

HHS Purports to Expand Civil Immunities Related to COVID-19 Vaccine

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Healthcare Alert

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On December 3, 2020, in anticipation of one or more forthcoming COVID-19 vaccines, the U.S. Department of Health and Human Services (HHS) purported to broadly expand civil immunity from tort claims related to the manufacture, distribution, administration and non-administration of COVID-19 countermeasures. If upheld by the judiciary, HHS' "Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration" (the Fourth Amendment Declaration or the Amendment) would extend the time period covered by civil immunity and vastly enlarge both the realm of immunized persons and enterprises, as well as the nature of immunized activities. Although at first blush the Fourth Amended Declaration seems to stretch the powers of the Executive Branch beyond normal boundaries, the COVID-19 pandemic may be deemed so threatening to the national interest that judges may have to uphold the expanded immunities.

In the absence of Congressional action to expand immunities, HHS' action aims to plow potential tort impediments from the path of forthcoming vaccines. The Amendment extends the Public Readiness and Emergency Preparedness (PREP) Act immunity to every person and entity in the public or private chain of distribution of any COVID-19 countermeasure. The purported immunity removes a prior prerequisite whereby "covered persons" seeking immunity had to act pursuant to an agreement with the federal government. Instead, an entity that makes, distributes, administers, or otherwise uses a covered, COVID-19 countermeasure under the authority of either the Food and Drug Administration (FDA) or National Institute for Occupational Safety and Health (NIOSH) (for respiratory devices) would be entitled to immunity. HHS' Amendment would apply to any proper person or healthcare facility, including a skilled nursing, assisted living or personal care facility, which administers a vaccine, even in the absence of a specific prescription. The Amendment also embraces telehealth practitioners.

Notably, the Fourth Amended Declaration would also apply to decisions *not* to administer a vaccine – an expansion of immunity apparently targeting decisions regarding the priority of vaccine delivery and administration. The Amendment also broadens civil immunity for "other diseases, health conditions, or threats that may have been caused by COVID-19." Taking that point even further, HHS purports to civilly immunize "the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of [future] infectious diseases."

The Amendment also seeks to divest state courts of the authority to adjudicate matters in which the PREP Act might apply to immunize a defendant's conduct:

"[T]he sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct..."

For this, the Amendment specifically relies on *Grable v. & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, an obscure, subject-matter jurisdiction decision confirming federal question jurisdiction for matters where there is a sufficient "national interest."

Notwithstanding the apparent expansion of civil immunity for virtually any negligence or product liability tort arising from a COVID-19 countermeasure, the Declaration Amendment is ripe for a wide range of legal challenges regarding federalism, executive authority and subject-matter jurisdiction. Generally speaking, and on any given subject, an Executive Branch department or agency cannot act

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beyond the express, Congressional authorizing legislation. That is, the Executive Branch cannot act by order, "guidance," "declaration" or any other federal fiat beyond the scope of authority granted by a Congressional action. Laudable as the goals of the Declaration Amendment are, it is not clear whether the Executive Branch has the authority to extend legal protections as far as HHS declares. The immunity expansion will be challenged first in state courts which are typically much more receptive to personal injury attorneys' perspectives than those of industry, healthcare and the federal government.

Healthcare providers will want to consult carefully with their litigation and healthcare counsel to understand the potential threats from HHS action, as well as the most prudent manner to act in light of its publication. If you have any questions please contact Bill Kennedy (kennedyw@whiteandwilliams.com; 215.864.6816), Patti Luczak (luczakp@whiteandwilliams.com; 215.864.6801) or another member of the Healthcare Group.

As we continue to monitor the novel coronavirus (COVID-19), White and Williams lawyers are working collaboratively to stay current on developments and counsel clients through the various legal and business issues that may arise across a variety of sectors. Read all of the updates [here](#)

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