No. 21-55224

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GILBERT GARCIA, et al.,
Plaintiffs – Appellants,

v.

WELLTOWER OPCO GROUP LLC, et al.,
Defendants-Appellees.

On Appeal from the United States District Court for the Central District of California, No. 8:20-cv-02250-JVS – Honorable James V. Selna

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BRIEF OF AMICI CURIAE ARGENTUM, CALIFORNIA ASSISTED LIVING ASSOCIATION, AMERICAN SENIORS HOUSING ASSOCIATION, AND AMERICAN HEALTH CARE ASSOCIATION/NATIONAL CENTER FOR ASSISTED LIVING SUPPORTING DEFENDANTS-APPELLEES

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Corporate Disclosure Statement

Pursuant to Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, *amici curiae*, Argentum, California Assisted Living Association, American Seniors Housing Association, and the American Health Care Association/National Center for Assisted Living are all trade associations of senior living communities. There are no parent corporations or publicly held corporations that own 10 percent or more of the stock of any of the amici.

/s/ Thomas Barker
Thomas Barker

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/s/ Thomas Barker
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Statement of *Amici* Interest[1]

Amici are the leading trade associations serving organizations that own, operate, and support professionally managed senior living communities in the United States, including assisted living, memory care, independent living and continuing care retirement communities.

Argentum members provide elderly individuals with safe, comfortable, and caring communities where residents have the supports needed to live actively and independently. Argentum provides representation and advocacy on behalf of its members to Congress, the executive branch, the media, and academia, and it works with state partners to monitor current state laws and regulations affecting senior living communities.

The California Assisted Living Association ("CALA") represents the state's Residential Care Facilities for the Elderly, which encompass assisted living, memory care, and continuing care retirement communities. CALA represents over 660 providers and more than 150 associated businesses. CALA provider members range from small, independently operated communities to large, multi-national

[1] Both Plaintiffs-Appellants and Defendants-Appellees do not object to the filing of this brief pursuant to Federal Rule of Appellate Procedure 29(a). Undersigned counsel for *amici curiae* certify that this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than *amici* and their counsel have contributed money to this brief.

organizations, and from providers that cater to an active lifestyle to ones that specialize in caring for residents with dementia.

The American Seniors Housing Association ("ASHA") advances the interests of organizations engaged in the development, ownership, operations and financing of seniors housing. As part of this role, ASHA works to educate policymakers about the industry and protect the interests of seniors housing owners and operators, as well as advocating for policies that benefit its residents and their families. ASHA is also engaged in national consumer education initiatives designed to help seniors, families and other influencers understand their senior living options and make empowered decisions.

The American Health Care Association/National Center for Assisted Living ("AHCA/NCAL") is a national trade association representing, among others, 5,000 assisted living providers by and through NCAL. By delivering solutions for quality care, NCAL is dedicated to improving 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.

Throughout the COVID-19 public health emergency amici have advocated for critical resources to help keep residents of senior living communities safe. *Amici's* members are similarly situated to Defendant-Appellees and have the potential to face similar lawsuits. *Amici* submit this brief in support of Defendant-

Appellees to educate the Court on the challenges facing senior living during the COVID-19 pandemic and the application of the PREP Act to the services senior living communities provide.

I. Introduction and Summary of Argument

The COVID-19 pandemic has created unprecedented challenges for senior living communities. Across the United States, nearly two-million elderly Americans call a senior living community home. Due to their age and related comorbidities, residents of senior living facilities are some of the most vulnerable to complications from COVID-19. As a result, senior living communities have been on the front lines of preventing the spread of COVID-19 among at-risk populations. Senior living facilities adopted infection control policies including restricting visitors, halting communal dining and group activities and cohorting residents and staff. Senior living facilities also reinvented physical spaces, enhanced sanitation and the use of personal protective equipment ("PPE"), and provided onsite COVID-19 testing. Throughout the COVID-19 pandemic, senior living communities addressed the safety and needs of their residents and their families despite nationwide shortages in testing, PPE, and other supplies, as well as rapidly changing guidance from state and federal regulators.

In the wake of the 2005 avian influenza epidemic, and in order to better prepare for a future public health emergency like COVID-19, Congress passed the Public Readiness and Emergency Preparedness Act ("PREP Act") to authorize the Secretary of Health and Human Services to limit legal liability for covered persons relating to administration of countermeasures used to combat a pandemic.

Congress recognized that broad liability protections were necessary to allow front line workers to take the critical steps needed to respond to a rapidly developing public health emergency. Accordingly, immunity under the PREP Act applies to a broad range of front line individuals and organizations. Senior living facilities are covered by the PREP Act when engaged in the use or administration of a covered countermeasure, such as use of PPE, use of thermometers for symptom screening, and the administration of *in vitro* diagnostic and antigen tests to detect COVID-19.

Consistent with both the language and purposes of the PREP Act and the Secretary's declaration regarding the COVID-19 pandemic, the District Court in this case correctly held that the PREP Act completely preempted Plaintiffs' claims against a senior living provider stemming from their supervision and administration of infection control programs during the COVID-19 pandemic. The District Court's order should be affirmed.

II. Argument

A. Congress Passed the PREP Act to Allow Front Line Health Care Personnel to Rapidly React to a Public Health Emergency

In 2005, Congress passed the Public Readiness and Emergency Preparedness Act ("PREP Act") to encourage the expeditious development and deployment of covered countermeasures during a pandemic or other public health emergency. *See* Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. § 247d-6d (2006)). The PREP Act was initiated by President George W. Bush as part of

the National Strategy for Pandemic Influenza, in response to the outbreak of the avian influenza. In the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered.

The PREP Act authorizes the Secretary of Health and Human Services ("HHS"), upon determining that a disease or other health condition constitutes a public health emergency, to issue a declaration immunizing covered persons from suits and liability for all claims for loss relating to the administration or use of a covered countermeasure. In the Secretary's declaration, the Secretary must specify the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures" to be subject to immunity under the PREP Act. The PREP Act grants the Secretary broad, unreviewable discretion on whether to issue a declaration and the substance of the declaration, only requiring the Secretary to consider certain factors such as the "desirability of encouraging the administration … and use of such countermeasure." 42 U.S.C. § 247d-6d(b)(6) & (7).

The PREP Act also grants the Secretary broad discretion to determine what will be a covered countermeasure. 42 U.S.C. § 247d-6d(b). A countermeasure includes any drug, biological product or device administered or used "to diagnose,

mitigate, prevent, treat, or cure a pandemic or epidemic" or "to limit the harm such pandemic or epidemic might otherwise cause" that is FDA-approved or granted Emergency Use Authorization ("EUA"). 42 U.S.C. § 247dd-6d(i)(7); *see also* Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. 35100 (June 8, 2020). Furthermore, "there can be situations where *not* administering a covered countermeasure to a particular individual can fall within the PREP Act and [the] Declaration's liability protections." *See* Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration, 85 Fed. Reg. 79190, 79194 (Dec. 9, 2020). For purposes of the PREP Act, administration of countermeasures includes planning, "activities and decisions" in response to a medical emergency, and the "[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive…." *Id.* at 79197.[2]

[2] *See also* Robert P. Charrow, General Counsel of the Department of Health and Human Services, Advisory Opinion 21-01 on The Public Readiness And Emergency Preparedness Act Scope of Preemption Provision (January 8, 2021), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf (stating that where there are scarce resources, a facility's

When the Secretary has issued a declaration, the PREP Act completely preempts any state law or legal requirement that "is different from," or "in conflict with[] any requirement applicable under" the PREP Act and that "relates to" the use or administration of a covered countermeasure. 42 U.S.C. § 247d-6d(b)(8). The PREP Act provides immunity to "all claims for loss" under federal and state law "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure,"[3] which includes all state law tort, medical malpractice, breach of contract, wrongful death, and state or federal statutory claims. *Id*. at § 247d-6d(a)(1). This broad scope of preemption and immunity furthers Congress's purpose to remove all barriers to the deployment of a countermeasure. Broad immunity is crucial in this context, as public health emergencies "give rise to numerous issues of liability for health care providers" which may serve to deter the participation of providers, thus compromising the pandemic response.[4]

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refusal to administer a covered countermeasure could be covered by the PREP Act).

[3] The PREP Act provides a "sole exception" to immunity from suit and liability of covered persons by way of an "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(1).

[4] S. Hoffman, *Responders' Responsibility: Liability and Immunity in Public Health Emergencies*, 96 Geo. L.J. 1913 (Aug. 2008), https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1137&context=faculty_publications.

Recognizing that this broad scope of immunity may leave some individuals who suffer losses as a result of the administration of a covered countermeasure without recourse, the PREP Act creates an exclusive remedy for injured plaintiffs – the Countermeasures Injury Compensation Program ("CICP"). 42 U.S.C. § 247d-6e. This administrative compensation fund is the exclusive remedy of "any other civil action or proceeding for any claim or suit" encompassed by the Act, other than claims for willful misconduct, which are not afforded immunity. *Id*. at § 247d-6e(d)(4).

Taken as a whole, the PREP Act framework is carefully tailored to encourage front line health care personnel to rapidly react and respond to a public health emergency by following continually evolving and at times conflicting federal and state directives without the threat of imminent litigation compromising such efforts, while also ensuring that individuals who suffer physical injuries or death are not without recourse. *See* 42 U.S.C. § 247d-6e(a)-(b) & (e).

B. Senior Living Facilities Provide Critical Supports to Elderly Individuals in Communities Across the Country

Senior living is a home and community based model that encompasses a wide range of care settings for older adults, combining housing, supportive services, and health care as needed. There are currently nearly two million residents calling senior living home across assisted living, memory care, independent living, and continuing care retirement services. Senior living

communities are designed for older individuals (*e.g.*, aged 55 and older) who can generally care for themselves without regular nursing or other routine medical assistance. Depending on state regulatory and licensing requirements, a senior living community may offer a continuum of accommodations and services for seniors including, but not limited to, assisted living, independent living, continuing care and memory care services. Senior living communities are regulated in all 50 states and the District of Columbia.[5]

Senior living facilities play a critical role in addressing the health needs of the elderly population. Within senior living communities, more than half of all residents are over age 85, and another 30% are between the ages of 75-84.[6] Residents often cope with multiple chronic conditions and require assistance with activities of daily living, such as eating, dressing, bathing, and the management or administration of medication.[7] Over 42% suffer from some type of cognitive impairment.[8]

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[5] While the licensing terminology for senior living communities varies from state to state, for ease of reference, the term "senior living community" is used herein to globally refer to retirement and assisted living communities for individuals age 55 and older that require a state license or are otherwise regulated in order to operate.

[6] National Center for Health Statistics, *Long-term Care Providers and Services Users in the United States, 2015-2016*, 3 Vital and Health Statistics 43 (Feb. 2019), https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

[7] *Id.*

[8] *Id.*

Senior living communities serve the population most vulnerable to COVID-19. People aged 65 years and older and those suffering from comorbidities, are at the greatest risk of complications from COVID-19.[9] Data from state and federal governments have demonstrated that older adults residing in senior living were particularly vulnerable to severe disease and death. While less than one percent of the nation's overall population lives in senior housing properties, one-third of the nation's confirmed and probable COVID-19 deaths were residents of skilled nursing and senior living.[10] Almost 80% of U.S. COVID-19 deaths have been in the 65-and-over age group, a cohort that is at increased risk for severe illness due to age and underlying chronic conditions.[11]

Because residents in senior living communities are older and more likely to suffer from comorbidities, they are dependent on the care of others, greatly complicating the ability for residents to socially isolate to prevent COVID-19 infection. According to the CDC, due to the congregate setting that increases opportunities for person-to-person contact and viral transmission, "residents of

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[9]Centers for Disease Control and Prevention, *People with Certain Medical Conditions* (May 13, 2021), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

[10] *See Long-Term Care COVID Tracker*, the COVID Tracking Project (March 2021), https://covidtracking.com/nursing-homes-long-term-care-facilities.

[11] *See* Centers for Disease Control and Prevention, COVID-19 Mortality Overview, Provisional Death Counts for Coronavirus Disease 2019 (COVID-19) (June 2021), https://www.cdc.gov/nchs/covid19/mortality-overview.htm.

senior living communities are at high risk for the spread of COVID-19 among residents who are at increased risk for severe illness."[12]

Given the above, since the beginning of the COVID-19 pandemic in the U.S., senior living communities have implemented enhanced protocols to prevent COVID-19 from entering the community, mitigate the spread of, and otherwise limit the harm from COVID-19. For example, properties implemented staff workflow changes and visitor restrictions to reduce disease spread.[13] Other steps include appropriate efforts to institute enhanced infection control protocols; restrict or cease move-ins; conduct health screenings and COVID-19 testing as available and appropriate for residents and employees; and administer vaccinations.[14]

Early in the pandemic senior living facilities were charged with protecting their residents while managing the challenges of nationwide shortages of COVID-19 diagnostic tests, critical care equipment, and protective gear.[15] For example, the United States experienced nationwide shortages of supplies needed to administer

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[12] Centers for Disease Control and Prevention, *Considerations for Preventing Spread of COVID-19 in Assisted Living Facilities* (May 29, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/assisted-living.html.

[13] A. C. Pearson et al., *The Impact of COVID-19 on Seniors Housing*, NORC at the University of Chicago (June 3, 2021), p. 18, https://info.nic.org/hubfs/Outreach/2021_NORC/20210601NICFinalReportand20ExecutiveSummary20FINAL.pdf. (hereinafter "the NORC Report").

[14] *Id*.

[15] NORC Report, p. 18.

and process COVID-19 diagnostic testing.[16] As testing supplies were scarce, the tests themselves were not always accurate, and diagnostic test results were frequently delayed due to long lab processing times.[17]

Accessing PPE has also been a well-documented challenge for organizations across health care, including in senior living.[18] In March 2020, 20% of assisted living and skilled nursing facilities were at risk of running out of PPE inventory within a week.[19] More than two-thirds of senior living facilities reported inadequate access to PPE needed for COVID-19 containment plans.[20] Given this shortage, the CDC directed senior living facilities to monitor PPE use each day, identify potential contacts that can provide PPE during shortages, and implement a

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[16] K. Ketchum & L. O'Connor, *COVID-19 Testing Problems Started Early, U.S. Still Playing from Behind*, Modern Healthcare (May 11, 2020), https://www.modernhealthcare.com/technology/covid-19-testing-problems-started-early-us-still-playing-behind.

[17] NORC Report, p. 18.

[18] *See* E. Livingston et al., *Sourcing personal protective equipment during the COVID-19 pandemic*, 323 JAMA 19, 1912-1914 (March 28, 2020).

[19] *See* C. Sudo, *Shortage of Supplies Rapidly Worsens in Senior Living as COVID-19 Spreads*, Senior Housing News (March 18, 2020), https://seniorhousingnews.com/2020/03/18/shortage-of-supplies-rapidly-worsens-in-senior-living-as-covid-19-spreads/.

[20] *See* Press Release, Premier Inc. Survey: More Than Two-Thirds of Senior Living Facilities Say They Can't Access Personal Protective Equipment Needed for COVID-19 Containment Plans (March 16, 2020), https://www.premierinc.com/newsroom/press-releases/premier-inc-survey-more-than-two-thirds-of-senior-living-facilities-say-they-cant-access-personal-protective-equipment-needed-for-covid-19-containment-plans.

process for decontaminating PPE such as face shields and goggles.[21] The CDC even provided guidance on how to optimize PPE such as N95 respirators, facemasks, isolation gowns, eye protection, ventilators, and gloves before a shortage can occur.[22]

In many instances, senior living communities were forced to balance infection control protocols with social supports and other services critical to maintaining the mental health and quality of life of community residents. When a resident is suspected to be infected or tests positive for COVID-19, protocols are in place to quarantine or isolate the resident, monitor progression of symptoms, and facilitate hospital transfers when necessary. In many instances, senior living communities limited or replaced communal dining in favor of personalized meal service and delivery and established virtual engagement opportunities between residents and loved ones. However, social distancing and disrupted schedules posed challenges for senior living residents, particularly memory care residents.[23] While social distancing measures were critical to reducing the spread of COVID-

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[21] *See* Centers for Disease Control and Prevention, *Preparing for COVID-19 in Nursing Homes* (Nov. 20, 2020), https://stacks.cdc.gov/view/cdc/97611.

[22] *See* Centers for Disease Control and Prevention, *Optimizing Supply of PPE and Other Equipment during Shortages* (July 16, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/general-optimization-strategies.html.

[23] NORC Report, p. 19.

19, seniors who have cognitive impairments are more likely to require additional care and support with activities of daily living.[24] Many residents with dementia are unable to comply with mask mandates, and are afraid of and disoriented by staff wearing masks.[25]

Moreover, senior living communities were faced with a shortage of critical PPE such as face masks, at a time when initial CDC guidance indicated that asymptomatic spread of COVID-19 was unlikely.[26]

Despite these many challenges and extraordinary circumstances, the front-line workers at senior living facilities took remarkable steps to continue to provide a high-level of care to residents.

C. FDA Took Aggressive Action to Deal With Shortages of Pandemic Products

The PREP Act designates all qualified pandemic products as covered countermeasures, including all drugs, biological products, and devices that are approved, cleared, or authorized for emergency use by FDA and used to diagnose, mitigate, prevent, treat, or otherwise limit the harm of a pandemic. *See* 42. U.S.C. § 247d-6d(i)(1)&(7); *see also* 85 Fed. Reg. 15198, 15202 (PREP Act Declaration

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[24] *Id*. at p. 5.

[25] *Id*.

[26] *See* Centers for Disease Control and Prevention, How COVID-19 Spreads (Mar. 4, 2020), https://stacks.cdc.gov/view/cdc/85631.

defining "covered countermeasures" to include drugs, products, or devices "used to treat, diagnose, cure, prevent or mitigate COVID-19"). In the early months of the COVID-19 pandemic, FDA took a series of regulatory actions to approve products and expand authorizations to address shortages in PPE, thermometers, diagnostic tests, alcohol-based hand sanitizers, and other products that were essential to diagnosing, mitigating, and preventing COVID-19.

Personal Protective Equipment. To address the nationwide shortage in PPE, the FDA took aggressive steps to expand authorizations for facemasks, gloves, gowns, and other protective equipment. At various points, FDA authorized the use of respirators previously only approved for industrial use or which were expired,[27] announced that it would not object to gloves, gowns, face masks, face shields, and other protective equipment that would ordinarily be subject to FDA regulations but

[27] Letter from RADM Denise M. Hinton, Chief Scientist, Food and Drug Administration, to Robert R. Redfield, Director, Centers for Disease Control and Prevention (March 11, 2020), https://www.fda.gov/media/136023/download#:~:text=To%20address%20that%20shortage%2C%20the,further%20transmission%20of%20COVID%2D19.

do not present undue risk,[28] issued an EUA for face masks, and clarified that cloth face coverings were covered by that EUA.[29]

Diagnostic Testing. Until March 16, 2020, the CDC laboratory was the only laboratory authorized to develop diagnostic tests for COVID-19. By late February 2020, it became clear that the CDC would not be able to timely test and process the specimens it would receive for COVID-19. On February 29, 2020 and March 16 2020, the FDA issued guidance to accelerate industry development of additional COVID-19 diagnostic tests.[30] While FDA issued nine EUAs for industry-

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[28] Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, Food and Drug Administration (March 2020), https://www.fda.gov/media/136540/download; Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance for Industry and Food and Drug Administration Staff, Food and Drug Administration (April 2020), [https://web.archive.org/web/20200403145256/https:/www.fda.gov/media/136449/download].

[29] Letter from RADM Denise H. Hinton, Chief Scientist, Food and Drug Administration, to Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders (April 18, 2020), [https://web.archive.org/web/20200423232400/https:/www.fda.gov/media/137121/download]; Letter from RADM Denise H. Hinton, Chief Scientist, Food and Drug Administration, to Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders (April 24, 2020), https://www.fda.gov/media/137121/download. (hereinafter "FDA April 24, 2020 Letter").

[30] *See* FDA News Release, Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics, Food and Drug Administration (Feb. 29, 2020), https://www.fda.gov/news-events/press-

developed tests between April 1, 2020 and May 4, 2020,[31] diagnostic tests remained in short supply and labs were overwhelmed for the following several months. Through June 30, 2020, FDA had still only issued 20 EUAs for molecular COVID-19 diagnostic testing. Testing residents in senior living communities for COVID-19 was still a challenge well into August 2020 prompting the Secretary of HHS, to issue PREP Act coverage for the use of antigen tests on residents in senior living communities with a CLIA Certificate of Waiver.[32]

Alcohol-Based Hand-Sanitizers. The FDA has long regulated over-the-counter antiseptic drug products, which includes alcohol-based hand sanitizers. The COVID-19 pandemic created increased demand for alcohol-based hand sanitizers, resulting in significant supply disruptions. In response to this challenge, the FDA announced in March 2020 that it did not intend to take action against "manufacturing firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs during this ongoing public health

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announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics.

[31] *See* FDA, "*In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2*", https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2.

[32] *See* HHS Secretary's Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (August 31, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf.

emergency as described in the guidance."[33] At the same time, FDA provided guidance to pharmacists to compound alcohol-based hand sanitizers.[34]

Thermometers. Thermometers are FDA regulated devices, which also faced similar shortages during the first months of 2020. Recognizing the significance of thermometers in infection control and COVID-19 screening, FDA announced in April 2020 that it was adopting new enforcement policies to expand the supply of clinical thermometers available for detecting fevers.[35]

Each of these regulatory actions by the FDA directly impacted the quantity of qualified pandemic products available to senior living communities.

D. Assisted Living and Senior Living Facilities Faced Evolving Guidance throughout COVID-19

In addition to the effort by FDA, other federal and state regulators took a number of steps to mitigate the threat of COVID-19 as the potential impact of the virus became apparent in the early months of 2020. Many of these early mitigation

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[33] FDA News Release, Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health (March 20, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost.

[34] *Id.*

[35] *See* Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff, Food and Drug Administration (April 2020), https://www.fda.gov/media/136698/download.

efforts focused on congregate living settings, such as senior living communities, due to their high-risk populations and increased likelihood of person-to-person contact. Although federal and state governments jointly regulate nursing care provided in skilled nursing facilities, assisted living is largely state regulated. In early 2020, the presence of the COVID-19 virus and the response by local policy-makers varied dramatically by state. And while some state regulations for senior living communities mirrored requirements for health care providers, this was not uniform across the country.[36] As a result, operators of senior living communities were forced to deal with regulatory directives that varied significantly between properties.

Further, the volume of federal and state governmental directives for senior living communities was compounded by the rapidly changing information about the virus, including how it spreads and which populations are particularly vulnerable. Specifically, the ability of asymptomatic individuals to spread the virus was not known at first, complicating detection and containment strategies. As a result, senior living communities were faced with changing instructions over the first few months of 2020.[37]

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[36] *See* NORC Report, p. 11.

[37] A. Schuchat, *Public Health Response to the Initiation and Spread of Pandemic COVID-19 in the United States, February 24–April 21, 2020*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR),

In California, senior living communities are regulated by the Community Care Licensing Division ("CCLD"). The CCLD designates assisted living communities in California as Residential Care for the Elderly ("RCFEs"). As of February 28 2020, the CCLD began communicating some of the risks of COVID-19 to RCFEs, encouraging facilities to "have a plan in place, and ample supplies, to respond to an [*sic*] COVID-19 outbreak in their area."[38]

Shortly thereafter, in the three-month period between March 1 and June 1, senior living communities in California were swamped with different governmental directives and guidance regarding the prevention of COVID-19. These involved, *inter alia*, the implementation of several FDA approved or authorized devices. At various points, senior living facilities were told to oversee the acquisition and use of PPE for respiratory hygiene, thermometers for temperature checks, alcohol-based hand-sanitizers for sanitation, COVID-19 diagnostic tests, and to implement infection control and disease prevention protocols.

69:551–556 (May 1, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6918e2.htm?s_cid=mm6918e2_w.

[38] Letter from Pamela Dickfoss, Deputy Director, Community Care Licensing Division, to All Adult and Senior Care Program Licensees (Feb. 28, 2020), https://www.cdss.ca.gov/Portals/9/CCLD/PINs/2020/ASC/200228-Coronavirus-PIN-COVID-19-ASC-Facilities.pdf. In the same letter, CCLD directed RCFEs to review California Department of Public Health All Facilities Letters for "information may be pertinent and helpful in community care settings" even though these letters are "directed toward health care facilities."

For example, on March 5, 2020, CCLD notified senior living communities in California about mitigating the spread of COVID-19.[39] This early guidance emphasized strategies to isolate *symptomatic* individuals. Specifically, the guidance included recommendations for isolating workers experiencing a fever and limiting visitors with COVID-19 symptoms. Similarly, residents with respiratory symptoms were instructed to stay in their rooms and wear a mask when leaving their rooms for medical purposes. The use of PPE was only recommended when treating individuals exhibiting respiratory symptoms.

In the two weeks that followed, the CCLD updated its directives on multiple occasions.[40] These updates continued to focus on isolating residents, staff, and visitors with symptoms or known exposure to a COVID-19 case, and instructing facilities to follow guidance and instructions from the CDC, the Centers for

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[39] *See* Letter from Pamela Dickfoss, Deputy Director, Community Care Licensing Division, to All Adult and Senior Care Program Licensees (March 5, 2020), https://www.cdss.ca.gov/Portals/9/CCLD/PINs/2020/ASC/PIN%2020-04-ASC_Coronavirus_ASCFacilities.pdf.

[40] *See* Letter from Pamela Dickfoss, Deputy Director, Community Care Licensing Division, to All Adult and Senior Care Program Licensees (March 13, 2020), https://www.cdss.ca.gov/Portals/9/CCLD/PINs/2020/ASC/PIN%2020-07-ASC%20COVID19%20Implementation%20with%20Statewide%20Waiver%20.pdf; *see also* Letter from Pamela Dickfoss, Deputy Director, Community Care Licensing Division, to All Adult and Senior Care Program Licensees (March 18, 2020), https://www.cdss.ca.gov/Portals/9/CCLD/PINs/2020/ASC/PIN_20-08-ASC.pdf.

Medicare and Medicaid Services, the California Department of Public Health ("CDPH") and local health departments.

At the same time the CCLD guidance focused on symptomatic transmission, the CDC started emphasizing the use of covered countermeasures as a source control strategy for potential *asymptomatic* transmission.[41] On March 21, 2020, the CDC provided its first COVID-19 guidance for retirement communities and independent living facilities.[42] In furtherance of its goals to mitigate asymptomatic transmission, the CDC issued several recommendations that varied from the CCLD's then-applicable guidance, including that visitors be limited to one per resident per day, residents be instructed on the use of alcohol-based hand sanitizers, workers and volunteers be screened when possible for symptoms using a no-touch thermometer, and workers be encouraged to "protect their personal health." Further, the CDC published findings from a study on skilled-nursing facilities indicating that symptom-based screenings may fail to identify all

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[41] Centers for Disease Control and Prevention, Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease (COVID-19) (March 7, 2020), https://web.archive.org/web/20200409033724/https:/www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.

[42] *See* Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19) (as of March 21, 2020), [https://web.archive.org/web/20200321200551/https:/www.cdc.gov/coronavirus/2019-ncov/community/retirement/index.html].

COVID-19 infections.[43] The report recommended that, "once a facility confirms a COVID-19 case, all residents should be cared for using CDC-recommended PPE, with considerations for extended use or reuse of PPE as needed."

By mid-April, the CDC had fully shifted to a strategy to reduce asymptomatic transmission, issuing guidance that recommended senior living communities use PPE, temperature checks, and alcohol based hand-sanitizer to reduce and mitigate the spread of COVID-19.[44] This shift, however, exacerbated the PPE shortage, prompting the CDPH[45] to recommend that healthcare providers conserve PPE by extending their use and suggesting alternatives to N95 respirators and face masks.[46]

While an exhaustive list of all federal and state directives and guidance for senior living facilities would be far too long to include in this brief, this sample

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[43] *See* A. Kimball et al., *Asymptomatic and Presymptomatic SARS-CoV-2 Infections in Residents of a Long-Term Care Skilled Nursing Facility — King County, Washington, March 2020*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR) (March 27, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e1.htm.

[44] *See* Centers for Disease Control and Prevention, Coronavirus Disease 2019 (COVID-19), Key Actions for Assisted Living Facilities, (as of April 16, 2020), [https://web.archive.org/web/20200416224858/https:/www.cdc.gov/coronavirus/2019-ncov/hcp/assisted-living.html].

[45] Previous CCLD instructions consistently referred senior living communities to CDPH guidance in addition to CCLD guidance.

[46] *See* Letter from CDPH to All Facilities, AFL 20-39 (April 13, 2020), https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-39.aspx.

illustrates the continually changing regulatory obligations facing senior living communities and their employees in the early months of 2020.

E. Senior Living Facilities Are Among the Front Line Facilities and Personnel Protected By the PREP Act

The PREP Act was adopted to protect front line personnel from liability and suits arising out of the implementation of countermeasures in response to the exact type of evolving directives and developing information that was prevalent at the start of the COVID-19 pandemic. In the early months of the pandemic, senior living communities were forced to make difficult choices, balancing this ever changing guidance with limited supplies of critical resources.

As a result, senior living communities had to develop polices on when to use limited PPE and how to prioritize limited access to testing, balancing infection prevention and mitigation with access to family, social supports, and mental health, which are also critical to a resident's long term-wellbeing. By engaging in the administration and use of covered countermeasures in this way, senior living communities fall well within the scope of the PREP Act's immunity provision.

Consistent with Congress's goals of facilitating a rapid response to a public health emergency, immunity under the PREP Act applies to a broad range of front line individuals and organizations. Specifically, the PREP Act covers "manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees" when administering or using a covered

countermeasure. 85 Fed. Reg. 15198, 15,199 (March 17, 2020) (PREP Act Declaration); *see also* 42 U.S.C. §247d-6d(i)(2). Senior living facilities are covered by the PREP Act when engaged in the use or administration of a covered countermeasure because they satisfy the statute's definitions of both a "program planner" and a "qualified person."

Senior living communities meet the definition of a "program planner" because the communities are "facilit[ies]" that, in part, are used to "administer or use" covered countermeasures, including COVID-19 related medications, diagnostics therapeutics, treatments, and respiratory protective devices. *See* 42 U.S.C. §247d-6d(i)(6) (defining a "program planner" to mean "a person who supervised or administered a program with respect to the administration . . . or use of" a covered countermeasure, "including a person who has established requirements, provided policy guidance," or other assistance with administering or using the countermeasure, and including an entity that "provides a facility to administer or use a covered countermeasure"). Specifically, and as described above, many of the senior living communities in the United States provide a facility that ensures the elderly are able to have access to PPE, symptom screening, and COVID-19 testing. Senior living communities provide the space for community employees to assist with and administer infection control programs,

including PPE, temperature checks, and other covered countermeasures, as needed to community residents.

Further, senior living communities are "qualified persons" because they were authorized by federal and state regulators to administer, dispense, or use PPE, thermometers, and other FDA approved and authorized products to diagnose, mitigate, or otherwise prevent COVID-19. Under the PREP Act, "qualified persons" include any individual who is authorized to "prescribe, administer, or dispense" drugs, biological products, or devices approved, licensed, or authorized by the FDA "to diagnose, mitigate prevent, treat, or cure a pandemic or epidemic" or used "to limit the harm such pandemic or epidemic might otherwise cause." 42 U.S.C. §247d–6d(i)(8) (defining qualified person); *id* at §247d–6d(i)(7)(defining "qualified pandemic or epidemic product"). Through the course of the COVID-19 public health emergency, and as explained further above, state regulatory agencies directed senior living communities to implement policies and protocols for distributing and administering PPE, cloth face coverings, respirators, thermometers, diagnostic tests and testing equipment, and other FDA approved devices for the diagnosis, mitigation, and prevention of COVID-19.[47]

[47] *See* FDA April 24, 2020 Letter, *supra* note 29 (includes cloth face coverings which the FDA states are authorized for use by health care providers in healthcare settings as "source control").

HHS has made clear that its PREP Act Declaration related to COVID-19 extends to senior living communities. HHS has stated that senior living facilities are program planners to the extent they provide a facility for the use of, or administer or use, a covered countermeasure.[48] HHS has further confirmed that a senior living community may be a qualified person where it was authorized in accordance with the public health and medical response of the authority having jurisdiction to prescribe or administer a covered countermeasure.[49] And as stated above, the Fourth Amendment to the PREP Act Declaration for COVID-19 clarifies that to extent senior living communities are engaged in the prioritization or purposeful allocation of covered countermeasures, a senior living community's failure to administer covered countermeasures is also protected by the PREP Act. 85 Fed. Reg. 79190, 79194

HHS did not draft the PREP Act Declaration related to COVID-19 in a vacuum, and its guidance stating that senior living communities are covered by the Declaration's scope are deliberate. Amid severe supply shortages, senior living communities were administering covered countermeasures to protect those most vulnerable to COVID-19. Subjecting their choices regarding the administration of

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[48] Letter from Ron Charrow, General Counsel, Department of Health and Human Services, to Thomas Barker, Foley Hoag LLP (Aug. 14, 2020) (hereinafter "Aug. 14, 2020 OGC Letter).

[49] Aug. 14, 2020 OGC Letter.

these countermeasures to liability would have impeded the ability of senior living communities to respond to the pandemic. This front-line care is exactly what the PREP Act was passed to protect.

F. The PREP Act Provides Immunity From Suit

State law claims against senior living communities implicating the use of covered countermeasures must be removable to federal court because otherwise the federal procedural protections stemming from the immunity from suit provisions of the PREP Act will be unenforceable in state courts.

The scope of immunity under the PREP Act includes both immunity from liability and *immunity from suit*. 42 U.S.C. §247d-6d(a)(1) ("a covered person shall be immune from suit and liability under Federal and State law"). The PREP Act also creates a variety of federal procedural protections where a plaintiff alleges that a program planner or qualified person under the PREP Act is liable for willful misconduct. For example, acts and omissions constituting willful misconduct must exclusively be brought in the United States District Court for the District of Columbia before a three-judge court, 42 U.S.C. § 247d-6d(e)(1), (5); facts supporting the misconduct allegations must be pled with particularity, *id.* at § 247d-6d(e)(3); the complaint must be verified, including the plaintiff's affidavit under oath, an affidavit from a physician explaining the proximate cause and seriousness of the plaintiff's alleged injuries, and certified medical records, *id.* at §

247d-6d(e)(4); and civil discovery is prohibited until any covered person has an opportunity to file a motion to dismiss, and exhaust any appeal stemming from that motion, *id.* at §247d-6d(e)(6). Perhaps most importantly, the PREP Act guarantees that the United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal filed by a covered person who is denied a motion to dismiss or a motion for summary judgment based on an assertion of immunity from suit under subsection (a) of the PREP Act – a subsection that encompasses *any and every* lawsuit for loss caused by, related to, or resulting from the administration or use of a covered countermeasure. *See* 42 U.S.C. §247d-6d(e)(10).

These procedural guarantees are of paramount importance for program planners and qualified persons asserting immunity under the PREP Act, and removal to federal court is essential to protecting these statutory rights. While state courts must, under the Supremacy Clause, apply the PREP Act's immunity from liability provisions by virtue of the preemption doctrine, federal procedural protections are not required to be applied by state courts. *See Johnson v. Fankell*, 520 U.S. 911, 919 (1997) (declining to require state courts to entertain interlocutory appeals under federal qualified immunity law because "[t]he general rule, 'bottomed deeply in belief in the importance of state control of state judicial procedure, is that federal law takes the state courts as it finds them.'"); *see also*

Minneapolis & St. Louis R. v. Bombolis, 241 U.S. 211, 221 (1916) (declining to require state courts that hear FELA actions to apply the federal court's procedural requirement for unanimous jury verdict). Accordingly, removal to federal court of actions originally filed in state court is the only way program planners and other qualified persons can be assured of access to the benefits of the PREP Act's federally granted procedural protections set out in 42 U.S.C. § 247d-6d(e).

III. Conclusion

For the foregoing reasons, the appeal should be denied, and this Court should affirm the Order below.

DATED this 16th day of June 2021

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[50] Pursuant to Circuit Rule 25-5(e), all parties on whose behalf the filling is submitted concur in the filing's content.

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FOR THE NINTH CIRCUIT

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