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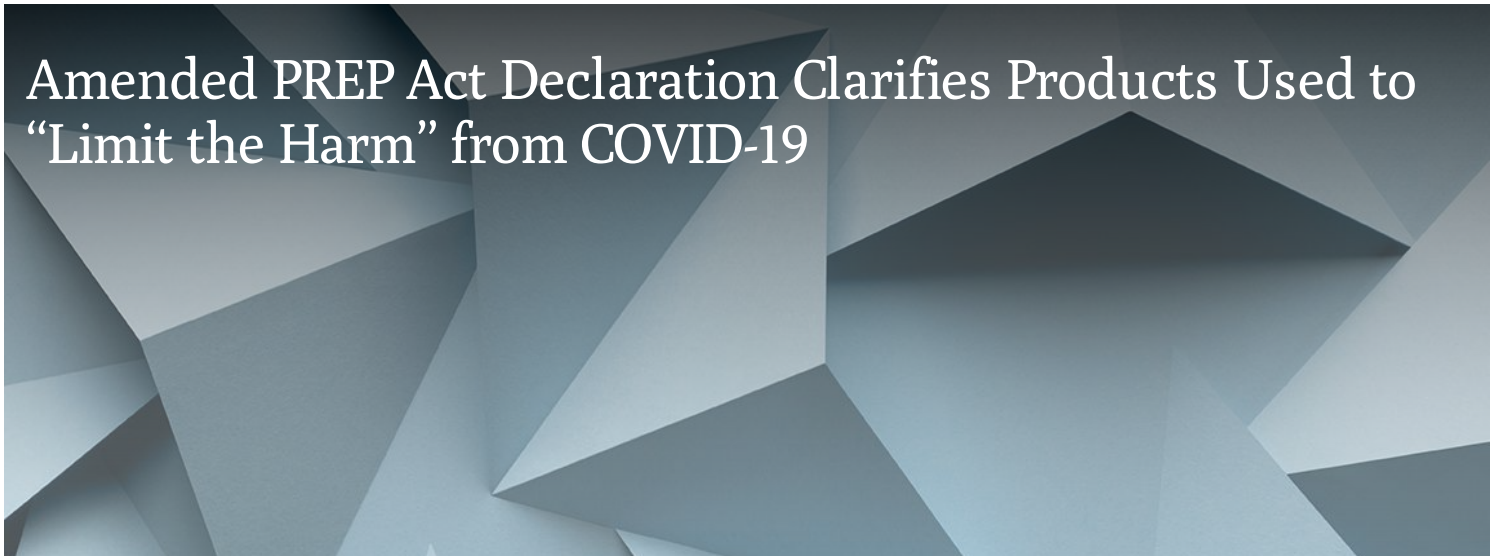
BLOG

Amended PREP Act Declaration Clarifies Products Used to "Limit the Harm" from COVID-19



JUNE 17, 2020

On June 4, 2020, the Secretary for the Department of Health and Human Services (HHS) issued a Second Amendment to the March 2020 Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for medical countermeasures against COVID-19. The stated purpose of the Amendment is to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause.

As discussed in our prior alerts (available here and here), the Declaration provides broad immunity from liability to persons who qualify as "Covered Persons" engaging in certain activities related to "Covered Countermeasures" in the fight against the pandemic. For COVID-19, the Declaration offers 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" are defined in Section VI of the Declaration to include drugs, biological products, or devices used to treat, diagnose, prevent, or mitigate COVID-19. 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 to protect against adverse effects from those products. For a product to qualify as a covered countermeasure, it generally must be either approved, licensed, or authorized by the FDA; cleared for investigational or emergency use under an Investigational Drug Application or Investigational Device Exemption by the FDA; authorized for emergency use under an Emergency Use Authorization; or described in the Emergency Use Instructions issued by the CDC.

The June Amendment clarifies that the identification of covered countermeasures inadvertently omitted language from the statutory definition that qualified pandemic and epidemic products may also include products that "limit the harm such a pandemic or epidemic might otherwise cause." While this language is included in the preamble to the Declaration, it is not present in the definition of covered countermeasures in Section VI of the Declaration. As a result of the June Amendment, the definition of covered countermeasures for COVID-19 now expressly includes any antiviral, drug, biologic, diagnostic, device, respiratory protective device, or vaccine used "to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause." The Amendment goes on to state that the Secretary "intended to identify the full range of qualified countermeasures" in the Declaration.

Importantly, the June Amendment further explains that "[q]ualified pandemic and epidemic products that limit the harm of COVID-19 are those that would not have been manufactured, designed or used but for the COVID-19 pandemic, even when the products were manufactured, designed or used for health threats or conditions other than COVID-19." It also provides as an example of harm that COVID-19 "might otherwise cause" a shortage of certain drugs or devices authorized by the FDA and used for COVID-19 and other health conditions. Filling those shortages "reduces the strain" on the healthcare system by "mitigating the escalation of adverse health conditions" from both COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources, including personal protective equipment and even healthcare providers themselves, which are "essential in the whole-of-Nation response" to the pandemic.

While the example set forth in the June Amendment highlights the potentially expansive nature of the immunity offered by the Declaration under the PREP Act, it also begs the question of how far courts will go in determining whether a drug or device was used to limit the harm of COVID-19—particularly when the drug or device is not intended for purposes specific to COVID-19, but instead limits the harm resulting from shortages due to the pandemic. Indeed, the FDA's Drug Shortage database identifies over 100 products currently facing shortages, many of which are due to increased demand or manufacturing delays arising from COVID-19. It is unclear whether all products that mitigate any such shortages—which the June Amendment arguably implicates—will ultimately enjoy the broad immunity provided by the Declaration.

For any questions regarding whether your company is covered under the Declaration, please contact Sandra Edwards, Rand Brothers, or your Winston relationship attorney.

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