R.R.REICH TESTIMONY SUBMITTED TO THE ILLINOIS HOUSE ENVIRONMENTAL COMMITTEE REGARDING BILLS HB5983 AND HB5985 AND THE ILLINOIS SENATE ENVIRONMENT AND CONSERVATION COMMITTEE REGARDING BILLS SB3630 AND SB3640 NOV 13 -14, 2018

My name is Bob Reich, and this written testimony is regarding House bills HB 5983 and 5985 concerning the critical issue of allowing continued ethylene oxide (EO) usage in the medical industry. I would like to emphasize that I do not support or defend any particular company, but am instead providing insight into the irreplaceable nature of EO in medical product sterilization. I am a microbiologist with over 40 years of experience working in the medical device and pharmaceutical industries. During my career, I have worked extensively with EO in various capacities:

- My career started with Castle Company (now Getinge) who manufactured sterilization equipment, including industrial and hospital EO sterilizers.
- After Castle, I worked for a company called Ethox. Ethox was a contract manufacturer of numerous types of medical devices. Ethox also offered contract EO sterilization at two different locations for which I was responsible.
- For the last 25 years I have worked as a consultant to the medical device and pharmaceutical industries. I founded a company called LexaMed 13 years ago. The focus of the company is microbial control, including all forms of terminal sterilization modalities, including EO.
- I am a past co-chair of the Association for the Advancement of Medical Instrumentation (AAMI) Industrial EO Sterilization Sub-committee and have authored over 75 articles and book chapters related to microbiology and sterilization.
- I am currently a visiting professor at Shanghai Tech where I am presenting courses on Quality Systems for medical devices and sterilization technologies, including EO.

Based on my background, I am qualified to competently comment on EO sterilization practices utilized in the medical industries, including control technologies.

The public is entitled to all **the factual data** available from EPA concerning the potential environmental and health effects of exposure to EO. There has been a great deal of undue anxiety generated by the media coverage and the current public conversation regarding EO. This has also resulted in inciting emotional responses from the public and unjustified reactionary responses from regulators.

The recent headlines and articles fail to document the significant and irreplaceable health care benefits of EO sterilization. Currently, more than 50% of all single-use medical devices manufactured world-wide are sterilized with EO. Additionally, there are approximately 400 hospitals that utilize EO as their sole low-temperature gaseous sterilization process. The loss of EO would have potentially catastrophic public health consequences, including:

- A compromise of hospital aseptic processes with a resultant increase in Hospital Acquired Infections (HAI).
- A probable significant increase in health-care costs
- Shortages of critical health care devices
- Increased loss of life due to improperly sterilized devices or the unavailability of needed devices.

Additionally, it should be emphasized that the medical sterilization facilities under current question all meet the required federal EPA requirements for the control of EO emissions and the OSHA requirements for worker EO exposure and are actively working with EPA and working internally on enhancing control measures. These requirements were established scientifically based on risk to the environment and the public.

I have read suggestions that hydrogen peroxide is a viable alternative to EO as a medical device sterilant. That, unfortunately, is not the case. I have worked with and performed research and published articles on hydrogen peroxide as a medical device sterilant:

- H2O2 does not have the penetrating capacity of EO and works primarily as a surface sterilant.
- Product therefore could not be sterilized in its final shipping configuration as currently performed with EO. Current industrial sterilization processes would have to be modified (if this were even possible), greatly increasing the processing time and personnel involvement while also increasing device costs.
- H2O2 is not as stable as EO and can not be used to sterilize products contained in shipping cartons as the corrugated carton (and other organic materials) will cause the decomposition of hydrogen peroxide rendering it ineffective as a sterilant. This would require additional handling of product after sterilization with H2O2 to complete packaging operations, adding to contamination risk and cost to the consumer.
- There are no hydrogen peroxide units scaled up for commercial sterilization application. As a reference scale, EO sterilization is often performed in chambers that would hold 24 pallets or more of product – with chambers the size of a garage.

There are no available viable alternatives to the use of EO for the sterilization of medical products. Other low temperature gaseous sterilization processes suffer from the same limitations as hydrogen peroxide and are not conducive to processing medical products in bulk shipping containers or in the presence of cellulosic materials. Nitrogen dioxide (oxides of nitrogen), peracetic acid and hydrogen peroxide all have niche medical device sterilization applications, but are not candidates to replace the broad sterilization application of EO.

Any legislator or decision-maker would be compromising our current health care system by summarily eliminating EO as a sterilant. The challenge of the medical device industry is therefore to educate the public and legislators to the significant and undeniable benefits of EO as a medical product sterilant as well as continuing to work with federal and state regulators to

develop rational approaches to improve the control of EO emissions if warranted by sound scientific data. Please do not ignore 60 years of science and successful EO medical device sterilization and risk significant public health consequences by banning the use of EO as a medical sterilant. A cooperative collaboration between the medical device industry, regulators and the public can result in a mutually agreeable mitigation strategy that will preserve human safety while allowing the continued use of EO as an irreplaceable medical device sterilant.

Thank you for your time and consideration.

November 12, 2018

Robert R. Reich

President, LexaMed LTD