



December 6, 2019

U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Request for Comments on Ethylene Oxide Sterilization of Medical Devices [Docket No. FDA-2019-N-3793]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) regarding the use of Ethylene Oxide (EtO) to sterilize medical devices.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs work with healthcare providers to support a safe and reliable supply of healthcare products. We help ensure quality medical products at the best value for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA and its member GPOs have a unique line of sight over the entire healthcare supply chain – from raw materials to the manufacturing process for drugs and medical devices to their delivery to patients. Even seemingly minor disruptions to the healthcare supply chain could have significant consequences for patients. In that vein, we appreciate the Agency's efforts to seek feedback and input on this critical matter.

GPOs play a crucial role in helping hospitals and other healthcare providers prevent and mitigate product shortages. GPOs work collaboratively with hospitals, physicians, manufacturers, distributors, and government agencies to ensure that providers and patients have access to the life-saving products they need. GPOs help hospitals source and safely migrate to alternate products when shortages arise, track data on potential shortages, communicate with suppliers about product demand, evaluate supplier reliability when awarding contracts, and negotiate fair, volume-based prices with suppliers to enable cost-effective production. To help lessen hospital exposure to shortages, GPOs evaluate manufacturer reliability when sourcing and awarding contracts, and help providers establish best-practice purchasing procedures. And they work with suppliers to communicate provider needs in advance, so that manufacturers can plan their production capacity and avoid shortage situations.

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HSCA, its member GPOs, and our member healthcare providers are committed to ensuring patient safety while also taking into account important environmental considerations. We applaud FDA for taking steps to foster improvements to medical device sterilization processes, further interagency collaboration efforts, and work with facilities to reduce the healthcare industry’s use of Ethylene Oxide (EtO) for sterilization. We are concerned, however, that additional closures of some sterilization facilities and the potential closures of other facilities that use EtO to sterilize medical devices could have unintended consequences that result in a shortage of medical devices that are critical for patient care. As FDA continues to explore long-term solutions for medical device sterilization that also protects the nation’s public health, we encourage the Agency to consider access in the near term in light of current limited sterilant options.

EtO is used to sterilize more than 50 percent of all medical devices sterilized annually. Many medical devices – including pacemakers, heart valves, and breathing tubes – can only be sterilized through the use of EtO and would be rendered ineffective or unsafe if sterilized through other methods. Should sterilization facilities fail to meet the emissions standards, however, regulators are faced with responding by closing facilities to ensure meeting of health and safety standards. These closures could lead to a shortage in the number of available sterilized medical devices for patients across the country.

HSCA respectfully makes the following recommendations that expand on the steps that FDA is already taking to address shortages of sterilized medical devices:

FDA Should Ensure a Safe and Effective Replacement Exists Before Taking Steps to Reduce EtO Availability Impacting Sterile Device Availability

HSCA supports FDA’s efforts to encourage the exploration and development of alternative sterilization methods. While we are encouraged by the progress that has been made, including FDA’s recent announcement of the Ethylene Oxide Sterilization Master File Pilot Program, the length of time necessary for identifying, developing, testing, and implementing alternative solutions will still be extensive. As such, we urge FDA to examine alternative solutions before taking steps that would restrict EtO availability as a major sterilant to ensure uninterrupted patient care.

FDA Should Engage Public and Private Stakeholders to Enable Increased Coordination and Communication

As FDA itself has noted, adequately addressing shortages requires a multi-stakeholder effort. FDA should continue to work with both public and private stakeholders around medical device sterilization to understand concerns, incorporate important feedback, and pursue potential solutions. Engaging all relevant stakeholders, including agencies, policymakers, providers, manufacturers, wholesalers, GPOs, and others, will help enable increased visibility in the supply chain, facilitate timely information-sharing, and strengthen public and private collaboration efforts.

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We would invite FDA to seek input from GPOs and hospitals on the strategies and barriers to mitigating shortages due to closure of sterilization facilities; identify and track sterilization facilities that serve medical device manufactures and monitor excess capacity levels; and actively assess risks of specific medical device shortages in the event of cascading sterilization facility closures. Gathering information on the risk of shortages posed by specific facility closures will help inform FDA's efforts and help meet needs of the Agency and stakeholders to mitigate potential risk of nationwide shortages.

We commend FDA for its efforts to protect the nation's public health and ensure availability of sterilized devices for medical care. In that vein, we would also welcome further discussion with you on more specific solutions to support FDA efforts and transition of guidance and standards over the long term.

We thank you for the opportunity to provide our comments, and we look forward to continuing to work with the Agency to address medical device shortages and sterilization methods. We believe HSCA and its members GPOs can be a resource for FDA. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or info@supplychainassociation.org.

Sincerely,

Khatereh Calleja, J.D.
President & CEO
Healthcare Supply Chain Association

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