



PREP Act Immunity Can Apply to "Non-Use" of COVID Countermeasures

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In an Advisory Opinion dated January 8, 2021, the Office of the General Counsel of the Department of Health & Human Services discussed the scope of liability immunity under the PREP Act (Public Readiness And Emergency Preparedness Act) for "covered countermeasures" used to combat the COVID-19 virus.

Specifically, the Opinion examines "whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used."

The Opinion references "a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment ("PPE"), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given."

Typically, such lawsuits are filed in state courts and defendants seek to remove them to federal court, citing the exclusive federal jurisdiction provided by the PREP Act. Because the PREP Act is a "complete preemption" statute, federal jurisdiction applies whenever the PREP Act is triggered. However, both state and federal courts have struggled with whether failure to use a covered countermeasure is a "use" that triggers the PREP Act protections.

The General Counsel Opinion noted that the statute applies to claims "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," and that therefore the failure to use a covered countermeasure, such as PPE or a vaccine, can fall within the PREP Act and its liability protections.

The Opinion concludes that the "prioritization or purposeful allocation" of a covered countermeasure is protected by the Act, particularly where resources may be scarce, noting that a key function of "program planners," who are expressly covered by the Act, may include "decision-making that leads to the non-use of covered countermeasures."

On the other hand, the Opinion states that "the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act," and that a plaintiff might allege that, by failing "to make any decisions whatsoever," a person may not qualify as a covered program planner.