

NOTICE: Liability Immunity for Countermeasures against COVID-19

EFFECTIVE: February 4, 2020:

SUMMARY: The Secretary of the Department of Health and Human Services has declared, pursuant to the Public Health Service Act § 319F-3 (42 U.S.C. § 247d-6d), that a covered person's activities related to medical countermeasures against COVID-19 will be immune from liability under Federal and State law.

**WHO IS A COVERED?
PERSON?**

Any qualified person or entity authorized in accordance with the public health and medical emergency response of the "Authority Having Jurisdiction" (any public agency or its delegate that has legal responsibility and authority for responding) – including a private sector employer, licensed health professionals, employees, and volunteers, among others.

**WHAT ACTIONS
ARE COVERED?**

Authorized actions to: (1) prescribe, (2) administer, (3) deliver, (4) distribute, or (5) dispense the "Covered Countermeasures," *absent* willful misconduct.

**WHAT ARE COVERED
COUNTERMEASURES?**

Any antiviral, any other drug, any biologic, any diagnostic, any device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product.¹

**WHAT IS THE
IMMUNITY?**

The liability protections provide that a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure. For example, negligence by a health care provider in prescribing the wrong dose of vaccine, slip-and-fall injury at distribution site, or injury from lax security at distribution site.

**ADDITIONAL
INFORMATION**

This Declaration by the Secretary of the Department of Health and Human Services can be found at:

<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>

ⁱ Covered Countermeasure must be "qualified pandemic or epidemic products," or drugs, biological products, or devices, authorized for investigational or emergency use, as that term is defined in the PREP Act of the Public Health Service Act (42 U.S.C. §§ 247d-6d, 247d-6e) and the FD&C Act (42 U.S.C. §§ 564A, 564B). A "qualified pandemic or epidemic product" means a drug or device that is (i) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, license, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biologic product, or device.