

Liability Immunity Under the Prep Act for COVID-19 Countermeasures: What Manufacturers Need to Know

The Secretary of HHS issued a public health emergency declaration, effective February 4, 2020, regarding COVID-19. The impact of that declaration is to trigger certain targeted liability immunity provisions under the Public Readiness and Emergency Preparedness Act (PREP Act).¹ Under those provisions, qualified pandemic products are “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 if a Declaration has been issued with respect to such countermeasure.” PREP Act liability immunity is not dependent on other emergency declarations; however, products that are not currently approved or cleared or that are seeking label expansions still have to go through the regulatory process in order to fit within the PREP Act provisions.

In this article, we outline how and when the immunity applies, instances where it may not apply, and some practical considerations for device manufacturers and pharmaceutical companies in securing and ensuring that the immunity remains available.

1. An Overview of the PREP Act and its Application

The PREP Act authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons)² against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “death or serious physical injury proximately caused by willful misconduct” as defined in the PREP Act.

¹ Codified at 42 U.S.C. § 247d-6d.

² Defined as the United States or State or local government administrator or a person or entity who manufactures, distributes, prescribes, administers, or dispenses a countermeasure.

As applicable here, the PREP Act states that a Covered Countermeasure must be a (1) “qualified pandemic or epidemic product,” (2) certain drugs, biological products and devices authorized for emergency use in accordance with FDA’s authority to authorize Emergency Use Authorization (EUA) for unapproved medical products, unapproved uses, extending expiration dates, and stockpiling during an emergency contained in sections 564, 564A, or 564B of the FD&C Act;³ or (3) as enacted on March 18, 2020 under the Families First Coronavirus Response Act (Families First Act),⁴ a personal respiratory device used in response to the Coronavirus.⁵

Qualified pandemic or epidemic product is defined as a drug, biological product, 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, licensed, 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; *or*

(iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device *and*

is approved or cleared under the FD&C Act, subject to exemption under the FD&C Act, or is authorized for emergency use under the FD&C Act.

The last portion of this definition is key: A pharmaceutical, biologic, or medical device must have regulatory approval, license, or clearance, or be subject to an exemption such as EUA, compassionate use, or an Investigational Device Exemption. Off-label use would not be covered without regulatory action.

Personal respiratory device is defined by the Families First Act as a device that is (i) approved by the National Institute for Occupational Safety and Health; (ii) subject to the EUA issued by the Secretary on March 2, 2020 or any subsequent EUAs; and (iii) “used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 319 as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV).”

³ 21 U.S.C. §§ 360bbb-3; 360bbb-3a; 360bbb-3b.

⁴ PL 116-127, March 18, 2020, 134 Stat 17.

⁵ There is another Covered Countermeasure not applicable here for security countermeasures. 42 U.S.C.A. § 247d-6b(c)(1)(B).

2. HHS Secretary Azar’s January 31, 2020 Emergency Declaration on COVID-19

Under the PREP Act, the Secretary has wide latitude to issue Emergency Declarations based on a disease or other health conditions that either constitute or may in the future constitute a public health emergency. The Secretary has issued Emergency Declarations under PREP for countermeasures related to Anthrax, Zika, and Ebola. On January 31, 2020, the Secretary declared COVID-19, an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus, to be a public health emergency.⁶ The Declaration provides immunity from liability under the PREP Act for the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures, which are defined as:

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.

In addition to the requirements in the PREP Act, the Declaration also states that liability immunity does not apply unless the activities are related to:

(a) Federal contracts, grants, or memoranda of understanding, or other Federal agreements or

(b) activities authorized by the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures. Authority Having Jurisdiction is broadly defined as “the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.” In other words, a local health department could authorize a countermeasure where activities associated with such countermeasure would be immune from liability under the Declaration, assuming all other requirements for liability immunity are met.

The liability immunity extends only through the period in which the Declaration is in effect or October 1, 2024, whichever occurs first. There is no geographic limitation.

3. The Liability Immunity Provisions of the PREP Act

The impact of COVID-19 Declaration is to trigger the liability immunity provisions codified at 42 U.S.C. § 247-6d. Under those provisions, qualified pandemic products are “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 if a Declaration has been issued with respect to such countermeasure.”

⁶ <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx>

These terms are intentionally broad. The Declaration gives the following examples to illustrate these principles: A liability claim for negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct, would be subject to the immunity. The immunity would even cover “a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.” But the immunity has limits: “[A] liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure’s administration or use.” Ultimately, whether immunity is applicable is a fact-based determination.

As described above, the liability immunity attaches as a covered countermeasure only where a device, drug or biological produce is:

- 1) approved and cleared under the FD&C Act;
- 2) exempt under the FD&C Act;
- 3) authorized for emergency use under the FD&C Act; or
- 4) is a biological product regulated under Title 42 of the United States Code (Public Health and Welfare).

And as relevant here, the countermeasure must be designed, to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm.

a. Exception to Liability Immunity: Willful Misconduct Causing Death or Serious Physical Injury

The PREP Act Liability Immunity provisions are focused on causes of actions based on negligent or reckless conduct or willful conduct that does not lead to serious injury. In fact, willful misconduct that leads to death or serious physical injury is specifically excepted. But the PREP Act sets a high bar for willful misconduct: a plaintiff must show clear and convincing evidence that the conduct must be (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.” And that willfulness “shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.” The language used to define willfulness is drafted in such a way to make this exception narrow. Scienter or willfulness would be met under most civil and criminal statutes where any one of three elements (i) through (iii) is present, but for the PREP Act, all three must be met to qualify as willful.⁷

⁷ There is one case where the court considered the willfulness requirement in the context of failure to obtain necessary consent for administering the H1N1 vaccine and concluded that the failure to obtain the consent constituted negligence and not willfulness. *See Parker v. St. Lawrence Cty. Pub. Health Dep’t*, 102 A.D.3d 140, 144, 954 N.Y.S.2d 259, 263 (2012);

In addition, the conduct must be the proximate cause of death or serious physical injury. Consequential damages such as interruption of business or lost income will not suffice.

Moreover, even in cases where there is willful misconduct that causes death or serious physical injury, if the misconduct involves an FD&C Act or Public Health Service regulated activity, the action will not constitute “willful misconduct” if neither HHS or DOJ have initiated an enforcement action⁸ or an enforcement action has been resolved without a covered remedy.⁹

The PREP Act provides a further protection and explicit defense for State and local governments and medical professionals, as a matter of law, even where there is potential willful conduct. This defense applies only where the State or local government or medical professional “acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure.” Moreover, either the Secretary, or a State or local health authority, must have been “provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff’s alleged loss within 7 days of the actual discovery of such information by such [government administrator or medical professional].”

b. Exception to Liability Immunity: Claims Brought by the United States

There is an important exception to the liability immunity: The immunity does not apply to claims brought by the United States: “Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of Title 28 (relating to tort claims procedure).”

⁸ Defined as a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of a biologics approval or clearance or of a licensure.

⁹ A criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of a biologics approval or clearance under chapter 5 [1] of such Act or of a licensure; and that results from a final determination by a court or from a final agency action.

The main purpose of the liability immunity provided by the PREP Act is to protect manufacturers, distributors, and medical professionals administering the drugs or device during a public health emergency from dealing with later products-liability claims. In order to facilitate innovation, Congress decided to remove, in part, the threat of private-party litigation. But this reasoning does not apply to claims that the government might have regardless of whether the conduct was willful or cause serious physical injury. Therefore, the government would be able to pursue a False Claims Act case, for example, premised on promotion of products for unapproved uses.

4. Practical Considerations: What Do Medical Device and Pharmaceuticals Companies Need to Know About the PREP Act Immunity?

- The PREP Act provides strong liability immunity to covered persons for claims resulting from the countermeasures covered under the COVID-19 Declaration of Public Health Emergency. The protections, however, do not apply to suits brought by the United States (and could even extend to relators who bring *qui tam* actions if the United States intervenes).
- The United States also wants to take the lead on cases involving regulatory violations even where there is willful conduct. If the United States does not pursue an enforcement action or resolves it without a covered remedy—criminal conviction, injunction, condemnation/seizure, civil monetary penalty, mandatory product recall, repair or replacement of a product, debarment, and termination of an exemption under the FD&C Act—is not “willful” under the PREP Act. Notably, a monetary settlement is not included as a covered remedy.
- As long as the drug or device is designed to treat, diagnose, cure, prevent, or mitigate COVID-19 and the drug or device is approved or cleared under the FD&C Act, subject to exemption under the FD&C Act, or is authorized for emergency use under the FD&C Act, it is a covered countermeasure.
- Companies should not mistake FDA guidance regarding enforcement discretion as bringing a product within the purview of the PREP Act. For example, on March 22, 2020, FDA announced a new “Enforcement Policy for Ventilators and Accessories and other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” (March 22, 2020 FDA Enforcement Policy) that it does not “intend to object” to minor modifications of FDA-cleared products to support patients with respiratory failure or respiratory insufficiency for the duration of the declared public health emergency.¹⁰ To ensure that a modified product falls within the PREP Act immunity protection, a company should seek FDA authorization. FDA also is encouraging all manufacturers seeking to distribute ventilators which previously have not been FDA-cleared or

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<https://www.fda.gov/media/136318/download>

wishing to retool existing facilities to manufacture ventilators, “to talk to FDA” about pursuing an EUA to allow them to distribute their ventilators.¹¹ For more information about the March 22, 2020 FDA Enforcement Policy click [here](#).

- The COVID-19 does not provide a lot of red tape for covered persons to secure cover of immunity (as long as they meet the definition of qualified pandemic product). If there is a federal contract, grant or memorandum of understanding, then this is sufficient to secure the authorization required for the immunity attach. In addition, the Declaration broadened the authorization to include activities authorized by local health departments (Authorities Having Jurisdiction).
- The PREP Act is aimed to protect covered persons against products liability tort claims where the misconduct did not willfully cause death or serious physical injury. This protection also could extend to *qui tam* False Claims Act relator suits where the government declines to intervene. The protection might extend to a stock drop suit or product liability class action if there are no serious injuries or deaths, but such arguments also may be relatively easy for plaintiffs to plead around.
- Negligence or even recklessness is not enough to show willfulness under the high bar set in the PREP Act. Again, the purpose of the high bar is to foster the creative development of drugs and devices to treat, diagnose, cure, prevent, or mitigate COVID-19 without concern that unintentional, less serious consequences will lead to private-party tort claims. Instead, those claims for injured private parties may be paid out of a fund if Congress appropriates money to that fund.

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¹¹ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-access-crucial-medical-products-including>