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BLOG

Advisory Opinion Clarifies Expansive PREP Act Preemption

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On January 8, 2021, the General Counsel for the Department of Health and Human Services (HHS) issued an Advisory Opinion (available **here**) clarifying the scope of preemption under the Public Readiness and Emergency Act (PREP Act) in response to questions as to whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used. These questions were "stimulated," in part, by "a spate of lawsuits, most involving nursing homes and other healthcare facilities," where plaintiffs alleged in part that the facilities failed to provide its staff with personal protective equipment (PPE), to teach the staff how to properly use that equipment, or to ensure that its staff used the PPE that it had been given. Our previous analyses of these cases are available **here** and **here**.

I. The PREP Act completely preempts all claims for which it is a defense

The Advisory Opinion first clarifies that the PREP Act is a "complete preemption" statute, such that the PREP Act both establishes "a federal cause of action" as the only viable claim and "vests exclusive jurisdiction in a federal court." Accordingly, the PREP Act serves "as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a)," after which a district court is "usually obligated to dismiss the case as pleaded." Further, the Advisory Opinion observes that complete preemption functions as an exception to the well-pleaded complaint rule, meaning that "federal courts are free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint" and whether sufficient facts exist to support a plaintiff's allegations that, for instance, a defendant "abandon[ed] its duty to act as a program planner or over covered person."

The Advisory Opinion also cites to the HHS Secretary's statement in the Fourth Amendment to the PREP Act Declaration (see our prior analysis **here**) that "there are substantial federal legal and policy issues, and substantial federal legal and policy interests . . . in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities." The Advisory Opinion therefore notes that once the PREP Act has been invoked, a federal district court "retains the case to decide whether the immunity and preemption provisions apply," and "if they do not apply, then the court would try the case as it would a diversity case."

II. Claims involving non-use of covered countermeasures made as the result of "conscious decision-making" fall under the purview of the PREP Act

However, as the Advisory Opinion observes, this preemption analysis "does not address the issue that appears to have perplexed district courts" of "when the PREP Act is triggered," specifically "whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime." Importantly, the Advisory Opinion notes the General Counsel's disagreement with how courts have interpreted the scope of immunity under the PREP Act to require actual "use" of a covered countermeasure. The Advisory Opinion states that this "'black and white' view clashes with the plain language of the PREP Act, which extends to anything '**relating to**' the administration of a covered countermeasure."

For situations involving non-use of a covered countermeasure that fall under the purview of the PREP Act, the Advisory Opinion provides as an example a healthcare professional's decision to administer a COVID-19 vaccine to a person in a vulnerable patient population instead of a person in a less-vulnerable patient population. The Advisory Opinion notes that such "[p]rioritization or purposeful allocation of a Covered Countermeasure" that results in an individual not receiving a covered countermeasure, "particularly if done in accordance with a public health authority's directive," can fall within the PREP Act's liability protections." The Advisory Opinion observes that the inclusion of "program planners" within the set of "covered persons" under the PREP Act similarly supports this interpretation, as "[p]rogram planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them."

Conversely, the Advisory Opinion provides that a 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. In other words, if the non-use of a covered countermeasure "was the result of conscious decision-making," that non-use will still enjoy various PREP Act protections, including complete preemption. However, as the Advisory Opinion notes, a "facility may still be liable under the PREP Act" if a plaintiff establishes that the decision regarding non-use of a covered countermeasure "was wanton and willful and resulted in death or serious injury."

III. Summary

Businesses and individuals should be aware of the continued expansion of PREP Act immunity both via amendments to the PREP Act Declaration or Advisory Opinions from the HHS General Counsel. Indeed, in light of the new Advisory Opinion and recent Fourth Amendment, it is difficult to envision situations in which a plaintiff can still successfully maintain actions in state court involving the use or conscious non-use of covered countermeasures and defeat a defendant's removal to federal district court. Moreover, while the Advisory Opinion notes that it only "sets forth the views of the Office of the General Counsel" and "does not have the force or effect of law," the incorporation of previous Advisory Opinions in the Fourth Amendment to the PREP Act Declaration suggests the HHS Secretary may subsequently include this Advisory Opinion as part of a final agency action as well.

For any questions about the effect of this Advisory Opinion, please contact Sandra Edwards, Rand Brothers, or your Winston relationship attorney.

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