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News

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Nation's Premier Surgeons Stress Importance of Ethylene Oxide for Medical Device Sterilization

Six Medical Societies Tell FDA We Need to Keep Ethylene Oxide Viable to "Ensure Patient Safety"

WASHINGTON, D.C. – This week, six leading medical groups sent a letter to FDA urging caution as regulators consider limiting the use of ethylene oxide (EtO) for medical device sterilization. The surgeons warned that without EtO sterilization, many medical devices on the market – including those used in critical emergencies – would become unavailable to the patients who need them. The letter was sent in advance of FDA's Medical Devices Advisory Committee Meeting scheduled for Nov. 6-7.

Scott Whitaker, president and CEO of AdvaMed, said, "There's no collective voice that matters more in this critical conversation about the crucial role ethylene oxide plays in protecting Americans' health than that of the surgeons who perform millions of life-saving surgeries every day with devices that can only be sterilized through this method. Unfortunately, some parties have grossly misrepresented the risk of EtO sterilization to public health. I hope everyone clearly understands what America's top surgeons are telling us: If we don't take a step back to truly understand the science as well as the critical role of EtO sterilization in health care, we will be putting millions of patients' lives at risk."

The six medical societies – the American College of Cardiology, Society of Interventional Radiology, American Society for Gastrointestinal Endoscopy, Society for Thoracic Surgeons, Heart Rhythm Society, and Society for Cardiovascular Angiography & Interventions – wrote: "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. These complex medical devices currently have limited alternative sterilization processes available while others are suboptimal."

The medical groups also cited the complexity and cost associated with replacing sterilization processes should medical device manufacturers be forced to develop, test, validate and submit for FDA approval new processes to replace EtO sterilization. They emphasized that those consequences could be passed along to patients in the form of

absences and delays of treatments, as well as price increases within the health care system.

“We urge caution in considering limitation of the use of EtO for medical device sterilization until there is a feasible action plan in place to ensure appropriate patient access to critical medical devices,” they wrote.

Read the full letter here.

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