PREP Act Q&As

The Public Readiness and Emergency Preparedness Act (PREP Act) added new legal authorities to the Public Health Service (PHS) Act to provide liability immunity related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics. It also added authority to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions.

The following is intended to address frequently asked questions from the manufacturing industry, the healthcare community, and state and local government officials about the PREP Act. It is not an exhaustive review of the PREP Act's provisions in all contexts or a protocol for the HHS's implementation of the PREP Act. In addition, other legal protections may be available at the federal, state, and local government level.

Overview

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) (HHS) to issue a PREP Act Declaration ("Declaration") that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct. A PREP Act Declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations issued by HHS or other government agencies. The PREP Act also authorizes a fund in the United States Treasury to provide compensation to eligible individuals for serious physical injuries or deaths directly caused by administration or use of a countermeasure covered by the Declaration.

1. What is Immunity from Liability?

Immunity means that courts must dismiss claims brought against any entity or individual covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related 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 recommended in a Declaration. This includes, but is not limited to, claims for:

death;
physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition;
any need for medical monitoring; or

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Public Readiness and Emergency Preparedness (PREP) Act Overview

Legal Authorities

Legal Authorities Overview
Legal Authority of the Secretary
Public Health Emergency (PHE) Declaration
PHE Frequently Asked Questions
1135 Waivers
Emergency Use Authorization
Pandemic and All-Hazards Preparedness Act
Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA)
Pandemic and All-Hazards Preparedness Reauthorization Act

property damage or loss, including business interruption loss.

The only exception is for claims of willful misconduct. (See Question 3: Are There Any Limitations on Immunity From Liability?).

2. Who May be Afforded Immunity from Liability Under a PREP Act Declaration?

A Declaration may provide liability immunity for covered persons. Covered persons may include, at the Secretary's discretion:

Manufacturers of countermeasures;
Distributors of countermeasures;
Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure, e.g., State or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility;
Qualified persons, i.e., persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a Declaration, e.g., volunteers;
Officials, agents, and employees of any of these entities or persons; and
The United States.

3. Are There Any Limitations on Immunity from Liability?

Immunity from liability under the PREP Act is not available for death or serious physical injury caused by willful misconduct. A "serious physical injury" is one that is life-threatening, or results in or requires medical or surgical intervention to preclude permanent impairment of a body function or results in permanent damage to a body structure. Willful misconduct is misconduct that is greater than any form of recklessness or negligence. It is defined in the PREP Act as an act or failure to act that is taken: 1) intentionally to achieve a wrongful purpose; 2) knowingly without legal or factual justification; and 3) 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. All three of these conditions must be proven with clear and convincing evidence. Willful misconduct cannot be found against:

A manufacturer or distributor for actions regulated by HHS under the Public Health Service Act or the Federal Food, Drug and Cosmetic Act, if HHS chooses not to take an enforcement action against the manufacturer or distributor, or if HHS terminates or settles an enforcement action without imposing a criminal, civil, or administrative penalty; or
A program planner or qualified person who acts in accordance with applicable directions, guidelines, or recommendations issued by the HHS regarding administration and use of a countermeasure as long as HHS or the State or local health authority is notified about the serious injury or death within seven days of its discovery.

In addition, immunity is not available for claims based on activities that fall outside the scope of the applicable Declaration. As described below (5. "When Does Immunity Under the PREP Act Become Available?"), the Declaration can specify the conditions under which a Declaration will provide immunity, such as the effective dates and geographic area for which immunity will be available. Immunity is not available for claims that fall outside these conditions.

Immunity is not available for claims of loss unrelated to the design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration.

Immunity from liability also is not available for foreign claims where the U.S. has no jurisdiction. Immunity may be available for administration or use of a countermeasure outside the United States if the claim is based on events that take place in U.S. territory or there is another link to the U.S. that makes it reasonable to apply U.S. law to the claim.

4. What Countermeasures May be Covered by Immunity from Liability?
A "covered countermeasure" may be:

A qualified pandemic or epidemic product;
A security countermeasure;
An unapproved drug, biological product, or device used under an Emergency Use Authorization (EUA) issued by FDA;
An approved drug, biological product, or device used pursuant to Federal law in conditions that are in consistent with its approval ; or
An unapproved drug, biological product, or device, or an approved drug, biological product, or device intended for an unapproved use, that is intended for emergency use and shipped and held by a government agency or someone working on that agency's behalf for use only when that use is authorized.

In general, these are products that are approved, cleared, or licensed by FDA; authorized for investigational use, i.e. an Investigational New Drug ("IND") or Investigational Device Exemption ("IDE"), by FDA, authorized under an EUA by FDA, or otherwise permitted to be held or used for emergency use in accordance with Federal law. However, each has a specific legal definition. See the PREP Act Glossary for more information.

5. When Does Immunity Under the PREP Act Become Available?

Immunity under the PREP Act becomes available when HHS issues a Declaration, beginning on the effective date or other triggering event stated in the Declaration. For example, the Declaration may specify that activities such as manufacture and testing are covered on the effective date of the Declaration, but emergency uses such as mass dispensing are covered following a declared public health or other emergency.

6. What Information is Included in a PREP Act Declaration?

A Declaration includes:

- A determination that a disease or health condition or threat to health constitutes a public health emergency, or thatthere is a credible risk that it will in the future constitute an emergency;
- A recommendation for manufacture, testing, development, distribution, administration or use of one or more "covered countermeasures;"
- The category of diseases, health conditions, or health threats for which administration and use of the countermeasure is recommended. (During the time period covered by the Declaration, it is presumed that the recommended countermeasure is used for the disease, condition, or threat identified in the Declaration);
- The effective time period (the Secretary may specify an extended time period for manufacturers to dispose of the countermeasure and for others to cease administration and use of the countermeasure);
- The population of individuals receiving the countermeasure and the geographic area of administration and use of the countermeasure for which immunity from liability is in effect for program planners and qualified persons (manufacturers and distributors are provided liability immunity regardless of who receives the countermeasure or where it is administered or used);
- Limitations (if any) on the geographic area or areas for which immunity is in effect with respect to administration or use of the countermeasure;
- Limitations (if any) on the means of distribution;
- Any additional persons identified as qualified to prescribe, dispense, or administer the countermeasure; and
- Any other limitations or conditions.

7. Where is the Declaration Published?

The Declaration and any amendments are published in the Federal Register. It is important to note, however, that unless the Declaration specifies otherwise, it is effective upon the Secretary's signature, not upon publication in the Federal Register.

8. What Factors Are Considered by the Secretary?

In deciding whether to issue a PREP Act Declaration, HHS must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administering, licensing, and use of the countermeasure recommended in the Declaration. HHS may also consider other relevant factors.

9. How is a PREP Act Declaration Different from a Declaration of Public Health Emergency under section 319 of the Public Health Service Act?

Under section 319 of the Public Health Service Act, HHS may issue a declaration of a public health emergency based upon a determination that: 1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. Following a section 319 declaration, the HHS can take a number of emergency actions, including:

- Waiving certain Medicare, Medicaid, State Children's Health Insurance Program, and Health Insurance Portability and Accountability Act requirements;
- Allowing States and localities to temporarily reassign personnel supported with federal funds during the period of the emergency.

A determination of a public health emergency is different from a PREP Act declaration. The declarations are made on different public health determinations, and have different legal effects. A PREP Act Declaration may be made in advance of a public health emergency and may provide liability immunity for activities both before and after a declared public health

emergency. A separate declaration under section 319 or other statutes is not needed for immunity under the PREP Act to take effect unless the PREP Act Declaration states that a public health or other emergency Declaration is needed to trigger immunity.

10. Is There Any Compensation for Injury?

The PREP Act authorized a "Covered Countermeasures Process Fund" to compensate eligible individuals who suffer injuries as the direct result of a countermeasure administered or used under the Declaration. Funds must be appropriated by Congress into this account to pay these claims. Requests for Benefits must be made to HRSA's Countermeasures Injury Compensation Program (CICP). If funds are appropriated, compensation for serious physical injuries may then be available to eligible requesters under the CICP. Serious physical injury means an injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. The CICP pays reasonable and necessary medical benefits, and/or lost wages for eligible injured countermeasure recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure. The CICP is payer of last resort, so benefits are reduced by the amounts payable by all other public and private third-party payers (such as health insurance and workers' compensation). The regulations implementing the CICP are at 42 CFR part 110.

11. How Does an Individual File a Claim for Benefits?

An individual who may have suffered a serious physical injury from the administration or use of a countermeasure under a Declaration may seek compensation by filing a Request for Benefits with the CICP. A Request for Benefits Form must be filed within one year of receiving the countermeasure. A legal or personal representative may file on the individual's behalf, but a representative generally is not required unless the injured person is a minor or an adult who lacks legal capacity to receive payments. If the injured person has died (regardless of cause of death), the executor or administrator of the estate may file for benefits on behalf of the estate. If the injured person died as a direct result of receiving the countermeasure, certain survivors may file a request for death benefits. As well as filing a Request for Benefits Form, the requester must submit all required medical records and other supporting documentation. Further information on filing a Request for Benefits is available on the CICP's website at http://www.hrsa.gov/cicp/

12. What Options does an Injured Individual have if Congress has not Funded the Compensation Fund?

If no funds have been appropriated to the compensation program, or if the Secretary does not make a final determination on the individual's request within 240 days, or if the individual decides not to accept the compensation, the injured individual or his representative may pursue a tort claim in the United States District Court for the District of Columbia, but only if the claim involves willful misconduct and meets the other requirements for suit under the PREP Act. Any award is reduced by public or private insurance or worker's compensation available to the injured individual. Awards for non-economic damages, such as pain, suffering, physical impairment, mental anguish, and loss of consortium are also limited. If the individual accepts compensation from the CICP, or if there is no willful misconduct, the individual does not have a tort claim that can be filed in a United States Federal or a State court.

13. Has there been any litigation related to the PREP Act?

On November 21, 2012, the Appellate Division of the New York Supreme Court in *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (2012) upheld PREP Act protections for a county that conducted a school based vaccination clinic in response to the H1N1 outbreak.

During the clinic, a nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the county had committed negligence and battery. The county moved to dismiss the complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, asserting that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent. The county appealed and the United States submitted an amicus brief supporting the county.

The appellate court dismissed the plaintiff's claims, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery. The court noted the alternative remedy provided by the countermeasure injury compensation program and the possibility of a federal cause of action for willful misconduct claims.

The period for appeal of the case has expired.

In another case, *Kehler v. Hood*, 2012 WL 1945952 (E.D.Mo.), plaintiffs alleged that the physician and her employing hospital were negligent in failing to obtain the adult patient's informed consent and a consult from a specialist prior to the administration of the vaccination, which resulted in a severe case of transverse myelitis to the patient, and loss of

consortium to the spouse. Defendants then brought third party product liability/failure to warn claims against the manufacturer.

The parties did not dispute that the manufacturer, was protected by the PREP Act, nor did they allege that it engaged in willful misconduct. As a result, the federal Eastern District Court of Missouri dismissed the claim against the manufacturer. Finding that it had no jurisdiction over plaintiffs' remaining claims, the federal court remanded the case to state court for further consideration of the plaintiffs' claims.

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