

## HHS Provides Liability Immunity for Coronavirus Countermeasures



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Makers, distributors, program planners and administering entities of coronavirus (COVID-19) countermeasures are protected from liability under a declaration (available at: <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx>) issued by the Department of Health and Human Services (HHS) Secretary on March 10, 2020. Recognizing that the coronavirus outbreak presents a significant public health challenge, HHS is encouraging companies to proactively develop and disseminate medical countermeasures undaunted by potential legal claims attendant to these products. Immunity protects covered entities from liability, except for acts of willful misconduct, for losses relating to use of the countermeasures.

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HHS issued this declaration under the authority granted by the Public Readiness and Emergency Preparedness Act (available at: <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>) (PREP Act). The Act reflects the HHS Secretary's determination that the development of countermeasures for coronavirus should be facilitated. The PREP Act was previously used to respond to Ebola, Zika and anthrax.

### **Who Is Covered?**

Immunity is afforded to countermeasure "manufacturers," "distributors," "program planners" and other "qualified persons," as well as their officials, agents and employees.<sup>1</sup> These terms are interpreted broadly:

- "Manufacturer" includes any supplier or licensor of a component or service rendered in the design, development, testing, investigation or manufacturing of a covered countermeasure.
- "Distributor" includes any entity engaged in the distribution of a covered countermeasure, ranging from repackers to retail pharmacies.
- "Program planners" include any entity that supervises or administers a countermeasure program, including any entity that "has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility" to administer covered countermeasures.
- "Qualified persons" include licensed health professionals and others authorized to prescribe, administer or dispense the countermeasure.

### **What Actions Are Covered?**

Courts must dismiss claims brought against covered entities for any loss relating to "any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure."<sup>2</sup> The declaration exempts liability for "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 the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product."<sup>3</sup> The declaration also covers products and technologies that increase the efficacy or minimize adverse events associated with covered products.<sup>4</sup>

## **What Is the Duration of Coverage?**

Legal immunity is retroactive from February 4, 2020 and extends through October 1, 2024. An additional 12 months of liability protection is granted for manufacturers and distributors to dispose of and collect the countermeasures or otherwise limit use of the countermeasures.<sup>5</sup>

## **Limitations on Immunity**

Immunity is not available for willful misconduct causing death or serious physical injury, meaning a life-threatening injury or one causing permanent damage. These are actions that rise beyond recklessness or negligence. Intentional action for a wrongful purpose, action known to be without legal or factual justification, and acts in disregard of risk that outweighs the benefits constitute willful misconduct. Immunity does not extend to foreign claims where the United States lacks jurisdiction; for example, under this declaration, an entity would still be liable for use of a covered countermeasure in another country. But immunity will be granted if the claim has a connection to the United States that allows U.S. law to govern the claim.<sup>6</sup> Similarly, entities are not protected from claims that are unrelated to the countermeasure; for example, a claim for a slip-and-fall at an administration site will not be dismissed.<sup>7</sup>

## **Endnotes**

- 1 “Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19,” Sect. V, <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx> (Mar. 10, 2020); 42 U.S.C. 247d-6d(i)(2)-(6), (8).
- 2 “Description of this Declaration by Section,” Sect. IX, Dep’t of Health & Human Services, <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx> (Mar. 10, 2020).
- 3 Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19, Sect. VI.
- 4 “PREP Act Glossary of Terms,” Dep’t of Health & Human Services, <https://www.phe.gov/Preparedness/legal/prepact/Pages/prep-glossary.aspx#qualified-pandemic-or-epidemic-product> (May 14, 2013).
- 5 42 U.S.C. 247d-6d(b)(3)(B) and (C).

- 6 “PREP Act Q&As,” Dep’t of Health & Human Services, <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q7> (Sept. 5, 2019).
- 7 “Description of this Declaration by Section,” Sect. IX, Dep’t of Health & Human Services, <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx> (Mar. 10, 2020).