Medical Products Sterilization: What They're Saying

As the EPA considers new regulations on Ethylene Oxide (EtO), multiple federal agencies and stakeholders have raised concerns about the unintended consequences of these regulations on the ability to sterilize products in the medical supply chain.

FDA Commissioner Robert M. Califf

"We do have concerns. Just a sudden restriction would create substantial difficulty with critical medical devices. So EPA is in the lead in this. We're working on it. There's an interagency process. We're also working with the industry to come up with alternatives. I wish I could say there's a ready alternative in a short period of time. There's not."

House Energy & Commerce Committee Hearing; May 11, 2023

Small Business Administration

"These actions would lead to a significant number of small entities leaving the market for commercial sterilization, and hurting patients needing sterilized medical devices."

Small Business Administration to EPA; June 23, 2023

Healthcare Distributors

"Healthcare distributors also want to protect public health, and to do so they must be able to deliver sterile critical medical products to providers without interruption in the supply chain. Regulatory policies that limit or abolish the use of EtO as a sterilization agent would have a profound negative effect on healthcare providers and patients."

Health Industry Distributors Association, June 27, 2023

Hospitals

"For many medical devices, EtO sterilization may be the only method that completely sterilizes the device without damaging its structural integrity. While the industry is working on developing additional technology to replace EtO sterilization or to dramatically reduce emissions associated with current sterilization processes, which the FAH supports, this technology does not yet exist on a market-wide basis."

Federation of American Hospitals; June 27, 2023

"Moving too quickly to implement and enforce new standards will result in the unexpected consequence of reducing EtO sterilization capacity, ultimately leading to delays in patient care."

American Hospital Association; June 27, 2023

Physicians

"…many complex medical devices, including but not limited to pacemakers and leads, angioplasty balloons, cardiac catheters, stents, and guiding sheaths, and other supplies and equipment used in the care of cardiovascular patients currently rely upon EtO for proper sterilization to ensure patient safety. Currently, these complex medical devices have limited alternative sterilization processes available while others are suboptimal."

The American College of Cardiology, the Heart Rhythm Society, the Society for Cardiovascular Angiography & Interventions, the Society of Interventional Radiology, and the Society of Thoracic Surgeons; June 27, 2023

"…because of the nature of the critical, time-sensitive care administered in the ED (emergency department), this rule, if finalized as proposed, could have the potential to lead to shortages of life-saving equipment... Given current hospital staffing shortages, a supply chain disruption impacting basic items used for patient care will undermine our ability to treat our patients."

American College of Emergency Physicians (ACEP); June 27, 2023

"Countless patients benefit from the availability of safe and effective orthopaedic devices and surgical procedures. A key component of safety is meticulous and scientifically demonstrated sterilization. Though many orthopaedic devices are sterilized by heat, radiation, and other methods, EtO continues to be used for a significant subset of orthopaedic devices. The rationale for its use is often related to technical factors such as material properties that affect clinical use and patient care."

American Association of Orthopaedic Surgeons (AAOS); June 14, 2023

"We are concerned that the EPA's proposed regulations of the ethylene oxide sterilization of medical technology could cause sterilization facility closures, temporary or permanent, and as a result, shortfalls in the supplies we rely on to serve our patients. Product shortfalls would cause us to delay care and force patients to have to wait longer for their vision-preserving, vision-restoring surgery."

American Academy of Ophthalmology, American Society of Cataract and Refractive Surgery, and Outpatient Ophthalmic Surgery Society; June 27, 2023

HIDA urges the Environmental Protection Agency (EPA) to have a thoughtful approach to regulation of ethylene oxide (EtO) gas in medical sterilization in a manner that safeguards the medical supply chain.