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Expert Analysis

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PREP Act civil liability immunity: a public health emergency defense of rare applicability

Abbye E. Alexander, Christopher J. Tellner and Henry E. Norwood of Kaufman Dolowich & Voluck discuss a law that provides for immunity from liability in response to a public health emergency and how it has been applied by the courts before and during the COVID-19 pandemic.

The Public Readiness and Emergency Preparedness Act (PREP Act) permits the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act declaration. A PREP Act declaration was issued in March 2020, in response to the COVID-19 pandemic.

The declaration grants immunity from liability (except for willful misconduct) for claims caused, arising out of, relating to, or resulting from the administration of care or services in response to a public emergency and from the manufacture, testing, distribution, and administration of countermeasures to the emergency.

Administration of countermeasures

What exactly falls within the PREP Act immunity scope for "administration of countermeasures" has been the point of contention in PREP Act litigation, even during prior PREP Act declarations.

The HHS declaration defines "administration of a covered countermeasure" as the physical provision of countermeasures to recipients; 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 purpose of distributing and dispensing countermeasures.

Litigation regarding administration and failure to administer countermeasures

Litigation regarding administration of countermeasures first arose in the wake of the H1N1 pandemic in 2009 and the responsive PREP Act declaration.

In a 2014 case before the Supreme Court of New York, *Casabianca v. Mount Sinai Medical Center*, the decedent had been hospitalized for a medical procedure but was not given the H1N1 influenza vaccine. He was later exposed to H1N1 and died.

His family sued the hospital for medical malpractice and wrongful death. The hospital sought protection under the PREP Act. However, the court noted that immunity under the PREP Act is limited to claims "resulting from the administration . . . or use" of a covered countermeasure, and that non-administration is not addressed, noting that "[n]othing is spoken of regarding a decision not to use the vaccine or of a failure to use it."

Accordingly, the court's reasoning in *Casablanca* can be succinctly stated as: the failure to administer countermeasures does not fall within the protection of the PREP Act immunity.

This same principle has been extended to PREP Act immunity cases that arose during the COVID-19 pandemic. In a more recent, 2020, case filed in the U.S. District Court for the District of New Jersey, Estate *of Maglioli v. Andover Subacute Rehabilitation Center I,* the estates of several decedents filed suit against two nursing home facilities for medical malpractice and wrongful death arising from the nursing homes' alleged failure to safeguard decedents — who were residents of the facilities — against the coronavirus.

Specifically, it was alleged that the nursing homes failed to distribute masks to all of their employees, failed to monitor visitors, failed to monitor food preparation, and failed to monitor residents having contact with persons outside of the nursing homes, resulting in the infection of several residents and the resulting deaths of the decedents.

The nursing homes, as defendants in the action, sought to remove the action to federal court, successfully arguing that the claims were preempted by the PREP Act.

In considering the estates' motion to remand the lawsuit back to state court, the District Court granted the motion to remand, holding that the acts of negligence alleged by the estates fell outside of the scope of PREP Act civil liability immunity, and therefore, federal preemption does not apply. Specifically, the court held the PREP Act applied to the administration of countermeasures to the COVID-19 virus, whereas the lawsuit alleged the failure to administer countermeasures to the virus.

The court distinguished the case of *Parker v. St. Lawrence Cty. Publ. Health Dep't*, a 2012 case filed in the Supreme Court Appellate Division of New York, in which it was alleged that a school district administered an H1N1 virus vaccination to a child without permission from the parents. In *Parker*, the court held that PREP Act civil liability immunity did apply.

The court in *Estate of Maglioli* reasoned that the PREP Act immunity provision properly applied to the *Parker* case because it involved an administration of a virus countermeasure — a vaccine — whereas the case before it involved the failure to administer a virus countermeasure, which it ruled fell outside PREP Act immunity.

The result reached in *Estate of Maglioli,* regarding the inapplicability of PREP Act immunity to allegations regarding the failure to implement countermeasures, has also been reached in excess of 25 COVID-19-related cases.

A new interpretation

Despite the overwhelming weight of authority holding PREP Act civil liability immunity does not apply to failures to administer countermeasures, there is a single case which was heard in the Central District of California in 2021 that reached the opposite conclusion, *Garcia v. Welltower OPCO Group, LLC*.

In *Garcia*, the defendants operated and managed a senior living facility at which the decedent was a resident. While a resident at the facility, the decedent contracted COVID-19 and died as a result. The resident's estate filed a lawsuit against the facility, alleging they were negligent in failing to adhere to proper COVID-19 preventative protocols, resulting in the decedent's death.

The defendants successfully removed the case from state to federal court, arguing the PREP Act presented a federal question applicable to the case. The estate sought remand to state court, arguing that PREP Act liability immunity only applied to the administration of COVID-19 countermeasures, whereas their lawsuit alleged the failure to administer countermeasures.

The court ultimately ruled in favor of the defendants, reasoning that their actions in failing to properly screen guests from visiting their facility, failing to properly supply personal protective equipment, and failing to maintain COVID-19-preventive protocols amounted to "unsuccessful attempts to administer countermeasures," as opposed to the failure to administer countermeasures.

On this basis, the court found that the defendants' alleged conduct amounted to misfeasance — not nonfeasance — and therefore, the case fell within the scope of the PREP Act, warranting denial of the estate's motion to remand the case back to state court.

Several courts ruling on the same issue have disagreed with the opinion in *Garcia*.

Although it is unlikely to be regarded as persuasive given the weight of authority in opposition, the *Garcia* opinion offers defendants an argument that PREP Act immunity should apply where an organization unsuccessfully attempts to administer countermeasures. This argument may be more persuasive where the defendant, like the defendant in *Garcia*, maintained COVID-19 procedures, but executed them poorly.

Conclusion

The rise in cases seen in 2021 related to the COVID-19 pandemic have resulted in defendants searching for viable defenses to raise in response. While the PREP Act civil liability immunity provision may appear, on paper, to provide a silver-bullet defense, judicial interpretation of the key phrase, "administration of countermeasures," has rendered the supposed immunity defense applicable to only the rare circumstances where plaintiffs fail to plead their way around it.

Footnotes

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