IDSA Headquarters
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

IDSA
Infectious Diseases Society of America

August 28, 2014

Francis Collins, MD, PhD
Director
National Institutes of Health
1 Center Drive
Bethesda, MD 20892

Margaret Hamburg, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Drs. Collins and Hamburg,

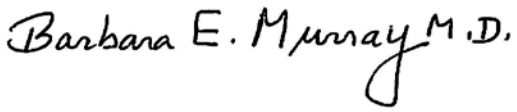
On behalf of the Infectious Diseases Society of America (IDSA), I thank you for hosting the recent public workshop: The Development of New Antibacterial Products: Charting a Course for the Future. As you know, IDSA has long been concerned with antibiotic resistance and the nearly dry antibiotic pipeline, and we were extremely pleased to participate in this important meeting to help advance antibiotic research and development (R&D). This workshop and the announcement of upcoming activities represented a significant advancement in the federal dialogue on addressing antibiotic resistance and the waning antibiotic pipeline. IDSA is heartened to see strong commitment to these issues at such high levels of our government and broad participation among multiple key stakeholders.

In particular, IDSA enthusiastically welcomes the announcement from the National Institutes for Health at the conclusion of the meeting of an upcoming public-private partnership (PPP) to address antibiotic development as well as an effort to establish a master clinical trials protocol. We offer you IDSA's support, expertise and assistance in designing and implementing these activities through the active engagement of our existing volunteer committees, helping to identify individuals with specific expertise, and making available any capacity or resource that would be helpful to you.

IDSA has long advocated for a high-level PPP with representation from the federal government, academia, industry, physicians and other key stakeholders, to promote innovation and improvement in the discovery, development, and evaluation of new antibiotics and diagnostics. Given the urgent need for these products and the significant scientific, economic, and regulatory challenges they face, these areas are well suited for a PPP to tackle. A new PPP in this space can complement other efforts to reinvigorate antibiotic development, such as the limited population antibiotic development (LPAD) approval mechanism and tax credits for antibiotic and diagnostic R&D, and offer welcome new approaches to early stage development and clinical trial design that would not be possible simply through individual stakeholders acting alone. We hope these efforts will also include a focus on diagnostic development, given the broad agreement that diagnostics are extremely valuable for identifying patients for antibiotic clinical trials and crucial for antibiotic stewardship.

Once again, thank you for your commitment to finding solutions to this critical public health threat. We look forward to hearing more details about the PPP, master clinical trials protocol and other plans in this area for the future. IDSA stands ready to help you in any way we can. If you have any questions or would like to share any information with IDSA, please do not hesitate to contact Amanda Jezek, IDSA's Vice President for Public Policy and Government Relations at ajezek@idsociety.org or 703-740-4790.

Sincerely,



Barbara E. Murray, MD, FIDSA
President, IDSA