No. 22-35218

IN THE 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.

APPELLANT'S OPENING BRIEF

Appeal from the United States District Court
for the District of Oregon

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INTRODUCTION

This case is a class action against the State of Oregon and ten leaders of Oregon state government for damages related to the COVID-19 pandemic in Oregon state prisons. Plaintiffs sue on behalf of all adults in custody ("AICs") who contracted the virus between February 1, 2020, and May 31, 2022. They allege that their contraction of COVID-19 constitutes cruel and unusual punishment under the Eighth Amendment, as well as negligence under state law, for which they should receive compensatory and punitive damages.

This interlocutory appeal concerns one specific claim in the class action: that the Oregon Governor violated the Eighth Amendment when, consistent with published guidance from the Oregon Health Authority, she did not prioritize all AICs to receive the first available Pfizer and Moderna vaccines in December 2020 and January 2021. Before the district court, the Governor moved to dismiss the claim as barred by the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d & -6e, which provides broad immunity from suit for public officials for responses to public health emergencies. The court denied the motion to dismiss but has stayed discovery on the claim pending this appeal.[1]

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[1] The district court also denied a motion to dismiss the vaccine prioritization claim against the Director of the Oregon Health Authority, Patrick Allen. Director Allen has filed a related interlocutory appeal. No. 22-35219 (9th Cir.).

This Court should reverse. As an initial matter, the Court has jurisdiction over the appeal. Like a denial of qualified immunity, a denial of PREP Act immunity for a public official is immediately appealable under the collateral-order doctrine. On the merits, the challenged action—the prioritization of a scarce vaccine by a state's governor, consistent with guidance from the state's public health authority—falls squarely within the broad immunity from suit provided under the Act. The district court's ruling to the contrary imperils public responses to the ongoing pandemic and to future health emergencies.

STATEMENT OF JURISDICTION

Plaintiffs sued under 42 U.S.C. § 1983 alleging, as pertinent here, that the Governor of Oregon violated the Eighth Amendment to the U.S. Constitution in her prioritization of the initial rollout of vaccines against COVID-19. ER-56–96. Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331.

The Governor appeals the court's denial of her motion to dismiss the vaccine prioritization claim based on the immunity from suit provided to public officials by the PREP Act, 42 U.S.C. §§ 247d-6d & -6e. As explained below, the Court has jurisdiction of the appeal under 28 U.S.C. § 1291 and the collateral-order doctrine.

The district court entered an Order denying the Governor's motion to dismiss the vaccine prioritization claim on February 8, 2022. ER-44–55. The Governor timely appealed on March 9, 2022. ER-164–67.

STATEMENT OF THE ISSUES

1. Whether a denial of immunity from suit for a public official under the PREP Act, 42 U.S.C. §§ 247d-6d & -6e, is immediately appealable under the collateral-order doctrine.

2. Whether the PREP Act confers the Governor of Oregon with immunity from suit for administering and managing the initial rollout of the Pfizer and Moderna vaccines against COVID-19 by prioritizing the rollout consistent with guidance from the state's public health authority.

The dual provisions of the PREP Act are set forth in an attached addendum.

STATEMENT OF THE CASE

The PREP Act provides immunity from suit for state and local governments when the Secretary of the U.S. Department of Health and Human Services ("HHS") declares a public health emergency and invokes the Act's immunity protections for specific responses to the emergency. Since March 2020, the Secretary has invoked the Act for responses to the COVID-19 pandemic, including for vaccine prioritization decisions of state public-health authorities. The Oregon Governor thereby prioritized the initial rollout of the Pfizer and Moderna vaccines consistent with published guidance from the Oregon Health Authority.

But the district court disagreed with the State of Oregon's vaccine prioritization. First, the court altered the prioritization, ordering the vaccination of

AICs ahead of elderly and other vulnerable Oregonians. Then, the court ruled that the PREP Act did not immunize the Governor's decision from suit.

A. Factual History

1. Congress enacts the PREP Act to provide immunity from suit for responses to public health emergencies.

In 2005, the White House called for a national strategy to prepare for a future worldwide pandemic. (RJN-8–25).[2] That year, a novel influenza virus had broken out among birds in Asia and Europe that threatened to jump to humans. (RJN-13–14). The White House reported that it was a question of when, not if, a novel virus would "emerge[] that infects and can be efficiently transmitted between humans." (RJN-13–14). A novel pandemic likely would "come in waves, each lasting months, and pass through communities of all size across the nation and world." (RJN-14). Countering such a pandemic would "require[] the leveraging of all instruments of national power, and coordinated action by all segments of government and society." (RJN-14).

To allow for that requisite action, Congress enacted the PREP Act in that year's defense authorization act. Pub. L. No. 109-148, 199 Stat. 2680, 2818–32 (Dec. 30, 2005). In short, the Act provides broad immunity from suit for responses

[2] "RJN" refers to the request for judicial notice filed concurrently with this brief. The Governor requests judicial notice of federal government documents related to the PREP Act from "sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2).

to public health emergencies. The Act's liability protections were intended, in part, to incentivize and promote the rapid development and distribution of vaccines to combat future pandemics. *See* 109 Cong. Rec. H12264 (daily ed. Dec. 18, 2005) (statement of Rep. Deal) ("We cannot afford not to take the important steps of making sure we can get and deliver a vaccine.").

To that end, the plain text of the statute provides immunity from suit for damage claims over the development and deployment of "countermeasures," such as a vaccine, during a public health emergency. 42 U.S.C. § 247d-6d(a)(1). As pertinent here, the Act defines covered persons to include "a program planner of such countermeasure," including "a State or local government," as well as "a person employed by the State or local government." *Id.* § 247d-6d(i)(2)(B)(iii), -6d(i)(6). The Act also defines covered countermeasures to include a "biological product" intended to "mitigate, prevent, treat, or cure a pandemic," such as a vaccine, that has been granted emergency-use authorization by the FDA. *Id.* § 247d-6d(i)(1)(C), -6d(i)(7)(A)(i)(I), -6d(i)(7)(B)(iii).

The PREP Act's broad liability protections lie dormant until invoked by the HHS Secretary in the face of a public health emergency. In particular, "if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency," then the Secretary may declare an emergency and activate a response "through publication in the Federal

Register." *Id.* § 247d-6d(b)(1). Specifically, the Secretary can recommend and invoke liability protections for "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." *Id.* § 247d-6d(a)(1), -6d(b)(1). In doing so, the Secretary must identify the applicable disease, time period, population, geographic area, and means of distribution for each covered countermeasure. *Id.* § 247d-6d(b)(2).

The Act's liability protections are sweeping. The Act provides immunity from suit to any covered person, for any claim of loss under either federal or state law, relating to the administration of countermeasures identified in an HHS Secretary's declaration under the Act. *Id.* § 247d-6d(a). In other words, the Act preempts and displaces all traditional federal and state law damage claims and remedies against covered persons for activities delineated by the Secretary.

In doing so, the Act creates a federal cause of action that provides the "sole exception" to its grant of immunity. *Id.* § 247d-6d(d)(1). Only individuals who have suffered "death or serious physical injury" due to "willful misconduct" by a covered person may seek relief. *Id.* § 247d-6d(d)(1)–(2); *see id.* § 247d-6e(e)(3) (same). First, the individual must request compensation from a fund that the Act automatically creates on the issuance of a declaration. *Id.* § 247d-6e(a), -6e(d)(1). Only after exhausting that administrative remedy can one file suit, and only in the U.S. District Court for the District of Columbia. *Id.* §§ 247d-6d(e)(1), -6e(d)(1).

2. The Secretary of HHS invokes the PREP Act for responses to the COVID-19 pandemic, including vaccine prioritization decisions.

COVID-19 is a novel coronavirus that began circulating the world in late 2019 and was declared a global pandemic by the World Health Organization on March 11, 2020. Less than a week later, HHS Secretary Alex M. Azar II invoked the PREP Act's liability protections to marshal a whole-of-nation response to the burgeoning pandemic. (RJN-52–58). Congress then quickly incorporated the Secretary's declaration in the CARES Act stimulus package. *See, e.g.*, Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, 134 Stat. 281, 534 (Mar. 27, 2020).

As pertinent here, the Secretary invoked the Act's liability protections for any state official for any decision relating to the distribution of an eventual vaccine against COVID-19. Specifically, the Secretary "determined that liability immunity is afforded to Covered Persons * * * for Recommended Activities involving Covered Countermeasures that are related to," among other things, "[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasure." (RJN-57).

In doing so, the Secretary defined "covered persons" to include "program planners" under the Act, including "their officials, agents, and employees." (RJN-56); *see* 42 U.S.C. § 247d-6d(i)(6) (defining "program planners" to include

"a State or local government"). Next, the Secretary defined "covered countermeasures" to include "any biologic, * * * or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19." (RJN-57). Then, the Secretary defined administering a countermeasure to include any "decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients." (RJN-57). Finally, the Secretary defined an "Authority Having Jurisdiction" to administer the countermeasure as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, * * * state * * * boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority." (RJN-57).

As the FDA neared granting emergency use authorization for the Pfizer and Moderna vaccines in December 2020, the Secretary amended the declaration to reiterate, among other things, that vaccine prioritization decisions would qualify for PREP Act immunity. (RJN-144–53). In particular, "[p]rioritization 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 th[e] Declaration's liability protections."[3] (RJN-152). A covered person need

[3] To date, the HHS Secretary has amended the PREP Act declaration for COVID-19 ten times. *See generally* HHS Administration for Strategic Preparedness & Response, *Public Readiness and Emergency Preparedness Act*, https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx (last visited Aug. 15, 2022).

only comply with "*any*" of "the public-health guidance issued by an Authority Having Jurisdiction over the person's activity or location in order to qualify for PREP Act immunity." (RJN-63; *see* RJN-147 & n.9 (so incorporating)).

To that end, HHS gave explicit guidance to the National Governors Association that states would be the primary authority with jurisdiction to prioritize and execute the initial rollout of the Pfizer and Moderna vaccines:

> The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. The jurisdiction's immunization program will then be responsible for managing and approving orders from enrolled providers within their jurisdiction using this allotment.

(RJN-157). The CDC would make recommendations, but "States [we]re not bound to follow federal prioritization recommendations." (RJN-158).

To aid states in their decision making, the CDC issued a vaccine "playbook" in October 2020 that provided operational guidance on how state and local health authorities might prioritize vaccine eligibility by phases and subgroups once the FDA granted emergency-use authorization to a vaccine. (RJN-83–86). The CDC also convened its Advisory Committee on Immunization Practices to recommend how states might prioritize the initial rollout "while vaccine supply is limited." (RJN-170–78). The committee emphasized that state and local health authorities ultimately should make their own prioritization decisions based on "local COVID-19 epidemiology and demand"; the committee also encouraged "[a]

flexible approach to allocation [to] facilitate efficient management and ensure that COVID-19 vaccine is administered equitably and without delay." (RJN-177).

The CDC's advisory committee recommended three priority phases:

- CDC Phase 1a: healthcare personnel and residents in long-term care facilities, such as nursing homes.
- CDC Phase 1b: persons aged ≥ 75 years and frontline essential workers, including corrections officers, teachers, and child care.
- CDC Phase 1c: persons aged ≥ 65 years, adults with underlying medical conditions, and essential workers not previously prioritized.

(RJN-175–77; *see also* RJN-171–72 (announcing CDC Phase 1a)). In doing so, the committee "balance[d] the vaccination program priorities of minimizing societal disruption and preventing morbidity and mortality." (RJN-177; *see* RJN-29 (announcing similar prioritization priorities)). As pertinent here, the committee did not recommend prioritizing AICs apart from their individual priority based on age and underlying medical condition. (*See* RJN-170–78).

3. The Oregon Governor prioritizes the initial rollout of the COVID-19 vaccines consistent with guidance from the Oregon Health Authority.

The Oregon Health Authority is the state agency charged with public health in Oregon. As pertinent here, it also was the public-health agency "responsible for determining vaccine priority and allocation of the COVID-19 vaccines provided to the State of Oregon." (ER-132). In addition, "[d]uring a state of emergency," such as a pandemic, "the Governor has complete authority over all executive agencies of

state government and the right to exercise * * * all police powers vested in the state by the Oregon Constitution in order to effectuate" an effective state response. Or. Rev. Stat. § 401.168(1).

The Oregon Health Authority, as the authority with jurisdiction over vaccine prioritization for the State of Oregon, published guidance in January 2021 recommending a phased rollout of the Pfizer and Moderna vaccines that largely mirrored the prioritization guidance from the CDC's advisory committee:

- Oregon Phase 1A: four subprioritized groups of healthcare personnel, residents in long-term care facilities, and corrections officers.
- Oregon Phase 1B: five subprioritized groups of teachers, childcare workers, and persons aged ≥ 65 years.

(ER-137). Remaining groups, including AICs not otherwise included in Phase 1A or 1B, would be prioritized later as the State received additional vaccine supply. (ER-133). The Governor, in turn, prioritized the initial rollout consistent with the published guidance. (*See, e.g.*, ER-156–60).

B. Procedural History

1. The district court orders the vaccination of all AICs ahead of elderly and other at-risk Oregonians.

As noted, this case is a class action on behalf of all AICs in Oregon state prisons who contracted COVID-19 between February 1, 2020, and May 31, 2022. In April 2020, plaintiffs sued the State, the Governor, and the central leadership of the Oregon Department of Corrections, alleging that defendants' efforts to respond

to COVID-19 violated the Eighth Amendment and constituted negligence under state law. (ECF 1).[4] Plaintiffs moved for an order reducing the prison population, which the district court denied. (ECF 14, 108).

In January 2021, plaintiffs then moved to certify a provisional vaccine class of all AICs who had not yet been offered a vaccine, arguing that the prioritization in Oregon Phase 1A of corrections officers, but not all AICs, constituted cruel and unusual punishment. (ECF 154 at 3). At that time, more than 1,400 AICs had been vaccinated, either as healthcare workers under Phase 1A or due to medical vulnerability. (ER-142). Plaintiffs asked the district court to prioritize, for immediate vaccination, the roughly 11,000 remaining AICs. (ECF 156).

As plaintiffs' motion was pending, the unprecedented rollout of the vaccines continued to shift by the day, if not the hour. For example, the State had hoped to start vaccinating Phase 1B on January 23 by prioritizing all persons aged 65 years or older; due to a lack of vaccine supply, however, the State ultimately delayed the vaccination of elderly Oregonians until February 8, 2020. (ECF 154 at 3 & n.1).

On February 2, 2020, the district court certified the provisional vaccine class and granted plaintiffs injunctive relief, ordering the immediate prioritization of approximately 11,000 AICs for vaccination, ahead of elderly and other at-risk

[4] "ECF" refers to the district court docket in this case.

Oregonians in Phase 1B. (ER-130). The court ruled that prioritizing corrections officers but not AICs constituted deliberate indifference as a purposeful failure to respond to AIC medical needs. (ER-123–24). The court rejected the argument that vaccines were in short supply, reasoning that the vaccination of those in Phase 1A "demonstrates that there is sufficient COVID-19 vaccine available." (ER-125). The court also found persuasive informal guidance from the CDC in which the CDC, in "FAQs," encouraged jurisdictions to vaccinate corrections officers and AICs "at the same time." (ER-125 & n.13 (emphasis omitted)).

Amidst the exigent and rapidly changing nature of the vaccine rollout, defendants complied with the district court's vaccine order rather than seek interlocutory review from this Court. (ECF 197).

2. The district court denies the Oregon Governor immunity from suit over the State's vaccine prioritization decisions.

By April 2021, more than half of all adults in the United States had been vaccinated; vaccine supply also began to outstrip demand. In September 2021, the district court dismissed as moot plaintiffs' claim for injunctive relief on behalf of the provisionally certified vaccine class, reasoning that "all Oregonians (ages twelve and over) are now eligible to receive a COVID-19 vaccine and vaccine supply in Oregon currently exceeds demand." (ECF 272 at 10, 12).

As a result, only class claims for damages remain. (ER-63). As pertinent here, plaintiffs allege that individual defendants violated the Eighth Amendment by

failing, over the course of the pandemic and across all state prisons, to implement or enforce adequate masking, social distancing, quarantine, and sanitation policies; plaintiffs also seek damages for the decision not to include all AICs in Phase 1A of Oregon's rollout of the Pfizer and Moderna vaccines. (ER-90–91).

In turn, all defendants moved to dismiss the vaccine prioritization claim for damages as barred by the PREP Act. (ECF 281 at 6). Defendants argued that the challenged vaccine prioritization decisions by state officials in this case fell within the broad grants of immunity from suit provided in the Act and Secretary's declaration. (ECF 281 at 8–13). Defendants further argued that plaintiffs had failed to allege that any defendant other than Governor Brown or Director Allen played any role in the vaccine prioritization. (ECF 281 at 9 & n.3).

In response, plaintiffs conceded "that Defendants are 'covered persons' within the meaning of the Act, that Plaintiffs' Eighth Amendment claim is one for 'loss,' and that COVID-19 vaccines are 'covered countermeasures' within the meaning of the Secretary's declaration." (ECF 283 at 6 n.6). Nevertheless, plaintiffs argued that the PREP Act did not displace their claim for damages under 42 U.S.C. § 1983. (ECF 284 at 7–9). Plaintiffs also argued that the PREP Act provides immunity only "for action, not inaction," and that choosing not to prioritize a group for vaccination did not constitute administering a countermeasure under the Act or Secretary's declaration. (ECF 284 at 9–10).

The district court granted in part and denied in part the motion to dismiss. The court dismissed the vaccine prioritization claim against all defendants other than Governor Brown and Director Allen, reasoning that plaintiffs had failed to plead sufficient allegations against them. (ER-54–55). But the court denied the motion as to Governor Brown and Director Allen. (ER-49–54). The court "[a]ssume[d] without deciding that the PREP Act applies to a public health authority's vaccine allocation plan" if done "in accordance with a public health authority's directive or public health guidance." (ER-54). But the court ruled of its own accord that the decision not to prioritize AICs was "contrary to public health guidance" because the CDC FAQs had encouraged jurisdictions to vaccinate corrections officers and AICs "at the same time."[5] (ER-53).

3. The Court denies plaintiffs' motion to dismiss this appeal.

After the Governor timely appealed the district court's denial of her motion to dismiss the vaccine prioritization claim, plaintiffs moved to dismiss the appeal for lack of appellate jurisdiction. (Mot. Dismiss, Docket Entry No. 4). A motions panel of the Court denied the motion to dismiss without prejudice to plaintiffs' renewing the jurisdictional argument in their answering brief. (ER-3–4).

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[5] Plaintiffs never argued that the Governor's prioritization decision was contrary to public health guidance, and the web link to the FAQs provided in the district court's order is now invalid. A copy of the then-extant FAQs, obtained from the Internet Archive's Wayback Machine, is included at RJN-179–83.

SUMMARY OF THE ARGUMENT

The Court should reverse the district court's denial of the Governor's motion to dismiss the vaccine prioritization claim against her. As an initial matter, the Court has jurisdiction over this interlocutory appeal under the collateral-order doctrine, as the appeal satisfies all three requirements to qualify for immediate review. The district court's order was both conclusive and collateral: The court interpreted the PREP Act not to provide the Governor immunity from suit over the challenged vaccine prioritization, a legal question separate and distinct from plaintiffs' Eighth Amendment claims. And the order threatens a value of high order. Congress enacted the PREP Act specifically to incentivize the rapid creation and distribution of vaccines in response to a public health emergency. In denying the Governor immunity from suit for her role in that distribution, the district court imperils future responses to COVID-19 and other health emergencies.

On the merits, the Governor's vaccine prioritization falls squarely within the plain text of the PREP Act and the invocation of the Act by the HHS Secretary. It is undisputed that the Governor is a "covered person" for plaintiffs' claim of "loss" for a "covered countermeasure." The Governor's prioritization decision also constitutes "administration" of a countermeasure. The statute plainly encompasses managing the rollout of a scarce countermeasure, and the HHS Secretary explicitly listed vaccine prioritization as a covered activity in his COVID-19 declaration.

STANDARD OF REVIEW

This case presents two questions of law: (1) whether a denial of immunity from suit for a public official under the PREP Act qualifies for immediate appeal under the collateral-order doctrine and, if so, (2) whether the Governor's prioritization of the initial rollout of the COVID-19 vaccines qualifies for immunity under the statute. The Court examines both legal questions de novo. *See SolarCity Corp. v. Salt River Project Agric. Improvement & Power Dist.*, 859 F.3d 720, 725 (9th Cir. 2017) (collateral-order doctrine); *Palmer v. United States*, 945 F.2d 1134, 1135 (9th Cir. 1991) (interpretation of an immunity statute).

ARGUMENT

I. The denial of a public official's request for immunity from suit under the PREP Act qualifies for immediate appeal under the collateral-order doctrine.

Under the collateral-order doctrine, interlocutory appeal is available when (1) a district court's order is conclusive; (2) the order addresses a question separate from the merits of the underlying case; and (3) the separate question raises a particular value of high order that will be lost if not reviewed immediately. *SolarCity*, 859 F.3d at 724. This appeal of an order denying immunity from suit for a public official under the PREP Act satisfies all three requirements.[6]

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[6] This case does not raise, and the Court need not reach, whether the collateral-order doctrine applies to denials of immunity from suit under the PREP Act for non-public officials, such as nursing homes.

A. The district court's order denying the Governor immunity from suit is conclusive.

First, to be appealable, an order must "conclusively determine the disputed question." *Will v. Hallock*, 546 U.S. 345, 349 (2006) (citation omitted). The denial of a motion to dismiss on the basis of immunity from suit, "to the extent that it turns on an issue of law," is final and conclusive under the collateral-order doctrine. *Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985) (qualified immunity); *see P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993) (Eleventh Amendment immunity); *Helstoski v. Meanor*, 442 U.S. 500, 507 (1979) (Speech and Debate Clause immunity); *Abney v. United States*, 431 U.S. 651, 659 (1977) (Double Jeopardy Clause immunity); *see also Nixon v. Fitzgerald*, 457 U.S. 731, 742 (1982) (absolute immunity).

As the Supreme Court has explained, denials of asserted claims of immunity from suit are "conclusive determinations that [defendants] have no right *not* to be sued in federal court." *P.R. Aqueduct*, 506 U.S. at 145 (emphasis added). An immunity from suit "is its possessor's entitlement not to have to answer for his [or her] conduct in a civil damages action." *Mitchell*, 472 U.S. at 525. Particularly with public officials, such immunity "give[s] government officials a right, not merely to avoid standing trial, but also to avoid the burdens of such pretrial matters as discovery, as inquiries of this kind can be peculiarly disruptive of effective

government." *Behrens v. Pelletier*, 516 U.S. 299, 308 (1996) (cleaned up). As such, a "denial of a motion to dismiss is conclusive as to this right." *Id.*

Here, the district court's order denying Governor Brown immunity from suit was both conclusive and turned on an issue of law. The Governor asserted immunity from suit, under the PREP Act, on plaintiffs' vaccine prioritization claim; the district court construed the PREP Act and associated Secretary declarations not to grant that immunity as a matter of law; and the court thereby denied her motion to dismiss the claim. (ER-54). As such, the district court's order is final and conclusive under the collateral-order doctrine.

In moving to dismiss the appeal, plaintiffs argued that the denial of immunity from suit on the vaccine prioritization claim is not conclusive because plaintiffs also assert *other* claims for relief against the Governor. (Mot. Dismiss at 11). Plaintiffs cited no case law to support their argument, and *Behrens* squarely forecloses it. There, the Supreme Court held that a right to immunity from suit "is a right to immunity *from certain claims*, not from litigation in general; when immunity with respect to those claims has been finally denied, appeal must be available, and cannot be foreclosed by the mere addition of other claims to the suit." 516 U.S. at 312. So too here. Indeed, for that reason, the district court has stayed discovery on the prioritization claim, and only on that claim, pending resolution of this appeal. (ECF 379).

B. The order addresses a question separate from the merits of plaintiffs' underlying claims.

Next, the district court order being appealed "must address a question that is separate from the merits of the underlying case." *SolarCity*, 859 F.3d at 724 (internal quotation marks omitted). As a general rule, "a question of immunity is separate from the merits of the underlying action." *Mitchell*, 472 U.S. at 528. Although "a reviewing court must consider [a] plaintiff's factual allegations in resolving the immunity issue," when based on a question of law, "a claim of immunity is conceptually distinct from the merits of the plaintiff's claim that his rights have been violated." *Mitchell*, 472 U.S. at 527–29. Put another way, "[c]ourts have generally found that claims of immunity are separate from the merits of the underlying action." *Burlington N. & Santa Fe Ry. Co. v. Vaughn*, 509 F.3d 1085, 1090 (9th Cir. 2007); *see Childs v. San Diego Fam. Hous. LLC*, 22 F.4th 1092, 1096 (9th Cir. 2022) (denial of derivative sovereign immunity conceded to be both conclusive and separate from the merits).

Here, the district court's order turned on a question of law separate from the merits of plaintiffs' case. Plaintiffs allege that the decision not to prioritize AICs in Phase 1A of Oregon's vaccine rollout constitutes cruel and unusual punishment in violation of the Eighth Amendment. But the order at issue here examined a separate and distinct legal question: whether, as a matter of law, the PREP Act's immunity from suit bars plaintiffs' damage claim against the Governor.

Plaintiffs previously argued otherwise, maintaining that the appeal "would require this Court to undertake an inquiry enmeshed in the merits of Plaintiffs' underlying claims," in violation of *Van Cauwenberghe v. Biard*, 486 U.S. 517 (1988). (Mot. Dismiss at 13). Plaintiffs are mistaken.

In *Van Cauwenberghe*, the Court held that "the denial of a motion to dismiss on the ground of *forum non conveniens* is not appealable under" the collateral-order doctrine. *Id.* at 529. The Court reasoned that, to assess the propriety of a particular forum, a district court "must look into the relative ease of access to sources of proof" and, in doing so, "must scrutinize the substance of the dispute between the parties to evaluate what proof is required, and determine whether the pieces of evidence cited by the parties are critical, or even relevant, to the plaintiff's cause of action and to any potential defenses to the action." *Id.* at 528 (internal quotation marks and citation omitted). The Court thus concluded that, "in the main, the issues that arise in *forum non conveniens* determinations will substantially overlap factual and legal issues of the underlying dispute." *Id.* at 529.

By contrast, as noted above, the Supreme Court and this Court have held that, as a category of cases, denials of immunity from suit involve a legal inquiry distinct from the underlying merits. *Mitchell*, 472 U.S. at 527–29; *Burlington N.*, 509 F.3d at 1090. This case is a textbook example of why that is so. Plaintiffs' Eighth Amendment claim asks whether (1) plaintiffs experienced a sufficiently

serious harm that society refuses to tolerate; (2) the Governor knew of and disregarded a substantial risk of that harm; and (3) the Governor unreasonably failed to abate that risk given the circumstances. *Farmer v. Brennan*, 511 U.S. 825, 834, 837, 847 (1994); *Helling v. McKinney*, 509 U.S. 25, 36 (1993). The question of immunity, however, requires a court to interpret and apply the terms of a federal statute. Specifically, whether the PREP Act immunizes the Governor from suit asks whether (1) the Governor is a "covered person" under the Act; (2) the claim at issue is one for "loss" as defined in the statute; (3) the claim concerns a "covered countermeasure" under the Act; and (4) the alleged loss "aris[es] out of, relat[es] to, or result[s] from the administration * * * or use" of that covered countermeasure. 42 U.S.C. § 247d-6d(a)(1). In short, the two inquiries are "conceptually distinct." *Mitchell*, 472 U.S. at 527.

C. The separate question of PREP Act immunity raises a particular value of high order that will be lost if not reviewed immediately.

Finally, "the separate question must raise some particular value of a high order and evade effective review if not considered immediately." *SolarCity*, 859 F.3d at 724 (internal quotation marks omitted). The denial of immunity from suit generally evades later review, as such immunity "is effectively lost if a case is erroneously permitted to go to trial." *Mitchell*, 472 U.S. at 526. Nonetheless, "it is not mere avoidance of a trial, but avoidance of a trial that would imperil a substantial public interest, that counts when asking whether an order is

'effectively' unreviewable if review is to be left until later." *Will*, 546 U.S. at 353. In sum, the appeal must raise "some particular value of a high order," such as "preserving the efficiency of government and the initiative of its officials," or "respecting a State's dignitary interests." *Id.* at 352.

Here, the district court's denial of immunity from suit for a public official raises a value of high order that evades effective review if not considered immediately. The White House called for a national response to prepare for an eventual pandemic, and Congress enacted the PREP Act to empower public officials to respond quickly to a public health emergency without fear of civil litigation. In doing so, Congress specifically sought to enable the rapid creation and distribution of vaccines in the face of a future pandemic. 109 Cong. Rec. H12264. That foresight succeeded with the historic rollout of the COVID-19 vaccines. Denying immunity from suit to a public official over that rollout—allowing a state's governor to be hauled into court and subjected to discovery by anyone who disagreed with that state's vaccine prioritization—defeats the purpose of the statute irretrievably, thereby imperiling public responses to the ongoing COVID-19 pandemic and to future health emergencies.

In response, plaintiffs asserted, without citation to any authority, that the existence of other claims against the Governor precludes appealing the denial of immunity from suit on the vaccine prioritization claim. (Mot. Dismiss at 16 n.7).

As noted above, the Supreme Court rejected that exact argument in *Behrens*, 516 U.S. at 312. Plaintiffs further argued that subjecting the Governor to civil suit and discovery on her pandemic decision-making would not imperil a substantial public interest. (Reply in Supp. at 7–8). But both the PREP Act itself, and case law on immunity more generally, demonstrate the need for interlocutory review here.

Congress, for its part, recognized that safeguarding immunity from suit under the PREP Act, through immediate appeal, is central to marshaling a whole-of-nation response to a public health emergency. In the statute, Congress explicitly authorized interlocutory appeals to the D.C. Circuit for denials of immunity from suit when cases are brought in that circuit and, further, prohibited discovery before an interlocutory appeal is resolved. 42 U.S.C. § 247d-6d(e)(6)(A), -6d(e)(10). To be sure, Congress did not explicitly authorize interlocutory appeals elsewhere, but likely only because Congress directed that such damage claims—against covered persons for covered countermeasures—could only be raised in D.C. District Court. *Id.* §§ 247d-6d(e)(1), -6e(d)(1). Although plaintiffs ignored that directive here, the importance of interlocutory review remains. Otherwise, a plaintiff could defeat a covered person's right to immediate appeal, and thereby subvert the statutory scheme, simply by raising the claim for damages in the wrong forum.

Notably, the D.C. Circuit recently examined whether it had interlocutory jurisdiction over denials of immunity from suit under the PREP Act from courts

other than D.C. District Court. *Cannon v. Watermark Ret. Cmtys., Inc.*, __ F.4th __, Nos. 21-7067 & 21-7096, 2022 WL 3130653, at *1 (D.C. Cir. Aug. 5, 2022). The court held that the answer was no, largely because other appellate courts have jurisdiction over other "trial courts' *grants* of dispositive motions" on the basis of PREP Act immunity. *Id.* at *10. In so ruling, the Court noted that the "collateral order doctrine" may "support interlocutory appeal to the appropriate circuit court from orders *denying* PREP Act immunity." *Id.* at *9 (emphasis added).

The Supreme Court similarly has held that, as to public officials, protecting immunity from suit through immediate appeal is vital to a properly functioning democracy. Specifically, forcing officials to endure civil litigation despite a legal claim to immunity imposes "a cost not only to the defendant officials, but to society as a whole." *Harlow v. Fitzgerald*, 457 U.S. 800, 814 (1982). Those costs include "distraction of officials from their governmental duties, inhibition of discretionary action, and deterrence of able people from public service." *Mitchell*, 472 U.S. at 526 (quoting *Harlow*, 457 U.S. at 816). As such, "even such pretrial matters as discovery are to be avoided if possible, as 'inquiries of this kind can be peculiarly disruptive of effective government.'" *Id.* (cleaned up) (quoting *Harlow*, 457 U.S. at 817). As a result, a denial of qualified immunity, when based on an issue of law, can be challenged through an interlocutory appeal to "preserv[e] the efficiency of government and the initiative of its officials." *Will*, 546 U.S. at 352.

The same applies with equal force to legal claims for immunity under the PREP Act by a public official. Indeed, a pandemic threatens more than just the "disrupti[on] of effective government." *Mitchell*, 472 U.S. at 526 (quoting *Harlow*, 457 U.S. at 817). As explained by the CDC, a pandemic poses a singular threat to the maintenance of civil society. (RJN-29). Public responses to a pandemic, such as the prioritization of a scarce vaccine, seek "to reduce the impact of the pandemic on health," "minimize disruption to society and the economy," "maintain homeland and national security," "provide health care and community support services," and "maintain critical infrastructure." (RJN-29, 32). The stakes of doing so for the COVID-19 vaccines were particularly high, where initial vaccine supply was limited, and the rollout was "much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses." (RJN-73–74). State officials, including the Governor, then were charged with directing those time-sensitive, life-saving efforts. (RJN-83–86, 158). A denial of immunity from suit for doing so threatens to distract and inhibit the Governor and other public officials for current and future public-health efforts. The court's order thus raises a value of high order that warrants immediate review.

* * *

In sum, a denial of immunity from suit for a public official under the PREP Act is conclusive, addresses a question separate from the underlying merits, and

raises a value of high order that warrants immediate review. The Court should hold that it has jurisdiction over this appeal under the collateral-order doctrine.

II. The PREP Act immunizes the Governor from suit over her vaccine prioritization during the initial rollout of the COVID-19 vaccines.

The PREP Act states:

> [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).

The statute thus requires four elements to grant an individual immunity from suit on a claim. As pertinent here, the Act immunizes the Governor from suit on plaintiffs' vaccine prioritization claim if: (1) the Governor is a "covered person"; (2) plaintiffs' claim is one for "loss"; (3) the claim concerns a "covered countermeasure"; and (4) the alleged loss "aris[es] out of, relat[es] to, or result[s] from the administration * * * or use" of that covered countermeasure. *Id.* For the reasons discussed below, all four elements are met here. As such, the Court should reverse the district court's denial of the Governor's motion to dismiss the claim due to immunity from suit under the PREP Act.

A. Plaintiffs concede that the Governor is a "covered person" and that their claim is for "loss" over a "covered countermeasure."

Plaintiffs conceded for "purposes of this Motion" below, and the district court ruled, that the first three elements are easily satisfied. (ER-49; ECF 283 at 6

n.6). In short, the Governor is a "covered person" for plaintiffs' claim of "loss" for a "covered countermeasure" under the PREP Act and associated declaration.

First, the Governor is a "covered person" under the PREP Act. The statute defines that term to include "a program planner" of a countermeasure, which includes "a State or local government," as well as "a person employed by the State or local government * * * who supervised or administered a program" for a countermeasure by, in part, "establish[ing] requirements" for the countermeasure. 42 U.S.C. § 247d-6d(i)(2)(B)(iii) (defining "covered person"), -6d(i)(6) (defining "program planner"). The HHS Secretary then incorporated that definition in his PREP Act declaration for the COVID-19 pandemic. (RJN-56, 150). Here, as plaintiffs alleged, the Governor (and Director Allen) had supervisory authority over the Oregon Health Authority, which was the agency charged with the initial allocation, prioritization, and distribution of the Pfizer and Moderna vaccines against COVID-19. (ER-59–62).

Next, plaintiffs' request for damages is a claim for "loss." The statute broadly defines the term as "any type of loss," including "physical, mental, or emotional injury, [and] illness." 42 U.S.C. § 247d-6d(a)(2). Here, plaintiffs seek compensatory and punitive damages for the physical injury and illness of contracting COVID-19; in their view, their contraction of COVID-19 was caused, in part, by not being prioritized earlier in the vaccine rollout. (ER-91).

Third, plaintiffs' claim concerns a "covered countermeasure." The statute defines the term to include a "biological product" intended to "mitigate, prevent, treat, or cure a pandemic," such as a vaccine granted emergency-use authorization by the FDA. 42 U.S.C. § 247d-6d(i)(1)(C), -6d(i)(7)(A)(i)(I), -6d(i)(7)(B)(iii). The HHS Secretary then incorporated that definition in his COVID-19 declaration to make explicit that the Act covered "any vaccine" used to "treat, diagnose, cure, prevent, or mitigate COVID-19." (RJN-57, 151). Here, plaintiffs' claim concerns the initial rollout of the Pfizer and Moderna vaccines, for which the FDA had granted emergency-use authorization to combat COVID-19. (ER-77, 91).

B. Prioritizing a scarce vaccine constitutes "administration" of a covered countermeasure.

The central dispute in this case is over the fourth element. Plaintiffs allege that they contracted COVID-19 because the Governor did not prioritize them in the rollout of the COVID-19 vaccines. (ER-91). The question, then, is whether the vaccine prioritization was caused by, arose out of, related to, or resulted from the administration or use of the vaccines as defined by Congress in the statute, and as invoked by the HHS Secretary in his declaration. The answer is yes: the statute plainly encompasses managing the rollout of a scarce countermeasure, and the HHS Secretary explicitly listed vaccine prioritization as a covered activity in his COVID-19 declaration. In ruling to the contrary, the district court contravened the plain text of both the statute and the HHS Secretary's declaration.

1. "Administration" includes managing scarce vaccine supply consistent with guidance from a public health authority.

The PREP Act immunizes, as pertinent here, the "administration" of a covered countermeasure. The text of the statute immunizes against loss that relates to the "administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). The statute then defines the scope of that clause as the full range of supply-chain activity for a countermeasure, from initial "design" to eventual "use." In full, the 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, 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*.

Id. § 247d-6d(a)(2)(B) (emphases added).

The "administration" of a countermeasure includes management of the resource. The statute does not further define the term "administration." In such scenarios, the Court generally looks to dictionaries "to accord the term its ordinary meaning." *United States v. Mohrbacher*, 182 F.3d 1041, 1048 (9th Cir. 1999) (internal quotation marks and citation omitted). Dictionaries broadly define "administration" as "the performance of executive duties: management." *Webster's Third New Int'l Dictionary* 28 (1993). The term "management" is then defined as "the conducting or supervising of something (such as a business),"

including "the executive function of planning, organizing, coordinating, directing, controlling, and supervising any industrial or business project or activity"; the term also is defined as the "judicious use of means to accomplish an end." *Id.* at 1372.

In his initial COVID-19 declaration, the HHS Secretary invoked PREP Act immunity for the "administration" and "management" of a countermeasure program. Specifically, the declaration invoked PREP Act immunity for "the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures." (RJN-56). Consistent with the above dictionary definitions, the declaration delineated "administration" immunity as:

> Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, *management and operation of countermeasure programs*, or management and operation of locations for purpose of distributing and dispensing countermeasures.

(RJN-57 (emphasis added) (citing 42 U.S.C. § 247d-6d(a)(2)(B))).

The HHS Secretary then further defined "management" of a program to include prioritization of a scarce countermeasure. In December 2020, as the initial vaccines neared emergency-use authorization by the FDA, the Secretary amended the PREP Act declaration "to make explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and th[e] Declaration's liability protections." (RJN-149). In

particular, "[p]rioritization 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 th[e] Declaration's liability protection." (RJN-152).

The amended declaration expressly incorporated an advisory opinion from the HHS General Counsel that explained that prioritizing a scarce resource is part and parcel of "management" of that resource under the plain meaning of the term:

> Management and operation of countermeasure programs and decisions directly relating to public and private delivery, distribution, and dispensing of countermeasures 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, as directed by an Authority Having Jurisdiction.

(RJN-65; *see* RJN-147 & n.9 (incorporating)). In so prioritizing, a covered person need only comply with "*any*" of "the public-health guidance issued by an Authority Having Jurisdiction over the person's activity or location in order to qualify for PREP Act immunity." (RJN-63; *see* RJN-147 & n.9 (incorporating)).

Here, plaintiffs challenge the Governor's prioritization of the Pfizer and Moderna vaccines in January 2021. It is beyond dispute that, at that point in the rollout, vaccine supply was exceedingly scarce. (*See* ECF 281 at 11–12 & nn. 4–7 (statistics on the initial vaccine supply that Oregon received from the CDC); *see also* RJN-188–89 (directive from the HHS Secretary in March 2021 that, due to increased supply, all adults would be eligible for vaccination as of May 1, 2021)).

In turn, the Oregon Health Authority prioritized individuals for vaccination by phase and subgroup, as the CDC suggested, largely by following recommendations from the CDC's advisory committee. (ER-137; RJN-83–86, 157–58, 175–77). The Governor then ordered that the rollout proceed consistent with the Oregon Health Authority's published guidance. (*See, e.g.*, ER-156–60).

As a matter of law, the Governor's vaccine prioritization constitutes "administration" of a covered countermeasure, both as defined in the PREP Act, and as invoked by the HHS Secretary to combat the COVID-19 pandemic. The plain meaning of the term includes management of a countermeasure; the HHS Secretary expressly invoked PREP Act immunity for the administration and management of a countermeasure program; managing a program necessarily entails prioritizing recipients when supplies are scarce; and the HHS Secretary made that implicit logic explicit in his amended declaration. 42 U.S.C. § 247d-6d(a)(2)(B); (RJN-56–57, 65, 149, 152; *see* RJN-147 & n.9). HHS and the CDC thereby designed the historic rollout of the COVID-19 vaccines intending and, indeed, directing that state leaders and public health authorities prioritize initial vaccinations while vaccine supply was scarce. (RJN-83–86, 157–58, 175–77). For that reason, the Fifth Circuit recently noted, in dicta, that the prioritization of a scarce countermeasure would "relate to its use or administration" under the PREP Act. *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 246 (5th Cir. 2022).

At a minimum, the HHS Secretary specifically provided in his amended declaration that the prioritization of a scarce countermeasure qualifies for PREP Act immunity "if done in accordance with a public health authority's directive." (RJN-152). As noted above, the Oregon Health Authority was the primary public health authority with jurisdiction to prioritize and allocate the rollout of the COVID-19 vaccines in Oregon. (ER-132; *see* RJN-57 (defining an "Authority Having Jurisdiction" to include a state public health authority)). The Governor then ordered that the rollout proceed in accordance with the Oregon Health Authority's published prioritization guidance. (*See, e.g.*, ER-156–60). The PREP Act thus immunizes the Governor's decision to do so from both suit and liability.

2. The district court misinterpreted "public health guidance."

As noted, the district court denied the Governor's motion to dismiss plaintiffs' vaccine priority claim based on immunity from suit under the PREP Act. In doing so, the court recognized that the HHS Secretary's COVID-19 declaration invoked PREP Act immunity for the "prioritization or purposeful allocation of the vaccine in accordance with a public health authority's directive or public health guidance." (ER-53). The court then assumed without deciding "that the PREP Act applies to a public health authority's vaccine allocation plan." (ER-54). The court ruled, however, that PREP Act immunity did not apply, and dismissal of the vaccine prioritization claim was not warranted, because Oregon's prioritization

was "contrary to public health guidance." (ER-53). That ruling misinterprets the HHS Secretary's declaration and contravenes indisputable facts in the record.

As discussed above, the Governor ordered that the vaccine prioritization proceed in accordance with published guidance from the Oregon Health Authority, which was the primary public health authority charged with vaccine prioritization in Oregon. (ER-132, 156–60; *see* RJN-57 (defining an "Authority Having Jurisdiction")). By the plain meaning of words, the challenged prioritization thus was "done in accordance with a public health authority's directive." (RJN-152).

Eliding that incontrovertible fact, the district court instead questioned the Oregon Health Authority's prioritization of corrections officers but not all AICs in Oregon Phase 1A. (ER-53). Indeed, Oregon made that difficult decision. But the policy decision followed and even exceeded the guidance from the CDC's advisory committee by prioritizing officers earlier than recommended. (*Compare* ER-137 (Oregon Phase 1A), *with* RJN-175–76 (CDC Phase 1b)). As the State explained:

> Almost every outbreak in the [prison] facilities ha[d] been caused by staff members brin[g]ing the virus into the prison before they were symptomatic. With limited supplies available, the State of Oregon determined that the most effective means of slowing transmission through the use of vaccines was to administer vaccines to staff as quickly as possible.

(ER-140; *see* ER-132 (same sentiment)). The CDC's advisory committee similarly recommended prioritizing officers, but not AICs, due to officers' roles as "essential critical infrastructure workers." (RJN-175).

The district court further took issue with the fact that those in long-term care facilities, e.g., nursing homes, were prioritized ahead of AICs. (ER-53). As an initial matter, the Oregon Health Authority was the public health authority charged with making that difficult decision for the State of Oregon amidst a global pandemic and limited vaccine supply. (ER-132; RJN-57, 63, 83–86, 152, 157–58, 177). Moreover, the CDC's own advisory committee similarly had recommended that those in long-term care facilities be prioritized first in the rollout, along with healthcare personnel. (RJN-171–72). Such facilities "provide a range of services, including medical and personal care, to persons who are unable to live independently." (RJN-171). The committed reasoned that residents of those facilities warranted initial prioritization, as "their age, high rates of underlying medical conditions, and congregate living situation" put them "at high risk for infection and severe illness from COVID-19." (RJN-171). The Oregon Health Authority's published guidance adopted that recommendation. (ER-137). The resulting prioritization thus followed the directive of *two* public health authorities.

Finally, the district court found that the Oregon Health Authority's published guidance contravened "public health guidance" because online CDC FAQs had recommended vaccinating corrections officers and AICs "at the same time." (ER-53). But the FAQs themselves disclaimed providing any public health guidance as to vaccine prioritization. The informal advisory specifically stated that

"[t]he prioritization of correctional staff and incarcerated persons differ by jurisdiction," as the "CDC does not determine strategic plans for distributing and administering vaccines." (RJN-180). Rather, the CDC had a formal advisory committee charged with recommending vaccine prioritization, the Advisory Committee on Immunization Practices, which provided non-binding guidance to state and local public health authorities. (RJN-170–78). That committee similarly recommended that corrections officers be prioritized ahead of AICs due to their role as "essential critical infrastructure workers." (RJN-175). And Oregon's prioritization followed, rather than contravened, that public health guidance.

At bottom, the district court disagreed with the policy decision from the Oregon Health Authority (and the CDC's Advisory Committee on Immunization Practices) that corrections officers should be prioritized ahead of AICs in the initial rollout of the Pfizer and Moderna vaccines against COVID-19. As explained by the CDC, however, vaccine prioritization seeks "to reduce the impact of [a] pandemic on health and minimize disruption to society and the economy" while vaccine supply is scarce. (RJN-29). First and foremost, prioritization aims "to maintain national security, health care, and other essential community services." (RJN-31). Here, HHS and the CDC delegated the difficult decisions for doing so to state leaders and state public health authorities, not to a district court.

3. Plaintiffs argued for a reading of "administration" that ignores the plain meaning of the statute.

In opposing the Governor's motion to dismiss below, plaintiffs notably did not argue that the Governor's vaccine prioritization was contrary to public health guidance. Instead, plaintiffs made two different arguments, both of which the district court rejected, and neither of which has merit.

First, plaintiffs argued that the PREP Act does not displace their claim for damages under 42 U.S.C. § 1983. (ECF 284 at 7–9). By the plain terms of the statute, however, the PREP Act provides "immun[ity] from suit and liability under Federal and State law with respect to all claims for loss." 42 U.S.C. § 247d-6d(a)(1). A suit for damages under § 1983 is a suit for loss under federal law.

Second, plaintiffs argued that "administration" of a countermeasure under the PREP Act immunizes only the decision to administer a vaccine "to particular individuals," not "the policy-level decision" of prioritization. (ECF 284 at 9–10). That argument ignores the plain text and meaning of both the statute and the HHS Secretary's declaration. As outlined above, the plain meaning of "administration" includes management of a countermeasure; management includes the executive process of coordinating and directing a particular activity; the HHS Secretary invoked PREP Act immunity for the administration and management of a countermeasure program; and the Secretary further made explicit that managing a program necessarily entails prioritizing recipients for a countermeasure when

supplies are scarce. 42 U.S.C. § 247d-6d(a)(1), -6d(a)(2)(B); *Webster's Third New Int'l Dictionary* 28, 1372 (1993); (RJN-56–57, 65, 149, 152; *see* RJN-147 & n.9). Plaintiffs cannot insert their own limitations into the text of the statute and associated declaration.

* * *

In short, the HHS Secretary issued a declaration under the PREP Act to invoke the Act's immunity protections to marshal a whole-of-nation response to the COVID-19 pandemic. Under the plain terms of the Act and associated declaration, the Governor is a "covered person" for plaintiffs' claim of "loss" for a "covered countermeasure." Further, the Governor's initial prioritization of the Pfizer and Moderna vaccines against COVID-19 consistent with published guidance from the Oregon Health Authority constitutes "administration" of a covered countermeasure "in accordance with a public health authority's directive." The Governor thus is entitled to immunity from suit and liability under the PREP Act on plaintiffs' vaccine prioritization claim.

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CONCLUSION

The Court should (1) hold that it has jurisdiction over this appeal under the collateral-order doctrine and (2) reverse the district court's denial of the Governor's motion to dismiss plaintiffs' vaccine prioritization claim against her.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7), I certify that Appellant's Opening Brief is proportionately spaced, has a typeface of 14 points or more and contains 9,155 words.

DATED: August 15, 2022

/s/ Robert A. Koch

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STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2, undersigned counsel for Appellant is aware of one related case pending in this Court: *Maney v. Allen*, No. 22-35219 (9th Cir.). That appeal arises out of the same case in the district court.

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No. 22-35218

IN THE 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.

ADDENDUM OF PERTINENT STATUTES, RULES, AND REGULATIONS

Appeal from the United States District Court
for the District of Oregon

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42 U.S.C.A. § 247d-6d

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

Effective: March 27, 2020
Currentness

(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;

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(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--

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(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.

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(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

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(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.

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(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:

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(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 5 [1] 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)

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(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

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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)),[2] 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.

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(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)),[2] biological product (as such term is defined by section 262(i) of this title), or device (as such term

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is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))[2] 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.

CREDIT(S)

(July 1, 1944, c. 373, Title III, § 319F-3, as added Pub.L. 109-148, Div. C, § 2, Dec. 30, 2005, 119 Stat. 2818; amended Pub.L. 113-5, Title IV, § 402(g)(2), (3), Mar. 13, 2013, 127 Stat. 196; Pub.L. 116-127, Div. F, § 6005, Mar. 18, 2020, 134 Stat. 207; Pub.L. 116-136, Div. A, Title III, § 3103, Mar. 27, 2020, 134 Stat. 361.)

Notes of Decisions (33)

Footnotes

1 So in original. Probably should be “chapter V”.

2 So in original. A third closing parenthesis probably should appear.

42 U.S.C.A. § 247d-6d, 42 USCA § 247d-6d
Current through P.L. 117-160. Some statute sections may be more current, see credits for details.

End of Document

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter II. General Powers and Duties
Part B. Federal-State Cooperation

42 U.S.C.A. § 247d-6e

§ 247d-6e. Covered countermeasure process

Effective: December 30, 2005
Currentness

(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.

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(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

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(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

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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.

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CREDIT(S)

(July 1, 1944, c. 373, Title III, § 319F-4, as added Pub.L. 109-148, Div. C, § 3, Dec. 30, 2005, 119 Stat. 2829.)

Notes of Decisions (4)

42 U.S.C.A. § 247d-6e, 42 USCA § 247d-6e
Current through P.L. 117-160. Some statute sections may be more current, see credits for details.

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2022, I directed the Appellant's Opening Brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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