No. 21-10477

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

TROY MITCHELL, individually and
on behalf of the Estate of Emma Mitchell,
Plaintiff-Appellee,

v.

ADVANCED HCS, L.L.C., doing business as Wedgewood Nursing Home;
WEDGEWOOD REHAB & NURSING GS, L.L.C.; TOM GS, L.L.C.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas, No. 4:21-CV-155
Hon. Mark Timothy Pittman, U.S. District Judge

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

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record for *amicus curiae* certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1, in addition to those listed in the Appellants' Certificate of Interested Persons, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

***Amici*:** The Chamber of Commerce of the United States of America ("Chamber") is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent company, and no publicly held company has 10% or greater ownership in the Chamber.

The American Hospital Association ("AHA") is a non-profit, tax-exempt organization incorporated in the state of Illinois. AHA has no parent company, and no publicly held company has 10% or greater ownership in the AHA.

The American Medical Association ("AMA") is a non-profit, tax-exempt organization incorporated in the state of Illinois. AMA has no parent company, and no publicly held company has 10% or greater ownership in the AMA.

The Texas Medical Association ("TMA") is a non-profit, tax-exempt organization incorporated in the state of Texas. TMA has no parent company, and no publicly held company has 10% or greater ownership in the TMA.

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Date: August 10, 2021

s/Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

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INTEREST OF *AMICI CURIAE*[1]

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

[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. All parties have consented to the filing of this brief.

AHA provides extensive education for healthcare leaders and is a source of valuable information and data on healthcare 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 Texas. The AMA and Texas Medical Association ("TMA") 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.

TMA is a private, voluntary, nonprofit association of over 55,000 Texas physicians, residents, and medical students, in all fields of medical specialization. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and the improvement of public health. Today, its vision is to "Improve the health of all Texans." Consistent with its vision, TMA has an interest in promoting access to healthcare for all Texans and protecting physicians against excessive costs that could increase healthcare costs statewide.

During the COVID-19 pandemic, America's businesses and healthcare providers have faced extraordinary challenges. Healthcare 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 healthcare 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.

INTRODUCTION AND SUMMARY OF ARGUMENT

In early 2020, an invisible, 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. Healthcare 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. Healthcare 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 a hidden 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 healthcare workers, more than half a million Americans had died—the vast majority of them over the age of 65.[2] Meanwhile, hundreds of senior care facilities have closed or today teeter on the edge of bankruptcy.[3]

These serious challenges to healthcare 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

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

[3] Tony Pugh, *Bankruptcies, Closures Loom for Nursing Homes Beset by Pandemic*, Bloomberg Law (Dec. 30, 2020), https://news.bloomberglaw.com/health-law-and-business/bankruptcies-closures-loom-for-nursing-homes-beset-by-pandemic.

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 may be 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 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 Healthcare 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.[4] In

[4] *See* Liz Szabo, *Many U.S. Health Experts Underestimated the Coronavirus Until It Was Too Late*, Kaiser Health News (Dec. 21, 2020),

responding to this emergency, businesses and healthcare 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,[5] to the mode of viral transmission,[6] to unprecedented restrictions on their operations.[7] 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 have closed their doors—many of them permanently.[8] Within the first two months of the pandemic, the number

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https://khn.org/news/article/many-us-health-experts-underestimated-the-coronavirus-until-it-was-too-late/.

[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] *See* U.S. Chamber of Commerce, *Why Temporary Coronavirus Liability Relief Is Needed for American Business*, https://www.uschamber.com/report/why-temporary-coronavirus-liability-relief-needed-american-businesses.

[8] 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.

of actively working business owners plummeted by 22 percent.[9] About 60 percent of small businesses reported being "very concerned" about the impact of COVID-19 on their livelihood.[10] A year later, according to a Federal Reserve Bank survey, nearly a third of the remaining small businesses continued to fear for their survival.[11]

Healthcare 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

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[9] 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/.

[10] 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.

[11] 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/.

resources and hindered providers' ability 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 more than half a million Americans who have died from COVID-19, 80 percent were over the age of 65.[14] More than 150,000 of those deaths have been residents of senior care

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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.

facilities.[15] Despite the efforts of the nation's healthcare 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.[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] 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

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[15] *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.

[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/.

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

[18] *Id.*

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 COVID-19, with businesses reeling and healthcare 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 healthcare 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

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[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.

[20] "Covered person[s]" under the PREP Act include manufacturers, distributors, and "program planner[s]" of countermeasures, as well as

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.

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); *GlobeRanger Corp. v. Software AG*, 691 F.3d 702, 705 (5th Cir. 2012). 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,

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"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).

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. *PCI Transp., Inc. v. Fort Worth & W. R. Co.*, 418 F.3d 535, 543 (5th Cir. 2005). 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, Congress need only have (1) preempted state law in a given area and (2) "create[d] a federal remedy . . . that is exclusive." *Beneficial Nat. Bank,* 539 U.S. at 11. 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).

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).

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); *Spear Mktg., Inc. v. BancorpSouth Bank*, 791 F.3d 586, 594 (5th Cir. 2015) (Copyright Act); *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796 (5th Cir. 2011) (Interstate Commerce Commission Termination Act); *Hoskins v. Bekins Van Lines*, 343 F.3d 769, 778 (5th Cir. 2003) (Carmack Amendment). 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 removal jurisdiction. *Id.* at 373, 380 (internal quotation marks omitted); *see* Mem. 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, including the court below, 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); *accord Mitchell v. Advanced HCS, LLC,* 21-cv-155, 2021 WL 1247884, at *4 (N.D. Tex. Apr. 5, 2021). 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 Elam*, 635 F.3d at 803 ("Congress's intent is the ultimate touchstone") (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 healthcare 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.[21]

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 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.

[21] *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/.

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 this case, the complaint alleged that Defendants failed to implement a proper infection control program, including provision of sufficient "medical supplies." ROA.21-10477.64 ¶ 37. Although the district court did not directly address the scope of preemption, the court appeared to suggest that, where, as here, allegations are framed in terms of a defendant's "failure to act," they do not implicate the PREP Act's concern with the "administration of a drug, product or device." *Mitchell*, 2021 WL 1247884, at *1. Such an approach would be misguided. Consistent with the Act's purpose of providing liability protection that facilitates the efficient deployment of

countermeasures, which include certain medical supplies, 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).

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 healthcare provider's administration of an infection control program 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 recent district court decisions interpreting the Act have adopted an unduly narrow understanding of what is "relat[ed] to . . . administration." *See* HHS Advisory Opinion 3 (citing, e.g., *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 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 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. 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 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.

District courts must accordingly scrutinize plaintiffs' allegations carefully, and order jurisdictional discovery if appropriate, rather than simply assuming that the PREP Act has no bearing on alleged "inaction." 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 decisionmaking is "expressly covered by the PREP Act," however adept plaintiffs may be at "fashioning their pleadings." *Id.* 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 reverse.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 10, 2021, I caused the foregoing amicus brief to be filed with the Court electronically using the CM/ECF system, which will send a notification upon the following CM/ECF users:

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I certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4) because it contains 4,848 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared using Microsoft Word in Century Schoolbook 14-point font.

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