No. _____

In the Supreme Court of the United States

OXNARD MANOR, LP; BERTIE KRIEGER; SHLOMO RECHNITZ; OXNARD HEALTHCARE & WELLNESS CENTRE, LP,
Petitioners,

v.

ANNA SIGALA; ANTHONY SIGALA,
Respondents.

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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QUESTION PRESENTED

"[W]hen a federal statute wholly displaces" a plaintiff's "state-law cause of action through complete pre-emption," the defendant may remove the case to federal court even though "the complaint does not" purport to "allege a federal claim." *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6, 8 (2003).

In the face of a public health emergency, the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, empowers the Secretary of the Department of Health and Human Services to designate countermeasures to assist in the diagnosis, prevention, treatment, and containment of disease. § 247d-6d(b). The Act grants immunity from suit and liability for certain "covered person[s]" on the front lines responding to public health emergencies for claims relating to the administration or use of a covered countermeasure, § 247d-6d(a)(1); creates an exclusive federal cause of action for claims of willful misconduct, § 247d-6d(d); and establishes a no-fault victim compensation fund for serious injury or death, § 247d-6e. There is a circuit split between the Third, Second, Fifth, and Eighth Circuits on one side and the Ninth Circuit on the other as to whether the Act completely preempts state-law claims for willful misconduct, but they and other circuits hold that the Act does not completely preempt other state-law claims, such as claims of negligence.

The question presented is:

Does the PREP Act completely preempt state-law claims against a covered person relating to the

administration or use of a covered countermeasure, such that the claims may be removed to federal court?

PARTIES TO THE PROCEEDING

Petitioners Oxnard Manor, LP; Bertie Krieger; Shlomo Rechnitz; Oxnard Healthcare & Wellness Centre, LP were defendants in the Central District of California and the appellants in the United States Court of Appeals for the Ninth Circuit. Respondents Anna Sigala and Anthony Sigala were plaintiffs in the Central District of California and respondents in the United States Court of Appeals for the Ninth Circuit.

CORPORATE DISCLOSURE STATEMENT

Petitioners Oxnard Manor, LP and Oxnard Healthcare & Wellness Centre, LP have no parent companies, and no publicly held corporation owns 10% or more of their respective stock.

STATEMENT OF RELATED PROCEEDINGS

This case arises from and is related to the following proceedings in the Central District of California and in the United States Court of Appeals for the Ninth Circuit:

- *Sigala v. Oxnard Manor, LP*, No. 56-2021-00561668-CU-PO-VTA, Los Angeles County Superior Court;
- *Sigala v. Oxnard Manor, LP*, No. 2:22-cv-02003-MEMF-MARx (C.D. Cal.), order issued June 27, 2022;
- *Sigala v. Oxnard Manor, LP*, No. 22-55710 (9th Cir.), order issued Oct. 12, 2023; order denying petition for rehearing issued Dec. 5, 2023.

There are no other proceedings in state or federal trial or appellate courts directly related to this

case within the meaning of this Court's Rule 14.1(b)(iii).

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PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully seeks a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The order of the Central District of California is unpublished but can be found at 2022 U.S. Dist. LEXIS 114623 and is reproduced as Appendix B. The opinion of the United States Court of Appeals for the Ninth Circuit is unpublished but can be found at 2023 U.S. App. LEXIS 27112 and is reproduced as Appendix A. The order denying the petition for rehearing in the United States Court of Appeals for the Ninth Circuit is unpublished but can be found at 2023 U.S. App. LEXIS 32115 and is reproduced as Appendix C.

JURISDICTION

The district court's remand order was appealable under 28 U.S.C. § 1447(d), as the case was removed in part pursuant to the federal-officer removal statute, § 1442. *See BP P.L.C. v. Mayor of Balt.*, 141 S. Ct. 1532, 1538 (2021). The Ninth Circuit entered judgment on October 12, 2023 and denied rehearing on December 5, 2023. This Court has jurisdiction under § 1254(1).

STATUTORY PROVISIONS INVOLVED

42 U.S.C. § 247d-6d is reproduced as App. D, and § 247d-6e is reproduced as App D.

INTRODUCTION

This case presents critically important questions about the interpretation of a key weapon in this country's fight against pandemics and bioterrorism: the PREP Act of 2005, 42 U.S.C. §§ 247d-6d, 247d-6e. One primary feature of the Act is limiting liability for those on the front lines responding to public health emergencies. Specified responders enjoy absolute immunity from suit and liability related to certain actions taken to protect public health. The only exception to immunity is for a claim for willful misconduct, which must be brought in a special three-judge federal district court. All other claims must be brought via a federally administered no-fault victim's compensation fund.

Before the COVID-19 pandemic, the PREP Act was largely untested. But the pandemic's death toll has yielded a tsunami of litigation with no end in sight. Throughout the country, plaintiffs have filed lawsuits in state courts, alleging mismanagement and misconduct in failing to stop the spread of COVID-19. Defendants--often hospitals, nursing homes, and other long-term-care facilities--have sought to remove these suits to federal court, explaining that the PREP Act is a complete-preemption statute that confers exclusive jurisdiction on federal courts. The courts of appeals have split on whether the PREP Act completely preempts claims for willful misconduct and they have erroneously held that the PREP Act does not preempt other claims.

This Court's review is urgently needed to relieve front-line responders from the crushing burden of COVID-19-response litigation that the PREP Act

was designed to prevent. And it is urgently needed before the next pandemic puts them in the position of just shutting down to avoid such liability. The courts of appeals have frustrated Congress's carefully calibrated response to public health emergencies, designed to balance compensating victims of pandemics and bioterrorism against ensuring that front-line responders like doctors and nurses can deal with unprecedented crises without the threat of litigation and massive damages awards. The PREP Act sought to ensure consistent, uniform decisions on the scope of immunity--and liability. But that uniformity depends on claims against front-line responders being litigated in federal court and specifically in the court that Congress designated.

If this Court does not intervene, fifty different state-court systems could adopt fifty different interpretations of the Act, depriving front-line responders of the uniform protections Congress promised them. The Court should grant review now to conclusively resolve the important question of complete preemption before front-line responders face ruinous liability in state court, impeding their ability to respond to public health emergencies and before the next pandemic arises to place them in the position of shutting down rather than facing that liability.

STATEMENT OF THE CASE

A. The PREP Act was enacted to ensure an immediate and robust response to public health crises.

The PREP Act was designed to advance the "important national security priority" of "[p]rotecting the American public against acts of bioterrorism like the 2001 anthrax attacks and natural disease outbreaks such as … the avian flu." 151 Cong. Rec. at 30725. Its overarching goal was to ensure that, upon the emergence of a novel public health threat, the private sector could respond quickly to neutralize the threat. *Id.* The PREP Act assumed that governmental entities--federal, state, and local--would have to cooperate with each other and with private parties. Congress understood that saving lives in a pandemic or bioterror attack would require quick and decisive action in difficult circumstances, based on limited and changing information. *Id.* at 30726.

It thus sought to ensure that the "climate of apprehension" regarding "litigation exposure" would not "chill[] the necessary private sector activity" to develop and administer much-needed countermeasures. *Id.* at 30727. Critical to achieving that goal was "liability[] and compensation reform," *id.* at 30726, to address "the growing burden of litigation" in the healthcare industry, which leaders feared would leave the country "vulnerable in the event of a pandemic," Pres. Bush, *NIH Remarks* (Nov. 1, 2005), https://tinyurl.com/2p9889f8.

The PREP Act's liability-limiting provisions are inoperative until the Secretary of the Department of

Health and Human Services (HHS) declares "a public health emergency." 42 U.S.C. § 247d 6d(b)(1). The declaration identifies the specific health threat and designates "covered countermeasures" recommended to respond to that threat. *See* § 247d-6d(b)(1), (2)(A). The statutory definition of "covered countermeasure" is broad. *See* § 247d-6d(i)(1). It includes not just measures "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" but also measures to "limit the harm such pandemic or epidemic might otherwise cause." § 247d-6d(i)(7)(A)(i).

Once the Secretary has declared a public health emergency and specified covered countermeasures, the PREP Act's four-pronged statutory scheme kicks in, providing: (1) immunity from suit and liability for those who administer covered countermeasures; (2) one "sole exception" to this immunity, which is an exclusive federal cause of action for willful misconduct; (3) a no-fault victim compensation fund; and (4) express preemption of all state laws inconsistent with the PREP Act.

Immunity. PREP Act immunity applies to any "covered person." That term is broadly defined to include anyone "authorized to prescribe, administer, or dispense … countermeasures." § 247d 6d(i)(2)(B)(iv), (i)(8). It also encompasses "program planners," meaning anyone "who supervised or administered a program with respect to the administration . . . or use of . . . a covered countermeasure," or "provides a facility to administer or use a covered countermeasure." § 247d-6d(i)(2)(B)(iii), (i)(6).

The immunity Congress granted is expansive. A covered person is "immune from suit and liability

under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." § 247d-6d(a)(1). And that immunity "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." § 247d-6d(a)(2)(B). Under this broad definition, not administering a covered countermeasure--for example, deciding which patients should have priority in receiving a scarce diagnostic test or mask--falls within the scope of PREP Act immunity. *See* 85 Fed. Reg. 79190, 79197 (Dec. 9, 2020).

Exclusive federal cause of action. The PREP Act's expansive immunity provision has just one exclusion: "[T]he sole exception to the immunity from suit and liability of covered persons . . . shall be for an exclusive Federal cause of action . . . for death or serious physical injury proximately caused by willful misconduct," as statutorily defined.[1] § 247d-6d(d)(1). The Act describes in detail how such a claim is to be adjudicated. *See generally* § 247d-6d(e). It must be brought in the U.S. District Court for the District of Columbia, § 247d-6d(e)(1), and be heard by "a panel of three judges," § 247d-6d(e)(5). The complaint must be verified using a particular procedure, § 247d-

[1] 1 The statute defines "willful misconduct" as "an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." § 247d-6d(c)(1)(A). It specifies that willful misconduct is "a standard for liability that is more stringent than a standard of negligence in any form or recklessness." § 247d-6d(c)(1)(B).

6d(e)(4), and must plead enumerated elements "with particularity," § 247d-6d(e)(3).

No-fault victim compensation fund. The PREP Act provides a remedy for any individuals who cannot show willful misconduct. Congress created a victim compensation fund--the Covered Countermeasure Process Fund--"for purposes of providing timely, uniform, and adequate compensation . . . for covered injuries directly caused by the administration or use of a covered countermeasure." § 247d-6e(a) (defining "covered injury" as "serious physical injury or death"). The Fund's procedures, eligibility requirements, and compensation are drawn from those governing the pre-existing smallpox vaccine injury compensation fund. *See, e.g.,* § 247d-6e(b)(4) (citing § 239a *et seq.*). The fund is the "exclusive" remedy "for any claim or suit [the PREP Act] encompasses," other than "a proceeding under section 247d-6d of this title"--i.e., a federal claim for willful misconduct. § 247d-6e(d)(4).

Preemption. The PREP Act contains an express preemption provision that broadly preempts a "State or political subdivision of a State" from "establish[ing], enforc[ing], or continu[ing] in effect with respect to a covered countermeasure[,] any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this section." § 247d-6d(b)(8). This means that no state can provide another cause of action beyond the exclusive federal remedy for willful misconduct, or a cause of action to supplement claims covered by the compensation fund.

That the foregoing scheme completely preempts state law was apparent at the time of the PREP Act's

enactment. In fact, Dean Erwin Chemerinsky cited complete preemption as a reason he opposed the bill. *See* 151 Cong. Rec. at 30735 (citing *Beneficial*, 539 U.S. at 8).

B. COVID-19 devastates the United States.

When the President declared COVID-19 a national emergency in mid-March 2020, the virus had infected about 1,600 people across forty-seven states. 85 Fed. Reg. 15337, 15337 (Mar. 18, 2020). A few days later, the HHS Secretary issued his own declaration of a "public health emergency." 85 Fed. Reg. 15198, 15201 (Mar. 17, 2020). That declaration activated the PREP Act's immunity from suit and liability for covered persons administering or using covered countermeasures, including drugs, diagnostics, or "any other Device . . . used to treat, diagnose, cure, prevent, or Mitigate COVID-19, or [its] transmission." *Id.* At 15202. Secretaries of HHS across two administrations now have amended the declaration ten times since it first issued, each time reaffirming the necessity of the Declaration, expanding its scope, and clarifying different aspects of the PREP Act's application as the pandemic evolved. *See* 87 Fed. Reg. 982, 983 (Jan. 7, 2022) (detailing prior amendments).

COVID-19 has now killed more than one million people in the United States. CDC, *COVID Data Tracker* (September 14, 2023), https://tinyurl.com/34jku6sc. About 75% of the victims have been over the age of 65. CDC, Weekly Updates by Select Demographic and Geographic Characteristics: Sex and Age (September 14, 2023), https://tinyurl.com/3eaave68.

C. Ms. Sigala dies of COVID-19.

Anna Sigala was a resident at the Oxnard Manor nursing home when the COVID-19 pandemic began spreading in California. Ms. Sigala contracted COVID-19 sometime before January 2021. As is discussed in more detail below, little was known at the time about how to treat or prevent COVID-19. And there were severe shortages of masks, gowns, and other personal protective equipment, as well as diagnostic tests, in the earliest days of the pandemic. It is in this context, that the complaint alleges that petitioners did not adopt certain countermeasures to prevent transmission of COVID-19 within the nursing home.

The allegations, which are taken as true at this juncture, are that petitioners failed to fulfill their duties to Ms. Sigala by failing to provide training and sufficient levels of staffing and that petitioners failed to provide infection control.

The complaint alleges that on an unspecified date, Ms. Sigala tested positive for COVID-19 and was placed in the designated COVID-19 unit before she died from respiratory infection on January 3, 2021. He was transferred to a hospital on April 19, 2020 and died several days later.

D. The Ninth Circuit holds that the PREP Act does not completely preempt state law and remands COVID-19 litigation against petitioners to state court.

Ms. Sigala's son filed a complaint in California state court. He asserted four state-law causes of action: (1) statutory elder abuse/neglect; (2) violation of

resident rights; (3) negligence; and (4) wrongful death. He also alleged that petitioners acted "willfully." Petitioners removed to federal court in the Central District of California.

Petitioners cited multiple grounds for removal, including the federal-officer removal statute, 28 U.S.C. § 1442. Most relevant here, petitioners argued for removal under the doctrine of complete preemption. Although ordinary defensive preemption is not grounds for removal, "[w]hen [a] federal statute completely pre-empts the State-law cause of action, a claim which comes within the scope of that [federal] cause of action, even if pleaded in terms of state law, is in reality based on Federal law" and the "claim is then removable." *Beneficial,* 539 U.S. at 8. In an unpublished order, the district court rejected petitioners' arguments and remanded the case to state court. *See* App. B.

On appeal, the Ninth Circuit affirmed the remand order in a cursory memorandum based on its earlier decision in *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022). App. A. Because the memorandum does not diverge from *Saldana*, petitioners will focus on that opinion in this petition.[2]

The *Saldana* court first focused on whether "congress provide[d] a substitute cause of action." 27 F.th at 687-88. The PREP Act does provide an

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[2] The Ninth Circuit earlier disposed of twenty-five cases in twenty-five nearly identical memoranda on June 21, 2023, in reliance on the opinion in *Saldana*. *See Court Rejects Like Contentions in 25 Separate Appeals*, Metro. News-Enter., Jun. 22, 2023, http://www.metnews.com/articles/2023/noexamination_062223.htm.

exclusive federal cause of action. 42 U.S.C. § 247d-6d(d). But in the Ninth Circuit's view, that "specifically defined" federal cause of action was too limited to find complete preemption, because it is available only for claims of "willful misconduct." 27 F.th at 688 (recall that other claims are barred entirely). And the court concluded that the no-fault victim compensation fund for non-willful-misconduct claims arising under the act was also insufficient to show complete preemption because it was not formally "an exclusive federal cause of action" to be litigated in court but rather an administrative fund. *Id.*

The Ninth Circuit proceeded to consider the alternative argument that, at minimum, the PREP Act completely preempted the claim for willful misconduct. 27 F.th at 688. This would have established federal-question jurisdiction over some of the claims and triggered supplemental federal jurisdiction over the remaining claims. *See* 28 U.S.C. § 1367(a). Nevertheless, the Ninth Circuit refused to find complete preemption as to the willful misconduct claim. 27 F.th at 688. It held that determining whether the "cause of action under state law for willful misconduct" was completely preempted would require evaluating "[w]hether any of the conduct alleged in the complaint fits the statute's definitions." *Id.* Without further explication, the Ninth Circuit held that the need to determine whether a particular claim is completely preempted somehow showed that the statute did not "entirely supplant[] state law causes of action" as to any claim. *Id.* (emphasis omitted).

REASONS FOR GRANTING THE PETITION

I. The Circuits Are Split on Whether the PREP Act Completely Preempts Willful Misconduct Claims.

"A civil action filed in a state court may be removed to federal court if the claim is one 'arising under' federal law." *Beneficial,* 539 U.S. at 6 (quoting 28 U.S.C. § 1441(b)). "[A]bsent diversity jurisdiction," plaintiffs can generally keep their cases in state court by pleading only state-law claims. *Id.* But the complete-preemption doctrine puts a twist on the familiar well-pleaded complaint rule. If a federal statute "wholly displaces [a] state-law cause of action," then any "claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law." *Id.* at 8. And the claim is therefore "removable" as "'aris[ing] under' federal law." *Id.* In other words, complete preemption "converts an ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule." *Metro. Life Ins. Co. v. Taylor,* 481 U.S. 58, 65 (1987).

Here, the Ninth Circuit split from the Third Circuit when it held that the PREP Act does not completely preempt state-law claims for willful misconduct related to the use of covered countermeasures during a public health emergency. And the Ninth Circuit's decision is wrong. At a minimum, this Court should grant review to resolve the split and correct the Ninth Circuit's erroneous decision. *See Beneficial*, 539 U.S. at 5-6 (granting review to resolve a split between two circuits).

A. The Third Circuit correctly recognized that the PREP Act completely preempts claims for willful misconduct.

"[T]his Court has found complete pre-emption" when a federal statute "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. In *Maglioli v. Alliance HC Holdings LLC*, the Third Circuit held that the PREP Act "easily satisfies the standard for complete preemption" with respect to willful-misconduct claims. 16 F.4th 393, 409 (3d Cir. 2021).

First, *Maglioli* recognized that "[t]he PREP Act unambiguously creates an exclusive federal cause of action" for such claims. 16 F.4th at 409. That conclusion flows directly from the Act's text, which says that the "sole exception to the immunity from suit and liability of covered persons . . . shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d)(1). That statutory phrase--"exclusive federal cause of action"--in fact comes word-for-word from *Beneficial*, 539 U.S. at 10. No other statute in the entire United States Code uses it.

As the Third Circuit observed, the PREP Act makes an even stronger case for complete preemption than the other statutes this Court has held to completely preempt state law. *Maglioli*, 16 F.4th at 408. Those statutes--§ 301 of the Labor Management Relations Act, § 502(a) of ERISA, and § 86 of the National Bank Act--"unambiguously created causes of action"

but "did not unambiguously make them exclusive." *Id.* at 409. Instead, this Court inferred exclusivity from congressional intent. *Id.* But the PREP Act's clear statutory language makes any inference unnecessary. *Id.* Indeed, it is hard to imagine a better indicator that "Congress has clearly manifested an intent to make causes of action . . . removable to federal court," *Metro. Life*, 481 U.S. at 66, than incorporating language in the statute's text drawn directly from this Court's complete-preemption jurisprudence.

Second, *Maglioli* explained that the PREP Act "also sets forth procedures and remedies governing that cause of action." 16 F.4th at 409 (brackets omitted), quoting *Beneficial*, 539 U.S. at 8. To name just a few:

- "A plaintiff asserting a willful-misconduct claim must first exhaust administrative remedies," *Id.* (citing § 247d-6e(d)(1));
- Then, a claim can be brought "only in the U.S. District Court for the District of Columbia," *Id.* (citing § 247d-6d(e)(1)); and
- The federal complaint "must 'plead with particularity each element of [the] claim,'" *Id.* (quoting § 247d-6d(e)(3)).

In short, *Maglioli* concluded that the complete preemption "analysis is straightforward" for claims of willful misconduct. 16 F.4th at 410. "Congress said the cause of action for willful misconduct is exclusive" of state remedies, "so it is." *Id.*

Indeed, *Maglioli* only affirmed the district court's remand order because, unlike here, the

plaintiffs did not allege willful misconduct against the defendant nursing homes. 16 F.4th at 410-11.

Other circuits have followed *Maglioli* in finding willful misconduct completely preemptive but remanding because the plaintiffs in those cases only alleged negligence. *See Cagle v. NHC Healthcare-Maryland Heights, LLC*, 78 F.4th 1061, 1067 (8th Cir. Aug. 28, 2023) (no allegations of willful misconduct); *LeRoy v. Hume,* 2023 U.S. App. LEXIS 8824, *6-11 (2d Cir. Apr. 13, 2023) (remand only because allegation of "willful negligence" was merely gross negligence not "willful misconduct"); *Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 60-61 (2d Cir. 2023) (no allegations of willful misconduct); *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 245 n.6 (5th Cir. 2022) (same); *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 586-87 (5th Cir. 2022) ("[a]ssum[ed] that the willful-misconduct cause of action is completely preemptive," but held plaintiff's negligence claims not willful misconduct).

B. The Ninth Circuit, diverging from the Third Circuit, wrongly found no complete preemption for willful misconduct claims.

The Ninth Circuit, like the Third Circuit, recognized that, at a minimum, the "text of the [PREP Act] shows that Congress intended a federal claim . . . for willful misconduct claims." *Saldana*, 27 F.4th at 688. But the Ninth Circuit parted ways with the Third Circuit in holding without qualification that "the PREP Act is not a complete preemption statute." *Id.*

Specifically, the Ninth Circuit held that the PREP Act did not completely preempt any state-law

claims--including claims for willful misconduct--because the PREP Act did not "entirely supplant[]" all state-law claims, such as "the [] other causes of action for elder abuse, custodial negligence, and wrongful death." *Saldana*, 27 F.4th at 688 (emphasis omitted). This deeply flawed holding cannot be reconciled with *Maglioli*, this Court's complete preemption cases, or the PREP Act's language.

The Ninth Circuit offered almost no reasoning in support of its holding that the PREP Act would have to completely preempt all state-law claims in order to completely preempt claims alleging willful misconduct. The court first opined that "[w]hether [a] claim is preempted by the PREP Act turns on whether any of the conduct alleged in the complaint fits the statute's definitions for such a claim." *Saldana*, 27 F.4th at 688. It then suggested that the most that could be said about the state-law willful-misconduct claim was that it "*may* be preempted" by the PREP Act. *Id.* (emphasis in original). The Ninth Circuit apparently viewed any individualized preemption analysis of a particular state-law cause of action as inconsistent with the complete-preemption inquiry; it therefore found no complete preemption of willful-misconduct claims on the ground that the PREP Act did not "*entirely supplant*[] . . . the [] other [state law] causes of action." *Id.*

That all-or-nothing approach is not how federal jurisdiction works. In *Beneficial*, this Court held that the defendant banks properly removed the case to federal court where the National Bank Act completely preempted only the plaintiffs' purported "state-law claim of usury," and not their remaining claims for

"intentional misrepresentation" and "breach of fiduciary duty," among other things. 539 U.S. at 11.

The Ninth Circuit's reasoning is flatly inconsistent with *Beneficial*. In mandating that a willful misconduct claim is exclusively a federal cause of action--which is precisely what the PREP Act says, § 247d-6d(d)--Congress "transform[ed]" what might have otherwise been a state law claim "into a federal action." *El Paso Nat. Gas Co. v. Neztsosie*, 526 U.S. 473, 484 (1999). A defendant has a right to have a federal claim litigated in federal court, 28 U.S.C. § 1441(a), whether or not it is accompanied by other claims, *Beneficial*, 539 U.S. at 11. The Ninth Circuit erred in depriving petitioners of that right.

This right is especially important because when one "claim in the complaint is removable," the defendant can remove related state-law claims that would not be independently removable "through the use of the supplemental jurisdiction statute, 28 U.S.C. § 1367(a)." *Beneficial*, 539 U.S. at 8 n.3. Here, that would have permitted petitioners to litigate in federal court all the claims against it. *See Cavallaro v. UMassMemorial Healthcare, Inc.*, 678 F.3d 1, 5 (1st Cir. 2012) ("on a minimum reading of the complete preemption cases, one or more of plaintiffs' claims are removable; any such claim makes the case removable, and even the claims not independently removable come within the supplemental jurisdiction of the district court," citations omitted).

The Ninth Circuit thus erred, at a minimum, in holding contrary to the Third Circuit that petitioners could not remove this case unless the PREP Act completely preempted every claim against petitioners.

This Court should grant review to resolve the split in authority.

II. The Courts of Appeals' Errors Reveal a Need for Guidance on the Proper Test for Complete Preemption.

A. Under the proper standard, the PREP Act completely preempts state-law negligence claims.

The Third Circuit got the complete preemption answer right for state-law claims that sound in willful misconduct. But it proceeded to hold that the PREP Act does not completely preempt claims that fall short of the willful-misconduct standard in § 247d-6d(d), particularly negligence claims. Other circuits reached the same conclusion, while the Ninth Circuit held that the PREP Act does not completely preempt any claims. However, the text and structure of the PREP Act, taken as a whole, reveal Congress's intent to funnel all claims relating to the use or administration of covered countermeasures to federal court or to the Act's compensation fund, leaving no role for state courts.

1. The PREP Act creates exclusive federal remedies for all claims related to the administration or use of a covered countermeasure.

The courts of appeals have thus far tripped over the lack of an explicit cause of action in the PREP Act for claims of negligence related to covered countermeasures. *See, e.g.*, *Saldana*, 27 F.4th at 688. The PREP Act does not establish a federal cause of action for non-willful-misconduct claims, but it does

establish an exclusive federal remedy sufficient to trigger complete preemption. It eliminates state-law claims and permits would-be plaintiffs to vindicate their rights exclusively under federal law via the compensation fund.

The exclusivity of the federal remedies under the PREP Act begins with the Act's grant of immunity from suit, as well as liability, for covered persons. § 247d-6d(a)(1). The immunity provision is then buttressed by the express-preemption provision, § 247d6d(b)(8)(A), which bars any state "law or legal requirement"--including a state common-law duty, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008)--that is "different from, or is in conflict with," the PREP Act. "[T]he sole exception to th[at] immunity" is the "exclusive Federal cause of action" for "willful misconduct." § 247d-6d(d)(1). "[T]here is, in short, no such thing as a state-law claim" for losses related to the use or administration of covered countermeasures. Any cause of action is either federal or barred by immunity. *Beneficial*, 539 U.S. at 11.

Nevertheless, Congress chose to create an exclusive remedy for non-willful-misconduct claims: the compensation fund. § 247d-6e(a). Congress expressly said that "[t]he remedy provided by [§ 247d-6e(a)] *shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses,* except for a [willful misconduct claim] under section 247d-6d of this title." § 247d-6e(d)(4) (emphasis added). Thus, the PREP Act expressly designates the compensation fund as the *exclusive remedy* for non-willful-misconduct claims under the PREP Act.

The compensation fund aims to eliminate litigation and "provide[] timely, uniform, and adequate compensation to eligible individuals for covered injuries" without burdening the front-line responders with lawsuits and possible adverse damages awards." § 247d-6e(a). Allowing plaintiffs to pursue state-law claims for damages in state court would defeat the compensation fund's purpose.

2. The PREP Act requires that claims related to the administration or use of covered countermeasures be adjudicated in federal court.

The PREP Act's jurisdictional provisions reinforce the conclusion that the Act completely preempts state-law claims for negligence.

First, the Act gives the District Court for the District of Columbia "exclusive federal jurisdiction" over any claims arising under § 247d-6d(d), the willful misconduct cause of action. § 247d-6d(e)(1). The purpose of funneling all litigation to a single federal district court (with appeals heard by a single federal court of appeals) is "consistency." *In re WTC Disaster Site*, 414 F.3d 352, 377 (2d Cir. 2005). Requiring all litigation of the PREP Act's exclusive federal cause of action to occur in the District Court for the District of Columbia would make little sense if plaintiffs could file claims in state court. State courts evaluating whether the claims evaded the standard for willful misconduct "would inevitably produce" precisely the inconsistency Congress sought to avoid when it channeled all litigation to a single court. *Id.* at 378.

Where Congress vests exclusive jurisdiction in a particular district court, "giv[ing] effect to that intent" requires interpreting the jurisdictional provision "as authorizing the removal of the action to the federal court." *In re WTC Disaster Site*, 414 F.3d at 375. That is why the Second Circuit held that the Air Transportation Safety and System Stabilization Act of 2001, which vested exclusive jurisdiction in the Southern District of New York for suits for damages arising from the September 11 terrorist attacks, "clearly evinced [Congress's] intent that any actions on such claims initiated in state court would be removable to that federal court." *Id.* at 380. The same is true of the PREP Act.

Second, the PREP Act says that the D.C. Circuit "shall have jurisdiction of an interlocutory appeal by a covered person . . . of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of" subsection (a)'s "immunity from suit." § 247d-6d(e)(10).

This provision contemplates that defendants will file motions to dismiss and motions for summary judgment asserting immunity, including by arguing that a plaintiff's claims do not meet the definition of willful misconduct set out in the PREP Act and so the exception to immunity does not apply. In other words, the PREP Act contemplates disputes about whether and how the Act applies. And importantly for complete preemption purposes, this provision mandates that these disputes be litigated and appealed *exclusively in federal court. See Neztsosie*, 526 U.S. at 484-85 (complete preemption provides "a federal forum . . . both for litigating a . . . claim on the merits and for

determining whether a claim falls [within the federal cause of action] when removal is contested").

Consider what happens when a plaintiff is allowed to bring negligence claims in state court. Imagine the defendant moves to dismiss, arguing that the PREP Act's immunity provision bars the claims. The state court denies the motion to dismiss, finding that, while the question is close, the plaintiff's claims do not relate to the administration of a covered countermeasure and immunity therefore does not apply. Under the PREP Act, the defendant has the right to an interlocutory appeal to the D.C. Circuit from that "order denying a motion to dismiss . . . based on an assertion of the immunity from suit conferred by [the PREP Act]." § 247d-6d(e)(10). The D.C. Circuit, however, would lack jurisdiction to hear that appeal. Under federalism, only this Court may review a state-court judgment. 28 U.S.C. § 1257. Congress has not "empowered" any other federal courts "to exercise appellate authority to reverse or modify a state-court judgment." *Exxon Mobil Corp. v. Saudi Basic Indus. Corp.*, 544 U.S. 280, 284 (2005) (internal quotation marks omitted).

For there to be an immediate appeal to the D.C. Circuit from an adverse immunity decision, the case must already be in federal court, which is decisive evidence of congressional intent for complete preemption. All this confirms that the PREP Act displaces both state law and state courts, requiring any claim for redress to be brought in a federal forum--judicial for willful-misconduct claims and administrative for non-willful claims. In doing so, Congress completely preempted state-law claims covered by the PREP Act.

Thus, the proper approach to determining whether a plaintiff's claim is completely preempted is to ask whether the plaintiff states a colorable claim that arises under--or "comes within the scope" of--the PREP Act's exclusive cause of action. *Beneficial*, 539 U.S. at 8. Here, that means deciding whether there is a non-frivolous argument that the PREP Act applies, i.e., that a plaintiff's claim is "for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," § 247d-6d(a)(1)--not whether the claim sufficiently alleges the elements of willful misconduct. If a claim can colorably be said to be for loss relating to the administration of a covered countermeasure, it necessarily arises under § 247d-6d(d), because that is the exclusive cause of action allowed for such loss and the sole exception to immunity from suit. The courts of appeals' holdings to the contrary disrupt the congressional design of a "unified whole-of-nation response to the COVID-19 pandemic" that would give the country the best chance of defeating a national public health emergency. 87 Fed. Reg. at 983.

B. The courts of appeals have wrongly read *Beneficial* to require an exclusive cause of action and a merits inquiry into the viability of a plaintiff's claims.

The circuits' conclusions on complete preemption rest on two erroneous rationales.

1. The first error is misconstruing *Beneficial* to require an exclusive federal cause of action for complete preemption when, in fact, an exclusive cause of action is only one way to show that a claim arises

under federal law. *See, e.g.*, *Saldana*, 27 F.4th at 688; *Maglioli*, 16 F.4th at 407-08; *Mitchell*, 28 F.4th at 586-87. This Court has never held that an exclusive federal cause of action is a necessary prerequisite to complete preemption. *Beneficial* observed only that it happened to be the fact pattern "[i]n the two categories of cases where this Court ha[d] found complete preemption." 539 U.S. at 8.

The key inquiry is instead whether the federal statute transforms the claim into one that "arises under" federal law, therefore permitting removal. *Beneficial*, 539 U.S. at 8 (discussing what is now 28 U.S.C. § 1441(a)). To be sure, creating an "exclusive [federal] cause of action," is one way Congress could signal that a claim arises under federal law. 539 U.S. at 8. So too is enacting a statute saying "expressly" that "a state claim may be removed to federal court." *Id.* But the same goes for a federal statute that both "wholly displaces the state-law cause of action," *id.*, and "create[s] a federal remedy . . . that is exclusive," *id.* at 11 (discussing the National Act). The combination of displacing state law and providing a federal means of redress federalizes the claim, such that a request for relief is "purely a creature of federal law" and "necessarily arises under federal law." *Id.* at 7 (quotation marks omitted).

There is no doctrinal reason why Congress must create a federal cause of action rather than a non-litigation federal remedy--for example, granting broad immunity from suit to foreclose litigation and creating a federal compensation fund that provides the exclusive remedy for those claims. The administrative or judicial character of an exclusive federal

remedy is immaterial so long as the claim can now be said to "arise[] under" federal law. *Id.* at 8. And a claim to an exclusive federal administrative remedy arises under federal law just as much as a claim pressed in court. In either situation, "there is, in short, no such thing as a state-law claim." *Id.* at 11. The fact that a plaintiff's suit, once removed, might be dismissed because federal law requires pressing that federal claim in a federal administrative proceeding rather than a federal lawsuit goes to the claim's merit, not to whether the claim has been transformed such that it is now federal in nature.

2. The courts have compounded the first error by interpreting the supposed "exclusive cause of action" inquiry to require a determination that the plaintiff has stated a meritorious claim for willful misconduct that mirrors the elements of the exclusive federal cause of action. By way of example, the decision below rejected complete preemption across the board because it concluded that the state-law claims for elder abuse, custodial negligence, and wrongful death did not match the PREP Act's standard for willful-misconduct claims. *Saldana*, 27 F.4th at 688; *Maglioli*, 16 F.4th at 410-11 (rejecting complete preemption for negligence claims because the plaintiffs did not plausibly allege wrongful intent); *Mitchell*, 28 F.4th at 586-87 (holding that the plaintiff's negligence claims "could not" satisfy the PREP Act's "stringent" standard). That is wrong for multiple reasons.

To start, that analysis contradicts *Aetna Health Inc. v. Davila*, where this Court expressly rejected the argument that an exclusive federal cause of action

completely preempts "only strictly duplicative state causes of action[s]." 542 U.S. 200, 216 (2004). *Davila* explained that "Congress' intent to make the ERISA civil enforcement mechanism exclusive would be undermined if state causes of action that supplement the ERISA § 502(a) remedies were permitted, even if the elements of the state cause of action did not precisely duplicate the elements of an ERISA claim." *Id.* (emphasis added). In short, this Court has never required a one-to-one match of elements for there to be complete preemption.

Moreover, the opinions that take this approach read as though they are resolving a kind of reverse motion to dismiss. If the plaintiff's state-law claims would not be cognizable under the exclusive federal cause of action--here, if the plaintiff has not plausibly alleged with particularity all the elements of a claim for willful misconduct--then the plaintiff wins and gets a remand to state court. That rule creates perverse incentives for litigants, allowing a creative plaintiff to evade the exclusive federal cause of action simply by flouting the PREP Act's detailed pleading requirements. *See* § 247d-6d(e).

The circuits have fallen into a common trap, collapsing "two sometimes confused or conflated concepts: federal-court 'subject-matter' jurisdiction over a controversy; and the essential ingredients of a federal claim for relief." *Arbaugh v. Y&H Corp.,* 546 U.S. 500, 503 (2006). Subject-matter jurisdiction exists whenever a plaintiff pleads a "colorable" federal claim, meaning one that is not "'wholly insubstantial and frivolous.'" *Id.* at 513 & n.10, quoting *Bell v. Hood*, 327 U.S. 678, 682-83 (1946). Importantly, not every

colorable claim will win on the merits or even make it past the pleading stage. That is because "[t]he jurisdictional question"--"whether the court has power to decide" the claim--is "distinct from the merits question" of whether the claim will succeed. *Mata v. Lynch*, 576 U.S. 143, 150 (2015). It is settled law "that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998). "Jurisdiction, therefore, is not defeated . . . by the possibility that the averments might fail to state a cause of action on which [a plaintiff] could actually recover." *Bell,* 327 U.S. at 682.

In *Arbaugh*, this Court rejected the defendant's argument that federal courts lacked subject-matter jurisdiction over the plaintiff employee's discrimination claim under Title VII because the defendant did not meet Title VII's definition of an "employer"--anyone who has at least fifteen employees. 546 U.S. at 503. Because the numerical requirement "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts," the Court held that it was "an element of a plaintiff's claim for relief, not a jurisdictional issue." *Id.* at 515-16 (quotation marks omitted). Thus, subject matter jurisdiction existed even though the employee's discrimination claim could not have succeeded on the merits if the defendant had timely raised that it had fewer than fifteen employees. *Id.* at 516.

Here too, the elements of the PREP Act's cause of action for willful misconduct do not use any jurisdictional language. *See* § 247d-6d(c)(1), (e)(3). Yet the

courts of appeals have treated those elements as barriers to entry into federal court.

As stated above, the jurisdictional question is limited to whether a plaintiff states a colorable or arguable claim arising under the PREP Act's exclusive cause of action--that is, whether there is a non-frivolous argument that the claim is for loss relating to use of a covered countermeasure. § 247d-6d(a)(1). This Court should grant review to clarify as much for the courts of appeals.

III. This Court's Review of the PREP Act Is Urgently Needed As Front-Line Responders Face a Crippling Wave of Litigation.

A. Front-line responders need the uniform guidance promised by the PREP Act to continue to serve their communities.

Prior to COVID-19, there were few opportunities to interpret the PREP Act. The HHS Secretary had declared public health emergencies only a handful of times. *See, e.g.*, 84 Fed. Reg. 764 (Jan. 31, 2019) (Ebola); 83 Fed. Reg. 38701 (Aug. 7, 2018) (Zika); 72 Fed. Reg. 4710 (Feb. 1, 2007) (avian flu); 80 Fed. Reg. 76514 (Dec. 9, 2015) (anthrax). Thankfully, however, those public health emergencies were not on the scale of the COVID-19 pandemic and did not cause significant casualties--or litigation. Before COVID-19, only a single federal case and two state cases had occasion to apply the PREP Act. *See Kehler v. Hood*, 2012 WL 1945952, *1 (E.D. Mo. May 30, 2012) (administration of H1N1 vaccine); *Casabianca v. Mount Sinai Med. Ctr.*, 2014 WL 10413521 (N.Y. Sup. Ct. Dec. 2, 2014)

(same); *Parker v. St. Lawrence Cnty. Pub. Health Dep't,* 102 A.D.3d 140, 145 (N.Y. App. Div. 2012) (same). Whether the statute completely preempted state-law claims had never been litigated.

Then the COVID-19 pandemic struck and proved to be exactly the nightmare scenario contemplated by the PREP Act. The disease was brand-new, so there were no diagnostic tests, treatments, or prevention strategies when it first emerged. Healthcare providers, scientists, and others rushed to fill the void, but things did not always go smoothly. When confronted with seriously ill patients, healthcare professionals had to analyze treatment options on the fly, before clinical trials could be completed--or even initiated. Press Release, *NIH, NIH Clinical Trial of Remdesivir to Treat COVID-19 Begins* (Feb. 25, 2020), https://tinyurl.com/5ykmw346 (noting that antiviral remdesivir had been administered to COVID-19 patients even before clinical trial). The situation was so grim in Spring 2020 that an organization previously dedicated to setting up field hospitals in war zones opened a 68-bed field hospital in New York City's Central Park to treat overflow COVID-19 patients. Sheri Fink, N.Y. Times, *Treating Coronavirus in a Central Park 'Hot Zone'* (Apr. 15, 2020), https://tinyurl.com/2p9eajb3.

Confronting this dystopian reality required the expenditure of enormous resources. In 2020, nursing homes and other long-term-care facilities spent $30 billion on personal protective equipment and increasing staffing. *See* Press Release, Am. Health Care Ass'n, *COVID-19 Exacerbates Financial Challenges of Long Term Care Facilities* (Feb. 17, 2021),

https://tinyurl.com/ycktz64y. It is unsurprising that longterm-care facilities lost over $90 billion between 2020 and 2021, given the magnitude of resources required to combat COVID-19. *Id.* This situation has played out across the healthcare industry, and it has placed many healthcare providers on the brink of closure.

Despite the heroic efforts of front-line responders, the human toll of the pandemic in the United States has been staggering. The CDC confirmed the first case of COVID-19 in the United States on January 20, 2020. CDC, *CDC Museum COVID-19 Timeline* (Sep. 14, 2023), https://tinyurl.com/5ak8dvsw. Just three months later more than 44,000 people had died. Only one month later that number had more than doubled, with over 95,000 dead. COVID-19 has now killed more than one million Americans. CDC, *COVID Data Tracker, Trends in Number of COVID-19 Cases and Deaths in The United States Reported to CDC, by State/Territory* (Sep. 14, 2023), https://tinyurl.com/384k8xec.

One consequence of COVID-19's devastating death toll has been a torrent of litigation, just as the PREP Act anticipated. Those cases include suits alleging various forms of mismanagement by nursing homes and hospitals in the heaviest days of the pandemic, when those institutions were on the front lines of a crisis, waging a life-or-death battle against a novel biological threat with little information and even fewer tools. This crushing wave of litigation is what the PREP Act was designed to avoid. If anything, the onslaught of COVID-19 litigation has worsened the "climate of apprehension" regarding "litigation

exposure" that the PREP Act sought to ameliorate. 151 Cong. Rec. at 30727.

It is critical for this Court to conclusively resolve the preemptive effect of the PREP Act now--before front-line responders barely surviving the financial difficulties caused by the pandemic collapse under the burden of litigation that is supposed to be barred by the PREP Act. This Court's review is necessary not only to settle the question of whether suits are properly filed in state or federal court, but also to ensure the development of a uniform body of law interpreting the PREP Act to limit liability and prevent the continued litigation of meritless claims.

As explained above, the purpose of the PREP Act funneling litigation into the District Court for the District of Columbia and the D.C. Circuit is "consistency." *In re WTC Disaster Site*, 414 F.3d at 377. In adopting this system, the PREP Act aimed to ensure the development of clear and uniform rules governing conduct and liability in a public health emergency.

If this Court declines to intervene and correct the errors of the courts of appeals, litigation will proceed in dozens of different state courts. Those courts will develop dozens of different rules governing the definition of "covered person," the breadth of "covered countermeasures," the boundaries of willful misconduct, and the many other interpretive questions raised by the Act--a far cry from the consistency that Congress sought.

Different standards in different states will undoubtedly result in different liability for front-line

responders. A long-term-care facility in Georgia, for example, might face ruinous liability for conduct that a court just across the state border in Florida finds to fall squarely within the PREP Act's immunity provision. Even a small number of outlier verdicts can have a devastating impact, forcing healthcare facilities teetering at the financial brink out of business and dissuading facilities in the future from operating during the next pandemic.

To be sure, the burden of litigation, both its direct financial impact and the chilling effect caused by the fear of future litigation, will impede the ability of front-line responders to rise to meet the next severe global health threat, which could emerge at any time. Healthcare providers and others on the front lines of public health emergencies deserve clear rules interpreting the PREP Act before crippling COVID-19 liability affects the response to the next public health crisis. That can only happen if the Court intervenes now.

B. This case--involving a rare appealable remand order--is a good vehicle for review.

An appeal from a district court's remand order offers the ideal vehicle for this Court to review the question presented. The issue was resolved at the outset of the case, so there are no adequate and independent state grounds that could impede this Court's review. And this is a rare case where a remand order is appealable. Usually, "[a]n order remanding a case to the State court from which it was removed is not reviewable on appeal or otherwise." 28 U.S.C. § 1447(d). Here, however, one of the grounds for removal was the federal-officer removal statute, § 1442. *See* App. 2.

When a case is "removed pursuant to section 1442," any "order remanding [the] case to the State court" is "reviewable by appeal." § 1447(d). And under § 1447(d), "the whole of [the] order"--not just the portion addressing federal-officer removal--is reviewable. *BP*, 141 S. Ct. at 1538. In sum, there may not be many opportunities for this Court to review the PREP Act going forward, so it should take the opportunity to address the critically important question presented here.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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