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Infectious Diseases Society of America

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February 8, 2016

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education, Labor, and Pensions (HELP)  
United States Senate  
455 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions (HELP)  
United States Senate  
154 Russell Senate Office Building  
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the Infectious Diseases Society of America (IDSAs), thank you for launching the Senate Health, Education, Labor and Pensions (HELP) Committee effort to advance biomedical innovations bills. This important endeavor, beginning with the first of three Committee markups on February 9, is a critical companion to the 21st Century Cures Act, which passed the House of Representatives by an overwhelming bipartisan majority in July 2015. We are pleased to offer our support for several bills included in the February 9 markup, specifically the Next Generation Researchers Act (S. 2014), Preventing Superbugs and Protecting Patients Act (S. 2503), and the FDA Device Accountability Act (S.1622).

While IDSAs is pleased to see this work continue, we are deeply concerned that the bipartisan Promise for Antibiotics and Therapeutics for Health (PATH) Act (S. 185) has not yet been included on the list of bills for the Committee's consideration, and we strongly urge you to advance this urgently needed legislation as part of the Committee's innovations activities. If the Committee has any concerns about the PATH Act or would like to further refine the bill's language, IDSAs would be happy to offer our expertise and assistance in working through any issues.

### **The Next Generation Researchers Act (S. 2014)**

IDSAs shares a concern expressed by many members of the Committee that fewer young people are pursuing careers in biomedical research. This disturbing trend could have dire consequences for our nation's future if it is not addressed. In the field of infectious diseases, we need a well-funded NIH to support research in a variety of areas that impact patients and public health, including antimicrobial resistance, influenza, HIV/AIDS, hepatitis, tuberculosis, vector-borne diseases, emerging infections, global infectious diseases, and the research and development of new vaccines, diagnostics, and antimicrobial drugs.

This legislation represents a promising first step, directing the National Institutes of Health (NIH) to advance policies and programs to improve opportunities for new researchers and promote earlier research independence, and to coordinate with other federal agencies and academic institutions to improve tracking of career progress of biomedical researchers and students.

We strongly encourage the Committee to also consider advancing another provision that was included in the 21st Century Cures Act with the goal of fostering the careers of young scientists. Specifically, IDSA strongly supports the House provision to increase the mandated cap from \$35,000 to \$50,000 annually for the NIH loan repayment program for NIH-funded researchers. We believe that updating the loan forgiveness amount to more accurately reflect the debt burden of training will help alleviate one of the major barriers to recruiting and retaining physician-scientists in the biomedical workforce, i.e., the uncertainty surrounding the ability to repay student loans. We also appreciate that this provision is well-aligned with efforts undertaken by the NIH Physician Scientist Workforce Working Group.

### **Preventing Superbugs and Protecting Patients Act (S. 2503)**

IDSA applauds the Committee for investigating outbreaks of Carbapenem-resistant Enterobacteriaceae (CRE) stemming from contaminated closed-channel duodenoscopes. These outbreaks 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 (CDC) 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, which 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 HELP Committee report, hospitals submitted scopes that had no obvious defects to manufacturers for evaluation, several were found to have critical flaws that compromised patient safety.

### **FDA Device Accountability Act (S. 1622)**

IDSA is happy to support the FDA Device Accountability Act as an effort to help ensure more consistent review and swifter approval of safe and effective diagnostic tests. The FDA employee training required by this bill would help ensure a more consistent approach to FDA review of

new devices, including diagnostic tests. IDSA also supports the bill's provision to allow use of a non-local IRB for device trials, as is already allowed for many other types of research.

Efforts to help bring to market new infectious diseases diagnostics are important to patient care and public health. Such diagnostic tests have tremendous potential to improve patient outcomes and shorten hospital stays by facilitating administration of appropriate treatment much earlier in the course of a disease. Diagnostic tests are also critical for guiding the appropriate use of antibiotics, which is necessary to limit the development of antibiotic resistance. In addition, diagnostics are critical for identifying outbreaks and triggering public health responses. Lastly, new diagnostic tests can be extremely useful in identifying patients eligible for antimicrobial drug clinical trials.

### **Promise for Antibiotics and Therapeutics for Health (PATH) Act (S. 185)**

IDSA is deeply concerned about the increasing numbers of patients contracting and dying from serious infectious caused by multi-drug resistant pathogens that cannot be safely and effectively treated with our existing arsenal of antibiotics. In addition to devastating and claiming lives, these infections are also placing a significant burden on our healthcare system—an estimated addition \$20 billion annually. New and more serious threats continue to emerge. Most recently, last November scientists discovered a new gene in China that makes common bacteria, including *E. coli*, resistant to all existing antibiotics, including drugs of last resort. Bacteria carrying this gene have since been identified in several Asian and European countries, making it just a matter of time before this deadly threat reaches the U.S. Without the PATH Act, researchers will be unable to develop and bring to market many of the life-saving new antibiotics patients desperately need.

Very few pharmaceutical companies continue to invest in antibiotic research and development (R&D), and the infeasibility of clinical trials for these drugs is a key factor in this problem. The PATH Act would help by allowing new antibiotics that treat a serious or life-threatening infection for which there is an unmet medical need to be studied in smaller clinical trials, similar to the approach used in the successful Orphan Drug program. This approach is necessary for this set of antibiotics because the infections for which these drugs are needed are currently occurring in a relatively small number of critically ill patients, making traditional, large scale clinical trials extremely difficult or impossible. Importantly, drugs approved under the PATH Act would be approved only for the limited population of patients who need them and for whom they have been proven safe and effective. Further, PATH drugs would be clearly labeled as “limited population” and their use would be monitored by the Department of Health and Human Services (HHS). Such safeguards are necessary to ensure that clinicians have the information necessary to use these drugs appropriately.

A provision very similar to the PATH Act was included in the 21st Century Cures Act, and this provision received tremendous bipartisan support in the House as a standalone bill, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act. The President's Council of Advisors on Science and Technology (PCAST) recommended this limited population approach to antibiotic development in its 2014 report to the President on antibiotic resistance. Over 40 organizations representing physicians and other healthcare providers, patients, public

health, and industry are supporting the PATH Act, and we hope you will advance this legislation swiftly as part of the Committee's efforts to advance biomedical innovation.

Once again, we greatly appreciate your commitment to advancing a biomedical innovations package. Should you have any questions, please contact Jonathan Nurse, at the Infectious Diseases Society of America, at 703-299-0202 or [jnurse@idsociety.org](mailto:jnurse@idsociety.org).

Sincerely,

A handwritten signature in black ink that reads "Johan S. Bakken MD, PhD". The signature is written in a cursive, slightly slanted style.

Johan S. Bakken, MD, PhD, FIDSA  
President, IDSA