U.S. CARES Act Supply Shortage Provisions: What Drug and Device Manufacturers Need to Know

by Elizabeth Mulkey, Julie Tibbets

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public discussion and concern over the availability and accessibility of critical medical devices, such as ventilators, and the pandemic has highlighted gaps in the U.S. Food and Drug Administration's (FDA's) authorities regarding medical product shortages. FDA has been able to collect information on drug shortages and take steps to help prevent or mitigate such shortages under authorities set forth in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). However, FDA had not, until now, had equivalent authority with regard to shortages of critical devices. Among the many provisions of the CARES Act ("the Act") are amendments and additions to the Federal Food, Drug, and Cosmetic Act (FDCA) that give FDA the ability to effectively address such shortages. Additionally, the Act enhances FDA's existing authority with respect to drug shortage measures. Below, we have highlighted the key provisions in these areas under the new law:

- The Act adds "personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile" to the items to be included in the Strategic National Stockpile (Sec. 3102).
- The Act adds respiratory protective devices to the category of "covered countermeasures" under Section 319F–3(i)(1)(D) of the Public Health Service Act, which includes qualified pandemic or epidemic products, security countermeasures, and drugs, biologics, and devices that are authorized for emergency use. In doing so, the Act extends liability protection for a manufacturer, distributor, program planner, qualified person, or agent of such an entity (i.e. "covered persons") to include respiratory protective devices. The Act gives immunity to covered persons from state or federal law liability for all claims of loss arising out of administration to or use by an individual of a respiratory protective device as a "covered countermeasure" (Sec. 3103).
- Under FDA's authority to address potential drug shortages, the agency already had the ability to expedite certain applications or establishment inspections that could help mitigate or prevent a drug shortage. The Act expands this authority to clarify that FDA "shall, as appropriate" not only expedite, but prioritize such reviews and inspections, though the Act is silent as to how much this prioritization may shorten the review period or time frame for inspections. These provisions are set to take effect 180 days after the enactment of the Act (Sec. 3111).
- The Act requires the manufacturer of a drug that is critical to the public health during a public health emergency to notify the Secretary of the Department of Health and Human Services ("the Secretary") of a permanent discontinuation in manufacture or interruption of the drug, or a permanent discontinuation or interruption in manufacturing of the drug's active pharmaceutical ingredient (API) that is likely to lead to a meaningful disruption in the supply of API. The manufacturer must also disclose the reason for and expected duration of the discontinuation or interruption, as well as the source of the API and any alternative sources known by the manufacturer. These requirements, along with the other changes under Section 3112, take effect 180 days after enactment of the Act (Sec. 3112).
- A manufacturer of a critical drug product (including those that are life sustaining, life supporting or intended for use or prevention of a debilitating disease or condition) must have in place a risk management plan that identifies and evaluates the risks to the supply of the drug for each establishment where the drug or API is manufactured. The risk management plan will be subject to review during an inspection of the manufacturer (Sec. 3112).

- Within 180 days after enactment, and every 90 days thereafter, the Secretary will send a report to the Administrator of its Centers for Medicare & Medicaid Services (CMS) on the current drug shortage list (Sec. 3112).
- As part of their annual registration and listing requirements, all drug companies will be required to submit a report of the amount of drug product they manufacture for commercial distribution. The Secretary may also require that this information be submitted at the time a public health emergency is declared. The Act permits the Secretary to determine that these reporting requirements may not apply to certain biological products that are not necessary to protect the public health; however, until such a determination is made, biological products are subject to this authority as well. There are no additional reporting requirements for medical device manufacturers under this section (Sec. 3112).
- The Act adds a new section to the FDCA (Sec. 506J), instituting a reciprocal requirement to the drug shortage reporting requirements in 21 U.S.C. § 356c for manufacturers of certain medical devices. The requirement applies to manufacturers of critical medical devices (those that are life-supporting, life-sustaining, or for use in emergency medical care or surgery) or devices for which the Secretary determines that information on meaningful supply disruptions is needed during or in advance of a public health emergency. These manufacturers must notify the Secretary during, or in advance of, a public health emergency of a permanent discontinuation in the manufacture of the device that is likely to lead to a meaningful disruption in the supply of the device and the reasons for such discontinuation or interruption. This notice must be submitted at least 6 months prior to the date of the discontinuation or interruption, or as soon as practicable, which mirrors the requirement for drug shortage reporting (Sec. 3121).
  - The new device authority provides additional context on how a “shortage” or “meaningful disruption” is defined. A “shortage” is a “period of time when the demand or projected demand for the device within the United States exceeds the supply of the device,” which tracks the definition of “drug shortage” in 21 U.S.C. § 356c.
  - The definition of “meaningful disruption” is similar to the definition for drug products, and includes “a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product.” However, the term as defined under the Act sets out additional circumstances that are not a “meaningful disruption”:
    - interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months (the drug authorities do not include a limit on what constitutes a “short period of time”);
    - interruptions in manufacturing of components or raw materials so long as such interruptions do not result in a shortage of the device and the manufacturer expects to resume operations in a reasonable period of time; and
    - interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test (Sec. 3121).
- Device shortage information may be made available to “appropriate organizations,” including physician, health provider, patient organizations, and supply chain partners. The addition of “supply chain partners” is a change from the comparable law for drug manufacturers. In another departure from the drug shortage authorities at 21 U.S.C. § 356c, the Secretary may choose not to make this information available to the public if the Secretary determines that the disclosure would adversely affect the public health (e.g., by increasing the possibility of unnecessary over purchase of a product, or otherwise disrupting the availability of medical products to patients) (Sec. 3121).
- The new device shortage provisions track the existing drug shortage authorities with regard to protecting confidential or trade secret information. Failure to meet the reporting requirements will similarly be addressed by a letter to the manufacturer requiring a response, which will be made public on FDA’s

website, unless there is a determination that the letter was issued in error, or that the entity had a reasonable basis for not submitting the required notification (Sec. 3121).

- Similar to the drug shortage authorities, the Act provides that the Secretary shall "prioritize and expedite" review of applications and establishment inspections that could help mitigate or prevent a device shortage, but does not stipulate an expedited time frame for FDA to meet in conducting such reviews or inspections (Sec. 3121).
- A new device shortage list will be maintained, containing information such as the name and manufacturer of each device, the reason for the shortage, and the estimated duration of the shortage, which is similar to the information available in FDA's existing drug shortage list. The Secretary may elect not to make this information available if there is a determination that making the information public would adversely affect the public health (e.g., by increasing the possibility of hoarding or disrupting the availability of the devices to patients) (Sec. 3121).

Although the CARES Act is a response to a still-developing pandemic, the updated and expanded FDA authorities under the Act will result in lasting obligations for drug and device manufacturers and suppliers, even after the COVID-19 pandemic is under control. Manufacturers will need to amend their SOPs to ensure alignment with expanded and new FDA authorities on reporting permanent discontinuations or interruptions leading to "meaningful disruptions" in supply. For device manufacturers, initial assessments may be required to determine whether any of a company's products fall under the new definition of a critical device. Drug manufacturers with critical drug products must now develop, maintain, and implement risk management plans that identify and evaluate the risks to the supply of such drugs for each establishment where the drug or API is made. Drug establishments will need to amend their standard operating procedures and inventory systems to aggregate annual production amounts for commercial distribution per listed product for reporting to FDA. While the statute allows the Secretary to exempt certain biological products from this reporting if unnecessary to protect the public health, biologics appear to be included until exempted and will need to adhere to these requirements as well. The drug shortage reporting requirements now include additional disclosure of the source and alternative sources of API, and API manufacturers should prepare for additional communication and engagement with their supply chain partners necessary to facilitate such reporting.

These provisions of the CARES Act represent important updates to FDA's authorities to manage medical product shortages, and we will continue to monitor FDA communication and guidance intended to help manufacturers fulfill these new obligations. Contact Goodwin FDA team members **Julie Tibbets** or **ElizabethMulkey** for any questions related to the supply shortage provisions of the CARES Act.

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