December 6, 2019

Via http://www.regulations.gov

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-N-3793 - The General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

The Society for Healthcare Epidemiology of America (SHEA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Infectious Diseases Society of America (IDSA) represent infection preventionists, epidemiologists, and infectious disease physicians who work to keep patients safe from the risk of multi-drug resistant organisms (MDROs). The societies appreciate the opportunity to provide written comments following up an oral presentation delivered on their behalf by Michael Anne Preas, MS, RN, CIC, FAPIC at the Food and Drug Administration (FDA) public advisory committee meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee held November 7, 2019.

Overview
SHEA, APIC, and IDSA are highly concerned about persistent duodenoscope contamination and the slow pace of progress on this issue. There are many patients for whom endoscopic retrograde cholangiopancreatography (ERCP) can be a lifesaving procedure and the benefits of the use of duodenoscopes outweigh the risks. However, these scopes continue to pose a risk for transmission of MDROs.

Although more rigorous manual cleaning and disinfection guidance has been shared over the last five years, transmissions continue to occur at an unacceptable rate. This problem has continued for far too long, and the risk to patients remains unacceptable. Interventions originally thought to prevent transmissions have not yielded results as hoped. While the number of outbreaks linked to scopes has decreased in the last few years, in the last five years, twenty-five MDRO outbreaks were molecularly linked to contaminated scopes without any evidence of underlying damage to the devices or of human errors or oversights in reprocessing in these cases1. In 2019, FDA indicated that the actual rate of scope contamination was far higher than predicted with 5.4 percent testing positive for high-concern organisms.ii

Recommendation
In an effort to reduce the risk of serious infection to patients who need procedures that utilize these life-saving devices, FDA must require either sterilization or single use devices. In the absence of data showing that current scopes can be adequately disinfected or data showing that newly introduced scope
enhancements will be an improvement, steps must be taken to assure the public that sterilization of these devices is possible or that single-use devices will eliminate the unacceptable risk of transmission observed today. If a sterilization requirement is implemented, device manufacturers must have adequate lead time to ensure device sterilization can be validated or to develop single-use scopes. The societies recommend FDA mandate device manufacturers make these changes no later than January 2021 and remove duodenoscopes that cannot be properly sterilized from the market.

Interim Action Steps
In the interim, low temperature sterilization methods should be studied for effectiveness, effects on medical device materials, and validated for use for devices currently available in the market. Ethylene oxide is a short-term solution for select healthcare facilities, but it is not feasible for the majority of facilities for the following reasons:

1) Facilities have limited stores of ethylene oxide if any, and supply is currently dedicated to other medical devices;
2) Existing users are challenged to maintain sufficient numbers of devices due to lengthy turn-around time on device sterilization. After completing manual cleaning of the device, a complex multi-step process, the typical turn-around time for EtO sterilization is 16 hours versus approximately 1 - 2 hours for high level disinfection;
3) Regulatory barriers are insurmountable in some states;
4) Risk of possible damage to the scopes;
5) Ethylene oxide is a carcinogen and poses a serious risk to human health through exposure.

Additionally, other low-temperature sterilization methods may be a short-term solution. Examples of available low temperature methods include vaporized hydrogen peroxide with or without ozone and liquid chemical sterilization methods using peracetic acid. However, data are not available for all devices on compatibility and efficacy of these methods.

Until sterilization of scopes can be mandated or single-use devices are developed, the societies welcome the continued availability of short-term solutions like protective seals for scopes and disposable components. However, evidence of the effectiveness of protective seals and disposable components in the real-world setting has not been demonstrated and is therefore unclear.

Summary
SHEA, APIC, and IDSA implore FDA to mandate the availability of scopes that can be sterilized or disposable, and that scopes that meet these criteria be made available in the medical device market no later than January 2021, at which time all scopes that do not meet these criteria are removed from the market. The societies feel strongly that sterilization is the best way to achieve the level of safety assurance needed to inspire confidence in patients that need life-saving procedures that utilize these devices.
Thank you for your time and attention on this matter. Future inquiries on this letter should be directed to Lynne Batshon (lbatshon@shea-online.org or 703-684-0761), Lisa Tomlinson (ltomlinson@apic.org or 202-454-2606), and Jaclyn Levy (jlevy@idsociety.org or 703-299-1216).

Sincerely,

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Thomas File, Jr. MD, FIDSA
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Attachment
