Michelle Jacobs, Suzie Trigg, Jennifer Kreick, Kayla Cristales in Bloomberg Law: INSIGHT: Maximizing Immunity Under the PREP Act for Covered Countermeasures

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As the race to combat COVID-19 continues, many companies providing countermeasures are more closely examining the scope of immunity under the Public Readiness and Emergency Preparedness Act (PREP Act). The secretary of Health and Human Services (HHS) first issued a declaration in February pursuant to the PREP Act to provide liability immunity for certain products intended for use in treating, preventing, diagnosing, or mitigating COVID-19. Then, on May 19, 2020, the HHS released a modified advisory opinion to address questions and concerns regarding the scope of the PREP Act as it applies to COVID-19.

With additional guidance now available, and with FDA recalls, voluntary withdrawals, and removals of various COVID-related products now also underway, it is time to review any hastily implemented steps taken in the spring and ensure best practices are in place as the public health emergency (PHE) continues.

Companies that are examining PREP Act immunity should review its scope as applied to specific products, individuals, and activities, and continue to obtain and maintain appropriate records to support PREP Act immunity in the event of a future challenge. Companies should also note that, although PREP Act immunity is intentionally broad, it will not shield a company from FDA enforcement action and other critical events related to noncompliance.

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