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February 4, 2016

The Honorable Patty Murray
Ranking Member
Health, Education, Labor and Pensions Committee
U.S. Senate
Washington, DC 20510

Dear Ranking Member Murray:

The beneficial role of gastrointestinal endoscopy for the prevention, diagnosis and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. As a professional society representing more than 14,000 members worldwide, the American Society for Gastrointestinal Endoscopy (ASGE) has led the publication of evidence-based guidelines for reprocessing gastrointestinal endoscopes. The risk of transmission of infection resulting from routine endoscopic procedures, like colonoscopy and upper endoscopy, is very low when guidelines for disinfection and sterilization are used. Regrettably, however, recent cases of transmission of multi-drug resistant bacteria during endoscopic retrograde cholangiopancreatography (ERCP), a highly technical procedure, have been linked to a specific type of scope — a duodenoscope — used for this procedure due to its complex design.

ASGE shares your long-standing commitment to patient safety and appreciates your recent efforts to reduce the risk of transmission of pathogens during endoscopic procedures, as well as other procedures that use complex, reusable medical devices. We believe the solution to preventing the transmission of, and deaths from, multi-drug resistant bacteria requires a multifaceted approach, and that is why ASGE endorses your legislation to require manufacturers of selected reusable medical devices to provide validation data to the Food and Drug Administration (FDA) for device cleaning, disinfection, and sterilization. We suggest there is a need for greater transparency, and therefore recommend that the FDA be required to publicly release reprocessing validation data alongside approval of a reusable device. ASGE also believes manufacturers would benefit from final FDA guidance, as called for in your legislation, regarding when notification to FDA for 510(k) clearance is required before marketing modified devices.

Understanding that preventing antibiotic resistant infections associated with advanced endoscopic procedures will require many different approaches, in March 2015, ASGE convened more than 60 experts and leaders in the fields of

epidemiology, infection control, gastrointestinal endoscopy and medical device design and safety to exchange knowledge, explore best practices and to set priorities in key areas for preventing antibiotic-resistant infections associated with ERCP. Among the key areas explored were research, reprocessing guidelines and education.

Since January 2014, following the Centers for Disease Control and Prevention *Morbidity and Mortality Week Report (MMWR),* "Notes from the Field" article outlining reported cases of NDM-producing carbapenem-resistant Enterobacteriaceae (CRE) being transmitted via ERCP, ASGE has taken every opportunity to provide its members with timely and accurate information regarding the association between reprocessed duodenoscopes and the transmission of infectious agents, including multi-drug resistant bacterial infections. An ASGE provider resource center is available to the public at www.asge.org. This resource provides the latest news, information and guidance pertaining to transmission of multi-drug resistant bacterial infections though ERCP.

While ASGE fully supports redesign and replacement of the difficult-to-clean elevator mechanism of existing duodenoscopes, there is a pressing need for research to evaluate the methods for detecting the presence of biofilm, bacteria or infectious materials on duodenoscopes. Research is also needed to identify best methods for eradication of biofilm and infectious material from scopes. In July 2015, ASGE awarded five research grants to study these and other questions. To the best of ASGE's knowledge, there is no other research currently occurring in this field. We are hopeful that our sponsored research will yield insight to important questions, but we believe a commitment of federal resources is needed to further this research.

Lastly, antibiotic resistance is among the most pressing public health issues facing the world today and puts at risk patients who are often the most vulnerable. Any time a complex medical procedure, including ERCP, is performed, the risk of infection exists. Physicians need tools at their disposal to fight these infections that, left untreated, can result in death. In addition to educating patients and providers on the judicious and appropriate use of antibiotics, we support incentives that will encourage the development of the next generation of antibiotics to combat drug-resistant organisms.

ASGE encourages Committee approval of the "Preventing Superbugs and Protecting Patients Act" and invites a federal commitment to initiate research that will help to close gaps in the understanding of optimal practices for device reprocessing, including, but not limited to, endoscopes.

Thank you for your leadership, and we look forward to working with you on this important safety issue. For more information, please contact Camille Bonta, ASGE representative, at (202) 320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

Douglas O. Faigel, MD, FASGE
President
American Society for Gastrointestinal Endoscopy