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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary is issuing this amendment pursuant to section 319F–3 of the Public Health Service Act to extend liability immunity for activities related to medical countermeasures against COVID–19 authorized under the Coronavirus Aid, Relief, and Economic Security Act.

DATES: The amendment to the Declaration published on March 17, 2020 (85 FR 15198) was effective as of March 27, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (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 was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136 was enacted on March 27, 2020. The CARES Act amended section 319F-3(i)(1)(D) of the PHS Act, first added by the Families First Coronavirus Response Act, Pub. L. 116-127 on March 18, 2020. These amendments created a new category of covered countermeasures eligible for liability immunity under the PREP Act, namely, respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

On January 31, 2020, the Secretary declared a public health emergency, pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the response of the nation’s health care community to the COVID–19 outbreak. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198 (March 17, 2020)). The Secretary is amending the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act.

This amendment is made in accordance with section 319F-3 of the PHS Act, which authorizes the Secretary to amend a PREP Act declaration at any time.

Description of This Amendment by Section

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.

This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. As amended by the CARES Act, to extend the Declaration to respiratory protective devices approved by NIOSH, the Secretary must also determine that a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency declared by the Secretary under section 319 of the PHS Act.

Accordingly, in Section I of the Declaration, the Secretary is amending his determination that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID-19,

constitutes a public health emergency for purposes of this Declaration under the PREP Act to include the determination that the use of any respiratory protective devices approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency declared by the Secretary on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the nation’s health care community response to the COVID–19 outbreak.

Section VI. Covered Countermeasures

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended such activities. As amended by the CARES Act, the PREP Act states that a “Covered Countermeasure” must be a “qualified pandemic or epidemic product,” a “security countermeasure,” a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act. Accordingly, in Section VI of the Declaration, the Secretary is amending the list of medical countermeasures against COVID-19 that are covered countermeasures under the declaration to include covered countermeasures authorized by the CARES Act, namely respiratory protective devices approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

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. Accordingly, the Secretary is amending Section XII of the Declaration to specify the effective time period for covered countermeasures authorized by the CARES Act.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Sections I, VI and XII of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID-19 are amended pursuant to section 319F-3(b)(4) of the PHS Act as described below. All other Sections of the Declaration remain in effect as published at 85 FR 15198 (March 17, 2020).

1. Determination of Public Health Emergency, Section I: delete in full and replace with:

I. Determination of Public Health Emergency

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

I have determined that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency. I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that I declared on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's health care community to the COVID-19 outbreak.

2. Covered Countermeasures, Section VI, delete in full and replace with:

VI. Covered Countermeasures

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

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective 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.

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, or any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations.

3. Effective Time Period, Section XII, delete in full and replace with:

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction, begins on March 27, 2020 and extends through October 1, 2024.

Liability immunity for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction, begins February 4, 2020 and extends through October 1, 2024.

Liability immunity for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with an emergency declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first.

Authority: 42 U.S.C. 247d–6d.

Dated: April 10, 2020.

Alex M. Azar II,

Secretary of Health and Human Services

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