



Alerts

HHS Limits Liability for Corporations and Health Care Providers Relating to COVID-19 Countermeasures

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Health Care Alert

In an effort to encourage the rapid development, design, and production of drugs, medical devices, and biological products to fight COVID-19, the U.S. Department of Health and Human Services (HHS) recently issued a [Declaration](#) to limit liability for companies and providers engaged in medical countermeasures against this pandemic. Specifically, the Declaration provides:

liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving 'willful misconduct' as defined in the PREP Act.

Although applicability of this protection must be determined on a case-by-case basis, the Declaration provides guidance regarding who and what may be immunized. "Covered Persons" includes manufacturers, distributors, program planners, and their officials, agents, and employees. Health care providers authorized to prescribe, administer, or dispense "Covered Countermeasures" are also included. "Covered Countermeasures" includes any drug, medical device, biological product, or vaccine used to test, cure, treat, or prevent COVID-19. These "countermeasures" must be approved by the U.S. Food and Drug Administration or otherwise authorized for emergency use. Manufacturers of respiratory protective equipment, including masks and ventilators, have also been granted liability immunity through Section 3103 of the [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#).

The Declaration provides specific examples of when immunity would apply, including but not limited to:

- Claims alleging negligence against a manufacturer in developing a vaccine;
- Claims alleging negligence against a health care provider in prescribing the wrong dose of a vaccine; or
- Claims relating to the management and operation of a countermeasure site, such as a slip-and-fall injury by a person receiving a countermeasure at a retail store serving as a dispensing location.