No. _____

In the Supreme Court of the United States

WINDSOR REDDING CARE CENTER, LLC, *et al.*,
Petitioners,

v.

NANCY HEARDEN, *et al.*,
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 preemption," 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 Windsor Redding Care Center, LLC; Shlomo Rechnitz; Brius Management Co.; Brius, LLC; Lee Samson; S&F Management Company were defendants in the Eastern District of California and the appellants in the United States Court of Appeals for the Ninth Circuit. Respondents Nancy Hearden; Johanna Trenerry; Irene Kelley; Sally Kelley; Matthew Trenerry; Beverly Fuller; Anthony Trenerry; Sharon McMaines; Janis Bodine; Dennis McMaines; Darlyn Dulaney; Karlene Wallace; Jeremiah Boeninger; Sandra Bryant; Tamara Dukes; Robert Rather; Larry Riggs; Robert Riggs; Sally Sorenson; Terrie Callaway; Robert Gutierres; Delores Gutierres; Caryl Endicott; Damon White; Carolyn Silva; Pamela Santos; Gary Mattos; Gordon Farmer; Scott Farmer; Charles Balding; Leonard Balding; Ronald Frisbey; William Trenerry were plaintiffs in the Eastern District of California and respondents in the United States Court of Appeals for the Ninth Circuit.

CORPORATE DISCLOSURE STATEMENT

Petitioners Brius Management Co, now known as Pacific Healthcare Holdings, and Brius, LLC, now known as Los Angeles Nursing Homes, LLC, have no parent companies, and no publicly held corporation owns 10% or more of their respective stock. Petitioner Windsor Redding Care Center, LLC's parent corporation is Windsor Norcal 13 Holdings, LLC, 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 Eastern District of California and in the United States Court of Appeals for the Ninth Circuit:

- *Hearden v. Windsor Redding Care Ctr., LLC*, No. 198083, Shasta County Superior Court;
- *Hearden v. Windsor Redding Care Ctr., LLC*, No. 2:22-CV-00994-MCE-DMC (E.D. Cal.), order issued January 31, 2023;
- *Hearden v. Windsor Redding Care Ctr., LLC*, Nos. 23-15195, 23-14452 (9th Cir.), order issued Aug. 16, 2024; order denying petition for rehearing en banc issued Nov. 18, 2024.

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 seek 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 Eastern District of California is unpublished but can be found at 2023 U.S. Dist. LEXIS 16121 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 2024 U.S. App. LEXIS 20751 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 2024 U.S. App. LEXIS 29290 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 August 16, 2024 and denied rehearing on November 18, 2024. 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 E.

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-6d(e)(4),

[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).

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 killed more than one million people in the United States. *See, e.g.*, 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. Residents of Windsor Redding Care Center Die of COVID-19.

The underlying lawsuit was brought by the representatives and family members of fifteen residents of Windsor Redding Care Center nursing home who allegedly contracted COVID-19 at the nursing home and died as a result. 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, throughout much 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 sufficient levels of staffing and that petitioners failed to provide infection control and sufficient COVID-19 testing.

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.

The complaint filed in Shasta County Superior Court asserted six state-law causes of action: (1) statutory elder abuse/neglect; (2) negligence; (3) violation of resident rights; (4) unfair business practices; (5) wrongful death; and (6) fraud/misrepresentation. Respondents' allegations necessarily alleged that

petitions acted willfully. Petitioners removed to federal court in the Eastern 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.

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 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 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).

Indeed, the dissenting opinion in a recent Eleventh Circuit panel opinion continued this reasoning and wrote that under *Davila*, the PREP Act should be interpreted to completely preempt state law claims and vest federal jurisdiction for any action in which "at least some portions of the claims alleged willful misconduct within the PREP Act's scope." *Schleider v. GVDB Operations, LLC*, 121 F.3d 149, 168 (2024) (Luck, J., dissenting). Although, as here, the complaint in *Schleider* did not contain a separate cause of

action for willful misconduct, the allegations made in the complaint necessarily also alleged willfulness. *Id.* at 169-70.

Judge luck noted that the complaint's allegations were "a close match with the 'willful misconduct' required under the PREP Act's exclusive cause of action" and that once any part of an action falls under the PREP Act, the ordinary negligence causes of action get sucked in as well, per *Davila*. *Schleider*, 121 F.3d at 170.

The *Schleider* majority and the other circuits have instead 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. 2-3. 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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February 18, 2025

APPENDIX

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APPENDIX A — MEMORANDUM OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED AUGUST 16, 2024

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 23-15195, 23-15452

D.C. No. 2:22-cv-00994-MCE-DMC

NANCY HEARDEN; *et al.*,

Plaintiffs-Appellees,

v.

SHLOMO RECHNITZ; *et al.*,

Defendants-Appellants.

MEMORANDUM*

Appeal from the United States District Court
for the Eastern District of California
Morrison C. England, Jr., District Judge, Presiding

August 13, 2024**, Submitted,
San Francisco, California
August 16, 2024, Filed

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* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

**The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

Appendix A

Before: GRABER, CALLAHAN, and KOH, Circuit Judges.

Defendants[1] appeal the district court's order remanding this case to state court. The district court ruled that it lacked subject matter jurisdiction over the case pursuant to *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022). Reviewing de novo jurisdictional questions, *United States v. Jeremiah*, 493 F.3d 1042, 1044 (9th Cir. 2007), and reviewing for abuse of discretion challenges to the district court's award of attorneys' fees and costs under 28 U.S.C. § 1447(c), *Grancare, LLC v. Thrower ex rel. Mills*, 889 F.3d 543, 547 (9th Cir. 2018) (citing *Moore v. Permanente Med. Grp., Inc.*, 981 F.2d 443, 447 (9th Cir. 1992)), we affirm.

Plaintiffs are surviving family members of residents of Defendants' skilled nursing facility who contracted COVID-19 in 2020 and who later died. Plaintiffs filed the underlying action in California state court, alleging six state-law claims: a statutory claim for elder abuse and neglect, a negligence claim, a statutory claim for violations of patients' rights, a claim for violations of California Business and Professions Code § 17200, a wrongful death claim, and a claim for fraud and breach of fiduciary duty. Defendants removed the case to federal district court, but that court remanded the action to state court. The district court also awarded attorneys' fees and costs to Plaintiffs. Defendants' timely appeal of both issues followed.

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1. Defendants consist of Brius Management Co. (now known as Pacific Healthcare Holdings); Brius, LLC (now known as Los Angeles Nursing Homes, LLC); Shlomo Rechnitz; Windsor Redding Care Center, LLC; Lee Samson; and S&F Management Company.

Appendix A

1. We rejected Defendants' federal question and federal officer jurisdiction arguments in *Saldana*, 27 F.4th at 688-89. Although Defendants note that Congress gave the United States District Court for the District of Columbia the authority to adjudicate willful-misconduct claims, Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d(c) to (e)(1), Defendants did not seek a transfer to that court. Instead, Defendants refer to that PREP Act provision simply as one of several reasons why, in their view, *Saldana* was wrongly decided. As a three-judge panel, we are bound by Saldana. *See In re Complaint of Ross Island Sand & Gravel*, 226 F.3d 1015, 1018 (9th Cir. 2000) (per curiam) ("A three judge panel of this court cannot overrule a prior decision of this court." (citing *Morton v. De Oliveira*, 984 F.2d 289, 292 (9th Cir.1993))). Accordingly, we affirm in No. 23-15195.

2. The district court did not abuse its discretion by awarding attorneys' fees and costs to Plaintiffs. Although the court stated incorrectly that it had "broad discretion to award costs and fees whenever it finds that removal was wrong as a matter of law," the court in fact applied the correct standard. *See United States v. Bonds*, 608 F.3d 495, 504 (9th Cir. 2010) (holding that the district court did not abuse its discretion despite misstatement of the law because "[a]ny such misstatement had no bearing on the court's ruling" given that the court "applied the correct standard"). The court expressly considered whether Defendants "lacked an objectively reasonable basis for seeking removal." *Martin v. Franklin Cap. Corp.*, 546 U.S. 132, 141, 126 S. Ct. 704, 163 L. Ed. 2d 547 (2005); *see*

also Lussier v. Dollar Tree Stores, Inc., 518 F.3d 1062, 1066-67 (9th Cir. 2008) (holding that, in applying *Martin*, courts should ask whether "the relevant case law clearly foreclosed the defendant's basis for removal"). The district court observed that Defendants removed the case "despite binding and on-point Ninth Circuit authority disposing of the same asserted bases for jurisdiction in comparable cases" and permissibly concluded that Defendants therefore lacked "an objectively reasonable basis to contend that *Saldana* does not control." Accordingly, we affirm in No. 23-15452.

AFFIRMED.

APPENDIX B — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF CALIFORNIA, FILED JANUARY 31, 2023

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

No. 2:22-cv-00994-MCE-DMC

NANCY HEARDEN, *et al.*,

Plaintiffs,

v.

WINDSOR REDDING CARE CENTER, LLC, *et al.*,

Defendants.

Decided: January 30, 2023
Filed: January 31, 2023

MEMORANDUM AND ORDER

Plaintiffs are the relatives of and successors-in-interest to 15 individuals who were residents of Windsor Redding Care Center LLC ("Windsor"), a skilled nursing facility, in the fall of 2020. According to them, the policies and practices of Defendants Windsor, Shlomo Rechnitz, Brius Management Company, Brius LLC, Lee Samson, and S&F Management Company (collectively, "Defendants") caused an outbreak of COVID-19 at Windsor that resulted in the death of 24 residents, including the residents named

in this case. On August 26, 2021, Plaintiffs filed their Complaint in Shasta County Superior Court, asserting the following causes of action: (1) abuse and neglect of an elder; (2) negligence and negligence per se; (3) violation of the Patient's Bill of Rights, California Health and Safety Code § 1430; (4) unfair business practices in violation of California Business and Professions Code § 17200; (5) wrongful death; and (6) fraud and misrepresentation. *See generally* Ex. B, Not. Removal, ECF No. 1-2. Defendants removed the action to this Court on June 6, 2022, basing subject matter jurisdiction, in part, on the embedded federal question doctrine.[1] *See* Not. Removal, ECF No. 1 ¶¶ 1, 28-30 ("Not. Removal"). Presently before the Court is Plaintiffs' Motion to Remand, which has been fully briefed. ECF Nos. 15 ("Pls.' Mot."), 20 ("Defs.' Opp'n"), 23 ("Pls.' Reply"). For the following reasons, Plaintiffs' Motion is GRANTED.[2]

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1. Defendants assert two additional grounds for federal jurisdiction: the federal officer removal statute, 28 U.S.C. § 1442(a)(1), and the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e ("PREP Act"). Not. Removal ¶¶ 1-2. In acknowledging "that the Ninth Circuit has rejected similar jurisdictional arguments," Defendants nevertheless assert those bases for jurisdiction here "in order to preserve their arguments for review, including by the Ninth Circuit sitting en banc and by the United States Supreme Court." *See id.* ¶¶ 7, 27, 40; *see also* Defs.' Opp'n, at 13-14. Therefore, the Court will not address these two bases for jurisdiction in resolving the present Motion.

2. Because oral argument would not have been of material assistance, the Court ordered this matter submitted on the briefs. E.D. Local Rule 230(g).

Appendix B

STANDARD

When a case "of which the district courts of the United States have original jurisdiction" is initially brought in state court, the defendant may remove it to federal court "embracing the place where such action is pending." 28 U.S.C. § 1441(a). There are two bases for federal subject matter jurisdiction: (1) federal question jurisdiction under 28 U.S.C. § 1331, and (2) diversity jurisdiction under 28 U.S.C. § 1332. A district court has federal question jurisdiction in "all civil actions arising under the Constitution, laws, or treaties of the United States." *Id.* § 1331. A district court has diversity jurisdiction "where the matter in controversy exceeds the sum or value of $ 75,000, . . . and is between citizens of different States, [or] citizens of a State and citizens or subjects of a foreign state. . . ." *Id.* § 1332(a)(1)-(2).

A defendant may remove any civil action from state court to federal district court if the district court has original jurisdiction over the matter. 28 U.S.C. § 1441(a). "The party invoking the removal statute bears the burden of establishing federal jurisdiction." *Ethridge v. Harbor House Rest.*, 861 F.2d 1389, 1393 (9th Cir. 1988) (citing *Williams v. Caterpillar Tractor Co.*, 786 F.2d 928, 930 (9th Cir. 1986)). Courts "strictly construe the removal statute against removal jurisdiction." *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992) (internal citations omitted). "[I]f there is any doubt as to the right of removal in the first instance," the motion for remand must be granted. *Id.* Therefore, "[i]f at any time before final judgment it appears that the district court lacks subject matter

jurisdiction, the case shall be remanded" to state court. 28 U.S.C. § 1447(c).

The district court determines whether removal is proper by first determining whether a federal question exists on the face of the plaintiff's well-pleaded complaint. *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392, 107 S. Ct. 2425, 96 L. Ed. 2d 318 (1987). If a complaint alleges only state-law claims and lacks a federal question on its face, then the federal court must grant the motion to remand. *See* 28 U.S.C. § 1447(c); *Caterpillar*, 482 U.S. at 392. Nonetheless, there are rare exceptions when a well—pleaded state-law cause of action will be deemed to arise under federal law and support removal. They are "(1) where federal law completely preempts state law, (2) where the claim is necessarily federal in character, or (3) where the right to relief depends on the resolution of a substantial, disputed federal question." *ARCO Env't Remediation L.L.C. v. Dep't of Health & Env't Quality*, 213 F.3d 1108, 1114 (9th Cir. 2000) (internal citations omitted).

If the district court determines that removal was improper, then the court may also award the plaintiff costs and attorney fees accrued in response to the defendant's removal. 28 U.S.C. § 1447(c). The court has broad discretion to award costs and fees whenever it finds that removal was wrong as a matter of law. *Balcorta v. Twentieth-Century Fox Film Corp.*, 208 F.3d 1102, 1106 n.6 (9th Cir. 2000).

Appendix B

ANALYSIS

A. Embedded Federal Question Doctrine

As stated before, Defendants argue that this Court has jurisdiction under the embedded federal question doctrine, specifically on the basis that Plaintiffs' causes of action implicate the PREP Act.[3] *See* Not. Removal ¶ 5. "Under this doctrine, 'federal jurisdiction over a state law claim will lie if a federal issue is (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.'" *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 688 (9th Cir. 2022) ("*Saldana*") (quoting *Gunn v. Minton*, 568 U.S. 251, 258, 133 S. Ct. 1059, 185 L. Ed. 2d 72 (2013)). "The well-pleaded complaint rule applies when determining whether the embedded federal question doctrine applies." *Id.* (citation omitted).

The Ninth Circuit, faced with causes of action comparable to those presented here, found that such claims are properly "raised under California law and do not raise questions of federal law on the face of the complaint" sufficient to confer this type of jurisdiction. *Id.* Furthermore, the Ninth Circuit concluded that, even if the defendant "seeks to raise a federal defense under

3. The provisions of the PREP Act, passed by Congress in 2005, are triggered when the Secretary of the Department of Health and Human Services makes a determination that a disease or other health condition poses a potential public health emergency. 42 U.S.C. § 247d-6d(b)(1).

the PREP Act, . . . a federal defense is not a sufficient basis to find embedded federal question jurisdiction." *Id.* (citing *Provincial Gov't of Marinduque v. Placer Dome, Inc.*, 582 F.3d 1083, 1090 (9th Cir. 2009)).

Defendants "acknowledge that this Court is bound by the Ninth Circuit's decision in *Saldana*," Not. Removal ¶ 30, but nevertheless argue that *Saldana* is factually distinguishable from the present case:

> While *Saldana* also rejected application of the embedded federal question [doctrine], it did so on the basis of materially different case-specific facts. Specifically, there the plaintiffs argued that the defendants had failed to employ approved countermeasures *at all*. This theory took them outside the PREP Act's scope, which is focused on covered countermeasures. Here, by contrast, Plaintiffs allege that Defendants *did* employ countermeasures falling with[in] the PREP Act's scheme, but failed to do so in a proper manner. This distinction is a critical one, demonstrating that *Saldana*'s holding as to the embedded federal question doctrine is distinguishable.

Defs.' Opp'n, at 8-9 (emphases in original).[4] However, the Ninth Circuit's holding is not so limited, for it

4. The PREP Act provides that "a covered person shall be 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 . . . " 42 U.S.C. § 247d-6d(a)(1). Countermeasures are defined in the Act as including a qualified pandemic or epidemic product, a drug, biological product or device, or a respiratory protective device. *Id.* § 247d-6d(i)(1).

acknowledged that, "according to the complaint, only some of the steps [the defendant] allegedly took, and did not take, may have involved a 'covered person,' under the PREP Act." *Saldana*, 27 F.4th at 689. In other words, the Ninth Circuit "said Saldana's claims may in part arise from the use or non-use of covered countermeasures," and thus any such distinction was not central to the Ninth Circuit's overall conclusion that a PREP Act federal defense was not a sufficient basis to find embedded federal question jurisdiction. *See* Pls.' Reply, at 4. Because the *Saldana* decision is binding precedent and is dispositive of all three grounds asserted by Defendants for federal jurisdiction, as Defendants concede, this Court lacks jurisdiction to hear this case. Accordingly, Plaintiffs' Motion to Remand is GRANTED.[5]

B. Attorneys' Fees

Should the Motion be granted, Plaintiffs request that the Court award them attorneys' fees and costs incurred in responding to Defendants' removal. *See* Pls.' Mot., at 22-25. Defendants removed this action in June 2022, over three months after the *Saldana* decision in February 2022 and over a month after the Ninth Circuit unanimously denied rehearing and en banc review of *Saldana* in April

5. Defendants' Request for Judicial Notice, ECF No. 22, is DENIED as moot because the Court need not consider the documents therein in reaching its decision. Similarly, Defendants filed an objection to Plaintiffs' Reply brief in which Plaintiffs relied on an unpublished Ninth Circuit decision, but the Court did not consider or rely on that decision here, thus Defendants' Objection, ECF No. 24, is OVERRULED.

2022.[6] *See* Pls.' Reply, at 9. In opposing an award of fees and costs, Defendants seemingly argue that them being "upfront about the existence and effect of binding circuit precedent on their arguments in their removal, in their meet and confer discussions, and in this briefing" should weigh in their favor especially since their intention was only to preserve these arguments for appeal. *See* Defs.' Opp'n, at 25. However, this simply confirms that Defendants removed this case despite binding and on-point Ninth Circuit authority disposing of the same asserted bases for jurisdiction in comparable cases. Furthermore, the alleged factual distinction between *Saldana* and the present case raised by Defendants is too insignificant to support the conclusion that "Defendants had an objectively reasonable basis to contend that *Saldana* does not control the embedded federal question here . . . " *Id.* at 24. Given the foregoing, the Court finds that Plaintiffs are entitled to attorneys' fees and costs associated with removal, and Plaintiffs' counsel will be directed to file a declaration attesting to those fees and costs incurred.

CONCLUSION

For the reasons set forth above, Plaintiffs' Motion to Remand, ECF No. 15, is GRANTED. Not later than seven (7) days from the issuance of this Memorandum and Order, Plaintiffs' counsel shall file a declaration setting forth the attorneys' fees and costs accrued in response to Defendants' removal. Defendants may, but are not

6. Following the conclusion of briefing on the present Motion, on November 21, 2022, the United States Supreme Court denied certiorari in *Saldana. See* Ex. A, ECF No. 27, at 5.

required to, file an opposition no later than seven (7) days after the declaration is filed.

IT IS SO ORDERED.

DATED: January 30, 2023

/s/ Morrison C. England, Jr.
MORRISON C. ENGLAND, JR.
SENIOR UNITED STATES
DISTRICT JUDGE

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED NOVEMBER 18, 2024

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 23-15195
23-15452

D.C. No. 2:22-cv-00994-MCE-DMC
Eastern District of California, Sacramento

NANCY HEARDEN; *et al.*,

Plaintiffs-Appellees,

v.

SHLOMO RECHNITZ; *et al.*,

Defendants-Appellants.

ORDER

Before: GRABER, CALLAHAN, and KOH, Circuit Judges.

Judges Callahan and Koh have voted to deny Appellants' petition for rehearing en banc, and Judge Graber has so recommended.

Appendix C

The full court has been advised of Appellants' petition for rehearing en banc, and no judge of the court has requested a vote on it.

Appellants' petition for rehearing en banc, Docket No. 61, is DENIED.

APPENDIX D — 42 U.S.C. § 247d-6d

§ 247d-6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections.

(1) In general. Subject to the other provisions of this section, a covered person shall be 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 if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss.

(A) Loss. For purposes of this section, the term "loss" means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope. The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions. Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions. With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).\

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of

immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method. The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) Rebuttable presumption. For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) Declaration by Secretary.

(1) Authority to issue declaration. Subject to paragraph (2), if the Secretary makes a

determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents. In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with

respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) Effective period of declaration.

(A) Flexibility of period. The Secretary may, in describing periods under paragraph (2)(B), have different periods for different

covered persons to address different logistical, practical or other differences in responsibilities.

(B) Additional time to be specified. In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) Additional period for certain strategic national stockpile countermeasures. With respect to a covered countermeasure that is in the stockpile under section 319F-2 [42 U.S.C. § 247d-6b], if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained

for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) Amendments to declaration. The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) Certain disclosures. In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5, United States Code.

(6) Factors to be considered. In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) Judicial review. No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) Preemption of state law. During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act [42 U.S.C. §§ 201 et seq.], or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq.].

(9) Report to Congress. Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) Definition of willful misconduct.

(1) Definition.

(A) In general. Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote 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.

(B) Rule of construction. The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) Authority to promulgate regulatory definition.

(A) In general. The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) Factors to be considered. In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) Temporal scope of regulations. The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) Initial rulemaking. Within 180 days after the enactment of the Public Readiness and Emergency Preparedness Act [enacted Dec.

30, 2005], the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) Proof of willful misconduct. In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) Defense for acts or omissions taken pursuant to Secretary's declaration. Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) Exclusion for regulated activity of manufacturer or distributor.

(A) In general. If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this Act [42 U.S.C. §§ 201 et seq.] or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq.], such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if—

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) Definitions. For purposes of this paragraph, the following terms have the following meanings:

(i) Enforcement action. The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(i) or 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. § 360bbb-3], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act [21 U.S.C. §§ 351 et seq.] or of a licensure under section 262 of this Act [42 U.S.C. § 262].

(ii) Covered remedy. The term "covered remedy" means an outcome—

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product

recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(i) or 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. § 360bbb-3], or a suspension or withdrawal of an approval or clearance under chapter 5 [chapter V] of such Act [21 U.S.C. §§ 351 et seq.] or of a licensure under section 351 of this Act [42 U.S.C. § 262]; and

(II) that results from a final determination by a court or from a final agency action.

(iii) Final. The terms "final" and "finally"—

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) Rules of construction.

(i) In general. Nothing in this paragraph shall be construed—

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq.], of this Act [42 U.S.C. §§ 201 et seq.], or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this Act [42

U.S.C. §§ 201 et seq.], under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq.], under title 18 of the United States Code, or under any other applicable statute or regulation.

(ii) Mandatory recalls. A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) Exception to immunity of covered persons.

(1) In general. Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, United States Code, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue. An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit.

(1) Exclusive Federal jurisdiction. Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law. The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity. In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was

filed suffered death or serious physical injury.

(4) Verification, certification, and medical records.

(A) In general. In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement.

(i) In general. The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief. Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded

for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required. In an action under subsection (d), the plaintiff shall file with the complaint—

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court. Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further

proceedings, including any trial. Section 1253 of title 28, United States Code, and paragraph (3) of subsection (b) of section 2284 of title 28, United States Code, shall not apply to actions under subsection (d).

(6) Civil discovery.

(A) Timing. In an action under subsection (d), no discovery shall be allowed—

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard. Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form

of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits.

(A) In general. In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation. No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined. For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf

of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages. In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional

pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions. Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal. The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary

judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States. Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28, United States Code [28 U.S.C. §§ 2671 et seq.] (relating to tort claims procedure).

(g) Severability. If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) Rule of construction concerning National Vaccine Injury Compensation Program. Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under title XXI of this Act [42 U.S.C. §§ 300aa-1 et seq.].

(i) Definitions. In this section:

(1) Covered countermeasure. The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F-2(c)(1)(B) [42 U.S.C. § 247d-6b(c)(1)(B)]);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act [42 U.S.C. § 262(i)]), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 360bbb-3, 360bbb-3a, or 360bbb-3b]; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared

under section 319 [42 U.S.C. § 247d].

(2) Covered person. The term "covered person", when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor. The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug

warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer. The term "manufacturer" includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person. The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) Program planner. The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security

countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) Qualified pandemic or epidemic product. The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))[)], biological product (as such term is defined by section 351(i) of this Act [42 U.S.C. § 262(i)]), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is—

(A)

(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)

(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 351 et seq.] or licensed under section 351 of this Act [42 U.S.C. § 262];

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(i) or 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 360bbb-3, 360bbb-3a, or 360bbb-3b].

(8) Qualified person. The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) Security countermeasure. The term "security countermeasure" has the meaning given such term in section 319F-2(c)(1)(B) [42 U.S.C. § 247d-6b(c)(1)(B)].

(10) Serious physical injury. The term "serious physical injury" means an injury that—

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

APPENDIX E — 42 U.S.C. § 247d-6e

§ 247d-6e. Covered countermeasure process

(a) Establishment of Fund. Upon the issuance by the Secretary of a declaration under section 319F-3(b) [42 U.S.C. § 247d-6d(b)], there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress [unclassified], this emergency designation shall remain in effect through October 1, 2006.

(b) Payment of compensation.

(1) In general. If the Secretary issues a declaration under 319F-3(b) [42 U.S.C. § 247d-6d(b)], the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

(2) Elements of compensation. The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 264, 265,

and 266 [42 U.S.C. §§ 239c, 239d, and 239e] in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 266(a)(2)(B) [42 U.S.C. § 239e(a)(2)(B)] shall not apply.

(3) Rule of construction. Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 266 [42 U.S.C. § 239e].

(4) Determination of eligibility and compensation. Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 262 [42 U.S.C. § 239a] (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) Covered countermeasure injury table.

(A) In general. The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) Amendments. The provisions of section 263 [42 U.S.C. § 239b] (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) Judicial review. No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) Meanings of terms. In applying sections 262, 263, 264, 265, and 266 [42 U.S.C. §§ 239a, 239b, 239c, 239d, and 239e] for purposes of this section—

(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;

(B) the terms "smallpox vaccine injury table" and "table established under section 263 [42 U.S.C. § 239b]" shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) Voluntary program. The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 319F-3 [42 U.S.C. § 247d-6d] and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) Exhaustion; exclusivity; election.

(1) Exhaustion. Subject to paragraph (5), a covered individual may not bring a civil action under section 319F-3(d) [42 U.S.C. § 247d-6d(d)] against a covered person (as such term is defined in section 319F-3(i)(2) [42 U.S.C. § 247d-6d(i)

(2)]) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 319F-3(d) [42 U.S.C. § 247d-6d(d)].

(2) Tolling of statute of limitations. The time limit for filing a civil action under section 319F-3(d) [42 U.S.C. § 247d-6d(d)] for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

(3) Rule of construction. This section shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

(4) Exclusivity. The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 319F-3 [42 U.S.C. § 247d-6d].

(5) Election. If under subsection (a) the Secretary determines that a covered individual qualifies

for compensation, the individual has an election to accept the compensation or to bring an action under section 319F-3(d) [42 U.S.C. § 247d-6d(d)]. If such individual elects to accept the compensation, the individual may not bring such an action.

(e) Definitions. For purposes of this section, the following terms shall have the following meanings:

(1) Covered countermeasure. The term "covered countermeasure" has the meaning given such term in section 319F-3 [42 U.S.C. § 247d-6d].

(2) Covered individual. The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) Covered injury. The term "covered injury" means serious physical injury or death.

(4) Declaration. The term "declaration" means a declaration under section 319F-3(b) [42 U.S.C. § 247d-6d(b)].

(5) Eligible individual. The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.