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

RE: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee); Request for Comments; Docket FDA-2019-N-3793

Dear General Hospital and Personal Use Panel of the Medical Devices Advisory Committee:

I write on behalf of the Health Industry Distributors Association (HIDA) in response to the above-referenced Notice of a public meeting and request for information published in the Federal Register on September 4, 2019.

HIDA is the trade association representing medical products distributors, all of which deliver medical products and supplies, manage logistics, and offer customer services to more than 294,000 points of care. HIDA members primarily distribute items used in every day medical services and procedures, ranging from surgical kits, to catheters, as well as gauze and gloves. Their customers include over 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the country, as well as numerous federal agencies and their healthcare facilities. Member companies differ by size, market, and specialty, but they share a focus on providing solutions that support patient care, enhance efficiency, and help providers manage total costs.

It is important that policymakers understand the complexities of device sterilization in order to protect patients, circumvent unintentional supply chain disruptions and avoid product shortages. Any change to policies that impact the ability to sterilize needs to be done in a thoughtful manner, ensuring a viable alternative path and a realistic timeline so patient care is not disrupted.

HIDA members share a close relationship with our manufacturer partners and together we ensure the many medical devices that go through distribution and ultimately come in contact with patients and healthcare providers are both safe and effective. Part of that process is ensuring their sterility, a critical component in preventing infections and ensuring the integrity of the device.

HIDA recognizes that the task of studying and implementing proper safety guidelines on a process this complex and with an impact on an industry as critical as ours. Approximately 50% of all medical devices are sterilized with EtO, accounting for more than 20 billion devices annually. Due to material sensitivities, EtO is the only option for sterilizing a large number of life-saving and life-enhancing devices, primarily those made of plastics or containing electronics, that cannot tolerate exposure to the extreme temperatures, radiation and moisture present in other sterilization methods.

The effect of steam and radiation on anti-microbial coatings on single-use plastic devices makes them an unacceptable alternative. Material integrity and degradation and damage to sensitive, sophisticated electronic devices and their components are also major concerns. Given the sensitive nature of the devices and the sterilization involved, the entire process is regulated by the FDA - where the use of EtO has been validated as a vital sterilization process.

As a low-temperature sterilizer, ethylene oxide gas won't damage the types of medical devices described below. Ethylene oxide also is used to sterilize other health care products such as bandages and ointments, reducing potential damage to the product that may occur from other means of sterilization.

Examples of Medical Devices that Require EtO Sterilization

Surgical kits	Catheters	Inhalation Therapy Supplies
Syringes	IV Sets	Surgical Telescopes
Sutures	Plastic Tubing	Anesthesia Masks

The FDA plays an important role in assuring that manufacturers' sterilization methods are properly validated and that distributors are delivering a safe and effective product. FDA regulations and guidance is very specific in addressing the use of EtO and other sterilants for medical devices. Our manufacturing partners conduct exhaustive studies to validate 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.

HIDA is profoundly concerned about a host of unintended consequences – such as product shortages and the inability to sterilize critical healthcare products. These would likely arise for the healthcare supply chain and the patients they serve as a result of any swift change in policy regarding the use of currently approved sterilization techniques.

Most devices sterilized with EtO have no acceptable alternative, putting the supply chain at significant risk without this vital mode of sterilization. Banning or heavily restricting the use of EtO would require the identification and validation of an alternative method, which currently does not exist. Additionally, it may require the redesign of many medical devices, and many products would require major changes to product design, material selection, manufacture and distribution – all regulated by FDA. The redesign process could take several years and require lengthy regulatory approval. The direct impact of any elimination or severe restriction would potentially threaten the entire health care system, as low product inventories and severe backorders of sterile single-use devices could result, putting patients at risk.

HIDA commends the agency for proceeding in a manner aimed at transparency and which encourages the greatest possible degree of public comment and participation. We are committed to working together to find the best way forward for the health and safety of countless patients across the country.

We urge FDA to work closely with HIDA and the rest of our industry partners to better understand the sterilization process, existing safety protocols, material limitations and the fragility of the supply chain with regards to sterilization needs. Our principal focus is on preventing a host of unintended consequences and ensuring that distributors are continuing to deliver a safe and effective product to our customers and the patients they treat. We look forward to working with FDA in whatever manner possible to ensure a safe and secure supply chain going forward.

Thank you for your consideration of HIDA's views. If you have any questions, I can be reached at 703.838.6125 or rouse@hida.org. We look forward to working with the agencies in the weeks and months to come.

Respectfully,

Linda Rouse O'Neill
Vice President, Government Affairs
Health Industry Distributors Association (HIDA)