

Product Manufacturers:

HHS Declaration Offers Tort Immunity to Combat COVID-19

The federal government has activated protections under the PREP and PAHPRA Acts to provide liability immunity for activities related to medical countermeasures against COVID-19.



What happened?

On March 10, 2020, the Secretary of the Department of Health and Human Services declared that certain drug and medical device manufacturers and distributors (among others) are **immune from tort liability** in connection with the manufacture, testing, development, and use of the "Covered Countermeasures." See [85 FR 15198](#) (HHS March 17, 2020); 42 U.S.C. §247d-6d.



Who is immune?

Manufacturers, distributors, program planners and other qualified persons providing "Covered Countermeasures" in furtherance of a "Recommended Activity" are immune from tort and product liability associated with their products or activities **subject to the limitations below**.



What is a "Covered Countermeasure"?

Covered Countermeasures are broadly defined as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" or "any device used in the administration of any such product, and all components and constituent materials of any such product."

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act.



What is a "Recommended Activity"?

"Recommended Activities" are the manufacture, testing, development, distribution, administration and use of the "Covered Countermeasures."



How is the Immunity Limited?

Liability immunity is afforded to “Covered Persons” **only** for “Recommended Activities” involving “Covered Countermeasures” **that are related to:**

- a. Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding or other federal agreements; or
- b. Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of emergency.



Why does the PREP declaration matter to me?

The expansive immunity conferred under the declaration is significant — **it eliminates all state or federal tort liability claims for defined loss** whether caused by, arising out of, relating to or resulting from the manufacture, distribution, administration or use of medical countermeasures. Acts of willful misconduct are not covered.

The declaration explicitly grants immunity relating to the management and operation of a countermeasure distribution program or site, **such as a slip-and-fall injury, vehicle collision, or physical injuries resulting from lax security or chaotic crowds**. Immunity is not available if resulting injuries are not directly related to the Covered Countermeasures.



How long do these protections last?

The immunity conferred under the declaration retroactively applies from February 4, 2020, and can extend to either October 1, 2024, or to when the declaration is rescinded. Which effective time period applies to a Covered Person will depend on their method of distribution of their Covered Countermeasures. Additionally, manufacturers and other Covered Persons have an additional 12 months of immunity from the applicable effective time period to assist with the disposition of their Covered Countermeasures.