FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PAUL JULIAN MANEY; GARY CLIFT; GEORGE W. NULPH; THERON D. HALL; DAVID HART; SHERYL LYNN SUBLET; FELISHIA RAMIREZ, personal representative for the Estate of Juan Tristan, individually, on behalf of a class of other similarly situated,

Plaintiffs-Appellees,

v.

KATE BROWN, Governor,

Defendant-Appellant,

and

COLETTE PETERS; HEIDI STEWARD; MIKE GOWER; MARK NOOTH; ROB PERSSON; KEN JESKE; STATE OF OREGON; PATRICK ALLEN; JOE BUGHER; GARRY RUSSELL,

Defendants.

No. 22-35218

D.C. No. 6:20-cv-00570-SB

OPINION

PAUL JULIAN MANEY; GARY CLIFT; GEORGE W. NULPH; THERON D. HALL; DAVID HART; SHERYL LYNN SUBLET; FELISHIA RAMIREZ, personal representative for the Estate of Juan Tristan, individually, on behalf of a class of other similarly situated,

Plaintiffs-Appellees,

v.

PATRICK ALLEN, in his individual capacity only,

Defendant-Appellant,

and

KATE BROWN, Governor; COLETTE PETERS; HEIDI STEWARD; MIKE GOWER; MARK NOOTH; ROB PERSSON; KEN JESKE; STATE OF OREGON; JOE BUGHER; GARRY RUSSELL,

Defendants.

No.22-35219

D.C. No. 6:20-cv-00570-SB

Appeal from the United States District Court for the District of Oregon Stacie F. Beckerman, Magistrate Judge, Presiding

Argued and Submitted April 20, 2023 Portland, Oregon

Filed February 1, 2024

Before: Johnnie B. Rawlinson, Carlos T. Bea, and Jennifer Sung, Circuit Judges.

Opinion by Judge Sung

SUMMARY*

PREP Act Immunity

Reversing the district court's denial of Oregon State Governor Kate Brown and Director of the Oregon Health Authority Patrick Allen's motion to dismiss a claim brought by Oregon state inmates for damages stemming from defendants' assignment of a lower priority COVID-19 vaccination tier to state inmates than to correctional officers, the panel held that defendants were immune from liability for the vaccination prioritization claim under the Public Readiness and Emergency Preparedness ("PREP") Act.

At the start of the COVID-19 pandemic, Governor Brown and Director Allen, both responsible for crafting the state's response to the virus's spread, established priority tiers to guide the state's vaccine rollout, and assigned state

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^{*} This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

prison inmates to a lower priority vaccination tier than correctional officers.

On March 17, 2020, the Secretary of Health and Human Services issued a declaration announcing that COVID-19 constituted a public health emergency and that immunity as prescribed in the PREP Act was in effect for the "manufacture, testing, development, distribution, administration, and use of" covered countermeasures.

The panel held that the statutory requirements for PREP Act immunity were met with respect to the vaccine prioritization damages claim because the "administration" of a covered countermeasure includes prioritization of that countermeasure when its supply was limited. The panel further concluded that the PREP Act's provisions extend immunity to persons who make policy-level decisions regarding the administration or use of covered countermeasures.

The panel next held that the PREP Act provides immunity from suit and liability for constitutional claims brought under 42 U.S.C. § 1983. Although the PREP Act does not specifically mention § 1983, Congress used terms that plainly and unambiguously define a broad scope of immunity that includes claims brought under § 1983. Congress, therefore, intended to expressly immunize covered persons from § 1983 actions for claims covered by the PREP Act, even if those claims are federal constitutional claims.

COUNSEL

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OPINION

SUNG, Circuit Judge:

At the start of the COVID-19 pandemic, the Governor of Oregon, Kate Brown, and the Director of the Oregon Health Authority ("OHA"), Patrick Allen, were responsible for crafting the state's response to the novel virus's rapid spread. When COVID-19 vaccines first became available, Brown and Allen established priority tiers to guide the state's vaccine rollout, and they assigned state prison inmates to a lower priority vaccination tier than correctional officers. This appeal concerns the affected inmates' claim for damages allegedly caused by this vaccine prioritization.

Defendants Brown and Allen moved to dismiss the vaccine prioritization damages claim, contending that it is barred by the immunity provision of the Public Readiness and Emergency Preparedness ("PREP") Act. The district court denied the motion to dismiss, and Defendants filed this interlocutory appeal. We conclude that Brown and Allen are entitled to immunity from suit and liability for the vaccination prioritization claim under the PREP Act. We therefore reverse and remand to the district court for further proceedings consistent with this opinion.

BACKGROUND

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"Congress passed the PREP Act in 2005 to encourage during times of crisis the development and deployment of medical countermeasures (such as diagnostics, treatments, and vaccines) by limiting legal liability relating to their administration." *Hampton v. California*, 83 F.4th 754, 762 (9th Cir. 2023) (cleaned up). The statute gives "covered person[s]" immunity "from suit and liability" for claims "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). 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." *Id.* § 247d-6d(a)(2)(B).

The Act's immunity lies dormant until the Secretary of Health and Human Services "makes a determination that a disease... constitutes a public health emergency" and "make[s] a declaration, through publication in the Federal Register," that the Act's immunity "is in effect." *Id.* § 247d-6d(b)(1). The Act requires the Secretary's declaration to define the scope of immunity, including by identifying the

covered countermeasures and the period during which the liability protections are in effect. *Id.* § 247d-6d(b)(1)–(2).

On March 17, 2020, the Secretary issued a declaration announcing that COVID-19 "constitutes a public health emergency" and that "immunity as prescribed in the PREP Act" was "in effect" for the "manufacture, testing, development, distribution, administration, and use of" covered countermeasures. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201 (Mar. 17, 2020). The Secretary broadly defined "covered countermeasures" to include "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19." *Id.* at 15202.

II

Plaintiffs are current and former inmates—or "adults in custody" ("AICs")—of the Oregon Department of Corrections, or their personal representatives, who contracted COVID-19 while in custody in Oregon prisons. Tragically, COVID-19 caused or contributed to the deaths of some inmates. In April 2020, Plaintiffs filed a class action complaint under 42 U.S.C. § 1983 against various Oregon officials, alleging multiple federal and state claims related to defendants' initial responses to COVID-19. Plaintiffs initially moved for injunctive relief to reduce the state prison population, which the district court denied.

Meanwhile, development of the first COVID-19 vaccines progressed rapidly, culminating in FDA approval of a vaccine in December 2020. On December 9, 2020, the Secretary amended the COVID-19 declaration for the fourth time. *See* Fourth Amendment to the Declaration Under the

Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190 (Dec. 9, 2020) ("Declaration"). In relevant part, the Secretary amended Section IX to clarify that "[p]rioritization or purposeful allocation" of a scarce covered countermeasure can fall within the PREP Act's liability protection. *Id.* at 79197.1

The Oregon Health Authority then published guidance recommending phased allocation of the vaccines. In Phase 1A, healthcare personnel, residents in long-term care facilities, and corrections officers were eligible for vaccines. In Phase 1B, teachers, childcare workers, and persons age 65 or older were eligible. Neither phase categorically covered AICs, but AICs who met the eligibility criteria were prioritized for vaccination on the same terms as the general population. For example, all AICs who were 65 or older were eligible for vaccination in Phase 1B. The Governor's initial rollout of the vaccines was consistent with OHA's guidance.

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¹ See also Declaration, 85 Fed. Reg. at 79194-95 & n.9 (clarifying that the Declaration must be construed in accordance with HHS general counsel advisory opinions and expressly incorporating them); Dep't of Health & Human Servs. Office of General Counsel, Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23. 2020, 6. https://www.hhs.gov/guidance/sites/default/files/hhs-guidancedocuments/AO4.2 Updated FINAL SIGNED 10.23.20-2.pdf [https://perma.cc/26RF-9A6Y] ("Management and operation countermeasure programs . . . involve decisions regarding prioritization of populations to receive countermeasures while there are limited doses. And prioritization necessarily entails temporarily withholding limited doses from some recipients ").

In response, Plaintiffs amended their complaint to add class claims for injunctive relief and damages, alleging that the vaccine prioritization of corrections officers, but not all AICs, violated the Eighth Amendment's prohibition against cruel and unusual punishment. On February 2, 2021, the district court certified a provisional class of all AICs who had not yet been offered a vaccine and granted Plaintiffs preliminary injunctive relief, ordering the immediate prioritization of approximately 11,000 AICs for vaccination. Defendants complied with the court's order.

In September 2021, when vaccines were no longer scarce, the district court dismissed as moot Plaintiffs' claim for injunctive relief because all Oregonians (ages twelve and over) were eligible to receive a COVID-19 vaccine and vaccine supply in Oregon exceeded demand. Plaintiffs' damages claims, however, remained.

In November 2021, Brown and Allen each moved to dismiss Plaintiffs' vaccine prioritization damages claim, contending that it is barred by the PREP Act. The district court denied both motions, and Defendants filed this interlocutory appeal. Although Plaintiffs' action involves additional claims and defendants, the only issue presented in this appeal is whether the PREP Act bars Plaintiffs' vaccine prioritization damages claim against Brown and Allen.

DISCUSSION

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We have jurisdiction over Defendants' immediate appeal of the district court's denial of PREP Act immunity. *Hampton*, 83 F.4th at 761–62 (holding that a denial of PREP Act immunity is immediately appealable under the collateral order doctrine).

We review de novo the denial of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *Mudpie, Inc. v. Travelers Cas. Ins. Co. of Am.*, 15 F.4th 885, 889 (9th Cir. 2021). We also review de novo the legal issue of whether Brown and Allen are entitled to immunity under the PREP Act. *See Cox v. Dep't of Soc. & Health Servs.*, 913 F.3d 831, 837 (9th Cir. 2019) (explaining that whether a public official is entitled to immunity is a question of law reviewed de novo).

H

We first consider whether the statutory requirements for PREP Act immunity are met with respect to Plaintiffs' vaccine prioritization damages claim. We then address Plaintiffs' argument that, regardless of whether those requirements are met, the PREP Act does not bar federal constitutional claims brought under 42 U.S.C. § 1983.

A

To determine whether Plaintiffs' vaccine prioritization damages claim meets the PREP Act's requirements for immunity, we begin with the statutory text. The Act's immunity provision states:

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.

42 U.S.C. § 247d-6d(a)(1). Additionally, in § 247d-6d(a)(2)(B), the Act defines the "scope" of immunity as including

any claim for loss that has a causal relationship with the administration to or use individual ofby а covered including countermeasure, causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation. packaging, marketing, promotion, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

Id. § 247d-6d(a)(2)(B).

Plaintiffs concede that both Defendants are covered persons, that COVID-19 vaccines are covered countermeasures, and that Plaintiffs seek damages for losses allegedly caused by Defendants' decisions to give corrections officers and others vaccine priority before AICs. Thus, the only question is whether Plaintiffs' vaccine prioritization claim falls within the scope of covered claims as defined in §§ 247d-6d(a)(1) and (a)(2)(B) and the Secretary's declaration.

For the following reasons, we conclude that the vaccine prioritization claim falls within the scope of covered claims because "administration" of a covered countermeasure includes prioritization of that countermeasure when its supply is limited.

The PREP Act does not explicitly define what it means to administer a countermeasure to an individual under § 247d-6d(a)(1). The phrasing "administration to ... an individual of a covered countermeasure" could refer only to the act of physically giving a countermeasure to a particular person—for example, injecting someone with a vaccine shot. However, in § 247d-6d(a)(2)(B), the Act provides that the scope of immunity under paragraph (1) includes various activities with a causal relationship to the administration of a countermeasure beyond injecting someone with a vaccine. Most significantly, subsection (a)(2)(B) lists several terms, including "administration," without reference to "an individual." This is consistent with the expansive causal relationship the subsection provides; for example, the "design, development," "manufacture," and "distribution" of a vaccine are multiple links removed in the chain of events from the ultimate injecting of an individual with a vaccine. By referring to "administration . . . of [a covered] countermeasure," in the context of a list that expands the conduct within the Act's scope of immunity, and without requiring a direct link to an individual, subsection (a)(2)(B) broadens the scope of immunity to administrative activities other than the physical act of directly injecting a particular person with a vaccine.

Consistent with the text of subsections (a)(1) and (a)(2)(B), the Secretary's Declaration defines "administration" to include both "physical provision of the countermeasures to recipients" and, in relevant part, "activities and decisions directly relating to . . . management and operation of countermeasure programs." 85 Fed. Reg. at 79197. The Declaration further explains: "Where there are

limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to... the administration to... an individual' under 42 U.S.C. § 247d-6d... Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections." *Id.* (first and second alteration in original).

Plaintiffs do not challenge the validity definition of "administration" Declaration's or interpretation of that term as including prioritization of scarce countermeasures. Moreover, that interpretation is consistent with the statutory text, as well as our decision in *Hampton*. In that case, we held that "the PREP Act provides immunity only from claims that relate to 'the administration by an individual of' or the use countermeasure—not such a measure's non-administration or non-use." Hampton, 83 F.4th at 763 (emphasis in original). However, we distinguished prioritization of a scarce countermeasure from non-administration or non-use. and we explained that, "for a countermeasure with limited availability, administering the countermeasure to one person could mean withholding it from another." Id.

Plaintiffs concede that the Declaration extends PREP Act immunity to claims arising from a "failure to administer" a COVID-19 vaccine to a particular individual when that omission occurred in the context of an individualized prioritization decision. They argue, however, that PREP Act immunity does not extend to "policy-level" failure-to-administer claims. We disagree.

Several of the PREP Act's provisions expressly show Congress's intent to extend immunity to persons who make policy-level decisions regarding administration or use of covered countermeasures and do not directly administer countermeasures to particular individuals. The Act defines the term "covered person," "when used with respect to the administration or use of a covered countermeasure," to include a "program planner of such countermeasure." 42 U.S.C. § 247d-6d(i)(2)(B)(iii). The Act further defines "program planner" to include, in relevant part, a state government, a person employed by a state government, a "person who supervised or administered a program with respect to the administration" of a countermeasure, and "a person who has established requirements [or] provided policy guidance . . . to administer or use a covered countermeasure." 2 Id. § 247d-6d(i)(6). The Declaration also defines "covered person" to include a governmental program planner. See 85 Fed. Reg. at 79195.

Plaintiffs cite the Secretary's Declaration, but they do not specifically identify any provisions that expressly or impliedly exclude policy-level prioritization decisions from the scope of immunity. Plaintiffs appear to rely on the fact that the Declaration used an "example" involving an individualized prioritization decision to illustrate when "not administering" a covered countermeasure could be protected

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² Individuals who directly administer countermeasures to other individuals fall within the definition of a "qualified person." 42 U.S.C. § 247d-6d(i)(8) ("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").

by the Act. See 85 Fed. Reg. at 79197. But the use of an illustrative example does not limit the scope of immunity to the circumstances of that example.

B

We next consider whether the PREP Act provides immunity from suit and liability for constitutional claims brought under 42 U.S.C. § 1983.

Section 1983 "is a mechanism for vindicating federal statutory or constitutional rights." Stilwell v. City of Williams, 831 F.3d 1234, 1240 (9th Cir. 2016) (citing Baker v. McCollan, 443 U.S. 137, 144 n.3 (1979)). Specifically, § 1983 provides that "[e]very person who, under color of [State law] subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured." 42 U.S.C. § 1983.

Congress, however, may "specifically foreclose[] a remedy under § 1983," and it "may do so expressly . . . or impliedly." *Blessing v. Freestone*, 520 U.S. 329, 341 (1997) (quoting *Smith v. Robinson*, 468 U.S. 992, 1005 n.9 (1984)). "We do not lightly conclude that Congress intended to preclude reliance on § 1983 as a remedy for the deprivation of a federally secured right." *Price v. City of Stockton*, 390 F.3d 1105, 1114 (9th Cir. 2004) (quoting *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 520 (1990)). And the defendant bears the burden to demonstrate that Congress intended to do so. *Id.*; *see also Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 107 (1989).

The PREP Act expressly states, in relevant part, 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). A suit for damages brought under § 1983 alleging a constitutional violation is a suit under federal law. *See Stilwell*, 831 F.3d at 1240; *Baker*, 443 U.S. at 144 n.3.

The PREP Act covers "all claims for loss" related to the administration or use of covered countermeasures. "The use of 'all' indicates a sweeping statutory reach." *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682, 690–91 (9th Cir. 2022). Of course, the PREP Act limits the scope of covered claims to those related to the administration or use of covered countermeasures. But that limitation does not categorically exclude constitutional claims.

The Act also carves out one "exception to the immunity" provided for in § 247d-6d(a) "for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by [the covered person's] willful misconduct." 42 U.S.C. § 247d-6d(d)(1). That exception may provide a remedy for constitutional claims that involve willful misconduct, as defined by the Act. But that exception does not categorically exempt federal constitutional claims from the Act's protection.

Plaintiffs assert that the PREP Act does not expressly foreclose § 1983 as a cause of action for constitutional claims, but they do not explain how the Act's express terms fail to reach such claims. Although the Act does not specifically mention § 1983, Congress used terms that plainly and unambiguously define a broad scope of immunity that includes claims brought under § 1983. Plaintiffs do not cite any precedent holding, or even

suggesting, that Congress can only expressly preclude § 1983 actions by specifically referencing § 1983. Thus, we conclude that Congress intended to expressly immunize covered persons from § 1983 actions for claims covered by the Act, even if those claims are federal constitutional claims.³

Plaintiffs also briefly argue that, even if the PREP Act forecloses a remedy under § 1983 for their constitutional claim, we have the power to grant a damages remedy for that claim. None of the cases Plaintiffs cite, however, suggest that we have the power to override Congress's express grant of immunity from suit and liability for certain claims. See Smith v. Robinson, 468 U.S. 992 (1984); Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics, 403 U.S. 388 (1971); Bell v. Hood, 327 U.S. 678 (1946).

CONCLUSION

Under the PREP Act, defendants Brown and Allen are entitled to immunity from suit and liability with respect to Plaintiffs' vaccine prioritization damages claim. We reverse the district court's denial of Brown's and Allen's motions to dismiss that claim and remand for further proceedings consistent with this opinion.

REVERSED and REMANDED.4

³ Because we conclude that the PREP Act expressly forecloses § 1983 actions for covered claims, we do not need to apply the standard for determining whether Congress impliedly foreclosed § 1983 actions for constitutional violations. *See Stilwell*, 831 F.3d at 1242–43 (discussing *Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246 (2009)).

⁴ Each party shall bear its own costs related to this appeal.