July 29, 2026

Dr. Rima Woods
Chief, Air Toxicology and Risk Assessment Section
Office of Environmental Health Hazard Assessment
1001 I Street, 12th Floor
Sacramento, CA 95814

Dear Dr. Woods:

On behalf of AdvaMed, Biocom California, and California Life Sciences, we appreciate the opportunity to provide comments on OEHHA's draft cancer inhalation unit risk (IUR) factor for Ethylene Oxide (EtO). Our organizations represent the companies that develop lifesaving, life-enhancing medical technology innovations for patients nationwide and around the world. Many of our members use and rely on ethylene oxide (EtO) as an essential infection prevention measure to sterilize the critical equipment used in surgeries, testing, and other life-changing medical care.

While OEHHA's draft IUR is a scientific assessment, it will serve as the foundation for future regulatory actions across California. As a result, the conclusions reached in this process will have significant downstream implications for medical device sterilization facilities and, ultimately, patient access to sterile medical technologies. Given these far-reaching consequences, it is critical that the final IUR reflects the best available science.

The medtech industry is committed to protecting and improving public health. In fact, we have long supported updates to emissions standards as knowledge and technology have evolved. We have consistently reinforced that regulations must be scientifically sound and grounded in the best, most current available science. The medtech industry has worked alongside the FDA and EPA on federal standards that achieve product sterility for patients while also protecting the health of employees at sterilization facilities and the communities around those facilities.

EtO sterilized devices can be found in many healthcare procedures from a standard blood draw during an annual physical to a complex surgical procedure such as open-heart surgery. EtO sterilization is crucial for preventing infection in patients. Medical device sterilization represents a tiny fraction of commercial use of EtO, representing only half of 1 percent of all commercial use, yet it sterilizes half, or 20

billion, of all medical devices used in the U.S. every year.

As EPA itself recognizes, it is the only effective, viable sterilization method for many medical devices. For these sensitive and intricate devices, there is no existing alternative method for sterilization. EtO allows for the sterilization of many critical medical technologies and devices that otherwise would be destroyed or unsafe by other sterilization methods as they would not be able to ensure sterilization without affecting the integrity and function of the device. Disruption to critical sterilization of medtech would prevent the use of many lifesaving technologies that have advanced medical care over the past 50 years. At the same time, as an industry we have been and will continue to advance alternatives where possible for safe and effective sterilization solutions that can meet the demands of patient care. To date, however, there is no viable alternative to replace EtO for the full range of devices that depend on it.

Medical device manufacturers have a responsibility to ensure that devices reaching patients are safe, effective, and appropriately sterilized. Millions of surgeries, outpatient procedures, hospitalizations, and diagnostic tests depend on sterile medical technologies. Maintaining reliable sterilization capacity is therefore essential to ensuring healthcare providers have timely access to the devices patients rely upon every day.

EtO sterilization facilities are already at capacity in the U.S. because of high demand for sterile medtech in our healthcare system. Thus, taking even a few facilities offline, or abrupt or otherwise infeasible implementation, could jeopardize the timely availability of medtech and cause delays in patient care. The FDA has also emphasized the importance of maintaining sterilization capacity to help prevent shortages of critical medical devices.

Given the importance of ensuring the final IUR reflects the best available science, AdvaMed requested an independent scientific review analysis from Board Certified Toxicologist Dr. Lucy Fraiser. Dr. Fraiser provides a thorough review of the science used by the U.S. Environmental Protection Agency's (EPA) to develop its most recent Integrated Risk Information System (IRIS) standard for EtO – which serves as the basis for OEHHA's IUR for EtO. Notably, Dr. Fraiser points out that the EtO IRIS is set magnitudes below ambient levels of EtO. Adopting this standard, and its resulting use in regulations across California, could jeopardize public health through disruptions and delays in medical care.

Our members remain committed to working collaboratively with OEHHA and other regulatory agencies to protect community health while ensuring patients continue to have access to safe and effective medical technologies. We urge OEHHA to

consider our feedback and revise the draft IUR to ensure the final value reflects the best available science while protecting public health.

Sincerely,

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