No. 20-56194

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JACKIE SALDANA, et al.,
Plaintiffs-Appellees,

v.

GLENHAVEN HEALTHCARE LLC, et al.,
Defendants-Appellants,

On Appeal from the United States District Court
for the Central District of California
Case No. 2:20-cv-05631-FMO-MAA
Hon. Fernando M. Olguin

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INTRODUCTION

This case involves garden-variety state-law tort claims. Plaintiffs-Appellees, Jackie Saldana and family members, allege that Defendants-Appellants Glenhaven, operators of the nursing home with which they entrusted the care of their husband and father Ricardo Saldana, breached its duty of care by failing to take appropriate steps to protect residents from the spread of the coronavirus. Specifically, they allege that Glenhaven prohibited staff from wearing masks or other face coverings and failed to isolate staff and patients that it knew were exposed to the coronavirus, resulting in Ricardo's death. The Saldanas allege that this conduct violated Glenhaven's duty of care under California law, and bring exclusively state-law causes of action against Glenhaven.

The global impact of the COVID-19 pandemic does not change the fact that this case arises under California state law, between California parties, and is not within federal courts' jurisdiction. The case does not concern a private entity's performance of federal governmental functions under detailed federal supervision, as is necessary to create federal-officer removal jurisdiction. Glenhaven's suggestion that general, industry-wide guidance from the federal government brought it under the direction of federal

officers is frivolous under well-established precedent, which holds that even a pervasive regulatory scheme does not convert regulated entities into arms of the federal government for jurisdictional purposes. Although intense regulation "plus" additional evidence of direct control can establish a relationship with federal officers that supports federal jurisdiction, no such evidence is present here. And states' extensive role in supervising nursing homes—explicitly contemplated and encouraged by the federal government—is strong evidence that America's nursing homes were not federalized with the onset of the pandemic. Moreover, there is no connection between the guidance Glenhaven cites and the claims in this case: Nothing the federal government said or did caused Glenhaven's "no face-covering" policy or its refusal to screen or isolate exposed individuals from residents like Ricardo.

This Court lacks jurisdiction to consider Glenhaven's alternative theories of federal jurisdiction. Furthermore, those theories lack merit, as reflected by the nearly unanimous district court consensus. The Public Readiness and Emergency Preparedness (PREP) Act, a statute that creates a defense for claims arising out of the "administration" or "use" of "covered countermeasures," has no relevance here. In adopting its no face-covering

policy and failing to screen or isolate exposed patients and employees, Glenhaven was not administering or using any drugs or medical devices that constitute "covered countermeasures" under the statute. Glenhaven's reliance on federal agency statements rests on a fundamental misunderstanding of administrative deference and ignores what the agencies actually said. Even if, as those statements asserted, the PREP Act applies to claims about the allocation of scarce supplies of certain respiratory protective devices, that would not help Glenhaven here. The Saldanas claim that Glenhaven *banned* the use of all face coverings—not that it improperly allocated approved respiratory protective devices.

Because the Saldanas' claims are not subject to the PREP Act's immunity provision, the Court need not address Glenhaven's argument that the Act completely preempts claims subject to that provision—an argument that in any event confuses defensive preemption with complete preemption. The PREP Act cannot completely preempt claims like the Saldanas' where the statute, undisputedly, does not provide a substitute federal cause of action.

Under Glenhaven's view of federal jurisdiction, all matters implicating federal policy interests belong in federal court. As the district court below and dozens of district courts across the country have held, that is not the law.

STATEMENT OF JURISDICTION

The district court correctly determined that neither 28 U.S.C. § 1442(a)(1) nor 28 U.S.C. § 1331 confer subject-matter jurisdiction over this action. Under 28 U.S.C. § 1447(d), this Court has appellate jurisdiction to review the district court's remand order to the extent it rejected Glenhaven's invocation of section 1442(a)(1). *See County of San Mateo v. Chevron Corp.*, 960 F.3d 586, 594–98 (9th Cir. 2020).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Relevant statutory and regulatory authorities appear in the Addendum to this brief.

ISSUES PRESENTED

(1) Whether federal agencies' issuance of guidance related to COVID-19 converted the nation's nursing homes into agents of the federal government.

(2) Whether, in creating an express preemption defense for claims related to the "administration" or "use" of "covered countermeasures" in

public health emergencies under the PREP Act, 42 U.S.C. § 247d-6d(a)(1), Congress completely preempted all state-law claims based on a failure to take infection control measures.

(3) Whether an anticipated federal defense brings this case into the special and small category of cases where *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), recognizes federal-question jurisdiction despite the absence of a federal-law claim.

STATEMENT OF THE CASE

I. The Federal-State Response to the Pandemic

Since the first reported COVID-19 cases in January 2020, federal agencies have issued dozens of guidance documents setting forth best practices and interpretations of how existing legal requirements apply to measures to reduce the spread of the disease. For instance, the Centers for Disease Control and Prevention (CDC), a division of the Department of Health and Human Services (HHS), has issued both broad guidance that applies to all "workplaces and businesses" and guidance for specific industries ranging from higher education institutions to amusement parks, and from homeless shelters to community gardens. *See* CDC, COVID-19,

Community, Work, and School.[1] And both CDC and HHS's Centers for Medicare & Medicaid Services (CMS) have issued guidance about infection control in nursing homes and other health care facilities. *See*, *e.g.*, Appellants' Request for Judicial Notice at RJN-35, 54, 59, 62, 172, 179, 183, 188.

These HHS guidance documents explicitly contemplate that state and local government agencies will retain their role as the primary protectors of public health and safety. *See*, *e.g.*, RJN-72 (CDC statement that "CDC guidance for COVID-19 may be adapted by state and local health departments to respond to rapidly changing local circumstances"); RJN-232 (CDC statement that nursing homes should seek "consultation and guidance" from "their local or state health department"); RJN-238 (CMS statement that "State and local health departments should work together with long-term care facilities in their communities to determine and help address long-term care facility needs"); CMS, "Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes," Mar. 2021 (Version 20).[2]

[1] https://www.cdc.gov/coronavirus/2019-ncov/community/index.html.

[2] https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf.

Consistent with this expectation, the State of California has taken a variety of actions to address the spread of COVID-19 in nursing homes. On March 15, 2020, for instance, Governor Newsom issued an executive order directing the Department of Social Services, the Division of Occupational Safety and Health (Cal/OSHA), and the Department of Public Health (CDPH) to take a variety of actions to address the risk of COVID-19 in facilities like Glenhaven "to protect the health and safety of Californians receiving care in these critical facilities." Cal. Exec. Order N-27-20 (Mar. 15, 2020).[3] And between January 2020 and April 13, 2020, when Ricardo died, CDPH issued detailed guidance to skilled nursing facilities, including Glenhaven, regarding the transmission of the coronavirus—including more than a dozen "All Facility Letters." *See* CDPH, All Facilities Letters – 2020;[4] *see also* RJN-65; RJN-77. For example, on March 20, 2020, CDPH provided skilled nursing facilities detailed guidance about the screening of staff and visitors, the isolation of exposed residents, and the use of personal protective

[3] https://www.gov.ca.gov/wp-content/uploads/2020/03/3.15.2020-COVID-19-Facilities.pdf.

[4] https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL20.aspx.

equipment (PPE). CDPH, AFL 20-25.1, Preparing for Coronavirus Disease 2019 (COVID-19) in California Skilled Nursing Facilities.[5]

In addition, in February 2020, Cal/OSHA informed all health care workplaces that the State's Aerosol Transmissible Disease standard required them to take certain steps to reduce transmission of the coronavirus. *See* Cal/OSHA, Release No. 2020-08, Cal/OSHA Issues Guidance on Requirements to Protect Health Care Workers from 2019 Novel Coronavirus (Feb. 3, 2020).[6] Cal/OSHA subsequently cited a number of skilled nursing facilities for violating this and other state workplace health and safety standards. *See*, *e.g.*, Cal/OSHA, Release No. 2021-13, Cal/OSHA Issues Citations to Multiple Employers for COVID-19 Violations (Feb. 4, 2021)[7]; Cal/OSHA, Release No. 2020-80, Cal/OSHA Issues Citations to Health Care Facilities and Public Safety Employers for COVID-19 Violations (Sept. 22, 2020).[8]

[5] Archived at https://bit.ly/3gvbwlQ.

[6] https://www.dir.ca.gov/DIRNews/2020/2020-08.html.

[7] https://www.dir.ca.gov/DIRNews/2021/2021-13.html.

[8] https://www.dir.ca.gov/DIRNews/2020/2020-80.html.

II. The PREP Act and Its Implementation

A. The PREP Act

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 [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: Limiting Liability for Medical Countermeasures* 1 (Dec. 21, 2020). The Act's provisions are triggered when the HHS Secretary formally declares a public-health emergency and "recommend[s]" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." 42 U.S.C. § 247d-6d(b)(1).

The term "covered countermeasures" includes certain drugs, biological products, and devices authorized for emergency use, 42 U.S.C. § 247d-6d(i)(1)(A)–(C). In 2020, Congress amended the statute, first in the Families First Coronavirus Response Act (FFCRA), and again in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, to provide that respiratory protective devices approved by the National Institute of Occupational Safety and Health (NIOSH) may also be covered

countermeasures in limited circumstances. Pub. L. No. 116-127, § 6005, 134 Stat. 178, 207 (2020); Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361 (2020), *codified at* 42 U.S.C. § 247d–6d(i)(1)(D).

The PREP Act limits liability with respect to "claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). Under subsection (a) of the Act, "a covered person" is "immune from suit and liability under Federal and State law" for claims with 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," subject to certain conditions. *Id.* § 247d-6d(a)(1), (a)(2)(B), (a)(3). Subsection (d) creates a carveout from the subsection (a)(1) immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). For these claims, the statute creates an "exclusive Federal cause of action," *id.*, and provides special procedures for their adjudication, with exclusive jurisdiction in the District Court for the District of Columbia, *id.* § 247d-6d(e).

The PREP Act also creates an administrative scheme, administered by HHS, to provide "compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure" subject to a PREP Act declaration. 42 U.S.C. § 247d-6e(a). Via notice-and-comment rulemaking, HHS has interpreted the statute to limit eligibility for compensation to "injured countermeasure recipients" and their survivors, 42 C.F.R. § 110.10(a), and to define "covered injuries" as excluding "injur[ies] sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used … (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease)," *id*. § 110.20(d).

B. The COVID-19 PREP Act Declaration and Amendments

On March 17, 2020, the HHS Secretary invoked the PREP Act by issuing a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. 85 Fed. Reg. 15,198, 15,198 (Mar. 17, 2020). The Secretary has amended the initial Declaration several times. The First Amendment, issued April 15, 2020, expanded covered countermeasures to include certain respiratory protective

equipment, based on the CARES Act. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020).

Well after the events of this case, and after the district court's decision, the Secretary's Fourth Amendment expressed his view 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 is a result of "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). The Fourth Amendment used as an example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *Id.* The Fourth Amendment also incorporated by reference four advisory opinions previously issued by the HHS Office of General Counsel (OGC). *Id.* at 79,191 & n.5.

In the waning days of the last administration and after the ruling below, OGC issued a fifth advisory opinion. *See* OGC, Advisory Opinion 21-01 (Jan. 8, 2021), RJN-161. The opinion states OGC's view that "the PREP Act is a [c]omplete [p]reemption statute" that applies to situations where a

covered person makes a decision regarding allocation of covered countermeasures "which results in non-use by some individuals," but *not* to cases where non-use was the result of "nonfeasance." RJN-162. It also asserts that the *Grable* doctrine of federal-court jurisdiction applies to any cases where there is a question about whether the PREP Act applies. RJN-164–65. Like the previous advisory opinions, the fifth opinion says that it "sets forth the current views" of OGC, is "not a final agency action or a final order," and "does not have the force or effect of law." RJN-165.

III. Glenhaven's Action and Inaction Leading to Ricardo's Death

Despite the range of guidance issued by state and federal agencies, and the well-publicized COVID-19 outbreaks in nursing homes throughout the country, ER226, Glenhaven failed to take basic safety measures throughout February and March 2020 to protect Ricardo and other residents from the serious risk posed by COVID-19. The Saldanas' complaint focuses on two such failures. First, the Saldanas allege that Glenhaven failed to provide *any* employees with PPE in the relevant time period and even went so far as to *prohibit* staff from wearing face coverings. ER222, 227. Under this "no facial covering" policy, one Glenhaven manager repeatedly told staff to take off any masks and bandanas they brought to the facility—including a nurse who

pleaded to keep her mask on because she was sick. ER227. When a local fire department delivered boxes of masks to the facility, Glenhaven management locked the masks in a cabinet and barred staff from using them. *Id.*

Second, Glenhaven failed to take any steps to isolate staff and residents that it knew had been exposed to, or infected by, the coronavirus. ER222, 227. Management allowed at least one staff member it knew had been exposed at another nursing facility to continue to work at Glenhaven and concealed her exposure for two weeks. ER222, 227. And without adopting any precautions, it allowed exposed residents to have close contact with other residents. Fearing positive results that it would need to report, Glenhaven failed to conduct any COVID-19 testing until April 7, 2020. ER228.

Ricardo Saldana was a victim of these policies. In 2014, Ricardo suffered a stroke and was hospitalized. ER225. The stroke left him in need of care beyond what his family could provide, and the hospital therefore discharged him to Elms Convalescent Hospital, a skilled nursing facility later acquired by Glenhaven. ER225–26. Ricardo was dependent on Glenhaven for all activities of daily life, including feeding, clothing, hydration, hygiene, and mobility, as well as medical care. ER226.

Nonetheless, until March 2020, Ricardo was stable and able to interact with his wife, Celia, and his children, Jackie, Maria and Ricardo, Jr., plaintiffs-appellees in this action. *Id.*

In late March, Glenhaven transferred a resident it knew had been exposed to the coronavirus into a shared room with Ricardo. ER222, 228. Shortly after, Ricardo developed COVID-19. ER228. His condition quickly degraded, and he died of COVID-19 on April 13, 2020. ER223, 228.

IV. Procedural History

The Saldanas commenced this action in Los Angeles County Superior Court on May 21, 2020, alleging that Glenhaven's failure to take appropriate measures to stop the spread of COVID-19 led to Ricardo's death. The operative complaint contains four state-law claims. First, pursuant to California Welfare and Institutions Code § 15657, the Saldanas allege that Glenhaven's failure to protect Ricardo from health and safety hazards, and its intentional and/or reckless acts exposing him to the coronavirus while he was in its care, constituted elder neglect. ER229–30. Second, the Saldanas allege that Glenhaven committed willful misconduct, as that term is used in California law, in forbidding staff from wearing appropriate PPE, failing to provide any staff with PPE, and failing to take steps to prevent exposed staff

and residents from infecting others. ER230–31. Third, they allege that Glenhaven's failure to implement policies, procedures, and safety measures necessary to prevent Ricardo's exposure to the coronavirus constituted custodial negligence. ER233. Finally, they allege wrongful death based on Glenhaven's acts. ER234.

Glenhaven removed the action to the U.S. District Court for the Central District of California on June 24, 2020. ER206. The notice of removal asserted that that court had federal-question jurisdiction pursuant to 28 U.S.C. § 1331 based on the PREP Act's immunity defense provision, 42 U.S.C. § 247d-6d(a)(1), and its express preemption provision, *id.* § 247d-6d(b)(8), and because the Saldanas' action raised a "significant federal question" under *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). ER208–12. Alternatively, Glenhaven argued that the district court had jurisdiction under 28 U.S.C. § 1442(a)(1), because Glenhaven was being sued for actions taken under the direction of federal officers, specifically, CMS and CDC. ER212–18.

The Saldanas moved to remand the action to state court for lack of subject-matter jurisdiction. ER174. Rejecting each of Glenhaven's arguments, the district court granted the motion on October 14, 2020. ER3–6.

SUMMARY OF ARGUMENT

To qualify for removal under section 1442(a)(1), a defendant must demonstrate that it is a federal officer or person "acting under" a federal officer, facing claims "for, or relating to" an act under color of federal office, and must raise a colorable federal defense. Federal officer removal is available only to entities that are in a special, subservient relationship with the federal government, and in cases where plaintiffs have brought claims against such entities arising out of actions performed on the federal government's behalf and at its direction. Federal *regulation* of a private entity, however intense, is not sufficient to support federal officer removal. Despite these well-established principles, Glenhaven asserts that generic, industry-wide guidance issued by HHS to the nation's nursing homes brought it under federal officer direction. Glenhaven, however, provides no evidence that its relationship with the federal government was different in kind from that of other highly regulated entities.

Further, Glenhaven has not established that the actions for which the Saldanas are suing Glenhaven—its no-facial-covering policy and failure to screen or isolate residents and staff exposed to the coronavirus—are "related to" any federal direction that Glenhaven received. And Glenhaven lacks a

colorable federal defense: The Saldanas' claims that Glenhaven prohibited the use of facial coverings and refused to isolate exposed residents and staff are not causally connected to the "administration" or "use" of "covered countermeasures," as those terms are used in the PREP Act. Accordingly, the PREP Act does not provide a colorable federal defense.

This Court does not have jurisdiction to consider Glenhaven's other claimed grounds for removal. In any event, the district court correctly held that the complete preemption doctrine does not provide federal jurisdiction. The Saldanas' claims do not fall under the PREP Act and are undisputedly not within the scope of the federal cause of action that the PREP Act creates. Thus, the Saldanas' claims are not completely preempted by the PREP Act. None of the administrative interpretations cited by Glenhaven states otherwise. To the extent those opinions suggest that the existence of a defensive preemption provision in the PREP Act, without a corresponding federal cause of action, establishes complete preemption over any claims, they are wrong and owed no deference.

Finally, the district court correctly rejected Glenhaven's *Grable* argument. *Grable* supports federal jurisdiction only where resolution of a question of federal law is necessarily raised by a plaintiff's affirmative claim.

Glenhaven's desire to raise a federal *defense* does not bring this action into the exceedingly small category of cases under which *Grable* provides federal-question jurisdiction absent a federal-law claim.

STANDARD OF REVIEW

This Court reviews the district court's remand order *de novo*. *See Riggs v. Airbus Helicopters, Inc.*, 939 F.3d 981, 984 (9th Cir. 2019).

ARGUMENT

I. Glenhaven has not established jurisdiction under the federal officer removal statute.

The federal officer removal statute allows removal to federal court of cases brought against "[t]he United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, in an official or individual capacity, for or relating to any act under color of such office." 28 U.S.C. § 1442(a)(1). To invoke the statute, a removing defendant must (1) demonstrate that it is a federal officer or person "acting under" a federal officer, (2) demonstrate that the plaintiff's claims are "for, or relating to" an act under color of federal office, and

(3) raise a colorable federal defense. *See Fidelitad, Inc. v. Insitu, Inc.*, 904 F.3d 1095, 199 (9th Cir. 2018).

In this case, the district court—like every district court to consider the issue—correctly held that nursing homes operating during the COVID-19 pandemic are not acting under the direction of federal officers for purposes of section 1442(a)(1), and thus that removal under section 1442(a)(1) was improper. ER5–6; *see also Perez v. Southeast SNF LLC*, 2021 WL 1318232, at *4–5 (W.D. Tex. Apr. 12, 2021); *Garcia v. N.Y. City Health & Hosps. Corp.*, 2021 WL 1317178, at *2 (S.D.N.Y. Apr. 8, 2021); *Winn v. Cal. Post Acute*, 2021 WL 1292507, at *6 (C.D. Cal. Apr. 6, 2021); *Nava v. Parkwest Rehab. Ctr. LLC*, 2021 WL 1253577, at *1–2 (C.D. Cal. Apr. 5, 2021); *Stone v. Long Beach Healthcare Ctr., LLC*, 2021 WL 1163572, at *8 (C.D. Cal. Mar. 26, 2021); *Ivey v. Serrano Post Acute*, 2021 WL 1139741, at *1 (C.D. Cal. Mar. 25, 2021); *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284, at *7–8 (C.D. Cal. Mar. 19, 2021); *Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *6–7 (C.D. Cal. Mar. 1, 2021); *Lyons v. Cucumber Holdings, LLC*, 2021 WL 364640, at *3 (C.D. Cal. Feb. 3, 2021); *Dupervil v. Alliance Health Ops., LCC*, 2021 WL 33517, at *15–16 (E.D.N.Y. Feb. 2, 2021); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC* (*Sherod II*), 2020 WL 6119479, at *1 (W.D. Pa. Oct. 16, 2020); *Martin v. Serrano*

Post Acute LLC (*Martin I*), 2020 WL 5422949, at *1 (C.D. Cal. Sept. 10, 2020); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 534–36 (D.N.J. 2020).

A. The federal officer removal statute applies to private entities only when they act on behalf of the federal government.

Recognizing that the federal government "can act only through its officers and agents, and [that] they must act within the States," *Tennessee v. Davis*, 100 U.S. 257, 263 (1880), section 1442(a) provides federal officers and agents with a federal forum to "protect the Federal Government from the interference with its operations that would ensue were a State able, for example, to arrest and bring to trial in a State court for an alleged offense against the law of the State, officers and agents of the Government acting within the scope of their authority." *Watson v. Philip Morris Cos.*, 551 U.S. 142, 1342 (2007) (quoting *Willingham v. Morgan*, 395 U.S. 402, 406 (1969)) (cleaned up). The statute applies not only to federal officers themselves but also to "any person acting under [an] officer," 28 U.S.C. § 1442(a)(1)—that is, to "[p]rivate persons 'who lawfully assist' the federal officer 'in the performance of his official duty.'" *Watson*, 551 U.S. at 151 (quoting *Davis v. South Carolina*, 107 U.S. 597, 600 (1883)). This provision supports the statute's

predominant concern: protecting vulnerable officers and employees of the federal government against prosecution or suit in state courts for the performance of their official duties. The paradigmatic application of the statute to a private person is *Maryland v. Soper (No. 1)*, 270 U.S. 9 (1926), where the Court acknowledged that a private individual hired to drive and assist federal revenue officers in busting up a still "had 'the same right to the benefit of' the removal provision as did the federal agents." *Watson*, 551 U.S. at 150 (quoting *Soper (No. 1)*, 270 U.S. at 30).

Although the federal-officer removal statute is "liberally construed," *Colorado v. Symes*, 286 U.S. 510, 517 (1932), section 1442(a)(1)'s authorization of removal by those "acting under" federal officials is "not limitless." *Watson* 551 U.S. at 147. Accordingly, when defendants have attempted to stretch the scope of the "acting under" provision, the Supreme Court has rejected those efforts. *See id.* at 152–57; *Int'l Primate Prot. League v. Adm'rs of Tulane Educ. Fund*, 500 U.S. 72, 79–87 (1991); *Mesa v. California*, 489 U.S. 121, 129–39 (1989). For example, in *Watson*, plaintiffs sued cigarette manufacturers for fraudulently marketing cigarettes as "light" to deceive smokers into believing that smoking them would deliver lower levels of tar and nicotine than other cigarettes and present less danger of disease. The manufacturers,

citing section 1442(a)(1), removed the action, claiming that they were "acting under" a federal officer because the Federal Trade Commission regulated the way they tested their cigarettes' tar and nicotine levels. *See* 551 U.S. at 154–56. The Eighth Circuit held that the FTC's "comprehensive, detailed regulation," "ongoing monitoring," and use of its "coercive power" to persuade the tobacco industry to enter into a voluntary agreement regarding advertising disclosures, as well as a record "filled with FTC announcements of its policy as well as communications between the FTC and the cigarette industry," were sufficient to show "that Philip Morris acted under the direction of a federal officer" in selling cigarettes. *Watson v. Philip Morris Cos., Inc.*, 420 F.3d 852, 859-61 (8th Cir. 2005).

The Supreme Court unanimously reversed. The Court explained that, as used in section 1442(a)(1), the term "under" refers to a relationship of subservience, and, therefore, the statute applies only where a private person undertakes "an effort to *assist*, or to help *carry out*, the duties or tasks of the federal superior." 551 U.S. at 151–52. Importantly, "the help or assistance necessary to bring a private person within the scope of the statute does *not* include simply *complying* with the law." *Id.* at 152. The statutory purpose would not be furthered by allowing "a company subject to a

regulatory order (even a highly complex order)" to have claims against it heard in federal, not state, court. *Id.* Such a scenario, "does not ordinarily create a significant risk of state-court 'prejudice,'" and a state-court lawsuit would be "[un]likely to disable federal officials from taking necessary action designed to enforce federal law" or "deny a federal forum to an individual entitled to assert a federal claim of immunity." *Id.* (citations omitted). Accordingly, the Court held, a private company's "compliance (or noncompliance) with federal laws, rules, and regulations does not by itself fall within the scope of the statutory phrase 'acting under' a federal 'official.' And that is so even if the regulation is highly detailed and even if the private firm's activities are highly supervised and monitored." *Id.* at 153.

This Court has consistently recognized that "*Watson* rejected the proposition that 'a company subject to a regulatory order (even a highly complex order)' is acting under a federal officer." *Fidelitad*, 904 F.3d at 1100; *see also County of San Mateo v. Chevron Corp.*, 960 F.3d 586, 600 (9th Cir. 2020); *Riggs*, 939 F.3d at 987–89. Rather, to qualify under section 1442(a)(1), a private entity must show that the federal government has delegated it authority to act on its behalf, that it is performing "basic governmental tasks," and that it is subject to a federal officer's close direction, making the

private actor's activity "so closely related to the government's implementation of its federal duties that the private person faces a significant risk of state-court prejudice, just as a government employee would in similar circumstances, and may have difficulty in raising an immunity defense in state court." *San Mateo*, 960 F.3d at 599–600 (quoting *Watson*, 551 U.S. at 152). These criteria reflect section 1442(a)(1)'s requirement that removing parties be "acting under" federal officers who are themselves acting "under color of" their federal office.

Glenhaven's argument that removal here was appropriate because it is subject to "pervasive" regulation or oversight by the federal government, Appellants' Br. 23, rests on a fundamental misunderstanding of the federal officer removal statute. Section 1442(a)(1) requires more: To qualify for federal officer removal, the relationship must be one where the private actor is not just subject to federal law but is essentially acting as an arm of the federal government.

B. Glenhaven is not acting "under" a federal officer by operating its nursing homes.

Glenhaven's operation of its nursing homes since the onset of the COVID-19 pandemic is not action "under" a federal officer. Glenhaven relies

on CDC and CMS guidance and regulatory orders related to infection control, but as the decision below and dozens of other district court decisions have held, such industry-wide guidance and regulatory orders, no matter their level of detail or the possibility of penalties for non-compliance, do not transform a private actor into a federal government agent. *Watson* is clear on this point.

Nonetheless, Glenhaven maintains that this case falls within a "regulation plus" category of removable cases because of the "unprecedent [*sic*] circumstances" and because Glenhaven was "part of the national critical infrastructure." Appellants' Br. 26–27. But Glenhaven provides no evidence of any "plus" beyond the regulatory guidance and orders themselves. Instead, it spends nine pages summarizing the industry-wide guidance issued by CDC and CMS, *id*. 29–37, and then asserts that these "detailed clinical directives and operational instructions … demonstrate[] that nursing facilities were acting under the 'subjection, guidance, or control' of the federal agencies," *id*. 38. These industry-wide documents fail to satisfy Glenhaven's "burden of providing candid, specific and positive' allegations that [it was] acting under federal officers." *In re Methyl Tertiary Butyl Ether*

("MTBE") Prods. Liab. Litig., 488 F.3d 112, 130 (2d Cir. 2007) (quoting *Willingham*, 395 U.S. at 408).

As the district court correctly explained, the materials on which Glenhaven relies "'are general regulations and public directives regarding the provision of medical services,' which are insufficient" to establish that Glenhaven was acting under a federal officer. ER6 (quoting *Martin I*, 2020 WL 5422949, at *1). Glenhaven's purported compliance with this guidance "fit[s] squarely within the precept of mere compliance with regulatory standards and outside the 'acting under' provision of 1442(a)(1)." *Riggs*, 939 F.3d at 989 (citing *Watson*, 551 U.S. at 153). Nothing about the guidance changed the nature of the relationship between the federal government and Glenhaven from one of regulation to one of delegation.

Glenhaven's suggestion that the rule of *Watson* does not apply because this guidance was "very detailed" or because there was a lot of it is foreclosed by *Watson* itself. There, the Court explicitly held that "differences in the degree of regulatory detail or supervision cannot by themselves transform Philip Morris' regulatory compliance into the kind of assistance that might bring the FTC within the scope of the statutory phrase 'acting under' a federal 'officer.'" 551 U.S. at 157. "'[S]imply complying with the

law,'" no matter how detailed that law is, "does not bring a private actor within the scope of the federal officer removal statute." *Fidelitad*, 904 F.3d at 1100 (quoting *Watson*, 551 U.S. at 152); *see also City of Walker v. Louisiana*, 877 F.3d 563, 571 (5th Cir. 2017) ("The Supreme Court's decision in *Watson* instructs that even onerous and specifically enforced regulations do not suffice to show the firm was 'acting under' a federal officer.").

Glenhaven's contrary argument "would have very far-reaching consequences." *Maglioli*, 478 F. Supp. 3d at 534. As the *Maglioli* court noted, thousands of businesses and nonprofits across the United States could point to "dutiful compliance with CDC guidelines for limiting occupancy, face coverings, and health and sterilization measures." *Id.* The guidance on which Glenhaven relies does not show that the federal government has assumed control over nursing homes any more than it has over amusement parks, airlines, or homeless shelters—all of which have been the subject of extensive COVID-19 related guidance.[9] That Glenhaven's view of section 1442(a)(1)

[9] *See, e.g.*, U.S. Dep't of Transp., Fed. Aviation Admin., SAFO 20009, COVID-19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews (updated March 3, 2021), https://bit.ly/3ndmRZi; CDC, COVID-19 Considerations for Traveling Amusement Parks and Carnivals (updated Dec. 30, 2020), https://bit.ly/3ei4AG1; CDC, Interim Guidance for

would bring all claims related to COVID-19 against such entities into federal court illustrates the incorrectness of its position.

Glenhaven's passing references to being a part of the nation's "critical infrastructure" do not alter this analysis. It has offered no evidence that all of the nation's critical infrastructure came under the control of the federal government with the onset of the pandemic. President Obama in 2013 designated healthcare as one of *sixteen* sectors that form the nation's critical infrastructure. *See* Presidential Policy Directive/PPD-21, Critical Infrastructure Security and Resilience (Feb. 12, 2013).[10] As the United States has stated, "it cannot plausibly be argued that every person in each of the [sixteen critical infrastructure] industries was 'acting under' the federal government" since the onset of the pandemic. Br. for the United States as Amicus Curiae in Support of Appellees at 12, *Buljic v. Tyson Foods*, No. 21-1010 (8th Cir. Apr. 13, 2021).

This point is confirmed by the one document about critical infrastructure Glenhaven cites—a press release issued by the Cybersecurity

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Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 (COVID-19) (updated Mar. 23, 2021), https://bit.ly/3sKqaIF.

[10] https://bit.ly/3jqTgcY.

& Infrastructure Security Agency (CISA) announcing new guidance. Appellants' Br. 28 (citing CISA, Press Release, CISA Releases Guidance on Essential Critical Infrastructure Workers During COVID-19 (CISA Press Release) (Mar. 19, 2020)).[11] As the release states, that guidance represented a federal government effort "to help state and local jurisdictions and the private sector identify and manage their essential workforce while responding to COVID-19." CISA Press Release. "Recogniz[ing] that State, local, tribal, and territorial governments are ultimately in charge of implementing and executing response activities in communities under their jurisdiction, while the Federal Government is in a supporting role," CISA provided a list of critical workers to assist those governments in "prioritizing activities related to continuity of operations and incident response." CISA, Memorandum on Identification of Essential Critical Infrastructure Workers During COVID-19 Response (Mar. 19, 2020).[12] CISA made clear that this list was *not* binding on any government or private entity, stating, "**this list is advisory in nature. It is not, nor should it be considered to be, a federal directive or standard in and of itself.**" *Id.* (bold in original). State and local

[11] https://bit.ly/2QbcSrp.

[12] https://bit.ly/2QD7rRM.

governments, and private entities like Glenhaven, were expected to "use their own judgment." *Id.*

These statements are consistent with both President Obama's 2013 Directive, which emphasized that "critical infrastructure security and resilience … is a *shared responsibility*" among federal, state, and local governments and the private sector, PPD-21, and the Critical Infrastructures Protection Act of 2001, which sets out "the policy of the United States" that "any physical or virtual disruption of the critical infrastructures of the United States" should be limited, and "that actions necessary to achieve" this goal should "be carried out in a public-private *partnership* involving corporate and non-governmental organizations," 42 U.S.C. § 5195c(c)(1)–(2) (emphasis added). The terms "partnership" and "shared responsibility" make clear that there is no general rule that private operators of critical infrastructure become subservient to the federal government *en masse* in times of national emergency.

The language of the CISA guidance and the authority under which it was issued are incompatible with Glenhaven's claim that critical infrastructure was under direct control of federal officers. Whereas an acting under relationship "must involve an effort to *assist*, or to help *carry out*, the

duties or tasks of the federal superior," *Watson*, 551 U.S. at 152, the opposite scenario was present here: CISA was helping state and local governments and private industry carry out *their* duties and tasks.

Finally, section 1442(a)(1) is "an incident of federal supremacy," *Florida v. Cohen*, 887 F.2d 1451, 1453 (11th Cir. 1989) (citing *Willingham*, 395 U.S. at 405). Its "basic purpose is to protect the Federal Government from … interference with its operations" by states. *Watson*, 551 U.S. at 150. Here, though, the federal government, in CISA, CDC, and CMS guidance, has repeatedly emphasized that states, not the federal government, have extensive, and indeed primary, authority. Accordingly, removal is not necessary to serve the statutory purpose.

C. No causal nexus exists between any federal direction and Glenhaven's "no facial covering" policy and its failure to isolate exposed staff and residents.

Removal under section 1442(a)(1) requires that a defendant show "a causal nexus between its actions, taken pursuant to a federal officer's directions, and plaintiff's claims." *Riggs*, 939 F.3d at 986–87. As Glenhaven concedes, defendants must "show that the challenged act[s] 'occurred because of what they were asked to do by the Government.'" Appellants' Br. 39–40 (quoting *Isaacson v. Dow Chem. Co.*, 517 F.3d 129, 137 (2d Cir. 2008));

see Goncalves v. Rady Children's Hosp. San Diego, 865 F.3d 1237, 1244 (9th Cir. 2017). Because Glenhaven was not under federal direction at all, as explained above, none of its actions or inactions that gave rise to the Saldanas' suit could have been caused by federal direction. Moreover, there is no causal nexus between the CDC and CMS guidance and the Saldanas' claims.

The Saldanas allege that Glenhaven's policy of prohibiting and failing to provide facial coverings, and its failure to isolate exposed staff and residents, led to Ricardo's contracting the coronavirus in late March 2020. ER227–28. They allege that Glenhaven failed to conduct *any* COVID-19 testing until April 2020—after Ricardo contracted COVID-19. ER228. The guidance documents Glenhaven "invoke[s] as the hook for federal-officer jurisdiction mandate none of those activities." *Rhode Island v. Shell Oil Prods. Co., L.L.C.*, 979 F.3d 50, 60 (1st Cir. 2020); *see also Sherod II*, 2020 WL 6119479 at *1 (finding no causal nexus with CMS and CDC guidance "because Plaintiff's claims are predicated upon the fact [the nursing home] did *not* take action"). *Cf. Ulleseit v. Bayer HealthCare Pharm.*, 826 F. App'x 627, 629 (9th Cir. 2020) (no causal nexus where the government neither directed the defendant to conceal risks nor prohibited more detailed warnings).

D. Glenhaven lacks a colorable federal defense.

Even where a defendant is acting under a federal officer, removal under section 1442(a)(1) is available only where the defendant has "a colorable defense arising out of [its] duty to enforce federal law." *Willingham*, 395 U.S. at 406–07. Here, Glenhaven asserts as a federal defense that it has "immunity under the PREP Act for [its] administration and use of 'covered countermeasures." Appellants' Br. 41. The Saldanas' allegations, however, do not relate to the administration and use of covered countermeasures. And as the plaintiffs, they are the master of the complaint. "[A]ltering [their] allegations to suit defendants' arguments ignores that governing principle." *Maltbia v. Big Blue Healthcare, Inc.*, 2021 WL 1196445, at *4–12 (D. Kan. Mar. 30, 2021).

PREP Act immunity applies only where four requirements are met: The plaintiff's claim must be (1) against a "covered person," (2) "for loss," (3) "arising out of, relating, to resulting from the administration to or the use by an individual," (4) of a covered countermeasure subject to a declaration of the HHS Secretary. 42 U.S.C. § 247d-6d(1). Here, the Saldanas' claims do not even arguably meet the third and fourth elements, and thus Glenhaven has not met even the low, "colorable" threshold. The Saldanas' complaint is

tied to two specific aspects of Glenhaven's failure to protect Ricardo from the coronavirus: (1) its no-facial covering policy, and (2) its failure to isolate individuals known to be exposed to, or infected with, the coronavirus. These claims do not relate to covered countermeasures at all, much less their "administration" or "use."

1. The Saldanas' claims do not relate to "covered countermeasures."

Although Glenhaven treats all measures that would protect against the spread of COVID-19 as "covered countermeasures," the statute does not. Only PPE 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 NIOSH, can be a covered countermeasure. 42 U.S.C. § 247d-6d(i)(1), (7). Glenhaven has no colorable argument that claims challenging its decision not to exclude from its facility staff members who it knew were exposed to the coronavirus, ER227, or its decision to move a resident it knew had been exposed to the coronavirus into Ricardo's room, ER228, concern devices that are covered countermeasures. Indeed, Glenhaven does not even attempt to make the argument. As a district court stated in a similar case, such allegations "refer

to policies and a failure to protect, not to any covered countermeasure, *i.e.*, drug, product, or device. Thus, the square peg of 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.

As to the no-facial-covering policy, masks that have been authorized for emergency use or approved by NIOSH may be covered countermeasures under the statute; other masks and other PPE may not. Because a majority of facial coverings are *not* covered countermeasures, the Saldanas' claims that Glenhaven banned facial coverings generally, including bandanas—which are not medical devices and not subject to authorization or approval—do not have a "causal relationship" with any actions by Glenhaven relating to PPE devices that constitute "covered countermeasures," as subsection (a) requires. 42 U.S.C. § 247d-6d(a)(2)(B).

2. The PREP Act does not apply to policies of total non-use of covered countermeasures.

Even if the no-facial-covering policy could be construed as a policy relating to covered countermeasures, the PREP Act's immunity defense does not apply for the additional reason that the Saldanas' claim is not related to *administration or use* of covered countermeasures.

a. The text, purpose, and history of the statute demonstrate the PREP Act does not apply to the Saldanas' claims.

Claims concerning *non*-use of a covered countermeasure are not subject to the PREP Act's subsection (a)(1) defense. The Act states explicitly that that defense "applies only if … the countermeasure *was administered or used* during the effective period" of a PREP declaration." 42 U.S.C. § 247d-6d(a)(3). The statute's list of protected activities includes only affirmative acts: "the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of [a covered] countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). The list does not include a failure to act.[13]

The statutory text reflects the Act's purpose. The Act was intended to encourage the manufacture and distribution of covered countermeasures. Supporters explained that the bill was designed to ensure that a pandemic flu "vaccine gets developed and to make sure doctors are willing to give it

[13] HHS regulations regarding the administrative compensation scheme similarly focus on affirmative acts: They specify that "injured counter-measure recipients"—not *non*-recipients—are eligible for compensation through the PREP Act's administrative compensation scheme. 42 C.F.R. § 110.10(a).

when the time comes." 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) (statement of Rep. Nathan Deal); *see also* 151 Cong. Rec. S14242-01 (daily ed. Dec. 21, 2005) (statement of Sen. Hillary Clinton, noting the "provision is being billed as a simple liability protection to help those who would manufacture avian flu vaccine"). Likewise, adding NIOSH-approved respiratory protective devices to the scope of covered countermeasures last March 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. Greg Walden). *See also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (2020) (Testimony of Dr. Robert Kadlec, HHS Asst. Secretary for Preparedness and Response, urging addition of respiratory protective devices to PREP Act to extend immunity for "manufacturers, distributors, and users" of covered countermeasures to respiratory devices to boost supply). Immunity for *non*-use of masks does not further this purpose.

When Congress intends to protect entities from liability for *inaction*, it knows how to do so. For example, in the CARES Act, Congress immunized volunteer healthcare professionals for harm caused by "an act *or omission* of the professional in the provision of health care services during the public

health emergency with respect to COVID–19." Pub. L. No. 116-136, § 3215(a), 134 Stat. at 374 (emphasis added). And throughout last spring and summer, Congress debated—but ultimately did not enact—adding liability protections for claims like the Saldanas.' *See*, *e.g.*, 106 Cong. Rec. S2358 (daily ed. May 12, 2020) (Statement of Sen. McConnell, discussing legislation to "raise the liability threshold for COVID-related malpractice lawsuits" and to "create a legal safe harbor" for entities that are "following public health guidelines to the best of their ability"). The subsequent debate over whether to immunize entities sued for failing to take infection control measures confirms that Congress had not already created such immunity when it added NIOSH-approved respiratory protective devices to the list of covered countermeasures in March 2020. *See Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) (noting Congress does not "hide elephants in mouseholes").

b. Administrative authority does not support Glenhaven's argument.

Glenhaven's argument that the PREP Act applies to the Saldanas' claims relies solely on statements by HHS.

First, Glenhaven points to the statement in the Fourth Amendment to the PREP Act Declaration that "not administering a Covered

Countermeasure to one individual in order to administer it to another individual can constitute [conduct] 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d." Appellants' Br. 55 (quoting 85 Fed. Reg. at 79,197). Whether or not the statement is correct, it has nothing to do with this case. The Saldanas' allegation is that Glenhaven prohibited *any* staff members from using facial coverings and did not provide them to *anyone*. Although the Secretary 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 this Declaration's liability protections," 85 Fed. Reg. at 79,197, he did not say, or even suggest, that the PREP Act immunizes an entity for the consequences of complete disavowal of the use of covered countermeasures, contrary to public health authority directives.

Indeed, OGC Advisory Opinion 21-01 states that such claims are not subject to immunity: It states that subsection (a)(1) applies to claims arising out of non-use of covered countermeasures when the claims relate to "allocation which results in non-use," but *not* to claims of "nonfeasance … that [] result[] in non-use." RJN-164. Accordingly, even if HHS's view that allocation decisions fall within PREP Act immunity were correct, that view

would not help Glenhaven here. For the distinction made in the advisory opinion to have any meaning, "cases of general neglect," like the one at issue here, must "fall outside the protection of the PREP Act. Otherwise, the [opinion's] limiting language and illustration would be superfluous, if not confounding." *McCalebb*, 2021 WL 911951 at *5. "The gravamen of the Complaint is that [Glenhaven] was generally neglectful in operating the Facility," *id.*, not that it erred in deciding how to allocate a scarce covered countermeasure. Thus, even if the PREP Act applies in *some* cases of non-use, it does not apply here.

Because neither the Fourth Amendment nor the Advisory Opinion 21-01 supports Glenhaven's theory of PREP Act immunity, the Court need not address Glenhaven's deference arguments. In any event, *Chevron* deference applies to neither document. An "administrative implementation of a particular statutory provision qualifies for *Chevron* deference [only] when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Glenhaven's assertion that Congress provided the Secretary the authority to unilaterally define the

terms "administration or use" without undertaking notice and comment rulemaking, Appellants' Br. 57, is not supported by the statute's text. The provision Glenhaven cites, 42 U.S.C. § 247d-6d(b)(1), allows the Secretary to issue a declaration "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." Nothing in the provision authorizes the Secretary to announce rules carrying the force of law about the meaning of the text or the immunity consequences those words attach to the Secretary's exercise of his authority to recommend countermeasures.

Glenhaven's assertion that Advisory Opinion 21-01 is owed *Chevron* deference "because the Secretary has delegated interpretive authority to the Office of General Counsel," Appellants' Br. 70, similarly misunderstands *Chevron* deference. As noted in the case OGC cites for its authority to issue advisory opinions, *see* RJN-165, advisory opinions "are not entitled to any deference in the federal courts." *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 645 (6th Cir. 2004). "Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and

enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *see also Hall v. U.S. Dep't of Agric.*, 984 F.3d 825, 835 (9th Cir. 2020). Indeed, Advisory Opinion 21-01 itself states that "[i]t does not have the force or effect of law." RJN-165; *see Hall*, 984 F.3d at 836 (agency interpretation containing similar language is not entitled to *Chevron* deference).

The agency's interpretations of what constitutes "administration" or "use" are therefore "only 'entitled to a measure of deference proportional to their power to persuade, in accordance with the principles set forth in *Skidmore v. Swift Co.*, 323 U.S. 134 (1944).'" *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)). Under *Skidmore*, deference to an agency's interpretation "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." 325 U.S. at 140. Here, neither interpretation "purport[s] to rely on agency expertise," *GCIU*, 909 F.3d at 1219, but rather cursorily opines on hypothetical scenarios without any examination of the statutory text, history, or purpose. Accordingly, not even *Skidmore* deference

is due. *Cf. Escobar v. Lynch*, 846 F.3d 1019, 1025 (9th Cir. 2017) (declining to afford *Skidmore* deference where agency "provided little reasoning").

II. The Saldanas' claims do not arise under federal law.

Because Glenhaven has not established the elements of federal-officer removal, the district court's order on that issue should be affirmed and the remainder of Glenhaven's appeal dismissed for lack of jurisdiction. *See San Mateo*, 960 F.3d at 597–98. Nonetheless, to avoid the need for further briefing should this Court's precedent be overturned by the Supreme Court in the pending case *BP p.l.c. v. Mayor and City Council of Baltimore*, No. 19-1189 (argued Jan. 19, 2021), the Saldanas address Glenhaven's claim that the case is removable as one arising under federal law within the meaning of 28 U.S.C. § 1331. Neither asserted basis for that claim—"complete preemption" under the PREP Act, or the *Grable* doctrine—is correct.

A. The PREP Act does not completely preempt the Saldanas' claims.

Glenhaven asserts that federal courts have jurisdiction over all actions in which defendants raise section (a)(1) of the PREP Act as a defense. That assertion rests on a misunderstanding of the so-called "complete preemption" doctrine, under which a narrow category of state-law claims

are deemed to arise under federal law when a statute entirely replaces state rights of action with federal ones.

It is "settled law that a case may *not* be removed to federal court on the basis of a federal defense, including the defense of pre-emption." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987). Distinct from "defensive preemption," though, the "complete preemption" doctrine "posits that there are some federal statutes that have such 'extraordinary pre-emptive power' that they 'convert an ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.'" *Retail Prop. Tr. v. United Bhd. of Carpenters & Joiners of Am.*, 768 F.3d 938, 947 (9th Cir. 2014) (quoting *Met. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987)). As the district court here and a "growing consensus" of district courts around the country have concluded, the PREP Act does not completely preempt claims based on nursing homes' failures to take adequate safety measures to protect residents from COVID-19. *Schuster v. Percheron Healthcare Inc.*, 2021 WL 1222149, at *2–3 (N.D. Tex. Apr. 1, 2021) (discussing growing consensus).[14]

[14] *See also, e.g.*, *Shapnik v. Hebrew Home for the Aged at Riverdale*, 2021 WL 1614818, at *10–16 (S.D.N.Y. Apr. 26, 2021); *Bolton v. Gallatin Ctr. for Rehab. & Healing*, 2021 WL 1561306, at *5–8 (M.D. Tenn. Apr. 21, 2021); *Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *4–5 (C.D. Cal. Apr. 19, 2021);

1. The Saldanas' claims are not within the scope of a federal cause of action.

Glenhaven's complete preemption argument conflates "defensive" or "ordinary" preemption with complete preemption. The doctrines of defensive preemption and complete preemption "serve distinct purposes and should be kept clear and separate in our minds." *Retail Property Trust*, 768 F.3d at 949. Complete preemption exists only in "the situation in which

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Perez, 2021 WL 1381232, at *2; *Winn*, 2021 WL 1292507, at *4–5; *Nava*, 2021 WL 1253577, at *2–3; *Estate of Cowan v. LP Columbia KY, LLC*, 2021 WL 1225965, at *3–6 (W.D. Ky. Mar. 31, 2021); *Maltbia*, 2021 WL 1196445, at *4–12; *Gibbs v. Southeast SNF LLC*, 2021 WL 1186626, at *2–3 (W.D. Tex. Mar. 30, 2021); *Stone*, 2021 WL 1163572, at *4–6; *Wright v. Encompass Health Rehab. Hosp. of Columbia, Inc.*, 2021 WL 1177440 (D.S.C. Mar. 29, 2021); *Martin v. Serrano Post Acute LLC* (*Martin II*), 2021 WL 1146380, at *1 (C.D. Cal. Mar. 25, 2021); *Lopez v. Life Care Ctrs. of Am.*, 2021 WL 1121034, at *7–15 (D.N.M. Mar. 24, 2021); *Smith*, 2021 WL 1087284, at *3–6; *McCalebb*, 2021 WL 911951, at *3–6; *Estate of Jones v. St. Jude Operating Co., LLC*, 2021 WL 900672, at *3–8 (D. Or. Feb. 16, 2021), *report and recommendation adopted by* 2021 WL 886217 (D. Or. Mar. 8, 2021; *Robertson v. Big Blue Healthcare, Inc.*, 2021 WL 764566, at *6–10 (D. Kan. Feb. 26, 2021); *Lyons*, 2021 WL 364640, at *3–6; *Dupervil*, 2021 WL 335137, at *8; *Goldblatt v. HCP Prairie Vill. KS OPCO LLC*, 2021 WL 308158 (D. Kan. Jan. 29, 2021); *Estate of Smith v. Bristol at Tampa*, 2021 WL 100376 (M.D. Fla. Jan. 12, 2021); *Parker v. St. Jude Operating Co., LLC*, 2020 WL 8362407, at *5–6 (D. Or. Dec. 28, 2020); *Gunter v. CCRC Opco-Freedom Square, LLC*, 2020 WL 8461513, at *3–5 (M.D. Fla. Oct. 29, 2020); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC* (*Sherod I*), 2020 WL 6140474, at *1 (W.D. Pa. Oct. 16, 2020); *Martin I*, 2020 WL 5422949, at *2; *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1189–95 (D. Kan. 2020); *Maglioli*, 478 F. Supp. 3d at 528–33.

federal law not only preempts a state-law cause of action, but also substitutes an exclusive federal cause of action in its place." *Hansen v. Grp. Health Coop.*, 902 F.3d 1051, 1057 (9th Cir. 2018). The determination whether complete preemption exists is not based on "a crude measure of the breadth of the preemption (in the ordinary sense) of a state law by a federal law." *Schmeling v. NORDAM*, 97 F.3d 1336, 1342 (10th Cir. 1996). "Many federal statutes—far more than support complete preemption—will support a defendant's argument that because federal law preempts state law, the defendant cannot be held liable under state law." *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 272 (2d Cir. 2005) (quoted in *Retail Property Trust*, 768 F.3d at 948). But the Supreme Court has only identified three statutes that give rise to federal jurisdiction via complete preemption: section 301 of the Labor Management Relations Act, section 502(a) of the Employee Retirement Income Security Act (ERISA), and sections 85 and 86 of the National Bank Act. *See City of Oakland v. BP PLC*, 969 F.3d 895, 905–06 (9th Cir. 2020).

The PREP Act meets neither of the requirements for complete preemption articulated by this Court in *Hansen*: It does not preempt the Saldanas' claim, much less provide them with a substitute federal cause of action. First, Glenhaven's assertion that claims subject to subsection (a) are

completely preempted is irrelevant since the Saldanas' claims do not fall within subsection (a). That is, as explained above, pp. 34–44, their claims are not causally connected to the use or administration of a covered countermeasure. *See Haro v. Kaiser Found. Hosps.*, 2020 WL 5291014, at *2–3 (C.D. Cal. Sept. 3, 2020) (holding PREP Act does not completely preempt wage claims based on unpaid pre-shift COVID-19 medical screenings); *cf. Hansen*, 902 F.3d at 1061 (finding no federal jurisdiction over claims against health-plans covered by ERISA because the claims did "not fall within the scope of, and so are not completely preempted by, ERISA section 502(a)(1)(B)").

Furthermore, subsection (a)(1) does not completely preempt all claims to which it applies. The PREP Act, unlike statutes that have been recognized to completely preempt, "is, at its core, an *immunity* statute; it creates no rights, duties, or obligations." *Schuster*, 2021 WL 1222149, at *3; *see also Dennis v. Hart*, 724 F.3d 1249, 1254 (9th Cir. 2013) (finding complete preemption inapplicable where statute imposed no new duties). It also creates no federal cause of action for the vast majority of claims to which subsection (a)(1) applies. *See Dennis*, 724 F.3d at 1254 (stating "that there is no federal cause of action for plaintiffs' claims [] places [a] case outside the realm of complete

preemption"). Congress preempted certain claims for negligence or recklessness, but replaced them with nothing. Because those claims do not "come[] within the scope of [a federal] cause of action," they are not "in reality based on federal law," and not subject to complete preemption. *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003).

The presence of subsection (d) "demonstrates … that Congress knew very well how to provide for an exclusive federal forum when it wanted to—*i.e.*, for actions under subsection (d)." *Maglioli*, 478 F. Supp. 3d at 530. Subsection (d) creates a federal cause of action for a narrow set of state-law claims: those "against a covered person for death or serious physical injury proximately caused by willful misconduct" that is causally connected to the use or administration of a covered countermeasure. 42 U.S.C. § 247d-6d(d), (a). Those claims, and only those claims, are committed to the exclusive jurisdiction of the District Court for the District of Columbia and subject to specific procedures there. *Id.* § 247d-6d(e). And the Court need not decide if *those* claims are completely preempted, because Glenhaven does not argue the Saldanas have brought subsection (d) claims.[15]

[15] In such cases, jurisdiction is expressly provided by the statute; it does not turn on the existence of implied complete preemption. *Cf. Romano v.*

Both Glenhaven, and HHS in Advisory Opinion 21-01, suggest the PREP Act's creation of an administrative fund from which certain individuals may seek compensation stands in for a federal cause of action. Appellants' Br. 46; RJN-162. First, under HHS's interpretation of the statute, the fund is not available to those injured by "the underlying condition or disease" a covered countermeasure was designated to combat. 42 C.F.R. § 110.20(d). It thus is irrelevant here. Moreover, "an administrative remedy will not suffice because the complete-preemption doctrine rests on the theory that any state claim within its reach is 'transformed into federal claims.'" *McCalebb*, 2021 WL 911951, at *4 (quoting *Rivet v. Regions Bank of La.*, 522 U.S. 470, 476 (1998)). This transformation, which "is the source of original federal jurisdiction by supplying a federal cause of action," *id.*, is lacking in an administrative scheme. This Court's decision in *Moore-Thomas*

Kazacos, 609 F.3d 512, 519 (2d Cir. 2010) (distinguishing between complete preemption and scenarios in which Congress "expressly provided for the removal of particular actions asserting state law claims in state court").

It is unremarkable that one provision of a statute may provide a federal cause of action for certain claims, while another provision of that same statute creates a preemption defense for other claims. For example, ERISA imposes "complete preemption under § 502(a), which provides a basis for federal question removal jurisdiction, and conflict preemption under § 514(a), which does not." *Marin General Hospital v. Modesto & Empire Traction Co* 581 F.3d 941, 945 (9th Cir. 2009).

v. Alaska Airlines, Inc., 553 F.3d 1241, 1245-46 (9th Cir. 2009), is instructive. There, the Court held that the Railway Labor Act's creation of a procedure by which airlines and their employees could "submit disputes to internal dispute-resolution processes and then to a division of the National Adjustment Board or an arbitration board selected by the parties" was not equivalent to providing "an exclusive federal cause of action" for complete preemption purposes. *Id.* at 1245.

Glenhaven's arguments about the broad power Congress granted HHS do not overcome the absence of a federal cause of action. In enacting subsection (a)(1), Congress "presumptively was aware of the longstanding judicial interpretation" that the mere presence of such a defense does not create complete preemption. *Lamar, Archer & Cofrin, LLP v. Appling*, 137 S. Ct. 1752, 1762 (2018). State courts "are presumed competent to resolve federal issues," *Chick Kam Choo v. Exxon Corp.*, 486 U.S. 140, 150 (1988), and the applicability of the ordinary immunity defense of subsection (a)(1) is no different.[16]

[16] This point is illustrated by *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (N.Y. App. Div. 2012). There, the state court found that section (a)(1) preempted a plaintiff's claims that an inoculation without consent constituted negligence and battery. *Id.* at 144–45. While the

2. The federal government's opinions about complete preemption warrant no deference.

Glenhaven relies heavily on three documents in which the federal government stated that the PREP Act "is a complete preemption statute": (1) Advisory Opinion 21-01; (2) the Fifth Amendment to the PREP Act Declaration, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021); and (3) a statement of interest filed in a case in the Middle District of Tennessee, RJN-19. The sole district court to agree with Glenhaven's argument similarly based its decision exclusively on deference to Advisory Opinion 21-01. *See Garcia v. Welltower OpCo Grp.*, 2021 WL 492581, at *6–7 (C.D. Cal. Feb. 10, 2021). Glenhaven's reliance is misplaced. None of these documents is entitled to deference, much less *Chevron* deference. Not only are the documents both cursory and contrary to precedent, none actually states that claims like the Saldanas' are subject to complete preemption.

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decision referenced the availability of a federal cause of action, it did not suggest that the mere question of whether section (a)(1) applies is exclusively within the province of federal courts, instead deciding it itself, relying on case law concerning defensive preemption. *Id.* at 142–43 (citing, *e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). *See also Casabianca v. Mt. Sinai Med. Ctr.*, 2014 WL 10413521, at *4 (N.Y. Sup. Ct. Dec. 2, 2014) (determining that section (a)(1) defense did not apply to malpractice claim for failure to administer vaccine).

First, "complete preemption is really a jurisdictional rather than a preemption doctrine," *Dennis*, 724 F.3d at 1254 (citation omitted). As this Court has held, an agency's "position on jurisdiction is not entitled to deference under *Chevron*." *Our Children's Earth Found. v. EPA*, 527 F.3d 842, 846 n.3 (9th Cir. 2008) (citing *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1038–39 (D.C. Cir. 2002)); *see also Dandino, Inc. v. U.S. Dep't of Transp.*, 729 F.3d 917, 920 n.1 (9th Cir. 2013) (noting this principle is "well-established"). The question whether Congress granted federal courts exclusive jurisdiction does not implicate any matter of special agency expertise, and "the authority Congress delegated to HHS to make rules carrying the force of law did not include authority to interpret the jurisdiction of the federal courts." *Jones*, 2021 WL 900672, at *6. "Determining federal court jurisdiction is exclusively the province of the courts regardless of what an agency may say." *Lindstrom v. United States*, 510 F.3d 1191, 1195 n.3 (10th Cir. 2007), *quoted in Dandino*, 729 F.3d at 920 n.1. Glenhaven's contrary argument is grounded in its confusion between defensive preemption and complete preemption. *See* Appellants' Br. 68 (citing cases concerning defensive preemption).[17] But

[17] Several of these cases do not concern deference to agency interpretations of statutes' preemptive effects, but rather the validity of regulations that

unlike complete preemption, defensive preemption is not a question of federal court jurisdiction. *See Retail Property Trust*, 768 F.3d at 946–50.

In terms of content, Advisory Opinion 21-01 offers no reasoning to support its conclusion that the PREP Act completely preempts state-law claims where its immunity defense applies. It simply cites four cases where the Supreme Court and the Second Circuit held that other statutes completely preempted state law and added: "The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both." RJN-162. The remainder of the section of the opinion titled "The PREP Act is a 'Complete Preemption' Statute," does not address this point at all, but rather whether and when claims of non-use fall under section (a)(1) of the PREP Act. RJN-162–164.

As several district courts have noted, the Advisory Opinion relies on "conclusory assertion[s]," is contrary to precedent, and mistakenly conflates the defense of section (a)(1) with the exclusive cause of action in section (d).

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purported to preempt state law under conflict preemption principles. *See, e.g.*, *City of New York v. FCC*, 486 U.S. 57, 68 (1988).

See McCalebb, 2021 WL 911951, at *4 n.5; *see also Dupervil*, 2021 WL 355137, at *10; *Jones*, 2021 WL 900672, at *6–7. Its assertion that an administrative remedy meets the federal cause of action requirement is contrary to precedent, as discussed above. And it fails to acknowledge that the statute only "vests exclusive jurisdiction in a federal court" for subsection (d) claims. And even under its stated view, the PREP Act completely preempts only claims arising out of "Prioritization or purposeful allocation of a Covered Countermeasure," not to claims like the Saldanas.' RJN-163; *see McCalebb*, 2021 WL 911951 at *5.

Nothing in the Fifth Amendment to the Declaration is more persuasive, or more relevant. The operative provision of the Fifth Amendment added to the categories of "covered persons" in the PREP Act Declaration, effective February 2, 2021, certain healthcare professionals who "prescribe, dispense, or administer COVID-19 vaccines." 86 Fed. Reg. at 7872–73. This case does not concern such professionals. The description accompanying this addition includes a sentence saying "[t]he plain language of the PREP Act makes clear that there is complete preemption of state law as described above." *Id.* at 7874. It is unclear to what "as described above" refers; nowhere does the document provide any analysis or application of

the complete preemption standard. It thus has no persuasive value and warrants no deference. *Cf. Wyeth v. Levine*, 555 U.S. 555, 578–81 (2009) (declining to afford any deference to agency statement in regulatory preamble).

Finally, the Statement of Interest filed in a case in Tennessee, opining that the PREP Act is a "complete-preemption statute," RJN-25, also warrants no deference. As the court in that case noted in rejecting its analysis, the Statement ignores the fact that subsection (d) does not provide a federal cause of action when subsection (a) applies, and it does not address any authority addressing the cause of action requirement. *See Bolton*, 2021 WL 1561306, at *7. Moreover, the Statement explicitly does *not* take a position on whether the claims in that case, or in any case, are "completely preempted by the Act." RJN-31; *see Bolton*, 2021 WL 1561306 at *7 n.8. In fact, a footnote expressly states the government is *not* disagreeing with district courts that remanded claims like the Saldanas' to state court and acknowledges that claims that do not arise out of the use or administration of a covered countermeasure are not completely preempted. RJN-29 n.4 ("This is not to say that the *Maglioli* court got the result there incorrect as well. It may be that the complaint there raised only claims outside subsection (a)'s ambit (i.e.,

claims that were not subject to complete preemption) such that it was correct to remand that case.").

B. The Saldanas' claims do not fall into *Grable*'s "special and small category" of cases.

As a last-ditch effort to obtain federal jurisdiction, Glenhaven invokes the Supreme Court's identification of a "special and small category of cases in which arising under jurisdiction still lies" despite the absence of a federal-law claim. *Gunn v. Minton*, 568 U.S. 251, 258 (2013). Under this doctrine, first set out in *Grable*, federal courts may exercise jurisdiction over state-law actions where a federal issue is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Id.* (citing *Grable*, 568 U.S. at 313–14). The well-pleaded-complaint rule applies in determining whether a state-law claim meets this standard. *Cal. Shock Trauma Air Rescue v. State Comp. Ins. Fund*, 636 F.3d 538, 542 (9th Cir. 2011) (citing *Grable*, 545 U.S. at 314). Because none of the elements of *Grable* jurisdiction are present here, the Saldanas' complaint "does not fit within the special and small category in which [Glenhaven] would place it." *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 699 (2006).

First, the Saldanas' complaint does not "necessarily raise" any issues of federal law. Their state-law claims of elder abuse, custodial negligence, willful misconduct, and wrongful death "are based entirely on California causes of action, … each of which does not, on its face, turn on a federal issue." *Cal. Shock*, 636 F.3d at 543. No disputed provision of federal law is relevant to "an essential element of those claims." *Williston Basin Interstate Pipeline Co. v. An Exclusive Gas Storage Leasehold & Easement in the Cloverly Subterranean, Geological Formation*, 524 F.3d 1090, 1102 (9th Cir. 2008).

Glenhaven's assertion that its intent to mount a federal defense under the PREP Act means that federal law is "embedded" in the Saldanas' state-law claims for *Grable* purposes, Appellants' Br. 72, 73, is incorrect. Where a federal issue arises only as part of a defense to state-law claims, rather than as an element of plaintiff's claims, the *Grable* doctrine does not apply. *See*, *e.g.*, *Principal Gov't of Marinduque v. Placer Dome, Inc.*, 582 F.3d 1083, 1090 (9th Cir. 2009) (that a federal issue was raised "only defensively" was "fatal" to claim of *Grable* jurisdiction). Accordingly, as every court to consider similar arguments has held, a PREP Act defense does not mean plaintiffs' state-law claims "necessarily raise" a substantial federal issue. *See*, *e.g.*, *Shapnik*, 2021 WL 1614818, at *14; *Bolton*, 2021 WL 1561306, at *4; *Padilla*, 2021 WL 1549689,

at *6; *Hopman v. Sunrise Villa Culver City* , 2021 WL 1529964, at *6 n.4 (C.D. Cal. Apr. 16, 2021); *Perez*, 2021 WL 1381232, at *3–4; *Winn*, 2021 WL 1292507, at *5; *Nava*, 2021 WL 1253577, at *3; *Cowan*, 2021 WL 1225965, at *6; *Maltbia*, 2021 WL 1196445, at *12 n.12; *Stone*, 2021 WL 1163572, at *7; *Ivey*, 2021 WL 1139741, at *3; *McCalebb*, 2021 WL 911951, at *3; *Robertson*, 2021 WL 764566, at *11 & n.19; *Jones*, 2021 WL 900672, at *7 n.8; *Lyons*, 2021 WL 364640, at *6; *Dupervil*, 2021 WL 355137, at *14–15; *Goldblatt*, 2021 WL 308158, at *11 n.7; *Martin*, 2020 WL 5422949, at *2.

Glenhaven's contrary argument is similar to that rejected by this Court in *Dennis*, 724 F.3d 1249. There, defendants invoked *Grable* in a state law shareholder derivative action, arguing that a provision of the Dodd-Frank Act barred any liability for the challenged conduct, claiming that "[t]his congressional desire to preclude liability … is a significant federal issue conferring federal jurisdiction." *Id.* at 1253. The Court held that, even if the defendants were correct that "such liability has been barred by Congress," and thus that the defendants had a "very strong federal defense," the general rule that federal defenses do not confer federal jurisdiction applied, and therefore *Grable* did not provide a basis for jurisdiction. *Id.* As in *Dennis*, *Grable* is inapplicable here because, "[a]side from their potential defense, the

defendants have identified no significant federal issue that would confer jurisdiction." *Id.* at 1254. Because this flaw is fatal to Glenhaven's invocation of *Grable*, the Court need not address any other *Grable* elements.

Furthermore, Glenhaven's suggestion that its defense implicates federal policy interests does not satisfy the requirements for *Grable* jurisdiction. Although the question whether nursing companies can be held liable in cases like this one may raise "an important policy question," such a question does not independently "raise a substantial question of federal law for the purpose of determining whether there is jurisdiction under § 1331." *Oakland*, 969 F.3d at 907; *see also McVeigh*, 547 U.S. at 701 (finding that federal government's policy interests did not "warrant turning into a discrete and costly 'federal case' … a federal worker's state-court-initiated tort litigation"). By definition, any preemption defense created by a federal statute necessarily reflects a substantive policy interest identified by Congress. *Grable* jurisdiction, however, requires more than such a policy, but "a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Grable*, 545 U.S. at 313. No such interest exists here, as "[t]he state court in which the personal-injury suit was lodged is competent to apply federal law, to the extent it is relevant." *McVeigh*, 547 U.S. at 701.

This Court owes no deference to either the HHS Secretary's or OGC's cursory assertions that *Grable* applies. As discussed above, *supra* p.52, agency opinions as to whether federal-court jurisdiction exists are owed no deference. Moreover, HHS has not meaningfully addressed the *Grable* factors. Instead, it simply pronounced an interest in having a "unified, whole-of-nation response" to the COVID-19 pandemic, Fourth Amendment, 85 Fed. Reg. at 79,194, and decreed that "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court," Advisory Opinion 21-01, RJN-164–65. But "[a] federal issue is not substantial," and thus does not give rise to jurisdiction under *Grable*, "merely because of its novelty or because it will further a uniform interpretation of a federal statute." *Oakland*, 969 F.3d at 905. In suggesting otherwise, the Opinion relies on "a selective (mis)quotation from *Grable*" to advance an "effective rewriting of diversity jurisdiction under 28 U.S.C. § 1332 and principles of subject-matter jurisdiction more generally." *Dupervil*, 2021 WL 355137, at *14. It is therefore "unpersuasive" and "unhelpful," and advances an "incredible position." *Id.*; *see also Hopman*, 2021 WL 1529964, *6 n.4 (noting "rising tide of district court

opinions that have found the OGC's opinion as to the *Grable* doctrine's relationship to the PREP Act unpersuasive").

Finally, in enacting the PREP Act, Congress allowed a narrow category of state-law cases to originate in federal court: claims brought by plaintiffs alleging willful misconduct arising out of the use or administration of covered countermeasures. Again, this is not one of those cases. Assuming jurisdiction over an *additional* category of state-law cases would not be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Grable*, 545 U.S. at 313. Under Glenhaven's theory, all cases involving the failure to take adequate precautions to minimize transmission of COVID-19 qualify under *Grable*. "If allowed, a predictable flood of state cases will arrive at the federal doorstep." *McCalebb*, 2021 WL 911951, at *3. Such an outcome would have "much more than 'a microscopic effect' on the federal-state divide," *id.* (quoting *Grable*, 545 U.S. at 315)—particularly in the health care context, where states have "special responsibly for maintaining standards among members of the licensed professions." *Gunn*, 568 U.S. at 264. At bottom, Glenhaven's *Grable* argument is that a federal court has jurisdiction just because it has invoked a federal defense—although that defense, on its face, does not apply to the Saldana's

state law claims. Even if the defense did apply, Glenhaven's argument would turn the narrow *Grable* doctrine into a vehicle for thousands of state law claims to be heard in federal court, contrary to the rule that, "as the master of the claim, the plaintiff can generally avoid federal jurisdiction by exclusive reliance on state law." *Oakland*, 969 F.3d at 905 (cleaned up). The Court should decline Glenhaven's attempt to change the balance of jurisdiction between state and federal courts so radically.

CONCLUSION

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

Respectfully submitted,

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April 28, 2021

STATEMENT OF RELATED CASES

Appellant is aware of the following related cases currently pending in this Court within the meaning of Ninth Circuit Rule 28-2.6, each of which raises similar arguments as to federal-officer removal, the PREP Act, and the *Grable* doctrine:

- 20-56067 – *Martin v. Filart* (consolidated with 20-56078 – *Martin v. Serrano Post Acute*)
- 21-55185 – *Lyons v. Cucumber Holdings, LLC*
- 21-55224 – *Garcia v. Welltower OpCo Group, LLC*
- 21-55302 – *Estate of McCalebb v. AG Lynwood, LLC*
- 21-55377 – *Smith v. Colonial Care Center*
- 21-55400 – *Martin v. Serrano Post Acute LLC*
- 21-55402 – *Ivey v. Serrano Post Acute LLC*

April 28, 2021

/s/ Adam R. Pulver
Adam R. Pulver

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 12,951 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 Book Antiqua.

April 28, 2021

/s/ Adam R. Pulver
Adam R. Pulver

ADDENDUM

ADDENDUM OF PROVISIONS INVOLVED

28 U.S.C. § 1442 Federal officers or agencies sued or prosecuted

(a) A civil action or criminal prosecution that is commenced in a State court and that is against or directed to any of the following may be removed by them to the district court of the United States for the district and division embracing the place wherein it is pending:

> (1) The United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, in an official or individual capacity, for or relating to any act under color of such office or on account of any right, title or authority claimed under any Act of Congress for the apprehension or punishment of criminals or the collection of the revenue.
>
> …

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

(a) Liability protections

> **(1) In general**
>
> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.
>
> **(2) Scope of claims for loss**

…

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if--

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who--

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

...

(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.

…

(8) Preemption of State law

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that--

> **(A)** is different from, or is in conflict with, any requirement applicable under this section; and
>
> **(B)** relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

…

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of Title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

…

(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.

…

(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 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.

…

42 U.S.C. § 247d-6e. Covered countermeasure process

(a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d-6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

42 C.F.R. § 110.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Injured countermeasure recipients, as described in § 110.3(n);

(2) Survivors, as described in § 110.3(cc) and § 110.11; or

(3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (i.e., executors or administrators).

…

42 C.F.R. § 110.20 How to establish a covered injury.

…

(d) Injuries resulting from the underlying condition for which the countermeasure was administered or used. An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

…

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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