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BLOG

Recent Decisions Provide Insights on Preemption and the PREP Act for COVID-19 Claims

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As litigation involving the Public Readiness and Emergency Preparedness Act (PREP Act) and the Department of Health and Human Services (HHS) COVID-19 Declaration begins, two recent court decisions provide initial insights on potential limits to the scope of preemption provided by the PREP Act immunity for COVID-19 claims: *Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 2020 WL 4671091 (D.N.J. Aug. 12, 2020) and *Baskin v. Big Blue Healthcare, Inc.*, 2020 WL 4815074 (D. Kan. Aug. 19, 2020).[1]

In both cases, plaintiffs brought state-law negligence claims against nursing home operators for failure to conduct testing, provide personal protective equipment, and follow CDC recommendations for COVID-19. The defendant nursing home operators removed the actions to federal court on the basis that they were "covered persons" under the PREP Act (as discussed in previous alerts **here** and **here**), and as such, the PREP Act preempted plaintiffs' state-law negligence claims so that the respective district courts had original federal question jurisdiction under 28 U.S.C. § 1331.[2]

In *Maglioli*, the District Court for the District of New Jersey addressed preemption directly, holding that Congress did not intend the PREP Act to completely preempt all state-law negligence claims. While noting that the PREP Act "covers the administration and distribution of products meant to curb the spread of COVID-19," the court also stated it does not, "by its plain terms, cover more generally the care received by patients in healthcare facilities." *Id*. at *9. The court further observed that the PREP Act is "designed to protect those who employ countermeasures, not those who decline to employ them," and that this interpretation is "consistent with guidance from the Secretary of HHS, which declared that 'the Act precludes for example . . . negligence by a health care provider in prescribing the wrong dose, absent willful misconduct.'" *Id*.

Applying this framework, the court found that the complaint did "not allege that Plaintiffs' injuries arose from, e.g., Defendants' administration to them of vaccines or medicines" or protective gear. *Id*. *10. Indeed, the court observed that the crux of plaintiffs' argument was that the defendant nursing home operators "committed negligence in that, among other things, they ***failed*** to take countermeasures." *Id*. (emphasis in original). And as the court noted, "ordinary claims of negligent or substandard care" that did not allege use or administration of a covered countermeasure, could survive PREP Act preemption and proceed in state court. *Id*. at *9. The court therefore held that plaintiffs' claims regarding the defendants' inaction did not fall under the PREP Act and the defendants' removal on the basis of PREP Act preemption was thus improper. Importantly, however, the court declined to rule that

defendants "are, or are not, entitled to a PREP Act defense to this or that claim," and only held that "the PREP Act does not so occupy the field as to squeeze out state court jurisdiction over what are state-law claims of negligence and require an exclusive federal forum." *Id*. at *11. In so doing, the court left open the possibility of asserting PREP Act defenses in state court proceedings even where certain claims are not exclusively subject to federal jurisdiction by virtue of PREP Act preemption.

In *Baskin v. Big Blue Healthcare, Inc.*, the defendant nursing home operator similarly removed plaintiffs' state-law negligence claims because "under the PREP Act, [plaintiffs'] claims . . . are completely preempted, which gives this Court subject-matter jurisdiction." 2020 WL 4671091, at *2. In assessing the defendant's preemption argument, the District Court for the District of Kansas noted that "the first step in determining whether this Court has jurisdiction is determining whether Plaintiffs' allegations fall within the purview of the PREP Act." *Id*. at *6. Because defendants were advocating for federal jurisdiction, the could held that it was "their burden to show that, first, the PREP Act applies to Plaintiffs' allegations, and second, that complete preemption would apply to the PREP Act." *Id*. The court found that defendants failed to carry their burden on the first issue, which obviated the need to address the second.

As with *Maglioli*, plaintiffs in *Baskin* alleged that "the decedent died of COVID-19 because Defendants failed to take preventative measures to stop the entry and spread of COVID-19 within the facility," not that they had affirmatively engaged in the administration or use of any covered countermeasure. *Id*. Given that there was "no clear allegation that any injury or claim of loss was caused by the administration or use of any covered countermeasure, let alone that the loss arose out of, related to, or resulted from the same," the court found that plaintiffs' claims did not fall under the purview of the PREP Act and removal on complete preemption grounds was thus improper. *Id*. at *7. In rejecting several of defendants' rebuttal arguments, the court also stressed the importance of "a causal connection between the injury and the use or administration of covered countermeasures"—a link missing even under defendants' interpretation of plaintiffs' complaint.

Both the *Maglioli* and *Baskin* decisions emphasized that PREP Act immunity exists only for actual use or administration of COVID-19 covered countermeasures. Under these courts' interpretation, state-law negligence claims relating to the general standard of care provided to patients in healthcare facilities or premised on a facility's ***inaction***, absent any administration or use of a covered countermeasure, will not necessarily fall under the purview of—and be preempted by—the PREP Act and therefore cannot be removed to federal court on that basis. Notably, product manufacturers are necessarily engaged in affirmative action when developing or manufacturing COVID-19 covered countermeasures such as prophylactics, treatments, or products that would otherwise "limit the harm of COVID-19" (as discussed in previous alerts on the expansion of "covered countermeasures" in the PREP Act COVID-19 Declaration's Second and Third Amendments, available here and here). Therefore, the *Maglioli* and *Baskin* decisions should not limit the ability of manufacturers to remove any state-law claims arising out of COVID-19-covered countermeasures to federal court for determination of whether PREP Act immunity applies.

For any questions regarding the PREP Act or removal to federal court based on the PREP Act, please contact Sandra Edwards, Rand Brothers, John Drosick, or your Winston relationship attorney.

Update: The recently issued Fourth Amendment to the PREP Act incorporates all Advisory Opinions and also broadens PREP Act immunity to cover situations where a covered countermeasure was ***not*** administered (see our recent alert here). Although the Fourth Amendment does not provide guidance on what types of circumstances would fall under this potentially large expansion of PREP Act immunity, it remains to see what impact the Amendment will have on decisions like those discussed here.

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[1] *Baskin* was one of 11 identical decisions issued by the District Court for the District of Kansas involving negligence claims against the same nursing home provider.

[2] The defendants in *Maglioli* also removed the actions under 28 U.S.C. § 1442(a)(1) on the basis that, as a private party, they were performing actions under the direction of the federal government.

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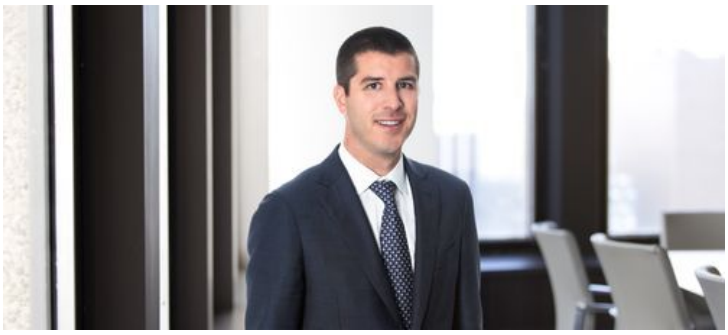

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