AdvaMed
Advanced Medical Technology Association

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March 14, 2023

Honorable Brian Feldman
Chair, Education, Energy, and the Environment Committee
Maryland State Senate
2 West
Miller Senate Office Building
Annapolis, MD 21401

RE: SB 916 (Beidle) – Opposed

Dear Senator Feldman:

AdvaMed, the Advanced Medical Technology Association, appreciates the opportunity to provide comments regarding SB 916 (Beidle).

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our more than 450 members range from small, emerging companies to large multinationals and include traditional device, diagnostic, and digital health technology companies.

AdvaMed respectfully opposes SB 916. This bill risks disrupting patient access to life-saving medical devices by banning the use of ethylene oxide (EtO) in Maryland. EtO sterilization of medical devices is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments. Both the U.S. Food and Drug Administration (FDA), which regulates medical device safety and effectiveness, including sterility assurance, and the Environmental Protection Agency (EPA), which regulates EtO emissions in the air, agree EtO is a critical medical device sterilization method.[1,2] Notably, the U.S. EPA is finalizing regulations in the coming weeks on the emissions controls for, and use of, EtO by commercial sterilizers.[3]

We share the bill sponsor's commitment to mitigating any hazardous pollutants found to pose a threat to the community. Our industry is continually identifying how it can lessen its impact on the environment, including reducing its use of EtO and

[1] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[2] https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information
[3] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/what-epa-doing-address-ethylene-oxide-and-learn-more-about

developing novel sterilization methods to replace it where appropriate.[4] However, according to the FDA, "other methods of sterilization cannot currently replace the use of EtO for many devices."[5]

EtO occurs naturally in addition to its commercial production and uses. There are several known emitters, including humans (from our breath), plants (living and decaying), school bus engines, and gas generators.[6] EtO has been detected at higher levels in a remote state park – far from any known commercial sterilizer facility – than just outside of a commercial sterilizer facility.[7] While using only half of one percent of all commercial EtO, commercial sterilizers have drawn more attention than other EtO users. Commercial sterilizers serving the medical device industry are governed by extensive regulatory obligations at every level of government. The new EPA regulation could preserve this critically important aspect of the health care system while reassuring community members of the safety of the facilities sterilizing medical devices with EtO.

EtO is used to sterilize approximately 50 percent of all medical devices – 20 billion – in the United States each year, including surgical kits, heart valves, and pacemakers, and is the only viable modality for many devices.[8] Other methods destroy or render these critical medical devices unusable. The appropriate sterilization method is determined during the concept and design phase of a device. Manufacturers opt to use the sterilization method for each device that meets design specifications, FDA requirements, patient safety, and the large-scale demand for devices, all without impacting device functionality.

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO-sterilized devices and equipment to protect millions of patients from the real risks of infection caused by bacteria, viruses, and fungi. For example, Maryland has 11,374 hospital beds and 26,201 professionally active physicians serving Marylanders.[9] When any of the 6.2 million residents of the Old Line State seek

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[4] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[5] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[6] https://www.advamed.org/industry-updates/policy-issues/sterilization-ethylene-oxide/
[7] https://epd.georgia.gov/document/document/eto-data-through-042821pdf/download
[8] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[9] https://www.kff.org/statedata/custom-state-report/?i=458128%7C24284bec~32444%7C24284bec~32446%7C24284bec~32448%7C24284bec~32450%7C24284bec~32452%7C24284bec~459977%7C24284bec~32772%7C2d11dde6~32486%7C2d11dde6~32771%7C2d11dde6&g=md&view=3

health care treatment, they deserve and receive treatment with sterile medical equipment, achieved in large part through sterilization with ethylene oxide.[10]

Any disruption in the availability of sterile medical devices and supplies could lead to delays in patient care – an outcome disastrous to patient safety, the daily practice of medicine, and overall public health in the United States. According to Marcus Schabacker, MD, PhD, President and CEO at the ECRI Institute, "If there's an ubiquitous ban on ethylene oxide today, we're going to have a health crisis on our hands, because in very short time and order, sterile products won't be available, and we don't have an alternative to replace that today."[11]

EtO sterilization facilities are subject to comprehensive emissions control rules, including the federal Clean Air Act and other EPA-enforced laws on emissions. The U.S. EPA is finalizing regulations on the emission control for EtO pertaining to commercial sterilizers, as well as for its labeling and use. The EPA has conducted extensive stakeholder engagement and outreach, over the course of several years, in developing this rule. This rule will likely result in significant upgrades to commercial sterilizers, in addition to what has already been done in recent years. AdvaMed supports EPA in this effort.

EtO sterilization is a highly regulated process, and device manufacturers, hospitals and third-party sterilizers must follow rigorous controls established by EPA, OSHA and other government agencies (including state and local entities) to protect patients, workers and the environment.

Federal regulations and international guidance on emissions, residuals and worker safety allow for the safe and responsible use of EtO to sterilize medical products. Device manufacturers and sterilizers capture, remove, and destroy EtO. In a recent Modern Healthcare piece, Dr. Lucy Fraiser, a Board-Certified Toxicologist, said, "If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions. The emissions from the facilities are that small and getting smaller all the time, as new capture technology becomes available, and facilities buy it and install it."[12]

In sum, SB 916 is unnecessary and could have the unintended effect of inhibiting medical care to Maryland patients.

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[10] https://msa.maryland.gov/msa/mdmanual/01glance/html/pop.html
[11] https://www.advamed.org/industry-updates/policy-issues/sterilization-ethylene-oxide/
[12] https://www.modernhealthcare.com/opinion/feedback-medical-device-sterilization-ethylene-oxide-emissions

Some additional information is attached to this testimony, including:

- More information on the role of EtO sterilized devices in infection prevention;
- Additional detail on the types of medical devices sterilized on EtO; and
- Commentary from an expert providing context on EPA modeling and data.

Thank you for the opportunity to provide comments today.

Sincerely,

Bobby Patrick
Vice President, State Government and Regional Affairs
AdvaMed

cc: Senator Pam Beidle, Maryland State Senate

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EtO Sterilization Prevents Infection

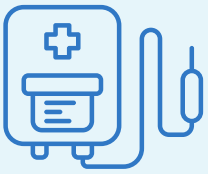
Americans are admitted to the hospital 33.4 million times[i] and visit doctors 1.0 billion times per year.[ii]

82.3 percent of adults and 91 percent of children see a health care professional each year.[ii]

That care requires billions of pieces of sterile medical equipment: syringes, catheters, and surgical tools.

33.4 M
hospital admissions

1.0 B
doctor visits



20 B
devices sterilized with EtO

Approximately half of those devices – 20 billion – are sterilized in the United States each year with ethylene oxide (EtO).[iii]

EtO is safe and proven effective to achieve FDA-required sterility.

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- That millions of patients experience medical care without life-endangering infection is the product of modern science, including EtO.
- Infections that do occur can be extremely dangerous.
- Sepsis, for example, is "a medical emergency ... that can lead to tissue damage, organ failure, and death." [iv]

Sepsis causes the deaths of

350,000 adults

each year in the United States. [v]

For survivors, it can cause amputations or result from amputations. [vi]

Antimicrobial resistance is another compelling reason to fight infection.

More than 2.8 million antimicrobial-resistant infections occur in the United States each year, causing more than 35,000 deaths. [vii]

MRSA, or methicillin-resistant Staphylococcus aureus, is a bacteria that is resistant to several antibiotics. It can cause bloodstream infections, pneumonia, or surgical site infections.

> **If left untreated, MRSA infections can become severe and cause sepsis—the body's extreme response to an infection.** [viii]

The Bottom Line

Health care providers fight infection around the clock. Their challenge would be far steeper without EtO, carefully controlled and regulated and the only sterilization option for many medical devices. The need for sterile medical equipment will only increase as the population ages, antibiotic-resistant infections proliferate, and health care professionals seek to keep patients safe.

[i] http://bit.ly/3KdqP1B
[ii] http://bit.ly/3Is74lo
[iii] http://bit.ly/3xpiDDP
[iv] http://bit.ly/3KaDPF9
[v] http://bit.ly/40YZDJM
[vi] http://bit.ly/3I6qCdU
[vii] http://bit.ly/3YQByD0
[viii] http://bit.ly/3EdAbX0

Ethylene Oxide's Invaluable Role In Protecting Public Health

Ethylene Oxide (EtO or EO) is a colorless gas used commercially in a wide variety of ways, including the production of textiles, personal care items, and the sterilization of medical devices, cosmetics, and spices. EtO is one of the most common ways to sterilize medical devices, which is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments.

Approximately 50 percent of all medical devices are sterilized with EtO, and for many of those, it is the only available option.

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these products, EtO sterilization is the most effective and efficient—and often the only viable—sterilization technology. The gentle yet thorough nature of EtO allows for the sterilization of many critical medical technologies and devices that would otherwise be destroyed and rendered unusable by other sterilization methods.

Many medical devices cannot be sterilized by methods other than EtO for the following reasons:

> Gamma and e-beam radiation can make plastics brittle, or cause certain non-woven materials to literally disintegrate

> Steam is high temperature and will melt plastics and/or damage products sensitive to heat and/or moisture

> Hydrogen peroxide and gas plasma are intended for small-scale, surface sterilization only and cannot penetrate devices that have interior chambers or two surfaces that are in contact with each other (e.g., piston and barrel of a syringe)

EtO also has the unique ability to penetrate packaging and plastic without damaging them and effecticely sterilize otherwise hard-to-sterilize product configurations (e.g., inside tubing, products that have two touching surfaces, connectors, etc.).

Medical Devices that Require EtO Sterilization:

> Fiberoptic endoscopes
> Specula
> Surgical kits
> Syringes
> Sutures
> Catheters
> IV sets
> Plastic tubing
> Inhalation therapy supplies
> Surgical telescopes
> Anesthesia masks and circuits
> Renal peritoneal dialysis sets
> Renal hemodialysis sets
> Tubing sets/bloodlines
> Gowns and drapes
> Heart valves
> Pacemakers
> Surgical drills
> Pumps
> Respirators
> Electrical equipment
> Uterine monitors
> Surgical staplers
> Diagnostic electrode catheters

Source: AdvaMed member companies

In addition to the high level of efficacy that EtO provides, it is highly compatible with a wide variety of medical device materials of construction, enabling medical device companies to manufacture many devices that would not be possible without EtO. The high level of performance and effectiveness of medical devices when sterilized by EtO is well understood. If EtO could not be used for sterilization of healthcare products, there would certinly be significant, and likely disastrous, adverse public health consequences. Elimination of this sterilization technology would introduce the real risks of increased morbidity and mortality.

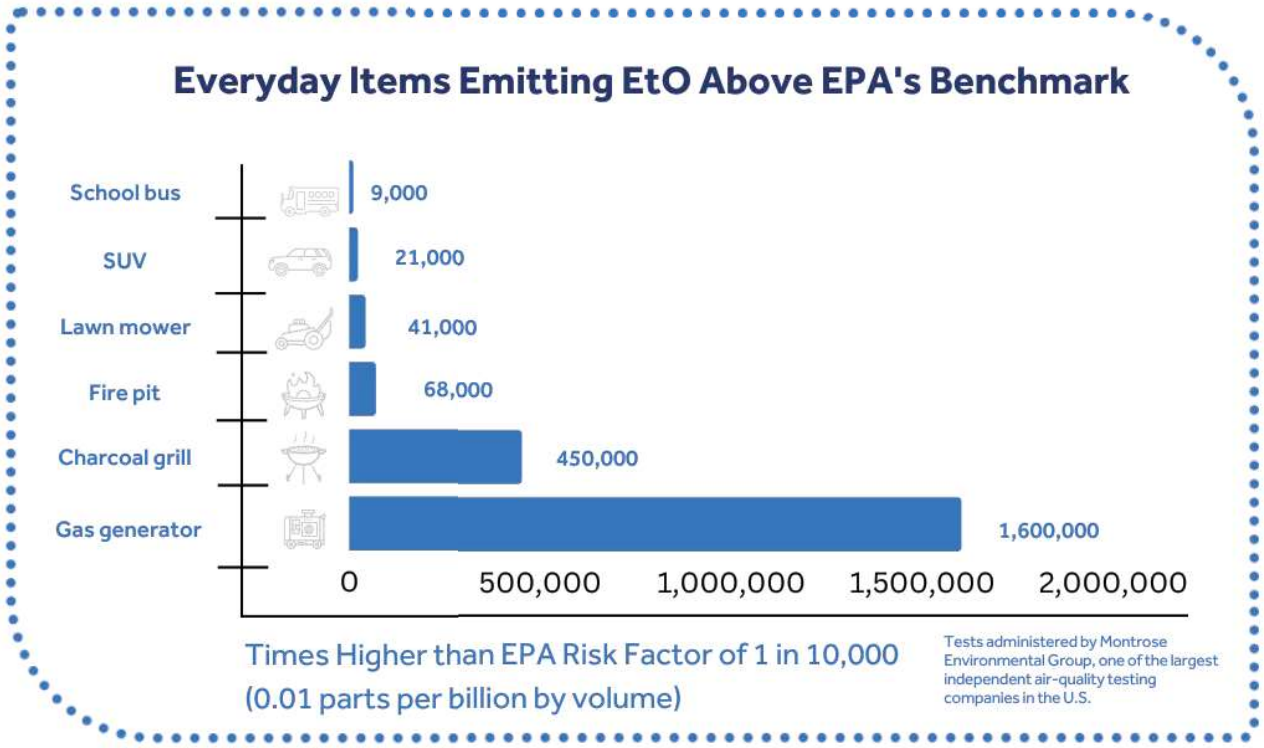
Strict government regulation controls EtO use in the U.S. FDA and other global regulators play an important role in ensuring that manufacturers' sterilization methods are properly validated. FDA regulations, guidance, and harmonized international standards include provisions that address the use of EtO and other sterilants for medical devices. Manufacturers must conduct exhaustive studies to demonstrate that the required sterility assurance levels are achieved by the process and to confirm that exposure to the sterilization process does not adversely affect the device's performance, safety, or effectiveness.

Manufacturers must comply with FDA's Quality Systems Regulation (QSR) relative to the methods used in, and facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices. This includes the use of contract sterilization firms, as the contract sterilizers are considered vendors and part of the regulated manufacturing process.

An international standard (ISO 11135:2014) specifies requirements for the development, validation, and routine control of an EtO sterilization process for medical devices in both the industrial and health care facility settings.

Under the Clean Air Act, the U.S. Environmental Protection Agency (EPA) sets limits on certain air pollutants. The EPA has set emission standards for EtO under the National Emission Standards for Hazardous Air Pollutants (NESHAP) rule, which applies to commercial sterilization operations. In addition, the U.S. Occupational Safety and Health Administration (OSHA) sets permissible EtO exposure limits for workers under the Toxic and Hazardous Substances rule. State permitting rules and enforcement also apply.

Manufacturers' finished products must meet global standards for device bicompatibility testing and assessment of EtO residuals remaining on the finished product post-sterilization. These requirements ensure patients and health care providers are not exposed to unacceptable levels of chemical residues from the sterilization process. Changing sterilization methods or making process changes requires manufacturers to reestablish product biocompatibility through repeat studies.



Modern Healthcare

Letter to the Editor: Article on device sterilization didn't provide the complete picture

LUCY FRAISER, PH.D | BOARD-CERTIFIED TOXICOLOGIST

OCTOBER 17, 2022

As a toxicologist, I have followed the Environmental Protection Agency's (EPA) work on ethylene oxide (EtO) closely, and I am concerned about how the recent article titled, "A Dirty Business: How the medical device sterilization process sickens some to heal others," portrays the EPA's findings on the sterilization of medical devices using EtO. Inaccurate, incomplete information about EtO can have dangerous repercussions for patient access to safe medical devices across the country. It can unnecessarily scare community members about their health.

This article fails to disclose that the EPA uses a "worst-case scenario," the agency's own phrase, of continuous exposure, for 70 years, 24 hours a day, a highly unlikely scenario, in its estimate of EtO's cancer risk.

The EPA emphasizes that its own models for estimating the safety of ethylene oxide are just that, models, not actual readings outside a commercial sterilization facility. The EPA also doesn't consider background air levels of EtO, so emissions from sources other than commercial sterilization facilities aren't a factor in its calculations, even though sterilization plants are far from being the largest source of EtO.

If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions. The emissions from the facilities are that small and getting smaller all the time, as new capture technology becomes available, and facilities buy it and install it.

> **"If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions."**

Modern Healthcare seeks to inform its readers but reporting without context or clarity is more harmful than useful. Your publication should present the full story on this issue going forward.

Lucy Fraiser is a board-certified toxicologist (Diplomate of the American Board of Toxicology) with over 30 years of experience.

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