No. 22-15496

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

PATRICIA POLANCO, et al.,
*Plaintiffs-Appellees*,

v.

RALPH DIAZ, et al.,
*Defendants-Appellants*,

and

STATE OF CALIFORNIA, et al.,
*Defendants*.

On Appeal from the United States District Court
for the Northern District of California
Case No. 3:21-cv-06516-CRB
Hon. Charles R. Breyer

# BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFFS-APPELLEES

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## CORPORATE DISCLOSURE STATEMENT

Amicus curiae Public Citizen, Inc. is a nonprofit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it.

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Amicus Curiae Public Citizen is a non-profit consumer advocacy organization with members in all 50 states. Public Citizen advocates for enactment and enforcement of laws to protect consumers, workers, and the public, including by advocating for policies that protect the health and safety of vulnerable populations. Among other things, Public Citizen works to support the ability of individuals to access the civil justice system to hold corporations and the government accountable for wrongdoing and, in that regard, often appears as amicus curiae to address issues such as statutory interpretation, preemption, and qualified immunity. Public Citizen has appeared as amicus curiae in cases in the Third, Seventh, and Eleventh Circuits addressing the scope

[1] The parties have consented to the filing of this brief. No party's counsel authored this brief in whole or part, no party or party's counsel contributed money intended to fund the brief's preparation or submission, and no person other than amicus curiae, its members, or its counsel contributed money intended to fund the brief's preparation or submission.

of the immunity provisions of the Public Readiness and Emergency Preparedness (PREP) Act.

Public Citizen submits this brief to explain that, if accepted, Appellants' erroneous arguments regarding the relevance and scope of the PREP Act would wrongly deprive injured plaintiffs of access to meaningful remedies.

## INTRODUCTION

In their opening brief, Appellants argue that the PREP Act—a statute that limits when and how claims can be brought against people or entities who administer certain drugs and medical devices consistent with public health officials' recommendations—provides Defendants-Appellants Cryer, Pachynski, and Garrigan (collectively, "medical officials") with qualified immunity for actions based on their failures to take precautions to stop the spread of the coronavirus at San Quentin State Prison. This argument lacks merit for at least two reasons.

First, the PREP Act is irrelevant to whether the medical officials have qualified immunity. As this Court has recognized, the dispositive question for qualified immunity is whether a reasonable officer would have known his conduct was unlawful in a given situation, not whether

he would have known that he would face consequences for that unlawful conduct. The PREP Act says nothing about this question. The statute neither creates nor abridges substantive rights; rather, it limits the remedies available for conduct that violates independently existing rights. That victims of unlawful conduct may have limited judicial remedies for such conduct in scenarios within the PREP Act's scope does not call into question whether that conduct was clearly unlawful in the first place. The Court should reject Appellants' claim that they are entitled to qualified immunity for clearly unlawful conduct based on a *different* form of immunity unrelated to the lawfulness of the underlying conduct.

Second, as the district court held, the PREP Act does not apply to the allegations in this case—allegations that Gilbert Polanco died because of Appellants' failures to adopt screening and isolation policies and to deploy any personal protective equipment (PPE) and testing. As two courts of appeals and dozens of district courts have explained, the PREP Act has nothing to do with such claims. Appellants' contrary argument has no support in either the statute or the complaint.

## BACKGROUND

Initially enacted in 2005 "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the [PREP Act] authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." Cong. Res. Serv., *The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures* 1 (updated April 13, 2022)[2]; *see also Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 687 (9th Cir. 2022) (summarizing statutory scheme).

The Secretary triggers the PREP Act by issuing a declaration determining that a public health emergency exists and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures," under certain conditions. 42 U.S.C. § 247d-6d(b)(1). The Secretary may designate only certain drugs, biological products, and devices authorized or approved for use by the Food and Drug Administration or the National Institute for

[2] https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

Occupational Safety and Health as "covered countermeasures." *Id.* § 247d-6d(i)(1)(A)–(D).

Subsection (a) of the PREP Act provides "covered persons" with immunity from liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a [designated] covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). Subsection (d) creates a carve-out from that immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct" in the administration or use of a covered countermeasure. *Id.* § 247d-6d(d)(1). Where a plaintiff alleges conduct that meets the special statutory definition of "willful misconduct" with respect to the administration or use of a covered countermeasure, rather than conferring immunity, the statute creates an "exclusive Federal cause of action," *id.*, and provides special adjudicatory procedures and exclusive jurisdiction in a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(e). Once a plaintiff meets the willful misconduct threshold, the PREP Act provides only procedural requirements for claims brought pursuant to that cause of action. The PREP Act does not provide any substantive law for decision; to the

contrary, the statute contemplates that the cause of action will generally be used to vindicate substantive rights created by state law. *See id.* § 247d-6d(e)(2) (providing that state law provides "[t]he substantive law for decision" for claims brought pursuant to willful-misconduct cause of action). The PREP Act also creates an administrative compensation scheme that, like subsection (d), is available only to individuals who suffered injuries "directly caused by the administration or use of a covered countermeasure" subject to a PREP Act declaration. *Id.* § 247d-6e(a).

On March 10, 2020, HHS Secretary Azar issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. 85 Fed. Reg. 15,198 (published Mar. 17, 2020). The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of certain countermeasures to combat COVID-19: "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device

used in the administration of any such product, and all components and constituent materials of any such product." *Id*. at 15,202.

The Secretary amended the initial Declaration several times. The First Amendment expanded covered countermeasures to include certain respiratory protective equipment. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020). Later, after the events at issue in this case, in the Fourth Amendment's preamble, the Secretary opined that "[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d," where it reflects "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,194 (Dec. 9, 2020). He gave as an example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *Id.* The Secretary also incorporated by reference four advisory opinions previously issued by HHS's General Counsel. *Id.* at 79,191 & n.5. In January 2021, the General Counsel issued a fifth advisory opinion. HHS General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021), ER-532. That opinion stated his

view that the PREP Act's liability protections apply to situations where a covered person makes a decision regarding allocation of covered countermeasures that "results in non-use by some individuals," but *not* where non-use was the result of "nonfeasance." *Id.* at ER-535. Like the previous advisory opinions, Opinion 21-01 states that it "sets forth the current views" of the Office of General Counsel but "does not have the force or effect of law." *Id.* at ER-536.

## ARGUMENT

### I. The PREP Act is not a basis for qualified immunity.

Appellants assert that the existence of the PREP Act means that "the law was not clearly established that correctional officers had the constitutional right to demand a certain level of inmate testing and PPE in a pandemic." Appellants' Br. 44. Putting aside Amicus's disagreement with the level of specificity at which Appellants are defining the right at issue, this argument conflates the question of whether a right exists with the question of what, if any, remedies are available for a violation of a right. The clearly established prong of qualified-immunity analysis is focused only on the former, and the PREP Act addresses only the latter. Because the statute says nothing about what rights do or do not exist, or

what conduct is or is not unlawful, it cannot serve as a basis for qualified immunity.[3]

The question of what remedies are available for a violation of a right "is 'analytically distinct' from the issue of whether such a right exists in the first place." *Franklin v. Gwinnett Cty. Pub. Schs.*, 503 U.S. 60, 65–66 (1992) (quoting *Davis v. Passman*, 442 U.S. 228, 239 (1979)). In regulating whether, when, and how a covered person can be sued for unlawful conduct, the PREP Act addresses only the former question. The statute itself "does not create rights, duties, or obligations," *Carrillo v. Sela Healthcare, Inc.*, 2021 WL 4556421, at *3 (C.D. Cal. Sept. 8, 2021), and does not eliminate them. It simply narrows the remedies available where duties, rights, or obligations have been violated. *Cf. Saldana*, 27 F.4th at 688–689 (holding that PREP Act creates only a defense to pre-existing claims, and does not displace them). For most claims based on

[3] Where the conditions specified in the statute and in the relevant secretarial declaration are met, the PREP Act provides immunity from suit and liability. 42 U.S.C. § 247d-6d(a)(1). That statutory immunity, however, is entirely different from common-law qualified immunity, as recognized in Appellants' briefing below, where they made two distinct arguments. *Compare* ER-553–55 (arguing that statutory immunity applies), *with* ER-555–60 (arguing for qualified immunity). The district court rejected Appellants' statutory immunity argument, ER-12–13, and Appellants do not challenge that holding in this appeal.

injuries caused by the administration to or use by an individual of a covered countermeasure that meet the statutory conditions and conditions imposed by the Secretary, the statute provides immunity from suit and liability, and replaces judicial remedies with an administrative one. 42 U.S.C. §§ 247d-6d(a)(1), 247d-6d(e). Where a plaintiff challenges conduct that constitutes "willful misconduct" as defined by the statute, the statute allows claims to proceed, but channels them to a specific court and prescribes special procedural requirements. *Id.* §§ 247-6d(d)–(e). The statutory regime says nothing about whether a substantive right does or does not exist, or whether given conduct is or is not lawful. And the statute explicitly provides that it does not displace the "substantive law" that governs claims that are channeled to the District of Columbia to the extent they are based on state law. 42 U.S.C. § 247d-6d(e)(2).

"The 'dispositive inquiry' in the clearly-established analysis is 'whether it would be clear to a reasonable officer that his conduct was unlawful in the situation he confronted'"—not whether it was clear any particular court could award monetary damages for that unlawful conduct. *Sandoval v. Cty. of San Diego*, 985 F.3d 657, 672 (9th Cir. 2021) (quoting *Estate of Ford v. Ramirez-Palmer*, 301 F.3d 1043, 1050 (9th Cir.

2002)) (emphasis omitted). As the Sixth Circuit recently noted, whether a defendant has an independent "defense to liability" that is unrelated to the lawfulness of the underlying conduct is a different question from whether the defendant is entitled to qualified immunity. *DeCrane v. Eckart*, 12 F.4th 586, 601 (6th Cir. 2021). In *DeCrane*, the court declined to address a statute of limitations argument in an interlocutory appeal from a denial of qualified immunity, recognizing that the defense to liability "has nothing to do with a qualified-immunity defense (which asks whether a defendant's conduct violated clearly established law)." *Id.* at 602. So too here, whether the PREP Act imposes limitations on the Polancos' ability to recover damages for violations of law is independent of the question whether the medical officials' conduct violated clearly established law.

## II. The PREP Act does not apply to the medical officials' alleged failures to act.

Not only is the statutory immunity created by the PREP Act irrelevant to qualified immunity analysis, it is irrelevant to the allegations in this case. The statute speaks only to claims for losses with "a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). And the

Polancos do *not* allege that Gilbert died because of the "administration to or use by an individual of a covered countermeasure"—to him or anyone else. Rather, they allege that Gilbert died because the medical officials, and other Appellants, engaged in a pattern of general neglect with respect to the transmission of COVID-19 within the prison, disregarding expert recommendations regarding infection control. As the Seventh Circuit has held, claims like these "are not even arguably" within the scope of the PREP Act. *Martin v. Petersen Health Ops., LLC*, 37 F.4th 1210, 1213 (7th Cir. 2022).[4] The PREP Act is inapplicable "where a plaintiff's claim is premised on a failure to take preventative measures to stop the spread of COVID-19, as here, and where none of the alleged harm was causally connected to the administration or use of any countermeasure, which is the focus of the PREP Act." *Gwilt v. Harvard Sq.*

[4] Like *Martin*, this Court's decision in *Saldana* addressed the question whether claims about inadequate COVID-19 infection control measures are completely preempted by the PREP Act. In light of its holding that "the PREP Act is not a complete preemption statute," the Court found it unnecessary to reach the question whether those claims were within the scope of the PREP Act at all. 27 F.4th at 688.

*Retirement & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[5]

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[5] This principle has been recognized by courts around the country, including in dozens of opinions issued by courts within this circuit. *See, e.g.*, *In re CIM-SQ Transfer Cases*, 2022 WL 2789808, at *6 (N.D. Cal. July 15, 2022); *Harris v. Allison*, 2022 WL 2232525, at *9–10 (N.D. Cal. May 18, 2022); *LaMonica v. Heights of Summerlin, LLC*, 2022 WL 6542565, at *4 (D. Nev. Feb. 23, 2022); *Crupi v. Heights of Summerlin, LLC*, 2022 WL 489857, at *6 (D. Nev. Feb. 17, 2022); *Ramirez v. Windsor Care Ctr. Nat'l City, Inc.*, 2022 WL 392899, at *4 (S.D. Cal. Feb. 9, 2022); *Kulhanek v. Penasquitos*, 2022 WL 126343, at *4 (S.D. Cal. Jan. 13, 2022); *Tercero v. Orinda Care Ctr., LLC*, 2022 WL 256511, at *2 (N.D. Cal. Jan. 3, 2022); *Iskowitz v. Northridge Subtenant, LLC*, 2021 WL 5822610, at *7–8 (S.D. Cal. Dec. 8, 2021); *Shankle v. Heights of Summerlin, LLC*, 574 F. Supp. 3d 820, 825 (D. Nev. 2021); *Sorace v. Orinda Care Ctr., LLC*, 2021 WL 5205603, at *6 (N.D. Cal. Nov. 9, 2021); *Lawler v. Cedar Ops., LLC*, 2021 WL 4622414, at *4–5 (C.D. Cal. Oct. 7, 2021); *Ossowski v. St. Joseph Transitional Rehab. Ctr., LLC*, 2021 WL 4699235, at *3–4 (D. Nev. Oct. 6, 2021); *Apothaker v. Silverado Sr. Living, Inc.*, 2021 WL 4173430, at *6 (C.D. Cal. Sept. 14, 2021); *Acra v. Cal. Magnolia Convalescent Hosp., Inc.*, 2021 WL 2769041, at *6 (C.D. Cal. July 1, 2021); *Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 2021); *Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5 (C.D. Cal. Apr. 19, 2021); *Hopman v. Sunrise Villa Culver City*, 2021 WL 1529964, at *5 (C.D. Cal. Apr. 16, 2021); *Nava v. Parkwest Rehab. Ctr. LLC*, 2021 WL 1253577, at *2–3 (C.D. Cal. Apr. 5, 2021); *Stone v. Long Beach Healthcare Ctr.*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 2021); *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284 (C.D. Cal. Mar. 19, 2021); *McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *see also, e.g.*, *DeMarcus v. Homesteadidence OPCO, LLC*, 2022 WL 3718480, at *5 (E.D. Ky. Aug. 29, 2022); *Milan v. Shenango Presbyterian Seniorcare*, 2022 WL 3647826, at *2–3 (W.D. Pa. Aug. 23, 2022); *Cagle v. NHC HealthCare-Md. Heights, LLC*, 2022 WL 2833986, at *8 (E.D. Mo. July 20, 2022); *Beaty v. Del. Cty.*,

As the district court correctly noted, many of the Polancos' allegations of unlawful conduct by the medical officials have nothing to do with covered countermeasures at all. ER-012. Only personal protective equipment that both qualifies as a medical device under 21 U.S.C. § 321(h) and is authorized for emergency use by the Food and Drug Administration, or is a respiratory protective device approved by the National Institute for Occupational Safety and Health, can be a covered countermeasure. 42 U.S.C. §§ 247d-6d(i)(1), (7). Appellants have no colorable argument that claims challenging its transfer policies, lack of social distancing, and failure to isolate exposed inmates, *see, e.g.*, ER-589, 591, concern devices that are covered countermeasures. These claims "refer to policies and a failure to protect, not to any covered countermeasure, *i.e.*, drug, product, or device. Thus, the square peg of

2021 WL 4026373, at *2 (E.D. Pa. Aug. 5, 2021); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4 (E.D. Wisc. July 20, 2021); *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1027–28 (D. Colo. 2021); *Eaton v. Big Blue Healthcare*, 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020); *Arbor Mgmt. Servs., LLC v. Hendrix*, 875 S.E.2d 392, 397 (Ga. Ct. App. 2022); *Whitehead v. Pine Haven Operating LLC*, 75 Misc.3d 985, 992 (N.Y. Sup. Ct. June 8, 2022).

Plaintiffs' allegations does not fit into the round hole of the PREP Act's definition of a covered countermeasure." *Smith*, 2021 WL 1087284, at *4.[6]

Although the complaint mentions COVID-testing and personal protective equipment, both of which, in certain scenarios, can constitute "covered countermeasures," "the mere mention of countermeasures in the complaint [] does not confer immunity." *CIM-SQ Transfer Cases*, 2022 WL 2789808, at *6. Under the PREP Act, immunity attaches only where a plaintiff claims that an injury was caused by the "administration to or use of a covered countermeasure to an individual." 42 U.S.C. § 247d-6d(a)(2)(B). The Polancos have made no such claims here.

Appellants also argue that the PREP Act would have led the medical officials to conclude that any "exercise [of] their discretion on how to use the prison's limited resources to allocate testing and PPE" would be lawful. Appellants' Br. 45. The Polancos' claims, however, are not

[6] If some part of the plaintiffs' claims had the requisite causal relationship with the administration or use of covered countermeasures, the PREP Act would be a basis for dismissal of the claims *solely to the extent* that they are based on the use or administration of a covered countermeasure. *Cf. Tobias v. Artega*, 996 F.3d 571, 575 n.1 (9th Cir. 2021) (holding qualified immunity was appropriate as to only one aspect of a fabrication-of-evidence claim); *Meredith v. Erath*, 342 F.3d 1057, 1064 (9th Cir. 2003) (holding qualified immunity was appropriate as to one aspect of an unlawful detention claim, but not another).

based on any such exercise of discretion: They do not allege that Gilbert died because the medical officials decided to allocate limited testing and PPE to some individuals and not others.[7] To the contrary, the complaint alleges that personal protective equipment and testing were in ample supply, but that the defendants chose not to use them anyway. *See, e.g.*, ER-590 ("Defendants even refused to provide adequate masks and personal protective equipment (PPE) to their own staff, even though masks and PPE were easily obtainable."); ER-598 (noting state agency finding that defendants "cho[se] not to provide testing despite the wide availability of tests"); ER-607 (alleging defendants "refuse[d] to acquire, and [] reject[ed] repeated no-cost offers of, COVID-19 testing resources").[8]

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[7] Below, Appellants relied on Advisory Opinion 21-01 to argue that the PREP Act barred the Polancos' claims. ER-553–54. That opinion post-dated the events giving rise to this action, and thus is irrelevant to the question of what the medical officers would have reasonably believed at the relevant time. Even now, the opinion does not support a finding that the PREP Act applies to the claims brought here. In it, the General Counsel explicitly distinguished "between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use." ER-534. As to countermeasures, the complaint here only alleges the latter.

[8] On appeal from a denial of a Rule 12(b)(6) motion, the plaintiffs' allegations, not recharacterizations of a plaintiffs' claims, govern. *See, e.g.*, *O'Brien v. Welty*, 818 F.3d 920, 936 (9th Cir. 2016) ("When, as here, defendants assert qualified immunity in a motion to dismiss under Rule 12(b)(6), 'dismissal is not appropriate unless we can determine, based on

Such claims that a defendant "did not deploy [covered countermeasures] at all" lie outside the scope of the statute. *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 246 (5th Cir. 2022). As Judge Easterbrook explained in *Martin*, an allegation of such *non*-use "is the opposite of a contention that a covered countermeasure caused harm." 37 F.4th at 1214.[9]

Appellants do not point to anything that would have allowed the medical officials reasonably to believe that the PREP Act applied to immunize all claims about infection control more generally. Nothing in the few cases interpreting the PREP Act prior to the events at issue

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the complaint itself, that qualified immunity applies.'" (quoting *Groten v. California*, 251 F.3d 844, 851 (9th Cir. 2001))).

[9] As with the inapplicability of the PREP Act to claims based on inadequate infection control measures generally, *see* n.5, *supra*, district courts are in broad agreement that the PREP Act is inapplicable to claims based on complete non-use of countermeasures. *See, e.g., Hampton v. California*, 2022 WL 838122, at *10–11 (N.D. Cal. Mar. 20, 2022); *Champion v. Billings Skilled Nursing Facility, LLC*, 2022 WL 3582298, at *6 (D. Mont. Mar. 17, 2022); *O'Neal v. CF Watsonville W. LLC*, 2022 WL 425557, at *5 (N.D. Cal. Feb. 11, 2022); *Burton v. Silverado Escondido, LLC*, 2021 WL 5087259, at *6 (S.D. Cal. Nov. 2, 2021); *Reynoso v. Corona Post Acute, LLC*, 2021 WL 4742706, at *3 (C.D. Cal. Oct. 11, 2021); *Reed v. Sunbridge Hallmark Health Servs., LLC*, 2021 WL 2633156, at *4–5 (C.D. Cal. June 25, 2021); *Padilla*, 2021 WL 1549689, at *5; *Lopez v. Life Care Ctrs. of Am., Inc.*, 2021 WL 1121034, at *12 (D.N.M. Mar. 24, 2021).

suggested as much. *See Parker v. St. Lawrence Cty. Pub. Health Dep't.*, 102 A.D.3d 140 (N.Y. App. Div. 2012) (holding PREP Act barred claims based on allegedly nonconsensual vaccination); *Casabianca v. Mt. Sinai Med. Ctr.*, 2014 WL 10413521 (N.Y. Sup. Ct. Dec. 2, 2014) (holding PREP Act immunity does not apply to claims based on non-administration of a covered countermeasure); *Kehler v. Hood*, 2012 WL 1945952, at *2-3 (E.D. Mo. May 30, 2012) (holding PREP Act barred claims based on side effects associated with vaccination). And both the statutory text and legislative history of the statute make clear that the statute only functions where the *use* of a covered countermeasure caused injury.

Starting with the text, the statute does not provide immunity for all claims relating to covered countermeasures. Rather, its limitations on liability apply only to claims for injuries with a "causal relationship with the administration to or use by an individual of a covered countermeasure" 42 U.S.C. § 247d-6d(a)(2)(B). When a facility does *not* use covered countermeasures, it is not "administering" a covered countermeasure to an individual, nor is a countermeasure being "used by" an individual. *See Manyweather*, 40 F.4th at 245–46. Other statutory provisions confirm that the Act cannot sensibly be read to apply where a

countermeasure was *not* administered or used. For instance, the statute provides for immunity "only if" the countermeasure was "administered or used" during the period of the declaration, for the condition specified in the declaration, and "administered to or used by" an individual within the population or area specified in the declaration. 42 U.S.C. § 247d-6d(a)(3). Similarly, healthcare professionals only obtain immunity if authorized to administer countermeasures "under the law of the State in which the countermeasure was prescribed, administered, or dispensed." *Id.* § 247d-6d(i)(8)(A). These conditions on immunity cannot function where a countermeasure was not administered or used at all, and Appellants offer no argument as to how the medical officials could have reasonably believed these, or any other conditions on immunity, are met in such scenarios.

This straightforward reading of the text is confirmed by the statute's purpose: to encourage the manufacture, distribution, and use of covered countermeasures. *See Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 529 (D.N.J. 2020) (noting statute's "evident purpose is to embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID 'countermeasures') with the

assurance that they will not face liability for having done so"), *aff'd on other grounds sub nom. Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021). Supporters explained that the bill would ensure that a pandemic flu "vaccine gets developed and to make sure doctors are willing to give it." 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) (statement of Rep. Deal); *see* Assessing the Nat'l Pandemic Flu Preparedness Plan: Hearing Before the H. Comm. on Energy & Commerce, Serial No. 109-59 at 20 (Nov. 8, 2005) (statement of HHS Secretary Leavitt) ("[T]he threat of liability exposure is too often a barrier to willingness to participate in the vaccine business.").[10] Likewise, a 2020 amendment to the PREP Act expanding the scope of potential covered countermeasures to include certain respiratory protective devices, Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3101, 134 Stat. 281, 361, was designed to "boost the availability and supply of critically needed respirator [masks]." 166 Cong. Rec. H1675-09 (daily ed. Mar. 13, 2020) (statement of Rep. Walden); *see also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight

[10] https://www.govinfo.gov/content/pkg/CHRG-109hhrg26891/pdf/CHRG-109hhrg26891.pdf.

& Reform, Serial No. 116-96 at 43 (2020) (testimony of HHS Asst. Secretary Kadlec, urging addition of respiratory protective devices to boost supply).[11] Immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, immunity for decisions *not* to administer or use covered countermeasures "would defeat the basic purpose of the statute." *Martin v. Petersen Health Ops., LLC*, 2021 WL 4313604, at *10 (C.D. Ill. Sept. 22, 2021), *aff'd by* 37 F.4th 1210.

Given the clarity of the statute, the medical officials had no reason to believe that the PREP Act would have immunized them from claims arising out of their generally inadequate response to COVID-19—much less that that response was lawful.

[11] https://www.govinfo.gov/content/pkg/CHRG-116hhrg40428/pdf/CHRG-116hhrg40428.pdf.

## CONCLUSION

For the foregoing reasons, the district court's order should be affirmed.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and the Rules of this Court, it contains 4,547 words.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 MSO in 14-point Century Schoolbook.

October 27, 2022

/s/ Adam R. Pulver
Adam R. Pulver

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I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate Electronic Filing system.

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

/s/ Adam R. Pulver
Adam R. Pulver
*Attorney for Amicus Curiae*