WINSTON & STRAWN LLP

BLOG

Immunity for Manufacturers and Distributors of COVID-19 Countermeasures

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Manufacturers and distributors of COVID-19 products (or countermeasures) necessary to combat the spread of infectious disease are understandably concerned about potential liabilities. Online advertisements are already offering legal services to pursue product liability and other claims related to COVID-19 treatments. To address those very real concerns, on March 17, 2020, the U.S. Department of Health and Human Services (DHHS) published an administrative Declaration under the Public Readiness and Emergency Preparedness Act (the PREP Act) that provides broad-based legal immunity for manufacturers, suppliers, and administrators of certain products and technologies used to combat COVID-19. This Declaration is retroactively effective as of February 4, 2020, and currently extends its protections through October 1, 2024.

THE PREP ACT GENERALLY

The PREP Act, codified at 42 U.S.C. 247d-6d, has been in existence since 2005 and authorizes the Secretary of the DHHS to issue a declaration to provide liability immunity in the event of a public health emergency. The PREP Act extends protection to covered entities and individuals against claims under federal and state law relating to the manufacture, distribution, administration, or use of medical countermeasures.

COVERAGE OF COVID-19 DECLARATION

For COVID-19, the Declaration under the PREP Act provides immunity against all claims of loss “caused by, arising out of, relating to, or resulting from” the “manufacture, testing, development, distribution, administration, and use” of “covered countermeasures.” Covered countermeasures include drugs, biological products, or devices used to diagnose, mitigate, prevent, treat, or cure COVID-19 or limit the harm COVID-19 might cause. Respiratory protective devices approved by NIOSH are included within the definition of a “covered countermeasure” as codified in Section 3103 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The immunity extends not only to COVID-19 drugs, but to other products and technologies intended to enhance the use or effect of a drug, biological product, or device, or protect against adverse effects from those products.

For a product to qualify as a covered countermeasure, it generally must be approved, licensed, or authorized by the FDA. A covered countermeasure can also, however, be a product cleared for investigational use (under an Investigational Drug Application or an Investigational Device Exemption) by the FDA or otherwise authorized for emergency use under federal law. Covered losses include death; physical, mental or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition (including the need for medical monitoring); and loss of or damage to property, including business interruption loss.

Those afforded immunity under the Declaration are manufacturers, distributors, program planners (or those involved in planning, administering, or supervising programs for the distribution of a countermeasure), and other qualified persons (including those who prescribe, administer, or dispense countermeasures such as health care and other providers). Despite the Declaration's broad protections, the Declaration does not provide immunity from liability for death or serious physical injury caused by "willful misconduct." "Willful misconduct" is defined in the PREP Act as 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.

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to compensate eligible individuals who suffer a serious physical injury or death as a direct result of the administration or use of a covered countermeasure. If funds are appropriated by Congress into this account, compensation may be available to eligible requesters.

APPLICATION OF COVID-19 DECLARATION

The Declaration makes clear the need to encourage the design, development, testing, manufacturing, and distribution of critical measures to help combat the COVID-19 pandemic. As we are seeing with other government agencies taking steps to relax certain requirements for lab and test requirements for Risk Evaluation and Mitigation Strategy (REMS), the federal government has also taken affirmative steps to provide manufacturers and distributors of approved countermeasures with immunities from future litigation. Even so, for protection under this Declaration, certain qualifications must be met and significant limitations apply.

For any questions regarding whether your company is covered under the Declaration, please contact Sandra Edwards, Sarah Krajewski, or your Winston relationship attorney. A link to the Declaration is here.

View all of our COVID-19 perspectives here. Contact a member of our COVID-19 Legal Task Force here.

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