

Client Alert

PREP Act Immunity from Liability for COVID-19 Related Medical Equipment

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Everyone wants to help by providing necessary equipment to the COVID-19 frontline: hospitals, doctors, nurses, and other healthcare providers battling COVID-19 need ventilators, masks, gowns and other supplies.

Here are answers to commonly asked questions on how companies position themselves to obtain the immunity from liability provided by The Public Readiness and Emergency Preparedness Act (“PREP Act”). Read more about the PREP Act in [our earlier alert](#).

1. I plan to make component parts to be used in ventilators. Do component parts fall within the liability protections of the PREP Act?

ANSWER: Yes. Under the PREP Act, suppliers and licensors of any “component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure” are considered Covered Persons, and the HHS Secretary’s Declaration under the PREP Act extends immunity protections to any device used in a Covered Countermeasure, as well as all components and constituent materials of Covered Countermeasures.

2. My component parts are not cleared by FDA for use in medical devices such as ventilators or masks. Will they be covered under the PREP Act?

ANSWER: The HHS Secretary’s PREP Act declaration does not override the requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). Drugs, devices and other articles regulated by FDA would still need to comply with regulatory obligations and fall within criteria for a “qualified pandemic or epidemic product” or “security countermeasure,” or be subject to an Emergency Use Authorization (EUA) issued by FDA. The HHS Secretary or the FDA Commissioner may issue an EUA 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 (PHSA) (for biological products). FDA is taking action to help lessen these barriers, and has issued several EUAs for Covered Countermeasures that would be subject to the PREP Act’s immunities.

On March 25, 2020, 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 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.

3. What could go wrong?

ANSWER: Three things primarily.

Making sure the product falls in the definition of Covered Countermeasures and has been distributed in accordance with the HHS Secretary's Order is critical. Having this acknowledged in writing by the federal government or state authorities could also prove useful, but may not be practicable given the extreme need for these items in some jurisdictions.

Also, the PREP Act does not apply to willful misconduct. Willful misconduct requires more than reckless or negligent behavior. To prove willful misconduct, the PREP Act requires clear and convincing evidence of an act or failure to act 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.

Timing can also go wrong, since the immunity expires in October 2024. The PREP Act has a provision for ensuring the return of unused items at the end of this period. Uniquely identifying them now by date code, to ensure they can be identified for retrieval later, will help mitigate any residual risk. If you are supplying a component, make sure to alert your customers of the need for traceability.

4. What if I use a 3D printer to make Covered Countermeasures or their component parts? Will I get coverage?

ANSWER: You can. 3D printing enables manufacturers to expeditiously bring their products to market, and is therefore attractive 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. FDA, like most federal agencies, does not regulate products based upon the method of manufacturing. It focuses on the result. [FDA did issue guidance in December 2017 to manufacturers of 3D-printed medical devices](#) and that guidance remains operative today.

5. Do I need to have contracted with HHS to supply the goods to the federal government in order to get PREP Act immunity?

ANSWER: No. You can contract with any federal agency to get immunity under the PREP Act. The immunities of the PREP Act cover items procured under "present or future federal contracts" or any "other federal agreements," regardless of the procuring agency. HHS Order VII (limiting scope only by contract term (present or future) but not procuring agency), citing 42 U.S.C. §§ 247d-6d(a)(5) and (b)(2)(E). As long as your company falls within the definition of a "Covered Person" and the products are "Covered Countermeasures," both highly likely here, the immunities flow as long as the products are being provided pursuant to a present or future contract.

6. Will the PREP Act immunities apply to supplying Covered Countermeasures to states rather than under a federal contract?

ANSWER: PREP Act benefits will likely flow to State level procurement activity. Procurement at the state level, however, must fall into the second prong of distribution methods allowed under the HHS Secretary's order. That allows for immunity if the supply of Covered Countermeasures falls within "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.”

“Authority Having Jurisdiction” means “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.” That would include the Public Health department and presumably the Governor and Mayor of a state with the right emergency declaration in place. There must be a state “Declaration of Emergency” which means “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.

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