

Exhibit D

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Ohio, Court of Federal Claims No: 20-0225V
 71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20-0231V
 72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20-0232V

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

DATES: The Declaration was effective as of February 4, 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. This Declaration is subject to amendment 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 Pandemic and All-Hazards Preparedness Reauthorization Act

enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of “Covered Countermeasures” and “qualified pandemic and epidemic products” in Section 319F-3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID-19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID-19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar 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 nation’s health care community response to the COVID-19 outbreak.¹ The outbreak remains a significant public health challenge that

requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID-19.²

Description of This Declaration 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. Accordingly in Section I of the Declaration, the Secretary determines 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.

Section II. Factors Considered by the Secretary

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 of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act’s Liability Immunity

The Secretary must delineate 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

¹ <https://www.phe.gov/emergency/news/>

² CDC COVID-19 Summary; <https://www.cdc.gov/coronavirus/2019-ncov/summary.html>, accessed

(Recommended Activities). In Section III of the Declaration, the Secretary sets out the activities for which the immunity is in effect.

Section IV. Limited 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 of the Declaration, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including Qualified Persons. The PREP Act defines Covered Persons to include, among others, the United States, and those that manufacture, distribute, administer, prescribe or use Covered Countermeasures. This Declaration includes all persons and entities defined as Covered Persons under the PREP Act (PHS Act 317F–3(i)(2)) as well as others set out in paragraphs (3), (4), (6), (8)(A) and (8)(B).

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

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 VI. Covered Countermeasures

As noted above, Section III of the Declaration describes the activities (referred to as “Recommended Activities”) for which liability immunity is in effect. Section VI of the Declaration 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

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 Drug Application or an Investigational Device Exemption) 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

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 (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency.

Section VII defines the terms “Authority Having Jurisdiction” and “Declaration of an emergency.” We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government

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

The Secretary must identify in the Declaration, 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 of the Declaration, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is COVID-19 caused by SARS-CoV-2 or a virus mutating therefrom.

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 of the Declaration, the Secretary defines “Administration of a Covered Countermeasure,” as follows:

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 a countermeasure, or if the claims are due to manufacture, 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

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. Likewise, the Act precludes 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. However, 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. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

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. Section X of the Declaration identifies which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or 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.”

It should be noted that under the PREP Act, liability protection extends beyond the Population specified in the Declaration. Specifically, 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 of the Declaration 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, including, as appropriate,

individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI of the Declaration 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 to individuals 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 of the Declaration 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 of the Declaration extends the effective period for different means of distribution of Covered Countermeasures through October 1, 2024.

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 accepting returns of Covered Countermeasures, 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. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continue during these

immunity is afforded during the “Effective Time Period,” described under Section XII of the Declaration, plus the “Additional Time Period” described under Section XIII of the Declaration.

Section XIII of the Declaration provides for 12 months as the Additional Time Period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any product 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. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV of the Declaration, “Countermeasures Injury Compensation Program,” explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP 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 CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV. Amendments

Section XV of the Declaration

any portion of this Declaration through publication in the **Federal Register**.

Declaration

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

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.

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, administration, and use of the Covered Countermeasures.

IV. Liability Immunity

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

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is 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.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials,

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