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COVID-19 Countermeasure Protections Are Not Absolute

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As cases of COVID-19 continue to rise around the country, federal, state and local governments have been racing to ensure that the country is adequately equipped with resources to both mitigate the spread of the virus and treat those who have fallen ill.

The Public Readiness and Emergency Preparedness Act was enacted in 2005 and serves as a means of incentivizing contributions of much-needed resources in such times of crisis. The PREP Act authorizes the secretary of the U.S. Department of Health and Human Services to issue a declaration immunizing individuals and entities from liability associated with the use of medical countermeasures.

On March 17, HHS Secretary Alex Azar issued such a declaration for medical countermeasures against COVID-19, with retroactive application effective Feb. 4. Specifically, the declaration decrees that covered persons in all U.S. jurisdictions cannot be held liable for any claim of loss "caused by, arising out of, relating to, or resulting from" the development, testing, manufacture, distribution, administration or use of designated covered countermeasures within the time period specified by the secretary.

Thus in a state tort action, for example, there would be no question of federal law preemption. The declaration's supplementary information also notes that the immunity for covered persons would encompass a wide variety of scenarios, ranging from allegations of negligence against manufacturers of vaccines, to claims against health care workers for prescribing incorrect dosages of medication, to allegations of lax crowd control by recipients injured while receiving a countermeasure at an administration or dispensing location.

Protections for Covered Persons and Covered Countermeasures

Covered persons under the declaration include the U.S.; the manufacturers, distributors and program planners of covered countermeasures; qualified persons who prescribe, administer or dispense covered countermeasures; and the officials, agents and employees of each of the aforementioned categories.

Suppliers and licensers of any "component or other article used in the design,

development, clinical testing, investigation, or manufacturing of a covered countermeasure" are also considered covered persons, meaning that liability protections will also be given to entities that create component parts for covered countermeasures.

Covered countermeasures must be (1) qualified pandemic or epidemic products; (2) security countermeasures; or (3) drugs, biological products or devices authorized for emergency use. These categories are further defined within the PREP Act at Title 42 of U.S. Code Section 247d-6d. The secretary's declaration also extends immunity protections to all component and constituent materials of covered countermeasures, as well as any devices used to administer covered countermeasures.

Federal Regulatory Standards Remain in Effect

It is important to note that the secretary's PREP Act declaration does not override the requirements of the Federal Food, Drug and Cosmetic Act. Drugs, devices and other articles regulated by U.S. Food and Drug Administration would still need to comply with regulatory obligations and fall within the criteria for qualified pandemic or epidemic products or security countermeasures.

Alternatively, covered persons can seek an emergency use authorization, or EUA, from the secretary or the FDA commissioner to have a product designated as a "drug, biological product, or device authorized for emergency use." EUAs may be issued for products otherwise not approved, licensed or cleared for commercial distribution under certain provisions of the FDCA (for drugs and devices) and the Public Health Service Act (for biological products). The FDA has already issued several EUAs for covered countermeasures that would be subject to the PREP Act's immunities.

On March 25, the FDA issued its most recent EUA for certain "ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators ... ventilator tubing connectors, and ventilator accessories that FDA determines meet the criteria for safety, performance and labeling."

Earlier this month, the FDA released an EUA concerning personal protective equipment. For products that don't fit squarely within the definition of qualified pandemic or epidemic products or emergency countermeasures, ensuring coverage by an EUA is important to maximize protection under the PREP Act.

One method of producing covered countermeasures companies have contemplated using is additive manufacturing, also known as 3D printing. 3D printing enables manufacturers to expeditiously bring their products to market, and is therefore appealing to companies seeking to quickly manufacture covered countermeasures for the first time.

In doing so, a manufacturer need only ensure that the products comply with existing regulatory requirements for that type of product. The FDA, like most federal agencies, does not regulate products based upon the method of manufacturing. It focuses on the result. The FDA did issue guidance in December 2017 to manufacturers of 3D-printed medical devices, and that guidance remains operative today.

Limitations on Immunity Under the PREP Act

While broad, immunity under the PREP Act is not absolute. For example, immunity does not extend to acts of willful misconduct. Willful misconduct means more than reckless or negligent behavior. To prove

willful misconduct, the PREP Act requires clear and convincing evidence of an act or omission that is taken (1) intentionally to achieve a wrongful purpose; (2) knowingly without legal or factual justification; and (3) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Furthermore, immunity is only granted for use of a covered countermeasure that is in some way authorized by a governmental entity. At the federal level, use of a covered countermeasure must be in connection with a present or future federal agreement, such as a federal contract, grant, interagency agreement, memorandum of understanding, or cooperative agreement.

The standard is more nuanced for procurement at the state and local level. Immunity extends to activities involving covered countermeasures which are related to "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 Declaration of an emergency."

An "authority having jurisdiction" is defined as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority."

This would include the public health department and presumably the governor and mayor of a state once the requisite emergency declaration has occurred. A declaration of emergency is "any Declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures." Every state order is different, and getting updated often, but supply to state officials can be covered if done right.

The secretary's declaration also specifies that immunity generally only extends through Oct. 1, 2024, though an additional 12 months has been granted to allow manufacturers to arrange for the disposition of covered countermeasures. The PREP Act has a provision for ensuring the return of unused items at the end of the designated period. Uniquely identifying each item now by date code, to ensure they can be identified for retrieval later, will help mitigate any residual risk. Entities that are supplying a component should be sure to alert customers of the need for traceability.

Recovery for Injured Plaintiffs

Plaintiffs who have suffered injury are not left entirely without recourse — those who sustain serious injury or death as a direct result of the administration or use of a covered countermeasure may be eligible for benefits under the Countermeasures Injury Compensation Program, authorized by the Public Health Service Act. To qualify, claimants must reliably prove direct causation between a covered countermeasure and a serious physical injury.

Conclusion

Those on the COVID-19 frontline, including hospitals, doctors, nurses and other health care providers, are in dire need of supplies. Resolving the COVID-19 crisis will require expeditious involvement from entities across virtually all spheres of industry. As manufacturers hasten to produce and deploy means assisting in the battle against COVID-19, protections under the PREP Act should provide some measure

of relief to entities that are concerned they will later be sued for any defects or other issues arising from use of their products.

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