Qualifying for Immunity Under the U.S. PREP Act During COVID-19

 As part of the U.S. government's response to the COVID-19 pandemic, on March 10, 2020, the Secretary of Health and Human Services ("Secretary") issued a Declaration pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d. This Declaration activated immunity from personal injury, property damage, and other types of claims for companies and certain professionals who manufacture, distribute, or use "covered countermeasures"— certain drugs and devices, or components thereof, that may be used to treat COVID-19 patients or combat the COVID-19 pandemic.[1] The PREP Act provides broad immunity from liability, but applies only to products and persons that qualify for the immunity under the PREP Act and the limits established in the Secretary's Declaration.

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UK Government Announces 'Future Fund' Financing Package for Start-Up Technology and Life Sciences Companies

 The UK Government has announced a new fund that provides financing to UK start-ups and scale-ups in the form of a convertible loan which is invested directly by the Government. For further detail on the fund please see: https://www.gov.uk/guidance/future-fund.

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Update: U.S. Health and Human Services Clarifies Broad Eligibility of Providers for Payments Under $30 Billion CARES Act Healthcare Provider Relief Fund

As discussed in Goodwin's prior Client Alert, on April 10, 2020, the U.S. Department of Health and Human Services (HHS) began disbursing $30 billion to Medicare providers and suppliers under the Public Health and Social Services Emergency Fund (PHSS Emergency Fund). HHS is requiring providers to agree to certain terms and conditions or return the payments. A number of the terms and conditions created some confusion as to whether providers who have not provided services directly related to COVID-19 may keep the payments. HHS has now clarified that providers may keep payments distributed under the PHSS Emergency Fund regardless of whether they have or will provide services directly related to COVID-19.

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Key Considerations for U.S. Public Company Compensation Committees in Light of COVID-19

As the COVID-19 pandemic continues to unfold, U.S. public company compensation committees face unique challenges as they focus on retaining and appropriately incentivizing employees while evaluating the impact of the pandemic on the company. This client alert provides a high-level overview of some key issues that compensation committees should be focusing on in this environment.

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U.S. Health and Human Services to Begin Disbursing $30 Billion of CARES Act Healthcare Provider Relief Fund

On Friday, April 10, 2020, the U.S. Department of Health and Human Services (HHS) announced it will begin disbursing $30 billion of the $100 billion of the Public Health and Social Services Emergency Fund recently allocated by the Coronavirus Aid, Relief, and Economics Security Act (CARES Act), signed March 27, 2020. Inclusive of the $30 billion, the $100 billion funding will be used to reimburse healthcare providers and facilities.

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U.S. CARES Act Enables Long-Awaited OTC Drug Regulatory Modernization: Key Highlights

Subtitle F of the recently enacted U.S. CARES Act substantially reforms the regulatory framework for non-prescription drugs, representing the most significant update of the review process for over-the-counter (OTC) drugs since that process was first established in 1972. The Act draws from recent legislative proposals to reform OTC regulation, incorporating a modified version of the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019" (S. 2740, H.R. 3443) that was passed 91-2 by the U.S. Senate in December 2019. At that time, Senate Health Committee Chairman Lamar Alexander (R-Tenn.) described the legislation as "the most important new law affecting the safety, innovation, and affordability of over-the-counter drugs since the 1970s."

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U.S. CARES Act Supply Shortage Provisions: What Drug and Device Manufacturers Need to Know

 On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public discussion and concern over the availability and accessibility of critical medical devices, such as ventilators, and the pandemic has highlighted gaps in the U.S. Food and Drug Administration's (FDA's) authorities regarding medical product shortages. FDA has been able to collect information on drug shortages and take steps to help prevent or mitigate such shortages under authorities set forth in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). However, FDA had not, until now, had equivalent authority with regard to shortages of critical devices. Among the many provisions of the CARES Act ("the Act") are amendments and additions to the Federal Food, Drug, and Cosmetic Act (FDCA) that give FDA the ability to effectively address such shortages. Additionally, the Act enhances FDA's existing authority with respect to drug shortage measures. Below, we have highlighted the key provisions in these areas under the new law.

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CMS Expands Availability of Advances on Medicare Reimbursement; U.S. CARES Act Increases Medicare Reimbursement Rates

 In response to the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) announced on Saturday March 28, 2020, that it is expanding its Medicare Accelerated and Advance Payment Program (AAPP) to allow nearly all Medicare providers and suppliers to receive advances on future Medicare reimbursement. To provide further relief to healthcare providers and suppliers, the Coronavirus Aid, Relief, and Economic Security U.S. Cares Act (CARES Act), which was signed into law on March 27, 2020, eliminates from May 1, 2020, through December 31, 2020 the 2% sequestration-mandated reductions to Medicare reimbursement. We review these developments in greater detail below.

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