



HHS Advisory Opinion Regarding Immunity Under PREP Act for COVID-19 Countermeasures

In response to the COVID-19 pandemic and the resulting medical-supply shortage, the Secretary of Health and Human Services (“HHS”) published a Declaration under the Public Readiness and Emergency Preparedness (“PREP”) Act immunizing entities from liability related to the manufacture, testing, development, distribution, and use of certain drugs, biologics and devices used to diagnose and/or treat COVID-19.

The purpose of the PREP Act is to allow companies and individuals to quickly respond to the COVID-19 public health emergency without being subject to liability for damage caused by the products. The Act confers immunity to “covered persons” from liability for losses resulting from used of a “covered countermeasure” to combat a threat to health constituting a public emergency.

On April 14, 2020, the HHS issued an Advisory Opinion discussing the scope of the PREP Act immunity during the COVID-19 pandemic. Although the Advisory Opinion is not a final agency action or binding as a matter of law, it provides clarification on the broad immunity under the PREP Act for COVID-19 countermeasures. The following will serve as a brief summary of the Advisory Opinion.

- **Covered Persons**

The Advisory Opinion provides that “covered persons” are those engaging in activities that include “(1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, state, or local level.” The immunity applies regardless of whether state or local authorities have declared a state of emergency.

- **Covered Countermeasures**

Under the Declaration, the Advisory Opinion clarified “covered countermeasures” to include “qualified pandemic or epidemic product[s]”. In order to meet the definition of a “qualified pandemic or epidemic product” a product “(1) must be used for COVID-19; and (2) must be (a) approved, licensed, or cleared by FDA; (b) authorized under an EUA [Emergency Use Authorization]; (c) described in an EUI [Emergency Use Instruction]; (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).”

The scope of the PREP Act is intended to be broad and Congress did not intend to impose a strict liability standard on covered persons when determining the status of a covered countermeasure. In other words, if a person or entity otherwise meets the requirements for PREP Act immunity, such person or entity will not lose that immunity even if the product was not a covered countermeasure so long as they reasonably could have believed that the product was a covered countermeasure.

- **Reasonable Precautions**

As established, immunity under the PREP Act is broad. A covered person is immune from all claims except in the case of willful misconduct which caused death or serious injury. HHS encourages all covered persons to document the reasonable precautions they have taken to safely use the covered countermeasures. HHS encourages distributors of personal protective equipment (“PPE”) to make available to the purchaser information about the reasonable efforts the distributor has taken to safely use the covered countermeasures. This will allow purchasers, such as hospitals, to make reasonable and informed decisions on the best use of the PPE.

The full text of Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act can be found at the following link:

<https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf>

The full text of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 can be found at the following link:

<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>

If you have any questions or need assistance with healthcare-related issues, contact Jennifer Groves Fusco at (203) 786-8316 or jfusco@uks.com. For questions concerning potential claims or litigation, please contact Richard Dighello at (860) 548-2633 or rdighello@uks.com.

Disclaimer: The information contained in this material is not intended to be considered legal advice and should not be acted upon as such. Because of the generality of this material, the information provided may not be applicable in all situations and should not be acted upon without legal advice based on the specific factual circumstances.