



September 24, 2018

Mr. Andrew Wheeler
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20004

Dear Acting Administrator Wheeler:

I am writing on behalf of AdvaMed members regarding the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry's Aug. 21 report concerning Sterigenics International Inc. in Willowbrook, Illinois. As you consider responding to the recent report, we ask that you please keep in mind the effect that any long-term disruption of ethylene oxide sterilization would have on patient access to life-changing technology.

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, and health information systems. Together, our members, most with fewer than 100 employees, support nearly 2 million jobs nationwide, produce \$150 billion in direct economic output, and manufacture much of the life-enhancing health care technology available in the United States and around the world.

At its core, our industry shares in your mission to protect and advance the human condition, and we support the Agency's mission to ensure safe environments for all Americans. Our members have invested hundreds of millions of dollars to improve workplace safety and environmental health. Through the implementation of new technology, our members have continued to reduce employee exposure and emissions of toxic substances to facilitate compliance with current OSHA and NESHAP regulations. We are equally committed to guaranteeing safe devices for patients, as well as a safe environment for manufacturers' employees and their surrounding communities.

Ethylene oxide (EtO) is critical to ensuring the safety of devices for clinicians and patients, and we understand that EtO's application as a sterilant for health care products accounts for less than 1% of all EtO usage globally. Many of our members

manufacture devices that cannot be sterilized by other means due to their complex nature, including pacemakers, implantable defibrillators, and combination products (devices that contain drugs). The Willowbrook Sterigenics facility, like many EtO sterilization process plants, is the sole sterilization facility for a number of medical device types. A disruption in production at this facility would halt sterilization of those products and result in an abrupt stop in the supply chain for those devices. Identifying a different facility, filing for use, and validating sterilization cycles at that facility can take months. This cessation could result in limited access to critical medical technology for millions of patients and lead to poorer health outcomes.

In 2014, AdvaMed expressed concerns to the EPA regarding the Agency's risk estimates of ethylene oxide and the Integrated Risk Information System (IRIS) Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (revised external draft-August 2014). Along with the American Chemistry Council and the Ethylene Oxide Sterilization Association Inc., we questioned the reliability and accuracy of the assessment and omission of several studies deemed relevant by the Science Advisory Board. It is our understanding that this IRIS assessment is the basis for the concern raised with regard to the Willowbrook Sterigenics facility.

We have the utmost respect for the Agency and know that it will act in the best interest of the environment and all Americans. In doing so, please consider the essential role the Willowbrook Sterigenics facility, and EtO in general, holds in the medical technology supply chain. Closure of this plant could affect access to important devices and thousands of Americans who benefit from medical technology.

Thank you for your attention to this matter

Sincerely,



Scott Whitaker
President & CEO
AdvaMed

CC: US Health & Human Services Secretary Alex Azar
US Food and Drug Administration Commissioner Scott Gottlieb

