**UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT**

**Thurgood Marshall U.S. Courthouse 40 Foley Square, New York, NY 10007 Telephone: 212-857-8500**

**MOTION INFORMATION STATEMENT**

**Docket Number(s):** 21-2158, 21-2159 Caption [use short title] Leroy v. Hume

**Motion for:** leave to file brief of DRI, Inc. as amicus curiae supporting Appellants and Reversal

Set forth below precise, complete statement of relief sought:

Grant leave to file brief as amicus curiae

**MOVING PARTY:** DRI, Inc. (amicus curiae) **OPPOSING PARTY:** Plaintiffs-Appellees

☐ Plaintiff ☐ Defendant

☐ Appellant/Petitioner ☐ Appellee/Respondent

**MOVING ATTORNEY:** William M. Jay **OPPOSING ATTORNEY:** Jordan Merson

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Court- Judge/ Agency appealed from: U.S. District Court for the Eastern District of New York / The Honorable Allyne K. Ross

**Please check appropriate boxes:**

Has movant notified opposing counsel (required by Local Rule 27.1):
☑ Yes ☐ No (explain):

Opposing counsel's position on motion:
☐ Unopposed ☑ Opposed ☐ Don't Know

Does opposing counsel intend to file a response:
☐ Yes ☐ No ☑ Don't Know

**FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUCTIONS PENDING APPEAL:**

Has this request for relief been made below? ☐ Yes ☐ No

Has this relief been previously sought in this court? ☐ Yes ☐ No

Requested return date and explanation of emergency:

Is oral argument on motion requested? ☐ Yes ☑ No (requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☑ No If yes, enter date:

**Signature of Moving Attorney:**

s/ William M. Jay **Date:** 1/3/2022 Service by: ☑ CM/ECF ☐ Other [Attach proof of service]

# 21-2158, -2159

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

JEFFRY LEROY, as Co-Guardian of Silvia Leroy, Incapacitated Person and Individually; SILVIA LEROY,

*Plaintiffs-Appellees*,

v.

HEATHER HUME, M.D., MIRA JOHN, M.D., MOUNT SINAI HOSPITAL, MARY TOUSSAINT-MILORD, M.D., KANIZ B. BANU, M.D., MAHREEN AKRAM, M.D., JAMIE CELESTIN-EDWARDS, BROOKDALE HOSPITAL MEDICAL CENTER, JILL BERKIN, M.D., KEVIN TROY, M.D.,

*Defendants-Appellants*,

MINDY BRITTNER, M.D.,

*Defendant.*

On Appeal from the United States District Court
for the Eastern District of New York
No. 20-cv-5325, The Honorable Allyne K. Ross

**MOTION OF *AMICUS CURIAE* DRI, INC. FOR LEAVE TO FILE BRIEF IN SUPPORT OF APPELLANTS AND REVERSAL**

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January 3, 2022

## CORPORATE DISCLOSURE STATEMENT

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

Pursuant to Federal Rule of Appellate Procedure 29(a), DRI, Inc. respectfully seeks leave to file the attached brief as *amicus curiae* supporting Appellants. Appellants consent to DRI's motion for leave; Appellees do not consent.

**A. Interest of the Amicus Curiae**

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 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 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.

### B. Reasons for Granting Leave to File

DRI's proposed amicus brief will aid this Court's consideration of this appeal. The brief provides additional insight as to how the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, completely preempts any state-law claim relating to the use (or decision not to use) of covered countermeasures as part of the whole-of-nation effort to combat the COVID-19 pandemic. The brief also explains why the District Court's contrary holding—that the court lacked removal jurisdiction over Plaintiffs' claims because none of the claims are completely preempted by the PREP Act—frustrates the uniformity and consistency that both Congress and the Secretary of Health and Human Services sought to achieve through the PREP Act (and the Secretary's administration thereof). DRI's brief amplifies on points made in Appellants' briefs, including the correct application of the complete preemption doctrine drawn from cases in other contexts, thus enabling the brief to be helpful to the Court on the issues raised by Appellants, without being redundant or cumulative.

DRI has filed amicus briefs in other cases presenting similar questions about removal jurisdiction based on the PREP Act, including a case currently pending in this Court on exactly the same schedule. Brief of DRI, Inc. as *Amicus Curiae* in Support of Appellants and Reversal, No. 21-2164, *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Center* (2d Cir. filed Jan. 3, 2022); Brief of DRI, Inc. as

*Amicus Curiae* in Support of Appellants and Reversal, Nos. 20-2833, 20-2834, *Estate of Joseph Maglioli v. Alliance HC Holdings* (3d Cir. filed Feb. 16, 2021). The parties to *Rivera-Zayas* have consented to DRI's filing, and DRI's brief in that case is substantively identical to the brief it seeks permission to file here. DRI respectfully submits that it should be afforded the same opportunity to provide the same insights in this case, which presents the same issue and is being considered at the same time.

For the foregoing reasons, this Court should grant DRI leave to file the proposed *amicus* brief in support of Appellants.

Dated: January 3, 2022

Respectfully submitted,

/s/ William M. Jay

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 567 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f).

I further certify that this motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this motion has been prepared in a proportionally spaced 14-point Times New Roman typeface using Microsoft Word 365.

/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.

/s/ William M. Jay
William M. Jay

# 21-2158, -2159

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FOR THE SECOND CIRCUIT

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v.

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

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# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**PAGE(S)**

**CASES**

**STATUTES**

**REGULATIONS**



**LEGISLATIVE HISTORY**



**OTHER AUTHORITIES**

## INTEREST OF THE AMICUS CURIAE[1]

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[1] 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.

## INTRODUCTION AND SUMMARY OF ARGUMENT

Throughout the COVID-19 pandemic, medical professionals have been called upon to make judgments about how to use the resources they have to care for their patients. The challenges posed by empty shelves and supply rooms were most acute and dire during the earliest days of the pandemic, when personal protective equipment was in such short supply it was often reused, testing capacity was minimal, and vaccines were only a distant ambition to be sought at warp speed.

To give healthcare providers some measure of certainty in this uncertain time, the Secretary of Health and Human Services (HHS) issued a declaration under the Public Readiness and Emergency Preparedness (PREP) Act, which allows the Secretary to provide immunity from suit and legal liability to "covered persons" using "covered countermeasures" as part of a whole-of-nation effort to combat a public health emergency. 42 U.S.C. § 247d-6d. Anyone seeking to recover for serious injuries or death resulting from actions subject to immunity is required to file a claim with a designated compensation fund administered by the Secretary and, in the case of willful misconduct, may pursue recovery by filing an action before a three-judge panel of the U.S. District Court for the District of Columbia, if the administrative fund does not provide an adequate remedy. Here, the Secretary's declaration for COVID-19 (and all corresponding amendments and guidance) established that decisions *relating to* the administration and use (or non-use) of

covered countermeasures, such as COVID-19 tests, would be subject to the PREP Act's immunity provisions. The Department of Health and Human Services also expressed the view that the broad immunity afforded to covered persons using COVID-19-related countermeasures completely preempted any state-law claims relating to such countermeasures.

Despite the broad, sweeping immunity and displacement of state-law claims afforded by the PREP Act, the District Court did not agree with the Secretary's conclusion that the PREP Act gives rise to federal jurisdiction by completely preempting state-law claims. Rather, in its order granting Plaintiffs' motion to remand ("Remand Order"), the District Court 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. SPA9.

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. 42 U.S.C. §§ 247d-6d(d)(1), (e)(10). 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.

For these reasons, the District Court's Remand Order should be reversed.

## 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 Health and Human Services (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 January 21, 2020, the Centers for Disease Control and Prevention confirmed that the first COVID-19 case had been detected in the United States. CDC, *First Travel-related Case of 2019 Novel Coronavirus Detected in the United States* (Jan. 21, 2020), https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html. Ten days later, the Department of Health and Human Services declared that COVID-19 posed a public health emergency in the United States. *Determination That a Public Health Emergency Exists* (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

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. (First, HHS addressed concerns relating to testing and protective equipment; later, it addressed issues relating to vaccine implementation.) *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 emphasizing that, for cases not involving "willful misconduct" (among other elements), "the [PREP] Act provides no causes of action at all." SPA7. What matters is 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, Brookdale Br. 25-31, Mt. Sinai Br. 23-28, 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 COVID-19 tests. 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 Plaintiffs' 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* Brookdale Br. 35; Mt. Sinai Br. 39, 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, whereas the federal courts can only hear a cause of action for willful misconduct. SPA8-SPA9. 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.

## 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 Rule of Appellate Procedure 29(a)(4), Local Rule 29.1(c), and Federal Rule of Appellate Procedure 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 4,508 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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