Patterson Belknap Webb & Tyler LLP

Products Liability Alert June 16, 2020

HHS Amends Tort Immunity Declaration Under the PREP Act to Clarify that Immunity Extents to Products that "Limit the Harm" COVID-19 "Might Otherwise Cause"

As we previously reported, on March 10, 2020, the Secretary of Health and Human Services, acting under the authority provided by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act), issued a Declaration providing liability immunity to certain entities and individuals against claims of loss arising from their designing, manufacturing and/or distributing of certain countermeasures to aid in the fight against COVID-19, which was published in the Federal Register on March 17, 2020. On June 8, 2020, the Secretary issued an Amendment to its prior Declaration to "clarify that covered countermeasures include qualified products that limit the harm of COVID-19 might otherwise cause." The full text of the June 8, 2020 amendment is available here.

This Amendment is not intended to expand the scope of the original immunity declaration, but rather to clarify that the original immunity declaration was intended to extend not only to specific countermeasures which were designed/manufactured/distributed specifically to combat COVID-19, but also those which were designed/manufactured/distributed for other purposes which were affected by COVID-19.

According to the Secretary, "section VI of the March 10, 2020 Declaration identified Covered Countermeasures under the Declaration as 'any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.' 85 FR 15202. That description omitted the phrase 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.' The Secretary intended to identify the full range of qualified countermeasures in the March 10, 2020 Declaration." 85 FR 35101.

By way of example, the Secretary explains, "the COVID–19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID–19 and other health conditions. Those shortages are 'harm[s] [COVID–19] might otherwise cause.' Filling those shortages caused by COVID–19 reduces the strain on the American healthcare system by mitigating the escalation of adverse health conditions from COVID–19 and non-COVID–19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID–19 pandemic." 85 FR 35101-2.

Thus, in light of this Amendment, companies that are stepping up to fill shortages of medicines and medical devices used for non-COVID-19-related purposes appear to be able to avail themselves of PREP Act immunity so long as the shortages that they are filling were themselves caused by increased demand for those medicines and medical devices flowing from COVID-19.

Until very recently, one specific illustration of such a shortage may have been that of hydroxychloroquine for lupus patients, who were regular users of that medicine who began experiencing shortages once hydroxychloroquine showed promise (and was stockpiled) as a treatment for COVID-19. Of course, now that FDA has revoked its emergency use authorization of hydroxychloroquine for the treatment of COVID-19, whether this Amendment still affords PREP Act immunity for hydroxychloroquine manufacturers is unclear.

As with everything else related to COVID-19, the regulatory response to the pandemic remains in flux, and we will continue to provide updates as information becomes available.

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