

No. 22-192

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In the  
**Supreme Court of the United States**

GLENHAVEN HEALTHCARE LLC,  
a California corporation, *et al.*,  
*Petitioners,*

v.

JACKIE SALDANA, *et al.*,  
*Respondents.*

On Petition for Writ of Certiorari to the United  
States Court of Appeals for the Ninth Circuit

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**BRIEF OF THE CHAMBER OF COMMERCE  
OF THE UNITED STATES OF AMERICA,  
THE AMERICAN HOSPITAL ASSOCIATION,  
THE AMERICAN HEALTH CARE  
ASSOCIATION, AND THE AMERICAN TORT  
REFORM ASSOCIATION AS *AMICI CURIAE*  
IN SUPPORT OF THE PETITION**

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## INTEREST OF *AMICI CURIAE*<sup>1</sup>

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.

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 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

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<sup>1</sup> The parties received timely notice of this brief under Rule 37.2(a). Petitioners and respondents have consented to the filing of this brief. Pursuant to Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that 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.

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, like this one, with important and far-ranging consequences for its members.

The American Health Care Association and the National Center for Assisted Living (“AHCA/NCAL”) is the largest association in the United States representing long term and post-acute care providers, with more than 14,000 member facilities. AHCA/NCAL’s diverse membership includes non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and development disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day. AHCA/NCAL files *amicus curiae* briefs in cases, like this one, that have important implications for long term and post-acute care.

The American Tort Reform Association (“ATRA”) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. ATRA files *amicus curiae* briefs in cases, like this one, involving important liability issues.

During the COVID-19 pandemic, America’s businesses and healthcare 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, are 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**

This case presents an issue of exceptional importance that has divided the courts of appeals: the proper interpretation of a federal statute regulating the nation’s emergency response during a once-in-a-century pandemic and other global health emergencies.

In early 2020, a highly contagious and deadly new virus began sweeping around the world and 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.

The impact of the COVID-19 pandemic on American business has been felt far and wide. And healthcare providers—including the senior care and other long-term-care providers that serve America’s most vulnerable populations—have faced especially

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 hamstrung by worldwide shortages of personal protective equipment, testing kits, and other pandemic countermeasures. Despite the heroic efforts of America's healthcare workers, more than a million Americans have died—the vast majority of them over age 65.<sup>2</sup> Meanwhile, hundreds of senior care facilities have closed and the sector is in a financial and workforce crisis.<sup>3</sup> CMS is also considering establishing new minimum staffing requirements for nursing homes, which would place further financial pressure on them.<sup>4</sup>

These serious challenges for healthcare providers are compounded by the threat of thousands of lawsuits alleging that the negligent or improper administration of infection control policies caused residents to contract COVID-19. A major issue in many of these cases, which have been filed in state courts across the

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<sup>2</sup> CDC, *Weekly Updates by Select Demographic and Geographic Characteristics* (Sept. 21, 2022), [https://www.cdc.gov/nchs/nvss/vsrr/covid\\_weekly/index.htm#SexAndAg](https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAg).

<sup>3</sup> Press Release, Am. Health Care Ass'n/Nat'l Ctr. for Assisted Living, *Survey: Nursing Homes Still Facing Staffing & Economic Crisis* (June 6, 2022), <https://www.ahcanal.org/News-and-Communications/Press-Releases/Pages/Survey-Nursing-Homes-Still-Facing-Staffing-&-Economic-Crisis.aspx>.

<sup>4</sup> Pauline Karikari-Martin, *Centers for Medicare & Medicaid Services Staffing Study to Inform Minimum Staffing Requirements for Nursing Homes*, CMS.gov (Aug. 22, 2022), <https://www.cms.gov/blog/centers-medicare-medicaid-services-staffing-study-inform-minimum-staffing-requirements-nursing-homes>.

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.

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

Crucially, 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. This structure, combining preemption with exclusive federal remedies, is the defining feature of a “complete preemption” statute, which creates federal removal jurisdiction even when claims are pleaded under state law. *See, e.g., Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1 (2003) (National Bank Act); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987) (ERISA); *Avco Corp. v. Aero Lodge No. 1735, Int’l Ass’n of Machinists & Aerospace Workers*, 390 U.S. 557 (1968) (Labor Management Relations Act).

The decision below upends Congress’s carefully calibrated scheme. Instead of recognizing the PREP

Act as a “complete preemption” statute and allowing removal of a broad class of tort claims arising from the administration of pandemic countermeasures—as the text, structure, and purpose of the Act require—the Ninth Circuit reasoned that the Act provides an exclusive cause of action only for “willful misconduct,” not negligence, and therefore “is not a complete preemption statute.” App. 15a–17a. This holding contradicts the Third Circuit’s conclusion that the PREP Act *is* a complete preemption statute—at least with respect to willful misconduct claims. *See Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 409 (3d Cir. 2021). And as to respondents’ negligence claims, the Ninth Circuit’s requirement of a one-to-one correspondence between the state-law claim and a replacement federal cause of action is inconsistent with this Court’s precedent, which makes clear that the elements of a state claim need not “precisely duplicate” the federal claim for complete preemption to apply. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 215–16 (2004). The Ninth Circuit’s holding in the alternative—that even if respondents’ willful misconduct claim is completely preempted, there is no federal jurisdiction because their other claims are not completely preempted, *see* App. 16a–17a—sets up a bizarre all-or-nothing test that likewise finds no support in this Court’s precedent.

The Chamber accordingly urges this Court to grant the petition for certiorari. The acknowledged split between the Ninth Circuit and the Third Circuit supports the Court’s review, and the proper interpretation and application of the PREP Act is too important to await further percolation.

## ARGUMENT

### I. The Question Presented Is of Exceptional Importance

#### A. 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.<sup>5</sup> In responding to this emergency, businesses and healthcare providers have had to adapt to rapidly changing circumstances and evolving guidance from public health officials on key issues ranging from the utility of face masks,<sup>6</sup> to the mode of viral transmission,<sup>7</sup> 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

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<sup>5</sup> 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/>.

<sup>6</sup> 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>.

<sup>7</sup> 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?>.



closed their doors—many of them permanently.<sup>8</sup> The rise of successive new variants of the virus has dealt repeated setbacks to the fragile economic recovery.<sup>9</sup> Amid the turmoil, healthcare and senior care providers have been especially hard hit. A delayed rollout of COVID-19 test kits, followed by months of shortages, hampered detecting the virus where it might do most harm, including at senior care and other long-term-care facilities that serve predominantly the elderly and infirm. Meanwhile, a severe nationwide shortage of respirator masks and other personal protective equipment, which persisted well into the course of the pandemic, required difficult decisions about how to allocate scarce resources and hindered providers' ability to protect front-line workers and patients.<sup>10</sup>

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<sup>8</sup> 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](https://www.wsj.com/articles/covid-19-shuttered-more-than-1-million-small-businesses-here-is-how-five-survived-11596254424?mod=article_relatedinline).

<sup>9</sup> Eliza Mackintosh, *The 'Worst Variant' Is Here*, CNN (July 14, 2022), <https://www.cnn.com/2022/07/13/world/coronavirus-news-letter-intl-07-13-22/index.html>; 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>; 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>.

<sup>10</sup> 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*

Not surprisingly, all of those factors took a major toll on long-term care and senior care facilities, with their vulnerable populations and communal living arrangements. In many ways, these facilities have performed admirably under the most difficult of circumstances; according to one study, about two-thirds of assisted living facilities had no deaths from COVID-19 in all of 2020.<sup>11</sup> 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.<sup>12</sup> More than 200,000 of those deaths have been residents or staff members of senior care facilities.<sup>13</sup> Despite the efforts of the nation's healthcare workers, who delivered care under extraordinary circumstances to protect the vulnerable, the sheer scale of the tragedy makes the potential for litigation enormous.

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*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/>.

<sup>11</sup> Caroline Pearson et al., NORC: Univ. of Chi., *The Impact of COVID-19 on Seniors Housing*, at 2–3 (2021), [https://info.nic.org/hubfs/Outreach/2021\\_NORC/20210601%20NIC%20Final%20Report%20and%20Executive%20Summary%20FINAL.pdf](https://info.nic.org/hubfs/Outreach/2021_NORC/20210601%20NIC%20Final%20Report%20and%20Executive%20Summary%20FINAL.pdf).

<sup>12</sup> CDC, *Weekly Updates*, *supra* note 2.

<sup>13</sup> 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.>

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.<sup>14</sup> In the first year of the pandemic (during 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.<sup>15</sup> The long-term care industry lost an estimated \$94 billion from 2020 to 2021,<sup>16</sup> and as of March 2022, 32 to 40 percent of residents lived in facilities at risk of closing due to financial strain, leaving vulnerable seniors in search of new homes, caretakers, and communities.<sup>17</sup> 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

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<sup>14</sup> CDC, *Nursing Home Care* (Sept. 6, 2022), <https://www.cdc.gov/nchs/fastats/nursing-home-care.htm>; CDC, *Residential Care Communities* (Sept. 28, 2022), <https://www.cdc.gov/nchs/fastats/residential-care-communities.htm>.

<sup>15</sup> Press Release, Am. Health Care Ass'n/Nat'l Ctr. for Assisted Living, *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#>.

<sup>16</sup> *Id.*

<sup>17</sup> 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>.

next three decades.<sup>18</sup> By weakening the PREP Act’s protections for healthcare providers, the Ninth Circuit’s decision exacerbates this mounting national crisis.

**B. The Decision Below Undermines the PREP Act’s Critical Safeguards for Front-Line Responders**

Congress foresaw 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 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 countermeasures such as vaccines, tests, and surgical masks—from liability that might prevent them from continuing to operate and perform their critical functions.<sup>19</sup> When those front-line responders are

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<sup>18</sup> 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](https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf).

<sup>19</sup> “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

faced with tort lawsuits, the Act also ensures access to a federal forum, even when plaintiffs try to plead their claims in terms of state law.

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* 293 (2008). Just as a lack of immunity for public officials exercising discretionary functions may result in “the diversion of official energy from pressing public issues, and the deterrence of able citizens from acceptance of public office,” *Harlow v. Fitzgerald*, 457 U.S. 800, 814 (1982), insufficient protection for private parties that assist the government in times of need may result in “unwarranted timidity” and a failure to act “with the decisiveness and the judgment required by the public good,” *Filarsky v. Delia*, 566 U.S. 377, 389–90 (2012) (quoting *Richardson v. McKnight*, 521 U.S. 399, 409 (1997) & *Scheuer v. Rhodes*, 416 U.S. 232, 240 (1974)).

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 HHS Secretary, including the development, distribution, and dispensing of medical countermeasures, as well as the design and

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authorized to prescribe, administer, or dispense” such countermeasures. *Id.* § 247d-6d(i)(8).

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 hindered the rollout of vaccines that could have saved untold numbers of lives.<sup>20</sup> As the Organization for Economic Cooperation and Development has observed, instituting “reliable and transparent legal provisions for the indemnification of vaccine manufacturers” is crucial for preventing a “wave of litigation” from “creating a disincentive for manufacturers to enter the vaccine market.”<sup>21</sup>

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 immunity it affords, to play out across 50 state court systems would defeat Congress’s purpose of ensuring uniformity and efficiency.

The stakes are high. Trial lawyers have spent tens of millions of dollars on advertisements related to

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<sup>20</sup> *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/>.

<sup>21</sup> OECD, *Enhancing Public Trust in COVID-19 Vaccination: The Role of Governments* (May 10, 2021), <https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/>.

COVID-19, and more than 10,000 lawsuits have already been filed—in every state across the land.<sup>22</sup> Making matters worse, liability insurers often refuse to cover claims like the one in this case. Rather, insurers have enacted broad COVID-19 exclusions, placed moratoria on new medical professional liability business, and have been “extremely selective” about what types of facilities they will do business with and what they will insure.<sup>23</sup> This has left long-term care facilities in a very vulnerable position.

Congress designed the PREP Act as the ultimate backstop. Yet the Ninth Circuit’s decision allows plaintiffs to plead around the PREP Act’s complete preemption regime by couching their claims in state tort law. By diverging from the Third Circuit’s reasoning in *Maglioli*, the decision also opened a rupture in how that important federal statute applies in different regions of the country and contradicted the federal government’s own considered position on the PREP Act. Both the U.S. Department of Health and Human Services and the U.S. Department of Justice have identified the PREP Act as a “complete preemption” statute. See Advisory Op. No. 21-01 on the PREP Act, at 1 (HHS OIG Jan. 8, 2021); Fifth

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<sup>22</sup> Am. Tort Reform Ass’n, COVID-19 Legal Services Television Advertising (2021), [https://www.atra.org/white\\_paper/covid-19-legal-services-television-advertising/](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>.

<sup>23</sup> Amy O’Connor, *COVID 19 Hits Already-Troubled Nursing Home Insurance Market*, Ins. J. (May 10, 2020), <https://www.insurancejournal.com/news/national/2020/05/10/567421.htm>.

Amendment to Declaration Under the PREP Act, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021) (“The 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.

Given the proliferation of state court litigation, and given how long cases take to wend their way through the state court system, many health-care providers and long-term care facilities simply cannot afford to wait longer for this Court to take up the question presented in this case. The only way to ensure that the PREP Act is applied as Congress intended, and that it provides the protective effect it was designed to provide in a time of crisis, is to grant review now.

Furthermore, COVID-19 will not be the last public health emergency the nation faces. Already, the Biden Administration has declared the ongoing spread of monkeypox virus in the United States a public health emergency.<sup>24</sup> In the wake of that announcement, commentators observed that a federal declaration under the PREP Act could “enhance access” to drugs used to treat monkeypox by “provid[ing] significant liability protections for

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<sup>24</sup> Press Release, HHS, *Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency* (Aug. 4, 2022), <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.



persons involved in the chain of medical countermeasure distribution and administration.”<sup>25</sup>

Ultimately, if courts continue to disregard the statute’s guarantees of broad immunity and exclusive federal jurisdiction, despite the plain text and the HHS Secretary’s consistent interpretation of it, companies and individuals who relied on those promises of forum exclusivity and liability protection will be less likely to put their trust in such guarantees the next time around. The PREP Act incentivizes the private sector to work with the government and take the necessary risks to address public health crises. Failure to enforce the PREP Act according to its terms therefore has serious implications not only for the COVID-19 crisis, but for future emergencies, in which private-sector coordination may “become more cumbersome and expensive for the Government, and willing partners more scarce.” *Salazar v. Ramah Navajo Chapter*, 567 U.S. 182, 191–92 (2012) (citing *United States v. Winstar Corp.*, 518 U.S. 839, 883 (1996) (plurality opinion)). The result will be a less effective national emergency response and needless loss of lives and livelihoods.

In sum, the PREP Act reflects Congress’s recognition that a national emergency like COVID-19 requires a whole-of-nation response. The Act therefore provides the Secretary with a comprehensive national regulatory tool to encourage

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<sup>25</sup> Lawrence O. Gostin & James G. Hodge, Jr., O’Neill Inst. for Nat’l & Global Health Law *Monkeypox: National Emergency Declaration & Powers* (Aug. 7, 2022), <https://oneill.law.georgetown.edu/monkeypox-national-emergency-declaration-powers/>.

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. In holding that the PREP Act is not a complete preemption statute, the Ninth Circuit thwarted that congressional design and made removal of tort claims turn not on their substance but on how plaintiffs choose to label those claims. That decision was inconsistent with precedents of this Court and other courts of appeals.

## **II. The Decision Below Creates a Circuit Split and Conflicts With This Court's Precedent**

As petitioners note, the Ninth Circuit's holding that the PREP Act is "not a complete preemption statute"—full stop—creates a clear split with the Third Circuit's decision in *Maglioli*, 16 F.4th 393. In *Maglioli*, the Third Circuit recognized that "[t]he PREP Act's language easily satisfies the standard for complete preemption" of claims alleging willful misconduct because "[i]t provides an 'exclusive cause of action . . . and also set[s] forth procedures and remedies governing that cause of action.'" *Id.* at 409 (quoting *Beneficial Nat'l Bank*, 539 U.S. at 8). The court found that the complete preemption regime did not apply in that case only because it read the complaint as "alleg[ing] negligence, not willful misconduct." *Id.* at 410. Here, in contrast, the Ninth Circuit acknowledged that the complaint asserts claims for both negligence and willful misconduct, App. 5a—and yet the court rejected complete preemption categorically, even for the willful misconduct claim, App. 15a–17a. That direct conflict

by itself, concerning the interpretation of a federal emergency-response statute, calls out for this Court's review.

The Ninth Circuit's decision also contravenes important precedents of this Court. The well-established test for complete preemption is whether Congress intended to "supersede" state laws and in their place "create a federal remedy . . . that is exclusive[.]" *Beneficial Nat'l Bank*, 539 U.S. at 11. Nothing in that test suggests that the federal substitute must be coextensive with the underlying state-law claim; indeed, such a rule would not make sense because Congress might well intend to replace certain state-law claims with more tailored federal remedies. As Judge Boudin once 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)).

And that is precisely how the PREP Act works. First, the Act displaces state-law tort claims within a defined area, regardless of scienter. 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." 42 U.S.C. § 247d-6d(a). Then 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. *Id.* § 247d-6d(d)(1). For other tort claims, the Act does not leave claimants without a remedy, but sets up a no-fault administrative compensation fund. *Id.* § 247d-6e(a).

The Ninth Circuit 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. App. 16a. But this Court has firmly rejected that mirror-image approach to complete preemption. As this 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*, 542 U.S. at 215–16. This Court explained that such an approach would not “be consistent with our precedent,” because “Congress’s 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). This Court has repeatedly recognized that “relat[ing] to” has a “broad common-sense meaning.” *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987) (internal quotation marks omitted). This powerfully preemptive language confirms that state-law negligence claims—which supplement the

remedies Congress chose to make available in the PREP Act—are completely preempted. In reaching the opposite result, the Ninth Circuit 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).

Moreover, puzzlingly, despite acknowledging that “Congress intended a federal claim . . . for willful misconduct claims,” the Ninth Circuit rejected complete preemption altogether. App. 16a. The court held flatly that the PREP Act “is not a complete preemption statute,” even for willful misconduct claims, because while respondents’ willful misconduct claim “*may* be preempted,” the Act does not “*entirely supplant[]* state law causes of action” such as respondents’ negligence-based claims. App. 16a–17a (quoting *Retail Prop. Tr. v. United Bhd. of Carpenters & Joiners of Am.*, 768 F.3d 938, 947 (9th Cir. 2014)). As petitioners rightly point out, this all-or-nothing reasoning ignores basic principles of federal jurisdiction, which do not require that every claim in a federal case contain a federal question. *See* Pet. 17–19. Indeed, the lack of such a requirement is the very premise of supplemental jurisdiction over state-law claims. *See* 28 U.S.C. § 1367. The Ninth Circuit’s novel test, for which it cited no authority, also conflicts with this Court’s approach in complete preemption cases. For example, in *Beneficial National Bank*, this Court upheld removal to federal court even though the National Bank Act completely preempted only the plaintiffs’ purported “state-law claim of usury,” 539

U.S. at 11, and not their remaining claims for “intentional misrepresentation” and “breach of fiduciary duty,” among other things, *Anderson v. H&R Block, Inc.*, 132 F. Supp. 2d 948, 949 (M.D. Ala. 2000).

The Ninth Circuit’s contrary approach turns that common-sense practice on its head and essentially nullifies the concept of supplemental jurisdiction in complete preemption cases. In addition to the importance of the question presented in its own right and the clear circuit split, these conflicts with established precedent make the case for this Court’s review all the more compelling.

**CONCLUSION**

The Court should grant the petition for certiorari.

Respectfully submitted,

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