

## Comments from Gaet Tyranski, Synergy Health

I am writing to express my significant concerns and objection to the Chemical Assessment Advisory Committee (CAAC) for the Integrated Risk Information System (IRIS) **Evaluation of the Inhalation Carcinogenicity of the Ethylene Oxide**, and the potential to disrupt EO processing or raise pricing significantly. Noting:

- EO sterilization plays a critical role in protecting the public health and the safe delivery of sterile devices and medical care;
- The current draft IRIS assessment will have significant adverse health impacts on the safe delivery of sterile devices and medical care; those who use EO to sterilize healthcare products, including increased risk of infection through inadequate sterilization; effective, impractical alternatives with significant adverse public health impacts;
- The IRIS assessment, as currently written, could force users to switch to less effective, impractical alternatives with significant adverse public health impacts;
- EO is the most widely used sterilization method for medical devices;
- Numerous medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect patients from the real risks of infectious disease;
- Many critical healthcare products can only be sterilized by EO, in some cases due to the heat or radiation sensitive nature of the components or the internal design of the device;
- EO sterilization is critical in the safe delivery of sterile devices and medical care;
- EO sterilization has led to the advancement and evolution of numerous delicate and complex medical devices and healthcare products, many of which can only be sterilized by EO; and
- A change in sterilization technology could introduce risks of medical device and complex medical devices and healthcare products, many of which can only be sterilized by EO; and integrity and biocompatibility that may exceed the currently known risks of EO sterilization.

Thank you for your consideration.

**Gaet Tyranski**  
**President, AST – Americas**  
Synergy Health  
401 E. Jackson Street, Suite 3100  
Tampa, FL 33602