petitioner never attempted to change its design unilaterally (*e.g.*, as a minor change), and it was never told by the FAA that the change would not be minor.

To the extent *Merck* is relevant, it only highlights that the drug preemption framework is wrong for cases about aviation products—because the right framework should actually be even less preclusive. In *Merck*, the Court emphasized that preemption is appropriate because "the FDA . . . makes careful judgments about what warnings should appear on a drug's label for the safety of consumers," slip op. 1, and that it seeks to avoid overwarning, which "could discourage appropriate use of a beneficial drug" *id*. at 3 (quotation marks omitted). No such agency judgment arises in aviation design because there is no such thing as an airplane that is too safe. Instead,

designs and design changes that meet minimum requirements are all approved. And the manufacturer does far more of the work to substantiate that compliance. Indeed, the protracted back-and-forth between the FDA and manufacturer in *Merck* contrasts sharply with the many perfunctory approvals of changes to the O-320 engine's type certificate—underscoring that aviation manufacturers have greater autonomy to change their designs than even brand-name drug manufacturers have to change their labels.

In light of the foregoing, a GVR for *Merck* would be inappropriate.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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