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BLOG

HHS Advisory Opinion on Immunity under the PREP Act

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As manufacturers and distributors of COVID-19 products respond to the pandemic, on April 14, 2020, the General Counsel for the Department of Health & Human Services ("HHS") issued an Advisory Opinion in response to numerous requests for more clarity on the scope of immunity from tort and contract claims under the Public Readiness and Emergency Preparedness Act ("PREP Act"). As discussed in our article here, HHS previously issued a Declaration in March providing liability immunity to "covered persons" against claims resulting from the manufacture, distribution, administration or use of "covered countermeasures" in response to COVID-19. The Advisory Opinion, while not legally binding, offers guidance on the views of the General Counsel, and the following summarizes how the Advisory Opinion may impact manufacturers and distributors of COVID-19 products:

- ***An "Authority Having Jurisdiction" Can Extend Who May Be a "Covered Person."*** Immunity under the PREP Act applies to "covered persons" such as manufacturers, distributors, program planners, qualified persons, and their officials, agents, or employees. The Advisory Opinion broadly defines program planners to include private sector employees who "supplied technical or scientific advice" or "guidance" to those administering covered countermeasures. The Advisory Opinion clarifies that while HHS is an "Authority Having Jurisdiction" to extend PREP Act immunity, so too are the public agencies or their delegates that have legal responsibility and authority for responding to the COVID-19 emergency.
- ***The Scope of Immunity Includes Arrangements with Government Agencies.*** If all requirements of the PREP Act and the Declaration are met, immunity covers claims for loss sounding in tort or contract, as well as for "loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements." It applies when a "covered person" engages in activities related to an agreement or arrangement with the federal government, or when a "covered person" acts according to an "Authority Having Jurisdiction" to respond to a declared emergency. Importantly, the arrangement with the federal government need not be a federal contract. The Advisory Opinion also clarifies that an "Authority Having Jurisdiction" includes regional, state, and local governments that can provide immunity to covered persons through agreements, arrangements, requests for assistance, or guidance in response to COVID-19 even if the authority has not issued an emergency declaration. This provides manufacturers and distributors with more assurances that even non-contractual arrangements with regional, state, and local governments may qualify for immunity.

- ***The Definition of Products as "Covered Countermeasures" Is Broad.*** PREP Act immunity covers "qualified pandemic or epidemic products" that are approved by the FDA, authorized by an Emergency Use Authorization ("EUA"), described in Emergency Use Instructions by the CDC, or declared an Investigation New Drug/Device. In addition, the CARES Act amended the PREP Act to include certain respiratory devices. While the Advisory Opinions states that the COVID-19 products "approved, licensed, or cleared are too numerous to list", it also catalogues a list of products covered by EUAs that includes diagnostic tests, serology tests, sterilization systems, personal protective equipment, respirators, and respirator accessories. This list shows the broad nature of devices being protected, and highlights how manufacturers and providers of COVID-19 products should review FDA's guidance to submit an EUA request. A link to the list of products covered by EUAs may be found here.
- ***Immunity Applies to Those with a Reasonable Belief About Qualifying as a Covered Person or a Covered Countermeasure.*** The Advisory Opinion specifically notes that Congress did not intend to impose a strict-liability standard on individuals or entities to determine whether a product is a covered countermeasure, or if a person or entity is a covered person. Immunity therefore extends to products that are not technically covered countermeasures, as long as the manufacturer or distributor "could have reasonably believed" that the product was a covered countermeasure. This same extension of immunity applies to manufacturers or distributors who have a reasonable belief they are a covered person.
- ***Immunity under the PREP Act Is Not Absolute.*** The Advisory Opinion clearly states that immunity under the PREP Act it is not absolute. There is no immunity against federal enforcement actions—whether civil, criminal, or administrative—nor against suit and liability for equitable relief claims under federal law. Immunity, exempting preemption, is limited to claims for personal injury or damage to property. And the Advisory Opinion notes that "PREP Act immunity must be read in light of the PREP Act's broad, express-preemption provision."

PREP Act immunity for manufacturers and distributors is broad, but it does not cover claims resulting from "willful misconduct" that proximately caused death or serious injury. The Advisory Opinion notes other federal laws, like 42 U.S.C. § 247d-6d(c)(5), exempt certain acts or omissions by manufacturers and distributors engaged in activities subject to regulation by the Federal Food, Drug, and Cosmetic Act that might otherwise construed as "willful misconduct." For example, under this provision, if regulators or the Attorney General do not pursue an enforcement action, or if an enforcement action has been initiated but terminated or resolved without a covered remedy, then manufacturers and distributors are immune from suit. That said, the Advisory Opinion concludes by stressing that HHS encourages all covered persons using a covered countermeasure to document the "reasonable precautions they have taken" to safely use the products and to "provide greater transparency" when possible.

The Advisory Opinion is not a final agency action or order, nor is it binding on HHS or federal courts. Although it provides helpful guidance regarding the General Counsel's views, the responsibility still lies with manufacturers or distributors to determine whether they are a covered person and their products are covered countermeasures under the PREP Act. For any questions about the effect of this Advisory Opinion, please contact Sandra Edwards, John Drosick, or your Winston relationship attorney. A link to the Advisory Opinion may be found here.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

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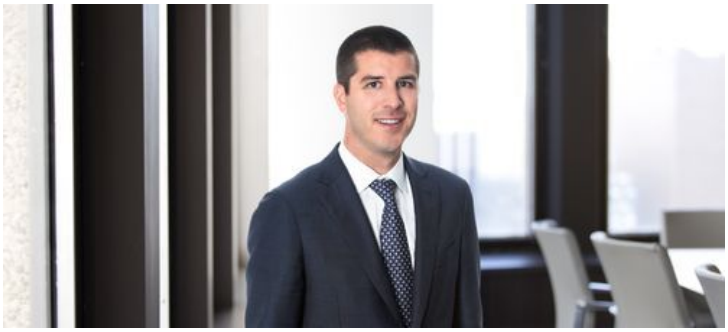

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