

# Report on Supply Chain Compliance Volume 3, Number 9. April 30, 2020

## Compliance professionals find some relief under PREP Act

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Companies that are switching production lines to help produce critical medical equipment have a measure of liability immunity under the Public Readiness and Emergency Preparedness Act (PREP Act).<sup>[1]</sup> The act authorizes the secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration granting immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, administration or use of medical countermeasures.

Compliance professionals in companies that are switching production, distribution or development supply chains to accommodate Defense Production Act requirements, for example, must establish entirely new ones within a very short time frame. This expedited movement presents a host of risks as vendors, suppliers and distributors are not subject to as rigorous a vetting process as they might have been before the pandemic. Companies—big and small—are caught up in the net, and the PREP Act declaration does provide breathing room for compliance professionals aware of the risks of suddenly retooling an entire production line.

“It normally takes companies several months—or sometimes years—to build effective compliance programs around a new line of business or market,” wrote Mengqi Sun and Kristin Broughton of *The Wall Street Journal*.<sup>[2]</sup> “But amid the pandemic, compliance teams have had to move briskly, striking a balance between accuracy and speed as they build compliance programs from scratch—all while adjusting to new remote-working environments.”

### The basics

A declaration includes the determination of a threat, recommendations for action, as well as the effective time period. Covered countermeasures include “vaccines, antidotes, medications, medical devices or other FDA regulated assets used to respond to pandemics, epidemics, or any biological, chemical, radiological, or nuclear threat.”<sup>[3]</sup>

“Tort claims include all claims (except for willful misconduct), under federal or state law for any type of loss including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss” caused by the covered countermeasure recommended in the PREP Act declaration. The following types of entities are generally included under the umbrella of immunity:

- “Manufacturers of countermeasures;
  - “Distributors of countermeasures;
  - “Program planners of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
  - “Qualified persons who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers); and
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- “Officials, agents, and employees of any of these entities or persons are also covered persons.”

## Actions taken thus far

The Secretary of HHS declared a public emergency Jan. 31, 2020. This act triggered the requirements for issuing a declaration under the PREP Act, which the secretary did March 10, 2020.<sup>[4]</sup> The secretary then further amended the declaration<sup>[5]</sup> on April 15 to include respiratory protective devices approved by the National Institute for Occupational Safety and Health under “covered countermeasures” and to specify the effective time period from the time the declaration goes into effect until the day the emergency ends or Oct. 1, 2024, whichever occurs first.

The April 14 advisory issued by HHS gave detailed descriptions of covered countermeasures and covered persons, and it provided insight into the department’s stance on what qualifies for immunity and what doesn’t. The advisory is extremely helpful for overtaxed compliance professionals who find themselves operating at reduced capacity while also handling normal operations and compliance issues that have appeared due to the pandemic.

The department also has an FAQ page dedicated to the PREP Act<sup>[6]</sup> that helps with understanding general provisions of the act and compensation information and provides a couple of examples of litigation related to the act.

In two cases mentioned by the department, *Kehler v. Hood* and *Parker v. St. Lawrence County Public Health Department*, claims were brought against health care providers for failing to obtain informed consent from an adult or, in the latter case, a parent before administering vaccinations.

In the former case, plaintiffs did not dispute the manufacturer of a vaccine was covered by the PREP Act and did not show the manufacturer was engaged in willful misconduct. The case was dismissed.

In the latter case, a lower court determined “that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent,” but the appellate court decided “that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff’s claims of negligence and battery.”

## Takeaways

- Entities that retool their operations to help combat pandemics are protected under the PREP Act from a variety of tort claims.
- Although PREP Act immunity is not absolute, a claim must show that an entity engaged in willful misconduct, is not a covered entity, or produced goods not covered under the PREP Act declaration in order to prevail in court.

**1** Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (March 17, 2020) .

**2** Mengqi Sun and Kristin Broughton, “Coronavirus-Related Production Shifts Bring Liability, Compliance Risks,” *The Wall Street Journal*, April 16, 2020, <https://on.wsj.com/2XTkYpX>.

**3** “The Public Readiness and Preparedness Act (PREP): What you need to know,” Minnesota Department of Health, last accessed April 23, 2020, <https://bit.ly/2S2dTj5>.

**4** HHS, “Advisory Opinion on The Public Readiness and Emergency Preparedness Act and The March 10, 2020 Declaration Under The Act,” April 14, 2020, <https://bit.ly/2VurodC>.

**5** Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical

Countermeasures Against COVID-19, 85 Fed. Reg. 21,012, 21,014 (April 15, 2020) .

6 “PREP Act Q&As,” Office of the Assistant Secretary for Preparedness and Response, HHS, last reviewed September 5, 2019, <https://bit.ly/2XRZGJk>.

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