

November 20, 2014

Via E-Mail (Yeow.Aaron@epa.gov)

Mr. Aaron Yeow  
Designated Federal Officer (DFO)  
Science Advisory Board Staff Office  
U.S. Environmental Protection Agency  
1200 Pennsylvania, Avenue, N.W.  
Washington, D.C. 20460-4164

**Re: Comments to the Chemical Assessment Advisory Committee for the Integrated Risk Information System Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft -- August 2014)**

Dear Mr. Yeow:

Zimmer appreciates the opportunity to submit these comments to the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) for consideration in responding to the draft charge questions for the revised draft Integrated Risk Information System (IRIS) assessment for ethylene oxide (EO).

Zimmer is a global leader in the orthopedic implant business. Our purpose is to restore mobility, alleviate pain, and improve the quality of life for patients around the world. All of the medical devices that we treat with EO can only be sterilized with EO processing. EO sterilization plays a critical role in protecting public health and reducing the risk of infection with the safe and efficient delivery of sterile medical devices to the medical community.

As users of EO, the accuracy and completeness of the scientific basis for the draft IRIS assessment is extremely important to us. Zimmer has significant concerns regarding the U.S. Environmental Protection Agency's (EPA) cancer risk estimates for EO and the revised draft IRIS assessment as a whole. In addition to our specific comments, we fully support all comments submitted by the American Chemistry Council's (ACC) EO Panel and the Ethylene Oxide Sterilization Association (EOSA). Zimmer believes the current assessment results in the risk of EO being inappropriately magnified. The EO levels that are deemed to be "safe" in this risk assessment are significantly lower than natural background levels of EO in the atmosphere and endogenous EO levels in humans. If this assessment is finalized, EO would also be identified as one of the most potent chemicals within the IRIS database. This exaggerated risk will not only severely and adversely impact the EO sterilization industry, but it will significantly disrupt an established sterilization method for medical devices essential to the general public. The CAAC must consider the benefits of EO sterilization as they review the draft IRIS risk assessment that we believe is not accurate regarding the EO risk estimates.

### **Benefits and Use of EO Sterilization**

Approximately 10% of Zimmer's sterile devices are sterilized using EO. Due to the chemical composition of these devices (high density polyethylene), they cannot be sterilized by another means of sterilization. Without these devices Zimmer will be unable to fulfill our mission to restore mobility, alleviate pain, and improve the quality of life for patients around the world.

Zimmer appreciates the opportunity to submit these comments on the draft IRIS assessment for EO. We urge the CAAC to review this information, and the comments submitted by the ACC EO Panel and EOSA as it develops draft responses to the charge questions. If you have any questions, or would like to request additional information, please do not hesitate to contact me.

Sincerely,

Larry J. Thompson, Ph.D.  
Director, Sterilization Technology  
Zimmer