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September 11, 2017

Robert Kadlec, MD Assistant Secretary for Preparedness and Response Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Dear Dr. Kadlec:

The Infectious Diseases Society of America (IDSA) would like to take this opportunity to congratulate you on your appointment as the new Assistant Secretary for Preparedness and Response (ASPR). IDSA has always valued a strong relationship with ASPR based on mutual commitment to public health and national security. We look forward to working closely with you both on pandemic and biothreat preparedness as well as antimicrobial resistance and incentives for new antimicrobial drugs, diagnostics and vaccine research and development. We hope that you will view IDSA as a key partner on these and other infectious diseases issues.

By way of background, though you may be familiar with IDSA, the Society has grown significantly to represent over 11,000 infectious diseases (ID) physicians and scientists devoted to patient care, prevention, public health, education, and research in infectious diseases. Our members not only care for patients with or at risk of serious infections such as HIV, hepatitis C virus (HCV) and infections caused by antimicrobial resistant pathogens but are often also on the front lines of responses to public health emergencies most recently outbreaks of Ebola virus, Zika virus, MERS-CoV, and influenza. ID clinicians are now front and center in leading antimicrobial stewardship and infection prevention programs that are key aspects to maintaining an effective antimicrobial armamentarium. With a view toward improving patient safety and leading cutting edge research, IDSA advocates for developing urgently needed new antimicrobial drugs, diagnostics, and vaccines.

As you assume key responsibilities in coordinating domestic and global pandemic preparedness and response, and play a vital role in supporting the research and development of urgently needed new and improved antimicrobials, diagnostics and vaccines to combat emerging biothreats and outbreaks, we would like to outline some of our Society's key priorities within these areas.

## **Biomedical Advanced Research and Development Authority (BARDA)**

IDSA strongly supports the work done by BARDA to create public-private partnerships that facilitate the types of innovation necessary to develop novel antimicrobials, diagnostics and vaccines. BARDA's broad spectrum antimicrobials program provides essential funding and support to large and small pharmaceutical companies for antimicrobial drug development. More recently, BARDA joined with other government and private partners to launch CARB-X, a biopharmaceutical accelerator geared toward advancing the discovery and early stage development of novel products to combat antimicrobial resistance. Given the growing threat AMR poses to public health and national security and the severe economic barriers to

antibiotic research and development that have caused nearly all large pharmaceutical companies to abandon this field, BARDA's work on this issue is vital and the antibiotic pipeline would almost certainly be even more fragile without BARDA's commitment.

As BARDA's reauthorization approaches, we urge you to work with Congress to strengthen BARDA's role in supporting antibiotic R&D, including providing BARDA the authority and funding to provide "pull" incentives for the most urgently needed new antibiotics—such as market entry rewards upon successful registration. Pull incentives are an important complement to the push incentives (support during development) that BARDA currently provides. Economists and AMR experts believe that a combination of push and pull incentives are needed to ensure the robust and renewable antibiotic pipeline that we need to address resistance threats.

BARDA has also played a vital role in ensuring industry participation in research and development of vaccines in response to disease outbreaks like Zika virus and Ebola virus, and could play an important role in the development of new drugs, diagnostics and a vaccine for tuberculosis, which is now the leading infectious disease killer globally. Development of vaccines for pandemics, outbreaks, and emerging threats carries significant risk, due in part to highly uncertain markets that can make return on investment difficult to achieve. Without these public-private partnerships facilitated by BARDA, industry would likely not have enough incentive to quickly develop desperately needed vaccines in these situations, leaving the public vulnerable.

## **Pandemic Preparedness**

IDSA also supports ASPR's broader role in coordinating preparedness and response to public health emergencies. Ensuring that hospitals and other healthcare facilities are ready for an emerging infectious disease threat helps prevent a local outbreak or isolated event from becoming a full blown epidemic or pandemic. This work includes putting into place communication channels and protocols for disseminating information as well as ensuring access to vaccines and other medical countermeasures. ID physicians often serve as the leaders of bioemergency preparedness at their institutions, and we look forward to opportunities to collaborate with you and support your efforts.

IDSA recognizes the many demands on your time, and we appreciate your attention to the infectious diseases issues that threaten public health. As you assume leadership at ASPR, we hope you will consider IDSA your partner and look to us as a resource. If you have any questions or wish to engage our membership on any issues, you may reach us through IDSA's Program Officer for Public Health Policy, Colin McGoodwin, at <a href="mailto:cmcgoodwin@idsociety.org">cmcgoodwin@idsociety.org</a> or (703) 299-0015.

Sincerely,

William G. Powderly, MD, FIDSA

Bill Powderly

President, IDSA