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Coronavirus Crisis Highlights FDA's Device Supply Chain Blind Spots

by Shawn M. Schmitt

The ongoing COVID-19 crisis has shone a light on the US agency's inability to clearly see medical device supply chain troubles to help stave off product shortages. Unlike makers of pharmaceuticals and biologics, there's no requirement for device firms to tell the FDA if there's a particular event that could lead to a shortage – but that could change thanks to language found in the agency's fiscal year 2021 budget request.

The ongoing coronavirus crisis has shone a light on the US Food and Drug Administration's inability to clearly see medical device supply chain troubles to help stave off product shortages.

That's because – unlike makers of pharmaceuticals and biologics – there's no requirement for device manufacturers to tell the agency if there's a particular event that could lead to a shortage.

And what's even more head-scratching is that device companies can simply ignore FDA inquiries about possible disruptions to supply chains.

"Enabling the FDA to have timely and accurate information about likely or confirmed national shortages of essential devices would allow the agency to take steps to promote the continued availability of devices of public-health importance," FDA commissioner Stephen Hahn *said in a late-evening statement* released on 27 February.

He said language found in the agency's recently released *fiscal year 2021 budget request* would help address shortages and the FDA's supply chain blind spots.

"FDA is seeking authority to: require firms to notify FDA of an anticipated significant interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of

the essential device(s) they manufacture; and authorize the temporary importation of devices whose risks presented when patients and health care providers lack access to critically important medical devices outweigh compliance with US regulatory standards," the budget request says.

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But until such measures are put in place, the FDA is taking "proactive steps" by engaging with device manufacturers, hospitals and group purchasing organizations to identify supply chain hiccups, Hahn explained.

"We are aware of 63 manufacturers which represent 72 facilities in China that produce essential medical devices; we have contacted all of them," he said. "We are aware that several of these facilities in China are adversely affected by COVID-19, citing workforce challenges, including the necessary quarantine of workers."

There are more than 11,000 manufacturers of class II and III devices in China.

An industry expert in Shanghai recently told *Medtech Insight* that exports of components and devices coming from China will continue to flow to the US and other countries for now, but there could be trouble soon if government quarantines and international travel bans remain in place. (Also see "*Chinese Device Exports, Supply Chains Holding Up In The Face Of Coronavirus – For Now*" - Medtech Insight, 6 Feb, 2020.)

While FDA chief Hahn confirmed that there have been no reported shortages to date, he nevertheless noted that there has been an "increased market demand" in protective medical equipment such as surgical gowns, gloves, masks and respirators.

Hahn urges device makers and health care facilities to let the agency know if they're facing shortages by emailing *deviceshortages@fda.hhs.gov*.

"This mailbox is closely monitored and has proven to be a valuable surveillance resource to augment FDA efforts to detect and mitigate potential supply chain disruption," he said.

The agency has become increasingly concerned about device shortages over the past year,

particularly in light of the shutdown of several ethylene oxide (EtO) sterilization plants in the US.

Those EtO facilities were either temporarily or permanently closed because of concerns from stakeholders about the potential risk of increased cancer around the plants. The device industry and the FDA have cautioned, however, that closing the plants could lead to shortages. (Also see "*US FDA Experts Caution Against Banning EtO, Encourage More Duodenoscope Training*" - Medtech Insight, 8 Nov, 2019.)