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THE TRUTH ABOUT ETHYLENE OXIDE

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The chemical ethylene oxide has gained notoriety recently, needlessly alarming many people. It earned the spotlight simply because the math used to estimate its potential risk was changed, putting it unnecessarily in the public and media crosshairs.

As a result, news articles suggest ethylene oxide is causing cancer in people who breathe it. Inexplicably, the articles single out two medical sterilization plants in Covington and Smyrna as potential sources of the problem. That has raised anxiety levels among citizens of these communities, who now fear a new cancer threat.

As a scientist, I don't believe I've come across a worse example of distorted truths, magical thinking and manipulated public opinion in my 40-year career in government, academia, the private sector, at the National Academy of Sciences and as a volunteer.

Because of my vast experience as a toxicologist, I have been asked by the Advanced Medical Technology Association to provide clarification on the issues directly to the public.

No doubt, scientific truths are desperately needed in the public dialogue. The most important truth being, there is no cancer threat from the tiny amounts of ethylene oxide released from these sterilization plants.

The backstory on the new math begins with the U.S. Environmental Protection Agency (EPA). Ethylene oxide is suddenly getting attention because an office within the EPA changed the way it calculated the amount it considers safe to breathe. No new science was used, just new math. Whether that change was justified is debated by scientists.

If valid, the new calculation means that the amount of ethylene oxide that we make normally in our bodies is almost 20,000 times higher than what would be considered safe to breathe. It would mean that the average amount of ethylene oxide normally found in urban and suburban air, including areas with no sterilization plants, is about 5,000 times higher than would be considered safe.

While it makes sense for the EPA to overestimate how dangerous a substance might be in the interest of protecting public health, comparisons like these suggest that the validity of the new calculation needs a reality check.

Due in part to the disagreement in the scientific community about this new calculation, the U.S. EPA hasn't used the new number to regulate anything. The number is over 5 million times more stringent than the scientific judgments underlying all other regulatory limits on ethylene oxide in the U.S. and worldwide.

Regrettably, Georgia's Environmental Protection Division (EPD) appears to have acted precipitously, adopting the newly calculated number in its ongoing modeling of emissions from the two medical device sterilization facilities. Given the level of serious debate around the new calculation, it is simply irresponsible for the Georgia EPD to use it in their modeling or decision-making.

In fact, the cancer risk estimates for ethylene oxide – or any other substance, for that matter – are not real numbers. They are not scientific or mathematical calculations of actual cancer risk. They are useful for comparing – but not predicting – risks. They do not mean that some number of people who live near ethylene oxide plants are getting, or are going to get, cancer as a result.

Risk estimates are worst-case, conservative over-estimates that are useful for setting priorities and guiding decisions about the best ways to minimize risk. Again, in the case of ethylene oxide, the risk estimates do not suggest people are getting cancer, but no one could argue with all efforts to minimize emissions.

Meanwhile, what are the residents of Covington and Smyrna supposed to think? Based on everything they've been reading, they're led to believe their air is unsafe, they are facing an elevated cancer risk, and that sterilization plants are at fault. They are angry and scared, and who could blame them?

They trust the state to give them the truth, but they can't hear officials now admit there is no direct link from these facilities to cancer because the state inadvertently pulled the alarm that began this trauma.

Some politicians have exacerbated the misunderstandings by calling for sterilization plant closures. But this will not safeguard the health of Covington and Smyrna residents because everyday ethylene oxide exposure occurs from many organic and industrial sources. (In fact, just 0.5% of the ethylene oxide usage in the U.S. is for medical device sterilization.)

The role of chemicals in modern life is complicated, especially with naturally occurring organic compounds such as ethylene oxide. People who worked in ethylene oxide plants for decades and breathed a lot of it every day for a very long time did not get cancer at a higher rate than people who never worked in such plants. Living near sterilization facilities and breathing low levels of ethylene oxide from a broad range of sources, including what we make in our own bodies, is not affecting cancer rates.

In closing, some might suggest my views should be discounted because I have worked for industry. The fact is, I have also worked for non-profits and government, including as director of the Toxicology and Risk Assessment Program at the National Academy of Sciences/National Research Council and as executive director of the Presidential/Congressional Commission on Risk Assessment and Risk Management during the administration of President Clinton.

I adhere to the facts and the science, wherever they take me.

Gail Charnley, Ph.D., a toxicologist and principal at HealthRisk Strategies LLC, in Washington, D.C. Charnley is an internationally recognized scientist specializing in environmental health risk assessment and risk management science and policy, who studies the relationship between environmental exposures and public health outcomes. She is a lifetime fellow and a past president of the international Society for Risk Analysis. She holds a bachelor's degree in biochemistry from Wellesley College and a Ph.D. in toxicology from the Massachusetts Institute of Technology.

Paid for by the Advanced Medical Technology Association

Medela LLC

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Dear Speaker Madigan,

Medela LLC ("Medela"), headquartered in McHenry, Illinois, appreciates the opportunity to write to you regarding proposed legislation to restrict or ban the use of ethylene oxide (EO) in Illinois to sterilize critical medical devices.

We respectfully oppose HB 3888 and HB 3885 because their restriction to EO use would lead to the inevitable elimination of EO sterilization in the state and will likely lead to further restrictions in other states. This process is essentially irreplaceable in its effectiveness to combat infection in hospital surgical settings, and is an essential step for Medela to support the most medically fragile in the Neonatal Intensive Care Unit (NICU).

Medela is one of the world's leading advocates for breast milk with a focus on babies' health and nutrition. Medela supports babies receiving mothers' milk early in life by providing research-based products together with clinical education. Every year, over one million mothers in the U.S. rely on our technology. From our McHenry offices, Medela has proudly served hospitals and American families for nearly 40 years, and employs more than 700 full-time personnel across the nation. Our company is fully dedicated to supporting mothers in providing breast milk to their babies for as long as they choose.

The sterilization process that is required for medical device companies is a critically important step to ensure the efficacy of our products for use in the neonatal and hospital environments. We currently sterilize millions of pieces of medical devices at the Medline facility in Waukegan, Illinois and it is our primary sterilizer after the shutdown of Sterigenics earlier this year. While we do have backup suppliers in qualification, the capacity at remaining sterilizers is a major concern for Medela and many other medical device manufacturers dependent on this process.

Medela serves more than 80% of U.S. hospitals and NICUs with sterile breast milk pumping kits, neonatal enteral feeding devices, sterile containers for breast milk and specialty feeding devices used in the NICU. Sterilization is the clinical standard of practice in the NICU to keep dangerous bacteria from appearing and affecting our most vulnerable infants.[i] Ethylene oxide is the recommended sterilization process used on medical devices because many product materials used do not withstand other sterilization methods. It has been reported that failure to comply with sterilization guidelines has contributed to outbreaks associated with contaminated medical devices and surgical instruments.[ii]

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Before any additional action is taken on EO, the General Assembly needs to recognize the considerable impact such actions would have on hospitals across the country, the care of our most vulnerable populations in the NICU, as well as the Illinois companies that depend upon the use of EO to serve customers nationwide, which includes our most medically fragile infant populations.

Thank you for your consideration.

Sincerely,

Melissa Gonzales
Executive Vice President of the Americas
Medela LLC

[i] Polin, R. A., Denson, S., & Brady, M. T. (2012). Strategies for Prevention of Health Care–Associated Infections in the NICU. *Pediatrics*, *129*(4). doi: 10.1542/peds.2012-0145

[ii] Sydnor, E. R. M., & Perl, T. M. (2011). Hospital Epidemiology and Infection Control in Acute-Care Settings. *Clinical Microbiology Reviews*, *24*(1), 141–173. doi: 10.1128/cmr.00027-10

Medical Device Societies Letter to FDA

On October 21, six leading medical groups sent a letter to FDA urging caution as regulators consider limiting the use of ethylene oxide for medical device sterilization.

October 21, 2019

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments in advance of the Medical Devices Advisory Committee Meeting, Docket # FDA-2019-N-3793

Dear Members of the General Hospital and Personal Use Devices Panel:

The American College of Cardiology (ACC), American Society for Gastrointestinal Endoscopy (ASGE), the Heart Rhythm Society (HRS), the Society for Cardiovascular Angiography and Interventions (SCAI), the Society of Interventional Radiology (SIR), and the Society of Thoracic Surgeons (STS) offer the following comments in advance of the Medical Devices Advisory Committee meeting on November 6 and 7, 2019 to help inform the advisory committee's deliberations regarding industrial ethylene oxide (EtO) sterilization of medical devices and its role in maintaining public health.

The undersigned medical organizations support efforts to minimize employee risk as well as reduce the environmental impact of sterilants through the minimization of emissions and exposure to EtO. When appropriate and feasible, the organizations support the substitution of toxic medical sterilants with less toxic medical sterilization alternatives.

However, as the Food and Drug Administration (FDA or Agency) has previously acknowledged, many complex medical devices, including but not limited to pacemakers and leads, angioplasty balloons, cardiac catheters, stents, and guiding sheaths, and other supplies and equipment used in the care of cardiovascular patients currently rely upon EtO for proper sterilization to ensure patient safety. These complex medical devices currently have limited alternative sterilization processes available while others are suboptimal. Therefore, when considering the overall impact of regulatory changes, the organizations urge the Agency to ensure continued patient access to critical devices as well as to minimize increased patient costs.

The organizations also acknowledge the complexity and cost with replacing the sterilization process. Given that the FDA mandates that medical device approval applications for these complex devices contain appropriate data to support the required sterilization process, not only would a new process need to be developed, but the process would also need to be tested and validated in each medical device. Thus, any shift would require an appropriate period to develop the necessary protocols, test those protocols, then replicate them throughout various supply chains with an acknowledgement that these additional steps will likely increase costs to our

patients. For these reasons, we urge caution in considering limitation of the use of EtO for medical device sterilization until there is a feasible action plan in place to ensure appropriate patient access to critical medical devices. The organizations also encourage the FDA to continue to work with other relevant agencies such as the Environmental Protection Agency (EPA) to investigate innovative ways to sterilize medical devices with lower levels of currently used agents, and employ less toxic agents or alternatives, while maintaining medical device safety and effectiveness.

We look forward to further communications with you on this important topic. Should you have any questions, please contact Laura Blum Meisnere, Vice President, Health Policy, Heart Rhythm Society at lblum@hrsonline.org or Joseph Cody, Associate Director, Research and Innovation Policy, American College of Cardiology at jcody@acc.org.

Sincerely,

Richard Kovacs, MD, FACC
President, ACC

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ADVAMED PRESS RELEASE

October 28, 2019

ADVAMED: NEONATAL PRODUCTS PROVIDED TO 80 PERCENT OF U.S. HOSPITALS THREATENED BY POTENTIAL MEDLINE SHUTDOWN

WASHINGTON – AdvaMed president and CEO Scott Whitaker today released a statement on efforts to close Medline's ethylene oxide (EO/EtO) medical device sterilization plant in Waukegan, Ill. Tomorrow, the Illinois state legislature's House Energy and Environment Committee is holding a hearing at 2:30 p.m. CT to discuss legislation that would force hospitals and sterilizers to phase out the use of EtO.

Medela LLC, headquartered in McHenry, Illinois, today wrote to Illinois state house speaker Michael Madigan saying they "respectfully oppose HB 3888 and HB 3885 because their restriction to EO use would lead to the inevitable elimination of EO sterilization in the state and will likely lead to further restrictions in other states. This process is essentially irreplaceable in its effectiveness to combat infection in hospital surgical settings, and is an essential step for Medela to support the most medically fragile in the Neonatal Intensive Care Unit (NICU)."

According to the March of Dimes, in a typical week in the state of Illinois, 2,970 babies are born and 299 are born prematurely.

Whitaker said: "The shutdown of Medline's sterilization plant in Waukegan will likely have a direct and devastating effect on the patients who are served by 135 Illinois hospitals as well as millions of patients across the country who depend on the safe, clean and critical surgical devices Medline sterilizes – including the most vulnerable newborns in NICUs nationwide."

Friday, the U.S. FDA announced that the agency is concerned about medical device shortages in light of two recent closures of ethylene oxide sterilization plants and the possibility of future plant closures. FDA acting Commissioner Sharpless said, "Without adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these devices and other critical devices including feeding tube devices used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts and other implantable devices. It's important to note at this time there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is critical to our health care system and to the continued availability of safe, effective and high-quality medical devices." See AdvaMed's statement on the FDA announcement.

And last week, six leading medical groups sent a letter to FDA urging caution as regulators consider limiting the use of EtO for medical device sterilization, warning that without EtO sterilization, many medical devices on the market – including those used in critical emergencies – would become unavailable to the patients who need them. Read AdvaMed's statement on the surgeons' letter.

Medical device sterilization techniques utilizing EtO are essential to ensuring the safety of more than 20 billion medical devices every year, approximately 50 percent of all devices sterilized annually. Without this sterilization method, millions of patients simply will not have access to critical, life-saving and life-sustaining treatments.