

October 21, 2019

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

***Re: Docket No. FDA-2019-N-3793 General Hospital and Personal Use Devices  
Panel of the Medical Devices Advisory Committee; Notice of Meeting;  
Establishment of a Public Docket; Request for Comments***

Dear Sir/Madam:

The Advanced Medical Technology Association (AdvaMed) provides these comments in response to a request regarding the Food and Drug Administration (FDA or “Agency”) Center for Devices and Radiological Health Federal Register notice “General Hospital and Personal Use Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments”; Federal Register Volume 84, Number 171 (Wednesday, September 4, 2019).

AdvaMed is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

Safety is critical to the medical technology industry. AdvaMed member companies’ commitment to safety extends not only to the patients we serve through the development and manufacture of life-changing medical devices, but also to the health of the tens of thousands of workers, engineers, and scientists we employ and to the communities where they live, work and raise their families. AdvaMed member companies make every effort to ensure their devices are safe and effective throughout the product lifecycle, including during the design, development, production, distribution, deployment and maintenance of the device. For many devices, sterility is essential to ensure its safe and effective use.

Ethylene Oxide (EtO) gas is the most common way to sterilize medical devices, a process that is critical for preventing infections and ensuring patients have safe surgeries and medical treatments. Since its discovery as an effective sterilant in 1938, EtO has played a



critical role in the sterilization of medical devices. Decades later, EtO is now used to sterilize more than 20 billion health care products each year in the U.S. alone. This represents more than 50 percent of all medical devices sterilized annually.

For many medical devices, due to their material composition, size, shape or complexity, EtO is the only effective method for sterilization. EtO provides the ongoing capacity and scale to process the billions of medical devices required by today's modern health care systems in delivering care to patients. Heart valves, pacemakers, implantable cardioverter/defibrillators, drug-eluting stents, feeding tubes and breathing tubes, surgical drapes and kits, and syringes are just a few of the many products critical to modern patient care that can only be sterilized using EtO. Ethylene Oxide's compatibility and effectiveness with the plastics and polymers commonly used in medical products allows for the sterilization of many medical devices that would otherwise be rendered ineffective or unsafe if sterilized by radiation, moist heat, dry heat, or other alternative methods.

For example, radiation, which is used to sterilize approximately 45% of devices used in hospitals, has also been available for decades and is, in general, a much faster method than use of EtO and, therefore, more desirable in meeting hospital needs. Despite this advantage, due to material compatibility constraints, radiation has not replaced EtO as the preferred method of sterilization.

FDA and other global regulators play an important role in assuring that manufacturers' sterilization methods are properly validated to ensure their safety and effectiveness. FDA regulations, guidance and harmonized international standards have provisions that address the use of EtO and other sterilants for medical devices. Medical device manufacturers have invested in microbiologists, sterility assurance experts, process safety and environmental engineers; and industrial hygienists who have worked for decades to ensure that they have standards and controls in place to responsibly manage the use of EtO. Manufacturers must conduct exhaustive studies to demonstrate that the required sterility assurance levels are achieved and maintained by their equipment and processes, and to confirm that exposure to the sterilization process does not adversely affect the device's performance, safety or effectiveness over the shelf life of the device.

At the same time, AdvaMed member companies are committed to further reducing the amount of EtO used for effective sterilization processes by actively exploring methods and processes that reduce the amount of EtO used for a sterilization cycle. The industry is committed to investigating alternative sterilization methods that will provide the same sterility assurance and result in the same device performance as EtO. Until there is a safe and effective replacement for EtO, we will continue to pursue our goal to reduce the amount of EtO used. Optimizing the EtO process itself, the medical device packaging and the approach to validation are examples of possible ways to minimize the amount of EtO sterilant necessary to sterilize devices.

However, none of these potential solutions can be achieved quickly or easily. Any change to minimize EtO use, if even feasible, would likely require extensive product and/or process modifications; validation and verification testing; potential facility upgrades; and required notifications, clearances and approvals from FDA.

In summary, AdvaMed member companies are committed to the safe and effective use of EtO for the sterilization of certain medical devices for which there is currently no acceptable alternate method. This commitment extends not only to the patients we serve but to the tens of thousands of workers, engineers and scientists we employ. We strive to be not only good corporate citizens but also responsible and conscientious members of our respective communities, because where we work is also where we live. We are also committed to reducing the amount of EtO needed for an effective sterilization cycle, thereby reducing the amount of EtO that must be abated. We will continue to research alternate sterilization methods and implement them once they are proven to be safe, effective and feasible. We look forward to working with FDA and other stakeholders on this important public health issue.

Sincerely,

/s/

Ruey C. Dempsey  
Vice President  
Technology & Regulatory Affairs