COVID-19's Lasting Impact on the Medical Device Regulatory Environment

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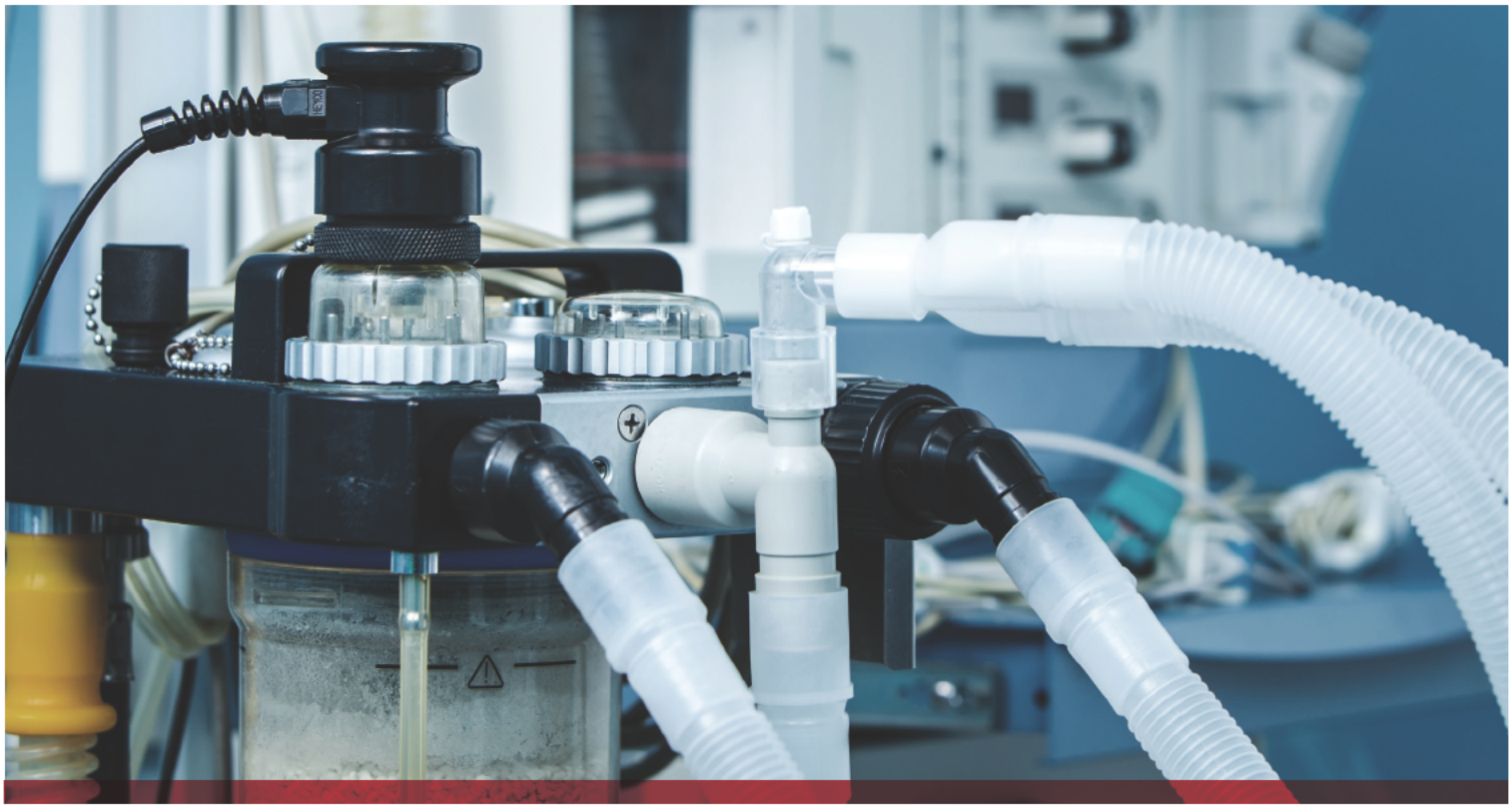

Congress has initiated new efforts to address supply chain security and supply shortages of critical drugs and medical devices in response to the ongoing outbreak of the novel coronavirus (COVID-19) pandemic. Under the current regulatory framework,[1] manufacturers of prescription drugs and biological products are required to notify the Food and Drug Administration (FDA) when they become aware of a circumstance that could lead to a potential shortage. To aid drug manufacturers in navigating the reporting process during the COVID-19 crisis, the FDA released a Guidance Document in March 2020[2] describing when and how to notify the FDA of discontinuances or interruptions in manufacturing during the pandemic. The Guidance Document directs drug manufacturers to notify the FDA of an event that may lead to a shortage six months in advance and that manufacturers should include details beyond those required by law, such as whether the event is preventable, the underlying reason or root cause, the estimated date of onset, and current and expected inventory levels over time. The Guidance Document further states that if six months' advance notice is not possible because the discontinuance or interruption in manufacturing was not reasonably anticipated, then the notification must be submitted as soon as practicable thereafter, but in no case later than five business days after the discontinuance or interruption in manufacturing occurs.

Paradoxically, the drug shortage regulations do not authorize the FDA to require medical device manufacturers to report devices shortages. However, lawmakers have sought to change that with new legislation introducing or strengthening notification requirements related to medical device product discontinuances and manufacturing interruptions.

1 21 CFR § 310.306.
2 *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act*, FDA, *available at* https://www.fda.gov/media/136486/download.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act,[3] a $2 trillion stimulus package responsive to the COVID-19 outbreak. Among its provisions, the CARES Act requires medical device manufacturers to disclose discontinuation or interruption in the manufacturing of essential medical devices or components; and to provide required information about the volume of impacted devices. The CARES Act also imposes a duty upon the FDA to make public a list of reported device shortages, similar to the public lists of reported drug and biologic shortages it is already required by law to maintain.[4]

In addition, the CARES Act revised the Strategic National Stockpile to include personal protective equipment (PPE), which the FDA defines as "protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness"[5]; and included a liability protection measure to incentivize manufacturers of PPE.

Moreover, the CARES Act requires certain drug[6] and active pharmaceutical ingredient manufacturers, as well as manufacturers of medical devices used for the preparation or administration of those drugs, to develop and maintain redundancy risk management plans to evaluate and mitigate risks to the supply of life-saving drugs during or in advance of a public health emergency. Per the FDA, the types of devices that would fall into the remit of the new law include, inter alia, ventilators, circulators, oxygen tents, and hyperbaric chambers.[7] While this requirement does not clearly implicate all medical device manufacturers, clients should anticipate that the same level of supply chain risk management applies to essential drug and device manufacturers unilaterally. As those medical device manufacturers that are covered by the new law put supply chain risk management programs in place, the implementation of same most likely will become a best practice across the medical device industry.

It is unclear when the FDA will begin implementing and enforcing each requirement responsive to the CARES Act, but we can expect that it will act as swiftly as possible in the confines of the ongoing public health emergency. Section 3101 of the law requires the Department of Health and Human Services to collaborate with the National Academies of Sciences, Engineering, and Medicine to publish a "National Academies Report on America's Medical Product Supply Chain Security" within sixty days of enactment.[8] Due on or before May 26, 2020, the report will examine the nation's dependence upon foreign sources for key medical products, evaluate the national security risks associated with that dependence, and offer recommendations for remediating any identified vulnerabilities. Presumably, implementation of the reporting requirements and other provisions will follow soon after.

While this new legislation was introduced in a concerted effort to mitigate the current pandemic, medical device manufacturers should expect and plan for the heightened reporting requirements to become permanent fixtures, as regulators and the public alike are now acutely attuned to the importance of ensuring a sufficient supply of essential medical devices such as masks, ventilators, and surgical gowns. In light of these more stringent supply reporting requirements, medical device companies may wish to assess and update policies, procedures, processes, and underlying systems related to device and component supply tracking to enhance their ability to comply. More generally, pharmaceutical and medical devices companies should continue to develop, implement, and improve robust medical-product supply-shortage risk assessment and mitigation programs and policies. While the formal requirement delineated in the CARES Act does not clearly implicate all medical device manufacturers, clients should anticipate that the same level of supply chain risk management applies to essential drug and device manufacturers unilaterally, and take action accordingly. The FDA emphasizes that it can—and will—issue a publicly available noncompliance letter to any manufacturer that fails to meet the notification requirements.

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3 Pub. Law No. 116-136 (2020).
4 *Current and Resolved Drug Shortages and Discontinuations Reported to FDA*, FDA, *available at* https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.
5 *Personal Protective Equipment for Infection Control*, FDA, *available at* https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control.
6 The drug manufacturers to whom this applies are defined as: "A manufacturer of a drug (1) that is (A) life-supporting; (B) life-sustaining; or (C) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery; and (2) that is not a radio pharmaceutical drug product or any other product as designated by the Secretary." *See* 21 U.S.C §§ 356c(a); 506c. "Life-supporting" or "life-sustaining" device means a "device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life." 21 CFR § 860.3(e).
7 List of Medical Devices, by Product Code, that FDA classifies as Implantable, Life-Saving, and Life-Sustaining Devices, FDA, *available at* https://www.fda.gov/media/85192/download.
8 CARES Act § 3101.

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