

CLIENT ALERT

NIOSH-Approved Respiratory Protective Devices Are Now "Covered Countermeasures" Against COVID-19

Apr. 15, 2020

The COVID-19 epidemic has led to a critical shortage in respiratory protective devices. An amendment to the Secretary of Health and Human Services' declaration under the Public Readiness and Emergency Preparedness (PREP) Act, published today in the Federal Register, may promote and expedite the production and use of such devices by allowing them to automatically be considered "Covered Countermeasures" for the purposes of PREP Act immunity.

Under the PREP Act, broad liability immunity is granted for the manufacture, distribution, and use of designated Covered Countermeasures. This immunity is outlined in 42 U.S.C. § 247d-6d, but only applies once the HHS Secretary has issued a declaration stating that the liability immunity is in effect and outlining exactly how and when the immunity will attach.

The HHS Secretary issued this requisite declaration in March with respect to medical countermeasures against COVID-19. Originally, these Covered Countermeasures had to fall within three categories: (a) a qualified pandemic or epidemic product, (b) a security countermeasure, or (c) a drug, biological product, or device authorized for emergency use.

However, the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended the PREP Act on March 27 to include a new, fourth category of Covered Countermeasure: respiratory protective devices. Two requirements apply for a respiratory protective device to be considered a Covered Countermeasure:

1. the device must be approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 C.F.R. part 84 or any successor regulations; and
2. the HHS Secretary must determine that such devices are a priority for use during a public health emergency.

HHS Secretary Azar's new amendments to the PREP Act declaration fulfill this second requirement by now declaring that "use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency," and officially designating NIOSH-approved respiratory protective devices as "Covered Countermeasures" against COVID-19.

Previously, sponsors of such respiratory devices would need to seek an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) before a device would be considered "a drug, biological product, or device authorized for emergency use" under the third broader category of Covered Countermeasures. Now that NIOSH-approved respiratory protective devices are independently designated as Covered Countermeasures, an EUA is no longer a prerequisite to PREP Act immunity.

Accordingly, manufacturers of NIOSH-approved N95 masks, for example, are deemed "Covered Persons" manufacturing "Covered Countermeasures," and are immune from claims of loss directly related to the development, manufacture, testing, distribution, administration, and use of the masks if other requirements are met.

Covered Persons must still adhere to requirements outlined in the PREP Act declaration regarding how and when the respiratory protective devices are used. This includes the requirement that their production, distribution or use relate to present or future federal contracts or agreements, or activities authorized by certain state or local agencies in response to a declaration of emergency. Thus, manufacturers cannot simply assume that immunity will apply to distribution agreements with private entities and should carefully examine whether the manufacture or distribution is somehow related to the requisite federal or state/local authorization.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Rebecca Baden Chaney

Partner – Washington, D.C.
Phone: +1 202.624.2772
Email: rchaney@crowell.com

Cheryl A. Falvey

Partner – Washington, D.C.
Phone: +1 202.624.2675
Email: cfalvey@crowell.com

John Fuson

Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Mariam Sarwar

Associate – Los Angeles
Phone: +1 213.443.5570
Email: msarwar@crowell.com