

The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures

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To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act ([PREP Act](#)) authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 ([the HHS Declaration](#)), the Secretary of HHS invoked the PREP Act and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures. Under the HHS Declaration, covered persons are generally [immune](#) from legal liability (i.e., they cannot be sued for money damages in court) for losses relating to the administration or use of covered countermeasures against COVID-19. The sole exception to PREP Act immunity is for death or serious physical injury caused by “[willful misconduct](#).” However, individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures may be [eligible](#) to receive compensation through the [Countermeasures Injury Compensation Program](#).

Courts have characterized PREP Act immunity as “[sweeping](#).” It [applies](#) to all types of legal claims under state and federal law. For example, under state [tort law](#), individuals who suffer injuries caused by the intentional or negligent acts or omissions of another person may generally sue that person to recover monetary compensation. Thus, in the health care context, if a health care provider negligently administers a drug or device that causes a foreseeable injury to a patient, the injured person may be able to sue the provider for compensation under state tort law.

Federal laws such as the PREP Act may [preempt](#) state tort laws—as well as other state and federal laws—in certain contexts. Preemptive federal legislation [displaces](#) state law to alter the usual liability rules or immunize certain individuals from liability. In the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and entities from liability [was necessary](#) to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered. This Sidebar reviews the structure of the PREP Act and the HHS Declaration to explain the scope of this liability immunity as it applies to COVID-19 countermeasures.

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The Public Readiness and Emergency Preparedness Act

Scope of Immunity from Liability

For the PREP Act to apply, the Secretary of HHS (the Secretary) must **determine** that a disease or other threat to health constitutes a public health emergency, or that there is a credible risk of such an emergency. The Secretary **shall consider** the desirability of encouraging the design, development, testing, manufacture, and use of countermeasures in determining whether to issue a PREP Act declaration. (A PREP Act declaration is **distinct** from the Secretary's power to declare a **public health emergency** under **Section 319** of the Public Health Service Act, which has a separate set of **legal implications**. The Secretary made a **Section 319 declaration** for COVID-19 on January 31, 2020.) The Secretary must publish the PREP Act declaration in the *Federal Register* and identify for each countermeasure the particular disease, time period, population, and geographical area that the declaration covers.

If within the scope of the declaration, the PREP Act **immunizes** a covered person from legal liability for all claims for loss relating to the administration or use of a covered countermeasure. The requirements for PREP Act immunity thus break down into four elements: (1) the individual or entity must be a “covered person”; (2) the legal claim must be for a “loss”; (3) the loss must have a “causal relationship” with the administration or use of a covered countermeasure; and (4) the medical product that caused the loss must be a “covered countermeasure.”

First, the PREP Act **defines** a *covered person* to include (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) “program planners”; and (iv) “qualified persons” who prescribe, administer, or dispense covered countermeasures. *Program planners* include Indian Tribes, state governments, and local governments who supervise programs that dispense, distribute, or administer covered countermeasures, or provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. *Qualified persons* include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other categories of persons identified by the Secretary in a PREP Act declaration. Employees and agents of all these persons and entities are also covered persons.

Second, PREP Act immunity reaches “**all claims for loss**” under federal and state law. *Loss* is broadly **defined** to mean “any type of loss,” including (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of such injury, including medical monitoring costs; and (iv) loss of or damage to property, including business interruption loss. This language seemingly includes, at a minimum, most state law tort, medical malpractice, and wrongful death claims arising from the administration of covered countermeasures.

Third, the loss must have a *causal relationship* to the administration and use of a covered countermeasure. As with the other elements, the PREP Act's causation language sweeps broadly. PREP Act immunity **applies** to any claim for loss that has “a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use” of a covered countermeasure.

Fourth, the medical product at issue must be a *covered countermeasure*. The PREP Act **specifies** four types of covered countermeasures: (i) a qualified “pandemic or epidemic product”; (ii) a “security countermeasure”; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use; and (iv) a “respiratory protective device” that is approved by the National Institute for Occupational Safety and Health (NIOSH).

A *pandemic or epidemic product* **includes** any drug, biological product, or device developed “to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic” or used “to limit the harm such pandemic or

epidemic might otherwise cause.” In addition, drugs, biological products, or devices used to treat the side effects of a pandemic or epidemic product, or to enhance their effects, may themselves be covered countermeasures. In either case, to be a covered countermeasure, the pandemic or epidemic product must be approved, licensed, or authorized for emergency use by FDA.

Security countermeasure refers to a drug, biological product, or device used “to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent” identified by the Secretary of Homeland Security as a material threat to national security.

The *emergency use* category of covered countermeasures includes drugs, biological products, and devices that FDA has authorized for use outside its ordinary regulatory processes via an [Emergency Use Authorization](#) (EUA). FDA has made wide use of its emergency authorities in response to the COVID-19 pandemic, [issuing EUAs](#) for certain in vitro diagnostic products (i.e., tests for COVID-19), antibody tests, personal protective equipment (e.g., respirators and face shields), ventilators, and therapeutic drugs.

[Section 6005](#) of the [Families First Coronavirus Response Act](#) and [Section 3103](#) of the Coronavirus Aid, Relief, and Economic Security Act ([CARES Act](#)) amended the PREP Act to add a fourth covered countermeasure category for certain *respiratory protective devices* (such as N95 respirators). To be covered by the PREP Act, the respiratory protective device [must be](#): (i) approved by NIOSH under 42 C.F.R. Part 84; and (ii) determined by the Secretary to be a priority for use during a public health emergency. FDA issued [an EUA](#) on March 2, 2020, for the use of NIOSH-approved filtering respirators intended for general use to protect health care personnel against COVID-19.

The “Willful Misconduct” Exception

If a claim is within the PREP Act’s scope, a covered person is generally immune from legal liability. The “[sole exception](#)” to immunity is when a covered person proximately causes death or serious physical injury to another person through willful misconduct. A *serious physical injury* [must be life threatening](#), permanently impair a body function, permanently damage a body structure, or require medical intervention to avoid such permanent impairment or damage. *Willful misconduct* [requires](#) that the covered person acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; *and* (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

The process by which injured persons (or their representatives) may prove willful misconduct under the PREP Act is [limited in several ways](#). Before filing a suit claiming willful misconduct, an [injured person must first seek compensation](#) through the Countermeasures Injury Compensation Program (see below), and they cannot sue if they elect to receive that compensation. If they choose to file a lawsuit, injured persons may sue [only](#) in the U.S. District Court for the District of Columbia. Such lawsuits [must](#) meet heightened standards for pleading and discovery, and are subject to procedural provisions generally favorable to defendants. [Injured persons must prove](#) willful misconduct by clear and convincing evidence (a higher standard than in a typical civil case), and recovery for noneconomic damages such as pain and suffering is limited.

In addition to these procedural and substantive limitations, the PREP Act contains two statutory defenses to claims of willful misconduct. First, program planners and qualified persons [cannot](#) be found to have engaged in willful misconduct if they “acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure,” and notify either the Secretary or a state or local health authority of the injury or death allegedly caused by the countermeasure within seven days. Second, countermeasure manufacturers and distributors may rely on regulatory compliance as a complete defense to a willful misconduct allegation. When the act or omission alleged to be willful misconduct is “subject to regulation” under the [Public Health Service Act](#) or the [Federal Food, Drug, and Cosmetic Act](#) (e.g., by FDA), an injured person [cannot](#) succeed on a willful

misconduct claim unless the Secretary or the Attorney General has brought certain “enforcement actions” against the manufacturer or distributor that result in the imposition of particular penalties.

The Countermeasures Injury Compensation Program

An individual seriously injured or killed by the administration of a covered countermeasure, whether or not as a result of willful misconduct, may seek compensation through the Countermeasures Injury Compensation Program (CICP). CICP is a [regulatory process](#) administered by HHS’s Health Resources and Services Administration. [HHS regulations](#) govern CICP’s procedures and eligibility determinations. In general, [eligible individuals](#) (or their survivors) who suffer death or serious physical injury directly caused by the administration of a covered countermeasure [may receive](#) reimbursement for reasonable medical expenses, loss of employment income, and survivor benefits in the case of death. Serious physical injuries under CICP are generally [limited](#) to those that warrant hospitalization or led to a significant loss of function or disability. Congress [funds](#) CICP awards through emergency appropriations to the Covered Countermeasure Process Fund.

Both the CARES Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA) appropriate funding that HHS may use for the Covered Countermeasure Process Fund. CPRSA [appropriates](#) \$3.1 billion to the Secretary to respond to COVID-19, including the development and purchase of countermeasures and vaccines, while allowing these funds to “be transferred to, and merged with” the Covered Countermeasure Process Fund. Similarly, the CARES Act [appropriates](#) \$27 billion to the Secretary for similar purposes, again providing that the Secretary may transfer these funds to the Covered Countermeasure Process Fund.

CICP is distinct from the [National Vaccine Injury Compensation Program](#) (VICP), which provides compensation for injuries caused by [most vaccines](#) routinely administered in the United States, such as childhood vaccines (e.g., MMR, polio, hepatitis A) and nonpandemic seasonal influenza vaccines. By contrast, CICP only applies to countermeasures covered by a PREP Act declaration of a public health emergency, such as those issued for [COVID-19](#), [pandemic influenza](#) (e.g., the 2009 H1N1 “swine flu”), and [the Ebola virus](#).

HHS’s COVID-19 Declaration, Amendments, and Advisory Opinions

On March 10, 2020, the Secretary invoked the PREP Act and [determined](#) that COVID-19 constitutes a public health emergency. The HHS Declaration therefore [authorizes](#) PREP Act immunity for the “manufacture, testing, development, distribution, administration, and use” of covered countermeasures. (These activities, however, [must either](#) relate to present or future federal contracts, or be part of the public health response to COVID-19 authorized by federal, state, tribal, or local governments.) The immunity applies to all covered persons as defined in the PREP Act, [including](#) any person authorized by state and local public health agencies (or an EUA) to “prescribe, administer, deliver, distribute or dispense” covered countermeasures. [Covered countermeasures](#) include “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.” The “administration” of a covered countermeasure [includes](#) “physical provision of the countermeasures” to patients, as well as “activities and decisions directly relating to . . . delivery, distribution and dispensing of” the countermeasures. The [HHS Declaration provides](#) PREP Act immunity “without geographic limitation” beginning on February 4, 2020, and ending as late as October 1, 2025.

The HHS Declaration has been amended three times, each time broadening the scope of PREP Act immunity. First, on April 10, 2020, [the Secretary amended](#) the declaration to include NIOSH-approved respiratory protective devices as covered countermeasures pursuant to the CARES Act’s amendments to the PREP Act. Second, on June 4, 2020, the [Secretary amended](#) the declaration to clarify that drugs, biological products, and devices that “limit the harm COVID-19 might otherwise cause” are covered

countermeasures, and that the HHS Declaration reaches “all qualified pandemic and epidemic products defined under the PREP Act.”

A [third amendment](#) to the HHS Declaration, issued August 19, 2020, expanded the definitions of covered diseases and covered persons. First, HHS expanded the categories of disease representing a public health emergency [to reach not just](#) COVID-19, but also “other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom.” In particular, such “other diseases” [include](#) diseases resulting from “the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.” The amendment thus [declares](#) that pediatric vaccines (if licensed by FDA and recommended by the Advisory Committee on Immunization Practices (ACIP)) are “covered countermeasures.”

[Relying](#) on the PREP Act’s preemption provision, the amendment adds a new category of “qualified persons” to [authorize](#) state-licensed pharmacists to administer ACIP-recommended vaccines to children aged three to eighteen, [notwithstanding](#) state laws to the contrary, if the pharmacists comply with certain federal requirements. Although pediatric vaccines are treated as covered countermeasures for preemptive purposes, the amendment nonetheless [states that](#) VICP will continue to apply to them “for the purposes of liability immunity and injury compensation,” unless compensation is not available under that program.

The General Counsel of HHS has issued two advisory opinions on the PREP Act. Although these opinions are nonbinding and [lack the force of law](#), they may inform the judicial interpretation of the PREP Act if courts find their reasoning [persuasive](#). First, in an [omnibus advisory opinion](#) issued April 17, 2020 (as revised May 19, 2020), the General Counsel summarized the elements for immunity under the PREP Act and set forth his view that [immunity extends to](#) (1) persons who “reasonably could have believed” that they were covered persons (even if they were not); and (2) products that a person “reasonably could have believed” were covered countermeasures (even if they were not). Second, in a May 19, 2020, advisory opinion, the [General Counsel set forth his opinion](#) that the PREP Act preempts any state or local requirement that effectively prohibits a pharmacist from ordering and administering an FDA-authorized COVID-19 diagnostic test.

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