Collaboration, License and other Commercial Agreements: Key Considerations for Life Sciences Companies in the Age of COVID-19

The COVID-19 pandemic is continuing to cause major global disruption to the activities of development stage and other life sciences companies due to, among other factors, limited or no access to clinical trial sites, reduced supply levels for active pharmaceutical ingredients or other key materials needed to make drug candidates or medical devices, and the inability of personnel to access laboratory and other specialized work spaces.

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Labor Cost Reduction Options for Employers in a Distressed Economy: The CARES Act and Other Considerations

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which was enacted on March 27, 2020, created new programs and expanded existing programs in ways that significantly affect the options for employers. This alert identifies key aspects of the CARES Act that can affect employers' decisions in managing payroll costs during this challenging period. This alert also reviews other considerations for employers, including federal and state plant closing laws and Fair Labor Standards Act ("FLSA") requirements. This alert focuses on considerations based on federal law and the laws of California, Massachusetts and New York.

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The Impact of COVID-19 on Disclosure Obligations for Public Companies in the Life Sciences Industry

The ongoing global outbreak of the novel coronavirus (COVID-19) raises important considerations for life sciences companies subject to U.S. Securities and Exchange Commission ("SEC") disclosure and reporting requirements. As the pandemic continues to disrupt markets and industries worldwide, companies should carefully assess the risks that COVID-19 poses to their operations, ensure that those risks are accurately reflected in their SEC filings and investor communications, and carefully consider their disclosures to investors as COVID-19 risks rapidly evolve each day.

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U.S. Senate Passes CARES Act, Heads to House; Would Make Available to Small Businesses $349B in SBA Paycheck Protection Loans and $10B in Economic Injury Disaster Loan Grants

Late Wednesday night, March 25, 2020, the U.S. Senate passed, 96-0, the "Coronavirus Aid, Relief, and Economic Security Act" or "CARES Act" (H.R. 748), which will make available to small businesses $349 billion in "paycheck protection loans" through the U.S. Small Business Administration's 7(a) Loan Guaranty Program (Paycheck Protection

Loans or PPLs) and $10 billion in economic injury disaster loan grants (EIDL Grants). The bill is now before the U.S. House of Representatives, where it is expected to pass in substantially its current form. Below is a summary of the bill as it currently stands with respect to the Paycheck Protection Loan program.

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Important Reminders for U.S. Boards of Directors Navigating COVID-19

 While COVID-19 will affect the operations of different companies in different ways, the boards of directors of every company should think critically about their oversight role in the context of this unprecedented global pandemic. Here are some things to remember based on the intersection of the pandemic with directors' duties.

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COVID-19: Business Interruption and Insurance Amid a Pandemic

 Businesses in the United States and around the world are undergoing a fundamental and unprecedented disruption as a result of the coronavirus pandemic (COVID-19). State governments have issued "shelter-in-place" and "stay-at-home" orders to the general population, postponed or otherwise cancelled schools in full, and shut down all businesses except those deemed "essential" or "critical" to the maintenance of our country. These actions have

already caused dramatic losses of income to business, and those losses will continue to grow as the actions necessary to combat the coronavirus continue to take hold. Fortunately, businesses may have an avenue available to them to recoup some or all of these losses through business interruption coverage in commercial property insurance.

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Coronavirus and the Interaction with Force Majeure Provisions in Real Estate Contracts

The COVID-19 pandemic is disrupting the world's economy in ways that were unimaginable a few weeks ago. Will this disruption excuse you or your counterparty's contractual rights and obligations under real estate related contracts? The answer may depend on the presence (and specific wording) or absence of a force majeure clause.

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The Implications of Coronavirus (COVID-19) On Contractual Performance and Negotiations

We encourage our clients to be proactive in responding to the potential impact of COVID-19 on both existing and potential business agreements and relationships. Now that the World Health Organization has formally classified the outbreak of COVID-19 as a pandemic, and the full spread of the virus remains uncertain, it is important that businesses consider

the potential implications of the virus on negotiation and performance of their contracts. Whether you are planning to negotiate or currently negotiating contractual agreements, or whether your commercial operations and relationships have already felt the impact of this novel coronavirus, there are several considerations to keep in mind to ensure the smooth operation of your business and to mitigate the potential for litigation amid a pandemic. This alert discusses those considerations.

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COVID-19 and the Impact on M&A

Although COVID-19 is rightfully viewed primarily as a public health and humanitarian issue, it is worth considering the potential impacts of the virus on M&A activity as this dynamic situation unfolds. We are seeing the issue find its way into M&A processes in various ways, and we have highlighted many of the issues here.

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Q&A on FDA's Requirements Related to Financial Disclosure by Clinical Investigators

What financial arrangements between clinical trial sponsors and clinical investigators must be disclosed in a drug, biologic or device marketing application?

In a marketing application, FDA requires that four types of financial arrangements be disclosed: (1) any financial arrangement between the sponsor and the investigator whereby the value of the

compensation to the investigator for conducting the study could be influenced by the outcome of the study; (2) any significant payments of other sorts from the sponsor, such as a grant to fund ongoing research, compensation in the form of equipment, a retainer for ongoing consultation, or honoraria, which are greater than $25,000 in cumulative value and given to the investigator or the investigator's institution to support the investigator's activities, exclusive of the costs of conducting the study, for the duration of the study and for one year following the study's completion; (3) any proprietary interest in the tested product held by the investigator; and (4) any significant equity interest in the sponsor held by the investigator, which is any amount for a non-publicly traded company or an equity interest in a public company valued over $50,000 for the duration of the study and for one year following the study's completion.

How is a clinical investigator defined in the context of FDA financial disclosure regulations?

In FDA's financial disclosure regulations, the agency defines a clinical investigator as a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator.

What does FDA look for with regard to financial interest?

FDA looks at several factors with regard to financial interest, including the size and nature of the disclosed financial interest, the steps taken to minimize the potential for bias, and the study design. For example, FDA will evaluate whether the study has been designed with multiple investigators (most without a disclosable interest), blinding, objective endpoints, or measurement of endpoints by someone other than the investigator. FDA may initiate audits of the data from the investigator at issue, request that the applicant submit further analyses of the data or conduct additional independent studies to confirm the results. The agency could also refuse to treat the study as providing data that can be the basis for an agency action. We recommend you contact your Goodwin life sciences or FDA lawyer for further explanation of the agency's financial disclosure regulations.