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# Public Readiness and Emergency Preparedness Act Questions and Answers

The Public Readiness and Emergency Preparedness Act (“PREP Act”) enacted as Division C of the Defense Appropriations Act for fiscal year 2006, Pub. L. No. 109-148, added new authorities under the Public Health Service (PHS) Act to alleviate concerns about liability related to the manufacture, testing, development, distribution, administration and use of countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics.<sup>1</sup> Questions have arisen from the manufacturing industry and the healthcare community regarding the scope of protections available under the PREP Act.

The following is not an exhaustive review of the PREP Act’s provisions in all contexts, nor a protocol for the Department’s implementation of the PREP Act.

## Overview

The PREP Act authorizes the Secretary of the Department of Health and Human Services (“Secretary”) to issue a declaration (“PREP Act declaration”) that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from tort liability, and is different from, and not dependent on, other emergency declarations. The PREP Act also authorizes an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the Secretary’s declaration.

### 1. What is Immunity from Tort Liability?

Immunity from tort liability means there is no legal tort claim that can be pursued in court, whether state or federal. Tort claims precluded by a PREP Act declaration include all claims (except for willful misconduct, which is explained below under Question 4, “Are There Any Limitations on Immunity From Liability?”) under Federal or State law for any type of loss including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss, with any causal relationship to any stage of development,

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distribution, administration or use of the covered countermeasure recommended in the declaration.

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

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The Secretary's declaration may provide liability immunity for *covered persons* involved in administration and use of a countermeasure recommended in the declaration. (See Question 6, below, "What Countermeasures May be Covered by Immunity From Liability?" for an explanation of what countermeasures may be covered by the declaration.) *Covered persons* may, at the Secretary's discretion, include:

- *Manufacturers* of countermeasures;
- *Distributors* of countermeasures;
- *Program planners* of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
- *Qualified persons* who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers); and
- *The United States*.

Officials, agents, and employees of any of these entities or persons are also covered persons.

A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licensor of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a covered countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: manufacturers; repackagers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A *program planner* means a State or local government, including an Indian Tribe; a person employed by the State or local government; or other person (such as a private sector employer or community group) who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a countermeasure, including a person who establishes requirements, provides

policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with the Secretary's declaration.

A *qualified person* means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense covered countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.

For *manufacturers* and *distributors*, immunity applies without regard to whether the countermeasure is administered to, or used by, populations designated in the Secretary's declaration or whether such administration and use occurs in the geographic areas designated in the Secretary's declaration.

For *program planners* and *qualified persons*, immunity applies when the countermeasure is administered to or used by persons designated in the Secretary's declaration and in geographic areas designated in the Secretary's declaration, or when the program planner or qualified person reasonably could have believed that these conditions were met.

### **3. What Types of Losses Are Covered?**

The PREP Act declaration provides immunity for any type of loss suffered by an individual who receives the countermeasure, including death; physical, mental, or emotional injury, illness, disability or condition; fear of physical, mental, or emotional injury illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption, with any causal relationship to any to stage of development, distribution, administration or use of the countermeasure.

### **4. Are There Any Limitations on Immunity from Liability?**

Immunity from liability is not available for death or serious physical injury caused by *willful misconduct*. An individual who would ordinarily be protected under the PREP Act can be sued for tort claims if he or she engages in willful misconduct. A *serious physical injury* is life-threatening, or results in or requires medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Immunity is not available for claims based on activities that fall outside the scope of the declaration. As described below ("When Does Immunity Under the PREP Act Become Available?"), the Secretary can specify the conditions under which the declaration will provide immunity from liability, including (but not limited to) the effective dates and geographic area for which immunity will be available. Claims related to administration and use of the countermeasures that are inconsistent with

those conditions are not afforded liability immunity under the declaration.

Immunity is not available for claims of loss that do not allege a *causal relationship* to the administration or use of a covered countermeasure and are not in fact based on such a causal relationship. A *causal relationship* with administration and use under the PREP Act includes 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 such countermeasure.

Immunity from liability also is not available under the PREP Act for claims filed under foreign law in courts outside the United States. Immunity may be available for claims filed under United States law in United States courts, even when based on events that took place outside the United States.

Immunity from liability is not available under the PREP Act for lawsuits other than tort claims. For example, a PREP Act declaration would not provide immunity for claims related to violations of civil rights laws, the Americans with Disabilities Act, labor laws, or other such claims that have no connection to a tort claim.

## **5. What is Willful Misconduct?**

*Willful misconduct* is an act or omission 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 those conditions must be met for a finding of willful misconduct.

The PREP Act further specifies that:

- The standard for willful misconduct (proof by clear and convincing evidence) is more stringent than a standard of negligence in any form or of recklessness;
- A manufacturer or distributor cannot be found to have engaged in willful misconduct for actions regulated under the Public Health Service Act or the Federal Food, Drug and Cosmetic Act, if no enforcement action is taken, or if an enforcement action is terminated or finally resolved without the imposition of a criminal, civil, or administrative remedy; and
- A program planner or qualified person who acts in accordance with applicable directions, guidelines, or recommendations by the Secretary regarding administration and use of a countermeasure covered by a declaration cannot be found to have engaged in willful misconduct as long as the Secretary, State, or local health authority is notified about the serious injury or death within seven days of its discovery by the program planner or

qualified individual.

In addition, the Secretary is required to publish regulations that further restrict the actions or omissions that qualify as willful misconduct.

## **6. What Countermeasures May be Covered by Immunity From Liability?**

A countermeasure covered under a PREP Act declaration may be:

- *A qualified pandemic or epidemic product;*
- *A security countermeasure;* or
- *An unapproved drug, biological product, or device used under an Emergency Use Authorization in accordance with the Federal Food, Drug and Cosmetic Act.*

As further explained in the definitions provided below, these terms include products that are approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, authorized for investigational use under the Federal Food, Drug, and Cosmetic Act, or authorized under an Emergency Use Authorization (“EUA”) under the Federal Food, Drug and Cosmetic Act.

*A qualified pandemic or epidemic product* means a drug, biological product, or device that is:

- 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; or
- 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, and
  - Approved or cleared under the Federal Food, Drug and Cosmetic Act;
  - Licensed under the Public Health Service Act;
  - Authorized for emergency use under the Federal Food, Drug, and Cosmetic Act; or
  - Exempted under the Federal Food Drug and Cosmetic Act for use as an investigational drug or device that is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or life-threatening condition caused by such a drug or device.

*A security countermeasure*, as defined in the Public Health Service Act, is a drug, biological product, or device that:

- The Health and Human Services Secretary determines to be a priority:

- To treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or
  - To treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;
- Is determined by the Health and Human Services Secretary to be a necessary countermeasure to protect public health; and is
  - Approved or cleared under the Federal Food, Drug and Cosmetic Act
  - Licensed under the Public Health Service Act
  - May reasonably be determined to qualify for approval or licensing within eight years after the Department's determination that procurement is appropriate, or
  - Authorized for emergency use under the Federal Food, Drug and Cosmetic Act.

A *drug*, as defined in the Federal Food, Drug, and Cosmetic Act, includes articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals and articles (other than food) intended to affect the structure or function of the body of man or other animals.

A *biological product*, as defined in the Public Health Service Act, means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic or analogous product, arsphenamine or its derivative (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings.

A *device*, as defined in the Federal Food, Drug, and Cosmetic Act, includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals or intended to affect the structure or function of the body of man or other animals which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

An unapproved drug, biological product, or device may be *authorized for emergency use* following a declaration of emergency by the Secretary of Health and Human Services. Such a declaration is based on one of the following:

- A determination by the Secretary of Homeland Security that there is an actual or significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological,

or nuclear agent(s);

- A determination by the Secretary of Defense that there is an actual or significant potential for a military emergency involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent(s); or
- A determination by the Health and Human Services Secretary that a public health emergency exists that affects or has significant potential to affect, national security and involves a specified biological, chemical, radiological, or nuclear agent(s) or a specified disease or condition that may be attributable to such agent(s).

The Health and Human Services Secretary, through the Food and Drug Administration, may then issue an emergency use authorization for a particular product if, among other things, the known and potential benefits of the product outweigh its known and potential risks, and there is no adequate, approved, and available alternative to the product. The Secretary must impose required conditions on the emergency use authorization and may impose additional conditions, consistent with the Food, Drug, and Cosmetic Act. For more information on the emergency use authority, please see <http://www.fda.gov/oc/guidance/emergencyuse.html>.

## **7. When Does Immunity Under the PREP Act Become Available?**

Immunity under the PREP Act becomes available when the Secretary issues a declaration, beginning on the effective date or other triggering event stated in the declaration.

## **8. What Information is Included in the Secretary's Declaration?**

The Secretary's declaration includes his determination that a disease or health condition or threat to health constitutes a public health emergency, or that there is a credible risk that it will in the future constitute an emergency; and his recommendation for manufacture, testing, development, distribution, administration or use of one or more countermeasures. The declaration then specifies the conditions for which protections from liability are in effect:

- 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);
- 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; and
- Any additional persons identified as qualified to prescribe, dispense, or administer the countermeasures.

## **9. Where is the Secretary's Declaration Published?**

The Secretary's declaration and any amendments to the declaration are published in the Federal Register.

## **10. What Factors Are Considered by the Secretary?**

In deciding whether to issue a PREP Act declaration, the Secretary 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. The Secretary also has discretion to consider other relevant factors.

## **11. 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, the Secretary 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 Secretary can take a number of emergency actions, including: issuing an Emergency Use Authorization of an investigational product; and waiving certain Medicare, Medicaid, State Children's Health Insurance Program, and Health Insurance Portability and Accountability Act requirements. In recent experience, a public health emergency under section 319 of the Public Health Service Act was declared in response to the terrorist events in New York and Washington on September 11,

2001, and the anthrax outbreak in Florida in the Northeast later that fall. The Secretary also declared a public health emergency in a number of states due to Hurricanes Katrina, Rita, and Wilma in September 2005.

The determination required for a PREP Act declaration, and the declaration's effect, are different. As stated above under question 8, “What Information is Included in the Secretary’s Declaration?”, prior to issuing a PREP Act declaration, the Secretary must determine that a disease or health condition or threat to health constitutes a public health emergency, or that there is a credible risk that it will in the future constitute an emergency. This determination is independent of, and may be made in advance of, a declaration of a public health emergency under section 319. A PREP Act declaration triggers the Act's immunity (“When Does Immunity Under the PREP Act Become Available?”) and a separate declaration under section 319 or other statutes is not needed for immunity under the PREP Act to take effect.

## **12. Is There Any Compensation for Injury?**

The PREP Act also authorized a “Covered Countermeasures Process Fund” to provide compensation to eligible individuals who suffer specified injuries from administration or use of a countermeasure pursuant to the declaration. While no funds have been appropriated for this purpose, any requests for compensation must be filed within one year of administration or use of the countermeasure. Requests would go to the HRSA Preparedness Countermeasures Injury Compensation Program (<http://www.hrsa.gov/countermeasurescomp/default.htm>). If funds are appropriated, compensation may then be available for medical benefits, lost wages and death benefits to eligible individuals for specified injuries in accordance with regulations published by the Secretary. Eligibility for compensation and the injuries for which compensation may be available are further defined by regulation.

## **13. How Does an Individual File a Claim?**

An individual who suffers a serious physical injury or death from administration and use of a countermeasure pursuant to a declaration (or his representative) must first seek compensation from the Covered Countermeasures Process Fund. A serious physical injury means an injury that is life threatening, results in, or requires medical or surgical intervention to prevent, permanent impairment of a body function or permanent damage to body structure. Any compensation will be reduced by public or private insurance or worker’s compensation available to the injured individual.

If no funds have been appropriated to the compensation program, 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, is pled with particularity required under the PREP Act, verified, and accompanied by an

affidavit by a physician who did not treat the individual and certified medical records. Any award is reduced by any 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, 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.

#### **14. How does Indemnification Provided under Public Law 85-804 Differ from Immunity Provided Under the PREP Act?**

Indemnification under Public Law No. 85-804 is available to government contractors who conduct national defense functions. Essentially, when a contractor is indemnified, the Department agrees to pay judgments against the contractor for tort liability. The Secretary has determined that development of some countermeasures, such as smallpox and pandemic influenza, may be considered a national defense function. Thus, in some cases, the Secretary may issue a declaration under the PREP Act that covers countermeasures for which manufacturers are also indemnified as government contractors. In that case, immunity from liability would apply to claims covered by the PREP Act declaration, and indemnification would be available for some tort claims, other than claims involving willful misconduct, that are not covered by the PREP Act declaration.

#### **15. How does Liability Protection Provided Under the Smallpox Emergency Personnel Protection Act Differ from Immunity Provided Under the PREP Act?**

Under section 304 of the Homeland Security Act and the Smallpox Emergency Personnel Protection Act (SEPPA), the Secretary may issue a declaration to provide that manufacturers, distributors, hospitals, healthcare entities, state and local government and their agencies, employees, agents and volunteers, and vaccinated individuals who accidentally transmit vaccinia are covered under the Federal Tort Claims Act for negligent or wrongful acts leading to injury or death from administration of a smallpox vaccine, other smallpox countermeasures, or substances used to control or treat adverse effects from vaccines and countermeasures. Essentially, the United States becomes the defendant for any claims filed against these individuals and entities. For more information about liability protections under SEPPA, please see

<http://www.bt.cdc.gov/agent/smallpox/vaccination/healthcare-304-guidance.asp>

SEPPA also provides a compensation program for injured individuals who receive the countermeasures in accordance with the declaration and participate in a smallpox emergency response plan approved by the Secretary. For more information about injury compensation available under SEPPA, please see

<http://www.hrsa.gov/smallpoxinjury/default.htm>.

<sup>1</sup> The PREP Act may be found in sections 319F-3 and 319F-4 of the PHS Act and is codified in the United States Code at 42 U.S.C. §§247d-6d, 247d-6e.