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October 27, 2017

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Strategic Planning Team
Attn: Strategic Plan Comments
200 Independence Avenue, SW
Room 415F
Washington, DC 20201

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to provide comments on the Department of Health and Human Services' (HHS) FY2018–2022 Strategic Plan. IDSAs represents more than 11,000 physicians and scientists who specialize in infectious diseases. ID physicians care for complex patients with or at risk of serious infections including patients with HIV, hepatitis C, and patients with infections caused by multidrug resistant pathogens. Our members conduct basic, translational and clinical research to drive innovation in therapeutics, diagnostics and vaccines. We lead population health efforts in our health care facilities and communities, including antimicrobial stewardship programs, infection prevention and control programs, bioemergency preparedness programs and other quality improvement activities. Moreover, we help lead public health responses to threats including Ebola, Zika, pandemic influenza, MERS-CoV and bioterror attacks.

We greatly appreciate the Department's emphasis to strengthen and expand our clinical and scientific workforce. By such measures, this aids in preventing, treating and controlling communicable diseases, specifically those caused by antibiotic resistant pathogens; preparing for and responding to public health emergencies; strengthening our surveillance, epidemiology and laboratory capacities; and advancing biomedical research. Below we offer specific feedback on individual objectives. We welcome the opportunity for further discussion and collaboration on these issues.

Objective 1.4: Strengthen and expand the healthcare workforce to meet America's diverse needs

IDSAs recommends that the infectious diseases physician workforce be a focus of the Department's efforts. We are deeply concerned that fewer young physicians are pursuing infectious diseases specialty training. According to the National Residency Match Program (NRMP), only 80% (or 312 out of 390) of available ID fellowship positions filled for 2017-2018. In many other medical specialty areas,

all or nearly all available fellowship positions fill. These data indicate an undervaluation of ID.

In 2014, IDSA surveyed nearly 600 internal medicine residents about their career choices. Very few residents self-identified as planning to go into ID. A far higher number reported that they were interested in ID but chose another field instead. Among that group, the salary was most cited as a reason for not choosing ID. Over 90% of the care provided by ID physicians is considered as evaluation and management (E&M) services. These face-to-face, cognitive encounters are less appreciated by the current payment systems compared to procedural practices (e.g., surgery, cardiology, and gastroenterology). Care of patients with serious infectious diseases has become more complex due to a variety of factors—therapeutic and diagnostic choices, rising rates of antimicrobial resistance, emerging infections, as examples. Despite such increasing challenges, there has been no adjustment in the definitions of E/M services, and only incremental changes in their valuations.

Over time, a significant compensation disparity between ID physicians and specialists who provide procedure-based care has grown. Young physicians face significant debt burden (\$200,000 average for the class of 2014) that understandably drive many toward more lucrative specialties, often requiring less training years.

IDSA strongly encourages the Centers for Medicare and Medicaid Services (CMS) to undertake the necessary research to understand better the work required in the full range of E/M services. Such findings can be used to update and, where necessary, develop new E/M codes. Appropriate valuation of ID services is essential to secure the ID workforce needed to protect patients and public health from existing and future ID threats.

Objective 2.2: Prevent, treat and control communicable diseases

IDSA appreciates the Department's focus on reducing the emergence and the spread of antibiotic-resistant infections both domestically and globally. The Society endorses the proposed strategies to increase surveillance, implement robust stewardship in both human and animal health, and advance development and adoption of rapid diagnostic tests. IDSA strongly supports progress made over the last two years in combating antibiotic resistance. Continued investment of resources is necessary to ensure the public health infrastructure and the biomedical research enterprises necessary to handle emerging infectious threats, evaluate interventions, and develop new tools and strategies to address antimicrobial resistance. IDSA also encourages the Department to advance requirements for healthcare facilities to implement antibiotic stewardship programs led by infectious diseases trained physicians. Such standards would ensure that all patients, regardless of where they receive care, can benefit from this valuable safety initiative. Further, broad implementation of stewardship is essential to maximize the public health impact. We also request the Department acknowledge the counterpart of stewardship for effective anti-infective treatment, in the pressing need for new antibiotics. Given the significant economic barriers hampering antibiotic research and development, we urge HHS to advance incentives sufficient to spur antibiotic R&D.

IDSA also endorses the Department focus on vaccine innovation and uptake, both domestically and globally. While current Department support for research strategies on vaccine uptake is lauded, we encourage HHS to advance policies to increase access to vaccines leading to better

immunization rates. Areas for focus include strengthening Medicare vaccine coverage, investment in adult immunization information systems (i.e., registries), and support for strong state childhood immunization mandates. We also encourage HHS to invest in vaccine innovation, particularly for high priority areas such as a universal influenza vaccine, vaccines for antibiotic resistant pathogens, vaccines for Lyme disease and other vector-borne diseases.

Objective 2.4: Prepare for and respond to public health emergencies

IDSA backs many of the strategies outlined to advance this objective. We are pleased to highlight a few priority areas. First, maintaining a strong public health infrastructure, domestically and globally, is an essential foundation for public health emergency preparedness. Workforce is another key component. As infectious diseases physicians are often on the frontlines responding to outbreaks and other public health emergencies—including the infectious diseases implications of recent hurricanes—securing a strong infectious diseases workforce as discussed under Objective 1.4 is critical to our nation’s emergency preparedness efforts. Also, timeliness of response to any emergency with an infectious diseases risk is crucial to prevent spread and lessen the impact on patients and public health. Recognizing the worrisome length of time for Congress to appropriate supplemental funding for emergencies such as the Zika outbreak or recent hurricanes, IDSA recommends the establishment of a mechanism to allow swift allocation of resources for public health emergency responses. This funding should not come at the expense of existing core public health infrastructure investment.

Objective 4.1: Improve surveillance, epidemiology, and laboratory services

IDSA strongly supports the Department commitment to strengthening surveillance, epidemiology and laboratory services. Vigorous surveillance systems, domestically and globally, are essential to detect emerging threats, track patterns in resistance, and assess the effectiveness of interventions. For greatest impact, information should be shared among facilities; local, state and federal agencies; and countries. Investment in new technologies and a skilled workforce are essential. For example, the \$30 million annual investment in the Centers for Disease Control and Prevention Advanced Molecular Detection initiative has already yielded significant improvements to detection methods that help limit foodborne diseases and other outbreaks. IDSA underlines the need for financial investment in surveillance, epidemiology and laboratory capacity that is necessary to achieve the Departmental objective.

Objective 4.2: Expand the capacity of the scientific workforce and infrastructure to support innovative research

IDSA is pleased to see the Departmental inclusion of scientific workforce and infrastructure in its strategic plan. We strongly support the National Institutes of Health (NIH) Next Generation Researchers Initiative. We continue to work with NIH, especially the National Institute of Allergy and Infectious Diseases, on a variety of efforts to stabilize research funding for mid-career investigators. Such initiatives would better enable resiliency among investigators, also ensuring they have protected time to compete for grant renewals. However, we must stress that the NIH budget must continue to grow to provide sufficient support of early and mid-stage investigators. Of note, reallocation of resources from more senior researchers, who often lead impactful programs, would be detrimental including to younger scientists they mentor.

Objective 4.3: Advance basic science knowledge and conduct applied prevention and treatment research to improve health and development

IDSA supports the Department commitment to advancing basic science, applied prevention and treatment research, particularly regarding vaccines; outbreak prevention, detection and response; and global health threats. We underscore that ample funding for research is essential to meet these objectives. We also recommend advances in regulatory science to foster the development of urgently needed antimicrobial drugs, including narrow spectrum antibiotics that can target pathogens with insufficient treatment options. IDSA has been pleased to work with the Food and Drug Administration (FDA) on workshops and advisory committee meetings over the last few years to advance conversations about appropriate clinical development programs for such antibiotics. We eagerly await draft FDA guidance in this area.

IDSA also strongly favors the inclusion to modernize product development and manufacturing in the draft strategic plan of innovative pharmaceutical technology. This direction will help ensure a consistent supply of high quality medicine. This should alleviate the antimicrobial drug shortages that persist throughout the US for the last several years. A 2016 survey conducted by the IDSA Emerging Infections Network found that 70% of responding physicians faced an antimicrobial drug shortage in the previous two years. Among responders, 73% stated that shortages negatively impacted patient care. Most commonly cited consequences of these shortages included broader spectrum antimicrobial use than necessary (75%), more expensive therapies (58%) and less effective treatments (45%). We would appreciate the opportunity to work with HHS to strengthen manufacturing practices and other activities that address drug shortages.

Thank you again for developing an outstanding draft strategic plan and for the opportunity to provide comments. We appreciate your attention to these vital issues and look forward to working with you for the betterment of our patients and public health.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul A. Auwaerter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Paul A. Auwaerter, MD, FIDSA
President, IDSA