

Medline Calls For National Academy Of Sciences Review

Scientific Studies Discredit Flawed IRIS Report on Ethylene Oxide Use in Sterilization of Critical Medical Supplies



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NORTHFIELD, Ill., Nov. 13, 2018 /PRNewswire/ -- *Attributed to Lara Simmons, Medline Group President, Quality Assurance and Regulatory Affairs*

Medline cares deeply about the health and safety of our employees and the communities where we live and work. We produce, package and distribute a variety of critical medical supplies, including sterile surgical packs that contain all of the disposable items necessary for a wide range of procedures – from tonsillectomies, C-sections and knee replacements to liver transplants and open-heart surgeries.



Worldwide, EO is the primary way to sterilize medical supplies. Current safety practices for the use of EO have been rigorously examined and proven safe in at least 13 scientific studies over the past 40 years. This industry-standard, FDA-recognized process currently is the only way to sterilize approximately 50 percent of critical medical products—specifically, complex devices that have connectors or materials that are not compatible with any other method of sterilization.

Current safety practices for the use of ethylene oxide (EO) have been rigorously examined and proven safe in many scientific studies for decades. EO sterilization is an industry-standard, FDA-recognized process that currently is the only way to sterilize many critical medical products—specifically, complex devices that have connectors or materials that are not compatible with any other method of sterilization.

Worldwide, EO is the primary way to sterilize the surgical procedure packs that are critical to our health care system in providing safe and timely patient care and operating room efficiency.

Any disruption of EO sterilization facilities would cause a near-immediate public health crisis. Illinois hospitals would lose access to sterilized medical packs needed for life-saving surgeries. The enormous disruption in the supply chain would put catastrophic impact on Illinois' hospital system. Hospitals would be forced to cancel surgical procedures and even shut down operating rooms. Critical care facilities with high volumes of emergent surgeries would be impacted immediately. Conducting non-sterile surgeries is not an option for obvious patient risk and hospital liability.

We have listened to recent concerns about EO sterilization, which stem predominantly from the 2016 EPA staff Integrated Risk Information System (IRIS) report, which the scientific community has strongly criticized as inconsistent with overwhelming evidence and widely accepted research supporting the safe use of EO. The report is a staff-level working document that has come under a great deal of scrutiny and was formally challenged under the

Information Quality Act (IQA), which requires federal government agencies to employ sound science in making regulations and disseminating information. Given that activity, we believe that additional thoughtful deliberation and scientific review is necessary.

Medline is calling for the National Academy of Sciences (NAS) to conduct an independent review of EPA's IRIS report to determine the facts on EO and provide recommendations, if needed. The NAS is a private, nonprofit society of distinguished scholars established by an Act of Congress charged with providing independent, objective advice to the nation on matters related to science and technology.

Additionally, Medline has engaged Dr. M. Jane Teta, a nationally-renowned epidemiologist with expertise in EO, as an independent consultant to advise us on the existing scientific research on this topic. Dr. Teta has publicly stated:

"The EPA's 2016 report is flawed. Their risk estimate is an overestimation inconsistent with other studies published over a 40-year period and they came to a totally different conclusion than the National Institute of Occupational Safety and Health (NIOSH) did based on the same study."

Dr. Teta explains that the EPA's flawed assessment is misleading and greatly exaggerates the health risk:

"The levels of EO naturally produced by the human body and the levels exhaled in human breath are hundreds if not thousands of times greater than the minute exposure level that EPA calculates as posing a risk to humans."

Challenges to the integrity of the IRIS assessment also call into question the updates made to the National Air Toxics Assessment (NATA) map it prompted. The misleading NATA map has been misinterpreted by many – to be clear, it does NOT reflect incidence of cancer. Rather, the NATA map uses the questionable IRIS risk value, limited data and computer models to estimate areas of elevated cancer risk. The EPA does not, in the IRIS report or any of its reports, track actual incidence of cancer based on its risk projections. Further, the EPA's own webpage

says, "NATA wasn't designed to be a final tool for assessing risks. Because of its national scale, it has some limitations in data and methods. Some of these will cause NATA to report higher risk estimates for an area than may truly exist."

EO is naturally emitted by plant decay, animal waste on farms, some cooking oils when heated over 300 degrees, and compost. It also is found in auto exhaust, sewage plants and cigarette smoke. Our bodies also produce EO as part of the normal metabolic process, and normal human breath carries EO at a level hundreds of times over the new level suggested by the IRIS report.

Medline has always focused on safety first. Everything we do is about advancing the health of people in Illinois and around the world. Medline will continue our ongoing work with regulators and experts to ensure the safety of our products and operations. We are dedicated to studying the latest scientific research and continuing to evaluate any new technology that can further protect our employees and the community.

We look forward to continuing conversations with community members and elected officials regarding our shared commitment to public health. Restricting or outlawing EO in Illinois would risk shutting down thousands of operating rooms each day, impacting countless patients who depend on sterile surgical supplies.

For more information, visit the Medline Newsroom.

About Medline

Medline is a global manufacturer and distributor serving the healthcare industry with medical supplies and clinical solutions that help customers achieve both clinical and financial success. Headquartered in Northfield, Ill., the company offers 550,000+ medical devices and support services through more than 1,600 direct sales representatives who are dedicated points of contact for customers across the continuum of care. For more information on Medline, go to www.medline.com or www.medline.com/social-media to connect with Medline on its social media channels.

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