No. 21-11765

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

HOWARD SCHLEIDER, FELICE VINARUB,
as Co-Personal Representatives for the
Estate of Sara Schleider, Deceased,

Plaintiffs-Appellees,

v.

GVDB OPERATIONS, LLC, d.b.a. Grand Villa of Delray East,
JSMGV MANAGEMENT COMPANY, LLC,
a Florida Limited Liability Company,

Defendants-Appellants.

On Appeal from the United States District Court
for the Southern District of Florida, No. 9:21-cv-80664-WPD

BRIEF FOR *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN HOSPITAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, AND FLORIDA MEDICAL ASSOCIATION IN SUPPORT OF APPELLANTS

Daryl Joseffer
Jennifer B. Dickey
U.S. CHAMBER
LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

Counsel for the Chamber of Commerce of the United States of America

Jeffrey S. Bucholtz
Alexander Kazam
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com

Counsel for the Chamber of Commerce of the United States of America and American Hospital Association

July 27, 2021 *(Additional counsel listed on inside cover)*

Leonard A. Nelson
AMERICAN MEDICAL ASSOCIATION
Office of General Counsel
330 N. Wabash Avenue
Chicago, IL 60611

Counsel for American Medical Association and Florida Medical Association

Geoffrey M. Drake
KING & SPALDING LLP
1180 Peachtree Street NE
Atlanta, GA 30309

Counsel for the Chamber of Commerce of the United States of America and American Hospital Association

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure, and 11th Cir. R. 26.1, *amici curiae* the Chamber of Commerce of the United States of America, American Hospital Association, American Medical Association, and Florida Medical Association state that, in addition to the persons listed in the Certificate of Interested Persons and Corporate Disclosure Statement filed by Appellants on June 7, 2021, the following persons and entities have an interest in the outcome of this case:

1. American Hospital Association, *Amicus Curiae*

2. American Medical Association, *Amicus Curiae*

3. Jeffrey S. Bucholtz, Counsel for *Amici Curiae* Chamber of Commerce of the United States of America and American Hospital Association

4. Chamber of Commerce of the United States of America, *Amicus Curiae*

5. Jennifer B. Dickey, Counsel for *Amicus Curiae*

6. Geoffrey M. Drake, Counsel for *Amici Curiae* Chamber of Commerce of the United States of America and American Hospital Association

7. Florida Medical Association, *Amicus Curiae*

8. Alexander Kazam, Counsel for *Amici Curiae* Chamber of Commerce of the United States of America and American Hospital Association

9. King & Spalding, LLP, Counsel for *Amici Curiae* Chamber of Commerce of the United States of America and American Hospital Association

10. Daryl Joseffer, Counsel for *Amicus Curiae* Chamber of Commerce of the United States of America

11. Leonard A. Nelson, Counsel for *Amici Curiae* American Medical Association and the Florida Medical Association

Amici curiae further state that they are non-profit membership organizations with no parent company and no publicly traded stock.

Date: July 27, 2021

s/Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

TABLE OF CONTENTS

TABLE OF AUTHORITIES*

Cases

* Authorities upon which we chiefly rely are marked with asterisks.

Statutes

Regulations

Other Authorities

INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The American Hospital Association ("AHA") is a national organization that represents nearly 5,000 hospitals, healthcare systems, networks, and other providers of care. AHA members are committed to improving the health of the communities that they serve and to helping ensure that care is available to and affordable for all Americans. The AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It ensures that members' perspectives and needs are heard and addressed

in national health-policy development, legislative and regulatory debates, and judicial matters. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for its members.

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including Florida. The AMA and Florida Medical Association ("FMA") join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

Founded in 1874, FMA is a professional association dedicated to the service and assistance of Doctors of Medicine and Doctors of Osteopathic Medicine in Florida. FMA represents more than 25,000 members on issues of legislation and regulatory affairs, medical economics and education, public health, and ethical and legal issues. FMA advocates for physicians and their patients to promote the public health, ensure the highest standards of medical practice, and to enhance the quality and availability of health care in the Sunshine State.

During the COVID-19 pandemic, America's businesses and health care providers have faced extraordinary challenges. Health care providers have been on the front lines, responding to a once-in-a-century emergency while adapting to rapidly changing circumstances and ever-evolving directives from government regulators. At the same time, pharmaceutical and medical device manufacturers have invested considerably to help the world combat COVID-19 through the development of new medications, vaccines, and other therapeutics. The just and efficient resolution of tort litigation arising from the COVID-19 pandemic, and the adjudication of such disputes in a proper forum, is of great concern to *amici* and their members.

Accordingly, *amici* have a strong interest in the proper interpretation of the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. §§ 247d-6d, 247d-6e, which affords health care providers, manufacturers, distributors, and other entities involved in the response to the pandemic important protections, including immunity from most tort liability and access to a federal forum in cases implicating the Act.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

No party or party's counsel authored this brief in whole or in part; no party or party's counsel contributed money to fund the preparation or submission of this brief; and no other person except *amici curiae*, their members, or their counsel contributed money intended to fund the preparation or submission of this brief. Both parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In early 2020, a highly contagious and deadly virus began sweeping across the country. Little at the time was known about COVID-19, how it spread, how it harmed those infected, how it could be contained, or how

it could be prevented. Health care providers were forced to adapt to rapidly changing circumstances and information.

As a result of this once-in-a-century health emergency, some sectors of the economy have taken an especially heavy toll. Health care providers in particular, including senior care and other long-term-care providers that serve America's most vulnerable populations, faced severe challenges. In an urgent struggle against an invisible foe, they not only lacked consistent, well-defined guidance from public health officials, but were often short-staffed and hamstrung by nationwide shortages of personal protective equipment, testing kits, and other pandemic countermeasures. Within a year, despite the widespread adoption of COVID-19 protocols and the heroic efforts of America's health care workers, more than half a million Americans had died—the vast majority of them over the age of 65.[1] Meanwhile, hundreds of senior care facilities have closed or today teeter on the edge of bankruptcy.[2]

---

[1] CDC, *Weekly Updates by Select Demographic and Geographic Characteristics* (June 16, 2021), https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAg.

[2] Tony Pugh, *Bankruptcies, Closures Loom for Nursing Homes Beset by Pandemic*, Bloomberg Law (Dec. 30, 2020), https://news.bloomberg

These serious challenges to health care providers are compounded by the threat of thousands of lawsuits alleging that the negligent administration of infection control policies caused patients and residents to acquire COVID-19. A major issue in many of these cases, which have been and will continue to be filed in various state courts across the country, is the availability of federal removal jurisdiction. While some cases arising from the COVID-19 pandemic may be appropriately adjudicated in state court, in other cases defendants are entitled to a federal forum.

Over a decade ago, Congress recognized the possibility of a nationwide public health emergency much like COVID-19, and expressly provided certain protections for those on the front line of responding to it, in the Public Readiness and Emergency Preparedness Act of 2005 ("PREP Act"), 42 U.S.C. §§ 247d-6d, 247d-6e. The PREP Act, enacted two years after the outbreak of the SARS epidemic, affords broad immunity from tort liability to individuals and entities involved in the administration, manufacture, distribution, use, or allocation of pandemic

---

law.com/health-law-and-business/bankruptcies-closures-loom-for-nursing-homes-beset-by-pandemic.

countermeasures. Indeed, that immunity extends to most claims "relating to" the use or administration of covered countermeasures such as vaccines, test kits, and certain protective equipment. *Id.* § 247d-6d(a)(1). In the preemption context, it is well established that the term "relating to" has an especially broad meaning. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992) (collecting cases); *see Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987) (noting "expansive sweep" of such language).

Rather than leave the adjudication of disputes arising from a national emergency response to disparate state courts across the country, Congress established an exclusive federal remedial scheme and expressly preempted state law that might interfere with that scheme. Together, the provisions of the PREP Act manifest the "extraordinary preemptive power" that the Supreme Court has identified as the hallmark of a "complete preemption" statute, *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987), that creates a basis for federal question jurisdiction even when certain claims are pleaded under state law.

ARGUMENT

I. COVID-19 Has Posed Unprecedented Challenges for American Businesses, Especially Health Care Providers

The COVID-19 pandemic has tested the resilience of American business like nothing before. At the outset of the pandemic, business owners confronted a novel, fast-moving threat that no one, not even the nation's top public health experts, fully understood or anticipated.[3] In responding to this emergency, businesses and health care providers had to adapt to rapidly changing circumstances and evolving guidance from public health officials on key issues ranging from the utility of face masks,[4] to the mode of viral transmission,[5] to unprecedented restrictions on their operations.[6] Even today, information about COVID-19 continues to evolve.

---

[3] *See* Liz Szabo, *Many U.S. Health Experts Underestimated the Coronavirus Until It Was Too Late*, Kaiser Health News (Dec. 21, 2020), https://khn.org/news/article/many-us-health-experts-underestimated-the-coronavirus-until-it-was-too-late/.

[4] Zaynep Tufekci, *Why Telling People They Don't Need Masks Backfired*, N.Y. Times (Mar. 17, 2020), https://www.nytimes.com/2020/03/17/opinion/coronavirus-face-masks.html.

[5] Apoorva Mandavilli, *The Coronavirus Can Be Airborne Indoors, W.H.O. Says*, N.Y. Times (July 9, 2020), https://www.nytimes.com/2020/07/09/health/virus-aerosols-who.html?.

[6] *See* U.S. Chamber of Commerce, *Why Temporary Coronavirus Liability Relief Is Needed for American Business*, https://

As a result of the pandemic and the ensuing lockdowns, more than a million American businesses have closed their doors—many of them permanently.[7] Within the first two months of the pandemic, the number of actively working business owners plummeted by 22 percent.[8] About 60 percent of small businesses reported being "very concerned" about the impact of COVID-19 on their livelihood.[9] A year later, according to a Federal Reserve Bank survey, nearly a third of the remaining small businesses continued to fear for their survival.[10]

---

www.uschamber.com/report/why-temporary-coronavirus-liability-relief-needed-american-businesses.

[7] Ruth Simon, *COVID-19 Shuttered More Than 1 Million Small Businesses*, N.Y. Times (Aug. 1, 2020), https://www.wsj.com/articles/covid-19-shuttered-more-than-1-million-small-businesses-here-is-how-five-survived-11596254424?mod=article_relatedinline.

[8] Robert Fairlie, *The Impact of COVID-19 on Small Business Owners*, 2020 J. Econ. & Mgmt. Strategy 1, 6 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7461311/.

[9] MetLife & U.S. Chamber of Commerce, *Special Report on Coronavirus and Small Business - April* (Apr. 3, 2020), https://www.uschamber.com/report/special-report-coronavirus-and-small-business.

[10] Khristopher J. Brooks, *9 Million U.S. Small Businesses Fear They Won't Survive Pandemic*, CBS News (Feb. 10, 2021), https://www.cbsnews.com/news/small-business-federal-aid-pandemic/.

Health care providers, and senior care providers in particular, have been especially hard hit. A delayed rollout of COVID-19 test kits, followed by months of shortages, hampered detecting the virus where it might do most harm, including at senior care and other long-term-care facilities that serve predominantly the elderly and infirm. Meanwhile, a severe nationwide shortage of respirator masks and other personal protective equipment, which persisted well into the course of the pandemic, required difficult decisions about how to allocate scarce resources and hindered providers' ability to protect front-line workers and patients.[11]

Not surprisingly, long-term care and senior care facilities, with their vulnerable populations and communal living arrangements, experienced some of the worst effects. In many ways, these facilities have performed admirably under the most difficult of circumstances; according to one recent study, about two-thirds of assisted living facilities had no

[11] *See* Andrew Jacobs, *Health Care Workers Still Face Daunting Shortages of Masks and Other P.P.E.*, N.Y. Times (Dec. 20, 2020), https://www.nytimes.com/2020/12/20/health/covid-ppe-shortages.html; Peter Whoriskey et al., *Hundreds of Nursing Homes Ran Short on Staff, Protective Gear as More Than 30,000 Residents Died During Pandemic,* Wash. Post (June 4, 2020), https://www.washingtonpost.com/business/2020/06/04/nursing-homes-coronavirus-deaths/.

deaths from COVID-19 in all of 2020.[12] But COVID-19 proved especially dangerous for the elderly. Of the more than half a million Americans who have died from COVID-19, 80 percent were over the age of 65.[13] More than 150,000 of those deaths have been residents of senior care facilities.[14] Despite the efforts of the nation's health care workers, many of whom risked their own lives to protect the vulnerable, the sheer scale of the tragedy makes the potential for litigation enormous. Trial lawyers have already spent tens of millions of dollars on advertisements related to COVID-19, and more than 7,500 lawsuits have already been filed.[15]

The pandemic wreaked havoc that has left the long-term care sector in dire straits. There are nearly 30,000 assisted living facilities and more than 15,000 skilled nursing facilities nationwide, about a third of which

---

[12] Caroline Pearson et al., The Impact of COVID-19 on Seniors Housing, NORC: Univ. of Chi., at 2–3 (2021), https://info.nic.org/hubfs/Outreach/2021_NORC/20210601%20NIC%20Final%20Report%20and%20Executive%20Summary%20FINAL.pdf.

[13] CDC, *Weekly Updates*, *supra* note 2.

[14] *Nearly One-Third of U.S. Coronavirus Deaths Are Linked to Nursing Homes*, N.Y. Times (Apr. 28, 2021), https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html.

[15] Am. Tort Reform Ass'n, COVID-19 Legal Services Television Advertising (2021), https://www.atra.org/white_paper/covid-19-legal-services-television-advertising/.

operate on a non-profit basis.[16] In 2020, long-term care facilities spent an estimated $30 billion on PPE and additional staffing alone.[17] The long-term care industry is expected to lose $94 billion from 2020 to 2021, and more than 1,600 skilled nursing facilities could close this year, leaving vulnerable seniors in search of new homes, caretakers, and communities.[18] Meanwhile, more and more seniors will likely need long-term care services, as the number of Americans over age 80 is expected to triple over the next three decades.[19]

II. The PREP Act Is a "Complete Preemption" Statute

Years ago, no one could have predicted the COVID-19 pandemic, when it would strike, or what course it would take. But Congress did foresee that a pandemic could create circumstances like those seen with

---

[16] CDC, *Nursing Home Care* (Mar. 1, 2021), https://www.cdc.gov/nchs/fastats/nursing-home-care.htm.

[17] Press Release, Am. Health Care Ass'n, *COVID-19 Exacerbates Financial Challenges of Long-Term Care Facilities* (Feb. 17, 2021), https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/COVID-19-Exacerbates-Financial-Challenges-Of-Long-Term-Care-Facilities.aspx#.

[18] *Id.*

[19] Nat'l Ctr. for Health Statistics, Long-Term Care Providers and Services Users in the United States, 2015–2016, at 3 (2019), https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

COVID-19, with businesses reeling and health care providers struggling to protect people from novel threats under a shadow of crippling liability. In enacting the PREP Act, Congress did not preempt all negligence claims arising from a pandemic. But it did seek to shield those on the front line of defending the American population against a pandemic—those involved in manufacturing, distributing, or allocating federally designated countermeasures, such as COVID-19 tests or surgical masks, as well as health care personnel authorized to prescribe, administer, or dispense those countermeasures—from liability that might prevent them from continuing to operate and perform their critical functions.[20] When those front-line responders are faced with lawsuits alleging tort liability, the Act also ensures access to a federal forum, even when plaintiffs try to plead their claims in terms of state law.

[20] "Covered person[s]" under the PREP Act include manufacturers, distributors, and "program planner[s]" of countermeasures, as well as "qualified person[s] who prescribed, administered, or dispensed countermeasure[s]." 42 U.S.C. § 247d-6d(i)(2). "Program planners" are those who "supervised or administered a program with respect to the administration, dispensing, distribution, provision or use" of certain countermeasures. *Id.* § 247d-6d(i)(6). A "qualified person" is a "licensed health professional or other individual who is authorized to prescribe, administer, or dispense" such countermeasures. *Id.* § 247d-6d(i)(8).

Ordinary preemption is a defense that does not give rise to federal subject matter jurisdiction. *See Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804 (1986). Under the "complete preemption" doctrine, however, claims pleaded under state law are removable to federal court where a federal statute has such "unusually powerful preemptive force" that the claims are deemed to arise under federal law. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7 (2003); *Gables Ins. Recovery, Inc. v. Blue Cross & Blue Shield of Fla., Inc.*, 813 F.3d 1333, 1337 (11th Cir. 2015) (per curiam). Both the U.S. Department of Health and Human Services and the U.S. Department of Justice have identified the PREP Act as such a "complete preemption" statute. *See* HHS, Advisory Opinion 21-01 on the PREP Act (Jan. 8, 2021) ("HHS Advisory Opinion"); Fifth Amendment to Declaration Under the PREP Act, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021) ("[t]he plain language of the PREP Act makes clear that there is complete preemption of state law as described above"); DOJ Statement of Interest, *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 20-cv-00683 (M.D. Tenn. Jan. 19, 2021), ECF No. 35-1 ("DOJ Statement of Interest"). The district court in this case erred in rejecting that well-supported interpretation.

A. The Text, Structure, and Purpose of the PREP Act Establish That It Completely Preempts State-Law Tort Claims Within Its Scope

Complete preemption is "jurisdictional in nature," as it confers federal jurisdiction where Congress intended to displace a state-law claim. *Conn. State Dental Ass'n v. Anthem Health Plans, Inc.*, 591 F.3d 1337, 1344 (11th Cir. 2009). That is, Congress may "so completely pre-empt a particular area" of law that any state-law claims within that defined area become "necessarily federal in character." *Metro. Life*, 481 U.S. at 63–64. To trigger that effect, Congress need only have (1) "preempt[ed] state substantive law" and (2) "'provid[ed] the exclusive cause of action for the claim asserted.'" *Dial v. Healthspring of Ala., Inc.*, 541 F.3d 1044, 1047 (11th Cir. 2008) (quoting *Beneficial Nat'l Bank*, 539 U.S. at 8). The PREP Act does both.

First, the Act displaces state-law tort claims within a particular area. Section 247d-6d(a) provides "immun[ity] 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" if a PREP Act declaration has been issued. 42 U.S.C. § 247d-6d(a). Such a declaration

may only be issued by the Secretary after "mak[ing] a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." *Id.* § 247d-6d(b)(1). It must be published in the Federal Register and recommend "the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures." *Id.* § 247d-6d(b)(1). It must also identify the disease for which the Secretary recommends these countermeasures, the population and geographic areas for which he or she recommends those measures, and the time period for which immunity is in effect. *Id.* § 247d-6d(b)(2). But as noted above, during that time period, covered persons are broadly immune from claims arising out of, relating to, or resulting from the administration or use of those countermeasures.

Indeed, in defining that immunity, it would have been difficult for Congress to choose language with more powerful preemptive effect. In preemption cases, the Supreme Court has repeatedly recognized that the term "relating to" has a "broad common-sense meaning." *Pilot Life*, 481 U.S. at 47; *see also Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724,

739 (1985) ("broad scope"); *Morales*, 504 U.S. at 383–84 ("deliberately expansive" and "conspicuous for its breadth") (internal quotation marks omitted). In the ERISA context, for example, a state law "relates to" a benefit plan if it has a "connection with, or reference to" such a plan. *Pilot Life*, 481 U.S. at 47 (internal quotation marks omitted). Given Congress's use of identical language in the PREP Act, it should be given similar effect here.

The preemptive force of the PREP Act's immunity provision is magnified by the Act's express preemption clause, which provides that "no State . . . may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement" that is "different from, or is in conflict with, any requirement applicable under this section." 42 U.S.C. § 247d-6d(b)(8). These preempted state "requirements" include common-law tort claims, because "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

Second, the Act provides a substitute cause of action for claims within the preempted area. The Act creates, as the "sole exception" to the immunity conferred by subsection (a), "an exclusive Federal cause of

action" for claims of willful misconduct causing death or serious injury. 42 U.S.C. § 247d-6d(d)(1). The exclusive venue for such claims is the U.S. District Court for the District of Columbia. *Id.* § 247d-6d(e)(1), (e)(5). For other claims within the scope of subsection (a), the Act also establishes a federal "Covered Countermeasure Process Fund," which is designed to provide "timely, uniform, and adequate compensation" through a no-fault claims process. *Id.* § 247d-6e(a). That federal administrative remedy, too, is "exclusive." *Id.* § 247d-6d(d)(1).[21]

This structure, combining preemption with exclusive federal remedies, is the defining feature of a "complete preemption" statute. *See Beneficial Nat'l Bank*, 539 U.S. 1 (National Bank Act); *Avco Corp. v. Aero Lodge No. 1735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557 (1968) (Labor Management Relations Act); *Metro. Life,* 481 U.S. 58 (ERISA); *Hall v. N. Am. Van Lines, Inc.*, 476 F.3d 683 (9th Cir. 2007) (Carmack Amendment); *In re Miles*, 430 F.3d 1083 (9th Cir. 2005) (Bankruptcy Code); *Spear Mktg., Inc. v. BancorpSouth Bank*, 791 F.3d

[21] In this very case, Plaintiffs initially filed a claim with the Fund, and withdrew the claim only after Defendants brought it to the attention of the district court. *See* ECF Nos. 11, 18, *Schleider v. GVDB Operations, LLC, et al.*, No. 21-cv-80664. This action illustrates the availability of substitute remedies for injuries of the kind Plaintiffs allege.

586, 594 (5th Cir. 2015) (Copyright Act). Like these statutes, the PREP Act "supersede[s] both the substantive and the remedial provisions" of the relevant state law "and create[s] a federal remedy . . . that is exclusive." *Beneficial Nat'l Bank*, 539 U.S. at 11. And the Act likewise "set[s] forth procedures and remedies governing that cause of action." *Id.* at 8; *see id.* § 247d-6d(e) (describing remedies and detailing "procedures for suit").

Structurally, the Act bears an especially close resemblance to the Air Transportation Safety and System Stabilization Act of 2001 ("ATSSSA"), 49 U.S.C. § 40101, enacted in the wake of the September 11, 2001 terrorist attacks. The main components of the ATSSSA included immunity for the airlines, a Victim Compensation Fund to provide expedited relief, and an exclusive cause of action for damages arising out of the attacks, for which the exclusive venue was the U.S. District Court for the Southern District of New York. *See In re WTC Disaster Site*, 414 F.3d 352, 373 (2d Cir. 2005). Based on these features, which closely parallel the principal components of the PREP Act, the Second Circuit identified the ATSSSA as a "complete preemption" statute providing for federal removal jurisdiction. *Id.* at 373, 380 (internal quotation marks

omitted); *see* Mem. at 3 n.3, *Rachal v. Natchitoches Nursing & Rehab. Ctr. LLC*, No. 21-cv-00334-DCJ-JPM (W.D. La. Apr. 30, 2021), ECF No. 13 (finding analogy to ATSSSA persuasive).

Some district courts have attempted to distinguish the ATSSSA from the PREP Act on the ground that it provided a broader substitute cause of action. *E.g.*, *Dupervil v. Alliance Health Operations, LLC*, No. 20-CV-4042PKCPK, 2021 WL 355137, at *10–11 (E.D.N.Y. Feb. 2, 2021); *see* ECF No. 25 at 6 ("District Court Order") ("approv[ing] of and adopt[ing]" *Dupervil*'s analysis). What this approach misses, however, is that "[f]or complete preemption to operate, the federal claim need not be co-extensive with the ousted state claim." *Fayard v. Ne. Vehicle Servs., LLC*, 533 F.3d 42, 46 (1st Cir. 2008) (Boudin, J.). On the contrary, "the superseding federal scheme may be more limited or different in its scope and still completely preempt." *Id.* (citing *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 391 n.4 (1987)). As the Supreme Court has explained, "[t]he nature of the relief available after jurisdiction attaches is, of course, different from the question whether there is jurisdiction to adjudicate the controversy." *Caterpillar*, 482 U.S. at 391 n.4 (quoting *Avco Corp.*, 390 U.S. at 561).

The statute's purpose reinforces the structural argument for complete preemption under the PREP Act. *See Dunlap v. G&L Holding Grp., Inc.*, 381 F.3d 1285, 1291 (11th Cir. 2004) ("[T]he touchstone of federal question jurisdiction based on complete preemption is congressional intent") (internal quotation marks omitted). Congress has delegated authority to the HHS Secretary to "lead all federal public health and medical response" to national emergencies. 42 U.S.C. § 300hh. In exercising that authority, the Secretary is responsible for ensuring the "[r]apid distribution and administration of medical countermeasures" in response to a public health emergency. *Id.* § 300hh-1(b)(2). The PREP Act is a tool that the Secretary may use to facilitate that important task.

In public health emergencies, the government works hand in hand with private sector partners, including health care providers, who generally lack the protection from liability enjoyed by public officials. *See* Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration*, 6 Biosecurity & Bioterrorism 1 (2008); DOJ Statement of Interest 2. Enacted shortly after a different coronavirus outbreak, the SARS

epidemic of 2003, the PREP Act addresses this concern by providing "targeted liability protection" for a range of pandemic response activities called for by the Secretary, including the development, distribution, and dispensing of medical countermeasures, as well as the design and administration of countermeasure policies. *See* 42 U.S.C. § 247d-6d. That immunity has proved crucial to America's integrated national response to COVID-19. For example, the lack of equivalent protections in other countries has hindered the rollout of vaccines that could save untold numbers of lives.[22]

At the same time, to ensure the uniform and efficient resolution of disputes relating to countermeasures, the PREP Act establishes an exclusive federal remedial scheme. *See id* §§ 247d-6d, 247d-6e (specifically noting interest in "timely" and "uniform" adjudication). Forcing litigation over the PREP Act, including the scope of its applicability and the scope of the immunity it affords, to play out across 50 state court systems in countless counties throughout the nation would

[22] *See, e.g.*, Neha Arora et al., *India, Pfizer Seek to Bridge Dispute Over Vaccine Indemnity*, Reuters (May 21, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/india-pfizer-impasse-over-vaccine-indemnity-demand-sources-2021-05-21/.

defeat Congress's purpose of ensuring uniformity and efficiency. Denying defendants the security of a federal forum in which to assert their federal right to immunity from suit would also deter businesses from taking the actions necessary for rapid deployment of countermeasures, thereby undermining one of the core purposes of the Act. *See* DOJ Statement of Interest 9. In sum, the PREP Act reflects Congress's recognition that a national emergency like COVID-19 requires a whole-of-nation response. And it therefore provides the Secretary with a comprehensive national regulatory tool to encourage the development of designated countermeasures, while limiting liability for loss related to the administration of such countermeasures and ensuring adjudication of such liability in a federal forum.

B. Complete Preemption Under the PREP Act Encompasses Claims About Decisions Not to Use or Administer Countermeasures

Whether the PREP Act provides for complete preemption, of course, is distinct from the question whether particular claims fall within the scope of the Act's preemptive effect. In fact, many district courts that have rejected complete preemption under the PREP Act have done so only because the claims pleaded did not, in the courts' view, come within

the Act's protections. *See* DOJ Statement of Interest 10–11 (collecting cases). By contrast, courts holding that the PREP Act supports federal jurisdiction have concluded that the structural features of the Act establish complete preemption before turning to the separate question of scope. *See, e.g.*, *Garcia v. Welltower OpCo Grp. LLC*, No. SACV 20-2250, 2021 WL 492581, at *3 (C.D. Cal. Feb. 10, 2021); *Rachal*, No. 21-cv-00334-DCJ-JPM; *cf. Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140, 143–45 (N.Y. App. Div. 2012) (analyzing structure and scope of PREP Act and dismissing state-law complaint for lack of jurisdiction).

In this case, the district court erred in failing to consider how plaintiffs' allegations relate to the administration of countermeasures. For example, the complaint alleges that several residents of the facility were wearing masks below their chin, and that staff members failed to instruct residents on how to use masks properly. *See* ECF No. 1-1 ¶ 45. The complaint also alleges that at times "[t]here were no face masks for the residents," *id.* ¶ 64, and that the facility rationed the use of medical gowns for staff and residents, citing "the lack of worldwide gown supply," *id.* ¶ 37.

That Plaintiffs themselves believed their claims implicated the Act is evidenced by the fact that they initially sought administrative compensation under the Act from the Covered Countermeasure Process Fund, and only withdrew their application for that exclusive remedy after Defendants brought it to the court's attention. *See supra*, 18 & n.21.

The district court also erred in holding categorically that state-law claims "based on a nursing home's inaction . . . are not within the scope of the PREP Act." District Court Order at 6. Consistent with the Act's purpose of providing liability protection that facilitates the efficient deployment of countermeasures, the Act provides immunity not only for direct application of a countermeasure but more broadly for claims "relating to . . . the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a). A "covered countermeasure" includes "a qualified pandemic or epidemic product," such as a diagnostic, a treatment, or protective gear, as designated by a declaration of the HHS Secretary. *Id.* § 247d-6d(i)(7).

As the Secretary has persuasively explained, even allegations of "failure" to use a countermeasure may "relat[e] to . . . the administration to or the use" of a covered countermeasure. The Secretary's Declaration

designating covered countermeasures for diagnosing, preventing, and treating COVID-19 adopted the common-sense interpretation of "administration" of a countermeasure to include not only "physical provision" of the countermeasure, but also "decisions directly relating to public and private delivery, distribution, and dispensing" of the countermeasure, as occurs in the context of a health care provider's administration of an infection control policy directed at controlling the spread of COVID-19. Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,200 (Mar. 17, 2020). The Secretary has repeatedly amended this Declaration in response to changing information about the pandemic, but has never altered this interpretation of the Act. *See, e.g.*, Seventh Amendment to the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14,462 (Mar. 16, 2021).

As the Secretary has further elaborated, some of the recent district court decisions interpreting the PREP Act have adopted an unduly narrow understanding of what is "relat[ed] to . . . administration." *See* HHS Advisory Opinion 3 (citing, for example, *Lutz v. Big Blue Health Care, Inc.*, 480 F. Supp. 3d 1207, 1217 (D. Kan. 2020)); *see also* Fourth

Amendment to the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 79,190, 79,192 (Dec. 9, 2020) (providing that the Declaration must be construed in accord with HHS advisory opinions). Like the court below, these courts take the position that the PREP Act is categorically inapplicable to the "non-administration or non-use" of countermeasures. *See id.*; *Lyons v. Cucumber Holdings, LLC*, No. 20-cv-10571-JFW, 2021 WL 364640, at *5 (C.D. Cal. Feb. 3, 2021) (citing cases), *appeal docketed*, No. 21-55185 (9th Cir.). But PREP Act immunity extends to all claims for loss "caused by, arising out of, *relating to*, or resulting from the administration to or the use" of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). We should assume that "relating to" has some meaning, *see Duncan v. Walker*, 533 U.S. 167, 174 (2001) (canon against surplusage), and courts have long recognized that "the ordinary meaning of ['relating to'] is a broad one." *Morales,* 504 U.S. at 383.

Thus, claims stemming from "prioritization or purposeful allocation" of countermeasures "relat[e] to . . . the administration" of such countermeasures. HHS Advisory Opinion 3. Indeed, it is entirely predictable that in the rollout of countermeasures to a national public

health emergency, difficult allocation decisions will need to be made. Such countermeasures may have just been developed or produced or may previously have been produced only at levels insufficient to meet the demands of the national emergency. If claims about purposeful allocation of those countermeasures are not covered, businesses and individuals would be dissuaded from working on the front lines to fight a pandemic—the exact opposite result from Congress's goal.

The district court accordingly should have scrutinized Plaintiffs' allegations more carefully, and ordered jurisdictional discovery if appropriate, rather than simply assuming that the PREP Act has no bearing on alleged "inaction." In the complaint, for example, Plaintiffs alleged that Defendants lacked adequate personal protective equipment for workers and residents. District Court Order at 3; *see* HHS Advisory Opinion 2 (noting that plaintiffs commonly allege that "the quantity of PPE was inadequate"). Yet as HHS has observed, an infection control program like the one administered by Defendants "inherently involves the allocation of resources" and "when those resources are scarce, some individuals are going to be denied access to them." HHS Advisory Opinion 4. That type of decision-making is "expressly covered by the

PREP Act," however adept plaintiffs may be at "fashioning their pleadings." *Id.* Accordingly, the district court should not have indulged Plaintiffs' attempt to avoid complete preemption simply by casting their claims as involving "lack of" or "failure to provide" countermeasures. District Court Order at 3. The PREP Act is far too important to permit plaintiffs to plead around it so easily.

CONCLUSION

For the reasons set forth above, this Court should vacate the decision of the district court.

Respectfully submitted,

s/Jeffrey S. Bucholtz

Jeffrey S. Bucholtz
Alexander Kazam
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com

Geoffrey M. Drake
KING & SPALDING LLP
1180 Peachtree Street NE
Atlanta, GA 30309
(404) 572-4600

Counsel for the Chamber of Commerce of the United States of America and American Hospital Association

Daryl Joseffer
Jennifer B. Dickey
U.S. CHAMBER LITIGATION CENTER
1615 H Street NW
Washington, DC 20062

Counsel for the Chamber of Commerce of the United States of America

Leonard A. Nelson
AMERICAN MEDICAL ASSOCIATION
Office of General Counsel
330 N. Wabash Avenue
Chicago, IL 60611

Counsel for American Medical Association and Florida Medical Association

July 27, 2021

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because this brief contains 5,443 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Century Schoolbook size 14-point font with Microsoft Word ProPlus 365.

Dated: July 27, 2021

s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system, which will notify all registered counsel.

I further certify that this document was served, with consent, via e-mail on the following person at the address shown:

Jodi Goldberg Barrett
HALL BOOTH SMITH, PC
4360 Northlake Blvd., Ste. 109
Palm Beach Gardens, FL 33410
(561) 472-1020
jbarrett@hallboothsmith.com

s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz