Nos. 20-2833 & 20-2834

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ESTATE OF JOSEPH MAGLIOLI, et al.,
Plaintiffs-Appellees,

v.

ALLIANCE HC HOLDINGS LLC, et al.,
Defendants-Appellants.

ESTATE OF WANDA KAEGI, et al.,
Plaintiffs-Appellees,

v.

ALLIANCE HC HOLDINGS LLC, et al.,
Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey
Case No. 2:20-cv-06605-KM-ESK
Hon. Kevin McNulty

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 & 29(a)(4), amicus curiae Public Citizen, Inc. states that it has no parent corporation and that there is no publicly held corporation that owns 10% or more of Public Citizen.

TABLE OF CONTENTS

TABLE OF CONTENTS ii
TABLE OF AUTHORITIES iii
INTEREST OF AMICUS CURIAE 1
SUMMARY OF ARGUMENT 2
BACKGROUND 4
I. The Federal-State Response to the Pandemic 4
II. The PREP Act and Its Implementation 6
A. The PREP Act 6
B. The COVID-19 PREP Act Declaration and Amendments 9
ARGUMENT 11
I. Alliance has not established jurisdiction under the federal officer removal statute. 11
A. The federal officer removal statute applies to private entities only when they act as or on behalf of the federal government. 12
B. Alliance is not “acting under” a federal officer in its operation of nursing homes. 17
C. Alliance lacks a colorable federal defense. 21
II. The PREP Act does not completely preempt Plaintiffs’ claims. 27
CONCLUSION 32

TABLE OF AUTHORITIES

Cases **Page(s)**

Air Brake Systems, Inc. v. Mineta,
357 F.3d 632 (6th Cir. 2004) 26

American Iron & Steel Institute v. EPA,
543 F.2d 521 (3d Cir. 1976) 31

Bamidele v. INS,
99 F.3d 557 (3d Cir. 1996) 32

Board of County Commissioners of Boulder County v. Suncor Energy (U.S.A.) Inc.,
965 F.3d 792 (10th Cir. 2020) 16, 19

Burrell v. Bayer Corp.,
918 F.3d 372 (4th Cir. 2019) 28

Caterpillar Inc. v. Williams,
482 U.S. 386 (1987) 27

Christensen v. Harris County,
529 U.S. 576 (2000) 26

City of Walker v. Louisiana,
877 F.3d 563 (5th Cir. 2017) 17

Colorado v. Symes,
286 U.S. 510 (1932) 14

In re Commonwealth's Motion to Appoint Counsel Against or Directed to Defender Ass'n of Philadelphia,
790 F.3d 457 (3d Cir. 2015) 11, 12, 16, 19

In re Community Bank of Northern Virginia,
418 F.3d 277 (3d Cir. 2005) 29

Davis v. South Carolina,
107 U.S. 597 (1883)....................13

Dukes v. U.S. Healthcare, Inc.,
57 F.3d 350 (3d Cir. 1995) 28

Dupervil v. Alliance Health Operations, LCC,
2021 WL 33517 (E.D.N.Y. Feb. 2, 2021) 12, 27, 32

Eaton v. Big Blue Healthcare, Inc.,
480 F. Supp. 3d 1184 (D. Kan. 2020) 28

Florida v. Cohen,
887 F.2d 1451 (11th Cir. 1989)....................20, 21

Franchise Tax Board of State of California v. Construction Laborers Vacation Trust for Southern California,
463 U.S. 1 (1983)....................30

Garcia v. Welltower OpCo Group,
2021 WL 492581 (C.D. Cal. Feb. 10, 2021) 31

Goldblatt v. HCP Prairie Village KS OPCO LLC,
2021 WL 308158 (D. Kan. Jan. 29, 2021) 27, 32

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36 F.3d 306 (3d Cir. 1994) 29

Gunter v. CCRC Opco-Freedom Square, LLC,
2020 WL 8461513 (M.D. Fla. Oct. 29, 2020)....................28

Haro v. Kaiser Foundation Hospitals,
2020 WL 5291014 (C.D. Cal. Sept. 3, 2020) 28

Hayes v. Harvey,
903 F.3d 32 (3d Cir. 2018) 26

International Primate Protection League v. Administrators of Tulane Education Fund,
500 U.S. 72 (1991)...14

Estate of Jones v. St. Jude Operating Co., LLC,
2021 WL 900672 (D. Or. Feb. 16, 2021) 27, 32

Joyce v. RJR Nabisco Holdings Corp.,
126 F.3d 166 (3d Cir. 1997) 28

In re Kaiser Aluminum Corp.,
456 F.3d 328 (3d Cir. 2006) 31

Lyons v. Cucumber Holdings, LLC,
2021 WL 364640 (C.D. Cal. Feb. 3, 2021) 12, 27

Martin v. Serrano Post Acute LLC,
2020 WL 5422949 (C.D. Cal. Sept. 10, 2020) 12, 28

Maryland v. Soper (No. 1),
270 U.S. 9 (1926)..13

Mays v. City of Flint, Michigan,
871 F.3d 437 (6th Cir. 2017) 16

Estate of McCalebb v. AG Lynwood, LLC,
2021 WL 911951 (C.D. Cal. Mar. 1, 2021) 12, 25, 27, 32

Mesa v. California,
489 U.S. 121 (1989)...14, 21

Metropolitan Life Insurance Co. v. Taylor,
481 U.S. 58 (1987)..30

New Jersey Carpenters & the Trustees Thereof v. Tishman Construction Corp. of New Jersey, 760 F.3d 297 (3d Cir. 2014) 29

Papp v. Fore-Kast Sales Co. Inc., 842 F.3d 805 (3d Cir. 2016) 16, 19

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Railway Labor Executives Ass'n v. Pittsburgh & Lake Erie Railroad Co., 858 F.2d 936 (3d Cir. 1988) 28, 30

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Rosenberg v. FVI Receivables XVII, LLC, 835 F.3d 414 (3d Cir. 2016) 29

Ruppel v. CBS Corp., 701 F.3d 1176 (7th Cir. 2012) 16

Saldana v. Glenhaven Healthcare LLC, 2020 WL 6713995 (C.D. Cal. Oct. 14, 2020) 12, 28

Schmeling v. NORDAM, 97 F.3d 1336 (10th Cir. 1996) 29

Shalala v. Guernsey Memorial Hospital, 514 U.S. 87 (1995) 18

Sherod v. Comprehensive Healthcare Management Services, LLC, 2020 WL 6119479 (W.D. Pa. Oct. 16, 2020) 12, 28

Shweika v. Department of Homeland Security, 723 F.3d 710 (6th Cir. 2013) 31, 32

Estate of Smith v. Bristol at Tampa,
2021 WL 100376 (M.D. Fla. Jan. 12, 2021) 27

Tennessee v. Davis,
100 U.S. 257 (1880)..12

Texas v. EPA,
829 F.3d 405 (5th Cir. 2016) 31

In re U.S. Healthcare, Inc.,
193 F.3d 151 (3d Cir. 1999) 27, 31

Watson v. Philip Morris Cos.,
551 U.S. 142 (2007)...*passim*

Watson v. Philip Morris Cos., Inc.,
420 F.3d 852 (8th Cir. 2005) 15

Whitman v. American Trucking Association,
531 U.S. 457 (2001)...25–26

Willingham v. Morgan,
395 U.S. 402 (1969)...13, 21

Statutes

21 U.S.C. § 321(h)...22, 23

21 U.S.C. § 360k(a)..28

28 U.S.C. § 1442(a)(1) ....*passim*

Public Readiness and Emergency Preparedness Act

42 U.S.C. § 247d-6d 9

42 U.S.C. § 247d-6d(a)...3, 4, 7, 8, 23

42 U.S.C. § 247d-6d(b) 6

42 U.S.C. § 247d-6d(d) 3, 4, 8, 22, 30

42 U.S.C. § 247d-6d(e)...3, 4, 8, 30

42 U.S.C. § 247d-6d(i) 7, 22

42 U.S.C. § 247d-6e(a) 8

Coronavirus Aid, Relief, and Economic Security (CARES) Act,
Pub. L. 116-136, 134 Stat. 281 (2020) 7, 25

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Pub. L. 116-127, 134 Stat. 178 (2020) 7

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85 Fed. Reg. 15,198 (Mar. 17, 2020)..9

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85 Fed. Reg. 21,012 (Apr. 15, 2020) 9

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85 Fed. Reg. 35,100 (Jun. 8, 2020) 23

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85 Fed. Reg. 79,190 (Dec. 9, 2020) 9

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Advisory Opinion 20-01 (Apr. 17, 2020) (as modified May 19, 2020)......10

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Statement of Sen. Hillary Clinton, 151 Cong. Rec. S14242-01 (daily ed. Dec. 21, 2005)....................24

Statement of Rep. Nathan Deal, 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005)....................24

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Statement of Rep. Greg Walden, 166 Cong. Rec. H1675-09 (daily ed. March 13, 2020)....................23

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INTEREST OF AMICUS CURIAE[1]

Amicus Curiae Public Citizen is a non-profit advocacy organization with members in all 50 states. Appearing before Congress, agencies, and courts on a wide range of issues, Public Citizen works for enactment and enforcement of laws to protect consumers, workers, and the public. Among other things, Public Citizen works to support individuals' ability to access the civil justice system to hold corporations and the government accountable for wrongdoing, and it often appears as amicus curiae to address issues such as federal-court jurisdiction and preemption. Public Citizen also advocates for policies to improve patient safety and to hold health care institutions, professionals, and policymakers accountable for protecting patients.

Public Citizen submits this brief because it believes that Appellants' erroneous arguments regarding the federal-officer removal statute and the scope of the Public Readiness and Emergency Preparedness (PREP) Act, if

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[1] The parties have consented to the filing of this brief. No party's counsel authored this brief in whole or part, no party or party's counsel contributed money intended to fund the brief's preparation or submission, and no person other than amicus curiae, its members, or its counsel contributed money intended to fund the brief's preparation or submission. Public Citizen notes that its counsel serves as appellate counsel for plaintiffs-appellees in *Saldana v. Glenhaven Healthcare LLC*, No. 20-56194, a pending Ninth Circuit appeal that raises these same issues.

accepted, would pose a substantial risk of depriving injured plaintiffs of access to meaningful remedies.

SUMMARY OF ARGUMENT

Appellants Alliance HC Holdings LLC, Alliance HC II LLC, Chaim Scheinbaum, and Louis Schwartz (together, Alliance) premise their removal of this action, and this appeal, on fundamental misunderstandings of three doctrines of federal-court jurisdiction. This amicus curiae brief addresses two of those doctrines: federal-officer removal and complete preemption.

First, Alliance argues that guidance issued by various federal agencies during the COVID-19 pandemic converted nursing homes from participants in a heavily regulated industry to entities "acting under" federal officer direction for purposes of the federal officer removal statute, 28 U.S.C. § 1442(a)(1). That argument ignores the Supreme Court's holding that regulation—no matter its specificity—does not transform a private entity into a federal officer. To the extent federal guidance imposed additional requirements on nursing homes, any change in the relationship between Alliance and the federal government was "one of degree, not kind." *Watson v. Philip Morris Cos.*, 551 U.S. 142, 157 (2007). Moreover, removal under § 1442(a)(1) is permissible only where the defendant has a colorable federal

defense. While Alliance points to the Public Readiness and Emergency Preparedness (PREP) Act, which provides a defense to certain tort claims that relate to the "use" or "administration" of the specific devices deemed "covered countermeasures" under that Act, that immunity does not apply here because the claims alleged do not relate to such use or administration.

Second, Alliance argues that removal was proper under the doctrine of complete preemption, because the PREP Act completely preempts Plaintiffs' claims. Again, the claims do not relate to the use or administration of covered countermeasures, and the PREP Act thus does not apply. Moreover, Alliance ignores the basic differences between ordinary preemption, which does not give rise to federal-court jurisdiction, and complete preemption, which does. Subsection (a)(1) of the PREP Act, an ordinary preemption provision, creates a defense to certain claims relating to the use of "covered countermeasures." 42 U.S.C. § 247d-6d(a)(1). Subsection (d) creates an exclusive federal-law cause of action for willful misconduct claims relating to such use, and subsection (e) directs such actions to federal court under specific procedures. *Id*. § 247d-6d(d)–(e). Although the parties dispute whether the ordinary defense provided by subsection (a)(1) applies to Plaintiffs' claims, there is no dispute that

subsections (d) and (e) do not. There is no evidence Congress intended for disputes over the applicability of subsection (a)(1) to be adjudicated exclusively in federal court, contrary to the general rule that federal-law defenses to state-law claims are not a basis for subject-matter jurisdiction. To the extent that guidance issued by the Department of Health & Human Services (HHS) suggests otherwise, that guidance, like any agency opinion on the scope of federal-court jurisdiction, is owed no deference.

BACKGROUND

I. The Federal-State Response to the Pandemic

Since the first reported cases of COVID-19 in January 2020, federal agencies have issued dozens of guidance documents relating to consumer and worker safety, including best practices and interpretations of how existing legal requirements apply with respect to measures to reduce the spread of the novel coronavirus. 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 specific to industries ranging from institutions of higher education to amusement parks and carnivals, and from homeless shelters to community gardens. *See* CDC, COVID-19,

Community, Work, and School, https://www.cdc.gov/coronavirus/2019-ncov/community/index.html (collecting guidance). And both the CDC and HHS's Centers for Medicare & Medicaid Services have issued non-binding guidance about infection control in nursing homes and other health care facilities. *See* Appellants' Br. at 7–11 (collecting guidance).

Many of the HHS guidance documents were explicitly directed at *state* regulatory agencies and contemplate that the states would take action with respect to facilities over which they had authority. *See*, *e.g.*, Appellants' Request for Judicial Notice, Ex.1 (memorandum to state agency directors); Ex. 4 (guidance sent to state and local health officials); CMS, "Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes," Feb. 2021 (Version 19), available at https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf. The State of New Jersey did, and continues to do, just that. On March 13, 2020, for example, the state Department of Health issued mandatory visitation guidelines, limiting visitors to long-term care facilities to end-of-life situations, and imposing screening and personal protective equipment (PPE) requirements. *See* N.J. Dep't of Health, Mandatory Guidelines for Visitors and Facility Staff (revised Mar. 16, 2020), https://nj.gov/health/legal/covid19/3-16-2020_

MandatoryGuidelinesforVisitors_andFacilityStaff_%20Supersedes3-13-2020Guidelines.pdf. *See also* N.J. Dep't of Health, Exec. Dir. 20-013 (revised May 20, 2020), https://nj.gov/health/legal/covid19/05-20-2020_ExecutiveDirectiveNo20-013_LTC_planCOVID19testing_revised.pdf (instituting a COVID-19 testing requirement for licensed long-term care facilities).

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), https://crsreports.congress.gov/product/pdf/LSB/LSB10443. The PREP Act liability 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 by HHS for emergency use. 42 U.S.C. § 247d–6d(i)(1)(A)–(C). In 2020, Congress amended the statute as part of the Families First Coronavirus Response Act (FFCRA) 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. 116-127 § 6005, 134 Stat. 178, 207 (2020). Congress again amended the definition of covered countermeasures as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, specifying that NIOSH-approved respiratory protective devices may be covered countermeasures whenever the Secretary designates a priority use during a public health emergency. Pub. L. 116-136 § 3103, 134 Stat. 281, 361 (2020), *codified at* 42 U.S.C. § 247d–6d(i)(1)(D)).

The PREP Act's primary function is to limit 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 by providing that covered persons may be sued "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). For these claims only, the statute creates an "exclusive Federal cause of action," *id.*, and provides special procedures for their adjudication, as well as exclusive jurisdiction in the United States District Court for the District of Columbia, *id.* § 247d-6d(e).

The PREP Act also creates an administrative scheme 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, to be administered by the HHS Secretary. 42 U.S.C. § 247d-6e(a). HHS regulations specify that only "injured countermeasure recipients" and their survivors are eligible to seek compensation, 42 C.F.R. § 110.10(a), and that "an injury 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)" is not a covered injury for purposes of the fund. 42 C.F.R. § 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 since amended the initial Declaration several times. Relevant to this case, the First Amendment expanded covered countermeasures to include respiratory protective equipment, based on the CARES Act. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020).

Well after the events at issue in this lawsuit, 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 the decision to give a COVID-19 vaccine to one individual over a less-vulnerable individual as an example. *Id.* The Fourth Amendment also stated that the "Declaration must be construed in accordance with" four "Advisory Opinions" previously issued by the HHS Office of General Counsel (OGC), which it incorporated by reference. *Id.* at 79,191 & n.5. Each of the four opinions states that it does "not have the force or effect of law." *See* Appellants' Request for Judicial Notice (RJN), Ex. 14 (OGC, Advisory Opinion 20-01 (Apr. 17, 2020) (as modified May 19, 2020) at 1; Ex. 17 (OGC, Advisory Opinion 20-04 (Oct. 22, 2020) (as modified Oct. 23, 2020)) at 7.[2] Rather, they solely "set[] forth the current views of" OGC and do not "bind HHS or the federal courts." *Id.*

In the waning days of the last administration and after the district court's ruling below, OGC issued a fifth advisory opinion. *See* Appellants' RJN, Ex. 18 (OGC, Advisory Opinion 21-01 (Jan. 8, 2021)). 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

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[2] The other OGC Advisory Opinions are available at https://www.hhs.gov/about/agencies/ogc/advisory-opinions/index.html.

allocation of covered countermeasures "which results in non-use by some individuals," but *not* in cases where non-use was the result of "nonfeasance." *Id.* at 2–5. Like the others, that opinion states 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." *Id.* at 5.

ARGUMENT

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

The federal officer removal statute provides for removal from state 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 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 and that the plaintiff's claims are "for, or relating to" an act under color of federal office, and must raise a colorable federal defense. *See In re Commonwealth's*

Motion to Appoint Couns. Against or Directed to Def. Ass'n of Phila., 790 F.3d 457, 467 (3d Cir. 2015).

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 do not qualify as entities acting under the direction of federal officers for purposes of 28 U.S.C. § 1442(a)(1), and thus that removal under § 1442(a)(1) was improper. AA29–34; *see Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951 (C.D. Cal. Mar. 1, 2021); *Lyons v. Cucumber Holdings, LLC*, 2021 WL 364640 (C.D. Cal. Feb. 3, 2021); *Dupervil v. Alliance Health Ops., LCC*, 2021 WL 33517 (E.D.N.Y. Feb. 2, 2021); *Sherod v. Comprehensive Healthcare Mgmt. Servs., LLC*, 2020 WL 6119479 (W.D. Pa. Oct. 16, 2020), appeal pending (No. 20-3287); *Saldana v. Glenhaven Healthcare LLC*, 2020 WL 6713995 (C.D. Cal. Oct. 14, 2020); *Martin v. Serrano Post Acute LLC*, 2020 WL 5422949 (C.D. Cal. Sept. 10, 2020).

A. The federal officer removal statute applies to private entities only when they act as or 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*, 551 U.S. at 1342 (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 that 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 pointed out 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*, two 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 on the ground that they were "acting under" a federal officer because (they claimed) the federal government regulated the way in which they tested the tar and nicotine levels of their cigarettes. *See* 551 U.S. at 154–56. The Eighth Circuit held that the Federal Trade Commission'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 manufacturing 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. In addition, the Court explained that 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, the Court stated, "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, 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.

Following *Watson*, this Court and others have consistently recognized that "acting under" a federal officer requires more than a regulator-regulated relationship: It applies only where "the federal government uses a private corporation to achieve an end it would have otherwise used its own agents to complete." *Papp v. Fore-Kast Sales Co. Inc.*, 842 F.3d 805, 812 (3d Cir. 2016) (quoting *Ruppel v. CBS Corp.*, 701 F.3d 1176, 1181 (7th Cir. 2012)). *See also In re Commonwealth's Motion*, 790 F.3d at 469; *Bd. of Cty. Comm'rs of Boulder Cty. v. Suncor Energy (U.S.A.) Inc.*, 965 F.3d 792, 822 (10th Cir. 2020); *Mays v. City of Flint*, 871 F.3d 437, 444 (6th Cir. 2017). This limitation reflects section 1442(a)(1)'s requirement that a person be "acting under" a federal officer acting "under color of" their federal office. 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. Alliance is not "acting under" a federal officer in its operation of nursing homes.

Alliance's operation of its nursing homes after the onset of COVID-19 is not action "under" a federal officer. At most, Alliance has shown that the COVID-19 pandemic resulted in its receipt of additional non-binding guidance from federal agencies. Non-binding guidance cannot transform a private actor into a federal officer. Indeed, "[t]he 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." *City of Walker v. Louisiana*, 877 F.3d 563, 571 (5th Cir. 2017).

Citing exclusively pre-*Watson* district court authority, Alliance contends that "a private party may be 'acting under' a federal officer if the acts that form the basis for the state civil suit were performed pursuant to the government's direct orders or are closely linked to detailed and specific regulations"—a theory it refers to as "regulation plus." Appellants' Br. 23. As to "direct orders," in some circumstances, Alliance may be correct. *Watson*, however, closed the door on the contention that "detailed and

specific regulations" may transform a private entity into a federal officer. As the Supreme Court stated, "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. The Court's opinion in *Watson* is thus flatly inconsistent with Alliance's assertion that "a more specific level of regulation is certainly sufficient to permit removal." Appellants' Br. 25.

Moreover, Alliance's argument rests entirely on industry-wide guidance. Yet guidance, by definition, is *not* binding and lacks the force of law. *See Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995). Labeling CDC and CMS guidance documents "directives" does not change the essential nature of the relationship between Alliance and the federal government; Alliance has been subject to similar "directives" throughout its existence as a participant in a highly regulated industry. To the extent Alliance's laundry list of additional guidance documents related to COVID-19 shows any difference after the onset of the pandemic, that "difference is one of degree, not kind." *Watson*, 551 U.S. at 157. As the district court correctly noted, "the only connection to the federal government is that Defendants—owners and

operators of privately owned nursing facilities—are required to comply with detailed federal regulations when operating these facilities and when providing care." AA32.

The provision of nursing care in the United States—unlike indigent defense for federal defendants, at issue in *In re Commonwealth's Motion*, 790 F.3d at 469, or the military, at issue in *Papp*, 842 F.3d at 805—is a function left to private industry. *Cf. Suncor*, 965 F.3d at 826 (stating that "the facilitation of fossil fuel resource development by private companies is not a critical federal function in the same vein as law enforcement"). The onset of the COVID-19 pandemic did not convert such private activity into federal government action. As the district court noted, any contrary view "would have very far-reaching consequences," extending the federal-officer statute to a wide range of companies in the many highly regulated industries in the United States. AA32. The guidance on which Alliance relies does not show that the federal government has assumed control over nursing homes any

more than it has amusement parks, airlines, or homeless shelters—all of which have been the subject of extensive COVID-19 related guidance.[3]

Finally, the high degree of continuing authority exercised by the State of New Jersey, as explicitly contemplated by the federal government, *see supra* pp.5–6, makes application of a doctrine designed to avoid state government involvement particularly illogical. *See Florida v. Cohen*, 887 F.2d

[3] *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://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO20009.pdf; CDC, COVID-19 Considerations for Traveling Amusement Parks and Carnivals (updated Dec. 30, 2020), https://www.cdc.gov/coronavirus/2019-ncov/community/parks-rec/amusement-park-carnival.html; CDC, Interim Guidance for Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 (COVID-19) (updated Feb. 25, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/plan-prepare-respond.html.

1451, 1453 (11th Cir. 1989) (citing *Willingham*, 395 U.S. at 405 (1969)) (noting federal-officer removal statute is "an incident of federal supremacy").[4]

C. Alliance 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 federal defense. *See Mesa*, 489 U.S. at 129. Here, Alliance contends that subsection (a)(1) of the PREP Act supplies that defense. Because Alliance was not acting as or under a federal officer, the district court did not address this contention, stating that it was "not rul[ing] that the Defendants are, or are not, entitled to a PREP Act defense to this or that claim. That is for the state courts to decide on remand." AA29. This Court may take the same path.

Nonetheless, should the Court reach the issue, it should hold that subsection (a)(1) of the PREP Act does not apply to Plaintiffs' claims. The defense 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] Because Alliance has not shown that it was under the direction of any federal officer, it cannot establish that Plaintiffs' claims "relat[e] to any act under color of such office," as required by 28 U.S.C. § 1442(a)(1).

(4) of a covered countermeasure subject to a declaration of the HHS Secretary. 42 U.S.C. § 247d-6d(1). The third and fourth elements are not met in this case.

As Alliance points out, Plaintiffs' complaints reference Alliance's lack of a policy requiring visitors and employees "to wear protective masks and/or gear," and Alliance's delay in distributing masks to all employees. AA82, AA177, AA199, AA200. Those allegations do not show that Plaintiffs' claims have a "causal relationship with the *administration to or use by* an individual" of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added). To begin with, not all PPE is a "covered countermeasure." Under the statute, 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). The Second Amendment's preamble reference to PPE does not suggest otherwise. There, the Secretary simply explained that including additional drugs and devices on the list of covered countermeasures would mitigate "the escalation of adverse health conditions from COVID-19 and non-COVID-19 causes," which would in turn "conserve[] limited healthcare resources—from

personal protective equipment to healthcare providers." 85 Fed. Reg. 35,100, 35,101.[5] Since a majority of PPE are *not* covered countermeasures, Plaintiffs' claims that Alliance failed to use PPE generally do not have a "causal relationship" with the administration or use of those PPE devices that do constitute "covered countermeasures," as subsection (a) requires. 42 U.S.C. § 247d-6d(a)(2)(B).

Moreover, claims concerning *non*-use of a covered countermeasure are not subject to the subsection (a)(1) defense. Rather, each activity that falls under the statutory immunity is an affirmative act: "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(2)(B). The list does not include a failure to act.[6]

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[5] Although Alliance (at 58) also references COVID-19 tests, which are considered "devices" under 21 U.S.C. § 321(h)(i), Plaintiffs' complaints do not mention COVID-19 testing.

[6] HHS regulations regarding the administrative compensation scheme similarly focus on affirmative acts: They specify that "injured countermeasure recipients"—not *non*-recipients—are eligible for compensation

The PREP Act's purpose confirms the plain meaning of the text. The Act was intended to encourage the manufacture and distribution of covered countermeasures—not to protect entities that did *not* use them. 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 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, the addition of NIOSH-approved respiratory protective devices as part of the FFCRA 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 liability for

through the PREP Act's administrative compensation scheme. 42 C.F.R. § 110.10(a).

"manufacturers, distributors, and users" of covered countermeasures to respiratory devices in order to boost supply).

When Congress intends to protect entities from liability for *inaction*, it knows how to do so. For example, in the CARES Act, Congress included liability protection for 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." § 3215(a), 134 Stat. at 374 (emphasis added). And well after the passage of the FFCRA and CARES Act, Congress debated—but ultimately did not enact—adding liability protections for claims like Plaintiffs'. *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 add liability protections for entities sued for failing to take infection control measures suggests that Congress had not already provided for such protection 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").

Alliance relies on HHS's OGC opinion letter, which took the view 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 "nonfeasance … that [] results in non-use." Advisory Op. 21-01.[7] Even if correct, that view would not help Alliance here. For this distinction to have any meaning, "cases of general neglect [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. In short, "the gravamen of the Complaint is that Defendant

[7] Alliance incorrectly asserts that Advisory Opinion 21-01 is owed *Chevron* deference. As noted in the case OGC cites for its authority to issue advisory opinions, such 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 Hayes v. Harvey*, 903 F.3d 32, 46 (3d Cir. 2018).

was generally neglectful in operating the Facility." *Id.* Thus, even if the PREP Act applies in *some* cases of non-use, as OGC suggested, it does not here.

II. The PREP Act does not completely preempt Plaintiffs' claims.

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 "ordinary preemption" defenses, however, so-called "complete preemption operates to confer original federal subject matter jurisdiction notwithstanding the absence of a federal cause of action on the face of the complaint." *In re U.S. Healthcare, Inc.*, 193 F.3d 151, 160 (3d Cir. 1999). As district courts have nearly unanimously concluded, the PREP Act does not provide for complete preemption of claims based on nursing homes' failures to take adequate safety measures to protect residents from COVID-19. *See McCalebb*, 2021 WL 911951; *Estate of Jones v. St. Jude Operating Co., LLC*, 2021 WL 900672 (D. Or. Feb. 16, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 2021 WL 764566 (D. Kan. Feb. 26, 2021); *Lyons*, 2021 WL 364640; *Dupervil*, 2021 WL 33517; *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 (D. Or. Dec. 28, 2020); *Gunter*

v. CCRC Opco-Freedom Square, LLC, 2020 WL 8461513 (M.D. Fla. Oct. 29, 2020); *Sherod*, 2020 WL 6140474; *Saldana*, 2020 WL 6713995; *Martin*, 2020 WL 5422949; *Haro v. Kaiser Found. Hosps.*, 2020 WL 5291014 (C.D. Cal. Sept. 3, 2020); *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184 (D. Kan. 2020).

Ordinary preemption exists where a federal law creates a "defense to a state law cause of action." *Joyce v. RJR Nabisco Holdings Corp.*, 126 F.3d 166, 171 (3d Cir. 1997). Such defenses do not give rise to federal jurisdiction, and federal courts "lack[] power to do anything other than remand to the state court where the preemption issue can be addressed and resolved." *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 355 (3d Cir. 1995). This principle applies even where a preemption provision is quite broad. For example, under the Food, Drug, and Cosmetic Act, state-law damages claims arising from injuries caused by FDA-approved medical devices are, generally, preempted. *See* 21 U.S.C. § 360k(a). This preemption defense, however, does not provide a basis for removal, despite the breadth of claims to which it applies. *See Burrell v. Bayer Corp.*, 918 F.3d 372, 382 (4th Cir. 2019).

By contrast, complete preemption refers to "the specific situation in which a federal law not only preempts a state law to some degree but also substitutes a federal cause of action for the state cause of action, thereby

manifesting Congress's intent to permit removal." *Schmeling v. NORDAM*, 97 F.3d 1336, 1342 (10th Cir. 1996), *quoted in In re Cmty. Bank of N. Va.*, 418 F.3d 277, 294 (3d Cir. 2005); *see also Rosenberg v. FVI Receivables XVII, LLC*, 835 F.3d 414 n.4 (3d Cir. 2016) (explaining differences between ordinary and complete preemption). "The Supreme Court has recognized the 'complete preemption' doctrine in only three instances:" section 301 of the Labor Management Relations Act, § 502(a) of the Employee Retirement Income Security Act (ERISA), and §§ 85 and 86 of the National Bank Act. *N.J. Carpenters & the Trustees Thereof v. Tishman Const. Corp. of N.J.*, 760 F.3d 297, 302 (3d Cir. 2014).

The determination of 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*, 97 F.3d at 1342. Rather, this Court has identified two prerequisites for removal of state-law claims on the basis of complete preemption. *See Goepel v. Nat'l Postal Mail Handlers Union, a Div. of LIUNA*, 36 F.3d 306, 311 (3d Cir. 1994) (citing *Railway Labor Execs. Ass'n v. Pittsburgh & Lake Erie R. Co.*, 858 F.2d 936 (3d Cir. 1988)). First, "the statute relied upon by the defendant as preemptive [must] contain[] civil enforcement provisions within the scope of which the plaintiff's state claim

falls." *Railway Labor*, 858 F.2d at 942 (citing *Franchise Tax Bd. of State of Cal. v. Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 24, 26 (1983)). Second, there must be "a clear indication of a Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law." *Id.* (citing *Met. Life Ins. Co. v. Taylor*, 481 U.S. 58, 66 (1987)).

Here, neither requirement is met. First, as explained above, see I.C *supra*, Plaintiffs' claims do not relate to the administration or use of a covered countermeasure. Thus, their claims are not within the scope of the PREP Act whatsoever.

Moreover, even if they were, the PREP Act contains a civil enforcement mechanism and demonstrates that Congress intended to permit removal only of a narrow set of state-law claims: those "against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d). Such claims, and only such claims, are committed to the exclusive jurisdiction of the United States District Court for the District of Columbia and subject to a specific statutory procedure. *Id.* § 247d-6d(e). As the district court noted, this provision "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), which this is not." AA24.

Alliance does not argue otherwise. It simply suggests (incorrectly) that the PREP Act's subsection (a)(1) ordinary preemption applies. But its assertion of that defense, regardless of its merit, does not support removal because Congress did *not* designate a federal forum to adjudicate whether the subsection (a)(1) defense applies to a state-law claim.[8]

The one district court opinion to conclude otherwise, *Garcia v. Welltower OpCo Grp.*, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021), was based exclusively on deference to OGC Opinion 21-01. But "an agency's interpretation of the law which governs [a federal court's] jurisdiction is not entitled to deference." *Am. Iron & Steel Inst. v. EPA*, 543 F.2d 521, 525–26 (3d Cir. 1976); *see also In re Kaiser Aluminum Corp.*, 456 F.3d 328, 344 (3d Cir. 2006); *Texas v. EPA*, 829 F.3d 405, 417 (5th Cir. 2016); *Shweika v. Dep't of Homeland Sec.*, 723 F.3d 710, 718 (6th Cir. 2013)). The question whether complete preemption exists "is not a matter within the particular expertise of" an

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[8] That one provision of a statute may completely preempt certain claims, while another provision of that same statute only creates a preemption defense for other claims, is unremarkable. As this Court recognized in *In re U.S. Healthcare*, in ERISA, section 502(a) completely preempts state-law claims, while section 514(a) provides an ordinary preemption defense to state-law claims. 193 F.3d at 160.

agency, but rather "a clearly legal issue that courts are better equipped to handle." *Bamidele v. INS*, 99 F.3d 557, 561 (3d Cir. 1996). Further, as several other 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). *See McCalebb*, 2021 WL 911951, at *4 n.5; *see also Dupervil*, 2021 WL 355137, at *10; *Jones*, 2021 WL 900672, at *6–*7; *Goldblatt*, 2021 WL 308158, at *9. Finally, the *Garcia* court failed to recognize that, even under OGC's view of the PREP Act, for claims alleging non-use resulting from nonfeasance, like those here, as opposed to a "purposeful allocation" of scare resources, there is no preemption. *See McCalebb*, 2021 WL 911951 at *5.

CONCLUSION

The decision of the district court should be affirmed.

Respectfully submitted,
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