FDA STATEMENT

Statement on concerns with medical device availability due to certain sterilization facility closures

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Statement From:

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As the agency responsible for ensuring the safety and effectiveness of all medical devices, the U.S. Food and Drug Administration has been closely monitoring the supply chain effects of closures and potential closures of certain large-scale sterilization facilities that use a gas called ethylene oxide (/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices) to sterilize medical devices prior to their use. The recent closure of a Sterigenics ethylene oxide sterilization facility in Illinois, the temporary closure of another Sterigenics facility in Georgia, and the potential closure of a large Becton Dickinson sterilization facility in Georgia could affect the availability of some sterile medical devices used by health care delivery organizations and patients. We have been working diligently with impacted device manufacturers and health care delivery organizations to ensure that they are aware of these developments and preparing to minimize adverse effects on patients whose care could be negatively affected if medical devices sterilized at these large facilities were not accessible. Medical devices that are sterilized to remove potentially harmful germs and other microorganisms prior to use are critical to our health care system and a shortage—especially of life-saving, life-sustaining, or other critical devices—can be a detriment to public health. In light of the possibility of continued ethylene oxide sterilization facility closures, we are again alerting the public to growing concerns about the future availability of sterile medical devices and impending medical device shortages.

Although medical devices can be sterilized by several methods, ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections. More than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50 percent of devices that require sterilization.

Medical devices made from certain polymers (such as plastic or resin), metals, or glass—or devices that have multiple layers of packaging or hard-to-reach crevices—are likely to be sterilized with ethylene oxide to avoid product damage during the process. These include surgical kits used in emergency procedures such as emergency Caesarean sections (“C-sections”)

and in routine procedures such as cardiac surgery and hip or knee replacement surgeries. Without adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these devices and other critical devices including feeding tube devices used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts and other implantable devices. It's important to note at this time there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is critical to our health care system and to the continued availability of safe, effective and high-quality medical devices.

The FDA recognizes that there are concerns associated with release of ethylene oxide into the environment if emissions were to occur at unsafe levels. Concerns about ethylene oxide emissions have resulted in certain state actions against sterilization facilities that are currently impacting manufacturers' ability to use the ethylene oxide process to sterilize their medical devices. In February, the FDA became aware that the Illinois Environmental Protection Agency (EPA) issued a state EPA Order (https://www2.illinois.gov/Pages/news-item.aspx?ReleaseID=19717) to stop Sterigenics from sterilizing medical products and other products with ethylene oxide at their Willowbrook, Illinois, facility. The state EPA order was due to the presence of levels of ethylene oxide higher than the EPA found to be acceptable in the air around the facility. This closure caused a temporary shortage (/news-events/press-announcements/statement-jeff-shuren-md-director-center-devices-and-radiological-health-agency-efforts-mitigate) of pediatric breathing tubes.

Another Sterigenics contract sterilization facility, in Atlanta, Georgia, has been closed since August while it undergoes construction to reduce ethylene oxide emissions. In October, the Sterigenics Willowbrook, Illinois, facility announced they would not reopen. As a consequence of these two large sterilization facilities being unavailable, the FDA continues to coordinate with multiple stakeholders on any impacts to medical device availability and to communicate with Sterigenics and medical device companies that may be affected. Because the number of ethylene oxide contract sterilization facilities in the U.S. is limited, we are very concerned that additional facility closures could severely impact the supply of sterile medical devices to health care delivery organizations that depend on those devices to take care of patients. The impact resulting from closure of these and perhaps more facilities will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care.

This is why today we are urging medical device manufacturers that use ethylene oxide facilities to assess their inventory for any potential downstream impacts of sterilization facility closures on their product distribution. We are committed to working with manufacturers to look for alternative sterilization options. When manufacturers keep the FDA apprised of progress and obstacles encountered, it helps ensure that everyone's best efforts are being made to mitigate any shortages and prevent potential shortages. When U.S. manufacturers are not able to resolve

a shortage and it involves a critical device needed for U.S. patients, the FDA may look for a firm that is willing and able to redirect safe and effective product into the U.S. market to address a shortage.

We also encourage health care facilities to perform similar inventory assessments of critical medical supplies that undergo contract terminal sterilization via ethylene oxide prior to shipping and reach out to the FDA so we can assist in any way we can to help identify sources of potential substitute devices. Hospitals and other health care delivery organizations should also work with their purchasing departments, group purchasing organizations and distributors, as appropriate, to help obtain product needed for patient care. So as to not exacerbate anticipated product availability concerns, we urge facilities to work together and not hoard product or attempt to purchase larger quantities of devices beyond their normal purchase volume.

We also encourage device manufacturers and health care providers to provide (/vaccines-blood-biologics/safety-availability-biologics/how-report-product-shortage-or-supply-issue-fda) us with information on potential supply issues. We have a device shortages mailbox (mailto:deviceshortages@fda.hhs.gov) so that any user, patient, manufacturer, or organization within the supply chain that is aware of a delay in distribution of new product, and/or anticipates a shortage, can notify us. It's never too early to contact us – the sooner we are aware of a potential shortage, the better we can assist in proactively developing a plan to mitigate its effects on patient care.

Since we first became aware of this issue earlier this year, we have continued to focus intently on addressing the immediate impacts of these closures and potential closures to help ensure patients can have access to the safe, effective, and high-quality medical devices they need today. We continue to communicate directly with manufacturers and monitor the supply of devices sterilized in facilities that have closed or that may close, paying special attention to life-saving, life-sustaining, and other critical devices. For instance, in the case of Smiths Medical's Bivona tracheostomy breathing tubes that were processed at the now-closed Sterigenics facility in Illinois, we helped mitigate that shortage by helping the manufacturer get a timely site change that kept supply interruptions to a minimum.

We share the public's objective to reduce over-reliance on ethylene oxide for medical device sterilization. And therefore, in addition to our shortage mitigation efforts, we have also been addressing the broader need for innovation and improvements to medical device sterilization techniques in general. For example, earlier this year we announced two new innovation challenges (/news-events/fda-voices-perspectives-fda-leadership-and-experts/preventing-medical-device-shortages-ensuring-safe-and-effective-sterilization-manufacturing) to encourage ideas from stakeholders, academics, industry and others about novel solutions for improving sterilization processes. This includes a call to identify new or alternative sterilization methods and technologies that are alternatives to those that use ethylene oxide, and another to develop new strategies to reduce ethylene oxide emissions.

In addition, we've previously announced we're holding a public advisory committee meeting (/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee) on November 6 and 7, 2019, dedicated to discussing how best to encourage innovation in medical device sterilization. We also continue to collaborate with the U.S. EPA, the entity responsible for reviewing and enforcing Clean Air Act regulations for sterilization facilities that emit ethylene oxide to ensure that facilities protect the public from significant risks, providing the U.S. EPA with updates on FDA activities in this area. And we'll continue to update stakeholders and the public as new information becomes available.

We want to be clear that we understand that there are very real consequences that medical device shortages have on patients, and we're committed to doing everything in our authority to help mitigate the adverse patient impact these sterilization facility closures are expected to have. We're also calling on all stakeholders—manufacturers, contract sterilizers, government agencies and other public health advocates—to join us and do your part to avert new device shortages and ensure patients have access to important and life-saving medical devices.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- FDA: Ethylene Oxide Sterilization for Medical Devices (/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices)

- FDA: Ethylene Oxide Sterilization Facility Updates (/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates)

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