



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

Updated March 19, 2021

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 (the Secretary) 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 and its amendments, 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.

Congressional Research Service

<https://crsreports.congress.gov>

LSB10443

The Public Readiness and Emergency Preparedness Act

Scope of Immunity from Liability

For the PREP Act to apply, 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, therapeutic drugs, and vaccines.

[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 lawsuit claiming willful misconduct, [injured persons 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**. VICP is funded through an **excise tax** on licensed vaccines **recommended** by the Centers for Disease Control and Prevention (CDC) for routine administration to children or pregnant women. Generally speaking, compensation through CICP is somewhat **more limited** than VICP. For example, attorneys' fees and pain-and-suffering damages are **not available** through CICP, and the statute **does not allow** for judicial review of HHS's CICP-compensation determinations.

While the PREP Act declaration for COVID-19 countermeasures remains in effect, persons seriously injured by the administration of a COVID-19 vaccine authorized by FDA through an EUA (such as **the Pfizer-BioNTech vaccine**, the **Moderna vaccine**, or the **Johnson & Johnson vaccine**) could seek compensation through CICP, **not VICP**. The available evidence indicates that adverse reactions to COVID-19 vaccines are rare, with serious (although treatable) allergic reactions **occurring** in approximately two to five people per million doses administered.

HHS's COVID-19 Declaration and Amendments

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 an "authority having jurisdiction," such as 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 subsequently been amended several times to broaden the scope of PREP Act immunity, and interpreted by HHS through its advisory opinions. 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 (the Third Amendment), 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 CDC’s Advisory Committee on Immunization Practices (ACIP)) are covered countermeasures.

[Relying](#) on the PREP Act’s preemption provision, the Third Amendment adds a new category of “qualified persons” to [authorize](#) state-licensed pharmacists to administer ACIP-recommended vaccines to children aged 3 to 18, [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 six 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, on May 19, 2020, 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. Third, on October 23, 2020, the General Counsel issued a [third advisory opinion](#) expressing his view that, with respect to the administration of pediatric vaccines by pharmacists authorized under the Third Amendment, the PREP Act preempts only more stringent state licensing laws, and that epinephrine, if used to treat an acute reaction to an ACIP-recommended vaccination, is a covered countermeasure. Fourth, and also on October 23, 2020, the General Counsel [re-emphasized](#) the breadth of PREP Act immunity, explaining that (1) private businesses may qualify as “program planners” (and thus covered persons) when performing certain functions, and (2) activities authorized by an “authority having jurisdiction” [include](#) uses of covered countermeasures recommended by applicable public-health guidance, such as CDC guidance. The [fifth advisory opinion](#) of January 8, 2021, analyzes whether PREP Act immunity may apply to claims based on the “non-use of a covered countermeasure,” such as allegations that a nursing home or health care facility negligently failed to provide PPE to residents and

workers. Finally, on January 12, 2021, the General Counsel [opined](#) that compliance with ACIP’s vaccine allocation recommendations (i.e., administering the COVID-19 vaccine to certain prioritized groups first) is not a precondition for PREP Act immunity.

On December 3, 2020, the Secretary issued a [fourth amendment](#) to the HHS Declaration (Fourth Amendment). Among other things, the amendment [states](#) that the HHS Declaration “must be construed in accordance with” the HHS advisory opinions, which are expressly “incorporate[d]” into the Declaration. The Fourth Amendment makes several changes to expand the scope of PREP Act immunity, including “mak[ing] explicit” that the HHS Declaration (1) [covers](#) “all qualified pandemic and epidemic products” within the meaning of the statute; and (2) [may apply](#) to claims based on *not* administering a covered countermeasure, such as when the countermeasure is in short supply. The Fourth Amendment further [creates](#) a new category of “qualified persons” to cover health care providers using telehealth to order or administer covered countermeasures across state lines; [adds](#) a third covered means of distribution to extend liability protections to “additional private distribution channels”; and [clarifies](#) the licensing requirements for pharmacists to administer routine pediatric vaccinations under the Third Amendment, while expanding this category to expressly include FDA-authorized COVID-19 vaccines as well.

Following the change in presidential administration, the Acting Secretary of HHS issued a [series](#) of [three amendments](#) to the HHS Declaration, all [intended](#) to “expand the pool of COVID-19 vaccinators” beyond providers already licensed in a given state. The amendments [accomplish](#) this end by broadening the definition of “covered persons” who may serve as COVID-19 vaccinators in the HHS Declaration, and preempting state laws to the contrary.

Under the currently operative [Seventh Amendment](#), issued on March 11, 2021, the covered persons who may administer COVID-19 vaccines as part of state, federal, and Tribal vaccination efforts [include](#) (1) health care professionals licensed by a state to administer vaccines, including outside their state of licensure; (2) members of uniformed services (such as the National Guard members) and certain authorized federal contractors, volunteers, and employees; (3) state-licensed midwives, paramedics, emergency medical technicians (EMTs), physician assistants, respiratory therapists, dentists, podiatrists, optometrists, and veterinarians; (4) physicians, registered and practical nurses, pharmacists, pharmacy interns, midwives, paramedics, EMTs, respiratory therapists, dentists, physician assistants, podiatrists, optometrists, and veterinarians whose licenses became inactive, expired, or lapsed within the previous five years; and (5) certain medical, nursing, pharmacy, dental, podiatry, optometry, veterinary, and other students under the supervision of a practicing health care professional. Most of these groups must meet [additional requirements](#) to be covered under the PREP Act, such as completion of CDC training, an observation period by a practicing health care professional, a current certificate in cardiopulmonary resuscitation, and compliance with applicable recordkeeping and reporting requirements.

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