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Op-ed: Risk, Regulation, and Reality Checks

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The over one million deaths from COVID-19 should teach us what a real risk to public health looks like. Another lesson is the importance of having a reliable and readily available supply of medical and personal protective equipment to help contain a pandemic. Unfortunately, both lessons are currently being undermined by the U.S. Environmental Protection Agency's (EPA's) hugely disproportionate portrayal of the alleged public health risk from the ethylene oxide gas used to sterilize much of that equipment. EPA appears to have created a problem where there was none.

Fifty percent of all medical devices are sterilized with ethylene oxide in the United States each year; according to the U.S. Food and Drug Administration (FDA), there is no effective substitute for sterilizing many of those. While EPA's recently proposed rules to limit ethylene oxide emissions from sterilization facilities might decrease the amount emitted, they will certainly not meaningfully reduce the extent to which people are exposed to ethylene oxide.

Ethylene oxide is ubiquitous in the air we breathe; sterilization facilities in compliance with current laws contribute only a very small fraction of the ethylene oxide that people already breathe. Ethylene oxide comes from many natural and industrial sources. In fact, just one half of one percent of the ethylene oxide used in the U.S. is used for medical device sterilization. The rest comes from other commercial sources and from automobile exhaust, food preparation, consumer products, decaying plants—and from our own bodies where we make it naturally and then exhale it. Today, by far, the largest source of ethylene oxide exposure is our own bodies, accounting for over ninety percent.

Of course, controlling ethylene oxide emissions from sterilization facilities makes sense, and rules have been in place for decades to do just that. The new rules are being proposed because a few years ago, EPA recalculated the potential cancer risk from ethylene oxide and concluded that it's a lot more dangerous than previously thought. That conclusion was not based on new science, but on new calculations and old science.

According to EPA's analysis, the ethylene oxide exposures that were mathematically associated with higher-than-expected cancer rates were as much as one hundred thousand times higher than what we make in our bodies. In other words, the exposure that was needed to mathematically increase cancer risk was the size of one to ten elephants, while the amount we're exposed to from our own bodies is the size of one cat, comparatively speaking. Meanwhile, the amount that EPA says is "safe" is the size of an ant. EPA did not acknowledge the presence of the cat when making its ant calculation. And while it might make sense for EPA to overestimate how dangerous a substance might be, in the interest of protecting public health, comparisons like these suggest that a reality check is needed.

Basing regulations to restrict sterilization plant emissions on ant-sized risks when there's an elephant in the room defies scientific (and any other form of) common sense. Simple logic suggests that the amount of ethylene oxide we should start to worry about is the amount that represents a detectable increase when added to the amount being made by our own bodies.

The fact that our own bodies produce ethylene oxide might raise its own question of risk. In fact, we can handle the amounts of ethylene oxide and other substances made by our own bodies because humans have evolved ways to protect ourselves from potential insults, whether made by our bodies or introduced from the environment. Our DNA, for example, is constantly undergoing spontaneous mutation. Every cell has enzymes that monitor DNA and can repair it when mistakes are found, whether spontaneous or chemically induced. When our cells' repair mechanisms are overwhelmed by, for example, too much exposure

to a potential carcinogen, the body's capacity for repair might be exceeded. In that case, a cell might escape its normal controls and turn into a cancer cell. If that cell is not detected and destroyed by our immune systems, it might develop into a tumor.

How much is too much exposure? It depends. EPA's new calculation says the amount of ethylene oxide that is too much is two thousand to twenty thousand times lower than the amount we exhale normally. Additional exposure to such a comparatively small amount of ethylene oxide would be meaningless in terms of actual risk because it's not detectable, either biologically or analytically. But that's the calculation on which EPA's new proposed rules for sterilization plants are based.

Meanwhile, EPA's revised risk estimate for ethylene oxide has already provoked two real problems: an imminent threat of personal protective equipment and sterile medical equipment shortages, and understandable outrage and panic among residents of communities near sterilization plants that have been classified as unsafe using EPA's biologically meaningless estimate of risk. In fact, when measured, very few of those neighborhoods have ethylene oxide levels significantly greater than those in neighborhoods with no sterilization plants.

The result of EPA's greatly exaggerated portrayal of ethylene oxide's risk is that people in communities near sterilization facilities are needlessly, but understandably, worried about their risks from cancer. It is unconscionable to warn people about undetectable risks misrepresented as real risks. Chemical contaminants pose a negligible public health risk compared to, for example, tobacco, alcohol, diet, firearms, motor vehicles, and microbes. That is in part due to EPA's diligent efforts to regulate chemical contaminants over the last fifty years. But now, devoting proportionately more and more of our limited resources to controlling smaller and smaller risks seems difficult to justify. EPA's mission might better be served by focusing more on areas that still need its help, such as water quality and habitat preservation, and less on undetectable chemical risks.

Dr. Gail Charnley is an internationally recognized scientist specializing in environmental health risk assessment and risk management science and policy. She has more than 40 years of experience in the biological, chemical, and social policy aspects of environmental and public health protection, writing and speaking extensively on issues related to the roles of science and risk analysis in environmental and public health risk management decision-making. Dr. Charnley focuses on strategic analysis and risk communication of complex scientific and regulatory issues to both nontechnical and scientific audiences. She works primarily on the safety of chemicals in food, environmental media, work environments, and consumer products. She has testified frequently on Capitol Hill and to many state and foreign legislative and administrative bodies. She has been the scientific spokesperson for a variety of organizations to print and television media. She has served on the National Academy of Sciences Board on Environmental Studies and Toxicology, the Board of the Environmental Law Institute, and on numerous peer review panels convened by the Environmental Protection Agency, the Food and Drug Administration, and Health and Welfare Canada. From 1994-1997 she was executive director of the Presidential/Congressional Commission on Risk Assessment and Risk Management, mandated by Congress to evaluate the roles that risk assessment and risk management play in federal regulatory programs. Before her appointment to the Commission, she served as director of the Toxicology and Risk Assessment Program at the National Academy of Sciences/National Research Council. She is a lifetime fellow and a past president of the international Society for Risk Analysis, for which she has also served as the first Sigma Xi distinguished lecturer. She holds an AB in biochemistry from Wellesley College and a PhD in toxicology from MIT.

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