Published on *The National Law Review* https://natlawreview.com

Liability Immunity for Qualified Coronavirus Countermeasures — How the PREP Act and HHS Declaration Apply

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On March 17, 2020, the Secretary of the Department of Health and Human Services (HHS) issued a Declaration energizing the PREP Act, which provides legal immunity for manufacturers, distributors, suppliers and administrators of qualified products and processes used to fight COVID-19. As discussed below, this Declaration provides certain important protections to encourage innovation and expedience, but it also includes qualifying criteria and exceptions that must be considered and evaluated on a case-by-case basis to determine whether protection is likely to exist. Like many such protections, its applicability in any given situation may be subject to litigation for many years to come.

The PREP Act

The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures. Activation of the Act requires a declaration by the Secretary of HHS after a determination that a disease constitutes a public health emergency.

The COVID-19 Declaration

Secretary Alex Azar issued his Declaration on March 17, 2020, but the Declaration was backdated to be effective as of February 4, 2020. The Declaration's protections will be in place until October 1, 2024. The Declaration, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. § 247d-6d), immunizes manufacturing and distribution of certain products and the provision of certain services related to medical countermeasures against COVID-19. More specifically, the Declaration provides:

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.

Who are Covered Persons?

The term “Covered Persons” 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 defines “manufacturers” and “distributors” broadly:

- A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure;

- A distributor means a person or entity 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.

- Other covered persons include “qualified person[s]” who are licensed health care 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.

Finally, the Declaration expands the PREP Act’s standard definition of “qualified person” to include: (a) any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered countermeasures in accordance with Section 564A of the FD&C Act.

The goal of this expanded definition was to provide avenues for groups who might not otherwise be covered by the PREP Act or considered within the typical population of health care providers to participate in and support the development of treatment and prevention models.

What are Covered Countermeasures?

These are any antiviral, any other drug or biologic, any diagnostic, any other device or any vaccine used to treat, diagnose, cure, prevent or mitigate COVID-19 or a virus mutating therefrom, including any device or component part or its constituent materials of any such product. This protection is limited to “qualified pandemic or epidemic products,” “security countermeasures,” or drugs, devices or biological products for emergency or investigational use as determined on a case-by-case basis.

What Immunity is Provided?

Immunity under the PREP Act includes “any claim [under Federal or State law] for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure.” A “loss” is defined to include death, personal injury, emotional injury, property damage, business

interruption and fear of personal injury. The protection is very broad and applies “without regard to the date of the occurrence, presentation or discovery of the loss.”

The Declaration includes an important limitation to immunity as it only applies to activities conducted pursuant to “(a) Present or future federal contracts, cooperative agreements, grants, other transactions…or other federal agreements; or (b) Activities authorized in accordance with … the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures….” Again, whether conduct qualifies for immunity should be determined on a case-by-case basis.

Importantly, there is a rebuttable presumption that the administration or use of a covered countermeasure was for the threat covered by the Declaration and thus to succeed a plaintiff will have to produce evidence to overcome the presumption that the “covered person” is not entitled to immunity.

What Does It All Mean?

The Declaration supports innovation by health care, pharmaceutical, medical device and public health professionals to combat COVID-19 by providing immunity now and in the future. The underlying purpose is to recognize that conduct determined to be reasonable in a crisis can be viewed differently after time has passed and calm has returned. This protection allows important work to be done without fear of perfect hindsight calling that work into question. Still, the protection comes with important qualifying criteria and technical limitations that must be considered before assuming immunity applies.

For additional web-based resources available to assist you in monitoring the spread of the coronavirus on a global basis, you may wish to visit the websites of the CDC and the World Health Organization.

National Law Review, Volume X, Number 85