



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against Andes Virus

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing a Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide liability protection for activities related to medical countermeasures against Andes virus consistent with the terms of the Declaration.

DATES: This declaration is effective as of the date of signature.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, 400 7th St SW, Washington, DC 20024; 202-260-0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (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) 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 "willful misconduct" as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant. The PREP Act also creates a compensation program. Liability immunity is addressed in section 319F-3 of the Public Health Service

(PHS) Act, 42 U.S.C. 247d-6d, and the compensation program is addressed in section 319F-4 of the PHS Act, 42 U.S.C. 247d-6e.

Andes virus is a type of hantavirus spread by rodents in South America and, less commonly, by other infected people. The rodents that carry Andes virus have not been found in the United States. It can cause a severe respiratory disease in people, called Hantavirus Pulmonary Syndrome (HPS). Andes virus is the only type of hantavirus that is known to spread person-to-person. This spread is usually limited to people who have close contact with a sick person. This includes direct physical contact, prolonged time spent in close or enclosed spaces, and exposure to the sick person's body fluids.

HPS is a severe and potentially deadly disease that affects the lungs. HPS can be life-threatening. Among patients who have severe respiratory symptoms, the case fatality rate has been estimated at approximately 38%. Symptoms of HPS caused by Andes virus usually appear within 4-42 days after exposure. Early symptoms can include fever, fatigue, and muscle aches, especially in large muscle groups like the thighs, hips, back, or shoulders. Early symptoms such as fever, headache, muscle aches, nausea, and fatigue can be easily confused with influenza or other viral illnesses. About half of all HPS patients have experienced headaches, dizziness, chills, and gastrointestinal symptoms, including nausea, vomiting, diarrhea, and abdominal pain. Late symptoms of HPS appear approximately 4-10 days after the initial phase of illness and can include coughing, shortness of breath, and chest tightness. Individuals are generally only infectious while symptomatic.

Currently, there are no available antiviral treatments or vaccines for HPS that are FDA-approved, or authorized by FDA for investigational or emergency use.

On May 2, 2026, the World Health Organization (WHO) was notified of a cluster of severe acute respiratory illness (SARI) among passengers and crew of a cruise ship (the M/V Hondius) in the Atlantic Ocean. The cluster included two deaths and one

critically ill passenger, whose laboratory tests confirmed hantavirus. On May 6, 2026, WHO confirmed that the type of hantavirus responsible for this outbreak is the Andes virus. As of May 8, 2026, WHO has reported eight cases (six confirmed and two suspected), including three deaths.

The cruise ship departed from Ushuaia, Argentina, on April 1, 2026, and traveled across the South Atlantic Ocean, stopping at several remote locations, including Antarctica, South Georgia Island, Tristan da Cunha, Saint Helena, and Ascension Island. It carried 147 people (86 passengers and 61 crew) from 23 different countries. The United States government repatriated 18 passengers from the cruise ship to the United States on May 10 and 11, 2026.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. Accordingly, in Section I, the Secretary determines that the spread of Andes virus and the resulting disease HPS constitutes a credible risk of a public health emergency for purposes of this Declaration.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, 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, administration, licensing, and use of the countermeasure. In Section II, the Secretary states that he has considered these factors.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (Recommended Activities). In Section III, the Secretary recommends activities for which the immunity is in effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, "[s]ubject to other provisions of [the PREP Act], a covered person shall be 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." In Section IV, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V, Covered Persons

The PREP Act's liability immunity applies to "Covered Persons" with respect to administration or use of a Covered Countermeasure. The term "Covered Persons" has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms "manufacturer," "distributor," "program planner," and "qualified person" as described below.

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 the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: manufacturers; re-packers; 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 who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered 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. Under this definition, a private sector employer or community group or other "person" can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word "person" as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.

Section V describes Covered Persons under the Declaration, including Qualified Persons.

Section VI, Covered Countermeasures

As noted above, Section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the Covered Countermeasures for which the Secretary has recommended such activities. The PREP Act states that a "Covered Countermeasure" must be: A "qualified pandemic or epidemic product," or a "security countermeasure," as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act 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; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that: (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat 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; and (ii) is

determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational New Drug (IND) Application or an Investigational Device Exemption (IDE)) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device.

A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate. Section VI lists medical countermeasures against Andes virus and HPS that are Covered Countermeasures under this declaration.

Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration

states that liability immunity is afforded to Covered Persons for Recommended Activities related to Covered Countermeasures obtained for voluntary administration to individuals in accordance with an IND Application.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is HPS caused by Andes virus.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term "administration" but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX, the Secretary defines "Administration of a Covered Countermeasure:"

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of "administration" extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under

the Act. Under the definition, these liability claims are precluded if they allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered--in short, those who should take a drug or other countermeasure. Section X provides that the population includes "any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration."

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X includes these statutory conditions in the Declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the Declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in countries outside the U.S. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI includes these statutory conditions in the Declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII extends the effective period through July 18, 2026.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for

other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d-6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continues during these additional time periods. Thus, liability immunity is afforded during the "Effective Time Period," described under XII of the Declaration, plus the "Additional Time Period" described under Section XIII of the Declaration.

Section XIII provides for one month as the additional time period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any products obtained for the SNS during the effective period of the Declaration.

Section XIV, Countermeasures Injury Compensation Program

Section 319F-4 of the PHS Act, 42 U.S.C. 247d-6e, authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires "compelling, reliable, valid, medical and scientific evidence." The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP.

Further, the administrative rules for the CICIP specify that if countermeasures are administered or used outside the United States, only otherwise eligible individuals at United States embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICIP benefits. Other individuals outside the United States may not be eligible for CICIP benefits.

Section XV, Amendments

The Secretary may amend any portion of this Declaration through publication in the Federal Register.

Declaration by the Secretary of Health and Human Services

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d-6d(b)(1)

I have determined that the spread of Andes virus and the resulting disease, hantavirus pulmonary syndrome (HPS), constitutes a credible risk of a future public health emergency.

II. Factors Considered

42 U.S.C. 247d-6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d-6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, and voluntary administration and use of the Covered Countermeasures in individuals possibly exposed to Andes virus on the M/V Hondius and in individuals who have had close contact with individuals possibly exposed to Andes virus on the M/V Hondius.

IV. Liability Protections

42 U.S.C. 247d-6d(a), 247d-6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

"Qualified person" includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a Declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d-6d(i)(8)

VI. Covered Countermeasures

42 U.S.C. 247d-6b(c)(1)(B), 247d-6d(i)(1) and (7)

Covered Countermeasures are favipiravir.

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for

investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the PHS Act.

VII. Limitations on Distribution

42 U.S.C. 247d-6d(a)(5), 247d-6d(b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving: Covered Countermeasures that are obtained for voluntary administration to individuals in accordance with an approved IND application.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles and perform emergency response functions in accordance with the PREP Act and this Declaration.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d-6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is HPS caused by the Andes virus.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d-6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(C)

The populations of individuals to whom the liability protections of this Declaration extend include any individual (regardless of age) who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(D)

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Period

42 U.S.C. 247d-6d(b)(2)(B)

Liability immunity for Covered Countermeasures extends through July 18, 2026.

XIII. Additional Period of Coverage

42 U.S.C. 247d-6d(b)(3)(B), 247d-6d(b)(3)(C)

I have determined that an additional one month of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d-6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as a direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical, and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the U.S. Department of Health and Human Services. Information about the CICP is available at the toll-free number 1-855-266-2427 or <http://www.hrsa.gov/cicp/>.

XV. Amendments

42 U.S.C. 247d-6d(b)(4)

Amendments to this Declaration will be published in the Federal Register, as needed.

Authority: 42 U.S.C. 247d-6d.

Robert F. Kennedy Jr.,

Secretary of Health and Human Services.

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