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HHS PROVIDES LIABILITY IMMUNITY TO PROVIDERS OF COVID-19 COUNTERMEASURES

On March 17, 2020, the United States Department of Health and Human Services ("HHS") published a **Declaration** in the Federal Register providing immunity from liability under state and federal law to certain individuals and entities using medical countermeasures in the fight against COVID-19.

The Public Readiness and Emergency Preparedness Act (the "PREP Act") of 2005 permits HHS to provide immunity from tort liability for any loss caused, arising out of, relating to, or resulting from the administration or use of countermeasures to diseases, threats and conditions determined to constitute a present or credible risk of a future public health emergency. The HHS Secretary can activate the Act's immunity provisions by making a declaration of a public health emergency.

Pursuant to this authority, HHS's Declaration states that effective February 4, 2020, "Covered Persons" will be provided liability immunity against claims of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of "Covered Countermeasures" against COVID-19. As explained below, the Prep Act and the Declaration contain detailed and nuanced definitions and parameters for the terms "Covered Persons" and "Covered Countermeasures." While HHS should be lauded for taking this drastic

measure to encourage companies and individuals to step up and do whatever they can to combat the virus, there is still a lot of uncertainty regarding the exact parameters of the Declaration. Here is what we know so far:

WHO IS AFFORDED LIABILITY IMMUNITY?

The Declaration applies to only certain "Covered Persons" including:

■ **"Qualified Persons"** are licensed health professionals or other individuals authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed.

■ **"Manufacturers"** include 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.

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■ **"Distributors"** are people or entities 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.

■ **"Program Planners"** means state or local governments; 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 of HHS'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.

WHAT ACTIVITIES ARE COVERED BY THE LIABILITY IMMUNITY?

The liability immunity applies to the "manufacture, testing, development, distribution, administration, and use" of "Covered Countermeasures." Covered Countermeasures include "any antiviral, any other drug, any biologic, and diagnostic or any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19" or its

transmission, or "any device used in the administration of any such product, and all components and constituent materials of any such product."

While this definition appears broad, note 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.

WHAT IS THE SCOPE OF THE IMMUNITY?

The immunity became effective as of February 4, 2020. It will remain in effect through October 1, 2024, with extensions available for certain distributors. As explained above, it applies to any suit and liability under federal and state law with respect to all claims of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of Covered Countermeasures, except for claims involving "willful misconduct."

Loss is broadly defined as "any type of loss, 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

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This publication is a summary of legal principles. Nothing in this article constitutes legal advice, which can only be obtained as a result of a personal consultation with an attorney. The information published here is believed accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.

monitoring; and loss of or damage to property, including business interruption loss. The immunity significantly applies "without regard to the date of the occurrence, presentation, or discovery of the loss."

The Prep Act authorizes HHS to specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. In this case, HHS states in its Declaration that liability immunity is afforded to Covered Persons for the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures, only if it is related to: (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memorandum of understanding or other federal agreements or (b) activities authorized in accordance with the public health and medical response of the federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures.

HHS provided the following examples of scenarios that would implicate the liability immunity:

- A negligence claim against a manufacturer in creating a vaccine.
- A negligence claim against a health care provider in prescribing the wrong dose of a vaccine.

■ A claim alleging lax security or chaotic crowd control at a retail store serving as an administration or dispensing location, in the event of a slip-and-fall injury or vehicle collision by a recipient receiving a Covered Countermeasure.

HHS also pointed out, however, that determining whether the claim was related to the administration of Covered Countermeasures would require a fact-specific inquiry. For example, HHS noted that if a slip and fall occurred at a retail store, but there was no direct connection to the countermeasure's administration or use, the immunity would not apply.

The liability immunity has no geographic limitation. It applies throughout the United States and may also apply outside of the country to the extent the claim may be resolved under U.S. law. The Prep Act specifically provides for preemption of any conflicting state law.

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The HHS Declaration of immunity liability has been excitedly received by the health care industry as everyone stretches to meet the demands of the battle against COVID-19. However, until additional guidance is issued, the extent of this new immunity remains uncertain. Those engaging in Covered Countermeasures should consult with counsel and insurers to ensure that all risks are sufficiently mitigated.