21-2164-cv

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

VIVIAN RIVERA-ZAYAS, as the Proposed Administrator
of the Estate of ANA MARTINEZ, Deceased,
Plaintiff-Appellee,

v.

OUR LADY OF CONSOLATION GERIATRIC CARE CENTER,
OUR LADY OF CONSOLATION GERIATRIC CARE CENTER DBA,
Our Lady of Consolation Nursing and Rehabilitative Care Center, OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of New York

BRIEF OF PLAINTIFF- APPELLEE

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Maryland v. Soper (No. 1),
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McCalebb v. AG Lynwood, LLC,
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Mitchell v. Advanced HCS, L.L.C.,
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Montefiore Medical Center v. Teamsters Local 272,
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Ruiz v. ConAgra Foods Packaged Foods, LLC,
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Shapnik v. Hebrew Home for the Aged at Riverdale,
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Skidmore v. Swift & Co.,
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Tennessee v. Davis,
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United States v. Robinson,
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Vaden v. Discover Bank,
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Veneruso v. Mt. Vernon Neighborhood Health Center,
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Walsh v. SSC Westchester Operations Co.,
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Watson v. Philip Morris Cos.,
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Watson v. Philip Morris Cos.,
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42 U.S.C. § 247d-6d(b)(7) 38

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Federal Regulations

42 C.F.R. § 110.10(a) 10, 31

42 C.F.R. § 110.20(d) 10, 51

42 C.F.R. § 483.80 64

Other Federal Administrative Materials

Centers for Disease Control, COVID-19, Community, Work, and
School (last updated Aug. 24, 2021),
https://www.cdc.gov/coronavirus/2019-ncov/community/
index.html 5

Centers for Disease Control, Precautions to Prevent Transmission of
Infections Agents, *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (2007)
https://www.cdc.gov/infectioncontrol/guidelines/isolation/
precautions.html. 14

Centers for Medicare and Medicaid Services, *COVID-19 Long-Term Care Facility Guidance*, Apr. 2, 2020,
https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf 6

Centers for Medicare and Medicaid Services, *Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes*, December 2021
(Version 25),
https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf 6

Department of Health and Human Services, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020) 10, 11, 34

Department of Health and Human Services, Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21,012 (Apr. 15, 2020) 11

Department of Health and Human Services, Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190 (Dec. 9, 2020) 11, 12, 68

Department of Health and Human Services, Office of General Counsel, Advisory Opinion 20-04 (as modified Oct. 23, 2020) 12, 35

Department of Health and Human Services, Office of General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021) 12, 13, 35, 56

State Materials

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New York Executive Order 202.30, May 10, 2020, https://www.governor.ny.gov/sites/default/files/atoms/files/EO202.30.pdf 8

New York Pattern Jury Instructions—Civil 2:10A (2021) 46

New York Public Health Law § 2801-d................................ 15, 42, 55, 56

New York Public Health Law § 2803-c 15

New York State Department of Health, Bureau of Healthcare Associated Infections, *Health Advisory: COVID-19 Cases in Nursing Homes and Adult Care Facilities,* Mar. 13, 2020,

https://coronavirus.health.ny.gov/system/files/documents/2020/03/acfguidance.pdf 7

New York State Department of Health, Bureau of Healthcare Associated Infections, *Health Advisory: Respiratory Illness in Nursing Homes and Adult Care Facilities in Areas of Sustained Community Transmission of COVID-19*, Mar. 21, 2020, https://coronavirus.health.ny.gov/system/files/documents/2020/03/22-doh_covid19_nh_alf_ilitest_032120.pdf 7

New York State Department of Health, Nursing Home COVID Related Deaths Statewide, https://www.health.ny.gov/statistics/diseases/covid-19/fatalities_nh.pdf 15

Other Authorities

Administer, Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/administer 27

Congressional Research Service, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures* (updated Jan. 13, 2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443 8

Statement of Interest of the United States, Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, M.D. Tenn., Jan. 19, 2021 .... 33, 34

Statement of Rep. Nathan Deal, 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) 30

Testimony of Dr. Robert Kadlec, HHS Assistant Secretary for Preparedness and Response, Hearing Before the House Committee on Oversight & Reform, Serial No. 116-96 (Mar. 12, 2020) 31

Testimony of Michael Leavitt, HHS Secretary, Assessing the National Pandemic Flu Preparedness Plan: Hearing Before the House Committee on Energy & Commerce, Serial No. 109-59 (Nov. 8, 2005) 30

Statement of Sen. Mitch McConnell, 106 Cong. Rec. S2358 (daily ed. May 12, 2020) 32

Statement of Rep. Greg Walden, 166 Cong. Rec. H1675-09 (daily ed. Mar. 13, 2020) 31

Wright & Miller, 14B Federal Practice and Procedure Jurisdiction § 3722.2 (2009 ed.) 22

INTRODUCTION

Plaintiff-Appellee Vivian Rivera-Zayas filed this state-law action on behalf of her deceased mother, Ana Martinez, one of at least 39 residents of Our Lady of Consolation Geriatric Care Center (OLOC) in West Islip, New York, who died of COVID-19 in spring 2020. She alleges that her mother's death resulted from OLOC's inadequate infection-control policies and practices—inadequacies that pre-dated the COVID-19 pandemic, as reflected in numerous citations from regulators.

Claims that a nursing facility's negligent practices led to a resident's death are state-law issues regularly adjudicated by New York state courts, notwithstanding that such facilities are subject to federal regulation and receive federal guidance. OLOC argues, though, that this case is different because the complaint alleges that OLOC's inadequate infection-control measures caused a death from COVID-19. But as another court of appeals recently observed in a case nearly identical to this one, "[t]here is no COVID-19 exception to federalism." *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 400 (3d Cir. 2021), *petition for rehearing en banc denied* (Feb. 7, 2022). Moreover, no exception to the

rule that state-law actions between non-diverse parties belong in state court applies in this case.

In arguing otherwise, OLOC primarily relies on the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d–6e, a 2005 statute enacted to encourage the manufacture and use during a pandemic of certain drugs, products, and devices, by providing liability protections against claims based on injuries caused by those products after their use has been recommended by the Secretary of Health and Human Services (HHS). By its plain text, the statute does not apply to *all* claims related to a pandemic. Rather, the statute applies only to claims arising from injuries with a "causal relationship" to the "administration to or use by an individual" of any countermeasure utilized in accordance with federal recommendations. 42 U.S.C. § 247d-6d(a)(1), (a)(2)(B). Because Ms. Rivera-Zayas's complaint lacks any allegations that such administration or use caused her mother's death, and instead is based on OLOC's failures to act, the PREP Act is irrelevant here.

Further, the PREP Act immunity defense invoked by OLOC, even if it applied, would not confer federal subject-matter jurisdiction over this

case. As three courts of appeals have held, Congress's creation of a narrow cause of action for claims (unlike those here) that meet a special statutory definition of "willful misconduct" does not divest state courts of their traditional role as arbiters of *other* tort claims, as required for jurisdiction under the complete-preemption doctrine. Nor does OLOC's invocation of the PREP Act provide jurisdiction under the "embedded federal question" doctrine.

In addition, OLOC cannot rely on the federal-officer removal statute, because there is no evidence that OLOC was subject to direction by a federal officer. The regulatory relationship OLOC had with federal regulatory agencies, which pre-dated the pandemic, does not satisfy the requirements of the federal-officer removal statute, as the dozens of federal courts to address the issue in similar cases have universally concluded.

At bottom, OLOC's argument is that it wants to invoke a defense based on a federal statute and that the absence of a federal forum poses a risk that state courts will interpret the federal statute incorrectly. But "under the present statutory scheme as it has existed since 1887," speculation that state courts may not follow federal law is not a basis to

disrupt the balance of state-federal jurisdiction. *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 10 (1983). Consistent with recent decisions of the Third, Fifth, and Ninth Circuits, of every district court in this Circuit to address the issue, and of dozens of district courts nationwide, this Court should reject OLOC's arguments and allow this case to return to state court for litigation of Ms. Rivera-Zayas's state-law claims.

STATEMENT OF JURISDICTION

Ms. Rivera-Zayas agrees with Appellants that this Court has jurisdiction over this appeal, although the district court properly concluded that it lacked subject-matter jurisdiction under either the federal-question jurisdiction statute, 28 U.S.C. § 1331 or the federal-officer removal statute, 28 U.S.C. § 1442.

STATEMENT OF THE ISSUES

1. Whether a nursing home patient's death alleged to be the result of longstanding inadequate infection control policies and procedures is an injury with a "causal relationship with the administration to or use by an individual of a covered countermeasure," thus bringing related claims within the ambit of the PREP Act.

2. Whether the PREP Act's exclusive federal cause of action for injuries caused by "willful misconduct" relating to the use or administration of a covered countermeasure completely preempts entirely different causes of action, such as those sounding in negligence.

3. Whether a defendant's intent to assert PREP Act immunity as a defense to a state-law claim creates an "embedded federal question."

4. Whether industry-wide guidance from federal agencies converted the nation's nursing homes from regulated entities into ones "acting under" federal officers for purposes of 28 U.S.C. § 1442(a)(1).

STATEMENT OF THE CASE

I. The Federal-State Response to the Pandemic

Since January 2020, federal agencies have issued guidance documents setting forth best practices and interpretations of how existing regulatory requirements apply to measures to reduce the spread of COVID-19. For instance, the Centers for Disease Control and Prevention (CDC), a division of the HHS, issued 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 (last updated Aug. 24, 2021).[1] And both CDC and HHS's Centers for Medicare & Medicaid Services (CMS) issued guidance about infection control in nursing homes and other health care facilities. *See*, *e.g.*, Appellants' Addendum, ADD-69–122 (collecting various guidance documents).

These HHS guidance documents explicitly contemplated that state and local governments would retain their role as primary protectors of public health. CMS told nursing homes to "follow the local health department recommendations" if any facility staff developed signs or symptoms of a respiratory infection and to "contact their local or state health department" if they noticed "an increased number of respiratory illnesses." ADD-76. CMS characterized its guidance as "recommendations to State and local governments and long-term care facilities." *See* CMS, *COVID-19 Long-Term Care Facility Guidance* (Apr. 2, 2020;[2] *see also* CMS, *Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes*, December 2021 (Version 25) (compiling

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

[2] https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf.

"the many creative plans that state governments and other entities have put into operation" to combat COVID-19 since early 2020).[3]

Consistent with CMS's expectation, New York State agencies and officials took a variety of actions to address the spread of COVID-19 in nursing homes. On March 13, 2020, for example, the New York State Department of Health (NYSDOH) issued an advisory to nursing homes and adult care facilities, identifying specific steps such facilities should take to prevent the introduction and minimize the spread of COVID-19. *See* NYSDOH Bureau of Healthcare Associated Infections, *Health Advisory: COVID-19 Cases in Nursing Homes and Adult Care Facilities* (Mar. 13, 2020).[4] That guidance has been regularly updated. *See, e.g.*, NYSDOH Bureau of Healthcare Associated Infections, *Health Advisory: Respiratory Illness in Nursing Homes and Adult Care Facilities in Areas of Sustained Community Transmission of COVID-19* (Mar. 21, 2020).[5] In May 2020, the Governor signed an Executive Order, requiring twice-

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

[4] https://coronavirus.health.ny.gov/system/files/documents/2020/03/acfguidance.pdf.

[5] https://coronavirus.health.ny.gov/system/files/documents/2020/03/22-doh_covid19_nh_alf_ilitest_032120.pdf.

weekly testing of all personnel of nursing homes and adult care facilities. N.Y. Exec. Order 202.30 (May 10, 2020).[6] The Commissioner of Health has also promulgated emergency regulations regarding infection control in nursing homes, including new requirements related to personal protective equipment, codified at 10 NYCRR 415.19(f).

II. The PREP Act and the 2020 Declaration

A. 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 (updated Jan. 13, 2022).[7]

The Secretary triggers the PREP Act by issuing a declaration determining that a public health emergency exists and "recommending" the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures," under certain conditions.

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[6] https://www.governor.ny.gov/sites/default/files/atoms/files/EO202.30.pdf.

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

42 U.S.C. § 247d-6d(b)(1); *see Maglioli*, 16 F.4th at 400–01 (describing statutory scheme). The Secretary may designate only certain drugs, biological products, and devices authorized or approved for use by the Food and Drug Administration or the National Institute for Occupational Safety and Health as "covered countermeasures." 42 U.S.C. § 247d-6d(i)(1)(A)–(D).

Subsection (a) of the PREP Act provides "covered persons" with immunity from liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a [designated] covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). Subsection (d) creates a carve-out from such immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). For claims within the carve-out, the statute creates an "exclusive Federal cause of action," *id.*, and provides special adjudicatory procedures and exclusive jurisdiction in a three-judge court of the District Court for the District of Columbia, *id.* § 247d-6d(e). Critically, however, resort to this exclusive cause of action is only necessary for claims that otherwise would fall within the immunity provision. The subsection (d) cause of

action does not displace state-law claims that are outside the scope of the subsection (a) immunity.

The PREP Act also creates an administrative compensation scheme, which, like subsection (d), is only available to those who suffered 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). HHS regulations specify that eligibility for compensation is limited to "injured countermeasure recipients" and their survivors, 42 C.F.R. § 110.10(a), and 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. On March 10, 2020, HHS Secretary Azar issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. 85 Fed. Reg. 15,198 (ADD-21) (published Mar. 17, 2020). The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of certain countermeasures to combat COVID-19: "any antiviral, any

other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id*. at 15,202.

The Secretary amended the initial Declaration several times. The First Amendment expanded covered countermeasures to include certain respiratory protective equipment. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020). Later, in the Fourth Amendment's preamble, the Secretary opined that "[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d," where it reflects "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,194 (Dec. 9, 2020). He gave as an example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *Id*.

The Fourth Amendment also incorporated by reference four advisory opinions previously issued by HHS's General Counsel. *Id.* at 79,191 & n.5. In one of those opinions, the General Counsel had opined that PREP Act immunity was available to persons "using a covered countermeasure in accordance with" guidance from public health authorities, including guidance on how to prioritize scarce counter-measures like vaccines. HHS General Counsel, Advisory Opinion 20-04, ADD-57–62 (Oct. 22, 2020, as modified on Oct. 23, 2020). The General Counsel provided "examples of program planners using covered countermeasures according to the guidance of" a public health authority that would, in his view, trigger PREP Act immunity, including the vaccination prioritization example given in the Fourth Amendment. *Id.* ADD-60–62.

In January 2021, the General Counsel issued a fifth advisory opinion. HHS General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021), ADD-64. That opinion stated his view that "the PREP Act is a [c]omplete [p]reemption statute" and that it applies to situations where a covered person makes a decision regarding allocation of covered countermeasures that "results in non-use by some individuals," but *not* where non-use was

the result of "nonfeasance." ADD-65. He also opined that "substantial federal question" jurisdiction, recognized in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), applies to any case where a defendant invokes the PREP Act. ADD-67–68. Like the previous advisory opinions, Opinion 21-01 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." ADD-68.

III. OLOC's Inadequate Infection Control Policies and the Resulting Death of Ms. Martinez

Appellants (collectively, OLOC) operate a nursing home in West Islip, New York. *See* A-61–65. Between 2016 and 2020, NYSDOH cited OLOC for regulatory violations 31 times. A-66. Several citations directly concerned OLOC's infection-control measures or lack thereof. For example, in September 2019, months before the COVID-19 pandemic, NYSDOH cited OLOC for failing to "ensure that an infection prevention and control program designed to help prevent the development of infections was maintained." A-66. That same month, NYSDOH cited OLOC for failing to properly implement contact isolation precautions

with respect to a resident with a highly contagious infection. A-66.[8] As alleged in the complaint, OLOC, despite being told its infection-control policies were inadequate, failed to take steps to prepare to prevent the spread of future infections. A-69. Even as the threat of COVID-19 became apparent, OLOC still failed to implement appropriate infection-control measures. *See, e.g.*, A68–69, 74–75.

On January 8, 2020, Ms. Martinez was admitted to OLOC for rehabilitation related to knee surgery. A-79. On March 21, 2020, she began to show respiratory symptoms associated with COVID-19. CA-7. Four days later, an OLOC doctor noted that he suspected Ms. Martinez had COVID-19. CA-5. On March 30, 2020, her condition deteriorated, and she was taken by ambulance to the hospital. CA-1. She died of COVID-19 on April 1, 2020. A-59, 74.

Ms. Rivera-Zayas filed suit against OLOC, alleging that OLOC's "abject and longstanding failure to maintain a system for preventing, identifying, reporting, investigating and controlling infections and

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[8] *See* CDC, "Precautions to Prevent Transmission of Infections Agents," *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (2007) (explaining contact precautions), https://www.cdc.gov/infectioncontrol/guidelines/isolation/precautions.html.

communicable diseases" caused her mother to contract, and die from, COVID-19. A-59. When the operative complaint was filed, more OLOC residents had died of COVID-19 than at any other nursing facility in Suffolk County, and OLOC had the sixth-highest death count in the state of New York. A-60. As of today, 72 OLOC residents are confirmed to have died of COVID-19.[9]

IV. Procedural History

Ms. Rivera-Zayas commenced this action in Kings County Supreme Court on June 5, 2020, and filed the operative, amended complaint on September 30, 2020. A-32, 59. Ms. Rivera-Zayas alleged that OLOC's negligent infection control violated her mother's rights under N.Y. Public Health Law § 2803-c, giving rise to a claim pursuant to N.Y. Public Health Law § 2801-d. A-69–75. She also asserted New York common-law claims for negligence, gross negligence, and wrongful death. A-75–83.

On October 26, 2020, OLOC removed the action to the United States District Court for the Eastern District of New York. As bases for removal, it invoked "Federal Officers Jurisdiction, a Federal Question

[9] *See* https://www.health.ny.gov/statistics/diseases/covid-19/fatalities_nh.pdf. The death count at OLOC is now the second highest in Suffolk County.

and Explicit and Complete Preemption." A-10. Ms. Rivera-Zayas moved to remand the action to state court. ECF 8. OLOC moved to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6), invoking the PREP Act and New York's Emergency or Disaster Treatment Protection Act, N.Y. Public Health Law § 3082. ECF 31.

On August 11, 2021, the district court granted the motion to remand and denied the motion to dismiss as moot. The district court relied heavily on *Dupervil v. Alliance Health Operations*, 516 F. Supp. 3d 238 (E.D.N.Y. 2021), which similarly involved a nursing home's attempt to remove a case alleging state-law claims based on inadequate infection control and COVID-19. A-212. The opinion in *Dupervil* had thoroughly analyzed and rejected each of the same three grounds for removal asserted by OLOC here. The district court below adopted *Dupervil*'s conclusion that the PREP Act does not completely preempt such claims, explaining that the Act "establishes an administrative remedy in the first instance and therefore does not create an exclusive federal cause of action," as required for a statute to be completely preemptive under this Court's decision in *Sullivan v. American Airlines, Inc.*, 424 F.3d 267 (2d Cir. 2005). A-212 (citing *Dupervil*, 516 F. Supp. 3d at 251). The district

court also cited two other district court decisions that, relying on *Dupervil*, also held that the PREP Act did not completely preempt analogous claims. A-213 (citing *Shapnik v. Hebrew Home for the Aged at Riverdale*, 535 F. Supp. 3d 301, 322 (S.D.N.Y. 2021), and *Garcia v. N.Y. City Health & Hosps. Corp.*, 2021 WL 1317178, at *1 (S.D.N.Y. Apr. 8, 2021)).[10] The court did not explicitly address OLOC's other jurisdictional arguments.

This appeal followed. OLOC moved the district court for a stay of the remand order pending appeal, which the district court denied, finding that OLOC failed to demonstrate its appeal presented a "serious legal question on the merits" given "the broad consensus rejecting [its] arguments" by courts around the country. A-219–20 (collecting cases).

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[10] Dozens of district courts around the country have expressly adopted the reasoning in Judge Chen's detailed opinion in *Dupervil*. *See, e.g.*, *Escobar v. Mercy Med. Ctr.*, 2022 WL 669366, at *2–3 (E.D.N.Y. Mar. 7, 2022); *Leroy v. Hume*, 2021 WL 3560876, at *4–7 (E.D.N.Y. Aug. 12, 2021); *Gwilt v. Harvard Sq. Retirement & Assisted Living*, 537 F. Supp. 3d 1231, 1249–50 (D. Colo. 2021); *Jones through Brown v. St. Jude Op. Co.*, 524 F. Supp. 3d 1101, 1109–12 (D. Or. 2021); *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, 535 F. Supp. 3d 709, 715–21(M.D. Tenn. 2021).

SUMMARY OF ARGUMENT

I. Like the Third, Fifth, and Ninth Circuits, this Court should reject OLOC's arguments that its intent to raise a PREP Act defense to Ms. Rivera-Zayas's state-law claims creates federal subject-matter jurisdiction.

A. The PREP Act does not completely preempt Ms. Rivera-Zayas's claims because (1) her claims are not within the ambit of the PREP Act at all, and (2) the PREP Act does not completely preempt claims that, like Ms. Rivera-Zayas's, sound in negligence.

First, the text of the statute limits both its immunity and exclusive cause of action provisions to claims based on injuries with a "causal relationship" to "the administration or use of a covered countermeasure by an individual." Ms. Rivera-Zayas does not allege that her mother died because of "the administration or use of a covered countermeasure" by anyone, but rather because of OLOC's broad failures to adopt effective infection-control policies—policies that are not "covered countermeasures." The statutory text, structure, and purpose make clear that the PREP Act applies only when injuries result from actual administration or use of a covered countermeasure, consistent with the

conditions specified by the HHS Secretary. HHS's interpretation that PREP Act immunity *can* extend to injuries caused by non-use attributable to the "purposeful allocation" of a covered countermeasure is inapplicable here, where purposeful allocation is not at issue. In any event, that interpretation is entitled to no deference.

Second, complete preemption exists only where Congress has converted state-law claims into federal claims by providing a replacement federal cause of action. While the PREP Act creates a cause of action for the tort of "willful misconduct," as defined by the statute, Ms. Rivera-Zayas has not alleged such a claim. OLOC's contrary argument—raised in this Court for the first time—is both waived and wrong on the merits. As the Third, Fifth, and Ninth Circuits have held, that Congress chose to create a federal cause of action for willful misconduct but *not* for negligence-based claims indicates it left the application of PREP Act defenses to the latter to state courts, which are presumptively capable of applying federal law. That Congress has created an administrative compensation scheme where PREP Act immunity applies cannot be the source of a missing federal cause of

action. HHS's thinly reasoned statements suggesting otherwise are wrong and owed no deference.

B. OLOC's brief invocation of the "embedded federal question" doctrine fails as well, given the well-established precedent that a federal defense does *not* implicate that doctrine. Federal jurisdiction over all garden-variety tort claims about negligent infection control would massively disrupt the balance of responsibility between state and federal courts.

II. The Court, following every federal court to have addressed the issue thus far, should also hold that nursing homes cannot invoke the federal-officer removal statute based on their continued operation throughout the pandemic. Neither additional federal regulatory guidance issued during the pandemic nor the inclusion of nursing homes in the sixteen sectors of the economy deemed "critical infrastructure" transformed each of the nation's nursing homes into a person "acting under" a federal officer. OLOC's argument is contrary to Supreme Court precedent establishing that regulation, no matter how detailed or specific, is not a basis for federal-officer removal. Further, OLOC points to no federal direction it received as part of its critical infrastructure role.

That OLOC, like every American, had a role in "the job of containment" of COVID-19 (Appellants' Br. 53) does not establish federal-officer jurisdiction. In addition, because the PREP Act, on its face, does not apply here, OLOC has not established the requisite colorable federal defense for federal-officer removal.

STANDARD OF REVIEW

"A party seeking removal bears the burden of showing that federal jurisdiction is proper." *Montefiore Med. Ctr. v. Teamsters Loc. 272*, 642 F.3d 321, 327 (2d Cir. 2011). Where a district court concludes that burden has not been met, this Court's review is *de novo*. *See Teamsters Loc. 404 Health Servs. & Ins. Plan v. King Pharms.*, 906 F.3d 260, 264 (2d Cir. 2018).

ARGUMENT

I. Ms. Rivera-Zayas's claims do not arise under federal law.

Although Ms. Rivera-Zayas brings claims only under New York law, OLOC argues that her claims arise under federal law for purposes of 28 U.S.C. § 1331 under two different theories, both of which relate to the PREP Act. First, OLOC asserts that her claims are completely

preempted. Second, it argues that they fall under the narrow "embedded federal question" doctrine. Both arguments are wrong.

A. The PREP Act does not completely preempt Ms. Rivera-Zayas's 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). But "[u]nder the complete-preemption doctrine, certain federal statutes are construed to have such 'extraordinary' preemptive force that state-law claims coming within the scope of the federal statute are transformed, for jurisdictional purposes, into federal claims—i.e., completely preempted." *Sullivan*, 424 F.3d at 272. The key question in determining whether complete preemption exists is not whether "Congress desired … to provide a federal defense to a state law claim" or how broad that defense may be. *Wurtz v. Rawlings Co.*, 761 F.3d 232, 238 (2d Cir. 2014) (quoting 14B *Fed. Prac. & Proc. Juris.* § 3722.2). Rather, "to determine whether a federal statute completely preempts a state-law claim within its ambit, [this Court] must ask whether the federal statute provides 'the exclusive cause of action' for the asserted state-law claim," *Sullivan,* 424 F.3d at

275–76, and thus that the state law claim is "recast as a federal claim for relief," *Vaden v. Discover Bank*, 556 U.S. 49, 61 (2009).

Dozens of courts have rejected arguments that the PREP Act completely preempts claims like Ms. Rivera-Zayas's under this standard based on one or both of two bases. First, courts have held that claims based on negligent infection-control policies are not "within [the PREP Act's] ambit at all, as they do not relate to "the administration to or use by an individual of a covered countermeasure," 42 U.S.C. §§ 247d-6d(a)(1), (a)(2)(B), and thus that the PREP Act cannot completely preempt those claims. *See*, *e.g.*, *Dupervil*, 516 F. Supp. 3d at 254–57; *McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *Khalek v. S. Denver Rehab., LLC.*, 543 F. Supp. 3d 1019, 1027–28 (D. Colo. 2021). Second, courts have recognized that the PREP Act does not create a federal cause of action for claims based on negligent acts and inaction, even where it provides an ordinary preemption defense to those claims, and thus that those types of state-law claims cannot be recast as federal ones. *See, e.g.*, *Mitchell v. Advanced HCS, L.L.C.*, __ F.4th __, 2022 WL 714888, at *2–4 (5th Cir. Mar. 10, 2022); *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 687–88 (9th Cir. 2022);

Maglioli, 16 F.4th at 407–13; *Dupervil*, 516 F. Supp. 3d at 249–54; *Shapnik*, 535 F. Supp. 3d at 313–17; *McCalebb*, 2021 WL 911951, at *3–4. Either holding is a sufficient basis to reject OLOC's complete preemption argument here.

1. Ms. Rivera-Zayas's claims are not within the ambit of the PREP Act.

Ms. Rivera-Zayas's "claims do not fall under the PREP Act, thus making it irrelevant whether the PREP Act is a complete preemption statute." *Thomas v. Century Villa Inc.*, 2021 WL 2400970, at *4 (C.D. Cal. June 10, 2021). Subsection (a)(1)'s immunity provision and the exceptions to that immunity provided for in subsections (d) and (e) of the Act apply only to claims for losses with "a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). But Ms. Rivera-Zayas does not allege that her mother died because of OLOC's "administration to or use by an individual of a covered countermeasure." Rather, she alleges that her mother died because of OLOC's "abject and longstanding failure to maintain a system for preventing, identifying, reporting, investigating and controlling infections and communicable diseases." A-59. As dozens of district courts have held, the PREP Act is inapplicable "where a

plaintiff's claim is premised on a failure to take preventative measures to stop the spread of COVID-19, as here, and where none of the alleged harm was causally connected to the administration or use of any countermeasure, which is the focus of the PREP Act." *Gwilt*, 537 F. Supp. 3d at 1241.[11] The only relationship such claims conceivably have with covered countermeasures are their *non*-use—contrary to, not consistent with, the Secretary's recommendations. But both the statutory text and purpose make clear that the PREP Act only applies where a plaintiff claims the actual use of a covered countermeasure caused an injury.

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[11] *See, e.g., Walsh v. SSC Westchester Op. Co.*, 2022 WL 846901, at *5–6 (N.D. Ill. Mar. 22, 2022); *Hampton v. California*, 2022 WL 838122, at *10–11 (N.D. Cal. Mar. 20, 2022); *Lilly v. SSC Houston Southwest Op. Co.*, 2022 WL 35809, at *3 (S.D. Tex. Jan. 8, 2022); *Mackey v. Tower Hill Rehab.*, 2021 WL 5050292, at *3–6 (N.D. Ill. Nov. 1, 2021); *Martin v. Petersen Health Ops.*, 2021 WL 4313604, at *10 (C.D. Ill. Sept. 22, 2021); *Lollie v. Colonnades Health Care Ctr. Ltd.*, 2021 WL 4155805, at *3–4 (S.D. Tex. Sept. 13, 2021); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4 (E.D. Wisc. July 20, 2021); *Maltbia v. Big Blue Healthcare, Inc.*, 2021 WL 1196445, at *5–12 (D. Kan. Mar. 30, 2021); *Stone v. Long Beach Healthcare Ctr.*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 2021); *Lopez v. Life Care Ctrs. of Am.*, 2021 WL 1121034, at *7–15 (D.N.M. Mar. 24, 2021); *Smith v. Colonial Care Ctr., Inc.*, 2021 WL 1087284, at *4 (C.D. Cal. Mar. 19, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271, 1281–86 (D. Kan. 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *Dupervil*, 516 F. Supp. 3d at 255–56; *Eaton v. Big Blue Healthcare*, 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020).

a. The statutory text limits immunity to claims with a causal relationship to the actual use of covered countermeasures.

"Statutory interpretation … begins with the text." *Ross v. Blake*, 578 U.S. 632, 638 (2016). In analyzing the text, this Court "consider[s] not only the bare meaning of the critical word or phrase but also its placement and purpose in the statutory scheme." *United States v. Robinson*, 702 F.3d 22, 31 (2d Cir. 2013). Here, the PREP Act's text indicates that only claims with a causal relationship to actual use of covered countermeasures fall within the scope of the PREP Act. *See* 42 U.S.C. § 247d-6d(a)(2)(b).

OLOC's suggestion that the phrase "relating to" expands the statute to any and all claims involving COVID-19 transmission ignores other important words in the text. OLOC asserts that "the express language of the PREP Act extends to anything 'relating to' the administration of covered countermeasures." Appellants' Br. 47 (quoting 42 U.S.C. § 247d-6d(a)(1)). What the statute actually says, though, is that it applies to claims relating to the "administration *to* or use *by an individual*" of a covered countermeasure. 42 U.S.C. §§ 247d-6d(a)(1), (2)(B) (emphasis added). Restoring these words shows that OLOC relies

on the incorrect meaning of the word "administration." To "administer" something can mean "to manage or supervise the execution, use, or conduct of," or it can mean "to provide or apply; dispense." Merriam-Webster.com Dictionary.[12] By altering the plain text of the statute, OLOC appears to invoke the former definition. But when the statute is read as written, only the latter definition makes sense—given the use of the prepositions "to" and "by," and the inclusion of the term "an individual." When a facility decides not to use a covered countermeasure, it may be administering its policies, but it is not *administering* a covered countermeasure *to an individual*, nor is a countermeasure being *used by an individual*. And although the term "relating to" is broad, that term must be construed in accordance with the "scope of claims for loss" provision—which requires a "causal relationship with the administration to or use by an individual of a covered countermeasure" for the statute to apply. 42 U.S.C. § 247d-6d(a)(2)(B). A relationship with *non*-use is insufficient.

[12] https://www.merriam-webster.com/dictionary/administer.

Other provisions confirm that the statutory immunity applies only to claims related to the actual administration or use of a covered countermeasure. For instance, the statute provides that immunity "applies only if" the countermeasure was "administered or used" during the period of the declaration, for the health condition specified in the declaration, and "administered to or used by" an individual within the population or geographic area specified in the declaration. 42 U.S.C. § 247d-6d(a)(3). In addition, licensed health professionals may only invoke PREP Act immunity if authorized to administer countermeasures "under the law of the State in which the countermeasure was prescribed, administered, or dispensed." *Id.* § 247d-6d(i)(8)(A). And the willful misconduct federal cause of action requires proof that the underlying "injury or death was proximately caused by the administration or use of a covered countermeasure." *Id.* § 247d-6d(e)(4)(C)(i). None of these provisions would make sense if the PREP Act applied where a countermeasure was *not* administered or used.

Nor does the statutory text support OLOC's suggestion that the PREP Act applies to all COVID-19 claims simply because OLOC "actively administered covered countermeasures to prevent the spread of COVID-

19 within its facility." Appellants' Br. 45. "[T]hat a facility us[ed] covered countermeasures somewhere in the facility is [in]sufficient to invoke the PREP Act as to all claims that arise in that facility. The PREP Act still requires a causal connection between the injury and the use or administration of covered countermeasures." *Eaton*, 480 F. Supp. 3d at 1194; *see Shapnik*, 535 F. Supp. 3d at 321 (rejecting argument that PREP Act applies where the decedent "suffered an injury at the hands of a person charged with administering a covered countermeasure, without regard to whether there was a 'direct relationship' between the injury and the use of a covered countermeasure"). Here, Ms. Martinez's death lacked any such connection.

b. Immunity for claims based on use, not non-use, is consistent with the statutory purpose.

"If the text of a statute is ambiguous, then we must construct an interpretation consistent with the primary purpose of the statute as a whole." *United States v. Ripa*, 323 F.3d 73, 81 (2d Cir. 2003). The PREP Act's purpose resolves any possible ambiguity in the text and leaves no doubt that it applies only where an injury was caused by actual use—not non-use—of covered countermeasures.

The PREP Act was intended to encourage the manufacture, distribution, and use of covered countermeasures. *See Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 529 (D.N.J. 2020) (noting that the statute's "evident purpose is to embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID 'countermeasures' with the assurance that they will not face liability for having done so"), *aff'd on other grounds*, *Maglioli*, 16 F.4th 393 (3d Cir. 2021). 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. Deal); Assessing the Nat'l Pandemic Flu Preparedness Plan: Hearing Before the H. Comm. on Energy & Commerce, Serial No. 109-59 at 20 (Nov. 8, 2005) (statement of HHS Secretary Leavitt) ("[A]s we seek to build domestic [vaccine] manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business....[T]he Administration is proposing limited liability protections

for vaccine manufacturers and providers.”).[13] Likewise, a 2020 amendment to the PREP Act expanding the scope of potential covered countermeasures to include certain respiratory protective devices, Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3101, 134 Stat. 281, 361, was designed to “boost the availability and supply of critically needed respirator [masks].” 166 Cong. Rec. H1675-09 (daily ed. Mar. 13, 2020) (statement of Rep. Walden); *see also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (2020) (testimony of HHS Asst. Secretary for Preparedness and Response Robert Kadlec, urging addition of respiratory protective devices in order to boost supply).[14] Providing immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, providing immunity for decisions *not* to administer or use covered countermeasures “would

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

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

defeat the basic purpose of the statute." *Martin*, 2021 WL 4313604, at *10.[15]

When Congress intends to immunize *inaction*, it knows how to do so. For example, in 2020, Congress separately immunized volunteer healthcare professionals for harms "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). If providing immunity for an act necessarily confers immunity for the failure to act, the term "or omission" would be superfluous. Notably, throughout 2020, Congress debated—but did not enact—liability protections for claims like the Ms. Rivera-Zayas's. *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 debate over whether to

[15] HHS regulations regarding the administrative compensation scheme, promulgated pursuant to its rulemaking authority under 42 U.S.C. § 247d-6e(b)(4), reflect a similar understanding by specifying that only "injured countermeasure *recipients*" are eligible for compensation. 42 C.F.R. § 110.10(a) (emphasis added).

immunize entities that failed to take adequate infection control measures confirms that Congress had not already created such immunity through the PREP Act in 2005.

c. HHS interpretations do not establish the PREP Act applies here.

OLOC points to two documents issued by HHS that it claims "control" and support its view that the PREP Act applies to the allegations here. These documents have no applicability to the claims of neglect alleged here, and would not be entitled to any deference regardless.

i. HHS has said nothing about claims like Ms. Rivera-Zayas's.

HHS has never stated that claims like Ms. Rivera-Zayas's fall within the scope of the PREP Act. To the contrary, in a Statement of Interest filed in a Tennessee district court, the United States explicitly *declined* to opine whether claims similar to Ms. Rivera-Zayas's fell within the scope of the PREP Act, limiting its views to the question whether the PREP Act is a "complete preemption" statute generally. *See* Statement of Interest of the United States, *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, M.D. Tenn., Jan. 19, 2021, ADD-123. The government

explicitly noted that "it may be that the complaint [in the *Maglioli* case, which alleged negligent infection control measures generally,] 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." ADD-133 n.4.

OLOC's suggestion that HHS had taken the contrary position in earlier statements is unsupported by the documents it cites. First, OLOC points to the definition of the term "Administration of a Covered Countermeasure" in the Declaration. Appellants' Br. 46 (citing Declaration, 85 Fed. Reg. at 15,200). That definition does not support the notion that the statute applies to claims based on non-use of covered countermeasures or inadequate policies more generally. Rather, it states that "administration" extends to both the "physical provision of a countermeasure to a recipient" and "activities related to management and operation of programs and locations for providing countermeasures to recipients … only insofar as those activities directly relate to the countermeasure activities." 85 Fed. Reg. at 15,200. The emphasis on the "physical provision" of countermeasures to "recipients" is incompatible with the notion that immunity could apply where countermeasures were

not provided to anyone. And the emphasis on a "direct relationship" undercuts the notion that providing a covered countermeasure to someone somewhere triggers immunity for *all* COVID-19 claims. Unlike in the examples given in the Declaration, here, Ms. Rivera-Zayas does not allege that her mother's death has a direct relationship with the "physical provision" of any covered countermeasure, so the Declaration does not help OLOC.

OLOC also cites to Advisory Opinion 20-04, ADD-56, but that document does not state that the PREP Act extends to all "decisions related to the use and management of covered countermeasures to prevent community-based transmission of COVID-19 to others," Appellants' Br. 47. That document addresses two topics not at issue here: "(1) the definition of a 'program planner' and (2) 'the activities authorized by an 'Authority Having Jurisdiction.'" ADD-57. In the course of that discussion, the General Counsel opined that PREP Act immunity would apply to a suit against a pharmacy that did not provide a COVID-19 vaccine to a person because it "prioritize[d] CDC-designated populations," because "by administering the COVID-19 vaccine pursuant to CDC prioritization, the pharmacy has complied with the guidance of

an Authority Having Jurisdiction." ADD-61. *See also* Advisory Opinion 21-01, A-80 (opining that "situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure" and be subject to immunity, distinguishing "between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use").

At most, these statements reflect HHS's opinion that the statute applies where "(1) there are limited covered countermeasures; and (2) there was a failure to administer a covered countermeasure to one individual because it was administered to another individual." *Lyons*, 520 F. Supp. 3d at 1285. Neither element is met here, though. The allegations are that Ms. Martinez died as a result of OLOC's negligent infection-control policies, which pre-dated the pandemic—not that Ms. Martinez died because OLOC chose to administer a scarce covered countermeasure to someone else. Such "cases of general neglect" do not fall under the PREP Act, even under HHS's view. *McCalebb*, 2021 WL 911951, at *5; *see also Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5–6 (C.D. Cal. Apr. 19, 2021) (explaining irrelevance of Advisory Opinion 21-01 to analogous claims); *Goldblatt v. HCP Prairie Village KS OpCo LLC*,

516 F. Supp. 3d 1251, 1264 (D. Kan. 2021) (similar). And unlike in the Advisory Opinion example, no allegation or evidence suggests that OLOC's failures to adopt adequate infection-control measures was the result of compliance with government recommendations.

ii. HHS's statutory interpretations are not "controlling."

Because nothing HHS has said resolves the issues in this case, the Court need not address whether HHS's views as to the scope of PREP Act immunity deserve deference. In any event, OLOC's statement that HHS's interpretations of the statute on this point are entitled to deference under *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984), Appellants' Br. 15 n.5 & 47, is wrong.

To start, OLOC's statement that "[t]he Third Circuit agreed" that HHS's views are "controlling," Appellants' Br. 47, is based on misquotation of the *Maglioli* opinion. In explaining how the statute operates generally, the court there stated, "The Secretary controls the scope of immunity through the declaration and amendments, *within the confines of the PREP Act*." 16 F.4th at 401 (italics added). *Cf.* Appellants' Br. 47 (omitting italicized language). This statement reflects the undisputed point that the Secretary has to issue a declaration for the

statute to be operative—not that the Secretary has unreviewable authority to say or do whatever he wants under the statute. And OLOC's citation of the Third Circuit's discussion of the PREP Act's judicial review bar, 42 U.S.C. § 247d-6d(b)(7), selectively quotes the opinion and flips its meaning. In fact, the Third Circuit *rejected* a nursing home's assertion that this provision is evidence that the Secretary has been delegated authority to interpret the statute, stating that it "*merely* strips courts of jurisdiction to review the Secretary's determinations under the PREP Act." 16 F.4th at 403 (emphasis added). *Cf.* Appellants' Br. at 47 (omitting "merely"). That Congress has disturbed the presumption of judicial review of agency action for PREP Act declarations does not mean that courts are required to accept HHS's statutory interpretations in *other* judicial proceedings, and does not mean "that the Secretary's interpretation of the PREP Act has the force of law." *Mackey*, 2021 WL 5050292, at *5 n.7.

In determining what degree of deference is appropriate for HHS's opinion about what injuries have a "causal relationship with the administration to or use by an individual of a covered countermeasure," 42 U.S.C. § 247d-6d(b)(2), this Court must look to three basic principles

of agency deference. First, where a statute is unambiguous, a court owes no deference to an agency interpretation. *See, e.g.*, *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 175 (2016). Second, where a statute is ambiguous, an agency's interpretation is deemed controlling under *Chevron* 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). And finally, where an agency interpretation "lacks the force of law," "[t]he weight appropriately afforded … depends 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.'" *Greathouse v. JHS Sec. Inc.*, 784 F.3d 105, 114 (2d Cir. 2015) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

Here, as explained above (at 26–32), the text and purpose of the PREP Act unambiguously demonstrate that only claims based on injuries caused by the actual administration or use of a covered countermeasure fall under the statute. The Court should proceed no further. Even if the

Act were ambiguous, though, in neither the Declaration nor Advisory Opinion 20-04 did HHS purport to be exercising any delegated authority "to make rules carrying the force of law" about the meaning of "related to the administration to or use by an individual of a covered countermeasure." Nor could it, as Congress only delegated to the Secretary the authority 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." 42 U.S.C. § 247d-6d(b)(1). That authority does not carry with it the power to define the meaning of the terms in subsection (a). *Cf. id.* § 247d-6d(c)(2)(A) (providing rulemaking authority to define the term "willful misconduct"). That the Secretary has been delegated authority to speak with the force of law as to *some* things with respect to the PREP Act does not mean that *everything* he says is entitled to the same level of deference.

Finally, nowhere in the Declaration or the Advisory Opinion does HHS consider the relevant statutory language, including the requirement of a "causal relationship" with the administration "to" or

"use by an individual," and nowhere does it consider the purpose of the statute—stimulating demand, manufacture, and use. Any conclusion the agency reached without doing so is not entitled to deference. *See, e.g.*, *Martin*, 2021 WL 4313604, at *10; *Mackey*, 2021 WL 5050292 at *5; *WorkCare, Inc. v. Plymouth Med., LLC*, 2021 WL 4816631, at *5 (C.D. Cal. Aug. 20, 2021).

2. Subsection (a)(1) does not completely preempt claims even where it does apply.

Because Ms. Rivera-Zayas's claims do not relate to the administration to or use by an individual of a covered countermeasure, the Court need not determine whether the PREP Act completely preempts claims that *do* fall within its scope. Nonetheless, the district court, like the Third, Fifth, and Ninth Circuits, was correct to conclude that, even in such cases, subsection (a)(1) provides nothing but an ordinary preemption defense—not complete preemption.

a. Ms. Rivera-Zayas's inability to bring her claims pursuant to a federal cause of action is dispositive.

"Only state-court actions that originally could have been filed in federal court may be removed to federal court by the defendant." *Caterpillar*, 482 U.S. at 392. Complete preemption is not an exception to

this rule; rather, it recognizes rare circumstances where Congress has converted certain state-law causes of actions into exclusively federal ones. *See Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003). The question of complete preemption does not hinge on whether Congress intended to preempt state law, but on whether it intended to preempt state law *and* "substitute[d] a federal remedy for that law." *Briarpatch Ltd. v. Phoenix Pictures, Inc.*, 373 F.3d 296, 305 (2d Cir. 2004). "[C]omplete preemption requires that a federal cause of action be available to the plaintiff," even if "it does not ensure that the plaintiff will find the remedy she seeks." *Johnson v. MFA Petroleum Co.*, 701 F.3d 243, 251 (8th Cir. 2012).

In enacting the PREP Act, Congress did not create a substitute federal cause of action for claims like Ms. Rivera-Zayas's claims under N.Y. Public Health Law § 2801-d, and for nursing and medical malpractice, ordinary negligence, gross negligence, and wrongful death. Where such claims are based on a loss caused by the administration to or use by an individual of a covered countermeasure, the PREP Act renders them "nonactionable," not completely preempted, as "such claims cannot be litigated in state court *or* in federal court." *Romano v. Kazacos*, 609

F.3d 512, 519 n.2 (2d Cir. 2010) (citing *Kircher v. Putnam Funds Tr.*, 547 U.S. 633, 637 n. 1 (2006)). "Had Congress wished to create a cause of action in federal court solely to determine whether a state-law claim" fell within the scope of the PREP Act's immunity provision, "it could have done so." *Sullivan*, 424 F.3d at 277. It did not.

This Court recognized this principle in *Sullivan*, where it held that the so-called "minor dispute" provisions of the Railway Labor Act do not completely preempt state-law claims related to such minor disputes, because the statute only creates an administrative tribunal to hear minor disputes—not a federal cause of action. 424 F.3d at 276. Since such claims "cannot be filed in the first instance in federal court" under a cause of action created by the RLA, they cannot be completely preempted by the RLA. *Id.* That reasoning applies equally here, as Ms. Rivera-Zayas could not have brought any of her claims under the PREP Act cause of action. *See Mitchell*, 2022 WL 714888, at *3 ("[A]ssuming—without deciding—that the willful misconduct cause of action is completely preemptive, the question is whether [plaintiff] 'could have brought' the instant claims under the cause of action." (quoting *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004)).

In its opening brief, OLOC, for the first time, argues that Ms. Rivera-Zayas has pleaded a claim for willful misconduct that could be brought under the cause of action created by subsection (d)(1) of the PREP Act, 42 U.S.C. § 247d-6d(d)(1). This argument is waived, as it appears nowhere in either OLOC's notice of removal, A-9–28, or opposition to the motion to remand, ECF 35, and there is no good reason for the Court to excuse such waiver. *See In re Tribune Co. Fraudulent Conveyance Litig.*, 10 F.4th 147, 168 (2d Cir. 2021). It is also wrong. What OLOC claims is a willful misconduct claim is the claim Ms. Rivera-Zayas brings for gross negligence. *See* Appellants' Br. 42 (citing A-81–83 ¶¶ 136–153). OLOC accurately notes that, in that claim, Ms. Rivera-Zayas accuses OLOC of "acting in so careless a manner as to show complete disregard for the rights and safety of others," "knowing that [its] conduct would probably result in injury," and with reckless disregard "for the consequences of [its] actions or inactions." *Id.* These allegations do not convert a New York gross negligence claim into a willful misconduct one under the PREP Act.

As the Third Circuit stated, "the elements of the state cause of action need not 'precisely duplicate' the elements of the federal cause of

action for complete preemption to apply." *Maglioli*, 16 F.4th at 411 (quoting *Davila*, 542 U.S. at 216)). "But complete preemption does not apply when federal law creates an entirely *different* cause of action from the state claims in the complaint. Congress could have created a cause of action for negligence or general tort liability. It did not. Just as intentional torts, strict liability, and negligence are independent causes of action, so too willful misconduct under the PREP Act is an independent cause of action." *Id.* (citations omitted)

Willful misconduct under the PREP Act requires "(1) 'an act or omission,' that is taken (2) 'intentionally to achieve a wrongful purpose,' (3) 'knowingly without legal or factual justification,' and (4) 'in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.'" *Maglioli*, 16 F.4th at 310 (quoting 42 U.S.C. § 247d-6d(c)(1)(A)). "The PREP Act also provides a rule of construction: the willful-misconduct requirement 'shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.'" *Id.* (quoting 42 U.S.C. § 247d-6d(c)(1)(B)). Here, though, like the plaintiffs in *Maglioli*, Ms. Rivera-Zayas does not "allege or imply that [OLOC] acted

'intentionally to achieve a wrongful purpose,'" or that OLOC "acted 'knowingly without legal or factual justification.'" *Id.* at 411 (quoting 42 U.S.C. §§ 247d-6d(c)(1)(A)(i), 247d-6d(c)(1)(A)(ii). In pleading the elements of a New York claim for gross negligence, which differs from a claim for willful misconduct under New York law precisely because of the lack of intent, *see* N.Y. Pattern Jury Instr.—Civil 2:10A (2021), Ms. Rivera-Zayas has alleged what the statute says is *not* a claim for willful misconduct.

Because Ms. Rivera-Zayas does not allege her mother died as a result of "willful misconduct" as that term is defined in the statute, there is no federal cause of action that she could have sued under in the first instance. Indeed, below, OLOC conceded as much, telling the district court that "neither this, nor any other court, has subject matter jurisdiction over plaintiff's claims." ECF 31 at 30. As recognized by the district court, A-213, OLOC's arguments thus raise the same "internal[] inconsisten[cy]" that the *Sullivan* court identified with the defendant's position there. 424 F.3d at 276. When a state-law claim is removed to federal court based on one of the statutes the Supreme Court has found to completely preempt state law claims, "the district court may then

adjudicate the claim on the merits under the relevant preemptive statute." *Id.* Here, though, OLOC argued that the court should assume jurisdiction simply to dismiss the claims for a lack of jurisdiction—exactly what this Court found to be problematic in *Sullivan*. *Id.*[16]

OLOC misses the point in arguing that the mere existence of the subsection (d) cause of action for willful misconduct, and procedures for the litigation of that cause of action in the District Court for the District of Columbia and the Court of Appeals for the D.C. Circuit, means that negligence-based claims that cannot be brought pursuant to that cause of action are also completely barred. Appellants' Br. 30, 39. The "complete preemption" inquiry is not whether the claims are barred, but whether they invoke a cause of action that arises under federal law. And as the Ninth Circuit explained, "[t]he provision of one specifically defined, exclusive federal cause of action undermines [OLOC]'s argument that

[16] In criticizing the district court for making this point, OLOC states it was appropriate for it to ask the district court to "dismiss the claim for failing to state a cause of action." Appellant's Br. 41. OLOC's motion to dismiss was brought under both Rules 12(b)(1) and 12(b)(6), though, and its PREP Act argument for dismissal was brought solely under Rule 12(b)(1). *See* ECF 31 at 25–30 ("Accordingly, OLOC respectfully asks this Court to dismiss the Amended Complaint, pursuant to F.R.C.P. 12(b)(1).")

Congress intended the Act to completely preempt all state-law claims related to the pandemic." *Saldana*, 27 F.4th at 688; *see also Maglioli*, 16 F.4th at 410 ("Just because the PREP Act creates an exclusive federal cause of action does not mean it completely preempts the estates' state-law claims.").

OLOC's argument, Appellants' Br. 30, based on 42 U.S.C. § 247d-6d(e)(10), which provides for interlocutory appellate jurisdiction, fails for the same reason—and others. First, Ms. Rivera-Zayas disagrees with OLOC and contends that paragraph 10, like each of the other numbered paragraphs of § 247-6d(e), applies only to willful misconduct actions brought in the District of Columbia district court pursuant to the subsection (d) cause of action. The D.C. Circuit is scheduled to hear argument on that question on April 28, 2022, in *Cannon v. Watermark Retirement Communities*, D.C. Cir. No. 21-7067, and *Beaty v. Fair Acres Geriatric Center*, D.C. Cir. No. 21-7096. Regardless, appellate jurisdiction and subject-matter jurisdiction are distinct concepts, and "the fact that the PREP Act provides federal appellate jurisdiction for interlocutory appeals does not change the fact that it does not provide original federal jurisdiction for any claims other than those of death or serious physical

injury proximately caused by willful misconduct." *Leroy*, 2021 WL 3560876, at *6. As with the creation of the subsection (d) cause of action as a whole, paragraph 10 simply shows that Congress *could* have created "a cause of action in federal court solely to determine whether a state-law claim" fell within the scope of the PREP Act's immunity provision, but failed to do so. *Sullivan*, 424 F.3d at 277.

That some plaintiffs may bring some federal claims relating to injuries caused by the administration or use of a covered countermeasure does not mean that *all* claims relating to such injuries are completely preempted, as reflected in case law concerning the scope of complete preemption under section 502(a) of the Employment Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1132(a). That statute, like the PREP Act, has both an ordinary preemption provision, ERISA section 514(a), 29 U.S.C. § 1144(a), and an exclusive federal cause of action, section 502(a), 29 U.S.C. § 1132(a). ERISA claims are only completely preempted where a plaintiff "could have brought his claim under ERISA § 502(a)(1)(B)." *Davila*, 542 U.S. at 210. That the ordinary preemption provision may apply is not a basis for federal jurisdiction, "regardless of

the strength of the defendant's argument for § 514 preemption." *Felix v. Lucent Techs., Inc.*, 387 F.3d 1146, 1158 (10th Cir. 2004)

So too here, even if OLOC had a strong argument for the applicability of the PREP Act's subsection (a)(1) immunity defense, Ms. Rivera-Zayas' claims "are not completely preempted, [and] they belong in state court," because they "do not fall within the scope of the exclusive federal cause of action." *Maglioli*, 16 F.4th at 408.

b. The administrative compensation scheme is not a cause of action.

The PREP Act's creation of an administrative fund from which certain individuals may seek compensation also cannot stand in for the requisite federal cause of action, because it does not provide a basis for subject-matter jurisdiction in federal court. *See Maglioli*, 16 F.4th at 411–13 (rejecting contrary argument as "even less plausible" than that based on willful-misconduct cause of action). "[A]n 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 absent in an administrative scheme. *See also Mitchell*, 2022 WL 714888, at *3–4 (rejecting compensation fund as source of complete preemption).

Moreover, the administrative fund is not available to parties like Ms. Rivera-Zayas, as her mother's injuries were not "directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). HHS, through regulations promulgated pursuant to an explicit congressional delegation, has interpreted that phrase to *exclude* injuries from "the underlying condition or disease" a covered countermeasure was designated to combat. 42 C.F.R. § 110.20(d). According to HHS, a death caused by COVID-19 is not a death "directly caused by the administration or use of a covered countermeasure" recommended to fight COVID-19.

OLOC points out that other statutes that have been found to be completely preemptive have administrative exhaustion requirements that a plaintiff must satisfy before commencing suit under an exclusive federal cause of action. *Id.* at 35–37. That observation is neither here nor there because, for non-willful misconduct claims to which it applies, the PREP Act administrative remedy is not an *exhaustion* requirement; it is

the *only* remedy. As "the compensation fund is not a cause of action," it cannot provide the federal cause of action necessary for complete preemption. *Maglioli*, 16 F.4th at 411–12. There is no basis to "presume that Congress, in creating an administrative remedy, intended to make state-law negligence claims removable to federal court." *Id.* at 412; *see also Sullivan*, 424 F.3d at 276–77 (holding that Congress's vesting of jurisdiction in arbitral panels did not provide a basis for complete preemption); *Strong v. Telectronics Pacing Sys., Inc.,* 78 F.3d 256, 261 (6th Cir. 1996) (finding administrative remedies available under the Medical Device Amendments to the Food, Drug, and Cosmetic Act were not a parallel federal cause of action and thus did not establish complete preemption).

c. No deference is owed to agencies' views on complete preemption.

OLOC briefly invokes HHS's position that "the PREP Act provides complete preemption." Appellants' Br. 33 (referencing the Fifth Amendment, Advisory Opinion 21-01, and a statement of interest filed in a Tennessee district court). But federal agencies' views on complete preemption, a question of federal-court jurisdiction, receive no deference. *See Mitchell*, 2022 WL 714888, at *2 n.3; *Saldana*, 27 F.4th at 687;

Maglioli, 16 F.4th at 403; *Leroy*, 2021 WL 3560786, at *5; *Shapnik*, 535 F. Supp. 3d at 319–19; *Dupervil*, 516 F. Supp. 3d at 252; *see also Bechtel v. Competitive Techs., Inc.*, 448 F.3d 469, 478 (2d Cir. 2006) (Leval, J., concurring) ("[B]ecause the statutory interpretation at issue concerns the scope of federal court jurisdiction, it is not a proper subject of deference under *Chevron*" (citation omitted)).

Rather, "the scope of federal courts' jurisdiction is a legal issue that is the province of the courts, not agencies." *Maglioli*, 16 F.4th at 403. Moreover, as the Third Circuit noted, "[e]ven if HHS has something valuable to say on the matter, we do not find it in these statements," which do not interpret the statutory text, cite any case law (besides *Grable*), or provide any legal reasoning." *Id.* (discussing the Fourth and Fifth Amendments and the general counsel's advisory opinions); *see also Mitchell*, 2022 WL 714888 at *3 n.3 (similar).

B. The narrow *Grable* doctrine does not apply.

OLOC also briefly argues that the Ms. Rivera-Zayas' case falls into the "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). *See* Appellants' Br. 48–50. 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). As this Court has previously recognized, the "Supreme Court has been sparing in recognizing state law claims fitting this criterion," which "signals caution in identifying the narrow category of state claims over which federal jurisdiction may be exercised." *NASDAQ QMX Grp, Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1019–20 (2d. Cir. 2014).

OLOC does not address *Grable*'s elements in its brief. And it does not acknowledge that every federal court to consider whether *Grable* provides jurisdiction in similar cases has concluded that it does not. *See, e.g.*, *Mitchell*, 2022 WL 714888, at *4–5; *Saldana*, 27 F.4th at 688–89; *Maglioli*, 16 F.4th at 413.[17] As in each of those cases, none of the elements

[17] District courts are likewise unanimous on this point. *See*, *e.g.*, *Escobar*, 2021 WL 669366, at *2–3; *Leroy*, 2021 WL 3560876, at *6; *Shapnik*, 535 F. Supp. 3d at 320; *Dupervil*, 516 F. Supp. 3d at 257; *Pirotte v. HCP Prairie Village KS OpCo LLC*, 2022 WL 179444, at *14–15 (D. Kan. Jan. 20, 2022); *Holman v. Knollwood Nursing Home, LLC*, 2021 WL 5578995, at * 4 (S.D. Ala. Oct. 22, 2021); *Martin*, 2021 WL 4313604, at

of *Grable* jurisdiction are present here, and Ms. Rivera-Zayas' complaint "does not fit within the special and small category in which [OLOC] would place it." *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 699 (2006).

First, the complaint does not "necessarily raise" any issues of federal law and, therefore, raises no "substantial" or "actually disputed" issues of federal law. When considering whether a complaint necessarily raises a federal issue, the well-pleaded complaint rule applies. *See Tantaros v. Fox News Network, LLC*, 12 F.4th 135, 142 (2d Cir. 2021). Thus, the only question is whether a federal issue is an "essential element[] of a prima facie case" for one of Ms. Rivera-Zayas's state-law claims. *Id.* PREP Act immunity—the federal question suggested by

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*12; *Lollie*, 2021 WL 4155805, at *6; *Dorsett v. Highlands Lake Ctr., LLC*, 2021 WL 3879231, at *10–11 (M.D. Fla. Aug. 31, 2021); *Elliot v. Care Inn of Edna LLC*, 2021 WL 2688600, at *6 (N.D. Tex. June 30, 2021); *Khalek*, 543 F. Supp. 3d at 1029; *Brannon v. J. Ori, LLC*, 2021 WL 2339196, at *4 (E.D. Tex. June 8, 2021); *Moody v. Lake Worth Inv. Inc.*, 2021 WL 4134414, at *6 (N.D. Tex. May 26, 2021); *Gwilt*, 537 F. Supp. 3d at 1243; *Bolton*, 535 F. Supp. 3d at 717; *Perez v. Southeast SNF LLC*, 533 F. Supp. 3d 430, 437 (W. D. Tex. 2021); *Winn v. Cal. Post Acute LLC*, 532 F. Supp. 3d 892, 900 (C.D. Cal. 2021); *Cowan v. LP Columbia KY, LLC*, 530 F. Supp. 3d 695, 705 (W.D. Ky. 2021); *Maltbia*, 2021 WL 1196445, at *12 n.12; *Stone*, 2021 WL 1163572, at *7; *McCalebb*, 2021 WL 911951, at *3; *Robertson*, 523 F. Supp. 3d at 1286; *Lyons*, 520 F. Supp. 3d at 1288; *Goldblatt*, 516 F. Supp. 3d at 1264 n.7.

OLOC—is *not* an essential element of a claim under N.Y. Public Health Law § 2801-d, or claims of medical and nursing malpractice, ordinary negligence, gross negligence, or wrongful death under New York common law. Such claims do not "necessarily" raise federal questions because none of the claims is "affirmatively 'premised' on a violation of federal law." *New York ex rel. Jacobson v. Wells Fargo Nat'l Bank, N.A.*, 824 F.3d 308, 315 (2d Cir. 2016) (citing *Grable*, 545 U.S. at 314).

A potential federal defense does not make federal law an "essential element" of a state-law claim. *See, e.g.*, *Tantaros*, 12 F.4th at 143. Despite OLOC and HHS's assertions, it is of no moment that resolution of OLOC's defense implicates important federal policy interests. Appellants' Br. 49–50. *Any* preemption defense created by a federal statute necessarily reflects a substantive policy interest identified by Congress, and the Supreme Court has made clear that preemption defenses do not satisfy the federal-question statute. *See, e.g.*, *Caterpillar*, 482 U.S. at 399. *Grable* requires "a serious federal interest in claiming the advantages thought to be inherent in a federal forum." 545 U.S. at 313. The mere desire to have a federal court interpret federal law, as HHS suggests, Advisory Opinion 21-01, ADD-68, is not such an interest. "The 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.

Jurisdiction is also barred by the fourth *Grable* factor, which asks whether the question is capable of resolution in federal court without disrupting the federal-state balance approved by Congress. In analyzing this factor, this Court looks to "the nature of the claim, the traditional forum for such a claim, and the volume of cases that would be affected." *Jacobson*, 824 F.3d at 316. None of these considerations supports transferring all "run-of-the-mill state-law" cases involving the failure to take adequate precautions to minimize transmission of COVID-19 into federal court, "dramatically alter[ing] the federal-state division of labor." *Shapnik*, 535 F. Supp. 3d. at 320. Such an outcome would have much more than "a microscopic effect" on the federal-state division of labor, *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. Moreover, it would ignore Congress's specific judgment in the PREP Act that only a narrow category of state-law cases may originate in federal court: claims brought by plaintiffs alleging "willful misconduct" arising out of injuries

caused by the use or administration of covered countermeasures. 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.

II. OLOC does not satisfy the requirements for federal-officer removal.

To invoke the federal-officer removal statute, "a defendant who is not himself a federal officer must demonstrate that (1) the defendant is a 'person' under the statute, (2) the defendant acted 'under color of federal office,' and (3) the defendant has a 'colorable federal defense.'" *Cuomo v. Crane Co.*, 771 F.3d 113, 115 (2d Cir. 2014) (quoting *Isaacson v. Dow Chem. Co.*, 517 F.3d 129, 135 (2d Cir. 2008)); *see Agyin v. Razmzan*, 986 F.3d 168, 181 (2d Cir. 2021).[18] As each of the dozens of courts to consider the issue has held, nursing homes like OLOC were not acting under color of federal office when they continued to operate during the pandemic—even if they received additional guidance and directives

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[18] In *Isaacson*, which OLOC cites for the relevant test, Appellants' Br. 51, the Court framed the three prongs slightly differently, collapsing "person" and "acting under a federal officer" into one prong. 517 F.3d at 135. The different formulations of the standard do not affect the outcome.

from regulatory authorities, and even if the work they did was important. Additionally, OLOC lacks a colorable federal defense, as the PREP Act has no bearing on Ms. Rivera-Zayas's claims.

A. The federal officer removal statute applies only to private entities acting 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, 150 (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)—including "[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 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. 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.

B. OLOC has not established that it was "acting under" any federal officer.

As the Fifth, Ninth, and Third Circuits have held, the onset of the pandemic did not convert the nation's heavily regulated nursing homes into entities "acting under" federal officer direction. *See Mitchell*, 2022 WL 714888, at *5–7; *Saldana*, 27 F.4th at 684–86; *Maglioli*, 16 F.4th at 405–06.[19] OLOC makes three arguments in support of its contrary claim,

[19] Districts courts agree. *See, e.g.*, *Rosen v. Montefiore*, 2022 WL 278106, at *5 (N.D. Ohio Jan. 31, 2022); *Mackey*, 2021 WL 5050292, at *8; *Martin*, 2021 WL 4313604, at *2–3; *Lollie*, 2021 WL 4155805, at *7; *Leroy*, 2021 WL 3560876, at *7; *Elliot*, 2021 WL 2688600, at *5; *Khalek*,

none of which demonstrates that OLOC was in a "special relationship" with any federal officer, as *Watson* requires. *Isaacson*, 517 F.3d at 137.

First, OLOC points to Ms. Rivera-Zayas' allegations that OLOC violated federal "mandates," and to various guidance documents issued by the CDC and CMS. Appellants' Br. 51–52. OLOC argues that these documents required OLOC, along with every other nursing home in America, "to comply with detailed infection control procedures." *Id.* at 52. But the agency documents that OLOC "relies on show nothing more than regulations and recommendations for nursing homes." *Saldana*, 27 F.4th at 686; *see also Mitchell*, 2022 WL 714888, at *6. And even if OLOC was "mandated" to comply with "intense regulation," that does not establish an "acting under" relationship that triggers the federal-officer removal statute under *Watson*. *Maglioli*, 16 F.4th at 405–06. *Cf. Veneruso v. Mt. Vernon Neighborhood Health Ctr.*, 586 F. App'x 604, 607 (2d Cir. 2014) (holding that "a host of federal requirements and regulations pertaining

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543 F. Supp. 3d at 1029–30; *Brannon*, 2021 WL 2339196, at *3–4; *Perez*, 533 F. Supp. 3d at 438; *Garcia*, 2021 WL 1317178, at *2; *Winn*, 532 F. Supp. 3d at 901; *Stone*, 2021 WL 1163572, at *8; *McCalebb*, 2021 WL 911951, at *6–7; *Lyons*, 520 F. Supp. 3d at 1283–84; *Dupervil*, 516 F. Supp. 3d at 259–61.

to the health services [a health center] provides, and the manner in which it expends its funds" do not create an "acting under" relationship).

Because compliance with federal regulations is not action under federal officer direction, allegations that OLOC "fail[ed] to follow these federally mandated directives" do not provide a basis for federal-officer removal, as OLOC suggests. Appellants' Br. 57–58. Nothing about COVID-19 changed the essence of the relationship between America's nursing homes and the federal government from one of "considerable regulatory detail and supervision" into "the kind of assistance that might bring [the relationship] within the scope of the statutory phrase '*acting under*' a federal officer." *Watson*, 551 U.S. at 157. By statute and regulation, facilities like OLOC are heavily regulated by the federal government as a condition of their receipt of Medicare and Medicaid funding, including with respect to infection control. *See, e.g.*, 42 U.S.C. §§ 1395i-3(d)(3)(A), 1396r(d)(3)(A); 42 C.F.R. § 483.80. None of the guidance documents that OLOC cites indicates that the federal government was

asserting a different kind of control than it previously had under these laws.

Second, OLOC argues that it was performing "the job of containment" of COVID-19, which it suggests was a "job the federal government had to do itself but could not." Appellants' Br. 53. But OLOC does not argue that the federal government specifically arranged with OLOC to operate a new facility for COVID-19 patients or otherwise delegated some duty or authority to OLOC. *Cf. Agyin*, 986 F.3d at 176 (emphasizing formal delegation in finding federal contractor entitled to invoke § 1442(a)(1)). OLOC simply continued to perform the same nursing and rehabilitation care that it provided as a private entity before the pandemic, with the same obligation to contain infection within its walls. Any difference was "one of degree, not kind." *Watson*, 551 U.S. at 157. Moreover, all Americans could say they were "enlisted" to assist the federal government in helping "contain" the coronavirus, by being asked to social distance, wear facial coverings, and stay at home if possible. That does not mean we were all "acting under" federal officers. As one district court noted, a nursing home's "argument that it is a federal officer because it implemented COVID-19 protocol that the federal government

promulgated generally to the entire country is borderline frivolous." *Moody*, 2021 WL 4134414, at *7. *Cf. Watson*, 551 U.S. at 153 (rejecting interpretation of "acting under" provision "that would expand the scope of the statute considerably, potentially bringing within its scope state-court actions filed against private firms in many highly regulated industries"). A private actor is not "acting under" federal officers every time it does something that the federal government appreciates, encourages, or even requires.

Finally, OLOC points to four district court decisions that held that the fact that meatpacking plants participate in one of the sixteen sectors of the economy designated as "critical infrastructure" meant certain "informal communications" between the federal government and a meatpacking company were sufficient to show the requisite special relationship. Appellants' Br. 53–55 (citing *Fields v. Brown*, 519 F. Supp. 3d 388 (E.D. Tex. 2021); *Wazelle v. Tyson Foods, Inc.*, 2021 WL 2637335 (N.D. Tex. June 25, 2021); *Johnson v. Tyson Foods, Inc.*, 2021 WL 5107723 (W.D. Tenn. Nov. 3, 2021); *Reed v. Tyson Foods, Inc.*, 2021 WL 5107725 (W.D. Tenn. Nov. 3, 2021)). Those cases are irrelevant. Unlike in those cases, OLOC made no reference to its status as critical

infrastructure in either its notice of removal, A-9, or its opposition to the motion to remand, ECF 35, and thus any such argument is waived. *See Agyin*, 986 F.3d at 181 ("[W]hen determining whether jurisdiction is proper, we look only to the jurisdictional facts alleged in the Notices of Removal.") (cleaned up); *In re Tribune*, 10 F.4th at 168 (waiver standard).

Moreover, four courts of appeals have now rejected the argument that a critical infrastructure designation, or the same guidance documents issued to critical infrastructure entities cited by OLOC (at 55), is meaningful for the "acting under" analysis. *See Mitchell*, 2022 WL 714888, at *6; *Saldana*, 27 F.4th at 685; *Buljic v. Tyson Foods*, 22 F.4th 730, 741 (8th Cir. 2021); *Maglioli*, 16 F.4th at 406. By characterizing the argument that critical infrastructure designation supports federal-officer removal as "absurd," *Mitchell*, 2022 WL 714888, at *6, the Fifth Circuit deprived the contrary assertions in two of the four cases cited by OLOC, *Fields* and *Wazelle*, of any authority. As the Eighth Circuit explained in *Buljic*, "the fact that an industry is considered critical does not necessarily mean that every entity within it fulfills a basic governmental task or that workers within that industry are acting under the direction of federal officers." *Buljic*, 22 F.4th at 741; *see also Mitchell*, 2022 WL

714888, at *6 (endorsing *Buljic*). "[D]octors, weather forecasters, clergy, farmers, bus drivers, plumbers, dry cleaners, and many other workers" are all part of the nation's essential critical infrastructure, but "Congress did not deputize all of these private-sector workers as federal officers." *Maglioli*, 16 F.4th at 406. A nursing home's "status as a critical infrastructure entity does not establish that it acted under a federal officer or agency, or that it carried out a government duty." *Saldana*, 27 F.4th at 685.

C. OLOC lacks a colorable federal defense.

OLOC also lacks a colorable federal defense, as required under section 1442(a). As explained above, pp. 26–32, OLOC's invocation of the PREP Act as a defense fails, because the complaint does not allege that Ms. Martinez's death had a "causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). Furthermore, even under the view of PREP Act immunity espoused by HHS, the PREP Act is inapplicable, because there is no allegation that Ms. Martinez died from non-use of a covered countermeasure that resulted from "prioritization or purposeful allocation" of such a covered countermeasure. Fourth Amendment, 85

Fed. Reg. at 79,194. Accordingly, the invocation of PREP Act immunity is "wholly insubstantial and frivolous." *Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286, 297 (5th Cir. 2020).

CONCLUSION

The Court should affirm the district court's remand order.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I certify that this brief complies with the typeface and volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(5), (a)(6), and (a)(7)(B) and Local Rule 32.1(a)(4) as follows: The proportionally spaced typeface is 14-point Century Schoolbook and, as calculated by my word processing software (Microsoft Word for Office 365), the brief contains 13,688 words, exclusive of those parts of the brief not required to be included in the calculation by Federal Rule of Appellate Procedure 32(f) and the rules of this Court.

/s/ Adam R. Pulver
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