21-2164

IN THE 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
No. 20-cv-5153, The Honorable Nicholas M. Garaufis

BRIEF OF DRI, INC. AS *AMICUS CURIAE*
IN SUPPORT OF APPELLANTS AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Amicus curiae DRI, Inc. has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

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DRI, Inc. is an international membership organization of approximately 16,000 attorneys who defend parties in civil litigation. DRI's mission includes enhancing the skills, effectiveness, and professionalism of civil defense lawyers, promoting appreciation for the role of defense lawyers in our legal system, and anticipating and addressing substantive and procedural issues that are germane to defense lawyers and the clients they represent. DRI has served as a voice in the ongoing effort to make the civil justice system more fair and efficient. To accomplish these objectives, DRI participates as *amicus curiae* in cases that raise issues of vital concern to its members, their clients, and the judicial system.

The COVID-19 pandemic has sparked considerable litigation concerning the standard of care and the protective measures used to combat the disease. Many defendants have sought removal on the basis that they acted under the direction of federal officers, and have invoked immunities conferred by federal law. The relevant federal statutes, and federal administrative action pursuant to delegated authority, should receive a consistent interpretation in federal court. DRI, its

[1] All parties have consented to the filing of this brief. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No person other than *amicus curiae*, its members, or its counsel contributed money that was intended to fund preparing or submitting this brief.

members, and their clients have a significant interest in ensuring that such claims are heard in federal court to the full extent provided by federal law.

INTRODUCTION AND SUMMARY OF ARGUMENT

In the early days of the pandemic—before vaccines and monoclonal antibody treatments—the fight against the COVID-19 pandemic called on Americans to follow a handful of public-health guidelines: wear a mask, stand six feet apart, wash your hands, and stay at home. Nursing homes, by contrast, had a much longer list of infection-control measures to follow, in large part because of the vulnerable population that they serve. And for the vast majority of those operators, the measures were not a choice or a recommendation, but a requirement imposed by the federal government. The federal government is able to command compliance not just because it wields regulatory authority, but also because of the outsized federal role in arranging care for the elderly and others who require assistance in their day-to-day lives.

Plaintiff filed suit in New York state court over measures that Defendants allegedly took—or failed to take—to stop the spread of COVID-19. Defendants removed to federal court, which had both federal-question jurisdiction (because of complete preemption under the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d) and jurisdiction under the federal-officer removal statute, 28 U.S.C. § 1442(a)(1). But instead of exercising jurisdiction, the District

Court remanded the cases back to state court ("Remand Order"). The Remand Order was incorrect, for at least two reasons.

I. The PREP Act confers federal jurisdiction. The Act provides that the only permissible civil action against certain "covered persons" about "covered countermeasures," as designated by the Secretary of Health and Human Services (HHS), is a federal one. The lawsuit here is about how Defendants deployed such countermeasures on a programmatic level—a type of suit that the Secretary has expressly stated should be barred by the PREP Act. Yet the District Court incorrectly reasoned that the PREP Act did not provide for complete preemption because the Act provided for a "federal administrative remedy," not an exclusive federal cause of action. A212.

The District Court's decision disregards the thoughtful, comprehensive scheme that Congress created for injuries caused by covered countermeasures. The PREP Act creates what it expressly labels an "exclusive Federal cause of action" for a narrow subset of claims involving willful misconduct, and it funnels all interlocutory appeals of decisions denying PREP Act immunity to a single federal court of appeals. The availability of compensation through a federal *administrative* regime, which the District Court emphasized, in no way undermines the PREP Act's focus on ensuring that any *suit* proceeds in federal court. If left to stand, the decision will undermine the uniformity that Congress intended when it enacted the PREP Act;

force healthcare providers to commit valuable resources to litigation defense that are better committed to combatting the pandemic; and complicate COVID-19-related risk assessment by creating a complex patchwork of state-court decisions.

II. The federal-officer removal statute, 28 U.S.C. § 1442(a)(1), which the District Court did not even address at all, also applies here because Defendants were "acting under" federal authority in responding to the COVID-19 pandemic. Nursing homes participating in the Medicare and Medicaid programs have a special relationship with the federal government, one in which they provide an essential service on the government's behalf. Skilled-nursing-facility operators like Defendants are following the COVID-19-related directives of the federal government not simply because they are subject to federal regulation, but because they risk sanctions (possibly even a loss of funding and certification) if they fail to comply. As part of that special relationship, Defendants "acted under" federal officers and the propriety of their actions must be assessed in federal court.

ARGUMENT

I. The PREP Act completely preempts Plaintiff's claims because it demonstrates Congress's intent that the Act be interpreted in a centralized, consistent way by federal courts alone.

A. The PREP Act gives the Secretary of HHS the authority to immunize those responding to public health emergencies (including pandemics) from federal and state-law claims, thereby completely preempting those claims.

Congress enacted the relevant provision of the PREP Act, 42 U.S.C. § 247d-6d, to give the Secretary of HHS the authority to "declare limited liability protection" when facing a public health emergency, such as "the threat of pandemic flu." 151 Cong. Rec. 30,409 (2005) (statement of Rep. Nathan Deal, chairman of the Health Subcommittee). Congress anticipated that such protection would be needed, for example, "to make sure doctors are willing to give [a vaccine] when the time comes." *Id.* Persons covered by the PREP Act are "immune from suit and liability under Federal and state law," except for an "exclusive Federal cause of action" for the most serious injuries caused by the most serious misconduct. 42 U.S.C. §§ 247d-6d(a)(1), (d)(1). That federal cause of action may be heard only in a specific federal court, in the District of Columbia, with specific rights of appeal to the D.C. Circuit. As an alternative to suing the private parties responsible for administering pandemic countermeasures, some claimants may receive compensation from a federal fund through a federal administrative process. The overall effect of this structure is to

federalize litigation and, to the extent a claim exceeds the federal statutory limits on cases that may come to court, to require the federal district court to dismiss it.

Specifically, the PREP Act gives the Secretary of HHS the power to declare that a "covered person" is "immune from suit and liability under Federal and State law" for any claim of loss "caused by, arising out of, or resulting from" "the manufacture, testing, development distribution, administration, or use of one or more covered countermeasures." 42 U.S.C. § 247d-6d(a)(1), (b)(1). Among the listed "covered countermeasures" are "a qualified pandemic or epidemic product," such as "a product manufactured, used, designed, developed, modified, licensed, or procured" to "diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic," and "a respiratory protective device that is approved by the National Institute for Occupational Safety and Health" and determined to be a "priority for use during a public health emergency" by the Secretary. *Id.* § 247d-6d(i)(1)(A), (D); *id.* § 247d-6d(i)(7). A "covered person" includes (inter alia) a "qualified person who prescribed, administered, or dispensed such countermeasure," and a "program planner" who supervised or administered a program for doing so. *Id.* § 247d-6d(i)(2)(B)(iii), (i)(2)(B)(iv), (i)(6).

As noted, the immunity resulting from the Secretary's declaration does not leave injured people without recourse. The PREP Act's other operative provision creates a federal "Covered Countermeasure Process Fund," which provides

compensation for individuals who suffer "serious physical injury or death" that is "directly caused by the administration or use of a covered countermeasure." *Id.* §§ 247d-6e(b)(1), (b)(3). An individual with an eligible injury may file an administrative claim for recovery from the Fund. *See* 42 C.F.R. pt. 110.

The Act states that "the sole exception to the immunity from suit and liability of covered persons … shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury *proximately caused by willful misconduct*, as defined." 42 U.S.C. § 247d-6d(d)(1) (emphasis added); *see id.* § 247d-6d(c)(1)(A) (defining "willful misconduct"). These actions must be filed in the U.S. District Court for the District of Columbia, to be heard initially by a three-judge panel. *Id.* § 247d-6d(e)(1), (5). And before filing suit, any potential plaintiff must first seek recovery from the Fund. *Id.* § 247d-6e(d)(1).

The PREP Act also specifies that the U.S. Court of Appeals for the D.C. Circuit "shall have jurisdiction of an interlocutory appeal by a covered person" regarding the denial of a motion to dismiss or motion for summary judgment "based on an assertion of the immunity from suit." *Id.* § 247d-6d(e)(10).

B. In response to the COVID-19 pandemic, HHS declares that COVID countermeasures are "covered" by the PREP Act, with an understanding that the declaration will completely preempt state-law claims.

On March 17, 2020, the Secretary issued a COVID-19-related PREP Act declaration, defining the universe of "covered countermeasures" as "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." Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020). HHS provided for immunity to apply broadly; the initial March 17, 2020 declaration stated that a covered "administration" of a countermeasure includes "*decisions* directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients," and that such declaration "precludes a liability claim relating to the management and operation of a countermeasure distribution program." *Id.* at 15,200 (emphasis added). And in its advisory guidance accompanying the various declarations made under the PREP Act, HHS's General Counsel has stated plainly that "[u]nder the PREP Act, immunity is broad." HHS, Office of the Secretary, General Counsel, *Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act April 17, 2020 as Modified on May 19, 2020*, at 7 (May 19, 2020), *available at* https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf.

HHS amended the Declaration nine times, issued seven guidance documents, and provided six advisory opinions on how to apply the Declaration, with each development tracking the progress of COVID-19 and the nation's response to it. *See*

HHS, *Public Readiness and Emergency Preparedness Act*, https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

HHS recognized in the early stages of the pandemic that covered persons had to make difficult decisions about how to administer medical care and should not be exposed to suit or liability for that decisionmaking. It declared that immunity relating to "covered countermeasures" included immunity from suits about the alleged failure to provide covered countermeasures. Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79,190, 79,197 (Dec. 3, 2020) ("Fourth Amendment") (scope of declaration includes decisions to "not administer[] a Covered Countermeasure to one individual in order to administer it to another individual").

In a subsequent Advisory Opinion ("Advisory Opinion 21-01"), HHS reaffirmed that "[p]rioritization or purposeful allocation of a Covered Countermeasure" and "decision-making that leads to the non-use of covered countermeasures by certain individuals" are "expressly covered by PREP Act." HHS, Office of the Secretary, General Counsel, *Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision* 3-4 (Jan. 8, 2021), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-

preemption-01-08-2021-final-hhs-web.pdf. In the agency's view, "program planning," which includes the "administration, dispensing, distribution, provision, or use of … a qualified pandemic or epidemic product," "inherently involves the allocation of resources," and "some individuals are going to be denied access to them." *Id.* at 4. These circumstances, according to HHS, were subject to the PREP Act's immunity: "[p]rioritization or purposeful allocation of a Covered Countermeasure … can fall within the PREP Act and this Declaration's liability protections." *Id.* at 3. HHS anticipated that the only instance where the PREP Act would not apply is a situation where the defendant fails "to make any decisions whatsoever." *Id.*

Advisory Opinion 21-01 also firmly states HHS's position that any suit "related to the use or non-use of covered countermeasures against COVID-19" is completely preempted. *Id.* at 1, 3-4. HHS has taken the view that "[t]he PREP Act is a 'complete preemption' statute," *id.* at 2, and a federal district court should not be stymied by a plaintiff's well-pleaded complaint alleging only violations of state law to conclude that the claims are completely preempted by the PREP Act, *id.* at 4.

II. The District Court's ruling misapplies complete-preemption doctrine and incorrectly authorizes a patchwork of state-court decisions on immunity.

Both in words and in substance, the PREP Act does exactly what a federal statute should do when Congress seeks to replicate the effect of other completely-

preemptive statutes. Complete preemption occurs when federal law "provide[s] the exclusive cause of action" for the type of claim being asserted. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8, 9 (2003); *accord, e.g.*, *Briarpatch Ltd., L.P. v. Phoenix Pictures*, 373 F.3d 296, 305 (2d Cir. 2004) ("exclusive federal cause of action"). That is *exactly* what the PREP Act says, *in those same words*: it creates "an exclusive Federal cause of action," which must be heard in a *specific* federal forum guaranteeing uniformity, and it provides that the exclusive Federal cause of action shall be "the sole exception to the immunity from suit and liability of covered persons." 42 U.S.C. § 247d-6d(d)(1). The District Court's reasons for refusing to apply complete preemption—that the cause of action is *limited* as well as exclusive, and that federal law provides some administrative compensation rather than leaving claimants empty-handed—misapply the law as laid down by the Supreme Court and this Court.

A. Complete preemption means that the only viable causes of action are federal—even if not every plaintiff will have a viable federal cause of action.

The District Court made precisely the same mistake that the Supreme Court has repeatedly reversed. When a federal statute gives rise to complete preemption, it disallows any cause of action other than the federal one. But some plaintiffs seeking to sue in state court under state law will not qualify for a federal cause of action. As the Supreme Court has repeatedly said, those claims are completely

preempted, too, even though they are subject to dismissal on the merits. The District Court here misunderstood that point.

When the "preemptive force" of a federal statute "is so powerful as to displace entirely any state cause of action," *i.e.*, where there is complete preemption, a federal court may exercise jurisdiction over a case despite the lack of a federal claim expressly alleged in the well-pleaded complaint, because the only available remedy is a federal one. *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 64 (1987) (citation and internal quotation marks omitted); *see Aetna Health Inc. v. Davila*, 542 U.S. 200, 207 (2004); *Briarpatch*, 373 F.3d at 305 (holding that complete preemption extends "to any federal statute that both preempts state law and substitutes a federal remedy for that law, thereby creating an exclusive federal cause of action").

In both *Davila* and *Beneficial*, the court of appeals had held that the plaintiffs' claim (under ERISA or the National Bank Act) was not completely preempted because it did not match the available federal cause of action. Thus, for instance, Davila wanted to sue his health plan for medical malpractice under a state statute; ERISA does not provide a cause of action for medical negligence, but only one for collecting benefits; so, the Fifth Circuit reasoned, the state cause of action was not completely preempted. *Roark v. Humana, Inc.*, 307 F.3d 298, 309-11 (5th Cir. 2002). The Supreme Court reversed, squarely rejecting the view "that only strictly duplicative state causes of action are pre-empted." 542 U.S. at 216; *accord*

Beneficial, 539 U.S. at 11 ("[T]here is, in short, no such thing as a state-law claim of usury against a national bank."); *Madden v. Midland Funding, LLC*, 786 F.3d 246, 250 (2d Cir. 2016) (confirming that this displaces "New York's stricter usury laws").

Thus, the District Court erred in holding that, because the PREP Act "establishes an administrative remedy in the first instance," it "does not create an exclusive federal cause of action." A212. The District Court should have considered whether the cause of action that the PREP Act *does* provide is exclusive of any other cause of action, federal or state, and whether Congress has set forth procedures governing recovery. As discussed below, the answer is yes.

B. Exclusive federal jurisdiction is critical for fulfilling Congress's intent in enacting the PREP Act.

1. Here, as Appellants explain (at 26-33), the PREP Act is a federal statute that is "so powerful as to displace entirely any state cause of action." *Beneficial*, 539 U.S. at 7. It provides a broad immunity *from suit and liability*, with a single, "exclusive[ly] Federal" exception. And the "exclusive Federal cause of action" comes with an even more exclusive federal forum designed to promote consistent decisionmaking. That text and structure refute any notion that Congress intended to allow hundreds of different state courts to reach their own conclusions about the meaning and scope of the PREP Act.

First, the immunity is markedly broad. The Act immunizes covered persons "from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, *relating to*, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The words "relating to" have a "broad" meaning: "to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (citation and internal quotation marks omitted). Properly applied to the Secretary's COVID-19 declaration and amendments, "relating to" should encompass any claim that in any way involves a decision to use (or not to use) a COVID-19 countermeasure, including personal protective equipment. And, notably, the statute expressly provides an immunity "*from suit*"; the appellate decision that the Supreme Court reversed in *Beneficial* had refused to apply complete preemption because it did not think the National Bank Act provided such an immunity "from facing suit in state court." *Anderson v. H&R Block, Inc.*, 287 F.3d 1038, 1045 (11th Cir. 2002). Congress in the PREP Act left no such ambiguity.

Second, as "the sole exception" to its decision to displace both federal and state causes of action, Congress allowed only a limited, "exclusive Federal cause of action." 42 U.S.C. § 247d-6d(d)(1). No other cause of action is permissible; rather, the alternative is a comprehensive compensation scheme for those who are seriously

injured or killed by the use of a covered countermeasure. That federal exclusivity exactly fits what the Supreme Court and this Court had both said, shortly before the PREP Act's enactment, is the key to complete preemption. *Beneficial*, 539 U.S. at 8 (complete preemption exists where "the federal statutes at issue provide[] the exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action"); *Briarpatch*, 373 F.3d at 305 (complete preemption exists where Congress "substitutes a federal remedy" for preempted state law and thus "create[s] an exclusive federal cause of action").

Third, Congress provided that a single federal district court would have jurisdiction over any suits in this area. And that district court would proceed, up through summary judgment, as a three-judge panel—an unusual measure designed to promote uniformity on pretrial legal rulings within even that single district. 42 U.S.C. § 247d-6d(e)(1), (5). Those textual indicia of federal exclusivity are even greater than in ERISA—which is a canonical example of complete preemption even though it allows a subset of its exclusively federal causes of action to be pursued in state court. *See* 29 U.S.C. § 1132(e)(1).

Fourth, Congress provided without limitation that any interlocutory appeal construing PREP Act immunity will go to the D.C. Circuit. Specifically, any "interlocutory appeal by a covered person … of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit

conferred by [§ 247d-6d(a)]" falls into the appellate jurisdiction of "[t]he United States Court of Appeals for the District of Columbia Circuit." 42 U.S.C. § 247d-6d(e)(10).

Fifth, confirming the point, the PREP Act also expressly prohibits a state from enforcing "any provision of [state] law or [state] legal requirement" that "is different from, or is in conflict with" any provision of the PREP Act that "relates to … the prescribing, dispensing, or administration by qualified persons of [any] covered countermeasure." *Id.* § 247d-6d(b)(8). A cause of action that supplements what the PREP Act allows is squarely "in conflict" with the PREP Act's decision to make its cause of action "exclusively Federal." *Cf. Davila*, 542 U.S. at 216 (explaining that "Congress' intent to make the ERISA civil enforcement mechanism exclusive would be undermined if state causes of action that supplement the ERISA § 502(a) remedies were permitted").

2. Allowing Plaintiff's claims to proceed in state court despite Congress's clear and complete preemption of any state-court claims would disrupt the uniformity expected by the PREP Act. As the Secretary stressed in the Fourth Amendment, "there are substantial federal legal and policy issues" and thus, a substantial federal interest "in having a uniform interpretation of the PREP Act." 85 Fed. Reg. at 79,194. Uniformity and consistency in legal liability relating to the

administration of COVID-19 countermeasures is essential, in the Secretary's view, to the "whole-of-nation response" to the persisting pandemic. *Id.*

The Secretary's desire for uniformity and consistency is well founded in the statute's text. Congress intended to achieve uniformity in decisionmaking about PREP Act liability by funneling all appeals about immunity to a single *federal* court of appeals. That uniformity would be frustrated if artfully-pleaded state-law claims that should be displaced by the PREP Act's comprehensive remedial scheme were to remain in state court. State court decisions cannot be reviewed by a federal court of appeals, *see* Appellants' Br. 30, and state appellate courts may reach disparate decisions about immunity on a similar set of facts.

Moreover, the exercise of federal jurisdiction is particularly appropriate where there is a need to "resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005); *e.g.*, *Treiber & Straub, Inc. v. UPS Inc.*, 474 F.3d 379, 383-84 (7th Cir. 2007) (federal jurisdiction by way of federal common law where there is a "need for uniformity in interstate shipping and commerce"); *Hussmann v. Trans World Airlines, Inc.*, 169 F.3d 1151, 1153 (8th Cir. 1999) (federal jurisdiction by way of complete preemption to advance the goals of "uniformity and certainty in the laws governing international air carrier liability"). Allowing state-law claims implicating covered countermeasures and covered

persons to proceed in state court would wreak considerable uncertainty upon health care providers, particularly those who operate in multiple jurisdictions. A health care provider operating in New York and Connecticut, for example, might find that it is subject to liability for a certain kind of treatment decision in New York, but not in Connecticut, *Mills v. Hartford Health Care Corp.*, No. HHDCV206134761S, 2021 WL 4895676, at *4 (Conn. Super. Ct. Sept. 27, 2021) (PREP Act immunity applies to claims based on a health-care provider's decision to withhold transfer until after COVID-19 test results were returned).

3. The PREP Act's immunity from suit *and* liability clearly reflects Congress's judgment that covered persons should devote their resources to fighting the pandemic at hand, not toward litigation that second-guesses decisions made as part of a whole-of-nation public-health response. Remanding this case (and others like it) to state court would thwart that intent. Failing to honor the uniformity plainly evident in the statutory scheme means that the state courts might choose not to apply the PREP Act's immunity provisions even if the D.C. Circuit has squarely held that immunity from suit should apply under identical circumstances. The provider would then be forced to keep litigating until it can obtain review by the U.S. Supreme Court, in order to vindicate the immunity that should have extinguished the suit at the outset. A covered provider operating in multiple jurisdictions would have to spend considerable resources defending the same policy judgment in different state courts,

whereas a single decision from the D.C. Circuit can provide certainty about whether particular conduct is immune. Immunity from suit is pointless if covered persons are required to go to such lengths to enforce a clear statutory protection. *Cf. Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985) (immunity from suit is "effectively lost if a case is erroneously permitted to go to trial"). Indeed, that is precisely the outcome that Congress sought to avoid when it routed all appeals regarding "an assertion of the immunity from suit" to the D.C. Circuit, and all original actions concerning willful misconduct to the three-judge panel of the D.C. district court.

C. Administrative compensation does not defeat complete preemption.

The District Court concluded that the PREP Act does not give rise to complete preemption because a federal agency provides some remedies to affected individuals. A212. That is no basis for refusing to apply complete preemption. The question is not whether a purely administrative scheme could be completely preemptive. The PREP Act *does* provide a judicial cause of action—a limited and exclusive one, just as ERISA or the National Bank Act does. That is why complete preemption applies, as explained. Adding a federal compensation mechanism preserves the uniformity goal and the liability shield, while providing some additional compensation. It is no reason to allow plaintiffs to sue in *state* court when, if Congress had provided *no* such federal compensation mechanism, their suits would plainly be completely preempted.

* * * * *

The PREP Act was intended to alleviate covered providers from having to fear liability when operating under the stresses of combatting a global pandemic. A single federal court would authoritatively interpret the boundaries of the only cause of action available. The District Court's Remand Order incorrectly strips providers of that certainty by forcing adjudication of state-law claims in state court—thereby inviting a patchwork of state-court decisions on the scope of immunity.

III. A skilled nursing facility that follows federal agency mandates to combat COVID-19 is "acting under" federal authority and thus may remove a civil action concerning its COVID-19 response to federal court.

The federal-officer removal statute, 28 U.S.C. § 1442(a)(1), allows for a civil action brought against "any person acting under" a federal officer to be removed to federal court, so long as the civil action is "for or relating to any act" performed under the federal officer. "The words 'acting under' are broad, and [the Supreme] Court has made clear that the statute must be 'liberally construed'" in a manner favoring access to the federal forum. *Watson v. Philip Morris Cos.*, 551 U.S. 142, 147 (2007) (citation omitted). To show that a civil action is "for or relating to any act," there need only be a "connection" or "association." *In re Commonwealth's Motion to Appoint Counsel Against or Directed to Defender Ass'n of Philadelphia*, 790 F.3d 457, 471-72 (3d Cir. 2015).

A private party that is "involve[d in] an effort to assist, or to help carry out, the duties or tasks of the federal superior" "acts under" a federal officer for purposes of § 1442(a). *Watson*, 551 U.S. at 152. While not every relationship between a private party and the federal government will qualify under the statute, private parties that "help[] officers fulfill [] basic governmental tasks" subject to "detailed regulation, monitoring, or supervision" fall squarely within the universe of defendants qualified to remove a civil action against them. *Id.* at 153. When a private party "perform[s] a job that, in the absence of a contract with a private firm, the Government itself would have had to perform," that party "acts under" a federal officer. *Id.* at 154.

Skilled nursing facilities that participate in Medicare and Medicaid have a "special relationship" with the federal government that has them "acting under" federal officers—namely, the Centers for Medicare and Medicaid Services (CMS). In exchange for federal funding, skilled nursing facilities that provide services to Medicare and Medicaid beneficiaries are subjected to extensive federal regulation, with almost every material aspect of their operations subject to CMS oversight and control. These facilities play an important role in Congress's deliberate design to have private actors provide essential public health services—extended institutional care—in lieu of the federal government, with the private actors' ability to provide such services conditioned on meeting CMS's standards of care. And as part of that

special relationship, skilled nursing facilities, including Defendants' facilities, implemented CMS's prescribed measures for combatting COVID-19.

A. Skilled nursing facilities have a "special relationship" with the federal government and fill a need that the government would otherwise have to provide.

Skilled nursing facilities are a relatively modern innovation. At the turn of the 20th century, the average life expectancy at birth was 47.3 years. Ctrs. for Disease Control, *Life Expectancy at Birth*, https://www.cdc.gov/nchs/data/hus/2010/022.pdf. The few Americans living past the age of 65 lived mostly in their own homes; to the extent that their families could not provide for them, private charities filled the gap. Cong. Research Serv., *Nursing Homes and the Congress: A Brief History of Developments and Issues, No. 72-224*, at 3 (1972) ("CRS Report"). Only the poorest older Americans "created a demand for institutional care"; as they were few in number, their needs were met by poorhouses. *Id.*

But life expectancy and quality of life drastically improved between 1900 and the 1930s, making the poorhouse an "inhumane, inadequate, and unnecessarily costly" answer to the question of senior care. *Id.* at 4. By 1945, private facilities could not satisfy demand for long-term institutional care, and many delivered substandard care. So government intervention became necessary to ensure not only capacity, but also a reasonable baseline standard of care and safety. H.R. Rep. No.

81-1300, at 43 (1949) (explaining that the "standard-setting function" of government was critical to "assur[ing] a reasonable standard of care"). State governments could not effectively regulate private nursing homes; the only tool at their disposal was to strip a nursing home of its license to operate, which was disfavored because the need for skilled care was so overwhelming. *See* CRS Report at 31.

Congress addressed both the lack of capacity and the lack of a minimum standard of care by allowing federal funds to be used for the purpose of building new nursing home facilities, and by requiring facilities that accepted federal dollars to adhere to certain federally mandated standards for the provision of care. CRS Report at 21.

When Congress established the Medicare and Medicaid programs, it continued the arrangement of promoting and funding skilled nursing homes in exchange for federal oversight and control over the quality of care. *See id.* at 1-2. The Medicare Act gave the Department of Health, Education, and Welfare (HHS's predecessor) the power to set standards for extended-care facilities receiving Medicare funding. Institute of Medicine, Committee on Nursing Home Regulation, *Improving the Quality of Care in Nursing Homes* 241 (1986), *available at* https://www.ncbi.nlm.nih.gov/books/NBK217556/pdf/Bookshelf_NBK217556.pdf. Skilled facilities in the Medicaid program initially followed state guidelines, but Congress quickly amended the Medicaid program "to develop standards and

regulations to be applied uniformly by the states," with "the authority to withhold federal funds from nursing homes not meeting the standards." *Id.* at 242.

Today, both the Medicare and Medicaid programs follow the same standards. Under current federal law, state agencies conduct "surveys" to determine whether skilled nursing facilities providing care to Medicare and Medicaid recipients satisfy the conditions for participating in the two programs. 42 U.S.C. § 1395i-3. One such survey is for infection control; skilled nursing facilities must "establish and maintain an infection control program … to help prevent the development and transmission of disease and infection." *Id.* § 1395i-3(d)(3)(A). While the "state survey agency" may make enforcement recommendations, ultimate authority over the continued operation of a skilled nursing facility rests with the Secretary of HHS. *Id.* § 1395i-3(h). Sanctions for failing to meet the conditions of participation include the denial of benefit payments, civil monetary penalties, and, for severe violations, termination of the facility's participation in the Medicare or Medicaid program. *Id.* § 1395i-3(h)(2).

When it comes to skilled nursing facilities participating in the Medicare and Medicaid programs, the federal government's role is not just that of a regulator, but that of a purchaser as well. Skilled nursing facilities have been a federal public-health priority since the 1940s and 1950s; Congress decided to fulfill the need and provide quality care by enlisting private contractors through the Medicaid and

Medicare programs. Had it not entered into private arrangements, the federal government would have had to provide such services directly, given the growing public demand and the inability of state governments to fill the gap in a manner that ensured quality care. When operators of skilled nursing facilities comply with CMS's infection-control mandates to satisfy their conditions of participation in the Medicare and Medicaid programs (with the ultimate risk of losing their contracts if they fail to comply), they are "acting under" federal authorities in rendering their services. *See Jacks v. Meridian Resource Co.*, 701 F.3d 1224, 1232-33 (8th Cir. 2012) (Congress's decision to "establish a health benefits program for federal employees" by "set[ting] up a partnership between [the federal government] and private carriers" meant private carriers rendering services were "acting under" federal officers for removal purposes). Skilled nursing facilities receive payments from Medicare and Medicaid, and in exchange for such payments, are, "at all times … subject to [CMS] oversight, … to [CMS's] regulatory requirements, and ultimately answer[] to federal officers." *Id.* at 1234. The fact that CMS retains the ability to withhold payment, impose a penalty, and terminate a facility's participation in Medicare or Medicaid, means that the federal government is acting as a purchaser and as a delegator of governmental responsibility, not just as a regulator. *Id.* at 1233-34.

B. Skilled nursing facilities "acted under" CMS by implementing COVID-19 related measures at the outset of the pandemic.

While the COVID-19 pandemic has affected every corner of the United States, nursing homes have suffered a significant and disproportionate impact because they care for people among those most at risk. Because most nursing home residents are "older adults with underlying medical conditions," they faced an "increased risk of infection and severe illness from COVID-19" at the outset of the COVID-19 pandemic. Ctrs. for Disease Control & Prevention, *People Who Live in a Nursing Home or Long-Term Care Facility* (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-in-nursing-homes.html. For nursing homes participating in Medicare and Medicaid, their responses to the challenges posed by the COVID-19 pandemic have been dictated by CMS. From the start of the pandemic, CMS has declared that nursing homes "*must* adhere to standards for infection prevention and control in order to provide safe, high quality care." Ctrs. for Medicare & Medicaid Servs., *CMS Prepares Nation's Healthcare Facilities for Coronavirus Threat* (Feb. 6, 2020), https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat (emphasis added). CMS has leveraged its "special relationship" with nursing-home providers to ensure that they implement extensive COVID-19 prevention measures. As a result, nursing homes that follow CMS's directives "act under" federal authority.

On January 31, 2020, HHS declared that COVID-19 posed a public health emergency in the United States. HHS, *Determination That a Public Health Emergency Exists* (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. A week after the declaration of a public health emergency, and as Plaintiff alleges (A68 ¶ 57), CMS issued a memorandum to state survey agency directors reminding skilled nursing facilities that they "must take steps to prepare" for the onset of COVID-19 by "reviewing their infection control policies and practices to prevent the spread of infection." Mem. from Director, Quality, Safety & Oversight Grp., CMS to State Survey Agency Directors, *Information for Healthcare Facilities Concerning 2019 Novel Coronavirus Illness (2019-nCoV)*, No. QSO-20-09-ALL, at 1 (Feb. 6, 2020), https://www.cms.gov/files/document/qso-20-09-all.pdf. CMS reminded facilities that compliance with infection control practices was "part of the normal survey process," and that they were expected to respond to "emerging infectious diseases" as part of their infection control protocols. *Id.* at 2.

On March 4, 2020—just days after the first confirmed case of community transmission in a long-term care facility—CMS issued a new guidance on managing the spread of COVID-19 in nursing homes. Mem. from Director, Quality, Safety & Oversight Grp., CMS to State Survey Agency Directors, *Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing*

Homes, No. QSO-20-14-NH (Mar. 4, 2020). The guidance instructed nursing homes on issues such as visitor access, the use of personal protective equipment (PPE) and maintenance of PPE inventory, the monitoring of nursing home staff, and the acceptance or transfer of residents with COVID-19. *Id.* On March 13, 2020, CMS issued a revised guidance, restricting "visitation of *all* visitors and non-essential health care personnel, except for certain compassionate care situations, such as an end-of-life situation." Mem. from Director, Quality, Safety & Oversight Grp., CMS to State Survey Agency Directors, *Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes (REVISED)*, No. QSO-20-14-NH (Mar. 13, 2020), https://www.cms.gov/files/document/3-13-2020-nursing-home-guidance-covid-19.pdf. The revised guidance also directed "active screening of residents and staff," provided new instructions on social distancing and hand hygiene, and required nursing homes to follow CDC guidance on the use of PPE. *Id.* at 2-4. CMS issued separate guidance on the use of PPE by healthcare workers, including those working in nursing homes. Mem. from Director, Quality, Safety & Oversight Grp., CMS to State Survey Agency Directors, *Guidance for Use of Certain Industrial Respirators by Health Care Personnel*, No. QSO-20-17-ALL (Mar. 10, 2020), https://www.cms.gov/files/document/qso-20-17-all.pdf.

While these directives were styled as "guidance," they were hardly voluntary. At the outset of the pandemic, CMS indicated that it would focus on infection-

control measures, and that surveyors would focus on the measures set forth in the guidance in evaluating whether nursing homes adequately complied with infection-control protocols. Mem. from Director, Quality, Safety & Oversight Grp., CMS to State Survey Agency Directors, *Prioritization of Survey Activities*, No. QSO-20-20-All (Mar. 20, 2020), https://www.cms.gov/files/document/qso-20-20-allpdf.pdf. Facilities that fail to follow CMS guidance are at risk of being deemed out of compliance as part of the survey process. *See* CMS, *COVID-19 Focused Survey for Nursing Homes* (Mar. 20, 2020), https://www.cms.gov/files/document/qso-20-20-allpdf.pdf. Indeed, the failure to follow the survey requirements forms the crux of Plaintiff's claim against Defendants: that Defendants failed "to provide proper infection prevention and control procedures," including ones set forth by CMS, which resulted in Plaintiff's alleged injuries and losses. A68-69 ¶¶ 57-62.

Many skilled nursing facilities have learned that CMS's COVID-19 guidance comes with bite. Between March and August 2020, CMS and state survey agencies completed more than 15,000 infection-control surveys and issued civil monetary penalties of "nearly $10 million to nursing homes in 22 states" for COVID-19 related violations. CMS, *Trump Administration Has Issued More Than $15 Million in Fines to Nursing Homes During COVID-19 Pandemic* (Aug. 14, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-has-issued-more-15-million-fines-nursing-homes-during-covid-19-pandemic.

C. Because COVID-19 infection-control protocols were dictated by CMS, and CMS enforces those protocols as conditions of care, claims regarding nursing homes' standard of care in infection prevention are related to acts "under" federal officers.

For much of its history, the federal-officer removal statute reached only those claims that "grow[] out of conduct under color of office." *Willingham v. Morgan*, 395 U.S. 402, 407 (1969). But in 2011, Congress amended the statute so that it covered any civil action "for or *relating to* any act under color of such office." Removal Clarification Act of 2011, Pub. L. No. 112-51, § 2(b)(1)(A), 125 Stat. 545 (codified in 28 U.S.C. § 1442(a)(1)) (emphasis added). "The ordinary meaning of the words 'relating to' is a broad one—'to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.'" *Defender Ass'n*, 790 F.3d at 471 (quoting *Morales*, 504 U.S. at 383). By adding the words "relating to" to the federal officer removal statute, Congress "intended to 'broaden the universe of acts'" that could be removed to federal court. *Id.* (quoting H.R. Rep. No. 112-17, pt. 1, at 425 (2011)).

For a nursing home with residents whose benefits are paid for by Medicare or Medicaid, the nursing home has no choice but to follow the CMS guidance or risk losing the opportunity to continue providing services on behalf of the federal government. As a result, a claim that the nursing home failed "to provide proper infection prevention and control procedures" will necessarily relate to acts taken under the direction of federal officers, in this case CMS officials. A69 ¶ 61. The

acts by which nursing homes "safeguard[ed] … residents from infection" and restricted visitor access are primarily acts that nursing homes took at CMS's direction. *E.g.*, A68 ¶¶ 57, 59; *see* Guidance No. QSO-20-14-NH (Revised) at 2 (prohibiting nursing-home visitors except in end-of-life compassionate situations, and requiring PPE and hygiene measures for permitted visitors); *id.* at 3-4 (prescribing staff screening measures and PPE use). Accordingly, Plaintiff's case is eligible for removal under the federal-officer removal statute.

CONCLUSION

This Court should reverse the District Court's Remand Order.

Dated: January 3, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(4), Local Rule 29.1(c), and 32(g)(1), I hereby certify that the foregoing Brief of DRI, Inc. as Amicus Curiae Supporting Appellants complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5). According to the word count feature of Microsoft Word, the word-processing system used to prepare the brief, the brief contains 6,981 words.

I further certify that the foregoing brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman font, a proportionally spaced typeface.

Dated: January 3, 2022

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2022, I electronically filed the foregoing document with the United States Court of Appeals for the Second Circuit by using the CM/ECF system.

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

Dated: January 3, 2022

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