

Ninth Circuit Decision Raises Questions about Whether the PREP Act Prescribes Complete Preemption of State Court Claims

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Key Takeaway

Ninth Circuit denies the removal to federal court of claims about the implementation of “covered countermeasures” under the PREP that included a willful and malicious claim, contrary to the advisory opinion issued by the Secretary of the Department of Human Health and Services.

A recent decision from the Ninth Circuit calls into question whether the Public Readiness and Emergency (PREP) Act provides complete immunity from state law claims related to medical countermeasures against COVID-19, finding that the federal statutory scheme is not so comprehensive that it entirely supplants causes of action based on state law. *Saldana v. Glenhaven Healthcare LLC*, No. 20-cv-05631-FMOMAAA (9th Cir. Feb. 22, 2022).

For background, the PREP Act provides that a “covered person shall be immune from suit and liability” under federal and state law with respect to all claims for loss relating to the “administration to or the use by” an individual of a “covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). The sole exception to this immunity relates to a federal cause of action for willful misconduct, which can be “filed and maintained” only in the United States District Court for the District of Columbia. § 247d-6d(e)(1). In March 2020, the Secretary of the Department of Health and Human Services (HHS) issued a declaration under the PREP Act to provide liability immunity for activities related to medical countermeasures against COVID-19. In January 2021, the General Counsel for HHS issued an advisory opinion stating that the PREP Act would provide “complete preemption” of all state law claims where it could be invoked as a defense (our previous analysis of this opinion is available [here](#)). In addition, the advisory opinion clarified that anything “relating to” a “covered countermeasure” would be covered as an immune activity under the PREP Act. This was a broad, sweeping opinion that provided strong persuasive authority for the removal to federal court actions related to COVID-19 countermeasures and to seek immunity for activities related to those countermeasures.

Recently, the Ninth Circuit became the second federal circuit court to reject removal to federal court based on the PREP Act, and the first to rule that a willful misconduct claim, when pled with other claims, is not removable. In *Saldana*, relatives of a nursing home patient sued the nursing home in state court for claims of elder abuse, custodial negligence, wrongful death, and willful misconduct. No. 20-cv-05631-FMOMAAA, at 2–4. The nursing home removed the action to federal court, arguing that removal was proper because the PREP Act’s “complete

preemption” confers “exclusive federal jurisdiction in certain instances where Congress intended the scope of federal law to be so broad as to entirely replace any state-law claim.” Further, even if “complete preemption” did not apply, a willful misconduct claim based on an activity related to covered countermeasures in the PREP Act creates exclusive federal jurisdiction regardless of other claims. *Id.* at 6, 11, 16. The district court rejected these arguments and remanded the case to state court.

The Ninth Circuit affirmed the district court’s ruling. Specifically, the Ninth Circuit stated that the plain language of the PREP Act only provides immunity for “willful misconduct claims, not claims for negligence or recklessness.” The Ninth Circuit specifically acknowledged that it would not defer “to an opinion of the [HHS Secretary and HHS] Office of General Counsel” and instead engaged in a textual analysis of the statute. *Id.* at 3. The Court found that the text of the statute shows that Congress intended for exclusive federal jurisdiction for willful misconduct claims only when no other claims like negligence and recklessness are pled. *Id.* at 15. The PREP Act, therefore, “neither shows the intent of Congress to displace the non-willful misconduct claims ... nor does it provide substitute causes of action.” *Id.* at 3. As a result, the Ninth Circuit rejected the argument set forth in the advisory opinion by the HHS that the PREP Act is a complete preemption statute. Because Plaintiffs alleged three causes of action along with willful misconduct, the Ninth Circuit found that the district court lacked subject matter jurisdiction based on complete preemption and determined that the willful misconduct claim was not a “substantial” part of Plaintiffs’ complaint to create subject matter jurisdiction based on a federal question. For those reasons, Plaintiffs could pursue a claim for willful misconduct in state court.

The decision highlights a limitation when relying on the HHS advisory opinion to argue that the PREP Act completely preempts all state law claims (see previous analysis of this limitation [here](#)). Under the Ninth Circuit’s decision, so long as a plaintiff alleges claims alongside a willful misconduct claim, a defendant will have difficulty removing a case to federal court in California. Similar removal questions are, however, still pending before other circuit courts. If other circuits disagree with the Ninth Circuit, then a future plaintiff might be incentivized to bring willful misconduct claims exclusively in California versus other venues.

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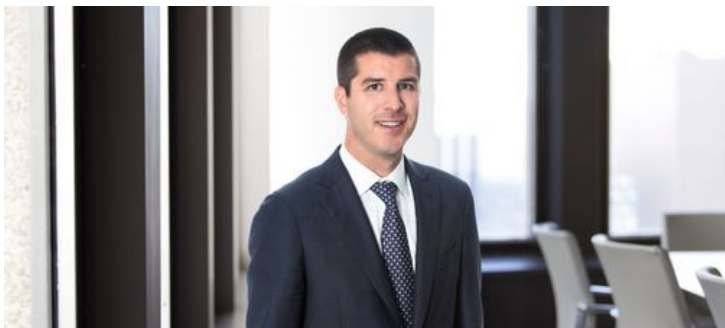
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