No. 21-3836

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LAURA HUDAK,
Executrix of the Estate of William P. Koballa, deceased,
Plaintiff-Appellee,

v.

ELMCROFT OF SAGAMORE HILLS; ELMCROFT BY ECLIPSE SENIOR LIVING; ECLIPSE SENIOR LIVING, INC.; ECLIPSE PORTFOLIO OPERATIONS, LLC; ECLIPSE PORTFOLIO OPERATIONS II, LLC; JAMIE ASHLEY COHEN,
Defendants-Appellants,

and

AL SAGAMORE HILLS OPERATIONS, LLC;
SENIOR CARE OPERATIONS HOLDINGS, LLC,
Defendants.

On Appeal from the United States District Court for the Northern District of Ohio, No. 5:21-cv-00060, Hon. Sara E. Lioi, U.S. District Judge

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

Jennifer B. Dickey
Tyler S. Badgley
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, Ohio Chamber of Commerce, and American Hospital Association

(Additional counsel listed in inside cover)

June 8, 2022

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

Counsel for American Medical Association and Ohio State Medical Association

Chad Golder
AMERICAN HOSPITAL ASSOCIATION
800 10th Street NW
Two CityCenter, Suite 400
Washington, DC 20001

Counsel for American Hospital Association

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

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

CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Amici make the following disclosures under Sixth Circuit Rule 26.1:

1. Is any *amicus* a subsidiary or affiliate of a publicly owned corporation?

No. The Chamber of Commerce of the United States of America, Ohio Chamber of Commerce, American Hospital Association, American Medical Association, and Ohio State Medical Association are nonprofit corporations. No entity has a parent company and none has issued stock.

2. Is there a publicly owned corporation, not a party to the appeal or an *amicus*, that has a financial interest in the outcome?

None known.

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

Counsel for Amici Curiae

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INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America 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. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

Founded in 1893, the Ohio Chamber of Commerce is Ohio's largest and most diverse statewide business advocacy organization. It works to promote and protect the interests of its more than 8,000 business members while building a more favorable business climate in Ohio by advocating for the interests of Ohio's business community on matters of statewide importance. By promoting its pro-growth agenda with

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The parties have consented to the filing of this brief.

policymakers and in courts across Ohio, the Ohio Chamber seeks a stable and predictable legal system which fosters a business climate where enterprise and Ohioans prosper.

The American Hospital Association 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. 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 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 Ohio. The AMA and the Ohio State Medical Association 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.

The Ohio State Medical Association was founded in 1846, initially as the Ohio State Medical Society, to "foster legislation and activities which would safeguard the interests of the public . . . and elevate the standards of the medical profession." The OSMA's purpose remains undiluted over 175 years later, and is advanced by courageous and conscientious Ohio physicians engaged in the practice of medicine in all medical specialties who are devoted to providing the best practicable and affordable medical care possible.

During the COVID-19 pandemic, America's businesses and health care providers have faced extraordinary challenges. 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. *Amici* have also filed briefs in several other appeals that present similar issues: *Saldana v. Glenhaven Healthcare LLC* (9th Cir. Mar. 30, 2022) (20-56194); *Martin v. Petersen Health Operations, LLC* (7th Cir. Jan. 31, 2022) (No. 21-2959); *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Ctr.* (2d Cir. Jan. 3, 2022) (No. 21-2164); *Leroy v. Hume* (2d Cir. Jan. 3, 2022) (No. 21-2158); *Maglioli v. Alliance HC Holdings, LLC* (3d Cir. Nov. 23, 2021) (No. 20-2833); *Mitchell v. Advanced HCS, L.L.C.* (5th Cir. Aug. 10, 2021) (No. 21-10477); *Garcia v. Welltower OpCo Group LLC* (9th Cir. June 16, 2021) (No. 21-55224); *Lyons v. Cucumber Holdings, LLC* (9th Cir. Aug. 17, 2021) (No. 21-55185); *McCalebb v. AG*

Lynwood, LLC (9th Cir. Oct. 20, 2021) (No. 21-55302); *Schleider v. GVDB Operations, LLC* (11th Cir. July 27, 2021) (No. 21-11765).

INTRODUCTION AND SUMMARY OF ARGUMENT

In early 2020, a highly contagious and deadly new virus began sweeping across the country and around the world. 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 worldwide 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, have faced many severe challenges. In an urgent struggle against an invisible foe, they have not only lacked consistent, well-defined guidance from public health officials, but were often hamstrung by worldwide shortages of personal protective equipment, testing kits, and other pandemic countermeasures. Within a little over two years, despite the widespread adoption of COVID-19 protocols and the heroic efforts of America's health

care workers, more than a million Americans have died—the vast majority of them over the age of 65.[2] Meanwhile, hundreds of senior care facilities have closed or teeter on the edge of bankruptcy.[3]

These serious challenges are compounded by the threat of thousands of lawsuits alleging that the negligent or improper administration of infection control policies caused patients and residents to acquire COVID-19. A major issue in many of these cases, which have been filed in 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, including this one, defendants are entitled to a federal forum.

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[2] CDC, *Weekly Updates by Select Demographic and Geographic Characteristics* (June 2, 2022), https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAg.

[3] Press Release, Am. Health Care Ass'n, *Nursing Homes Need Financial Support to Prevent Mounting Closures* (June 17, 2021), https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/Nursing-Homes-Need-Financial-Support-To-Prevent-Mounting-Closures.aspx; John George, *'A Heck of a Beating': Staffing and Funding Shortages Have Many Nursing Homes on the Ropes*, Phila. Bus. J. (Dec. 2, 2021), https://www.bizjournals.com/philadelphia/news/2021/12/02/whats-next-for-philadelphia-nursing-homes.html.

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 PREP Act. 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 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. 42 U.S.C. § 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

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.[4] 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

[4] *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/.

masks,[5] to the mode of viral transmission,[6] to unprecedented restrictions on their operations. Even today, information about COVID-19 continues to evolve.

As a result of the pandemic and the ensuing lockdowns, more than a million American businesses 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

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[5] 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.

[6] 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?.

[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.

Federal Reserve Bank survey, nearly a third of the remaining small businesses continued to fear for their survival.[10] The rise of successive new variants of the virus has dealt repeated setbacks to the fragile economic recovery.[11]

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 testing shortages and delays in testing results, hampered detecting the virus where it might do the 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

[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/.

[11] Theo Francis et al., *The Delta Variant Is Already Leaving Its Mark on Business*, Wall St. J. (Aug. 15, 2021), https://www.wsj.com/articles/-delta-variant--business-economy-11629049694; Patricia Cohen, *Omicron Could Knock a Fragile Economic Recovery Off Track*, N.Y. Times (Dec. 2, 2021), https://www.nytimes.com/2021/12/02/business/economy/omicron-economy.html.

decisions about how to allocate scarce resources meant to protect front-line workers and patients.[12]

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 deaths from COVID-19 in all of 2020.[13] But COVID-19 proved especially dangerous for the elderly. Of the approximately one million Americans who have died from COVID-19, about 75 percent were over the age of 65.[14] More than 200,000 of those deaths have been residents or staff

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[12] *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/.

[13] 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.

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

members of senior care facilities.[15] Despite the efforts of the nation's health care workers, who delivered care under extraordinary circumstances 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 10,000 lawsuits have already been filed, across all 50 states.[16]

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 operate on a non-profit basis.[17] In the first year of the pandemic (during

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[15] Priya Chidambaram, Kaiser Family Found., *Over 200,000 Residents and Staff in Long-Term Care Facilities Have Died From COVID-19* (Feb. 3, 2022), https://www.kff.org/policy-watch/over-200000-residents-and-staff-in-long-term-care-facilities-have-died-from-covid-19/#:~:text=More%20than%20200%2C000%20long%2Dterm,deaths%20over%20this%20bleak%20milestone.

[16] Am. Tort Reform Ass'n, COVID-19 Legal Services Television Advertising (2021), https://www.atra.org/white_paper/covid-19-legal-services-television-advertising/; Hunton Andrews Kurth, *COVID-19 Complaint Tracker* (2022), https://www.huntonak.com/en/covid-19-tracker.html.

[17] CDC, *Nursing Home Care* (Jan. 21, 2022), https://www.cdc.gov/nchs/fastats/nursing-home-care.htm.

which the events at issue in this case took place), long-term care facilities spent an estimated $30 billion on PPE and additional staffing alone.[18] The long-term care industry lost an estimated $94 billion from 2020 to 2021,[19] and 32 to 40 percent of current residents live in facilities that could close due to financial strain, leaving vulnerable seniors in search of new homes, caretakers, and communities.[20] 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.[21]

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

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[18] 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#.

[19] *Id.*

[20] Press Release, Am. Health Care Ass'n/Nat'l Ctr. for Assisted Living, *AHCA Releases Report Highlighting Unprecedented Economic Crisis in Nursing Homes* (Mar. 2, 2022), https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/AHCA-Releases-Report-Highlighting-Unprecedented-Economic-Crisis-in-Nursing-Homes.aspx.

[21] 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.

foresee that a pandemic could create circumstances like those seen with 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 tort 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.[22] 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.

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[22] "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 planner[s]" 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 Pharms., 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); *see Hogan v. Jacobson*, 823 F.3d 872, 879 (6th Cir. 2016). Both the U.S. Department of Health and Human Services ("HHS") and the U.S. Department of Justice ("DOJ") have identified the PREP Act as such a "complete preemption" statute. *See* Advisory Opinion No. 21-01 on the PREP Act, at 1 (HHS OIG 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 "more aptly described as a jurisdictional doctrine," as it confers federal jurisdiction where Congress intended not just to provide a federal defense to a state law claim but also to replace any state-law claim. *Hogan*, 823 F.3d at 879 (internal quotation marks omitted). That is, Congress may "so completely preempt 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, a federal statute need only (1) "preempt state law" in a particular area and (2) "provide[ ] the exclusive cause of action for the claim asserted." *Roddy v. Grand Trunk W. R.R.,* 395 F.3d 318, 323 (6th Cir. 2005) (internal quotation marks omitted). The PREP Act does both.

First, the Act preempts 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 of HHS 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.* 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 "relate[s] 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, the Court should give it 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).

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. 735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557 (1968) (Labor Management Relations Act); *Metro. Life,* 481 U.S. 58 (ERISA); *Ritchie v. Williams*, 395 F.3d 283 (6th Cir. 2005) (Copyright Act); *Gibson v. Am. Bankers Ins. Co.*, 289 F.3d 943 (6th Cir. 2002) (National Flood Insurance Act); *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005) (Air Transportation Safety and System Stabilization 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* 42 U.S.C. § 247d-6d(e) (describing remedies and detailing "procedures for suit").[23]

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 at 373. Based on these features, which closely parallel the principal components of the PREP Act, the Second Circuit identified the ATSSSA

[23] The district court stated that the Sixth Circuit has "limited expansion of complete preemption" and that "[b]oth the Supreme Court and the Sixth Circuit have recognized complete preemption with respect to *three* federal statutes" (ERISA, the Labor Management Relations Act, and the National Bank Act). RE 31 (Order of Remand), Page ID 464 & n.12 (emphasis added). But the court overlooked this Court's decisions also finding complete preemption under the Copyright Act and the National Flood Insurance Act, *see supra* at 19.

as a "complete preemption" statute providing for federal removal jurisdiction. *Id.* at 373, 380 (internal quotation marks omitted); *see also* 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 the ATSSSA provided a broader substitute cause of action. *See, e.g.*, *Dupervil v. All. Health Operations, LLC*, 516 F. Supp. 3d 238, 249–52 (E.D.N.Y. 2021). The Third Circuit made the same error in its decision in *Maglioli v. Alliance HC Holdings, LLC*, 16 F.4th 393 (3d Cir. 2021), *petition for reh'g denied*, No. 20-2833 (Feb. 7, 2022). There, while recognizing that the PREP Act "easily satisfies the standard for complete preemption of particular causes of action," the panel held that the Act does not completely preempt state-law *negligence* claims because the only judicial remedy it provides is for "willful misconduct," rather than negligence. *Id.* at 409–12. The court below likewise rejected complete preemption of negligence claims because "[w]ith the exception of willful misconduct," the PREP Act "does

not provide an exclusive federal cause of action[.]" RE 31 (Order of Remand), Page ID 465–467.

But that mirror-image approach to complete preemption is neither logical nor consistent with precedent. The Supreme Court's test for complete preemption is whether federal law not only preempts a state law to some degree but also substitutes a federal cause of action. *Beneficial Nat'l Bank*, 539 U.S. at 6–8. Nothing in that test suggests that the federal substitute must be coextensive with the underlying state-law claim; indeed, such a rule would be puzzling because Congress might well intend to replace certain state-law claims with more tailored federal remedies. As Judge Boudin observed, "[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). 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 made clear in the ERISA context, complete preemption has never been "limited to the situation in which a state cause of action precisely duplicate[d] a cause of action under [the

federal statute]." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 215–16 (2004). The Court explained that such an approach would not "be consistent with our precedent," because "Congress' intent to make the ERISA civil enforcement mechanism exclusive would be undermined if state causes of action that supplement the [ERISA] remedies were permitted, even if the elements of the state cause of action did not precisely duplicate the elements of an ERISA claim." *Id.*

The same goes for the PREP Act. Indeed, the PREP Act's preemption provision employs the same key language—"relating to"—as ERISA. 42 U.S.C. § 247d-6d(a). The Supreme Court has repeatedly recognized that the term "relat[ing] to" has a "broad common-sense meaning." *Pilot Life*, 481 U.S. at 47 (internal quotation marks omitted). This powerfully preemptive language confirms that state-law negligence claims—which would supplement the remedies Congress chose to make available in the PREP Act—are completely preempted. In reaching the opposite result, the court below failed to apply a basic principle of federal jurisdiction: "[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).[24]

The statute's purpose reinforces the structural argument for complete preemption under the PREP Act. *See Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 561 (6th Cir. 2007) ("[O]ur inquiry is ultimately one of congressional intent"). Congress delegated authority to the Secretary of HHS 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

[24] Apart from these formal principles, the allegations in this case also illustrate the practical difficulty of sorting out, at the jurisdictional stage, whether tort claims ultimately sound in negligence or willful misconduct. Based on the same set of core facts, Count 1 alleges simple negligence, Count 2 alleges "reckless, intentional, willful, and wanton misconduct," other counts refer to wrongful conduct "whether negligent, reckless, intentional, willful or wanton," and Count 5 seeks punitive damages for "malicious" conduct. *See* RE 1-1 (Complaint), Page ID 23–26.

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. The PREP Act addresses this concern by providing "[t]argeted 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.[25]

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).

[25] *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/.

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 defeat Congress's purpose of ensuring uniformity and efficiency. *Cf. Klepsky v. United Parcel Serv., Inc.*, 489 F.3d 264, 270 (6th Cir. 2007) (noting that the "uniform interpretation" of federal law is "the driving rationale behind the doctrine of complete preemption"). 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.*, Mem. at 3 n.3, 6–12, *Rachal*, No. 21-cv-00334-DCJ-JPM; *cf. Parker v. St. Lawrence Cnty. 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).

Although the PREP Act's preemptive force is extraordinary, its scope is carefully defined. Consistent with the Act's purpose of providing "targeted" liability protection and facilitating the efficient deployment of countermeasures, the Act provides immunity only 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). Through the issuance of declarations and amendments, the Secretary has "broad authority" to "control[ ]the scope of immunity." *Maglioli*, 16 F.4th at 401.

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. HHS Advisory Opinion 2–4. 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 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). These courts take the position that the PREP Act is categorically inapplicable to the "*non*-administration or *non*-use" of countermeasures. *See* HHS Advisory Opinion 3 (quoting *Lutz*, 480 F. Supp. 3d at 1218).

The court below declined to "express any opinion" on "whether plaintiff's claims fall under the purview of the PREP Act" because it held that, in any event, "the PREP Act is not a complete preemption statute." RE 31 (Order of Remand), Page ID 463, 470. Had the court reached the question, however, there would have been strong grounds for concluding that the allegations do fall within the scope of the Act or, at a minimum, ordering jurisdictional discovery to clarify that important issue.

Plaintiff's complaint alleges failures to adhere to COVID-19 protocols, including requirements that "all [facility] employees . . . wear masks[.]" RE 1-1 (Complaint), Page ID 19–20, 22 (emphasis omitted). Some courts have held that even if, as a general matter, the PREP Act might completely preempt certain claims arising from the use or administration of a covered countermeasure, a claim falls outside the PREP Act's scope if it alleges only the failure to use countermeasures. *See supra* at 29. 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). Courts should assume that "relating to" has some meaning, *see Duncan v. Walker*, 533 U.S. 167, 174 (2001)

(canon against surplusage), and recognize that "[t]he ordinary meaning of ['relating to'] is a broad one." *Morales,* 504 U.S. at 383. Thus, claims stemming from "[p]rioritization 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 just have been produced or may have previously 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 health care pandemic—the exact opposite result from Congress's goal.

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, district courts should scrutinize plaintiffs' allegations carefully, and order jurisdictional discovery if appropriate, instead of indulging plaintiffs' attempts to avoid complete preemption by casting their claims as involving "non-use" rather than administration or use. 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
Counsel of Record
Alexander Kazam
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jbucholtz@kslaw.com
akazam@kslaw.com

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

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

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

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

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

Counsel for American Medical Association and Ohio State Medical Association

Chad Golder
AMERICAN HOSPITAL ASSOCIATION
800 10th Street NW
Two CityCenter, Suite 400
Washington, DC 20001

Counsel for American Hospital Association

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5). This brief contains 6,100 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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Date: June 8, 2022

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 8, 2022, an electronic copy of the foregoing was filed with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the CM/ECF system.

The undersigned also certifies that service of the foregoing on registered users will be accomplished by the CM/ECF system and by email on the following counsel:

Adam R. Pulver
Allison M. Zieve
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Christian D. Foisy
Patrick T. Murphy
DWORKEN & BERNSTEIN
1468 W. Ninth Street
Suite 135
Cleveland, OH 44113
(216) 861-4211

Counsel for Appellee

Thomas Graham
HALL BOOTH SMITH
366 Madison Avenue, 5th Floor
New York, NY 10017
(212) 805-3630

Teresa Tomlinson
HALL BOOTH SMITH
1301 First Avenue, Suite 100
Columbus, GA 31901
(706) 494-3818

Keith Hansbrough
MARSHALL DENNEHEY
WARNER COLEMAN & GOGGIN
127 Public Square, Suite 3510
Cleveland, OH 44114
(216) 912-3809

Counsel for Appellants

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz