No. 22-15481

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MICHAEL HAMPTON, et al.,
Plaintiffs-Appellees,

v.

STATE OF CALIFORNIA, et al.,
Defendants-Appellants,

On Appeal from the United States District Court
for the Northern District of California
Case No. 3:21-cv-03058-LB
Hon. Laurel Beeler, Magistrate Judge

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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INTEREST OF AMICUS CURIAE[1]

Amicus curiae Public Citizen is a nonprofit consumer advocacy organization with members in all fifty states. Public Citizen advocates for enactment and enforcement of laws to protect consumers, workers, and the public, as well as 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 filed briefs as amicus curiae addressing the scope of the immunity provisions of the Public Readiness and Emergency Preparedness (PREP) Act in *Polanco v. Diaz*, No. 22-15496 (a pending appeal in this Court raising similar issues) and in cases in the Third, Seventh, and Eleventh Circuits.

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[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.

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

INTRODUCTION

In 2005, Congress enacted the PREP Act—a statute designed to encourage the manufacture, distribution, and use of certain drugs and medical devices consistent with public health officials' recommendations in times of crisis. In relevant part, the statute effectuates that goal by providing immunity in the narrow set of cases where a plaintiff seeks to recover for an injury "that has a causal relationship with the administration to or use by an individual" of such a drug or device, where that drug or device was used in accordance with conditions specified by the statute and by the Secretary of Health and Human Services (HHS). 42 U.S.C. §§ 247d-6d(a)(1)–(3).

In this case, plaintiff Jacqueline Hampton does not allege that her late husband Michael Hampton died as a result of the "administration to or use by an individual of a covered countermeasure." Rather, she alleges that Michael died because California officials transferred 122 prisoners

from the California Institution for Men (CIM), a facility that was in the throes of a severe COVID-19 outbreak, to San Quentin, a facility that, at that point, had *no* cases of COVID-19, with knowledge that that transfer would put the health of prisoners like Michael at risk of death, and without taking *any* of the mitigating steps recommended by health officials. ER 183 (Complaint). As the district court put it, "[t]he plaintiffs' claims are predicated on the botched transfer of infected prisoners from CIM and the defendants' refusal to implement basic safety measures to reduce the spread of COVID-19, which caused Mr. Hampton's death." ER 6.

As the Seventh Circuit has held, claims of such neglect "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).[2] Nor are the aspects of the claims that concern California's failure to administer COVID-19 tests to the prisoners it transferred to San Quentin. The

[2] Like *Martin*, this Court's decision in *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022), addressed 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. *Id.* at 688.

statutory text belies California's argument that the PREP Act immunizes claims based on *non*-use of covered countermeasures, and the allegations of the complaint do not implicate the agency advisory opinion upon which California relies, which is in any event incorrect and not binding on this Court. The district court thus correctly concluded that based on the allegations of the complaint, California is not entitled to immunity under the PREP Act.

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 Apr. 13, 2022)[3]; *see also Saldana*, 27 F.4th at 686–87 (summarizing statutory scheme).

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

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

Subsection (a) of the PREP Act provides "covered person[s]" 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), (2)(B). The Act provides "[c]ertain conditions" on that immunity, namely, that immunity only applies where "the countermeasure was administered or used" during the effective period of a secretarial declaration and for the purposes specified in the declaration, and "administered to or used by an individual" who was in the population

specified in the declaration. *Id.* § 247d-6d(a)(3). The Act also authorizes the Secretary to impose further conditions. *Id.* §§ 247d-6d(b)(1)–(3).

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, the statute, rather than conferring immunity, 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). 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 15,201–02.

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 "[p]rioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,197 (Dec. 9, 2020)

(first and second omissions in original). 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), ADD-058. 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 ADD-061. 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 ADD-062.

ARGUMENT

Because Ms. Hampton does not allege that her husband's death had "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), the district

court correctly denied the motion to dismiss on the basis of PREP Act immunity.

I. The PREP Act does not address claims relating to isolation, staffing, and social-distancing policies.

California's argument that the PREP Act applies to the claims in this case is based solely on their recasting of the complaint as "alleg[ing] that Mr. Hampton's death was a direct and proximate result of the timing of Defendants' administration of COVID-19 tests to the CIM transferees." Cal. Br. 51. But although the complaint includes allegations relating to inadequate testing of transferees, the allegations are far broader—including allegations that the buses used for transfer were overcrowded, that no isolation or quarantine policies were adopted once the men were transferred to San Quentin, that prison staff were not trained on COVID-19 safety protocols, and that prison staff were not screened for symptoms of COVID-19. *See, e.g.*, ER 192–93. These claims do not concern "covered countermeasure[s]"—a term limited to drugs, medical devices, and biological products that meet certain criteria. 42 U.S.C. §§ 247d-6d(i)(1), (7). Rather, the claims "refer to policies and a failure to protect." *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284, at *4 (C.D. Cal. Mar. 19, 2021); s*ee also Ossowski v. St. Joseph Transitional Rehab. Ctr., LLC*,

2021 WL 4699235, at *3 (D. Nev. Oct. 6, 2021) ("Isolation and social distancing measures are not Covered Countermeasures under a plain reading of the statute."); *Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5 (C.D. Cal. Apr. 19, 2021) (similar).

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 counter-measure, which is the focus of the PREP Act." *Gwilt v. Harvard Sq. Ret. & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[4] Accordingly, there is no basis

[4] Analyzing the text of the statute, dozens of state and federal courts around the country have reached the same conclusion. *See, 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); *Arbor Mgmt. Servs., LLC v. Hendrix*, 875 S.E.2d 392, 397–98 (Ga. Ct. App. 2022); *Whitehead v. Pine Haven Operating LLC*, 75 Misc .3d 985, 992 (N.Y. Sup. Ct. 2022); *LaMonica v. Heights of Summerlin, LLC*, 2022 WL 542565, 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, 825–26 (D. Nev. 2021);

for dismissing those aspects of Ms. Hampton's claims on the basis of PREP Act immunity.[5]

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); *Apothaker v. Silverado Sr. Living, Inc.*, 2021 WL 4173430, at *6 (C.D. Cal. Sept. 14, 2021); *Beaty v. Del. Cty.*, 2021 WL 4026373, at *2 (E.D. Pa. Aug. 5, 2021); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4–5 (E.D. Wisc. July 20, 2021); *Acra v. Cal. Magnolia Convalescent Hosp., Inc.*, 2021 WL 2769041, at *6 (C.D. Cal. July 1, 2021); *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1027–28 (D. Colo. 2021); *Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 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., LLC*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 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); *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020). California's dismissal of these dozens of cases as "giv[ing] short shrift" to the statutory question, Cal. Br. 56 n.10, ignores the detailed analysis engaged in by these courts.

[5] If some part of Ms. Hampton's 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. *See Jones v. Bock*, 549 U.S. 199, 221 (2007) ("As a general matter, if a complaint contains both good and bad claims, the court proceeds with the good and leaves the bad."); *cf. Tobias v. Arteaga*, 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); *Close v. Sotheby's, Inc.*, 894 F.3d 1061, 1074 (9th Cir. 2018) (dismissing claims as preempted to the extent that they were based on sales post-dating the

II. Claims relating to alleged failures to test are not barred by the statute.

Although approved COVID tests are covered countermeasures, the complaint's reference to a lack of sufficient COVID-19 testing does not trigger the statute. "[T]he mere mention of countermeasures in the complaint[] does not confer immunity." *In re CIM-SQ Transfer Cases*, 2022 WL 2789808, at *6 (N.D. Cal. July 15, 2022); *see also Eaton*, 480 F. Supp. 3d at 1194 (rejecting the notion that the fact "that a facility using covered countermeasures *somewhere* in the facility is sufficient to invoke the PREP Act as to all claims that arise in that facility"). The statutory text specifies that immunity is available only where a plaintiff alleges an injury "that has 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 statutory purpose confirms its inapplicability to claims that a defendant "did not deploy [covered countermeasures] at all." *Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 246 (5th Cir. 2022). As Judge Easterbrook explained in *Martin*, an allegation of *non*-use "is the opposite of a contention that a covered countermeasure caused

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effective date of the Copyright Act, but declining to dismiss to the extent that they were based on earlier sales).

harm." 37 F.4th at 1214. District courts are likewise in broad agreement that the PREP Act is inapplicable to claims based on non-use of countermeasures. *See, e.g., 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). The outlier decision on which California relies, *Garcia v. Welltower Opco Group*, 522 F. Supp. 3d 734 (C.D. Cal. 2021), has been vacated by this Court, 2022 WL 17077501 (9th Cir. Nov. 18, 2022).

A. The text and purpose of the statute confirm its inapplicability to claims relating to the non-use of covered countermeasures.

Starting with the text, the statute does not provide immunity for all claims relating to covered countermeasures. Rather, the PREP Act's 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. Here, when California decided not to test inmates in a facility with a COVID outbreak before transferring them to another facility where they would intermingle with other inmates, no countermeasure was "administered to or used by" any individual.

Other statutory provisions confirm that the Act cannot sensibly be read to apply to claims that an injury resulted from the *non*-administration or use of a countermeasure. For instance, the statute provides for immunity "only if" the countermeasure was "administered or used" during the period of the PREP Act 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, and

California offers no argument as to how these, or any other conditions on immunity, are met in such scenarios.[6]

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, H12264 (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

[6] California's failure, and indeed inability, to show how these conditions were met here provides an independent basis for the Court to affirm the denial of PREP Act immunity.

Secretary Leavitt) ("[T]he threat of liability exposure is too often a barrier to willingness to participate in the vaccine business.").[7]

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, § 3103, 134 Stat. 281, 361, was designed to "boost the availability and supply of critically needed respirator[] [masks]." 166 Cong. Rec. H1675-09, H1689 (daily ed. Mar. 13, 2020) (statement of Rep. Walden); *see also* Coronavirus Preparedness & Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (Mar. 11–12 2020) (testimony of HHS Ass't Secretary Kadlec, urging addition of respiratory protective devices to boost supply).[8] 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

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

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

statute." *Martin v. Petersen Health Ops., LLC*, 2021 WL 4313604, at *10 (C.D. Ill. Sept. 22, 2021), *aff'd* 37 F.4th 1210. Yet it is exactly such immunity that California seeks here.

B. Administrative authority does not support California's argument.

Rather than engaging with the text of the statute, California relies on language in the HHS General Counsel's nonbinding Advisory Opinion 21-01 and the now-vacated decision in *Garcia*, which was based on that opinion. *See* Cal. Br. 52–57. Advisory Opinion 21-01, however, does not help California here.

In providing his views on complete preemption in Advisory Opinion 21-01, the General Counsel opined that, in some situations, a failure to administer a covered countermeasure hypothetically *could* fall within the scope of the PREP Act's immunity provision. In so doing, he stated that "[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 Secretary's] Declaration's liability protections"; "nonfeasance, on the other hand, that also results in non-use," cannot. ADD-060–061.

Regardless of whether this view is correct, it does not support California's claim to immunity here because the complaint does not allege "purposeful allocation." As the district court in a related matter explained:

> [T]he facts as alleged bear no indication that the failure to test the transferring prisoners had any relationship to the testing of other prisoners. And the allegations are of non-use resulting from non-feasance rather than allocations. Defendants do not even suggest that the reliance on old COVID tests was the result of a limited number of tests and a choice to use the tests on a different population.

In re CIM-SQ Transfer Cases, 2022 WL 2789808, at *6.[9] Not only does Ms. Hampton not allege that California's failure to test inmates before they were transferred from CIM was the result of a purposeful allocation of limited resources, but the complaint alleges that the failure to test inmates was *contrary to*, not in accordance with, public health guidance. *See, e.g.*, ER 182, 184.

[9] The district court stated that "the facts are disputed about whether the defendants purposely allocated countermeasures or failed to act." ER 23. The collateral order doctrine, on which California relies as a basis for appellate jurisdiction of the district court's non-final order, does not provide jurisdiction to review a district court's denial of immunity "on the basis of a disputed issue of material fact." *Rodriguez v. Lockheed Martin Corp.*, 627 F.3d 1259, 1265 (9th Cir. 2010).

California does not point to any allegations in the complaint that would allow a contrary inference, much less *require* one, as would be necessary at this procedural posture. Rather, it suggests that it "prioritized … removing vulnerable inmates from a dangerous situation over testing." Cal. Br. 55. Although California's brief use the word "prioritized" in making this factual assertion (a factual assertion that is not properly before the Court on review of a Rule 12(b)(6) motion), this claim describes decisionmaking that is fundamentally different from that covered by the PREP Act under the former HHS General Counsel's opinion, which refers to prioritizing the administration of covered countermeasures to some individuals over others, not prioritizing other goals over that of administering countermeasures. Whether or not California's decision to prioritize other things over using covered countermeasures was reasonable, it is not a decision covered by the PREP Act.

To the extent that California reads the Advisory Opinion differently, this Court owes no deference to the opinion in any event. For one, where, as here, "the statute is clear and unambiguous, no deference is required and the plain meaning of Congress will be enforced." *High*

Sierra Hikers Ass'n v. Blackwell, 390 F.3d 630, 638 (9th Cir. 2004). The Advisory Opinion itself expressly acknowledges that it lacks "the force or effect of law." ADD-062. Accordingly, it is not entitled to "*Chevron*-style deference." *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see Hall v. U.S. Dep't of Agric.*, 984 F.3d 825, 835–36 (9th Cir. 2020). At most, the former General Counsel's views of what constitutes an injury with a causal relationship to the administration to or use by an individual of a covered countermeasure would be "entitled to a measure of deference proportional to [their] power to persuade." *GCIU-Emp. Ret. Fund v. Quad/Graphics, Inc.*, 909 F.3d 1214, 1219 (9th Cir. 2018) (quoting *Tablada v. Thomas*, 533 F.3d 800, 806 (9th Cir. 2008) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944))). However, in providing his interpretation, the General Counsel did "not purport to rely on agency expertise," *id.*, and opined on hypothetical scenarios without any examination of the statutory text, history, or purpose. Accordingly, not even *Skidmore* deference is due. *See id.*; *Escobar v. Lynch*, 846 F.3d 1019, 1025 (9th Cir. 2017) (declining to afford *Skidmore* deference where agency "provided little reasoning"); *see also, e.g.*, *Mackey v. Tower Hill Rehab., LLC*, 569 F. Supp. 3d 740, 747–48 (N.D. Ill. 2021) (declining to

afford any deference to Advisory Opinion 21-01's discussion of non-use); *WorkCare, Inc. v. Plymouth Med., LLC*, 2021 WL 4816631, at *5 (C.D. Cal. Aug. 20, 2021) (same).

CONCLUSION

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

Respectfully submitted,

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January 6, 2023

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 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 4,314 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.

January 6, 2023

/s/ Adam R. Pulver
Adam R. Pulver

CERTIFICATE OF SERVICE

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.

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/s/ Adam R. Pulver
Adam R. Pulver