AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

A. Scott Whitaker
President and CEO
Direct :: 202 434 7200
swhitaker@advamed.org

January 18, 2023

President Joseph Biden
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

On behalf of the Advanced Medical Technology Association, the world's largest trade organization representing the medical technology field, I am writing on a critical public health matter: the update on emissions standards for facilities using ethylene oxide (EtO) to sterilize medical devices. We commend the Environmental Protection Agency for completing its proposed regulation and sending it to the Office of Management and Budget for review. We urge you to consider the following points as your Administration finalizes the regulation of the process sterilizing half of all medical devices — approximately 20 billion — in the U.S. each year.

We welcome the updated regulation. The EPA last updated EtO emissions standards for sterilization facilities in 2006, 16 years ago. Since that time, two states have enacted legislation on the issue, and an increasing number of states are considering following suit. State and local government subdivisions, such as California's 35 local air districts, also regulate the facilities. As a result, companies face shifting regulatory thresholds and uncertainty. In August 2022, the EPA named 23 facilities as elevating potential cancer risk to community members under a conservative "worst-case scenario." Those limitations and caveats were largely lost in resulting media coverage and community reaction, which is understandable, given some of the alarming and confusing verbal messages from the agency in its community meetings.

Medical technology producers' number-one priority is improving patient health, and that includes the public health as well. We ask the EPA to carefully reconsider language that might unreasonably alarm residents near sterilization facilities. When a facility is in compliance with all applicable regulations, in the absence of updated federal regulations, and regularly reducing emissions even more than required, and risk projections are based on highly conservative modeling rather than actual data, the public condemnation from a federal agency is unfair and undeserved.

We would ask that you consider the potential threat to patient care if any sterilization facilities shut down. With 20 billion medical devices sterilized using EtO each year in the U.S. at about only 100 facilities,[i] [ii] the closure of even a small percentage of facilities could harm patient access to health care. EtO sterilization is at capacity. With 80 percent of surgical kits alone sterilized using EtO, any shutdown-induced disruption could reverberate from screening to the operating room to post-operative care.

A prior closure of just one facility caused a temporary shortage of pediatric breathing tubes, according to the FDA. [iii] The FDA has expressed standing concern about medical device availability if facilities close. [iv]

As the population ages, demand for medical devices is increasing. Pandemics have continued and will continue to create unanticipated needs. If domestic facilities shut down, the only options for the millions of devices sterilized with EtO would be sending them overseas for EtO sterilization, then shipping them back, or redesigning them entirely and seeking FDA approval for the new products with their new sterilization method, including sterility assurance.

Each option would harm supply levels, cause delays in patient care, and increase health care costs. Relying on overseas sterilization would disrupt a stable U.S. domestic function and risk turbulence with volatile partners and markets.

We call on the EPA to embrace technology-neutral solutions to meet new emissions targets. EtO sterilization is a highly controlled engineering process. Multiple technologies could be necessary to achieve regulatory goals. Methods that are too prescriptive might foreclose options that would keep the facilities open and operating safely while serving American patients nationwide.

We ask the EPA to consider background EtO levels in ambient air and the tiny proportion of that represented by medical device sterilization EtO use. It is important to recognize that EtO emissions have numerous sources, many possibly far less studied, measured, or controlled than emissions from commercial sterilizers. Medical device sterilization uses half of one percent of commercially produced EtO. The gas is a building block for multiple commercial products. Emissions are byproducts of ubiquitous community and household items: combustion engines, lawn mowers, fire pits, charcoal grills, and gas generators. While the EPA "is not yet certain about exact background EtO levels due to uncertainty with current measurement methods," the agency nonetheless singled out medical device sterilization facilities for public scrutiny. In fairness, the agency also says it "considers EtO critical for sterilizing medical equipment and necessary to protect public health," a view the FDA shares. [v] [vi]

It is also important to note that there are no alternative sterilization methods for a substantial portion of medical devices. Other methods would destroy and render

unusable certain devices, such as those made of plastic, or would be unworkable for devices with interior chambers or two surfaces in contact with each other, such as the piston and barrel of a syringe. Where alternatives are possible, a number of medical technology firms will continue to work with the FDA to explore alternatives. Our field will continue to pursue best practices in reducing EtO emissions well beyond local, state, and federal requirements.

Thank you, Mr. President, for your consideration. AdvaMed and our members look forward to continuing to communicate with the White House, the EPA, and the FDA about this life-saving aspect of the U.S. health care system and answering any questions as we work together on this issue.

Sincerely,

Scott Whitaker

CC: Office of Public Engagement

---

[i] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

[ii] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-commercial-sterilization-facilities

[iii] https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures

[iv] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

[v] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/what-epa-doing-address-ethylene-oxide-and-learn-more-about

[vi] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization