

THE TRUTH ABOUT ETHYLENE OXIDE

GAIL CHARNLEY, PH.D.

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 .05% 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.