What COVID-19 Means for FDA-Regulated Industry

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U.S. and international health authorities continue to respond to the outbreak of the novel coronavirus (COVID-19). While originally detected in Wuhan City, Hubei Province, China, as of the date of this alert the virus has now been detected in approximately 60 countries worldwide, including the United States.

Nearly 90,000 cases have been confirmed worldwide. Until last week, cases in the U.S. had been limited to those who had traveled abroad and those who had close contact with returned travelers; however, a number of cases have now been diagnosed in several states in individuals without an obvious traceable source. These may be the first signs of "community spread," and U.S. health authorities are preparing for the emergence of more cases nationwide. As authorities acknowledge, the situation is rapidly evolving.

Impact on FDA-Regulated Industry

The survivability of COVID-19 on surfaces is not fully known, but, to date, there has not been any evidence to suggest that COVID-19 can be spread through the shipment of goods from areas where the virus has been detected. On February 25, 2020, the FDA released an update stating, "Fortunately, currently, we are not seeing the impacts of this outbreak resulting in an increased public health risk for American consumers from imported products. There is no evidence to support transmission of COVID-19 associated with imported foods and there have not been any cases of COVID-19 in the United States associated with imported goods."

Nevertheless, the outbreak of the virus has already had a significant impact on international commerce, particularly with respect to goods produced in China which, as the majority of health care businesses and providers know, is well integrated within the global economy and international transportation system.

The impact is being keenly felt by FDA-regulated industry, which imports a wide variety of goods from China. As FDA has noted, at this time 60% of FDA regulated products imported from China are medical devices and 20% are housewares (e.g., food packaging). China is also a major supplier of drugs (including active pharmaceutical ingredients) and biologics to the United States – according to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, as of August 2019, 13% of APIs for the U.S. market were made in China. Of particular relevance, China also produces numerous medical devices utilized by health care workers, such as protective masks, gloves, respirators and gowns.

The COVID-19 virus presents a unique threat to this stream of goods as China's public health concerns and disease intervention methods have placed many provinces on an effective lock down.

Authors

Michael M. Gaba
Practice Vice Chair
mgaba@polsinelli.com

Stuart M. Pape
Practice Chair
spape@polsinelli.com

Anne D. Spiggle
Of Counsel
aspiggle@polsinelli.com

Erica L. (Beacom) Reagan
Associate
ebeacom@polsinelli.com

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Restrictions on manufacturing sites, public transportation and general public interaction have been imposed in an effort to curtail the spread of the disease. Additionally, in light of the U.S. Department of State's travel advisory, the FDA is not currently conducting facility inspections in China and will rely instead on tools such as import screening, examinations, sampling, import alerts, and records inspection in its effort to have comprehensive oversight of FDA-regulated products entering the U.S.

FDA's inspection suspension combined with China's public health restrictions create the real possibility of a shortage of critical medical products. According to FDA Commissioner Dr. Stephen Hahn, the agency is "keenly aware that the outbreak will likely affect the medical product supply chain, including potential disruptions to suppliers [and] shortages of critical medical products in the U.S."

Industry Considerations and Recommendations

Given the rapidly evolving situation and its impact on business operations, you can be assured that your customers will be asking you what you are doing to respond to the threat of COVID-19 and how you can ensure timely fulfillment of your obligations to them. Therefore, businesses should remain on alert and should consider the following recommendations, as appropriate:

- Routinely monitor and adhere to the recommendations of national and international health authorities. This is a wise approach both legally and as a matter of common sense.
- Continually assess internal and external business practices and make adjustments to align with current health authority recommendations.
- Take steps, to the extent feasible, to limit the risk of human to human transmission among employees. Such steps might include encouraging appropriate hygiene practices (e.g., washing hands) and limiting or restricting travel. Employees who are ill should receive prompt medical attention and refrain from coming to work.
- Follow CDC recommendations for cleaning and sanitizing of work spaces and commonly touched surfaces such as handrails, countertops and doorknobs.
- Be wary of applying sanitizers in novel circumstances that may fall outside of authorized intended uses.
- If you receive components, ingredient, or finished products from China or other reported outbreak zones, engage in early and consistent communication with your suppliers and contract manufacturers to understand what steps they are taking to constrain the spread of the virus, as well as to obtain assurances of compliance with cGMP or QSR requirements and any assurances they can provide that your products are not susceptible. The more information and communication you receive, the easier it will be to prepare for and respond to customer inquiries.
- Evaluate and actively monitor your supply chain to identify potential challenges and anticipate any potential disruption in your ability to obtain products and materials.
- Consider your options for sourcing of components, ingredients, or finished products. Do you have sufficient inventory to continue operations in the event of a future supply shortage? Are there other sources, outside the outbreak zones, for the materials you need? Can you accelerate or increase shipment of goods from foreign locations to the U.S. now, in order to build inventory in advance of a potential shortage or restriction on shipment?
- Consider consulting with your legal counsel regarding the content of communications with your manufacturing/supply partners and/or with consumers.

The dynamic nature of the COVID-19 outbreak makes it difficult to predict how significant supply issues may become or whether/when the impact on industry might ease. For now, adherence to health authority recommendations and vigilance over your supply chain offer the best ways to help limit the spread of the virus and to prepare for and, hopefully, minimize the impact of the virus on your business.

Polsinelli's FDA, health care, employment and customs and trade practices are all available to assist clients in navigating these issues.

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