EOSA **The Ethylene Oxide Sterilization Association, Inc.**
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October 3, 2018

Via E-Mail

The Honorable Lisa Madigan
Attorney General
State of Illinois
100 West Randolph Street
Chicago, IL 60601

Re: Recent Developments Regarding Ethylene Oxide Sterilization

Dear Madam Attorney General:

The Ethylene Oxide Sterilization Association, Inc. (EOSA) is a non-profit organization that advances the interests of a diverse community of ethylene oxide (EO) suppliers, in-house and contract sterilizers, sterilization equipment manufacturers, medical device manufacturers, analytical equipment and systems suppliers, and laboratories. We write to express our urgent and grave concerns over the recent developments surrounding EO sterilization and specifically, the Sterigenics Willowbrook, Illinois, facility.

Since its discovery as an effective sterilant in 1938, EO has played a critical role in the sterilization of medical devices and pharmaceutical products that protect the general public. Decades later, EO is now used to sterilize more than 20 **billion** (20,000,000,000) healthcare products each year in the U.S. alone. This represents a significant portion of all medical devices sterilized annually. EO sterilization is critical in the safe delivery of sterile devices to the healthcare field, and is essential to a functioning and effective healthcare system. The use of EO sterilization provides unparalleled benefits to society.

Applicable EO sterilization practices have been approved by the U.S. Food and Drug Administration (FDA) for use in the healthcare industry. The Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) have developed consensus-based standards that are recognized and enforced by FDA. The U.S. Occupational Safety and Health Administration (OSHA) also developed its workplace standard for EO. The OSHA standard addresses matters such as permissible exposure limits (PEL), monitoring, engineering controls, and compliance. Sterilization facilities utilize emissions control and abatement systems to assure compliance with all regulatory standards. By following these standards, hospitals and commercial sterilization facilities are well equipped to ensure the safe and effective use of EO sterilization in compliance with all public health and environmental requirements.

The Medical Device industry relies heavily on the use of EO to assure that its products are sterile and, therefore, safe for use in the millions of medical procedures performed every day. In Illinois, over 3,000,000 surgical kits are assembled per year. Of these, 63 percent are sterilized in the state using EO. Over 600,000 of those kits are used by hospitals throughout the state.

There is currently no other validated method for sterilization of these kits. EO's unique profile and its ability to penetrate materials such as plastics without causing damage to the material makes

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it indispensable to the medical industry. It is recognized and used world-wide as the primary mode of product sterilization.

Furthermore, capacity for EO sterilization in the U.S. is extremely limited. Shutting down an operation in the State of Illinois does not mean there is available capacity to transfer that volume of product to another location. Other constraints, such as the requirement by FDA to validate sterilization cycles at each specific location, also hinder the ability to shift volume to other locations.

Shutting down EO sterilization would, without question, cause a severe and immediate harm to public health and cause a public health crisis. The lack of sterile medical supplies to the Operating Room would result in delayed or even cancelled procedures, which would almost certainly pose grave risk to those in urgent medical need. These supplies are used in virtually every surgical procedure performed.

There is a strong body of evidence refuting the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) assessment and the reclassification of the safety profile of EO. We strongly urge the Attorney General to review all of the evidence related to this situation, and ask that outreach be conducted to industry experts in toxicology, statistics, and other areas that recently performed the critical evaluation of the IRIS assessment so their direct input may be obtained. We also urge you to reach out to the medical healthcare community to gain further perspective on the critical nature of the EO sterilization operation. We ask that the Governor of Illinois and the Attorney General's office ask the National Academy of Sciences to review the flawed science behind EPA's IRIS assessment of EO.

We trust that the Illinois Attorney General will review the facts carefully and make the right decision for the good of the public whose health will be at risk if these critical sterilization facilities are shut down. If you have any questions or require additional information from EOSA, please contact its Executive Director Jake Vandevort at jvandevort@bc-cm.com or its legal counsel Lynn L. Bergeson at lbergeson@lawbc.com.

Sincerely,

Jake Vandevort

Jake Vandevort
Executive Director
The Ethylene Oxide Sterilization Association, Inc.

cc: Governor Press Secretary Patty Schuh (via e-mail)
Illinois Environmental Protection Agency Director Alec Messina (via e-mail)
Attorney General Chief of Staff Ann Spillane (via e-mail)
Attorney General Chief of Environmental Enforcement Matt Dunn (via e-mail)