No. 22-192

IN THE

Supreme Court of the United States

GLENHAVEN HEALTHCARE LLC, a California corporation; CARAVAN OPERATIONS CORP., a California corporation; MATTHEW KARP, an individual; BENJAMIN KARP, an individual,
Petitioners,

v.

JACKIE SALDANA; CELIA SALDANA; RICARDO SALDANA, JR.; MARIA SALDANA, as individuals and as successors and heirs to Ricardo Saldana, deceased,
Respondents.

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

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

In the PREP Act, Congress crafted a comprehensive federal regime for claims for losses related to the use or administration of countermeasures during a public health emergency. For claims not involving willful misconduct, the "exclusive" "remedy" is a federal compensation fund. 42 U.S.C. § 247d-6e(a), (d)(4). For willful-misconduct claims, Congress created "an exclusive Federal cause of action" that must be filed in the District Court for the District of Columbia. § 247d-6d(d)(1), (e)(1). Because those exclusive federal remedies are coupled with a statutory immunity-from-suit provision and preemption of all state laws "different from" or "in conflict with" the PREP Act, § 247d-6d(a)(1), (b)(8), "there is … no such thing as a state-law claim" for losses related to the use or administration of covered countermeasures. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 11 (2003). Such claims are completely preempted.

The courts of appeals have uniformly—and erroneously—concluded otherwise for non-willful claims. And they are split on whether the PREP Act completely preempts willful-misconduct claims. This Court's intervention is essential to ensure that long-term-care and other medical facilities decimated by COVID-19 are not forced to close their doors at a time of skyrocketing demand. Review is also necessary to provide healthcare workers uniform guidance on the PREP Act's scope so as not to chill the private sector's response to this and future public health emergencies.

ARGUMENT

I. This Case Implicates A Circuit Split On Complete Preemption For Willful-Misconduct Claims.

A. In *Maglioli v. Alliance HC Holdings LLC*, the Third Circuit concluded that "[t]he PREP Act's language easily satisfies the standard for complete preemption" for willful-misconduct claims. 16 F.4th 393, 409-10 (3d Cir. 2021). Respondents seek to minimize *Maglioli*'s analysis as dicta. Opp. 18-21. But the above-quoted language was the court's holding on the first prong of its two-prong complete-preemption test: whether "the PREP Act create[s] an exclusive federal cause of action." 16 F.4th at 407. The Third Circuit "fully debated" that issue, *Cent. Va. Cmty. Coll. v. Katz*, 546 U.S. 356, 363 (2006), which the parties hotly contested, *Maglioli*, 16 F.4th at 407-11. And the relevant discussion spanned several pages in the Federal Reporter—far from a stray statement or "bit part" of the decision. *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 548 (2013).

Respondents also insist that *Maglioli* "did not state that the plaintiffs' claims *would* have been completely preempted had they alleged the elements of willful misconduct under the PREP Act." Opp. 19. But *Maglioli* said exactly that. The court began its analysis by setting out its two-part test for complete preemption—whether "the PREP Act create[s] an exclusive federal cause of action," and if so, whether "any of the [plaintiffs'] claims fall within the scope of that cause of action." 16 F.4th at 407. It observed that if both prongs were satisfied, "the [plaintiffs'] claims

are completely preempted and removable to federal court." *Id.* The court then concluded that the first prong of the test was satisfied, but not the second. *Id.* at 410-11. Had Respondents' claims satisfied the second prong of the test, *id.* at 407, they would have been preempted. And in a future Third Circuit case where the plaintiff alleges a state-law claim that comes within the scope of the PREP Act's exclusive federal cause of action, that claim would be completely preempted.

In the Ninth Circuit, however, that same claim would be sent back to state court.

B. The Ninth Circuit's decision not only splits from the Third Circuit but also conflicts with this Court's precedents. Pet. 17-19.

In their brief, Respondents devote several pages to the principles of complete preemption. Opp. 26-28. But under those principles, as the Third Circuit correctly held, the PREP Act completely preempts claims for willful misconduct. *Maglioli*, 16 F.4th at 407-10; Pet. 14-16. The PREP Act "provide[s] the exclusive cause of action for the claim asserted and also set[s] forth procedures and remedies governing that cause of action." *Beneficial,* 539 U.S. at 8; *see* 42 U.S.C. § 247d-6d(d)(1) ("exclusive Federal cause of action"); Pet. 15-16 (discussing various procedures for willful-misconduct claims).

In Respondents' view, it does not matter that the PREP Act satisfies *Beneficial*'s criteria, because the Act borrows state law as "the source of 'the substantive law for decision.'" Opp. 28-29 (quoting § 247d-

6d(e)(2)). But Respondents cannot explain what state law could ever apply. Under § 247d-6d(e)(2), state law applies "unless such law is inconsistent with or preempted by Federal law, *including provisions of this section*." (Emphasis added). *See also* § 247d-6d(b)(8) (state law preempted if "different from, or … in conflict with" the PREP Act). The PREP Act itself defines the elements of "willful misconduct," § 247d-6d(c)(1)(A); instructs how to "construe[]" those elements, (c)(1)(B); establishes a heightened burden of proof, (c)(3); sets out certain defenses to and exclusions from the Act, (c)(4), (c)(5)(A); and creates a process for "verify[ing]" a complaint with documents such as "certified medical records," (e)(4). Conceivably state law could operate to fill some gaps, but only if it is not inconsistent with federal law. And still the core elements of a willful-misconduct claim derive from federal law.

Thus, the Act does not simply "preserve[] state-law claims that meet the willful-misconduct requirement." Opp. 29. Instead, it creates an exclusive federal cause of action that must be brought in a single federal district court—the *only* claim a plaintiff can bring related to death or serious injury caused by a covered countermeasure. Pet. 14-16, 22.

Respondents also contend Glenhaven never argued below that the PREP Act completely preempts willful-misconduct claims. Opp. 31. Not so. Glenhaven argued in its opening brief that the PREP Act completely preempts *all* state-law claims related to the administration of a covered countermeasure. *E.g.*, CA9 Op. Br. 47. And it explained in reply, addressing Respondents' arguments, that the complaint at least

alleges a completely preempted willful-misconduct claim. *See* CA9 Reply Br. 24 n.9 ("Plaintiffs' complaint specifically alleges a separate willful misconduct cause of action to which [§ 247d-6d(d)] undoubtedly applies."). Certainly the Ninth Circuit understood Glenhaven to raise the alternative argument that the PREP Act completely preempts willful-misconduct claims, because it addressed that argument: After rejecting Glenhaven's complete-preemption argument as to "non-willful misconduct claims," it proceeded to consider—and reject—Glenhaven's argument specific to willful-misconduct claims. Pet. App. 16a-17a ("Glenhaven argues that the PREP Act may preempt one of [Respondents'] claims—the second cause of action … for willful misconduct."). This Court may review "an issue [even if] not pressed [below] so long as it has been passed upon." *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995) (internal quotation marks omitted).

Finally, Respondents claim there is no split because the Ninth Circuit's holding on willful-misconduct claims "was limited to" saying "that ordinary preemption of a single claim is insufficient to establish federal jurisdiction." Opp. 30-31. That makes no sense in context. Glenhaven's understanding of the Ninth Circuit's holding is the better one: In the Ninth Circuit's view, the fact that the PREP Act's exclusive cause of action reaches some claims (for willful misconduct) but not other claims (for non-willful conduct) meant it could not completely preempt *any* claims. Pet. 17-19. But whatever the Ninth Circuit's reasoning, it addressed and rejected the willful-misconduct-specific argument, which is all that is required for this Court's review. And there is no way to square the

Ninth Circuit's broad holding that "the PREP Act is not a complete preemption statute," Pet. App. 16a-17a, with *Maglioli*'s holding that the PREP Act "easily satisfies the standard for complete preemption" of at least willful-misconduct claims, 16 F.4th at 409-10.

C. Respondents correctly note that the courts of appeals have uniformly held that *non-willful* claims are not preempted by the PREP Act. Opp. 12-13. Far from weighing against review, Opp. 1, this fact illustrates that errors on the question presented are deeply entrenched and in need of correction.

As the petition explains, the courts of appeals have repeatedly made the same two errors in analyzing whether the PREP Act completely preempts non-willful claims. First, they wrongly require the existence of an exclusive federal *cause of action*, rather than any type of exclusive federal remedy. Pet. 26-27. Second, they incorrectly frame the question as whether a given claim is sufficiently meritorious to survive a motion to dismiss, rather than whether there is an *arguable* case for federal jurisdiction. Pet. 27-30. These repeated errors warrant this Court's intervention.

II. Respondents' Asserted Vehicle Problems Are Meritless.

Respondents lob numerous vehicle objections, but none poses an obstacle to this Court's review. The Ninth Circuit's decision cleanly tees up the complete-preemption issue free from any questions about whether Respondents' claims relate to the administration or use of a covered countermeasure, or

whether any of their claims satisfy the PREP Act's definition of willful misconduct, because the Ninth Circuit never considered those questions. Whoever ultimately has the better of the argument on the PREP Act's application to the facts here, the question presented—a pure question of law—warrants review.

A. Respondents' argument about the PREP Act's scope does not militate against review.

Respondents argue that this case is a poor vehicle to consider the complete-preemptive effect of the PREP Act because their claims do not involve the administration or use of any covered countermeasure. Opp. 17-18, 23-25. That is wrong.

First, the Ninth Circuit never evaluated Respondents' argument that their claims do not "relat[e] to … the administration" or "use … of a covered countermeasure," § 247d-6d(a)(1), such that the PREP Act does not apply. Pet. App. 15a-18a. That the question presented might not be outcome-determinative *if* the Ninth Circuit later rules in Respondents' favor on the scope of the PREP Act is not an obstacle to review here. Indeed, this Court routinely grants review despite a respondent's claim that any error is harmless or otherwise not outcome-determinative for reasons not addressed below. *See, e.g.*, *Badgerow v. Walters*, No. 20-1143; *Hemphill v. New York*, No. 20-637.

Moreover, Respondents are wrong on the merits. The PREP Act applies to all claims "relating to" the administration or use of a covered countermeasure, § 247d-6d(a)(1), also defined in the Act as any claim

having "a causal relationship with the administration … or use … of a covered countermeasure," § 247d-6d(a)(2)(B). And the Act covers "omissions" as well as affirmative conduct. *E.g.*, § 247d-6d(c)(1)(A), (e)(3)(A). HHS has thus explained that the PREP Act extends to claims involving *nonuse* of a given countermeasure. 85 Fed. Reg. 79190, 79197 (Dec. 9, 2020); Pet. 7.

In support of their contrary argument, Respondents overstate the holdings of the Fifth and Seventh Circuits. In *Manyweather v. Woodlawn Manor, Inc.*, the Fifth Circuit acknowledged that "a failure to use a covered countermeasure *could* relate to its use or administration." 40 F.4th 237, 246 (5th Cir. 2022) (discussing rationing a covered countermeasure "in limited supply"). And that case includes only two sentences of reasoning in support of its conclusion that the plaintiffs' claims did not involve the administration or use of any covered countermeasure. *Id.* Similarly, *Martin v. Petersen Health Operations, LLC* includes a single sentence stating in conclusory fashion that the PREP Act does not extend to the failure to use a covered countermeasure. 37 F.4th 1210, 1214 (7th Cir. 2022).

At least some of the allegations in Respondents' complaint are exactly those *Manyweather* suggested would trigger the PREP Act. For example, the complaint alleges that Glenhaven rationed the use of personal protective equipment, "only permitt[ing] each staff member to use one mask per eight-hour shift." Pet. App. 40a. And the complaint adds that "supply continued to be a problem" and "Glenhaven frequently ran out of masks and gowns." *Id.* In sum, Respondents allege that masks were "in limited supply"

and that Glenhaven was "purposeful[ly] allocati[ng]" their use, but nonetheless running out. *Manyweather*, 40 F.4th at 246.

B. Respondents' argument that their claims are not willful-misconduct claims does not foreclose review.

Respondents also argue that the question presented is not "implicated by this case" because their claims are not willful-misconduct claims as defined in the PREP Act. Opp. 21. Again, the Ninth Circuit did not consider whether Respondents raised a claim for willful misconduct. *Supra* 7. How a court would later rule on this issue does not bear on whether the question presented warrants this Court's review. *Supra* 7.

At any rate, Respondents are wrong about the question at this stage of the case. It is not whether Respondents have adequately pleaded a claim for willful misconduct under the PREP Act that would survive a motion to dismiss. Pet. 28-30; *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 503, 515-16 (2006). It is whether their federal claim is "colorable" rather than "wholly insubstantial and frivolous." *Arbaugh*, 546 U.S. at 513 & n.10. Respondents' federal claim would fail on the merits, but it is not so frivolous that federal courts lack jurisdiction over it.

Even meeting Respondents on their own terms, the complaint includes state-law claims specifically for "willful misconduct" and "elder abuse." Pet. App. 41a-46a. And the complaint alleges that Glenhaven "took intentional and cruel actions in its response" to COVID-19, Pet. App. 31a, including:

- Even after it became apparent in early 2020 that elderly nursing-home residents were "most vulnerable" to COVID-19, Glenhaven "stopp[ed] its staff from protecting … residents." Pet. App. 38a.

- Glenhaven received face masks from the fire department but "locked the masks in a cabinet" so no one could use them. Pet. App. 39a.

- Until the second week of April 2020, Glenhaven refused to administer COVID-19 tests because it knew there were infections in the facility and it did not want to have to report them. Pet. App. 40-41a; *see also* Pet. App. 32a (Glenhaven "sought to avoid scrutiny from local regulators").

In short, the question presented is not academic or "hypothetical." *Cf.* Opp. 20-23. It is squarely implicated here. The complaint alleges the elements of "a claim for willful misconduct under the PREP Act": "wrongful intent, knowledge that the act[s]" related to the use of covered countermeasures such as masks and diagnostic tests "lacked legal or factual justification, and disregard of a 'known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.'" *Maglioli*, 16 F.4th at 410 (quoting § 247d-6d(c)(1)(A)). To create federal subject-matter jurisdiction, that claim need only be "colorable." Pet. 28-30. Whether it will succeed on the merits is a different question from having subject-matter jurisdiction to address it. *Mata v. Lynch*, 576 U.S. 143, 150 (2015). Respondents' conclusory protests (at 22) that the complaint "d[oes] not plead the elements of PREP Act willful misconduct" cannot change what the complaint says.

C. This Court's intervention is needed before a split on the substance of the PREP Act develops.

Respondents also argue that because state courts have not yet split on the scope of PREP Act liability, any conflict is "[h]ypothetical," weighing against review. Opp. 25-26. This ignores the pressing need for uniformity in the application of the PREP Act.

To begin, it is not "speculative" to acknowledge the reality that 50 state-court systems cannot provide completely uniform guidance. As the Second Circuit has explained, allowing litigation to proceed "in the various state and federal courts would *inevitably* produce … inconsistent or varying adjudications of actions based on the same sets of facts." *In re WTC Disaster Site*, 414 F.3d 352, 378 (2d Cir. 2005) (emphasis added).

Moreover, Congress chose to require the "exclusive" federal cause of action under the PREP Act to proceed in a single federal district court. Pet. 22-23. It did so to ensure that persons covered by the Act have consistent and uniform guidance when responding to public health emergencies, and to reduce the risk of an outlier decision resulting in crushing liability. *Id.*

As the Chamber of Commerce and other amici have explained, the stakes of respecting Congress's choice are high. Around one-third of long-term-care residents in the country live in facilities at risk of closing due to financial strain, with the number of people likely to need long-term-care services expected to rise steeply in coming years. Chamber Br. 10-11. Liability

insurers have dramatically cut back on the extent of the medical professional liability coverage they offer. *Id.* at 14. And future emergencies may be right around the corner and require a robust response. Pet 35; Chamber Br. 15-16. During COVID-19, a strong volunteer response had medical professionals crossing state lines to help where the need was greatest. Atlantic Legal Found. Br. 20. But future volunteers might think twice about traveling to another state with the possibility of inconsistent judgments hanging over them.

In sum, failing to act now puts the healthcare industry, as well as the efficacy of future responses to public health emergencies, at risk.

D. This Court may not have other opportunities to review this important issue.

Respondents acknowledge that the question presented would not be reviewable absent Glenhaven's prior assertion of the federal-officer-removal statute. Opp. 31. But they maintain that, despite the circuits' rejection of the federal-officer-removal theory, defendant nursing homes will "continue to assert that theory as a basis for federal jurisdiction." Opp. 32. Respondents ignore the possibility of Rule 11 sanctions. As more circuits, and more cases within a circuit, reject federal-officer removal, parties will become increasingly unlikely to raise it. And the pool of possible vehicles to address the complete-preemption question will dry up because those remands will not be appealable. *Cf.* 28 U.S.C. § 1447(d). Although a handful of appeals raising similar issues to this case remain

pending in other circuits, Opp. 31, there is no guarantee that those parties will seek further review or the cases will provide appropriate vehicles to review the question presented. Thus, if this Court does not grant review here, PREP Act claims might soon be relegated to state courts without this Court ever weighing in on the issue.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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