Protect Your Business As You Combat COVID-19

Liability Immunity Under the PREP Act

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In times of crisis, Americans give. They create. They innovate. And, most importantly, they help their neighbors.

The COVID-19 pandemic will unleash the full strength of American ingenuity as we mobilize to find, develop, create, and manufacture drug therapies, vaccines, medical devices, gloves, masks, and all of the other tools that our frontline warriors will use to defeat this nemesis.

Enacted in 2005, The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services to issue a "PREP Act Declaration" that provides immunity for claims of loss caused by "countermeasures" to diseases. Immunity means that courts must dismiss claims brought against individuals or entities protected by the PREP Act. The PREP Act immunizes covered individuals and entities against claims including, but not limited to, those for death, injury, property damage, and business interruptions.

Secretary Alex M. Azar issued a PREP Act Declaration for the COVID-19 pandemic on March 10, 2020.

Companies operating in this space should take steps to make certain that they avail themselves of the protections afforded by the PREP Act. Because, just as sure as moments of national emergency highlight our collective virtuous traits, they also invite prolonged litigation. Some lawyers have already started advertising, seeking to attract clients that claim harm as a result of the COVID-19 pandemic.

Do what is necessary to protect your company now from the wave of litigation that will certainly follow this outbreak.

Covered Products

The PREP Act protects "Covered Countermeasures," which may be a qualified pandemic/epidemic product, security countermeasure, and/or drugs, biological products, or medical devices. When the dust settles, plaintiffs will certainly question whether certain products fit the definition of a Covered Countermeasure. Take the steps now to enhance your immunity prospects.

The PREP Act also applies to 3D printing of Covered Countermeasures.

Covered Entities

- Manufacturers and distributers of countermeasures.
- Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure, e.g., state or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility.
- Qualified persons, i.e., persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a Declaration, e.g., volunteers.
- Officials, agents, and employees of any of these entities or persons.
- The United States (as a party).

If you are in the transportation and logistics space responding to the COVID-19 emergency, work with your counsel to maximize the protections available to you.

Covered Activities

The manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures, subject to certain limitations, are known as the "Recommended Activities."

Administration is defined as "the 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." Under some circumstances, this provision could provide coverage to transportation and logistics companies dealing with the Covered Countermeasures. These companies should work with legal counsel to ensure coverage.

Limitations

At present, PREP Act immunity for COVID-19 will expire on October 1, 2024. It's also retroactive, extending back to February 4, 2020. And after October 1, 2024 (when the Declaration ends), manufacturers get an additional 12 months of liability protection to assist with collecting and disposing Covered Countermeasures.

That said, Covered Countermeasures regulated by the FDA still must comply with all such obligations and fall within a criteria for a "qualified pandemic or epidemic product" or "security countermeasure." You can seek an Emergency Use Authorization (EUA) issued by the FDA to gain approval for a Covered Countermeasure. The FDA is taking action to lessen these barriers and has already issued several EUAs for Covered Countermeasures. One example is the FDA's recent March 25, 2020, 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.

The PREP Act does not apply to willful misconduct. Ambitious plaintiffs' lawyers will attempt to prove that companies ran afoul of this standard, so documentation is key.

Practical Considerations for Your Business

Take proactive steps to protect your business now:

- Continue to use all due care in designing and manufacturing Covered Countermeasures, despite the PREP Act's broad grant of immunity. Do not assume that you can take shortcuts.
- Review your supply agreements and/or sales contracts to include specific invocation of the PREP Act. While that would not likely be dispositive of whether immunity attaches, it will help.
- Store all research, development, and design documents in files named "COVID-19 Countermeasures" or "Coronavirus Countermeasures."
- Work closely with your compliance professionals to strictly adhere to FDA guidelines.
- Maintain thorough documentation for all actions, products, and other materials created for COVID-19 clinical trials.
- Carefully track the PREP Act's language in all such documentation to ensure that your products and activities receive coverage. For example, when developing or manufacturing a product, refer to it as a "Countermeasure" in your internal documents.
- Define your Covered Countermeasures, Covered Persons, and Recommended Activities in accordance with the PREP Act. For example, if you're a manufacturer, include the PREP Act's broad definition in your materials.
- Consistently update your documents as you continue to take action.
- When developing clinical trials, continue to work with your outside counsel to make certain that documents establishing informed consent are up to date. This is not the time to rely upon documentation that is showing its age.

For more information

MATTHEW D. GURBACH, Partner, Litigation Practice Group, *Cleveland*
mgurbach@beneschlaw.com | T: 216.363.4413

ALYSSA A. MOSCARINO, Associate, Litigation Practice Group, *Cleveland*
amoscarino@beneschlaw.com | T: 216.338.7939