UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

VIVIAN RIVERA-ZAYAS, as Administrator of the Estate of ANA MARTINEZ, Deceased, *Plaintiff*, – v. – OUR LADY OF CONSOLATION GERIATRIC CARE CENTER, OUR LADY OF CONSOLATION GERIATRIC CARE CENTER d/b/a OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER, and OUR LADY OF CONSOLATION NURSING AND REHABILITATIVE CARE CENTER, *Defendants*.	**Case No. 20-cv-05153-NGG-JMW**

AMICI CURIAE BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTEREST OF *AMICI CURIAE*

The Greater New York Hospital Association ("GNYHA") and the Healthcare Association of New York State, Inc. ("HANYS") submit this brief as *amici curiae* ("*Amici*") in support of Defendants' motion to dismiss Plaintiff Vivian Rivera-Zayas's ("Plaintiff") Complaint.

GNYHA represents the interests of approximately 150 hospitals, most of which are in New York State. All members of GNYHA are either not-for-profit charitable organizations or publicly-sponsored institutions that provide state-of-the-art, tertiary services as well as basic primary care needed by their communities. To assist its members, GNYHA engages in advocacy, policy analysis, education, research, and communication services at the local, state, and federal levels. GNYHA has long played a pivotal role in emergency preparedness and response, staffing a dedicated desk at the New York City emergency operations center during all manner of crises, from blizzards to terrorist attacks.

HANYS is New York's statewide hospital and healthcare system association representing not-for profit and public hospitals and hospital-based skilled nursing facilities, home health agencies, and hospices. HANYS' members range from rural Critical Access Hospitals to large, urban Academic Medical Centers and other Medicaid and safety net providers. HANYS seeks to advance the health of individuals and communities by providing expertise, leadership, representation, and service to health providers and systems across the entire continuum of care.

The COVID-19 pandemic has challenged the state and nation with an unprecedented health crisis. Hospitals, health care facilities, and practitioners have provided a front-line response to protect and treat those infected with the contagion. As participants in New York State's emergency response structure and representatives of statewide healthcare institutions, *Amici* have a strong interest in the impact of laws and lawsuits relating to, or arising from, COVID-19. As their

members battle on the front lines to defeat the pandemic, *Amici* have been providing support through advocacy, logistics, and operations, while also observing the risks health care providers face treating patients afflicted with this deadly disease. In addition, they have worked closely with the State government on its emergency response. Thus, *Amici* have extensive first-hand knowledge and deep insight about the risk health-care institutions and providers face treating patients afflicted with COVID-19.

By this brief, *Amici* seek to assist the Court in its determination of whether New York's repeal of the Emergency or Disaster Treatment Protection Act ("EDTPA")[1] is retroactive. By its terms, the EDTPA was in effect on or after March 7, 2020, until its repeal effective on April 6, 2021. While the legal conclusion based on the plain language of the repeal is clear – the repeal has no retroactive effect – *amici* will show that sound public policy also dictates that the Court find the repeal of the EDTPA to be prospective.

During this unprecedented emergency, New York's hospitals and healthcare professionals worked tirelessly to provide the best possible care to COVID-19 patients, as well as other patients, under extremely adverse conditions. The EDTPA conferred broad state law liability protections to protections to "health care facilities" and "health care professionals" providing "health care services" to individuals during the COVID-19 emergency, so long as those services were impacted by the pandemic and rendered in good faith, among other conditions. Health care providers and facilities relied on those immunity protections to care for patients during the nation's worst healthcare crisis in the past century.

Finding the EDTPA's repeal to be retroactive would expose those individuals and institutions who relied on the EDTPA's legal protections to criminal and civil liabilities that the

[1] Codified at N.Y. Pub. Health L. § 3082.

Legislature never intended. Doing so would have far-ranging consequences, including potentially inhibiting the State's response to future pandemics and mass-casualty events. It would signal to healthcare workers that the New York State legislature and government cannot be trusted. The story of the EDTPA, with its partial repeal only a few months after enactment and its total repeal one year later -- before the declared emergency is even over -- already runs that risk. This Court should not deem the Legislature to have offered safe harbor to frontline workers and care facilities during the toughest of times, only to retroactively repeal that protection in a flurry of hindsight once the emergency began to abate.

Amici also seek to ensure that the interpretation and application of federal laws are uniformly, justly, and appropriately applied in a manner that will help — not hinder — treatment and prevention of COVID-19 and give meaning to the very purpose of those laws intended to protect providers and others working on the emergency response. The unprecedented scope of the crisis demands the most comprehensive view available, which in our American court system means our federal courts. A patchwork of fifty different answers to the same fundamental national issue would be unworkable. We, therefore, urge this Court to follow the language and meaning of the Federal Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d *et seq*., by ruling that the PREP Act confers federal jurisdiction over the instant case.

INTRODUCTION

A. What our Healthcare Facilities and Providers Faced as the Frontline Defense Against COVID-19.

At the first (and most grim) peak of the COVID-19 pandemic, doctors, nurses, hospitals, nursing homes, and other patient care facilities risked their lives and livelihood to diagnose and treat COVID-19. In late March 2020, New York was the national epicenter of the pandemic's first

wave. The first case of COVID-19 was confirmed on March 1, 2020.[2] By the end of the month over 25,000 cases had been confirmed in New York City, and the death toll had reached 366.[3] A makeshift morgue had to be constructed outside of Bellevue Hospital to address the anticipated surge of deaths.[4]

On April 13, 2020, New York hospitalizations for COVID-19 reached its peak, with an extraordinary 18,825 COVID-19 patients hospitalized.[5] (To put this in context, the total number of COVID-19 hospitalizations in New York State as of this writing is 709.) The healthcare system experienced unprecedented challenges in its efforts to provide care. There were critical shortages of PPE, including appropriate masks and gowns; testing kits, inpatient and intensive care unit beds; and a limited supply of lifesaving devices such as ventilators and respirators. Pre-existing staffing shortages were exacerbated by frontline healthcare workers who were either exposed to or tested positive for COVID-19.

As these demands stretched the system beyond its capacity, both the state and federal governments took executive action to allocate resources and ease the strain, directing hospitals and others to take numerous steps in support of these efforts. In New York State, for example, Governor Andrew M. Cuomo issued executive orders declaring a state of emergency and suspending and modifying numerous laws governing the health care sector. Notably, the Governor relaxed laws and regulations so that healthcare capacity and the ranks of frontline health care providers could be swiftly expanded. When the pandemic was reaching its peak, on March 23,

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[2] *See* https://www.nbcnewyork.com/news/coronavirus/person-in-nyc-tests-positive-for-covid-19-officials/2308155/ (last checked June 11, 2021).

[3] *See* https://www.nydailynews.com/coronavirus/ny-coronavirus-cases-death-toll-new-york-city-20200327-l6x6q3t3wfa2lczoqym5f2jhfa-story.html. (last checked June 11, 2021).

[4] *Id.*

[5] *See* https://www.usnews.com/news/top-news/articles/2020-04-14/new-york-hospitalizations-fall-for-first-time-in-coronavirus-pandemic-governor (last checked June 11, 2021).

2020, the Governor issued Executive Order No. 202.10.[6] He found that "ensuring the State of New York has adequate [hospital] bed capacity, supplies, and providers to treat patients affected with COVID-19, as well as patients afflicted with other maladies, is of critical importance;" and that "eliminating any obstacle to the provision of supplies and medical treatment is necessary to ensure the New York healthcare system has adequate capacity to provide care to all who need it[.]"

Thus, it was not just a matter of increasing bed capacity in hospitals, but also ensuring the most important resource—health care providers – were available to staff those beds. For example, the Governor suspended the state's professional licensing laws so that professionals from other states and Canada could practice in New York without liability. He also allowed healthcare facilities to redeploy staff out of retirement and from one specialty to another to ensure that people were on hand to treat the COVID-19 patients who were streaming in for care. Finally, he modified laws to allow New York's Health Commissioner to issue provisional emergency medical services provider certifications to meet the increased demand for services by allowing practitioners to provide necessary services that would otherwise be outside their scope of practice, subject to appropriate supervision.

In this emergency, there was no other choice but to waive these requirements. The EDTPA was a realistic acknowledgement of the dire circumstances facing health care providers and facilities. But the EDTPA struck an important balance -- it provided protection from certain kinds of liability while imposing conditions to ensure that gross negligence and other egregious behavior would not be protected.

New York was not alone in taking these necessary actions as such measures were being implemented across the country. At the federal level, former U.S. Department of Health and

[6] *See* https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency (last checked June 11, 2021).

Human Services ("DHHS") Secretary Alex M. Azar II declared a public health emergency for the entire United States to aid in the nation's response to the COVID-19 pandemic. The Federal Centers for Disease Control and Prevention ("CDC") issued emergency guidance to help hospitals and public health officials manage staffing, PPE, and pandemic countermeasure availability. On March 24, 2020, the U.S. Food and Drug Administration ("FDA") issued an umbrella emergency use authorization for ventilators and ventilator accessories. This emergency authorization included the modification of anesthesia equipment and ventilator splitting.[7] The authorization fact sheet for patients noted that "[t]he use of a ventilator may help your condition improve and allow you to recover" and noted that the risks of using modified equipment had not been studied.[8]

Illustrating the severity of the crisis, the CDC recommended health care professionals use masks beyond their designated shelf life, prioritize the use of masks during procedures with a higher risk of splashing or spraying, re-use the same facemask for multiple patient encounters, and use cloth masks when no approved masks are available.[9] The CDC has issued similar operational guidance for healthcare facilities to help manage surges of the pandemic, including reducing or eliminating quarantine times for healthcare professionals who have had a high-risk COVID-19 exposure but are not known to be infected.[10]

B. The EDTPA's Grant of Immunity Recognized the Dire Conditions Healthcare Facilities and Workers were Forced to Face.

The EDTPA must be viewed through the lens of a State's response to an exponentially growing public health crises that had, by the time it was enacted, brought health care facilities

[7] *See* Emergency Use Letter from FDA to Manufacturers and Other Stakeholders, dated March 24, 2020 (located at https://www.fda.gov/media/136423/download) (last checked June 11, 2021).
[8] *See* FDA Fact Sheet for Patients (located at https://www.fda.gov/media/136425/download) (last checked June 11, 2021).
[9] *See* https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html#crisis-capacity (last checked June 11, 2021).
[10] *See* https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html. (last checked June 11, 2021).

close to the breaking point and shuttered the world's 15th largest economy. In April 2020 – near the height of the pandemic's first wave – the New York Legislature passed and the Governor signed the EDTPA. The underlying policy purpose of the EDTPA was clear: to provide limited immunity from criminal and civil prosecution to healthcare providers and facilities given the uncertain and unprecedented nature of the COVID-19 pandemic. In August 2020, the Legislature passed a revised version of the EDTPA, clarifying that immunity only applies to the assessment or care of an individual as it relates to COVID-19, and removed protections for facilities and health care professionals who arrange for health care services. On April 6, 2021, the Legislature passed, and the Governor signed a bill repealing the EDTPA, roughly a year after it was first enacted.[11]

These actions illustrate the severity and uniqueness of the crisis New York's health care providers have been facing for over a year. The pandemic has played out as a series of peaks and valleys, with the spring 2020 surge being the most challenging due to it being the first test of the system and the sheer volume of patients affected by a novel disease. Vaccines, masks, and social distancing have helped put the worst of the pandemic behind us, but highly contagious variants linger, and the next public health challenge is unknowable. The health care sector has and will continue to meet the challenges presented by COVID-19 with a combination of grit, lessons learned, and the vaccine. But, as New York turns a corner on its recovery from this devastating disease, Courts, in deciding cases arising out of the pandemic, should not forget the important purpose that immunity statutes like the EDTPA play in allowing healthcare professionals and institutions to preserve the lives of those affected by COVID-19 without fear of liability.

[11] C. 96, L. 2021. Bill No. A.3397/S.5177.

C. The PREP Act Also Protects Frontline Healthcare Providers Making Split-Second Decisions About Pandemic Treatments in Crisis Situations

Congress enacted the PREP Act to ensure all levels of the nation's healthcare system could immediately respond, in a robust fashion, to address and contain the impact of a specific and significant contagion threat. To this end, the PREP Act creates a comprehensive immunity and compensation structure to provide healthcare professionals working under extraordinarily challenging conditions, often making split-second clinical decisions with limited information and resources, with the assurance that those decisions will not later be second-guessed in a courtroom.

Specifically, the PREP Act provides liability immunity against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures. It provides that "a covered person shall be immune 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 declaration under subsection (b) has been issued with respect to such countermeasure."[12] A "covered person" includes a "program planner," and means, *inter alia*, any "person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration [by the Secretary]."[13] Clinicians are also covered, as the term "covered person" includes a licensed health care professional and other individuals who can prescribe and administer countermeasures.

[12] 42 U.S.C. § 247d-6d(a)(1) (emphasis added).
[13] *Id.* § 247d-6d(i)(6).

The PREP Act forecloses traditional tort remedies, instead establishing the Covered Countermeasure Process Fund to compensate eligible individuals for serious physical injuries or deaths from pandemic countermeasures identified in declarations issued by the Secretary.[14] Claims must be adjudicated exclusively before a three-judge panel of the Federal District Court for the District of Columbia.[15] The sole exception for the PREP Act's immunity from liability is for "willful misconduct," which is defined as "an act or omission that is 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."[16] Absent the protection afforded by the PREP Act, hospitals, doctors, nurses, and others doing their level best in a crisis will be unfairly exposed financially and reputationally. They might also be apt to practice defensive, less effective medicine in response to a threat such as COVID-19, which is precisely the result Congress sought to avoid.

ARGUMENT

I. THE EDTPA REPEAL IS NOT RETROACTIVE AND FINDING IT TO BE RETROACTIVE WOULD THWART THE LAW'S UNDERLYING PUBLIC POLICY PURPOSE.

The public policy underlying the EDTPA is clear: in the face of a life-threatening and unknown disease, doctors, nurses, clinicians, and healthcare facilities should not be subject to liability arising from decisions, acts, and omissions driven by the emergency. Healthcare providers and care facilities are the frontline defense against a pandemic. The need to diagnose, treat, house, and rehabilitate large numbers of patients infected with an emerging disease that puts the lives of those frontline workers and their families at risk, and that demanded new and unchartered

[14] *Id.* § 247d-6d(e).
[15] *Id.* §§ 247d-6d(e)(1), (e)(5).
[16] *Id.* § 247d-6d(c)(1)(A); *see also id.* § 247d-6d (e).

treatments and countermeasures that may or may not prove effective. Exposure to potentially crushing liability, in addition to the palpable physical danger that these workers and institutions face, does not encourage swift and difficult staffing decisions. It also does not foster the administration of cutting-edge countermeasures, treatments and techniques needed to combat an unknown pathogen at a time of supply scarcity.

To support the frontline defense against the COVID-19 pandemic, the Legislature passed the EDTPA, which conferred, at the outset, broad immunity from civil and criminal liability to healthcare providers and institutions. Clinicians and institutions were supported by that provision of immunity when diagnosing and treating COVID-19 patients. Retroactively removing that protection is not supported by the language of the EDTPA repeal and engaging in interpretive gymnastics to do so undermines the sound public policy goals the prompted the passage of the statute in the first place.

The canons of statutory construction compel the Court to find this unambiguous statute prospective on its plain language alone.[17] The repeal of the EDTPA states that "[t]his act shall take effect immediately." It contains no ambiguity with respect to retroactivity, and the Court's interpretation of the retroactivity of the EDTPA repeal should end with an examination of its plain language.[18]

When drafting retroactive legislation, the Legislature knows how to make such a retroactive effect clear. It did not do so here. Indeed, when the Legislature first passed the EDTPA

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[17] *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002) **(**"As in all statutory construction cases, we begin with the language of the statute. The first step is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case."**);** *Getty Petroleum Corp. v. Bartco Petroleum Corp.*, 858 F.2d 103, 108 (2d Cir. 1988) **(ST**atutory construction begins with the plain language employed by the Legislature "and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."**)**

[18] *CFCU Community Credit Union v. Hayward*, 552 F. 3d 253 (2d Cir. 2009), upon which Plaintiff relies, is inapt. That case involved the retroactive effect of a remedial statute intended to correct a defect in a prior law. The repeal of the EDTPA is not a remedial statute. It repeals a law, expressing a public policy preference of the Legislature. It does not correct a defect in a prior law. It should, consistent with its plain language, be applied prospectively.

in April 2020, it made clear that it was retroactive to March 7, 2020, stating: "This act shall take effect immediately and shall be deemed to have been in full force and effect on or after March 7, 2020 and shall apply to a claim for harm or damages only if the act or omission that caused such harm or damage occurred on or after the date of the COVID-19 emergency declaration and on or prior to the expiration date of such declaration; provided, however, this act shall not apply to any act or omission after the expiration of thie COVID-19 emergency declaration."[19] Such specific language made apparent that the EDTPA was intended to apply retroactively. But when the Legislature repealed the EDTPA, it included no such language, instead simply stating, as it does with all prospectively applicable legislation, the repeal "shall take effect immediately."

And even if the Court were to find that the words "shall take effect immediately" were ambiguous – which they are not – finding that the EDTPA repeal is retroactive would have policy implications for the entire healthcare industry that would reverberate for years. When the EDTPA was enacted in April 2020, healthcare providers and care facilities relied upon it in making patient care decisions aimed at aggressive treatment of an emerging disease that causing severe injuries, including fatalities. This allowed the healthcare industry to recruit frontline workers who might otherwise be reluctant to engage in COVID-19 care, expand capacity, and provide patient and resident care.

The Legislature chose to first limit the liability protections as the first wave of COVID-19 receded, and, recently, to repeal the law altogether. Were such a repeal to be deemed retroactive, the healthcare industry could never again put its faith in the legal protections that the State provided. Retroactively removing liability protections after the entire healthcare system, from hospital administrators to frontline workers, relied on them during the nation's worst healthcare

[19] At least two courts have affirmed that the EDTPA had a retroactive effect. *See Hampton v. City of New York*, No. 28392/2020E (Sup. Ct. Bronx. Co. May 18, 2021) (citing *Matos v. Brian Bobby Choing, M.D.*).

crisis in a century would amount to a disintegration of the social contract under which law and political order protect against arbitrary, capricious, and, ultimately, tyrannical rule.

Such a rift in the legal and social fabric that binds healthcare providers, institutions, and government, would have far-reaching policy implications. When the next healthcare crisis occurs, government will undoubtedly need to ensure that diagnosis, care, and treatment are effectively provided to patients. This will likely be provided, once again, by healthcare facilities that are stretched beyond normal limits and by healthcare workers who are redeployed and repurposed to practice settings and specialties for which they have inadequate supplies and other resources. Were the EDTPA repeal be retroactively applied here, the healthcare industry would have a difficult time relying on any future governmental action in response to such a crisis. Sound public policy demands that this Court find that the EDTPA's repeal was prospective only, and that it has no retroactive effect.

II. THE PREP ACT COMPLETELY PREEMPTS STATE LAW TORT CLAIMS AND CONFERS FEDERAL JURISDICTION OVER ALLEGATIONS RELATED TO A COVERED COUNTERMEASURE

A. The PREP Act Provides Broad and Complete Preemptive Immunity Protection for Clinicians and Administrators.

The General Counsel for DHHS has stated the purpose of the PREP Act and its importance to ensuring that clinicians and public health decisionmakers and administrators are insulated from liability in the face of a declared pandemic:

> COVID-19 is an unprecedented global challenge. As we learn more about the highly contagious pathogen that causes COVID-19, public-health guidance and directives tend to change to reflect the new knowledge. Those changes do not always occur uniformly or simultaneously among scientists and across America's federal, state, territorial, tribal, local, and other public-health authorities—leading to uncertainty. Those uncertainties present potential legal risk for public and private individuals and organizations as they combat the pandemic, restore and strengthen America's economy, ensure that transportation remains available, and provide safe environments for education and worship. Unfortunately, such perceived risks may

> hinder those essential efforts. They should not. The PREP Act exists, in part, to remove legal uncertainty and risk.

DHHS Gen. Counsel Advisory Opn. 20-04 (Oct. 23, 2020).

This clear and unambiguous purpose would be undermined by delegating the legal determination of whether the PREP Act applies to a given complaint by remanding a properly removed lawsuit to state court. That would defeat the PREP Act's primary directive of providing certainty, consistency and removing legal risk so frontline health care professionals and administrators can assess, treat, and defend the public from COVID-19. This is especially true where, as here, the basis for federal removal is the complete preemption of state law by a federal immunity statute.

The doctrine of complete preemption provides a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) where a federal statute: (1) establishes a federal administrative or judicial cause of action, as the only viable claim; or (2) vests exclusive jurisdiction in a federal court. *See Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (the Labor Management Relations Act of 1947 completely preempts state court jurisdiction). The PREP Act satisfies both requirements.

As noted, the PREP Act provides for complete immunity from state law tort claims arising out of, relating to, or, resulting from the administration of covered countermeasures. The PREP Act further provides only one exception to its grant of immunity — willful misconduct — and establishes an exclusive venue for the adjudication of such excepted claims: "only" before a three-judge panel of the United States District Court for the District of Columbia. 42 U.S.C. § 247d-6e(d)(1). It thus meets both hallmarks of complete preemption: the establishment of a federal cause of action, and an exclusive federal forum to hear the narrow universe of claims permissible under the statute.

Indeed, the PREP Act makes clear that a plaintiff's claims are preempted where they arise out of, relate to, or, result from the administration of covered countermeasures, and, where such claims fall into the willful misconduct exception, it establishes an exclusive federal venue to adjudicate them. Nothing in the PREP Act can be read to suggest an intent to leave the determination of its application to state courts. A contrary conclusion would risk multiple, inconsistent, intra and interstate rulings by state courts that would undermine Congressional intent and place healthcare providers and administrators at significant jeopardy for their attempt to quell an unprecedented disease outbreak.

B. The DHHS Secretary's PREP Act Declarations Establishes that Purposeful Allocation of Covered Countermeasures Relates to the Administration of a Covered Countermeasure.

Between February 4, 2020 and January 28, 2021, the DHHS Secretary issued six declarations and amended declarations, triggering the PREP Act's immunity provisions. These declarations include within the definition of a "covered countermeasure" the administration of COVID-19 diagnostic tests, resource management, operation of locations, and the use of other treatments and devices used in the COVID-19 response. The Secretary's fourth amended declaration, dated December 9, 2020, defined "Covered Countermeasure" to mean the physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures. 85 FR 7919085, at 79. That declaration further defines "Covered Countermeasures" as "any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured: (i) to diagnose, mitigate, prevent, treat, or

cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or (ii) to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause." 85 FR 7919085, at 79, 197.

Additionally, the Secretary's declaration states that "[p]rioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections." *Id.* "Where there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to . . . the administration to . . . an individual' under 42 U.S.C. § 247d-6d." *Id.*

Accordingly, should this Court find that plaintiffs allege affirmative acts, omissions, or allegations of purposeful allocation of a countermeasure, such as withholding a diagnostic test, or the administration of any device used to treat COVID-19, it must retain jurisdiction over the lawsuit. Such allegations clearly fall within the definition of the administration of a Covered Countermeasure, as contemplated in the PREP Act and as set forth in DHHS's declarations.

Recently, a California District Court, relying on DHHS's declarations and guidance, reached the conclusion that the PREP Act completely preempts state law and provides federal jurisdiction. In *Garcia v. Welltower OpCo Grp.*, the District Court, relying on DHHS's guidance, held that the PREP Act "provides for complete preemption."[20] No. 20-CV-2250 (JVS) (KES) (C.D.Ca. Jan. 5, 2021) (slip op) (Selna, J.) at 11. The Court went on to find that the PREP Act applied broadly to the administration of infection control programs, not narrowly, as the plaintiffs had urged. Additionally, the court found that allegations of momentary lapses in adherence to

[20] The court in *Garcia* captioned its decision as "tentative"; however, nothing in the docket suggests that the decision was subsequently altered.

local or federal health guidelines did not abrogate the immunity that the PREP Act conferred. *Id.* at 14.

Also instructive, in this connection, is *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005). There, the Second Circuit addressed claims of frontline workers injured in the aftermath of the terrorist attack that destroyed the World Trade Center attack. The District Court had retained jurisdiction over certain lawsuits "relating to" injuries and illnesses suffered in the massive demolition in the days and weeks following the attack. Defendants asserted that the Air Transportation Safety and System Stabilization Act of 2001 ("TSSSA"), which, like the PREP Act, established a compensation fund and federal cause of action, completely preempted Plaintiffs' state law claims. To determine the breadth of the TSSSA's preemptive effect, the Second Circuit looked to the "relating to" and "arising out of" language of the TSSSA — a phrase also used in the PREP Act — and found that the use of "relating to" and "arising out of" was inherently and intentionally more expansive than "resulting from."

The Second Circuit concluded that the intended federal cause of action was sufficiently broad to cover claims of respiratory injuries of workers who worked around debris. *Id.* at 376. The Second Circuit also found that "in making the TSSSA-created federal cause of action the exclusive remedy for damages arising out of the September 11 plane crashes, Congress clearly expressed its intent to preempt state-law remedies for damages claims arising out of those crashes," and by selecting a venue for such claims, "Congress clearly evinced its intent that any actions on such claims initiated in state court would be removable to that federal court." *Id.* at 380.

WTC Disaster Site should control here. Like the TSSSA, the PREP Act broadly confers immunity, creates a narrow class of "willful misconduct claims," and sets an exclusive venue for those claims in the D.C. District Court. Even if a claim is ultimately determined not to be "related

to" COVID-19 or otherwise outside the scope of the PREP Act's immunity provisions and the reach of DHHS's declarations, the fora in which to determine those legal issues should be the federal courts, not the state courts. *See, e.g., Barretto v. Gonzolez*, 2006 U.S. Dist. LEXIS 86424 (S.D.N.Y. Nov. 29, 2006) (determining that the federal court had jurisdiction to determine whether a fiduciary duty claim among survivors of a fireman who died in the aftermath of the September 11 attacks fell within the purview of the TSSSA).

A few decisions misinterpret the PREP Act as requiring an injury to have been directly caused by the administration of a covered countermeasure. In *Dupervil v. Alliance Health Operations, LCC, et al.,* for example, District Judge Pamela K. Chen ruled that the PREP Act did not completely preempt state law, and, even if it did, the plaintiffs' claims did not call within its scope. No. 20-CV-4042 (PKC) (PK), 2021 U.S. Dist. LEXIS 20257 (E.D.N.Y. Feb. 2, 2021). That case, it is respectfully submitted, was wrongly decided and should not be followed here.[21]

First, *Dupervil* incorrectly determined that the PREP Act is a "field preemption" statute. It found that the PREP Act provided for "field preemption" under which "state law is preempted where it regulates conduct in a field that Congress intended the federal government to occupy exclusively." *Id*. at *27 (citations and quotation marks omitted). *Dupervil* further reasoned that complete preemption, on the other hand, created federal subject matter jurisdiction and provides a basis for removal, whereas field preemption provides a mere federal defense. *Id.* But, turning to address the DHHS Office of General Counsel opinion to the contrary, *Dupervil* elides the fact that the PREP Act goes far beyond creating a simple federal immunity defense, and creates both a cause of action and jurisdiction, both hallmarks of complete preemption. Finding that the DHHS

[21] *See also Baskin v. Big Blue Healthcare, Inc.*, 2:20-CV-2267-HLT-JPO, 2020 WL 4815074, at *8 (D. Kan. Aug. 19, 2020) (slip op); *Estate of Maglioli v. Andover Subacute Rehabilitation Center I*, 2020 WL 4671091 (D.N.J. Aug. 12, 2020) (slip op). These cases are not controlling in the Second Circuit and are at odds with Second Circuit precedent, such as *WTC Disaster Site.*

opinion "lacks the power to persuade," and characterizing the willful misconduct cause of action and venue before a 3-judge panel in the D.C. District Court, *Dupervil* found that this was an "administrative remedy" provision. *Id.* at *29. Further rejecting the position stated by the U.S Government in a Tennessee PREP Act case, which had urged the Court to follow the Second Circuit's ruling in *WTC Disaster Site*, *Dupervil* then reiterated its erroneous conclusion that the PREP Act merely limits the causes of action a plaintiff can bring, creates a compensation fund, and does not provide cause or right of federal action. The PREP Act creates a comprehensive statutory structure of immunity, a narrow federal cause of action for willful misconduct that must be prosecuted in federal court, and a compensation fund. The PREP Act bears all the hallmarks of a complete preemption statute, and this Court should not follow *Dupervil* for that reason.

C. The PREP Act Creates Federal Jurisdiction Over Claims That Fall Within Its Ambit.

COVID-19 has shaken New York, the nation, and the globe to its core, affecting every aspect of the economy and threatening to overwhelm public health systems. Frontline workers, clinicians, hospitals and their administrative staff have acted to stem the spread of this disease at great personal risk to their health, and under circumstances that are medically, scientifically, and financially uncertain. Throughout the pandemic, they have faced a limited supply of tests, vaccines, drugs, personal protective equipment, respirators, and other countermeasures employed to treat and prevent COVID-19.[22]

In enacting the PREP Act, Congress sought to provide a modicum of certainty that the good faith actions and decisions of these frontline workers would be immune from lawsuits and legal liability. To this end, Congress created a narrow class of cases involving willful misconduct and

[22] *See, e.g.,* https://www.modernhealthcare.com/technology/covid-19-testing-problems-started-early-us-still-playing-behind (last checked June 9, 2021).

provided an exclusive federal forum to resolve those cases. The PREP Act provides immunity in all other cases "relating to" the administration of covered countermeasures against a declared pandemic. In so doing, the PREP Act completely preempts state law, and created federal jurisdiction over claims falling within the PREP Act's ambit. Exposing these providers to the very liability the PREP Act seeks to prevent by subjecting them to uncertain and conflicting treatment in state court defeats the express purpose of the PREP Act, contravenes Congress's intent, and thwarts the battle against the pandemic.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request this Court to grant Defendants' motion to dismiss Plaintiff's claims, as Congress and the New York Legislature intended and public policy demands.

Dated: Albany, New York
June 11, 2021

Respectfully submitted,

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