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IDSA
Infectious Diseases Society of America

April 26, 2016

The Honorable Ted Lieu
United States House of Representatives
415 Cannon House Office Building
Washington, DC 20515

Dear Representative Lieu:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for initiating an investigation—by the House Committee on Oversight and Investigations—on outbreaks of Carbapenem-resistant Enterobacteriaceae (CRE) stemming from contaminated closed-channel duodenoscopes. IDSA represents over 10,000 physicians, scientists and other health care professionals. Many of our members witness firsthand the impacts of antibiotic-resistant infections on individuals. We applaud your recent introduction of the Preventing Superbugs and Protecting Patients Act, which would help prevent such outbreaks in the future.

The 2015 outbreaks of CRE in Los Angeles and around the globe highlight the need to advance a comprehensive set of policy solutions to address antibiotic resistance, including steps to prevent the spread of new infections as called for in the Preventing Superbugs and Protecting Patients Act. As you know, CRE claims the lives of almost half of those who develop a bloodstream infection and was included in the most serious tier of threats identified in the Centers for Diseases Control and Prevention report, *Antibiotic Resistance Threats in the United States, 2013*. IDSA concurs with Committee's goal of clarifying the process for, and improving the timeliness of, reporting new infections from medical devices.

We support the Preventing Superbugs and Protecting Patients Act, as it would require the Food and Drug Administration (FDA) to publish a list of reusable devices that would need to provide proposed cleaning instructions as part of a 510(k) pre-market submission process. Importantly, devices on this list would also need to provide FDA with validation data showing that proposed cleaning instructions are effective. As the legislation moves forward, we believe that it would be helpful to add a requirement for manufacturers to establish a maintenance schedule for such devices. Currently, there is no requirement of maintenance after a specific number of procedures or otherwise and mechanical defects that could predispose to contamination might go unrecognized and unaddressed. During CRE outbreaks identified in the Committee's investigation, hospitals submitted scopes that had no obvious defects to manufacturers for evaluation, several were found to have critical flaws that compromised patient safety.

Once again, we greatly appreciate your efforts to prevent the spread of antibiotic-resistant infections. We are greatly encouraged that the Senate Health, Education,

Labor and Pensions Committee has already favorably reported the Senate companion to your bill, and we look forward to working with you toward advancing this issue in the House. Should you have any questions, please contact Jonathan Nurse on the IDSA staff at 703-299-0202 or jnurse@idsociety.org.

Sincerely,

Johan S. Bakken MD, PhD

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