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June 13, 2016

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations
Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations
Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Murphy and Ranking Member DeGette:

On behalf of the Infectious Diseases Society of America (IDSAs), I write to thank you for scheduling the hearing, "Combating Superbugs: U.S. Public Health Responses to Antibiotic Resistance," for June 14. IDSAs also applauds members of the Subcommittee on Oversight and Investigations as well as the full Energy and Commerce Committee for leading efforts in the House of Representative to spur research and development (R&D) for desperately needed antibiotics and antifungal drugs through passage of the 21st Century Cures Act, H.R. 6. We greatly appreciate the Subcommittee's continuing attention to this important issue and urge strong congressional action to advance the solutions necessary to protect patients and public health, including incentivizing antibiotic and diagnostic R&D; promoting ID physician-led antibiotic stewardship; enhancing surveillance, data collection and research; and investing in an ID physician workforce central to all efforts to combat antibiotic resistance and other ID threats.

IDSAs represents over 10,000 infectious diseases physicians and scientists. The Society has been sounding the alarm for over a decade about the danger of antibiotic resistance that is sickening and killing patients and jeopardizing our ability to conduct both routine and lifesaving medical care, including surgery, transplants, chemotherapy, and the care of preterm infants. ID physicians continue to be at the forefront of this battle, caring for patients with serious and life-threatening infections caused by multidrug-resistant organisms; leading antibiotic stewardship programs in health care facilities; running clinical trials to develop urgently needed new antibiotics, diagnostics, and vaccines; and advancing public health efforts to strengthen surveillance, data collection, and infection control and prevention. IDSAs has worked with Congress and the Administration to promote these activities, all of which are now key components of the *National Action Plan for Combating Antibiotic Resistant Bacteria (CARB)*.

New evidence continues to indicate the threat antibiotic resistance poses to patients and public health. U.S. Department of Defense researchers recently detected a gene conferring resistance to colistin—an antibiotic of last resort—in a bacterium infecting a Pennsylvania woman. This resistance gene was first discovered in China last year. Experts believe that the gene will soon spread to other bacteria, making them resistant

to colistin as well. Of particular concern is the high likelihood this gene will spread to bacteria already resistant to most other antibiotics, such as carbapenem resistant Enterobacteriaceae (CRE), making infections caused by those pathogens even more difficult or impossible to treat.

Incentivizing Antibiotic and Diagnostic R&D

Antibiotic resistance continues to increase while necessary R&D fails to keep pace. Antibiotics are difficult and costly to develop, used for a short duration and held in reserve to protect their utility—all making them an unattractive and often infeasible investment for many companies. In 2012, Congress passed the Generating Antibiotics Incentives Now (GAIN) act, which gave additional exclusivity for antibiotics to treat serious and life threatening infections. While this was a critical first step, experts agree that additional incentives are needed help antibiotics compete against more lucrative drugs for company resources.

In the CARB National Action Plan, the Administration promised to release a report and recommendations on economic incentives for antibiotics. Unfortunately, the report and recommendations have not been released, despite requests from a variety of stakeholders including IDSA. **We encourage the Subcommittee to request that the Administration release the report and recommendations on antibiotic incentives promptly.**

IDSA also strongly supports incentives for new, rapid diagnostic tests. Such tests are critical to guide the appropriate use of antimicrobial drugs, inform infection control activities, and identify patients for antibiotic clinical trials. Unfortunately, new diagnostics also face barriers, including high R&D costs, insufficient financial support, inappropriate reimbursement, and difficulty accessing clinical specimens and expert laboratories needed to validate new tests.

IDSA strongly supports the [Reinvigorating Antibiotic and Diagnostic Innovation \(READI\) Act](#), H.R. 3539, by Representatives Charles Boustany (R-LA), Mike Thompson (D-CA), John Shimkus (R-IL), and Gene Green (D-TX). This bill, modeled after the Orphan Drug tax credit, would provide a 50% tax credit for new antibiotics and antifungal drugs designed to treat serious or life-threatening infections and that address an unmet medical need, as well as for new rapid diagnostic tests. **We strongly encourage members of the Subcommittee to cosponsor the READI Act, H.R. 3539.**

IDSA also continues to strongly support the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, legislation led by Representatives Shimkus and Green, and included in H.R. 6, to address a key regulatory barrier to antibiotic R&D. The ADAPT Act would allow antibiotics that treat a serious or life-threatening infection and address an unmet medical need to be studied in smaller, more rapid clinical trials and approved only for the limited population of patients who need them and for whom they have been proven safe and effective. IDSA continues to urge passage of this legislation in the Senate.

Antibiotic Stewardship

IDSA has long advocated for the judicious use of antibiotics to slow the emergence of resistance and extend the lifetime of antibiotics. Specifically, IDSA [led the effort](#) to urge the Centers for Medicare and Medicaid Services (CMS) to require all healthcare facilities to implement an antibiotic stewardship program as a Medicare condition of participation (COP). In our

[comments on the proposed rule for stewardship programs in long term care facilities](#), IDSA underscored the importance of ID physician leadership for stewardship programs to ensure appropriate expertise and optimal patient care and outcomes. IDSA continues to look forward to a proposed rule requiring stewardship programs in acute care hospitals. We urge Congress to support these efforts.

Federal Funding

IDSA encourages the Subcommittee to work with colleagues on the House Appropriations Committee to make certain that necessary resources are provided to fully implement the *National Action Plan*. IDSA continues to lead advocacy in support of federal funding for the Centers for Disease Control and Prevention (CDC) antibiotic resistance activities, namely through the new Antibiotic Resistance Solutions Initiative that will soon establish prevention programs based on best practices in all 50 states and major U.S. cities. The CDC program will also include a regional laboratory network allowing for faster detection of outbreaks of antibiotic-resistant bacteria. Funding for the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) to support research to better understand how to combat resistance and R&D leading to new antibiotics, rapid diagnostics, and vaccines is also critically important.

Infectious Diseases Workforce

ID physicians are central to the multifaceted solutions needed to effectively combat antibiotic resistance. We care for patients with or at risk of infections caused by multidrug resistant pathogens; conduct research and development of new antibiotics, diagnostics, and vaccines; lead antibiotic stewardship programs; and inform on a variety of public health activities. Unfortunately, the pipeline of new ID physicians is waning. Data from the National Residency Match Program indicate a disturbing decline in the number of young physicians pursuing careers in ID, with 342 ID fellowship applicants and 89% of ID training positions filled in 2010-11, compared with only 221 ID fellowship applicants and 65% of ID training positions filled in 2016-17. Without strong interventions, the next generation may not have the ID physician leaders necessary to protect patients and public health.

In 2014, IDSA surveyed nearly 600 Internal Medicine residents about their career choices. While results have not yet been published, we can share that very few residents self-identified as planning to go into ID. A far higher number reported that they had been interested in ID but chose another field instead. Among that group, salary was the most often cited reason for not choosing ID. Average salaries for ID physicians are significantly lower than those for most other specialties and only slightly higher than the average salary of general Internal Medicine physicians, even though ID training and certification requires an additional 2-3 years. Young physicians' significant debt burden (\$200,000 average for the class of 2014) is understandably driving many individuals toward more lucrative specialties, often with faster paths to practice.

IDSA is committed to doing all we can to ensure the future availability of ID physicians, including expanding a robust set of mentoring and scholarship opportunities that we offer for medical students and young physicians. But we cannot solve this problem alone. As the Subcommittee considers the tools needed to combat antibiotic resistance and other ID threats, we urge you to consider ID workforce needs and the following recommendations to help ensure the

next generation of ID physicians:

Patient Care

- Direct the CMS to undertake research to identify better inputs to value evaluation and management (E&M) codes that serve as the basis for Medicare payment for the vast majority of ID and other cognitive services;
- Provide payment increases for physicians that primarily provide E&M (cognitive) services under Medicaid and Medicare;
- Support development of ID quality measures to allow ID physicians to utilize new payment models;
- Ensure appropriate distribution to cognitive physicians of shared savings achieved through alternative payment models; and
- Provide loan repayment and loan forgiveness opportunities for ID physicians providing ID care generally or more narrowly to patient populations with unmet needs (e.g. hepatitis C, HIV, etc.).

Research

- Expand the NIH loan repayment programs and increase the loan forgiveness amount to more accurately reflect the debt burden of training (as in H.R. 6);
- Increase the pay scale of NIH Career Development (K) awards or provide other federal funding options for the training of physician scientists;
- Explore novel pilot approaches to increase the award rate for new investigators;
- Establish a new physician-scientist granting mechanism to facilitate the transition from career development (K) to independent (R) level awards at the NIH; and
- Encourage the NIH to advance its Physician Scientist Workforce recommendations.

Public Health

- Provide mechanisms to appropriately pay physicians for important non-clinical services (such as care coordination, antibiotic stewardship, and public health activities); and
- Provide loan repayment and forgiveness opportunities to ID physicians working primarily in public health, or to ID physicians engaged in public health emergency responses important to national security.

Once again, IDSA thanks you for scheduling the hearing on antibiotic resistance and looks forward to continuing to work with you on this important issue. Should you have any questions, please contact Amanda Jezek, IDSA Vice President for Public Policy and Government Relations, at (703) 740-4790 or ajezek@idsociety.org.

Sincerely,



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