No. 21-55224

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GILBERT GARCIA, by and through his successor in interest, Paul Garcia; PAUL GARCIA, individually; RONALD GARCIA, individually; GARY GARCIA, individually,

Plaintiffs-Appellants,

v.

WELLTOWER OPCO GROUP LLC, DBA Sunrise Villa Bradford; SUNRISE SENIOR LIVING MANAGEMENT, INC.; RUZICA CALABRESE, an individual,

Defendants-Appellees.

On Appeal from the United States District Court for the Central District of California, Santa Ana, No. 8:20-cv-02250-JVS-KES
The Honorable James V. Selna, Senior District Judge

MOTION FOR LEAVE TO FILE BRIEF FOR *AMICI CURIAE* THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, CALIFORNIA CHAMBER OF COMMERCE, AMERICAN HOSPITAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, CALIFORNIA DENTAL ASSOCIATION, CALIFORNIA HOSPITAL ASSOCIATION, AND CALIFORNIA MEDICAL ASSOCIATION IN SUPPORT OF APPELLEES

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MOTION FOR LEAVE TO FILE BRIEF FOR *AMICI CURIAE*

The Chamber of Commerce of the United States of America ("the Chamber"), California Chamber of Commerce, American Hospital Association, American Medical Association, California Dental Association, California Hospital Association, and California Medical Association respectfully move for leave to file the accompanying brief as *amici curiae* in support of Defendants-Appellees. Counsel for the Chamber sought consent from the parties to file this brief. Defendants-Appellees consented; Plaintiffs-Appellants stated that they "will not oppose" but have not responded to counsel's request to clarify whether they consent.

The 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 California Chamber of Commerce ("CalChamber") is a non-profit business association with over 13,000 members, both individual and corporate, representing virtually every economic interest in the state of California. For over 100 years, CalChamber has been the voice of California business. While CalChamber represents several of the largest corporations in California, 75 percent of its members have 100 or fewer employees. CalChamber acts on behalf of the business community to improve the state's economic and jobs climate by representing business on a broad range of legislative, regulatory and legal issues. CalChamber often advocates before federal and state courts by filing *amicus curiae* briefs and letters in cases, like this one, involving issues of paramount concern to the 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 California. The AMA and California Medical Association ("CMA") 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 CMA is a nonprofit, incorporated, professional association of more than 50,000 member-physicians practicing in the State of California, in all specialties. The California Dental Association ("CDA") represents over 27,000 California dentists, more than 70 percent of the dentists practicing in the State. CMA's and CDA's memberships include most of the physicians and dentists engaged in the private practices of medicine and dentistry in California. The California Hospital Association ("CHA") represents the interests of more than 400 hospitals and health systems in California, having approximately 94 percent of the patient hospital beds in California, including acute care hospitals, county hospitals, nonprofit hospitals, investor-owned hospitals, and multi-hospital systems. Thus, *amici* represent much of the health care industry in California.

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.

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.

This brief is timely because it is filed within seven days of the June 9, 2021 filing of Defendants-Appellees' brief. This brief complies with Federal Rule of Appellate Procedure 29(a)(5) because it contains fewer than 6,500 words.

Given their substantial interest in this case, *amici* respectfully seek leave to file the attached brief.

Respectfully submitted,

s/Jeffrey S. Bucholtz

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INTEREST OF *AMICI CURIAE*[1]

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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.

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. 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.[2] Meanwhile, hundreds of senior care facilities have closed or today teeter on the edge of bankruptcy.[3]

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

[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.

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 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.[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 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,[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]

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

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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 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.[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 2020, long-term care facilities spent an estimated $30 billion on PPE and additional staffing alone.[18] The long-term care industry is expected to lose $94 billion from 2020 to 2021,

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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] 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#.

and more than 1,600 skilled nursing facilities could close this year, leaving vulnerable seniors in search of new homes, caretakers, and communities.[19] 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.[20]

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 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,

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[19] *Id.*

[20] 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.

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.[21] 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.

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); *see Marin Gen. Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009). Both the U.S.

[21] "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).

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"). And the district court in this case correctly found that well-supported interpretation persuasive.

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 "really a jurisdictional rather than a preemption doctrine," as it confers federal jurisdiction where Congress intended "to entirely replace any state-law claim." *Marin Gen. Hosp.*, 581 F.3d at 945 (citation and 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, Congress need only have "(1) intended to displace a state-law cause of action, and (2) provided a substitute cause of action." *City of Oakland v. BP PLC*, 969 F.3d 895, 906 (9th Cir. 2020), *as amended* (Aug. 12, 2020). 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).

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). 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). 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. *Cf. In re Miles*, 430 F.3d at 1089 (looking to "structure and purpose" of Bankruptcy Code). 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

[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/.

(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. 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, including the court below, 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 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 correctly held that the PREP Act supports complete preemption and properly rejected the misconception that a mere allegation of a "failure to . . . administer" countermeasures is

sufficient to evade the coverage of the Act. *Garcia v. Welltower OpCo Grp. LLC*, No. SACV 20-2250, 2021 WL 492581, at *9 (C.D. Cal. Feb. 10, 2021). 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).

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. 79190, 79192 (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 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 just have been produced or 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.

The district court accordingly recognized that a court should look carefully at a plaintiff's allegations before simply assuming that a case arises out of a total failure to administer or use countermeasures. *Garcia*, 2021 WL 492581, at *10. Here, Plaintiffs alleged that Defendants lacked adequate personal protective equipment for staff members in the early months of the pandemic. *Garcia*, 2021 WL 492581, at *9; *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." *Id.* at 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 correctly rejected Plaintiffs' attempt to avoid complete preemption simply by casting their claims as involving "non-use" of countermeasures. *Garcia*, 2021 WL

492581, at *9 (quoting HHS Advisory Opinion 4). The PREP Act is far too important to permit plaintiffs to plead around it so facilely.

CONCLUSION

The district court's judgment should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that:

This brief complies with the length limitations of Fed. R. App. P. 29(a)(5) and Ninth Circuit Rule 32-1 because this brief contains 5,331 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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 using Microsoft Word 365ProPlus in Century Schoolbook 14-point font.

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