Nos. 20-2833, 20-2834

IN THE
UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ESTATE OF JOSEPH MAGLIOLI, BERNARD MAGLIOLI, DANTE MAGLIOLI, ESTATE OF DALE PETRY, CHRISTOPHER PETRY,
Plaintiffs-Appellees,

v.

ALLIANCE HC HOLDINGS, d/b/a Andover Subacute & Rehabilitation, ALLIANCE HC II LLC, d/b/a Andover Subacute & Rehabilitation II, CHAIM SCHEINBAUM, LOUIS SCHWARTZ,
Defendants-Appellants.

(Caption continued on inside cover)

On Appeal from the United States District Court
for the District of New Jersey

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

Andrew Kim
William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
(202) 346-4000
andrewkim@goodwinlaw.com
wjay@goodwinlaw.com

Counsel for Amicus Curiae

February 16, 2021

ESTATE OF WANDA KAEGI, VICTOR KAEGI, ESTATE OF STEPHEN BLAINE, SHARON FARRELL,

Plaintiffs-Appellees,

v.

ALLIANCE HC HOLDINGS, d/b/a Andover Subacute & Rehabilitation, ALLIANCE HC II LLC, d/b/a Andover Subacute & Rehabilitation II, CHAIM SCHEINBAUM, LOUIS SCHWARTZ,

Defendants-Appellants.

United States Court of Appeals for the Third Circuit

Corporate Disclosure Statement and Statement of Financial Interest

No. 20-2833, 20-2834

ESTATE OF JOSEPH MAGLIOLI et al. (No. 20-2833);
ESTATE OF WANDA KAEGI et al. (No. 20-2834),
Plaintiffs-Appellees

v.

ALLIANCE HC HOLDINGS, d/b/a Andover Subacute & Rehabilitation et al. (Nos. 20-2833 & 20-2834),
Defendants-Appellants

Instructions

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure any nongovernmental corporate party to a proceeding before this Court must file a statement identifying all of its parent corporations and listing any publicly held company that owns 10% or more of the party's stock.

Third Circuit LAR 26.1(b) requires that every party to an appeal must identify on the Corporate Disclosure Statement required by Rule 26.1, Federal Rules of Appellate Procedure, every publicly owned corporation not a party to the appeal, if any, that has a financial interest in the outcome of the litigation and the nature of that interest. This information need be provided only if a party has something to report under that section of the LAR.

In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate shall provide a list identifying: 1) the debtor if not named in the caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is an active participant in the bankruptcy proceedings. If the debtor or the bankruptcy estate is not a party to the proceedings before this Court, the appellant must file this list. LAR 26.1(c).

The purpose of collecting the information in the Corporate Disclosure and Financial Interest Statements is to provide the judges with information about any conflicts of interest which would prevent them from hearing the case.

The completed Corporate Disclosure Statement and Statement of Financial Interest Form must, if required, must be filed upon the filing of a motion, response, petition or answer in this Court, or upon the filing of the party's principal brief, whichever occurs first. A copy of the statement must also be included in the party's principal brief before the table of contents regardless of whether the statement has previously been filed. Rule 26.1(b) and (c), Federal Rules of Appellate Procedure.

If additional space is needed, please attach a new page.

Pursuant to Rule 26.1 and Third Circuit LAR 26.1, Amicus Curiae DRI, Inc. makes the following disclosure:
(Name of Party)

1) For non-governmental corporate parties please list all parent corporations:

None.

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

None.

3) If there is a publicly held corporation which is not a party to the proceeding before this Court but which has as a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

None.

4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is active participant in the bankruptcy proceeding. If the debtor or trustee is not participating in the appeal, this information must be provided by appellant.

Not applicable.

s/ Andrew Kim
(Signature of Counsel or Party)

Dated: 02/16/2021

TABLE OF CONTENTS

TABLE OF AUTHORITIES

PAGE(S)

CASES

STATUTES AND LEGISLATIVE HISTORY

REGULATIONS AND REGULATORY MATERIALS

OTHER AUTHORITIES

INTEREST OF THE AMICUS CURIAE[1]

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. DRI, its members, and their clients have a significant interest in ensuring that such claims are heard in federal court, especially where the claims are (1) based on actions taken at the direction of the federal government, and (2) subject to immunities conferred by federal law.

[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.

INTRODUCTION AND SUMMARY OF ARGUMENT

For most Americans, the fight against the COVID-19 pandemic involves following a handful of public-health guidelines: wear a mask, stand six feet apart, wash your hands, and stay at home. Nursing homes, by contrast, have to follow a much longer list of infection-control measures, in large part because of the vulnerable population that they serve. And for the vast majority of those operators, the measures are 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.

Plaintiffs filed lawsuits in New Jersey state court over measures that Defendants allegedly took—or failed to take—to stop the spread of COVID-19. Defendants removed to federal court, and the cases should have stayed there; both the federal officer removal statute, 28 U.S.C. § 1442(a)(1), and the immunity and complete preemption provided by the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, provided separate bases for the District Court to exercise federal jurisdiction. But instead of recognizing its original jurisdiction, the District Court issued an order sending the cases back to state court ("Remand Order"). The decision to remand was wrong, for at least two reasons.

I. The federal officer removal statute, 28 U.S.C. § 1442(a)(1), applies here because Defendants, as nursing homes participating in the Medicare and Medicaid programs, were "acting under" federal authority in responding to the COVID-19 pandemic. The District Court incorrectly concluded that Defendants had shown only that they are "highly regulated" entities. AA31. Their showing went much further: they 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 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 by carrying out the federal government's COVID-19 directives. Because Plaintiffs' lawsuits necessarily implicate the federal directives that Defendants were required to follow, the suits were removable under § 1442(a)(1).

II. The PREP Act confers a separate basis for federal jurisdiction. The Act immunizes certain "covered persons" like Defendants from civil suits about "covered countermeasures," as designated by the Secretary of Health and Human Services. The lawsuits here are about Defendants' failure to offer such countermeasures—a type of suit that the Secretary has expressly stated should be barred by the PREP Act. The Secretary's determination that such lawsuits would

hinder the fight against COVID-19 is entitled to deference, as Congress has deemed the Secretary uniquely qualified to adjudge which claims concerning COVID-19 countermeasures should be kept out of court and resolved by the exclusive mechanism for relief provided under the statute, the Countermeasures Injury Compensation Program (CICP).

ARGUMENT

I. 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"; there is no obligation to show the acts taken under a federal officer caused the events giving rise to the civil action. *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; *Baker v. Atl. Richfield Co.*, 962 F.3d 937, 942-43 (7th Cir. 2020) (private party "acts under" federal authority when "working hand-in-hand with the federal government to achieve a task that furthers an end of the federal government").

Skilled nursing facilities that receive federal funding 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. And as part of that special relationship, skilled nursing facilities, including Defendants', implemented CMS's prescribed measures for combatting COVID-19.

A. Skilled nursing facilities have had 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. The Great Depression left the increasing number of senior citizens in need of public assistance. *Id.* While the

Social Security Act of 1935 provided some "Old-Age Assistance" (OAA) to the elderly, that did not solve the problem of the growing need for long-term residential care for senior citizens, as OAA could not be spent on residence in "public institutions." *Id.*

By 1945, private facilities could not satisfy demand for long-term institutional care. Moreover, many privately run nursing homes failed to meet basic standards of living and 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" and protection "against fire hazards, unsanitary conditions, and overcrowding"); CRS Report at 16 ("Obviously, there was a serious skill shortage in the number of truly skilled care facilities in the country."). State governments attempted to regulate private nursing homes, but they had no effective enforcement mechanism for doing so; the only action they could take was to strip a nursing home of its license to operate, which was a disfavored measure because the need for skilled care was so overwhelming. *See* CRS Report at 31 (noting states' reluctance to engage in "strict enforcement of regulations," as that would "close the majority of the homes").

Congress opted to address both the lack of capacity and the lack of a minimum standard of care by amending the Hill-Burton Act in 1954 to allow 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 (noting that the Hill-Burton Amendments were "one of the first attempts on the part of Congress to define the institutions and the 'level of care' provided in such facilities for which Federal financial aid would be available").

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* CRS Report at 1-2 (Medicare and Medicaid legislation "greatly expanded the Government's previous role and importance as a *purchaser of nursing home care* for the aged and the poor in the United States" (emphasis added)). The Medicare Act gave the Department of Health, Education, and Welfare (HEW) 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. Congress modified both programs again in 1972, directing HEW to implement the same standards for skilled nursing facilities in both the Medicare and Medicaid programs. *Id.*

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 area covered by the surveys is 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 Health and Human Services. *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 jeopardizing the health and safety of residents, 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 consumer as well. Skilled nursing facilities have been a 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. Operators of skilled nursing facilities subject to the Medicaid and Medicare conditions of participation are thus "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 consumer and as a delegator of governmental responsibility, not just as a regulator. *Id.* at 1233-34 (OPM's contracts, payments, and ability to "withdraw approval of [a health benefits] carrier or terminate its contract" demonstrated that the contracted carriers "acted under" federal officers).

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 face an "increased risk of infection and severe illness from COVID-19." 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 the Medicare and Medicaid programs, 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, 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. This came only 10 days after the U.S. Centers for Disease Control confirmed the first U.S.-based COVID-19 case. Ctrs. for Disease Control & Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States*, https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html.

A week after the declaration of a public health emergency, 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—five 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); *see also* Eric Boodman & Helen Branswell, *First Covid-19 Outbreak in a U.S. Nursing Home Raises Concerns*, Stat News (Feb. 29, 2020), https://www.statnews.com/2020/02/29/new-covid-19-death-raises-concerns-about-virus-spread-in-nursing-homes/ (noting first case of widespread transmission of COVID-19 in a long-term care facility occurred on February 29, 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) ("Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey."), https://www.cms.gov/files/document/qso-20-20-allpdf.pdf. The survey

criteria are the measures set forth in CMS's guidance documents. The categories include: (1) hand hygiene, (2) use of PPE, (3) precautions to prevent transmission, (4) infection surveillance, (5) visitor entry restrictions, and (6) staff education and monitoring. Indeed, the very "protocols and procedures" that Defendants allegedly failed to follow are the ones prescribed by CMS and enforced through the survey process. AA 123 ¶ 28; AA 180 ¶ 28. *Compare* AA 120 ¶ 21(a) (alleging failure to take staff and visitor temperatures and requiring appropriate use of PPE); AA 177 ¶ 21(e) (same); and AA 121 ¶ 21(e) (alleging "cross-contamination between [] facilities"), *with* No. QSO-20-14-NH (Revised) at 3 (mandating "active screening of residents and staff for fever and respiratory symptoms," active screening of "staff that work at multiple facilities," and the use of PPE by visitors to a nursing facility).

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.

In holding that the federal officer removal statute did not apply to Plaintiffs' suits, the District Court failed to account for the "special relationship" between skilled nursing facilities and the federal government, and the fact that nursing homes' compliance with CMS guidance on COVID-19 infection control is compelled by the leverage that the federal government possesses as part of that "special relationship." While the District Court likened a nursing home's compliance with CMS and CDC guidelines and receipt of federal funding to a person receiving "federal funds under the CARES act and its Paycheck Protection Program ('PPP')" while also complying with "CDC guidelines for limiting occupancy, face coverings, and health and sterilization measures," AA32, that analogy is flawed because PPP recipients generally do not have a "special relationship" with the federal government. For most Americans, including recipients of PPP and other CARES Act funding, the CDC recommendations are voluntary, and there is no government-imposed penalty for failing to follow all of the infection-control recommendations. Nursing home facilities, by contrast, are expected to comply with CMS guidance as part of their participation in Medicare and Medicaid; noncompliance means paying a penalty or even possibly losing federal funding. Because this compliance is expected of nursing home providers as part of their conditions for participating in a program in which the providers fulfill a public-health need that the federal government must otherwise offer, providers complying

with CMS's COVID-19 directives, including Defendants, are "acting under" federal authorities for purposes of the federal officer removal statute.

C. Because COVID-19 infection-control protocols were dictated by CMS, 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 v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992)). 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, every aspect of the nursing home's COVID-19 response is affected by CMS guidance. As a result, a claim that the nursing home "failed to take the proper steps to protect the residents and/or patients at their facilities from the Covid-19

virus" will necessarily implicate the nursing home's compliance with CMS guidance. AA 119 ¶ 13; AA 176 ¶ 13 (emphasis added). How nursing homes "permit[] visitors and/or employees to come to [the facility]" and the "safety and/or preventive measures" used at the home are governed primarily by acts that nursing homes took at CMS's direction. AA 120 ¶ 21(a)-(b); AA 177 ¶ 21(a)-(b); *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).

Because a nursing home's compliance with CMS's COVID-19 infection control guidance may inform the standard of care in a negligence suit about COVID-19 transmission in a nursing home, claims like Plaintiffs' here "relate" to CMS's directives and thus are eligible for removal under the federal officer removal statute.

Indeed, the District Court even acknowledged that there was "a nexus between Plaintiffs' negligence claims and the infection control procedures they followed as part of the federal government's COVID-19 response," but it applied the wrong standard to conclude that Plaintiffs' claims were not "for, or relating to an act under color of federal office." AA33. The District Court determined that the federal officer removal statute requires that a cause of action be "predicated on . . . the acts forming the basis of the state suit [which] were performed pursuant to an officer's

direct orders or comprehensive and detailed regulations," citing decisions from 2006 and 2007. *Id.* (citing *Orthopedic Specialists of N.J. PA v. Horizon Blue Cross/Blue Shield of N.J.*, 518 F. Supp. 2d 128, 135-36 (D.N.J. 2007)).

That may have been true up until 2011, but then Congress amended the statute to include the "relating to" language. By adding the words "or relating to," Congress expanded the universe of civil actions that could be removed under the federal officer removal statute. "Relating to" means a case or controversy simply *connected* to, or *associated* with a private party's "acting under" a federal officer is enough to remove the case to federal court.

Thus, the District Court remanded based solely on applying an outdated standard. The facts that justify removal under the post-2011 statute are facts that the District Court *itself* recognized are present here. It follows that the court should have denied the motion to remand.

II. The PREP Act completely preempts Plaintiffs' claims, and the District Court should have given deference to the Secretary's COVID-19-related PREP Act pronouncements.

Even if jurisdiction could not be sustained under the federal officer removal statute, the District Court should have retained jurisdiction over Plaintiffs' lawsuits because a provision of the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, preempts them. The PREP Act gives the Secretary of Health and Human Services (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." *Id.* § 247d-6d(a)(1), (b)(1). The Secretary designated the types of claims raised by Plaintiffs here as ones subject to the PREP Act's liability shield, exclusive method of compensation, and limited federal cause of action. That designation meant the District Court should have retained jurisdiction over the suits.[2]

Federal courts have original jurisdiction, and thus removal jurisdiction, over any civil action "arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. §§ 1331, 1441(a). Preemption ordinarily does not serve as a basis for federal jurisdiction or removal because it is an affirmative defense (and thus does not appear on the face of a complaint). *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6 (2003). But 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 possible claim is a federal one. *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 64 (1987) (citation and internal quotation marks omitted); *DiFelice v. Aetna U.S. Healthcare*,

[2] Whether this Court may review, under 28 U.S.C. § 1447(d), all of the grounds for removal addressed in the Remand Order is currently before the U.S. Supreme Court in *B.P. plc v. Mayor & City of Baltimore*, No. 19-1189.

346 F.3d 442, 445-46 (3d Cir. 2003) ("[W]hen a purportedly state-law claim comes within the scope of an exclusively federal cause of action, it necessarily arises under federal law, and is completely preempted." (citation and internal quotation marks omitted)).

The PREP Act provides such complete preemption and a basis for removal here. It confers immunity "from suit and liability under Federal and State law" for any "covered person . . . 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" for which the Secretary of Health and Human Services has made a declaration. 42 U.S.C. § 247d-6d(a)(1). The "sole exception" to a covered person's immunity is "for an exclusive Federal cause of action" set out in the PREP Act. *Id.* § 247d-6d(d)(1).[3] A "covered person" includes a "qualified person who prescribed, administered, or dispensed such countermeasure," *id.* § 247d-

[3] Congress made clear in the PREP Act that it wanted questions about the application of the PREP Act's immunity provisions to be heard *only* in federal court. The Act commits to the D.C. Circuit any interlocutory appeal of an order "denying a motion to dismiss or a motion for summary judgment based on the assertion of the immunity from suit" provided by the PREP Act. 42 U.S.C. § 247d-6d(e)(10). But if the PREP Act does not confer federal jurisdiction because of its preemptive power, and questions about the application of the PREP Act's immunity are litigated only in state court, then there is no way to give effect to this provision—a party cannot lodge an appeal to the D.C. Circuit from state court. *See generally* 28 U.S.C. § 1291 ("The courts of appeals . . . shall have jurisdiction of appeals from all final decisions of the district courts of the United States . . . .").

6d(i)(2)(B)(iv).[4] It also includes "program planners," *i.e.*, those "who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product." *Id.* § 247d-6d(i)(6).[5] At the onset of the COVID-19 crisis, Congress amended the PREP Act to include "a respiratory protective device" determined by the Secretary to be "a priority for use during a public health emergency" as part of the list of covered countermeasures. *Id.* § 247d-6d(i)(1)(D), *as amended by* Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361 (2020).

The Secretary issued a COVID-19 related PREP Act declaration on March 17, 2020, defining the universe of "covered countermeasures" as "any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective 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). The Secretary later amended that declaration to state that immunity

[4] A "qualified person" is a "licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures," or a person identified by the Secretary as "qualified" in a declaration. 42 U.S.C. § 247d-6d(i)(8).

[5] Immunity does not mean a person suffering harm related to a covered countermeasure is left without compensation; rather, compensation is exclusively available through the Countermeasures Injury Compensation Program. 42 C.F.R. pt. 110.

relating to "covered countermeasures" shall include 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 (Dec. 3, 2020) ("Fourth Declaration") ("Where 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."), *available at* https://www.phe.gov/Preparedness/legal/prepact/Pages/4-PREP-Act.aspx.

The Department of Health and Human Services (HHS) has taken a broad view about the scope of PREP Act immunity for covered countermeasures administered during the COVID-19 pandemic. 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 has taken the view that PREP Act immunity is so comprehensive, it covers instances where a qualified person *thinks* a product is a covered countermeasure, but

it turns out not to be. *Id.* at 4-5 (citing 42 U.S.C. § 247d-6d(a)(4)(B)). Addressing removal specifically, HHS has 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," and subject to complete preemption. 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.

The PREP Act's sweeping immunity provisions, combined with the Secretary's PREP Act declarations made in relation to COVID-19, completely preempt Plaintiffs' claims in this case. These lawsuits are about how nursing homes decided to deploy their limited number of covered countermeasures. *See* AA 119 ¶ 14; AA 176 ¶ 14 (alleging that "management provided masks only to registered nurses, not to others who also interacted with residents"), AA 123 ¶ 28; AA 180 ¶ 28 (alleging failure "to have or provide personal protective equipment[] in place for the prevention of the spread of the Covid-19 virus"). HHS has made clear that such claims fall squarely within the scope of the immunity that it intended to provide in its COVID-19-related PREP Act declarations. *See* Fourth Declaration.

The Secretary's decision to immunize the decision *not* to administer or provide covered countermeasures is entitled to deference. "Federal regulations have no less preemptive effect than federal statutes." *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984). When an agency "promulgates regulations intended to pre-empt state law, the court's inquiry is . . . limited: If [its] choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, [a court] should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned." *Id.*

The Secretary's ability to declare a public health emergency and immunize covered persons for suits *relating to* covered countermeasures signals Congress's determination that HHS is "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Here, the Secretary has concluded that subjecting nursing homes and other "covered persons" to liability for their decisions on how to deploy their limited stock of covered countermeasures would hinder, rather than aid, the fight against the COVID-19 public health emergency. Nothing about that determination is contrary to the

statutory text or other indicators of "what Congress would have sanctioned." *Capital Cities*, 467 U.S. at 699.

The District Court feared that construing PREP Act immunity so broadly so as to reach claims for medical malpractice based on actions *not* taken—for example, making "a decision to do nothing" to abate the pandemic—would escape judicial review. *See* AA51-52. That fear was misplaced. There is still a limited, exclusively federal cause of action available under the PREP Act: willful blindness to a dangerous global pandemic could constitute willful misconduct actionable under 42 U.S.C. § 247d-6d(d)(1). *See also Advisory Opinion 21-01* (noting that "wanton and willful" decisions to deprive individuals of therapeutics are still subject to liability under the PREP Act). And "no lawsuit" does not mean "no relief"; rather, outside the exclusive federal cause of action for certain injuries resulting from willful misconduct, the exclusive available recourse is for an aggrieved party to file a claim with the Countermeasures Injury Compensation Program. 42 C.F.R. pt. 110.

Under the PREP Act, Plaintiffs' claims cannot survive as state-law claims. The Secretary has made a determination about the deployment of covered countermeasures and has interpreted the PREP Act to foreclose lawsuits over how providers like Defendants choose to allocate their limited resources on such countermeasures. Under the PREP Act, the causes of action in Plaintiffs' lawsuits

raise exclusively federal subject matter. However pleaded, they are federal claims removable under 28 U.S.C. § 1441(c).

CONCLUSION

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

Dated: February 16, 2021

Respectfully submitted,

/s/ Andrew Kim

Andrew Kim
William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
(202) 346-4000
andrewkim@goodwinlaw.com
wjay@goodwinlaw.com

Counsel for Amicus Curiae DRI, Inc.

RULE 32(A) CERTIFICATE OF COMPLIANCE

This brief complies with the type volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,077 words, excluding the parts exempted by Rule 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because it appears in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: February 16, 2021

/s/ Andrew Kim

Andrew Kim
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
(202) 346-4000
andrewkim@goodwinlaw.com

Counsel for Amicus Curiae DRI, Inc.

CERTIFICATE OF SERVICE AND COMPLIANCE WITH VIRUS CHECK

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system on February 16, 2021, and the text of the electronic brief is identical to the text of the paper copies.

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.

I further certify that a virus-detection program, Symantec Antivirus Software, has been run on the electronic brief, and no virus was detected.

Dated: February 16, 2021

/s/ Andrew Kim

Andrew Kim
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
(202) 346-4000
andrewkim@goodwinlaw.com

Counsel for Amicus Curiae DRI, Inc.

CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Local Rule of Appellate Procedure 46.1(e), the undersigned hereby certifies that he is a member of the bar of the United States Court of Appeals for the Third Circuit.

Dated: February 16, 2021

/s/ Andrew Kim

Andrew Kim
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
(202) 346-4000
andrewkim@goodwinlaw.com

Counsel for Amicus Curiae, Inc.