October 21, 2019

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**RE: Comments in advance of the Medical Devices Advisory Committee Meeting, Docket # FDA-2019-N-3793**

Submitted electronically via www.regulations.gov

Dear Members of the General Hospital and Personal Use Devices Panel:

The American College of Cardiology (ACC), American Society for Gastrointestinal Endoscopy (ASGE), the Heart Rhythm Society (HRS), the Society for Cardiovascular Angiography and Interventions (SCAI), the Society of Interventional Radiology (SIR), and the Society of Thoracic Surgeons (STS) offer the following comments in advance of the Medical Devices Advisory Committee meeting on November 6 and 7, 2019 to help inform the advisory committee's deliberations regarding industrial ethylene oxide (EtO) sterilization of medical devices and its role in maintaining public health.

The undersigned medical organizations support efforts to minimize employee risk as well as reduce the environmental impact of sterilants through the minimization of emissions and exposure to EtO. When appropriate and feasible, the organizations support the substitution of toxic medical sterilants with less toxic medical sterilization alternatives.

However, as the Food and Drug Administration (FDA or Agency) has previously acknowledged, 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. Therefore, when considering the overall impact of regulatory changes, the organizations urge the Agency to ensure continued patient access to critical devices as well as to minimize increased patient costs.

The organizations also acknowledge the complexity and cost with replacing the sterilization process. Given that the FDA mandates that medical device approval applications for these complex devices contain appropriate data to support the required sterilization process, not only would a new process need to be developed, but the process would also need to be tested and validated in each medical device. Thus, any shift would require an appropriate period to develop the necessary protocols, test those protocols, then replicate them throughout various supply chains with an acknowledgement that these additional steps will likely increase costs to our patients. For these reasons, 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. The organizations also encourage the FDA to continue to work with other relevant agencies such as the

Environmental Protection Agency (EPA) to investigate innovative ways to sterilize medical devices with lower levels of currently used agents, and employ less toxic agents or alternatives, while maintaining medical device safety and effectiveness.

We look forward to further communications with you on this important topic. Should you have any questions, please contact Laura Blum Meisnere, Vice President, Health Policy, Heart Rhythm Society at lblum@hrsonline.org or Joseph Cody, Associate Director, Research and Innovation Policy, American College of Cardiology at jcody@acc.org.

Sincerely,

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