

HHS Provides Limited Tort Immunity to Companies Providing Pandemic Response Countermeasures under the PREP Act

"This is a rapidly evolving situation and CDC will provide updated information and guidance as it becomes available."

This statement is the headline to the CDC's [Situation Summary](#) for COVID-19. And along with this emerging situation comes an inherently unpredictable future landscape – especially as it relates to potential litigation.

In an effort to encourage rapid innovation and production of necessary pharmaceuticals and medical devices during this pandemic, lawmakers have recognized that companies on the front lines of the fight against COVID-19 will need certain protections. To that end, last week the U.S. Department of Health and Human Services ("HHS") published in the Federal Register a "notice of declaration" (the "COVID-19 Declaration") conferring limited immunity from certain tort liability for those engaging in activities related to medical countermeasures against COVID-19.

The power to issue this declaration derives from the Public Readiness and Emergency Preparedness Act ("PREP Act"), [42 U.S.C. § 247d-6d](#). The PREP Act empowers the Secretary of HHS to immunize certain companies from liabilities arising from "countermeasures to diseases, threats and conditions related to a public health emergency" such as the COVID-19 pandemic. The full text of the COVID-19 declaration can be found [here](#).

Pharmaceutical and medical device companies, among others, should take comfort in the immunity provided by the COVID-19 Declaration and the meaningful protections provided by the PREP Act. However, issues related to COVID-19 and the pandemic itself continue to be fluid. For example, as of this writing, numerous commentators, public health authorities, and even politicians are making broad claims about the potential efficacy of certain medicines to treat COVID-19 that are not presently approved for that purpose, and the COVID-19 Declaration is silent about whether it confers immunity for promoting off-label uses.

We will continue to monitor how legal developments related to the COVID-19 pandemic touch on products liability issues. We all need to be nimble as we navigate through these uncharted waters.

This alert is for general informational purposes only and should not be construed as specific legal advice. If you would like more information about this alert, please contact one of the following attorneys or call your regular Patterson contact.

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