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Legal Sidebar

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 February 4, 2020 Declaration (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.

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 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 of HHS made the 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 would seem to include, 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 three general types of covered countermeasures: (i) a qualified "pandemic or epidemic product"; (ii) a "security countermeasure"; and (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use. (As discussed below, Congress recently added a fourth category specifically for respiratory protective devices.) A *pandemic or epidemic product* includes any drug, biological product, or device developed "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" that FDA has approved, licensed, or authorized for emergency use. *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 final category of covered countermeasure includes drugs, biological products, and devices that FDA has authorized for use outside of the ordinary regulatory process through 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), personal protective equipment (e.g., respirators), and devices modified for use as ventilators.

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 an injured person (or their representative) may prove willful misconduct under the PREP Act is limited in several ways. Before filing a suit claiming willful misconduct, the 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.

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. CICP's procedures and eligibility determinations are governed by HHS regulations pursuant to the PREP Act. 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.

CICP is distinct from the National Vaccine Injury Compensation Program, 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 non-pandemic 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

On February 4, 2020, the Secretary of HHS 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. This 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.

Recent Congressional Actions on COVID-19 Countermeasures Liability

Three recent congressional enactments in response to the COVID-19 pandemic, all now signed into law, relate to the scope of immunity for individuals engaged in the COVID-19 response.

Section 6005 of the Families First Coronavirus Response Act and Section 3103 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amend the PREP Act to clarify that certain "personal respiratory protective devices" (such as N95 respirators) are covered countermeasures. To be covered by the PREP Act, the respiratory protective device must be: (i) approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 C.F.R. Part 84; and (ii) determined by the Secretary of HHS 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 in healthcare settings, and expressed its view that the PREP Act covered these respirators prior to the amendment because of their medical use.)

Section 3215 of the CARES Act contains an independent immunization from liability for volunteer health care professionals responding to the COVID-19 pandemic. Under Section 3215, licensed health care professionals are generally immune from state or federal liability for harm they cause in the course of providing health care services in response to the COVID-19 public health emergency as a volunteer, if they act within the scope of their license and in good faith. There are two exceptions to this immunity: (1) if the volunteer health care professional's acts constituted willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed; or (2) if the volunteer health care professional rendered health care services under the influence of drugs or alcohol. Section 3215 immunity may overlap with PREP Act immunity or extend beyond it in some cases (such as situations not involving a covered countermeasure).

Finally, 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 of HHS 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 of HHS for similar purposes, again providing that the Secretary may transfer these funds to the Covered Countermeasure Process Fund.

Author Information

Kevin J. Hickey
Legislative Attorney

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