

FDA FACT SHEET

MITIGATING AND PREVENTING MEDICAL DEVICE SHORTAGES AND PRIORITIZING PUBLIC HEALTH



Before the pandemic took hold in the U.S. in early 2020, most of the public had never heard the term “PPE,” or personal protective equipment—the surgical masks, gowns, and other medical equipment that help keep frontline health care workers safe from infection. But just weeks after the U.S. declared COVID-19 as a public health emergency (PHE), most Americans knew about dire PPE shortages at hospitals, and many were soon directly impacted by the lack of test supplies and long wait times for results.

Shortages in various medical devices critical to public health and safety have remained a problem throughout the pandemic. To help the nation cope with these shortages, the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) received new statutory authority, under the CARES Act in 2020, to help mitigate and prevent device shortages during or in advance of a PHE.

While this new authority has been important, it does not cover all situations that can lead to a shortage. Some medical device shortages are likely to continue beyond the pandemic, and others will arise in the future when there is no PHE—for example, during a natural disaster that is not a PHE, or after a medical device recall. CDRH would be in a much better position to prevent and mitigate these shortages if it were to have more comprehensive statutory authority to help strengthen medical device supply chains. In addition, because we know that shortages can occur even when there is no PHE, the FDA is in the process of creating a new supply chain program to try to help prevent these issues before they impact public health.

What did the pandemic teach us about medical device shortages?

The pandemic highlighted how important medical devices are to our health care system and public health. The shortages hit hard, not only in PPE, but also for such critical devices as ventilators, test supplies, and even some of the equipment needed to administer vaccines. COVID-19 exposed the weaknesses in our national supply chain, particularly in terms of our dependence on devices and components imported from China and other countries. When devices go into shortage, patients everywhere are impacted, and U.S. public health suffers.



What is CDRH’s current authority to help address the shortages?

The CARES Act, enacted in March 2020, gave the FDA device shortages authority for the first time. It required certain medical device manufacturers to provide information to the FDA on product availability, and on potential meaningful supply chain disruptions, during or in advance of a PHE. Thanks to that authority, CDRH has been able to better understand and monitor the complex web of supply chains that feed the medical device industry, and to be more proactive in solving problems before they occur.

CDRH has been able to work closely with manufacturers to ease some shortages and prevent other potential shortages altogether. For example, CDRH worked with testing and diagnostics manufacturers to help ease shortages of resins that were the result of the 2021 Texas winter storm. This work helped avert disruptions and shortages in COVID-19 diagnostic test availability.



Won't the shortages end with the pandemic?

We all hope the worst of the pandemic is behind us. But new supply chain problems will continue to arise and threaten public health and safety in the months and years to come. Even before COVID-19, a hurricane caused widespread shortages of IV bags. And now, we're currently in the middle of a shortage for the plastic resins that are an essential material for a wide range of medical devices from tests to PPE. That shortage has been caused by weather events, not COVID-19.

Thanks to the authority from the CARES Act that requires manufacturers to notify the FDA of supply disruptions during or in advance of a PHE, CDRH has been closely monitoring these and other potential supply chain problems from the time they were first developing. As a result, we've recommended actions, such as those described in [CDRH's 2021 annual report](#), that have helped industry mitigate the potential damage. Because these problems occurred in the midst of a PHE, we received information from manufacturers about product availability and potential meaningful supply chain disruptions so that we could catch the problems early, and the nation might otherwise have been hit by more severe shortages that impacted patients and the public.

What will help prevent future shortages?

Dealing with medical device supply chain disruptions requires getting ahead of problems before they become serious shortages. The authority CDRH has had under the CARES Act has been critical to being proactive as new supply chain issues arose. At the beginning of the pandemic, before we had that CARES authority, we reached out to more than 1,000 manufacturers to request supply chain information, but only about one-third responded, and often incompletely, because the FDA's requests for this information were voluntary. As a result, we were forced to play catch up when shortages emerged.

Whether or not there is a PHE in effect, we need comprehensive authority to be kept informed by manufacturers on the state of their supply chains.

What additional authority will CDRH need?

To better protect public health, the statutory authority should be revised to require notifications from manufacturers to CDRH any time there is the potential for a device shortage (similar to the FDA's broader authority for drugs)—and not just during or in anticipation of a PHE. Without more comprehensive authority, our device supply chain and U.S public health remain at risk.

How do these authorities help industry?

The authorities granted to CDRH under the CARES Act have led to a highly productive collaboration between CDRH, manufacturers, and other partners to tackle supply chain vulnerabilities. For example, using this new authority, the FDA worked with manufacturers to plan for expedited marketing submissions, as well as helped increase device availability for products that were most needed for the COVID-19 response, including vaccine administration. With more comprehensive authorities, that collaborative effort could be enhanced and better protect the health of America's patients and health care workers into the future. The authorities are good for business, good for patients, and good for public health.