COVID-19: FDA Developments and Legal Considerations for Healthcare and Life Science Companies and Investors

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The novel coronavirus, otherwise known as COVID-19, poses unique challenges for healthcare and life science companies. While some organizations can suspend operations or order employees to work from home, providers are on the front lines treating patients, and life science companies are engaged in critical COVID-19-related research, development, and manufacturing of essential vaccines, antiviral drugs, and diagnostics.

Below, we address a number of legal development impacting healthcare and life sciences companies, including Food and Drug Administration ("FDA") regulatory developments.

Patient Privacy When Providers and Staff Are Working Remotely. At a time when organizations may seek to reduce the number of personnel in close proximity to patients, providers may consider expanding their capability to deliver certain types of care via telemedicine and enabling certain "back office" staff to work remotely. Having these functions carried out from home, however, creates the risk that patient privacy may be compromised—potentially in violation of the Health Insurance Portability and Accountability Act ("HIPAA").

The U.S. Department of Health and Human Services ("HHS") issued a bulletin providing "a reminder that the protections of the Privacy Rule are not set aside during an emergency." In particular, HHS expressed concern about improper disclosure of patient data—a risk that may be enhanced if personnel are working from home or other places where parties may have access to patient data. Additionally, according to HHS, when making disclosures that are allowed under HIPAA (*e.g.*, to public health authorities for the purpose of preventing or controlling the Coronavirus outbreak), covered entities should only share the "'minimum necessary' to accomplish that purpose," with the caveat that "]c]overed entities may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the purpose, when that reliance is reasonable under the circumstances."[1] Although every situation is different, in light of the public health

[1] For additional information about cybersecurity risks posed by COVID-19, see our client update.

emergency, providers should typically err on the side of providing public health officials with whatever information they reasonably need.

Contract Obligations. COVID-19 may create unanticipated challenges in meeting contractual obligations. Life science companies, for example, may face the inability to satisfy their contractual obligations for a variety of reasons, including supply chain disruptions that have made it very difficult or impossible to manufacture a particular product, or may need to shift resources away from routine manufacturing activities to specific products for which there is an immediate need. Healthcare companies may find that they do not have a sufficient number of employees to carry out certain contracted services. The roles may be reversed as well: companies may have counterparties who are unable to satisfy their obligations, e.g., a supplier that cannot provide a needed component or a life sciences company that cannot manufacture a particular product it was obligated to provide to a healthcare facility.

No matter the circumstances, organizations should carefully study their pre-existing contractual obligations, which will be in an important element in the development of any strategic response to the current health crisis. As part of this contractual review, companies should focus on those contractual provisions that establish what constitutes a breach of contract and what rights, obligations and protections parties have in the event of a breach. Companies may want to pay special attention to contractual provisions relating to notification requirements, termination provisions, and provisions governing what happens in case of delayed performance or nonperformance. Companies should also consider whether any contractual provisions incorporate a "commercially reasonable" or similar standard. If so, companies should consider how the definition of "commercially reasonable" may be affected under the circumstances of the COVID-19 outbreak. Additionally, for any contract with a *force majeure* clause, the company should conduct a careful analysis of the wording of the clause at issue to determine how it may (or may not) apply under the circumstances.

After an organization ascertains its contractual rights and obligations, it should proceed with caution. Even if an organization believes it has strong arguments regarding why performance should be excused under these circumstances, there is a meaningful risk that a court (depending on the circumstances) may decline to relieve an organization of its contractual obligations—particularly if the counterparty has suffered significant financial harm. Therefore, in many cases, the best policy may be to approach affected counterparties to determine whether mutual agreement can be made to adjust contractual obligations under the circumstances. To avoid any misunderstandings, such agreements typically should be in writing and carefully reviewed by counsel.

FDA Regulation: Supply Chain Disruption and Domestic Alternatives. The COVID-19 pandemic will almost certainly impact the drug and medical device supply chain in

the United States, which relies heavily on imported active pharmaceutical ingredients ("APIs") and finished products, in particular from China and India. This vulnerability in the U.S. drug supply chain was an area of focus for the FDA and Congress even before the outbreak, but the intense public scrutiny and immediate threat of shortages in the midst of the crisis may now lead to swift policy change.[2]

On February 27, 2020, FDA Commissioner Stephen Hahn issued an announcement regarding how "the COVID-19 outbreak would likely impact the medical product supply chain."[3] The announcement noted that the FDA had identified 20 drugs "which solely source their [APIs] or finished drug products from China" and had contacted manufacturers operating 72 facilities in China that produce essential medical devices.[4] FDA may have limited data to assess the potential impact: Janet Woodcock, FDA's director of the Center for Drug Evaluation and Research ("CDER"), acknowledged in recent congressional testimony that "data available to FDA do not enable [the agency] to calculate the volume of APIs being used for U.S.-marketed drugs from China or India, and what percentage of U.S. drug consumption this represents."[5] Also on February 27, 2020, FDA announced one confirmed drug shortage due to difficulties obtaining API as a result of COVID-19.[6] FDA has asked manufacturers "to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak."[7]

Supply chain disruptions due to COVID-19 are quickly becoming a reality. On March 3, 2020, the Indian government announced that it would restrict the export of 26 pharmaceutical ingredients and the drugs made from them, including Paracetamol, a

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2 For more information on recent FDA and Congressional scrutiny of foreign drug companies, and potential impact on the drug supply chain, see a recent Debevoise article focusing on Indian companies. Debevoise & Plimpton LLP, *Indian Pharma: Congress and FDA Continue Scrutiny of Foreign Drug Companies with Heightened Focus on Companies Located in India* (Feb. 12, 2020), https://www.debevoise.com/insights/publications/2020/02/indian-pharma-congress-and-fda-continue-scrutiny.

3 FDA Statement from Stephen M. Hahn, FDA Commissioner, *Coronavirus (COVID-19) Supply Chain Update* (Feb. 27, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update.

4 *Id.*

5 Hearing on Safeguarding Pharmaceutical Supply Chains in a Global Economy Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 116th Cong. 7 (2019) (statement of Janet Woodcock, M.D., Director of the Ctr. for Drug Evaluation and Research), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Woodcock-API_103019.pdf.

6 *Id.*

7 FDA, Drug Shortages (Mar. 13, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

common pain reliever, and several antibiotics.[8] These APIs and finished products reportedly account for 10% of all Indian pharmaceutical exports.[9] On the day India announced the restrictions, FDA informed U.S. Senators that it would evaluate how the restrictions will affect the U.S drug supply.[10] As of August 2019, 18% of the API manufacturers supplying the U.S. market were located in India.[11]

The supply chain vulnerabilities exposed by COVID-19 may result in a legislative effort to strengthen domestic drug and device manufacturing. On March 12, 2020, the bipartisan Commission on America's Medical Security Act was introduced in the Senate, which calls for the National Academy of Sciences, Engineering and Medicine to study the problem of U.S. dependence on foreign drug and device supply and to recommend solutions. On the same day, Senator Cory Booker reintroduced legislation to increase access to capital for entrepreneurs seeking to scale-up and commercialize advanced manufacturing operations in the United States. These efforts will likely not address drug shortages caused by the current COVID-19 crisis, however, as it typically takes many years to build new drug or device manufacturing facilities.[12]

Investors considering potential acquisitions should carefully assess the origins of critical supplies during the diligence process and the potential for business interruption if those suppliers are cut off. Moreover, going forward, companies may evaluate whether it is prudent to engage in transactions to develop domestic drug ingredient or component supply sources, whether by agreements with domestic suppliers, joint ventures, or acquisitions.

FDA Inspections. On March 10, 2020, FDA announced that it would postpone most foreign inspections through April 2020 and would limit domestic inspections to

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8 Chris Thomas & Neha Dasgupta, Global Supplier India Curbs Drug Exports as Coronavirus Fears Grow, REUTERS (Mar. 3, 2020), https://www.reuters.com/article/us-health-coronavirus-india/global-supplier-india-curbs-drug-exports-as-coronavirus-fears-grow-idUSKBN20Q0ZZ.

9 *Id.*

10 *Id.*

11 *Hearing on Safeguarding Pharmaceutical Supply Chains in a Global Economy Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 116th Cong. 1 (2019) (statement of Janet Woodcock, M.D., Director of the Ctr. for Drug Evaluation and Research), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Woodcock-API_103019.pdf.

12 Compounding pharmacies may present a solution in certain circumstances. On March 14, 2020, FDA issued a guidance document stating that it would not take action against compounders that prepare alcohol-based sanitizers (an over-the-counter drug product) for consumer use for the duration of the COVID-19 public health emergency. FDA, *Immediately in Effect Guidance for Industry: Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency* (Mar. 14, 2020), https://www.fda.gov/media/136118/download.

mission-critical sites.[13] To ensure the safety of imported products, FDA said it will use other tools, in particular its authority to inspect and sample products at the U.S. border and to deny entry of any potentially unsafe products.[14] FDA also has the authority under the Federal Food, Drug, and Cosmetic Act to request records in advance or in lieu of on-site inspections.[15]

Postponed inspections may result in delays of some drug approvals, as FDA generally conducts on-site pre-approval inspections of the manufacturing and packaging facilities prior to approval. FDA uses a risk-based system to determine whether to conduct a pre-approval inspection, considering factors such as prior issues at the manufacturing facility, whether this is the first application filed by a company, and whether there is a shortage situation. It is possible that FDA will adjust its risk framework to take the COVID-19 crisis into account when making decisions on pending applications.

Diagnostics and FDA's Emergency Use Authorization ("EUA"). FDA's EUA authority permits the agency to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by emerging infectious diseases.[16] On February 4, 2020, FDA declared that the circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19.[17] To this date, FDA has issued EUAs to three entities with COVID-19 diagnostic tests: the Centers for Disease Control and Prevention ("CDC") (issued February 4), the New York State Department of Health ("NYSDOH") (issued February 29), and Roche Molecular Systems, Inc. ("Roche") (issued March 12).[18] FDA purportedly issued the Roche EUA within 24 hours of receiving the application.

FDA has acknowledged limitations of certain EUA requirements in the rapidly evolving health crisis. For example, the EUA required that the CDC rerun COVID-19 tests conducted by public health labs, which slowed down the testing process. On February 29, 2020, FDA issued guidance announcing that it would allow labs to move forward with testing provided they notify FDA that the new test has been validated and they submit an EUA request within 15 days of validating the test.[19] FDA Center for Devices

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13 FDA Statement from Stephen M. Hahn, FDA Commissioner, *Coronavirus (COVID-19) Update: Foreign Inspections* (Mar. 10, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections.

14 *Id.*

15 21 U.S.C. 374(a).

16 21 U.S.C. § 360bbb-3.

17 FDA, Emergency Use Authorizations, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

18 *Id.*

19 FDA Guidance for Clinical Laboratories and FDA Staff: Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA Prior to Emergency Use Authorization for Coronavirus

and Radiological Health ("CDRH") Director, Jeff Shuren, said that more than 30 labs have said they plan to begin testing under the new policy and more than 60 developers have worked with the agency on potential EUA submissions.[20]

Advertising. Any healthcare or life science company should carefully consider any communications that could imply that a product affords protection to individuals or their families against COVID-19. The FDA and the Federal Trade Commission are carefully monitoring any claims that may create the implication that a given product mitigates the risk of being infected by COVID-19, and both agencies have already issued warnings to companies engaged in allegedly unlawful promotion.[21]

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Please do not hesitate to contact us with any questions.

Disease-2019 during the Public Health Emergency (Feb. 29, 2020), https://www.fda.gov/media/135659/download.

[20] FDA News Release, Coronavirus (COVID-19) Update: FDA Gives Flexibility to New York State Department of Health, FDA Issues Emergency Use Authorization Diagnostic (Mar. 13, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gives-flexibility-new-york-state-department-health-fda-issues.

[21] FDA News Release, Coronavirus Update: FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19 (Mar. 9, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or.

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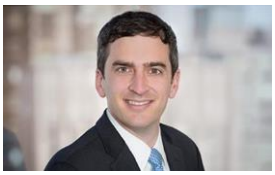

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