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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Conduct of Clinical Trials During the COVID-19 Pandemic: Recommendations from FDA

 As the COVID-19 pandemic unfolds, our drug, biologic, and medical device clients conducting or planning to conduct clinical trials may be faced with challenges related to quarantines, travel limitations, site closures or access restrictions, infection transmission concerns of site research personnel and study subjects, and supply chain interruptions. Nonetheless, it remains critical during the COVID-19 pandemic to continue to assure the safety of trial participants, comply with good clinical practice (GCP) requirements, and minimize risks to trial integrity. In this client alert which follows our earlier article on product development considerations for COVID-19 and article on FDA scrutiny of COVID-19 medical product marketing, we briefly discuss the impact the COVID-19 pandemic may have on our life sciences clients, and we provide an

overview of FDA's "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" issued on March 18, 2020.

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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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Insurance Considerations in Light of COVID-19

 "In the recent weeks our risk management team has identified

a number of insurance-related issues relevant to clients dealing with the outbreak of the disease caused by the novel coronavirus, known as COVID-19, that we felt important to share with clients.

This alert is focused on business-related insurance (not individual or health insurance) and in particular, is primarily focused on management liability insurance (Directors and Officers (D&O), Employment Practices Liability (EPL), and Fiduciary liability policies), professional liability insurance (also known as Errors & Omissions (E&O) liability policies) and transaction liability insurance (such as Representations & Warranties Insurance (R&W Insurance)).

We have highlighted key issues on these corporate policies to provide guidance on: (1) what types of loss may be covered under insurance that could potentially arise from the COVID-19 outbreak; (2) issues that could impact coverage for such claims; and (3) negotiating and underwriting policies during this pandemic."

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Racing Against COVID-19: An Introduction to China's Regulatory Fast-Track Processes

In response to the outbreak of a pneumonia-like disease caused by coronavirus (COVID-19), Chinese regulatory authorities adopted a few emergency measures under certain "Special Review and Approval Procedures" to fast-track the review and approval process for developing diagnostic kits, vaccines and therapies for combating COVID-19 infections. There are several types of "fast track" procedures available under the current Chinese regulatory framework. The most important three are Special Review and Approval Procedure of 2005, Special Review and Approval Procedure of 2007, and Priority Review and Approval Procedure of 2017, all of which are summarized in this alert.

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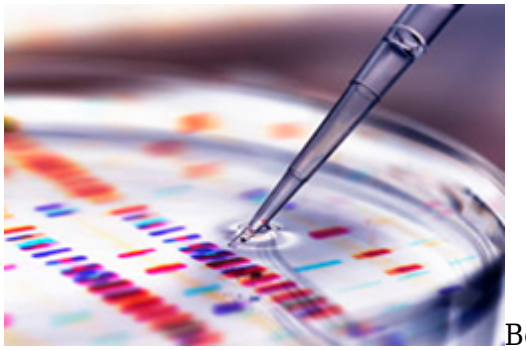
Clinical Holds: Tips for Handling FDA's Call and What to Do Next

 Because life sciences companies hope to never end up on clinical hold, preparing for such a call from the U.S. Food and Drug Administration (FDA) is often not on the to-do list. But there can be significant advantages to advance preparation. Our Goodwin Insight shares some tips for life sciences companies on navigating that first call with FDA and the actions that follow.

Read the Insight >>

Developing Medical Products for Public Health Emergencies

 The 2019 novel coronavirus (coined COVID-19 by the World Health Organization) is the latest in a series of public health emergencies in recent years to challenge product developers in the life sciences community. With every challenge comes an opportunity, in this case to leverage product development plans and technologies to be first-to-market with products useful in remediating some aspect of COVID-19 and its spread. Earlier this year, the U.S. Food and Drug Administration (FDA) announced its commitment to extend all available resources to help expedite the development and availability of medical countermeasures (MCMs) to prevent, treat, or diagnose COVID-19 and, in fact, issued the first emergency use authorization (EUA) shortly thereafter. For life sciences companies exploring potential opportunities to leverage their programs to help treat, detect, or address some aspect of COVID-19, a number of regulatory mechanisms may be available to facilitate and advance product development plans.

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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.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: New Frontiers in Digital Diagnostics and MedTech

 On Wednesday, January 15, 2020, during the J.P. Morgan Healthcare conference, Goodwin and KPMG held their initial all-day Symposium at the St. Regis hotel in San Francisco. The Symposium was composed of five separate "bursts" entitled (i) New Frontiers in Digital Diagnostics and MedTech, (ii) Europe Unleashed, (iii) Knowing the Best IPO Strategy, (iv) Trends in Biopharma and (v) Mergers and Acquisitions. Stéphane Bancel, the Chief Executive Officer of Moderna Therapeutics, provided the keynote address.

Burst One consisted of three parts. Roger Cohen from Goodwin provided an overview of the current state of the healthcare sector and regulations. During this session, Roger provided an overview of the FDA's definition of a medical device subject to FDA regulation, highlighting whether digital technologies would be encompassed within such definition. In addition, Roger reviewed other key federal and state laws of importance to companies involved in the digital healthcare space – including privacy laws such as HIPPA – and state laws regarding the corporate practice of medicine.

The second part of Burst One was a panel entitled "*New Frontiers in MedTech Space on the Global Stage: What are the Challenges in IP, Regulatory and Commercial*?" This panel was moderated by **Kristin Ciriello Pothier** from KPMG, and consisted of **Nicholas Mitrokostas** from Goodwin, Stefan Scherer from GlaxoSmithKline, Joseph Zaccaria from TrialSpark and Reena L. Pande from AbleTo. In this panel, participants provided their perspectives regarding the numerous challenges associated with bringing new medical technology to market, including as it relates to intellectual property, regulatory approvals, reimbursement and commercialization.

The final part of Burst One was a panel entitled "*Issues Facing Therapeutic Companies Using ML and AI in Drug Discovery Methods.*" This panel was moderated by **Danielle Lauzon** from Goodwin and consisted of David Berry from Flagship Pioneering, and Dan Housman from Graticule and Courage Therapeutics. In this panel, participants provided their insights regarding how artificial intelligence, or AI, and machine learning, or ML, is used in the drug development process, and debated what type of input data is necessary for AI and ML to be truly useful in the drug development process.

Key takeaways from Burst One were as follows:

1. ***MedTech, digital diagnostic and health IT companies should seek guidance from experienced counsel as early on in the process as possible as laws and regulations are numerous and complicated.*** Various panel members noted that one of the biggest mistakes that companies in the evolving medtech, digital diagnostics and health IT spaces make is failure to consider the numerous, complicated laws and regulations that may apply to their

technologies. Therefore, they highly recommended obtaining experienced lawyers early in the company lifecycle to avoid potential missteps. For example, determining whether certain medical software will be regulated as a medical device by the FDA is very fact intensive and requires input from an experienced regulatory specialist as there are dire consequences for making the wrong determination. In addition, it is important to note that these laws and regulations are constantly evolving, therefore, something that may be permissible today may not be permissible in the future. Experienced counsel can keep you up-to-date on pending developments that might affect your company.

2. ***In many areas, the law has not kept pace with the speed of technological innovations; therefore, a great deal of gray space remains.*** Panelists noted that legal issues facing companies in rapidly-evolving sectors may not have a clear answer as the law has not kept pace with the speed of technological innovations. For example, in patent law, folks have had to consider whether a computer should be deemed the investor of the output from certain AI processes.
3. ***In order for new technologies in areas such as medtech, healthcare IT and digital diagnostics to become successful on a large scale, there is a need to balance the innovative mindset with the entrenched mindset and there must be an openness to collaboration both internally and externally.*** Many panelists cautioned that in order for new innovations in medtech, digital diagnostics and healthcare IT to be accepted by the current healthcare system, it will require a great deal of cooperation between the innovators and the entrenched players. Therefore, panelists advised that companies developing new technologies in these areas should seek to involve more entrenched players into their decision-making and development process as early as possible, and to seek returns on a smaller scale before seeking returns on a larger scale in order to build credibility.
4. ***AI has a great deal of promise in drug development, but questions remain regarding (i) how to obtain a sufficient amount of data for useful predictions, and (ii) the quality of the data that is used to arrive at predictions.*** Panelists noted that AI can be used throughout the drug development lifecycle, from assisting with target selection to helping predict the patient population that is most likely to respond to a product candidate. However, a panelist cautioned that the hype associated with AI should be toned down, as AI has yet to provide many of the promised benefits. Furthermore, there are many differing positions regarding the type of quality of data needed for AI to be truly useful in the drug development process.