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April 16, 2015

Ms. Leslie Kux
Associate Commissioner for Policy
Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-2153, Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes; Draft Guidance for Industry.

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comments on the *FDA Draft Guidance for Industry: Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes*. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. As we have seen with recent outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) linked to contaminated duodenoscopes, insufficiently reprocessed medical devices can lead to sometimes deadly healthcare-associated infections. In order to protect patients from harm, APIC welcomes the opportunity to work with both FDA and industry to ensure that devices used for necessary medical procedures are as safe as possible and do not cause increased risk to patients.

APIC applauds the FDA's efforts at providing guidance to mitigate the risk of contamination from valves and accessories used for irrigation through flexible gastrointestinal endoscopes. We agree that requiring the use of standard (not similar) definitions will provide consistency and clarity for the end user.

We concur that a functional one-way valve to prevent backflow is essential; however, we request clarification of the following statement in paragraph IV(A)(1): "this valve or other feature should be tested with chemical and/or microbiological assays to demonstrate that it is capable of preventing the backward flow of fluids and contamination..." (see page 7). APIC suggests the FDA be specific in its instructions to



manufacturers as to what is expected in regards to specifications for medical devices, such as stating that manufacturers will provide the specifications for testing and frequency of testing, as well as *by whom*.

In paragraph IV(A)(3) *Reprocessing or disposal of the irrigation system* (see page 8), the phrase “performance data to support use in multiple patients and over the proposed time duration...” suggests this is optional. We suggest a more definitive statement such as, “the FDA recommends the manufacturer provide performance data to support use in multiple patients and over the proposed time frame.”

We also recommend in this and all future documents on reusable medical devices, the FDA reiterate the procedures recommended in its own industry guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*,¹ specifically, the criteria for reprocessing instructions including appropriate labeling of the device, requiring thorough pre-cleaning of the device, and the required microbicidal process for the device, as well as ensuring reprocessing instructions are technically feasible, comprehensive, and comprehensible. In addition, the FDA should emphasize the need that such activities need to be scientifically sound and validated. Instructions should be created from a perspective of patient safety and not from avoidance of manufacturer’s risk.

Thank you again for the opportunity to provide input on this draft guidance. APIC looks forward to continuing to work with FDA and medical device manufacturers to ensure patient safety.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning". The signature is written in a cursive, flowing style.

Mary Lou Manning, PhD, CRNP, CIC, FAAN
2015 APIC President

¹ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff. Available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf>