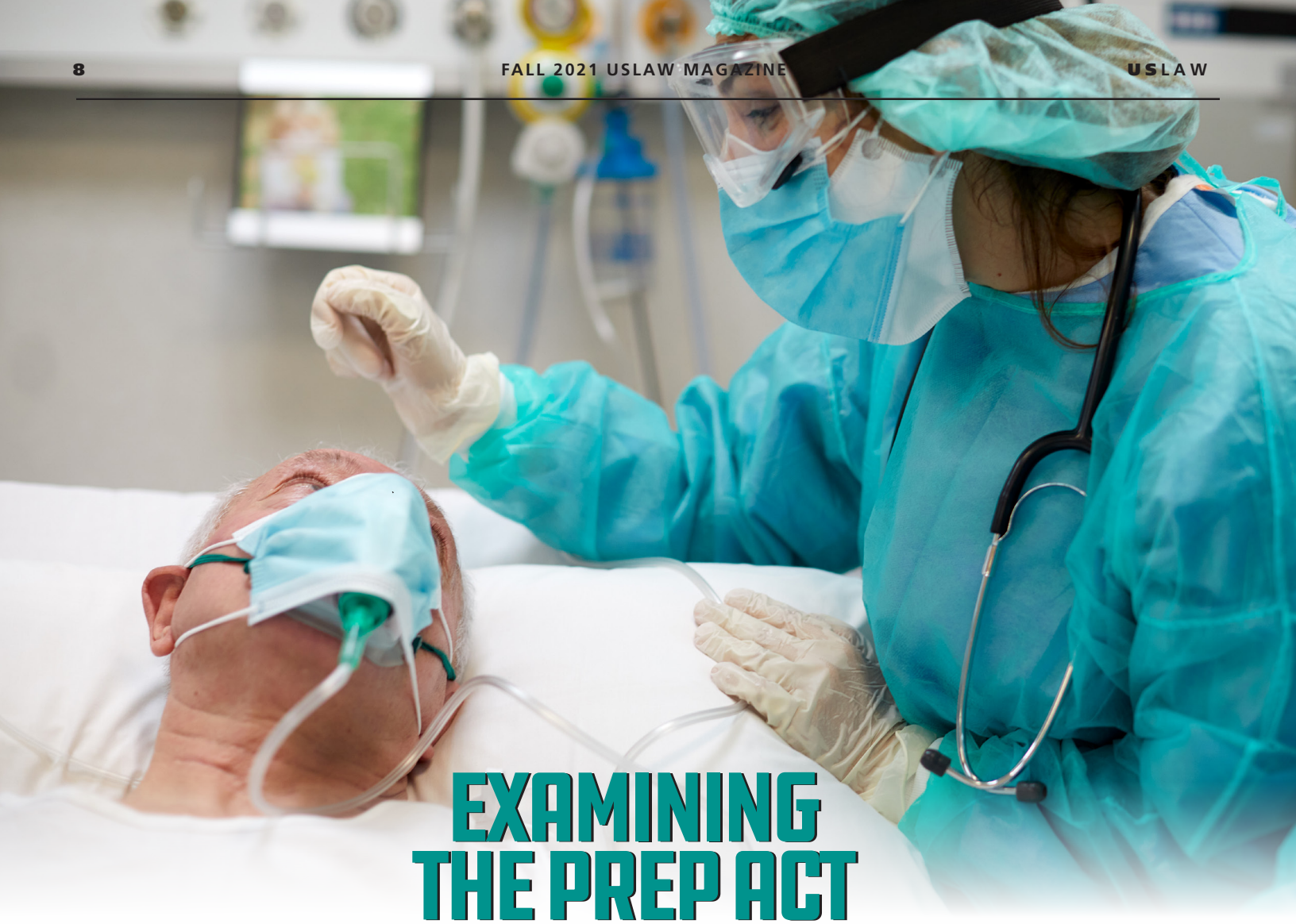

EXAMINING THE PREP ACT

Healthcare Provider Liability Immunity During the COVID-19 Pandemic

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In 2020, the COVID-19 pandemic swept the globe, resulting in millions of hospitalizations and hundreds of thousands of deaths in the United States.[1] The healthcare provider industry, at the forefront of combatting this insidious virus, faced severe challenges, including unprecedented inundation of medical facilities with severely sick patients, equipment, medication, and bed shortages and overburdened, under rested, and often sick, staff to treat patients. Healthcare providers were given little guidance and support in handling the pandemic and confronted with quickly shifting executive orders and regulations from state and government officials. Within a few months, our society was thrown into a state of deep economic and social disrepair. The effects of the pandemic will be felt throughout the world and legal and healthcare communities for years to come.

This is not the first time the United States faced a health crisis with the potential to disrupt the operation of our health care system. The avian flu posed a real risk of overwhelming all aspects of the United States healthcare system, prompting Congress' enactment of the Public Readiness and Emergency Preparedness Act ("PREP Act") in 2005.[2] The PREP Act authorizes the Secretary of Health and Human Services ("Secretary") to issue a declaration providing immunity from Federal and State liability, to persons involved in the manufacture, testing, distribution, administration and use of countermeasures, arising from public health emergencies. On March 17, 2020, the Secretary published a declaration to the PREP Act, extending liability protections to countermeasures against Covid-19.[3]

The PREP Act provides immunity to any person or entity that manufacturers, distributes, prescribes, or administers countermeasures, including licensed health professionals that have treated patients with defined countermeasures. Countermeasures are defined as qualified pandemic or epidemic products, drugs, biological products, or devices the Secretary deems a priority for use during the public health emergency. The PREP Act provides immunity for any loss that has a causal relationship with the administration or use by an individual, of a covered countermeasure during the declaration's effective period. This includes a causal relationship with the design, development, clinical testing, investigation, manufacturing, labeling, distribution, and other activities, of covered countermeasures.

Congress, understanding the need for some limitation on blanket immunity, carved out an exception for causes of action for death or serious physical injury caused by the willful misconduct of a cov-

ered person.[4] Willful misconduct is any "act or omission that is taken intentionally to achieve a wrongful purpose, knowingly without legal or factual justification, and 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."[5] This criterion is construed to establish a more stringent standard of liability than ordinary negligence or recklessness.

Herein we explore the Court's interpretation of PREP Act immunity in lawsuits against healthcare providers for failure to prevent COVID-19 transmissions to its patients.

COURTS' INTERPRETATIONS OF THE ACT

With over 33 million COVID-19 diagnoses, the United States is experiencing a rise in state and federal lawsuits against healthcare facilities based on an alleged failure to use appropriate countermeasures to prevent the spread of COVID-19.[6] Typically, defendant healthcare providers sued in State Court seek removal to Federal Court, arguing the PREP Act completely pre-empts state law. Courts' interpretation of the PREP Act has been decidedly "black and white," with the majority of courts holding the PREP Act inapplicable if allegations in the complaint do not fall within the narrow language of the statute.

For example, pending before the Kentucky Federal District Court are 12 related cases stemming from COVID-19 deaths at a single post-acute rehabilitation facility. Defendants in each of the cases successfully removed the case from State Court, and then moved to dismiss based on immunity afforded under the PREP Act. Plaintiffs, in turn, sought to remand the cases to State Court arguing that the PREP Act does not apply. In *Brown v. Big Blue Healthcare, Inc.*,[7] one of the 12 cases decided by the Court, plaintiff alleges decedent died of COVID-19 because defendants failed to take preventative measures to stop its spread within the facility. The Court, in remanding the case, explained that plaintiff's allegations are not "causally connected to the administration or use of any drug, biological product, or device," and accordingly, the PREP Act is inapplicable. The Court distinguished allegations of inaction, as opposed to action, stating that those who employ countermeasures are protected by the Act, not those who decline to employ them.

The District Courts in Pennsylvania, Florida, New Jersey, and California have made similar holdings in remanding cases to State Court, finding that the PREP Act does not apply to allegations that a facility failed to use countermeasures to prevent patients from contracting COVID-19.[8]

The Courts' decisions in the above cases are consistent with former Secretary Alex Azar's March 2020 Declaration that "Administration of the Covered Countermeasure means (i) physical provision of the countermeasures to recipients, or (ii) 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."[9] However, evolution of treatment and a focus on prevention of COVID-19 through vaccination has forced refinement of PREP Act definitions. On December 3, 2020, Secretary Azar issued a Fourth Amendment to the Declaration interpreting "Administration of a Covered Countermeasures" to include "not administering a Covered Countermeasure to one individual in order to administer it to another individual."

This amendment clearly contemplates a scenario where the failure to administer a countermeasure will fall within the immunity protection of the PREP Act. Thus, the Kentucky District Court in *Maltbia v. Big Blue Healthcare, Inc.*,[10] was forced to revisit its prior holding in *Brown* and its sister cases. The Court, evaluating the new amendment and relevant Federal Court jurisprudence on this issue, held that two conditions are required for PREP Act immunity in 'inaction claims': (i) the claim alleges liability for not administering a covered countermeasure; and (ii) close causal relationship between the injurious inaction and corresponding administration or use that caused it.[11] The Court, in remanding the case, held that plaintiff's complaint contains no allegations that decedent's death is related to the provider's failure to administer a covered countermeasure, nor from a failure to administer the countermeasures because it was administered to another individual.

CONCLUSION

Interpretation of the applicability of the PREP Act will continue to evolve as the pandemic persists, treatments expand, and Amendments are issued. However, as current case law establishes, plaintiff's complaint must allege the specific PREP Act terms that trigger immunity if defendant is to avoid remand and achieve dismissal.

Finally, while healthcare providers have a limited ability to take advantage of immunity under the PREP Act, many states enacted favorable immunity statutes during the pandemic that may allow for dismissal of a case for failure to prevent the transmission of COVID-19.

1 https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendsdeaths.
2 42 U.S.C. §247d-6d.
3 85 FR 15198 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures). Declaration was published on March 17, 2020, and was made retroactively effective from February 4, 2020, thru October 1, 2024.
4 42 U.S.C. §247d-6d(c)
5 *Id.*
6 https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases
7 *Brown*, 480 F.Supp.3d 1196, 1196 (D. Ky. Aug. 19, 2020).
8 *See, e.g., Sherod v. Comprehensive Healthcare Management Services, LLC*, 2020 WL 6140474 (W.D. Pa. Oct. 16, 2020) (plaintiff's claim falls outside the PREP Act because the complaint alleges defendant failed to provide decedent with any protection/countermeasures); *Gunter v. CCRC OPCO-Freedom Square, LLC*, 2020 WL 8461513 (M.D. Fla. Oct. 29, 2020) (allegations including the failure to provide necessary medical supplies, reducing the cleaning practices in the facility and failing to effectively communicate with defendants' residents and families had nothing to do with "the administration of a qualified pandemic or epidemic product, drug, biological product, or device for which the PREP Act provides immunity"); *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 531 (D.N.J. Aug 12, 2020) (claims alleging countermeasures were not used are not preempted by the PREP Act); *Martin v. Serrano Post Acute LLC*, No. CV 20-5937 DSF (SKX), 2020 WL 5422949 at *1-2 (C.D. Cal. Sept. 10, 2020) (PREP Act does not apply when plaintiff alleges defendants failed to staff the nursing facility, failed to take proper precautions to prevent the spread of COVID-19 and failed to react properly to the infections).
9 85 Fed. Reg. at 79, 1973.
10 *Maltbia*, No. CV 20-2607 DDC (KGG), 2021 WL 1196445 at *1 (D. Ky. March 30, 2021).
11 *Id.*

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