APPENDIX

APPENDIX

TABLE OF CONTENTS

APPENDIX A

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

No. 21-56011

D.C. No. 2:21-cv-06106-DMG-AGR

[Filed August 11, 2023]

ERIC HOLLOWAY, deceased, by and through his legal representative and successor-in-interest, Shalimah Abdullah; SHALIMAH ABDULLAH, individually,	)
Plaintiffs-Appellees,	)
v.	)
CENTINELA SKILLED NURSING & WELLNESS CENTRE WEST, LLC, DBA Centinela Skilled Nursing & Wellness Centre West, a California Skilled Nursing Facility; BRIUS MANAGEMENT CO., a California company,	)
Defendants-Appellants,	)
and	)

TAMAR RECHNITZ, an individual; DOES, 1-25, inclusive; SAIDAH HOLLOWAY, an individual, nominal defendant; AKBAR ABDULLAH, an individual, nominal defendant; RIHEIM HOLLOWAY, an individual, nominal defendant,	)
Defendants.	)

MEMORANDUM[*]

Appeal from the United States District Court
for the Central District of California
Dolly M. Gee, District Judge, Presiding

Submitted August 11, 2023[**]

Before: WALLACE, O'SCANNLAIN, SILVERMAN, Circuit Judges.

Centinela Skilled Nursing & Wellness Centre West, LLC, doing business as Centinela Skilled Nursing & Wellness Centre West, a California Skilled Nursing Facility, and Brius Management Co. (collectively "Centinela") appeal from the district court's order remanding this case to state court for lack of federal subject matter jurisdiction. Centinela argues that the district court had three independent grounds for such jurisdiction: federal officer removal, complete

[*] 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).

preemption, and the presence of an embedded federal question.

I

The district court did not have federal subject matter jurisdiction under the federal officer removal statute, 28 U.S.C. § 1442(a)(1), because Centinela's actions were not "taken pursuant to a federal officer's directions." *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 684 (9th Cir. 2022) (cleaned up). While Centinela has demonstrated that, like the defendants in *Saldana*, it was subject to federal laws and regulations throughout the COVID-19 pandemic, "simply *complying* with a law or regulation is not enough to bring a private person within the scope of the [federal officer removal] statute." *Id.* (cleaned up). Similarly, recommendations, advice, and encouragement from federal entities do not amount to the type of control required for removal under the statute. *See id.* at 685.

II

The district court did not have federal subject matter jurisdiction under the doctrine of complete preemption because the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, is not a complete preemption statute—that is, it is not one of those "rare" statutes "where a federal statutory scheme is so comprehensive that it entirely supplants state law causes of action." *Saldana*, 27 F.4th at 686 (cleaned up). While the PREP Act may preempt some state-law claims, any such conflict preemption would be an affirmative defense,

and would not create federal subject matter jurisdiction. *See id.* at 688.

III

The district court did not have embedded federal question jurisdiction because the state-law causes of action in the complaint do not "necessarily" raise "substantial" federal issues that are "actually disputed" and "capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Id.* at 688 (cleaned up). Although a federal defense may be available under the PREP Act, "a federal defense is not a sufficient basis to find embedded federal question jurisdiction." *Id.*

IV

In short, all of Centinela's challenges are controlled by *Saldana*. Centinela argues that *Saldana* was wrongly decided, but cites no "clearly irreconcilable" intervening authority permitting us to overrule it. *Miller v. Gammie*, 335 F.3d 889, 900 (9th Cir. 2003) (en banc). Accordingly, we apply *Saldana*.

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES—GENERAL

JS-6 / REMAND

Case No. CV 21-6106-DMG (AGRx)

[Filed August 17, 2021]

Date August 17, 2021

Title ***Eric Holloway, et al. v. Centinela Skilled Nursing & Wellness Centre West, LLC, et al.***

Present: The Honorable DOLLY M. GEE, UNITED STATES DISTRICT JUDGE

KANE TIEN	NOT REPORTED
Deputy Clerk	Court Reporter

Attorneys Present for Plaintiff(s)	Attorneys Present for Defendant(s)
None Present	None Present

Proceedings: IN CHAMBERS—ORDER REMANDING ACTION TO LOS ANGELES COUNTY SUPERIOR COURT

On May 12, 2021, Plaintiff Eric Holloway, by and through his successor-in-interest Shalimah Abdullah, and Shalimah Abdullah, individually, filed a Complaint in Los Angeles County Superior Court against Centinela Skilled Nursing & Wellness Centre West, LLC, Brius Management Co, and Tamar Rechnitz,[1] alleging claims for (1) elder neglect in violation of California Welfare and Institutions Code section 15600 *et seq.*; (2) violation of patient rights under California Health & Safety Code § 1430(b); (3) negligence; and (4) wrongful death.[2] [Doc. # 1, Ex. A.] On July 28, 2021, Defendants removed the action to this Court, asserting federal jurisdiction under the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. §§ 247d-6d, 247d-6e, and federal officer removal jurisdiction under 28 U.S.C. section 1442(a)(1). Notice of Removal at ¶¶ 10, 44 [Doc. # 1.].

On August 4, 2021, Defendants filed a motion to dismiss. [Doc. # 9.] On the same day, the Court ordered defendants to show cause why this action should not be remanded to Los Angeles County Superior Court for lack of subject matter jurisdiction. [Doc. # 8.] As the Court noted, this Court has previously held in a similar case that the PREP Act is not a complete preemption statute and that assertion of a defense under the PREP Act does not suffice to confer federal question subject

---

[1] Defendants state in their Notice of Removal that Tamar Rechnitz has not been served and is not part of the state court proceeding.

[2] Saidah Holloway, Akbar Abdullah, and Riheim Holloway are Nominal Defendants to the wrongful death claim.

matter jurisdiction over a removed action under 28 U.S.C. sections 1331 and 1441. *See Padilla v. Brookfield Healthcare Ctr.*, No. CV 21-2062-DMG (ASX), 2021 WL 1549689, at *2-6 (C.D. Cal. Apr. 19, 2021). Moreover, in a case cited in *Padilla*, *Lyons v. Cucumber Holdings, LLC*, No. CV 20-10571-JFW (JPRx), 2021 WL 364640 (C.D. Cal. Feb. 3, 2021), another court in this district found no federal officer removal jurisdiction for a defendant nursing facility and company owner based solely on implementation of federal COVID-19 policies. *Id.* at *3. The Court ordered Defendants to show cause why this case should not be remanded in light of the reasoning set forth in *Padilla* and *Lyons*.

Defendants filed their response on August 10, 2021. [Doc. # 11.] For the reasons laid out below, this Court lacks subject matter jurisdiction over Plaintiffs' claims.

1. Federal Question Jurisdiction

Defendants assert that the PREP Act completely preempts Plaintiff's claims and that Plaintiffs' Complaint contains a substantial federal issue giving rise to federal question jurisdiction under *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005).

In *Padilla v. Brookfield Healthcare Ctr.*, No. CV 21-2062-DMG (ASX), 2021 WL 1549689 (C.D. Cal. Apr. 19, 2021), a defendant nursing home sought to remove to federal court on the basis that the PREP Act completely preempts state law claims that fall within its scope, giving rise to federal question jurisdiction.

This Court found that the PREP Act does not have complete preemptive effect. The Court explained that

> Under the doctrine of complete preemption, a state claim arises under federal law when Congress "so completely preempt[s] a particular area that any civil complaint raising th[e] select group of claims is necessarily federal in character." *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63–64 (1987). A state law cause of action is only completely preempted when "the federal statute[ ] at issue 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 Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003). In short, Congress must intend the statute to provide the exclusive cause of action. *Id.* at 9. [. . . T]he PREP Act provides for a federal *administrative* remedy for injuries arising from non-willful behavior, not an exclusive federal cause of action. [. . .] Because the PREP Act does not provide an exclusive cause of action to be filed in federal court, it does not completely preempt all state law claims.

Padilla, 2021 WL 1549689, at *4 (citations omitted).

The Court's conclusion has not changed. A number of other courts in this district have come to the same conclusion. *See, e.g.*, *Acra v. California Magnolia Convalescent Hospital, Inc.*, No. ED CV 21-898-GW (SHKx), 2021 WL 2769041, at *5 (C.D. Cal. July 1, 2021) (collecting cases). Because the PREP Act is not a

complete preemption statute, it cannot serve as the basis for removal here.

This Court also found that the *Padilla* plaintiffs' state law claims, which involved allegations that the defendant nursing home failed to care for the decedent, who died of COVID-19, did not raise a substantial federal issue under *Grable*. *See Padilla*, 2021 WL 1549689, at *5. The Court explained:

> The "substantial question" doctrine is a longstanding exception to the "well-pleaded complaint" rule. *Cal. ex rel. Lockyer v. Dynegy, Inc.*, 375 F.3d 831, 838 (9th Cir. 2004). The Supreme Court has not stated a "single, precise, all-embracing test for jurisdiction over federal issues embedded in state-law claims." *Grable*, 545 U.S. at 314 (internal citation omitted). Under *Grable*, a complaint based entirely on state law claims can invoke federal question jurisdiction only if: (1) the case necessarily raises a federal issue; (2) the federal issue is substantial and actually in dispute; and (3) the exercise of federal jurisdiction would be "consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331." *Id.* at 313-14 (internal citations omitted); see also *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393 (1987); *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 817 (1986).

Id., at *5. In *Padilla*, the plaintiffs' claims did not implicate the PREP Act because none of their arguments "involve[d] the use of drugs, biological

products, or devices used to treat, mitigate, or prevent COVID-19, such as personal protective equipment [. . .], therapeutics, or vaccines." *Id*. Rather, they involved policies—such as social distancing—that "[did] not constitute covered countermeasures under the PREP Act." *Id*. The plaintiffs' allegation that the defendants failed to adequately test for COVID-19 within the facility did not raise a substantial federal issue because "inaction generally does not fall under the scope of the PREP Act." *Id*. Finally, this Court found that "even if Plaintiffs' claims based on the lack of COVID-19 testing fall under the PREP Act's covered countermeasures, immunity under the PREP Act is a defense, not a necessary aspect of Plaintiffs' state law claims. It is axiomatic that federal jurisdiction cannot rest upon an actual or anticipated defense." *Id*., at *6 (citing *Vaden v. Discover Bank*, 556 U.S. 49 (2009)).

As in *Padilla*, Plaintiffs' claims do not raise a substantial federal issue involving the PREP Act. Plaintiffs here allege primarily that Defendants failed to adequately staff their facility or train the staff they had, such as by allowing LVNs to perform the work of RNs. Compl. ¶¶ 60, 74. As in *Padilla*, "[n]one of these arguments involve the use of drugs, biological products, or devices used to treat, mitigate, or prevent COVID-19, such as personal protective equipment ("PPE"), therapeutics, or vaccines." 2021 WL 1549689, at *5. Defendants do not point to any allegations in the Complaint that relate even tangentially to COVID-19. Defendants also do not attempt to distinguish the facts of this case from those in *Padilla*, or engage with the reasoning of *Padilla* at all. Defendants have therefore failed to show that *Grable* provides a basis for removal.

2. Federal Officer Removal Jurisdiction

A state court action may be removed to federal court under 28 U.S.C. section 1442(a)(1) if "(a) [the removing party] is a 'person' within the meaning of the statute; (b) there is a causal nexus between its actions, taken pursuant to a federal officer's directions, and plaintiff's claims; and (c) it can assert a 'colorable federal defense.'" *Fidelitad, Inc. v. Insitu, Inc.*, 904 F.3d 1095, 1099 (9th Cir. 2018).

Defendants have not established that the actions that are the subject of Plaintiffs' Complaint were taken "pursuant to a federal officer's directions." Defendants assert that in complying with guidelines promulgated by the Centers for Disease Control and other government entities to prevent the spread of COVID-19, they were acting "pursuant to a federal officer's directions." But "[a] private firm's compliance (or noncompliance) with federal laws, rules, and regulations does not by itself fall within the scope of the statutory phrase 'acting under' a federal 'official,'" even when "the regulation is highly detailed and [. . .] the private firm's activities are highly supervised and monitored." *Watson v. Philip Morris Companies, Inc.*, 551 U.S. 142, 153 (2007).

More than ten courts in this district have analyzed similar facts and reached the same result, reasoning that "the directives that Defendants rely on are nothing more than general regulations and public directives regarding the provision of medical services." *Lyons v. Cucumber Holdings, LLC*, --- F. Supp. 3d ----, 2021 WL 364640, at *3 (C.D. Cal. Feb. 3, 2021); *see also Winn v. California Post Acute LLC*, --- F. Supp. 3d ----,

2021 WL 1292507, at *6 (C.D. Cal. Apr. 6, 2021) (holding that defendant nursing home's compliance with state and federal directives intended to limit the spread of COVID-19 was insufficient to establish federal officer jurisdiction). Because Defendants' actions do not bring this case within the ambit of the federal officer statute, removal under that statute was therefore improper.

The Court has considered Defendants' request to stay proceedings. It is well established that indefinite stays are disfavored, and the Court can identify no exceptions to that principle here. *See Dependably Highway Express, Inc. v. Navigators Ins. Co.*, 498 F.3d 1059, 1066–67 (9th Cir. 2007) (reversing the district court's stay where the order "provide[d] no specific deadline for when the stay w[ould] terminate"). Moreover, the Court sees no reason why the parties should not continue with their case in state court. The request to stay proceedings is therefore **DENIED**.

Defendants have failed to establish any basis for subject matter jurisdiction. The Court therefore **REMANDS** this action to the Los Angeles County Superior Court. Defendants' Motion to Dismiss [Doc. # 9] is **DENIED** without prejudice as moot.

IT IS SO ORDERED.

Initials of Deputy Clerk KT

APPENDIX C

STATUTORY PROVISIONS INVOLVED

United States Code
Title 42. The Public Health and Welfare

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 247d-6b of this title, 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.

(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 chapter, or under the Federal Food, Drug, and Cosmetic Act.

(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 December 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 chapter or by the Federal Food, Drug, and Cosmetic Act, 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, 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, or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act or of a licensure under section 262 of this title.

(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, a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act, or a suspension or withdrawal of an approval or clearance under chapter 51 of such Act or of a licensure under section 262 of this title; 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, of this chapter, 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 chapter, under the Federal Food, Drug, and Cosmetic Act, under Title 18, 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, 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 and paragraph (3) of subsection (b) of section 2284 of Title 28 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 (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 subchapter XIX of this chapter.

(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 247d-6b(c)(1)(B) of this title);

(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 262(i) of this title), 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; 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 247d of this title.

(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 262(i) of this title), 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 or licensed under section 262 of this title;

(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; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

(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 247d-6b(c)(1)(B) of this title.

(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.

United States Code
Title 42. The Public Health and Welfare

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 247d-6d(b) of this title, 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, 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 247d-6d(b) of this title, 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 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title 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 239e of this title.

(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 239a of this title (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 239b of this title (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 239a, 239b, 239c, 239d, and 239e of this title 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 239b of this title" 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 247d-6d of this title 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 247d-6d(d) of this title against a covered person (as such term is defined in section 247d-6d(i)(2) of this title) 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 247d-6d(d) of this title.

(2) Tolling of statute of limitations

The time limit for filing a civil action under section 247d-6d(d) of this title 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, 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 247d-6d of this title.

(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 247d-6d(d) of this title. 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 247d-6d of this title.

(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 247d-6d(b) of this title.

(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.