THE COURT OF APPEALS
OF THE STATE OF GEORGIA

APPEAL NO. A22A0068

ARBOR MANAGEMENT SERVICES, LLC,
Appellant,

v.

CARLOS HENDRIX, et al.,
Appellees.

BRIEF OF AMICI CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND GEORGIA CHAMBER OF COMMERCE IN SUPPORT OF APPELLANT ARBOR MANAGEMENT SERVICES, LLC

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STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America is the world's largest business federation. It directly represents approximately 300,000 members, and it indirectly represents the interests of more than 3 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—a community that includes countless physicians, hospitals, congregate living communities, senior assisted living communities, and other healthcare providers throughout the country.

The Georgia Chamber of Commerce serves the unified interests of its nearly 50,000 members – ranging in size from small businesses to Fortune 500 corporations – covering a diverse range of industries across all of Georgia's 159 counties, including the healthcare industry. The Georgia Chamber is the State's largest business advocacy organization and is dedicated to representing the interests of both businesses and citizens in the State. Established in 1915, the Georgia Chamber's primary mission is creating, keeping, and growing jobs in Georgia. The Georgia Chamber pursues this mission, in part, by aggressively advocating the businesses

and industry viewpoint in the shaping of law and public policy to ensure that Georgia is economically competitive nationwide and in the global economy

For the past year and a half, America's healthcare providers have faced extraordinary challenges. They have been on the front lines responding to a once-in-a-century emergency while adapting to changing circumstances and ever-evolving guidance and directives from public health authorities and government regulators. At the same time, private pharmaceutical and medical device manufacturers have invested considerably to help the world combat COVID-19 through new vaccines, medications, and other therapeutics. The just and efficient resolution of tort litigation arising from the COVID-19 pandemic is of great concern to amici and their members.

To that end, ammici have a strong interest in courts' properly interpreting and applying the federal Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, as well as the Georgia COVID-19 Pandemic Business Safety Act, O.C.G.A. §§ 15-16-1, *et seq*., and the Georgia Emergency Management Act, O.C.G.A. §§ 38-3-1, *et seq.* Those statutes afford America's healthcare providers—particularly those engaged in the often thankless task of caring for the elderly and infirm—much-needed immunity from ordinary tort liability so they can focus on continuing to provide the necessary services on which the Nation has relied through the darkest days of the pandemic.

SUMMARY OF ARGUMENT

The COVID-19 pandemic has battered healthcare providers across Georgia and throughout the United States. They've been forced to navigate a labyrinth of changing and sometimes conflicting guidance while working to keep people healthy. And they are experiencing operational and financial strains unimaginable only two years ago.

Presciently, Congress enacted the PREP Act years ago to give the Secretary of Health and Human Services authority to coordinate the national response to a pandemic like this one. Congress anticipated that healthcare providers and other private institutions would be essential to an effective response and, to that end, provided broad immunity from suit for actions undertaken by covered persons and "related to" the administration or distribution of countermeasures designated by the Secretary to combat the pandemic, including decisions about whether to distribute (or not) those countermeasures. The immunity is absolute for all claims other than those arising out of "willful misconduct," which must be brought in the U.S. District Court for the District of Columbia. The Act expressly and completely preempts contrary state law and also establishes a federal fund designed to compensate claimants for no-fault claims of loss.

The protection provided under the PREP Act is crucial to maintaining essential healthcare services during times of crisis like the ongoing pandemic.

Plaintiffs cannot plead around that immunity by attempting to recast decisions about the allocation and administration of covered countermeasures as "nonuse" of such countermeasures. If plaintiffs could evade the PREP Act's broad immunity with nothing more than bare allegations that a defendant failed to act with "slight diligence" while navigating conflicting guidance and shortages of labor, supplies, and equipment, the PREP Act would prove a hollow reed in Congress's efforts to protect those who have protected us. That is not what Congress provided, and it should not be the law in Georgia.

Congress was not alone in providing substantial immunities for healthcare providers fighting the pandemic. In Georgia, the General Assembly enacted the Pandemic Business Safety Act to provide immunity from COVID-19 related litigation to all businesses that have maintained operations during the pandemic, affording protection that was designed to be among the "strongest" in the nation. And exercising his authority under the Emergency Management Act, the Governor engaged Arbor and other healthcare providers in the State's efforts to respond to the pandemic and cloaked them with immunity under the Act for conduct taken under government directives. The immunity afforded under those state laws does not extend to claims of gross negligence, but if those laws are to serve their intended purpose, courts must hold plaintiffs to their burden of pleading and proving facts that in fact amount to gross negligence.

ARGUMENT AND CITATION OF AUTHORITIES

I. THE COVID-19 PANDEMIC PRESENTED UNPRECEDENTED CHALLENGES FOR HEALTHCARE PROVIDERS.

The COVID-19 pandemic has tested the resilience of American businesses like nothing before. At the outset of the COVID-19 epidemic, business owners confronted a novel, fast-moving virus that no one—not even the nation's top public health experts—anticipated or understood.[1] Businesses were forced to adapt on the fly to changing circumstances while evaluating fluctuating (and sometimes contradictory) guidance on issues such as masks[2] and the mode of viral transmission.[3] Although the uncertainty was greatest at the beginning, even today the guidance on COVID-19 precautions continues to evolve.[4]

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[1] *See, e.g.*, 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/; *see also* HHS Advisory Opinion 3 (October 23, 2020) ("[P]ublic-health guidance and directives tend to change to reflect the new knowledge . . . . changes do not always occur uniformly or simultaneously among scientists and across America[]—leading to uncertainty.").

[2] *See, e.g.*, 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.

[3] 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.

[4] *Compare* Daniel E. Slotnik & Dan Levin, *The C.D.C. Director Reaffirms That Vaccinated People in the U.S. Don't Need Masks in Most Situations*, N.Y. Times (June 30, 2021), https://www.nytimes.com/2021/06/30/world/cdc-mask-guidance.html, *with* Heather Hollingsworth, *New CDC Guidelines Set Off Rush to Reimpose Mask Mandates*, PBS (July 28, 2021),

Given the rapidly changing circumstances, evolving and often contradictory guidance, and uncertainty among the public, businesses of all types have struggled to continue operating while implementing and adapting to changing mitigation strategies. Owing in large part to those struggles, more than a million American businesses have closed their doors during the pandemic, many of them permanently.[5] Within months of the pandemic's onset, nearly 60 percent of small business owners reported being "very concerned" about COVID-19's impact on their livelihood, and,[6] a year later, nearly a third of remaining businesses continued to fear for their survival.[7]

Healthcare providers, and senior and long-term care providers in particular, have been among the hardest hit. From delayed rollouts of COVID-19 test kits to months-long shortages of personal protective equipment that resulted in volunteers hand-sewing masks for healthcare workers, senior and long-term care facilities were

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https://www.pbs.org/newshour/politics/new-cdc-guidelines-set-off-rush-to-reimpose-mask-mandates.

[5] 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.

[6] 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.

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

hampered in their response to the virus.[8] Nationwide shortages of respirator masks and other personal protective equipment (PPE) required difficult decisions about how to allocate scarce resources and hindered providers' ability to protect front-line workers and patients.[9]

And senior and long-term care facilities were left to make difficult decisions affecting the quality of life for their residents. Residents of those facilities often have unique psychological and emotional needs that require a network of social support and interaction with others to ensure their well-being. At the outset, nursing home facilities were left to weigh the costs and benefits of allowing residents to interact with each other or see outside visitors (typically the residents' children and grandchildren) as a means of providing desperately needed interaction and support, on the one hand, or depriving residents of social contact and connectedness in the name of protecting them from exposure to the virus during what may be their last remaining years, on the other. There were, and continue to be, loud voices on both

[8] *See, e.g.*, Tammy Webber et al., *Volunteers Sew Masks for Health Workers Facing Shortages*, ABC News (March 24, 2020), https://abcnews.go.com/US/wireStory/volunteers-sew-masks-health-workers-facing-shortages-69764445.

[9] *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/.

sides of the debate about quality of life and the appropriate level of mitigation measures for seniors, and there remains no "consensus" about whether elderly residents receive a net benefit from, or are more harmed by, policies of isolation and exclusion.[10] Decisions about those policies are incredibly difficult for facilities to make because they have a lasting impact on both the residents and their families.

Many of those facilities have performed admirably under the most difficult of circumstances. But despite the valiant efforts of the nation's healthcare workers, many of whom risked their own lives to protect the vulnerable, COVID-19 proved especially dangerous for the elderly. Of the more than half a million Americans who have died from COVID-19, roughly 80 percent were over the age of 65.[11] Given the disproportionate impact that COVID-19 has on older populations, it is unsurprising that nearly a third of all deaths (more than 150,000) have been residents of senior care facilities.[12]

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[10] *See, e.g.*, Emily Paulin, *Is Extended Isolation Killing Older Adults in Long-Term Care?*, AARP (Sept. 3, 2020), https://www.aarp.org/caregiving/health/info-2020/covid-isolation-killing-nursing-home-residents.html; Jason Karlawish *et al*., *Opinion: Continued Bans on Nursing Home Visitors are Unhealthy and Unethical*, Wash. Post (July 13, 2020), https://www.washingtonpost.com/opinions/2020/07/13/residents-good-nursing-homes-should-consider-re-allowing-visitors/.

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

[12] *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.

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 there are already more than 12,000 COVID-19 related lawsuits in the pipeline.[13] The operational and financial tolls that those lawsuits exact are hitting those facilities at a time when they can least afford the distractions and costs that litigation brings.

The pandemic itself has already wreaked havoc that 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.[14] In 2020, long-term care facilities spent an estimated $30 billion on PPE and additional staffing alone.[15] 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 tens of thousands of vulnerable seniors in search of new

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

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

[15] 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-CareFacilities.aspx#.

homes, caretakers, and communities.[16] With a shrinking base of available facilities and services, those entities that do manage to survive the year will be under even more pressure to deliver care with limited resources. In fact, the number of Americans over age 80 is expected to triple over the next three decades, leading to even more strains on the remaining infrastructure.[17]

Given the challenges that healthcare providers have endured, the operational and financial tolls that providing care to elderly residents throughout the COVID-19 pandemic has created, and the risk and scope of litigation associated with caring for the most at-risk populations, it is unsurprising that healthcare providers and senior care facilities have been the focus of protection efforts. Congress, the Secretary, the General Assembly, and the Governor have all spoken with a unified voice to ensure that providers are afforded broad immunity from suit so they can continue supplying the healthcare services for vulnerable populations that the country and the State need now more than ever.

II. THE PREP ACT BARS PLAINTIFFS' CLAIMS.

The PREP Act preempts all state laws that would otherwise impose liability for claims related to the administration of countermeasure programs in a pandemic

[16] *Id.*

[17] Nat'l Ctr. for Health Statistics, *Long-term Care Providers and Services Users in the United States, 2015–2016*, Series 3, No. 43 (Feb. 2019), at 3, https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

like COVID-19 and provides broad and complete immunity to healthcare providers for all action or inaction other than willful misconduct. Given the PREP Act's broad protections and goal of protecting critical healthcare infrastructure during the uncertainties of a pandemic, the courts should not allow plaintiffs to artfully plead around its protections.

A. The PREP Act is a complete preemption statute that bars state-law causes of action within its scope.

The PREP Act is a complete preemption statute that bars state-law causes of action within its scope.

Although nobody could have predicted how COVID-19 has affected the country, Congress *did* learn from prior health emergencies that a pandemic could overwhelm healthcare providers charged with protecting people while facing potentially crippling financial liability from a wrong step. In enacting the PREP Act, Congress sought to shield those entities defending the American population against a pandemic—those involved in manufacturing, distributing, allocating, or administering federally designated "countermeasures," such as COVID-19 tests or surgical masks—from liability that might prevent them from continuing to operate during times of crisis.[18] And "covered countermeasures" include preventative

[18] The PREP Act extends immunity to "covered person[s]," which include manufacturers, distributors, and "program planner[s]" of countermeasures, as well as "qualified person[s] who prescribed, administered, or dispensed such countermeasure[s]." 42 U.S.C. § 247d-6d(i)(2)(B)(iv). "Program planners" are those

measures (such as "respiratory protective device[s]") that mitigate or prevent the transmission of COVID-19. *Id.* § 247d-6d(i)(1)(A-D). In fact, the Secretary issued a Fourth Amended Declaration under the PREP Act "to make explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act." Fourth Amended Declaration, 85 Fed. Reg. at 79124.

The PREP Act could not more clearly state that its goal is to accomplish a "[p]reemption of state law" so that "no State or political subdivision of a 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). The 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). Both the Department of Health and Human Services and the Department of Justice have accepted the Act on its terms and described the PREP Act as a "complete preemption" statute. *See* HHS Advisory Opinion 21-01 on the PREP Act Scope of Preemption Provision (Jan. 8, 2021) ("HHS Advisory Opinion"); Fifth Amendment

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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)(A).

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").

HHS and DOJ's position is consistent with the PREP Act's framework as a whole. Congress may "so completely pre-empt a particular area" of law that any state-law claims within that defined area become "necessarily federal in character." *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63–64 (1987). For that to be so, Congress need only have (1) "preempt[ed] state substantive law" and (2) "'provid[ed] the exclusive cause of action for the claim asserted.'" *Dial v. Healthspring of Ala., Inc.*, 541 F.3d 1044, 1047 (11th Cir. 2008) (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003)). 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)(1). The Secretary can issue a PREP Act declaration only 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.* And 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).

Second, the Act provides a substitute, federal cause of action for certain claims that are otherwise preempted. The "sole exception" to the broad immunity conferred by the Act is "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 those claims is the U.S. District Court for the District of Columbia. *Id.* §§ 247d-6d(e)(1), (e)(5).[19] For other claims *within* the scope of PREP Act preemption, plaintiffs are not left without a remedy. The Act establishes a federal "Covered Countermeasure Process Fund," which is designed to provide "timely, uniform, and adequate compensation" through a no-fault claims process.

[19] Amici do not address the question of whether removal or transfer is appropriate in this case.

Id. § 247d-6e(a). That federal administrative remedy is also "exclusive." *Id*. § 247d-6d(d)(1).

This structure, combining preemption with exclusive federal remedies, is the defining feature of a "complete pre-emption" statute. *See Beneficial Nat'l Bank*, 539 U.S. at 7-8 (National Bank Act); *Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557, 559-60 (1968) (Labor Management Relations Act); *Metro. Life (Taylor)*, 481 U.S. at 63-64 (ERISA); *Hall v. N. Am. Van Lines, Inc*., 476 F.3d 683, 687 (9th Cir. 2007) (Carmack Amendment); *In re Miles*, 430 F.3d 1083, 1088 (9th Cir. 2005) (Bankruptcy Code); *Spear Mktg., Inc. v. BancorpSouth Bank*, 791 F.3d. 586, 594 (5th Cir. 2015) (Copyright Act). Like those 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.

What is more, the statute's purpose reinforces the structural argument for complete preemption under the PREP Act. Congress has delegated authority to the Secretary to "lead all federal public health and medical response" to national emergencies. 42 U.S.C. § 300hh(a). 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)(D). As we have seen over the last 20 months, rapid distribution and administration of

countermeasures is a task that requires the government to work hand-in-hand with—and quite often rely heavily on—private-sector partners, including healthcare providers, who generally lack the array of immunities with which public officials are commonly cloaked. And the PREP Act is a key tool that allows the Secretary to facilitate a whole-of-nation response by extending the "targeted liability protection"—including the preemption of state law liability—to private entities called upon by the Secretary to develop, distribute, dispense, and administer designated countermeasures. *See* 42 U.S.C. § 247d-6d.[20]

B. The PREP Act preempts the claims in this case.

Given the Act's sweeping grant of immunity for claims within its scope, it is unsurprising that plaintiffs try to avoid preemption with creative pleading. The PREP Act provides that "[1] a covered person shall be immune from suit and liability under Federal and State law with respect to claims for loss [2] caused by, arising out of, relating to, or resulting from [3] the administration to or the use by an individual of a covered countermeasure [4] if a declaration . . . has been issued with respect to such countermeasures." 42 U.S.C. § 247d-6d(a)(1). In the trial court, there was no genuine dispute that the defendants were "covered person[s]" or that a "declaration . . . has been issued" with respect to COVID-19 countermeasures. But in finding

[20] *See also* Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration*, 6 Biosecurity & Bioterrorism 1 (2008); DOJ Statement of Interest 2.

that the claims in this lawsuit fall outside the PREP Act's preemptive scope, the trial court limited the PREP Act's reach in a manner that flies in the face of both its text and the Secretary's interpretation.

1. The complaint alleges losses related to the administration of designated countermeasures.

Plaintiffs' claims rest on purported harm from (1) the use of PPE, (2) restrictions on outside visitors or social distancing requirements, and (3) policies on allowing employees who had been exposed to COVID-19 to continue working. *See, e.g.*, Amended Complaint, [V1-382-91] at ¶¶ 23-25 ("On March 11, 2020, Arbor Terrace announced restrictions on outside visitation and contact among residents due to COVID-19 . . . . Arbor Terrace failed to exercise even slight diligence to enforce them as individuals from outside the facility were still permitted to visit individual[s] inside . . ."); *id.* at ¶ 26 ("Arbor Terrace . . . allow[ed] staff members to work at the facility without masks or other protective equipment."); *id.* at ¶ 27 ("As late as March 25, 2020, Arbor Terrace was not consistently implementing PPE use among its staff . . ."); *id.* at ¶ 28 ("Arbor Terrace . . . allow[ed] asymptomatic staff who had been exposed to COVID-19 to continue to work at Arbor Terrace."); *id.* at ¶ 29 ("Arbor Terrace . . . fail[ed] to implement mandatory PPE use for residents and social distancing guidelines . . . in the common areas until on or after March 17, 2020."). All of those allegations "relate to" the administration of designated countermeasures as contemplated by the PREP Act.

The trial court (which incorporated its prior order on the motion for judgment on the pleadings, *see* Order [V1-705] at 3) erroneously found that the Plaintiffs' allegations "do not on their face appear to relate to the administration or use of a covered countermeasure" and are "wholly unrelated to the provision of any countermeasures under the Act." Order on Motion for Judgment on the Pleadings [V1-418-19] at 3-4. But the PREP Act provides immunity not only from claims arising directly from the use of countermeasures but also from claims "*relating to* . . . the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1) (emphases added). 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). In preemption cases, the Supreme Court has explained many times that the term "relating to" has a "broad common-sense meaning." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987); *see also Metro. Life Ins. Co. v. Mass.*, 471 U.S. 724, 739 (1985) ("broad scope"); *Morales v. Trans World Airlines*, 504 U.S. 374, 383–84 (1992) ("deliberately expansive" and "conspicuous for its breadth" (internal quotation marks omitted)).

Consistent with the statutory language, the Secretary has interpreted "administration" to include "decisions directly relating to public and private delivery, distribution, and dispensing" of countermeasures, as well as "management

and operation of countermeasure programs[] or management and operation of locations for purpose of distributing and dispensing countermeasures." Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,200 (Mar. 17, 2020) (emphases added). That covers the allegations in this case.

Contrary to the trial court's finding, even allegations of "failure" to use a countermeasure may "relat[e] to . . . the administration to or the use" of a covered countermeasure. Fourth Amended Declaration, 85 FR 79,190, 79,197. In fact, the Secretary expressed concern over "the growing number of suits related to the use *or non-use* of covered countermeasures against COVID-19, including PPE." HHS Advisory Opinion at 1. The Secretary has explained that decisions to forgo a particular countermeasure or inconsistent or ineffective application come within the Act's preemptive reach:

> At one extreme, plaintiff may have pleaded that the facility failed *in toto* to provide any of its staff or patients with any PPE, a covered countermeasure . . . Other plaintiffs allege that the quantity of PPE was inadequate, that staff were not timely provided PPE or that staff were not adequately trained to use PPE . . . . Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act.

Id. at 2, 4.[21] Although the Secretary acknowledged that there will "be circumstances where plaintiff pleads that defendant's culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner," that is "a small hole through which to wiggle to avoid complete preemption." *Id.* at 4 (emphases added). And the Secretary called upon courts to prevent that hole from "grow[ing] as plaintiffs become more adept at fashioning their pleadings." *Id.*[22]

As the Secretary has emphasized, 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, including non-use or inconsistent use of those countermeasures as long as it is connected to some decision-making about the use of designated countermeasures 42 U.S.C. § 247d-6d(a)(1) (emphasis added); HHS Advisory Opinion. The Court must assume that "relating to" has meaning. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (canon against surplusage); *Lucas v. Beckman Coulter, Inc.*, 303 Ga. 261, 263 (2018) (courts must seek "to avoid a construction that makes some language [of a statute] mere surplusage"). And courts

[21] *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).

[22] The Secretary rightly criticized recent decisions—like the lower court's here—that narrowly construed the phrase "relat[ed] to . . . administration" in a manner that is inconsistent with the goal of the Act. *See, e.g.*, *id.* at 3; *see also 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. Mar. 2, 2021).

have long recognized that "[t]he ordinary meaning of ['relating to'] is a broad one." *Morales*, 504 U.S. at 383.

As anyone could have predicted, the rollout of countermeasures to a health emergency brought difficult allocation decisions—made in the swirl of changing policies, priorities, and treatment protocols. If claims about how to implement or allocate countermeasures are *not* covered, institutional and individual healthcare providers would have little incentive to continue working on the front lines—the opposite of what Congress sought to accomplish with the PREP Act.

As HHS has observed, an infection control program like the one that Arbor administered "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 at 4. That type of decision-making and administration is "expressly covered by the PREP Act," however adept plaintiffs may be at "fashioning their pleadings." *Id.* The court below should not have indulged Plaintiffs' attempt to avoid complete preemption by casting their claims as involving "lack of" or "failure to provide" countermeasures. The PREP ACT is not so easily evaded.

2. Plaintiffs' allegations do not fit within the sole exception to the PREP Act's protection.

Congress declared that "the *sole exception to the immunity from suit* and liability of a covered person . . . shall be "for death or serious physical injury

proximately caused by *willful misconduct*," and such an action must be filed and maintained in the U.S. District Court for the District of Columbia. 42 U.S.C. § 247d-6d(d)(1) (emphases added), 247d-6d(e).[23] Willful misconduct includes actions taken "(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." *Id.* § 247-6d(c). But the standards are stricter still. For instance, a "program planner or qualified person shall not have engaged in 'willful misconduct' as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure." *Id.* § 247-6d(c)(5). The takeaway is that healthcare facilities enjoy broad immunity unless they have a culpable mental state—a deliberate or conscious disregard of risk or a complete abandonment of a duty to act as a program planner and implement a plan. HHS Advisory Opinion at 4.

[23] Congress provided immunity "from suit," not immunity from "liability." Plaintiffs suggested in their Opposition to Interlocutory Appeal that the "trial court's decision has no adverse impact on Petitioner's right to pursue their defenses under State and Federal law . . . . The only impact here is that the Petitioner's [sic] will have to participate in discovery . . . ." Opp. to Interlocutory Appeal at 2. But denying healthcare providers immunity from *suit* undermines Congress's goal of preventing covered persons such as healthcare operators from enduring the financial and operational costs associated with litigation.

Plaintiffs cannot meet the high bar for a suit under the "willful misconduct" exception. Plaintiffs allege in threadbare fashion that "Arbor Terrace failed to exercise even slight diligence to enforce [social distancing] as individuals from outside the facility were still permitted to visit individual[s] inside the facility," that "Arbor Terrace did not even implement a policy of social distancing among residents and in the common areas until on or after March 17, 2020," and that "Arbor Terrace hosted a St. Patrick's Day social among residents in its common area" on March 17. Amended Complaint, [V1-382-91] at ¶¶ 23-25, 29. Plaintiffs also allege that residents were "taken on a scenic ride . . . . [while] not seated at least six feet apart." *Id.* ¶¶ 32-33. As to PPE and quarantine policies, Plaintiffs allege that "Arbor Terrace was not consistently implementing PPE use among its staff" and "allowing asymptomatic staff who had been exposed to COVID-19 to continue to work at Arbor Terrace." *Id.* ¶¶26-28. But through those allegations, Plaintiffs concede that Arbor *in fact* put a plan into place and highlight the difficult decisions that residential healthcare facilities faced when implementing COVID-19-related policies in spring of 2020.

First, inconsistent use of PPE and social distancing efforts does not amount to "willful misconduct" as the PREP Act defines it. Plaintiffs' allegations that Arbor culpably delayed implementing social distancing efforts by failing to establish a social distancing policy before March 17, 2020, ignores the realities of early 2020.

The President first declared a national emergency for the "novel (new) coronavirus" on Friday, March 13, 2020. *See* Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, Proc. 9994, 85 Fed. Reg. 15,337. The Governor declared a corresponding public health state of emergency on Saturday, March 14, 2020. *See* Exec. Order No. 03.14.20.01. And the White House announced social distancing guidelines on Monday, March 16, 2020.[24] Arbor allegedly put in place a social distancing plan the following day, hardly a delay suggesting willful misconduct. Similar points could be made about Plaintiffs' allegations regarding PPE. Even setting aside the conflicting guidance on the efficacy of masks, PPE was scarce at the outset of the pandemic, making it difficult to enforce PPE requirements.[25]

Second, quarantining asymptomatic healthcare staff who had "been exposed to COVID-19" in a long-term care facility—at a time of lockdown orders and public uncertainty—could have created personnel shortages and prevented healthcare facilities from providing life-saving service and assistance to residents. The Georgia

[24] *See* Richard Harris, *White House Announces New Social Distancing Guidelines Around Coronavirus* NPR (March 16, 2020), https://www.npr.org/2020/03/16/816658125/white-house-announces-new-social-distancing-guidelines-around-coronavirus.

[25] *See* William Wan, *America is Running Short on Masks, Gowns, and Gloves. Again.*, Wash. Post (July 8, 2020) ("For weeks, nurses have posted online testimonials about a lack of PPE, with some given surgical masks instead of N95 masks because of shortages.").

Department of Public Health has recognized that "staffing levels and access to supplies and testing may vary by facility . . . [so] decisions about relaxing restrictions in a facility" should be based on a number of different factors, including a heavy focus on "[a]dequate staffing."[26] In the pandemic's early days (the timeframe relevant to the Complaint), healthcare facilities had to provide services and staff facilities notwithstanding the challenges that COVID-19 presented—and in the face of an already shrinking labor supply.

Plaintiffs cannot sidestep the PREP Act's protections by Monday-morning quarterbacking the decisions that defendants were forced to make with far less information about COVID-19 and while operating under serious resource constraints. And even if they wanted to try, their exclusive remedy would be to file suit in the in the U.S. District Court for the District of Columbia, not in a Georgia state court.

Worse, Plaintiffs' claims here challenge conduct that may be condoned or even encouraged *today*. For nearly two years now, the benefits of social interaction among residents has been an issue for senior care facilities navigating lockdowns and restrictions. The CDC's recent guidance allows visitation for unvaccinated residents and "communal activities" for everyone except for "patients/residents with

[26] Georgia Department of Public Health, Long-Term Care Facility Administrative Order (Updated Mar. 15, 2021).

[active] SARS-CoV-2 infection, or in isolation because of suspected COVID-19" or "patients/residents [actually] in quarantine."[27] It would be a bizarre interpretation of the PREP Act that would impose liability for conduct that the CDC—with an additional year and a half of data about COVID-19—now deems responsible.

III. GEORGIA LAW PROVIDES ALTERNATIVE SOURCES OF IMMUNITY.

Because the PREP Act had not been frequently litigated before the COVID-19 pandemic began (*see* Pub. Law 109–148, Division C, Section 2, December 2005 enactment), many states took their own steps to ensure that healthcare workers and other businesses could continue operating during the COVID-19 pandemic without facing ruinous liability. Georgia was among them. As a result, if the PREP Act did not foreclose the claims asserted here (it does), Georgia law would provide immunity against the claims that Plaintiffs have asserted in any event.

A. The General Assembly enacted the Pandemic Business Safety Act to protect all Georgia businesses.

The Georgia COVID-19 Pandemic Business Safety Act provides that

> No healthcare facility, healthcare provider, entity, or individual shall be held liable for damages in an action involving a COVID-19 liability

[27] *See* CDC, *Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html (Updated April 27, 2021) ("Post-acute care facilities, including nursing homes . . . Indoor visitation for unvaccinated residents should be limited solely to compassionate care situations [only] if the COVID-19 county positivity rate is >10% and <70% of residents in the facility are fully vaccinated.").

> claim against such healthcare facility, healthcare provider, entity, or individual, unless the claimant proves that the actions of the healthcare facility, healthcare provider, entity, or individual showed gross negligence, willful and wanton misconduct, reckless infliction of harm, or intentional infliction of harm.

O.C.G.A. § 51-16-2.[28] To avoid any confusion, the General Assembly explained that immunity under the Act is "in addition to, and shall in no way limit, any other immunity protections that may apply in state or federal law." *Id.* § 51-16-2(b)

The General Assembly granted that protection not just to healthcare providers, but to every single "entity" operating in Georgia, regardless of the services or goods they provide—from healthcare facilities to grocery stores. *See id.* § 51-16-1 (defining "entity" as *any* association, corporation, company, or other type of organization). The General Assembly viewed immunity from suit as critical to protecting businesses that provide the essential services that Georgians have relied on throughout the pandemic. In fact, the Georgia Senate Research Office has described the Pandemic Business Safety Act as providing "blanket immunity" from liability for COVID-19 claims and "some of the strongest protections in the United

[28] *See also id.* § 51-16-1 (defining "COVID-19 liability claim" to include any cause of action for COVID-19 exposure, infection, or transmission, at any premises, or caused by any "actions of any healthcare provider or individual" resulting in injury or death).

States" to ensure that Georgia citizens can still rely on the businesses that keep them housed, fed, and healthy.[29]

B. The Emergency Management Act further protects healthcare providers.

In addition to the Pandemic Business Safety Act's protections, the Governor has exercised his authority under the Emergency Management Act, O.C.G.A. §§ 38-3-1, *et seq* to issue multiple executive orders, which have the effect of conferring immunity under the Act. The Emergency Management Act functions like the PREP Act—it enables the Governor to enter orders to coordinate public and private responses in "the event of actual or impending . . . pandemic influenza emergency . . . or a public health emergency," to "[s]uspend any regulatory statute prescribing procedures for conduct of state business," and to "[c]ompel a health care facility to provide services or the use of its facility if such services or use are reasonable and necessary for emergency response." O.C.G.A. § 38-3-51(a), (d). When a private entity "acts in accordance with an order, rule, or regulation entered by the Governor pursuant to the authority granted by [the Emergency Management Act]," it "will *not be held liable* to any other individual, partnership, association, or corporation by reason thereof *in any action* seeking legal or equitable relief." *Id.* § 35-3-51(j) (emphases added). The immunity stretches to "all other activities necessary or

[29] James Beal, *Revisiting the Georgia COVID-19 Pandemic Business Safety Act*, Georgia State Senate Research Office (2020).

incidental to the preparation for and carrying out of" emergency management activity. *Id.* § 38-3-3(2). And the immunity must be "construed liberally" to effect its purpose. *Id.* § 38-3-6. The only exception to immunity is for "willful misconduct, gross negligence, or bad faith." O.C.G.A. § 38-3-35.

The Governor exercised his authority under the Emergency Management Act to enter multiple orders designating the COVID-19 pandemic as a state of emergency in Georgia and directing that "all state and local authorities as well as public and private hospitals, healthcare facilities, clinics, and medical personnel shall fully comply with orders by the Governor." Exec. Order No. 03.14.20.01. The Governor also designated healthcare institutions and their employees as "auxiliary emergency management workers," who engage in "emergency management activities," which extends the Emergency Management Act's immunity to those entities. Exec. Order No. 04.14.20.01; *see also* O.C.G.A. § 38-3-35; *id* § 38-3-51.

The Governor made that designation because "[h]ealthcare institutions and facilities *require additional flexibility to provide the critical assistance and care needed by this state during this unprecedented emergency*." Exec. Order No. 04.14.20.01. The Governor's office emphasized that, "[f]or the duration of the Public Health State of Emergency, this order [04.14.20.01] will limit the civil liability of 'auxiliary emergency management workers' engaging in 'emergency

management activities' while providing patient care if such care results in the death or injury of a patient."[30]

C. Plaintiffs' allegations do not fit within the exception to immunity under Georgia law.

The General Assembly and the Governor have spoken in unison to provide immunity from all forms of COVID-related litigation regardless of the relief sought (whether legal or equitable). Georgia's COVID-19 immunities provide businesses with the "strongest protections" possible from the economic damage that lawsuits cause to Georgia's pandemic-battered businesses. And the General Assembly and the Governor have clarified that those protections must be construed liberally to achieve their goals. Conclusory allegations of gross negligence thus cannot nullify the immunity that Georgia law provides. Rather, plaintiffs must plead facts that put defendants on notice of conduct that constitutes "gross negligence."

For the same reasons that Plaintiffs have failed to allege any willful misconduct that would bypass the immunities provided by the PREP Act, they have also failed to allege "gross negligence" under Georgia law. "Gross negligence" under Georgia law requires a lack of the "degree of care which every man of commonsense, however inattentive he may be, exercises under the same or similar

[30] Office of the Governor, *Kemp Designates Auxiliary Emergency Management Workers, Emergency Management Activities***,** (April 14, 2020 Press Release), https://gov.georgia.gov/press-releases/2020-04-14/kemp-designates-auxiliary-emergency-management-workers-emergency.

circumstances." *Gliemmo v. Cousineau*, 287 Ga. 7, 13 (2010) (quotation omitted); *see also id.* (defining gross negligence as the "lack of [] diligence that even careless men are accustomed to exercise" (quotation omitted)). None of Plaintiffs' allegations relating to inconsistent use of social distancing, PPE, or quarantining staff meet that standard. *See, e.g.*, *Johnson v. Omondi*, 294 Ga. 74, 78 (2013) ("While questions of gross negligence and slight diligence are usually to be determined by a factfinder, courts may resolve them as matters of law in plain and indisputable cases."); *Wolfe v. Carter*, 314 Ga. App. 854, 859 (2012) ("[T]his case presents such a plain and indisputable case . . . it is a well-settled principle of negligence law that the occurrence of an unfortunate event is not sufficient to authorize an inference of negligence . . . . Nor can it support an inference of gross negligence." (cleaned up)).

Indeed, if the allegations in this case were sufficient to plead "gross negligence," the immunity provided would be worth less than the statute provides.[31]

[31] *See, e.g.*, Chris Marr, *COVID-19 Liability Shield in Effect for Georgia Businesses*, Bloomberg Law (Aug. 6, 2020), https://news.bloomberglaw.com/daily-labor-report/covid-19-liability-shield-takes-effect-for-georgia-businesses (Senator Chuck Hufstetler described the protection as a "fair compromise" to protect businesses from ongoing litigation); *see also* Claire Simms, *Georgia House Votes to Extend COVID-19 Liability Protections*, Fox5 (Feb. 9, 2021), https://www.fox5atlanta.com/news/georgia-house-votes-to-extend-covid-19-liability-protections (Representative Kasey Carpenter, a "small business owner himself," said that "frivolous lawsuits" over COVID-19 exposure caused the General Assembly to extend by the Pandemic Business Safety Act's protection).

If imperfect implementation of social distancing and PPE requirements constituted gross-negligence whenever senior citizens were involved, no businesses serving such citizens would be protected. But nothing in the statutes suggests that result, and this Court should not permit plaintiffs to plead around the statutes with nothing but labels.

CONCLUSION

The Court should reverse the trial court's decision and remand with instructions to dismiss Plaintiffs' complaint with prejudice as barred by the PREP Act, the Pandemic Business Safety Act, or the Emergency Management Act.

[Signature on following page]

Respectfully submitted this 7th day of September, 2021. This submission does not exceed the word count limit imposed by Rule 24.

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CERTIFICATE OF SERVICE

I certify I have on this day caused a true and correct copy of the foregoing Brief of Amici Curiae Chamber of Commerce of the United States of America and Georgia Chamber of Commerce in Support of Appellant Arbor Management Services, LLC to be served upon all counsel of record by this Court's Odyssey E-fileGA System, which will automatically send email notification of such filing to all counsel of record, and have further served copies via U.S. Mail, postage prepaid, addressed as follows:

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