

# PREP Act Amendments

## Summary

Healthcare workers and first responders on the frontlines of the COVID-19 pandemic response are faced with a precarious shortage of necessary personal protective equipment (PPE) and other necessary countermeasures. In response, many manufacturers are repurposing their production and distribution capacity to provide much-needed PPE and other countermeasures while other companies are donating critically needed supplies. While the Public Readiness and Emergency Preparedness (PREP) Act currently provides liability protections for some key countermeasures, it fails to cover other important PPE and materials necessary to strengthen the COVID-19 response. Manufacturers of PPE and other materials needed to respond to COVID-19 that are not currently covered by the PREP Act are concerned that they will be overwhelmed with speculative litigation related to the use of their products in the coming months and years as it relates to COVID-19. Corporate “Good Samaritans”—acting as good corporate citizens by donating these products—have similar concerns. And end-users of them should not face liability when using them to combat COVID-19 as recommended by the government.

To help address these concerns and incentivize manufacturing activity that leads to greater access to PPE and other needed products during the COVID-19 pandemic, the proposed PREP Act Amendments would extend liability protections to:

- Alcohol-based hand sanitizers that are produced in compliance with Food and Drug Administration (FDA) guidance and deemed a priority by the Secretary of Health and Human Services (HHS) for use during a public health emergency;
- Disinfectants that are registered with and approved by the Environmental Protection Agency (EPA) for combatting COVID-19 and deemed a priority by the HHS Secretary for use during a public health emergency;
- Donors of approved countermeasures; and
- Users of approved countermeasures who follow applicable government guidance.

There are likely additional products, as well as uses and implementations of products, that should receive PREP Act liability protection. These proposed amendments are not intended to be exhaustive. Additional protections should be considered and provided on an ongoing basis.

## Analysis

**Alcohol-based hand sanitizers:** This proposal provides PREP Act liability protection to businesses that produce alcohol-based hand sanitizers in accordance with the FDA’s guidance on alcohol-based sanitizers. (The PREP Act does not protect “willful misconduct”).

- In response to the demand for alcohol-based sanitizers due to COVID-19, certain entities (i.e., breweries, distilleries, etc.) that do not produce PPE in their ordinary course of business are now producing and distributing hand sanitizer products for public use.
- By adding alcohol-based hand sanitizer as a covered countermeasure, businesses that follow government guidelines and assist the public by manufacturing much-needed alcohol-based hand sanitizer will be protected from opportunistic lawsuits.
- This liability protection will incentivize more businesses to produce hand sanitizer, while shielding them from lawsuits for their valuable efforts.

**EPA-registered disinfectants:** This proposal provides PREP Act liability protection to businesses that produce disinfectants that are registered and approved for use by the EPA to combat COVID-19. (The PREP Act does not protect “willful misconduct”).

- This liability protection will protect businesses that produce EPA-registered disinfectants from opportunistic lawsuits alleging that the disinfectant failed to protect against COVID-19 exposure.

**Donors:** This proposal provides liability protection to entities that donate approved countermeasures to combat COVID-19.

- This provision will protect entities who choose to donate PPE or other countermeasures from lawsuits exploiting their goodwill and valuable contributions. Inclusion of this protection will incentivize critical PPE donations.

**Recommended uses of approved countermeasures:** Finally, this proposal provides liability protection to any person who uses approved countermeasure in accordance with government standards and guidance.

- This provision would expand the PREP Act’s protections to those employing approved countermeasures from civil liability, so long as they use such countermeasures in accordance with applicable government standards and guidance.
- Users of approved countermeasures that fail to use it in accordance with government standards and guidance may still be subject to civil liability.