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February 19, 2014

The Honorable Barack H. Obama
President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

On behalf of the Infectious Diseases Society of America (IDSA), which represents more than 10,000 physicians and scientists, thank you for highlighting the need for innovation to address drug-resistant bacteria in your recent State of the Union address. We look forward to partnering with your Administration on executing concrete actions to address resistance.

As you know, antibiotic resistance is sickening and killing increasing numbers of patients and costing our healthcare system billions of dollars. We need a multi-pronged approach that includes new tools such as vaccines, antibiotics and diagnostics; expanded surveillance of resistance and antibiotic use; strong antibiotic stewardship programs; more research on novel strategies, best practices and evaluation of methods to prevent, control and eradicate antimicrobial resistant organisms; and other public health interventions.

You have an important opportunity to lead a robust federal response to resistance. The U.S. needs a comprehensive implementation strategy to put in place activities to combat resistance. The effort must include participation of all stakeholders and operate on an aggressive, clearly defined timetable in order to prevent further loss of lives due to resistant infections. The U.S. Interagency Task Force on Antimicrobial Resistance (ITFAR) is charged with coordinating federal efforts. However, the ITFAR lacks the high-level, centralized leadership it needs to ensure measurable progress and accountability. We urge you to designate an Office and Director under the Secretary of Health and Human Services (HHS) to lead the ITFAR and coordinate the Federal response. This enhanced leadership would help facilitate better coordination, including a stronger ongoing dialogue with nongovernment experts.

Investing in the research and development (R&D) for new antibiotics and diagnostics is a critical component of our response to resistance. Public-private partnerships (PPP) are needed to bring together the diverse stakeholders required to tackle the challenges facing antibiotic and diagnostics R&D. The European Union is already making important strides with its New Drugs for Bad Bugs PPP (ND4BB), launched under the Innovative Medicines Initiative. ND4BB has brought together government leaders, academia, industry and other experts for an unprecedented

sharing of information. The focus of the overall program is to develop better networks of researchers, create more fluid clinical trials designs and provide incentives for companies. We urge you to launch a complementary effort in the US to ensure that we are not left further behind.

Antibiotic stewardship is critical to protect current and new antibiotics from the rapid development of resistance that renders them ineffective. Antibiotic stewardship programs (ASP) are effective at guiding appropriate antibiotic use and saving precious healthcare dollars. We urge you to work, through the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) in particular, to mandate implementation of ASP in all healthcare facilities across the nation.

Congress is considering multiple proposals that will also help foster the development of new antibiotics and combat resistance, and we urge you to support these proposals and work with congressional leaders toward their enactment:

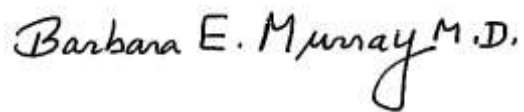
- The [Antibiotic Development to Advance Patient Treatment \(ADAPT\) Act](#) would speed patient access to desperately needed new antibiotics to treat serious or life-threatening infections for which there is an unmet medical need by establishing a new limited population approval pathway, under which these drugs could be approved based upon smaller clinical trials. The ADAPT Act contains multiple provisions to foster appropriate use of drugs approved under the new pathway. In addition, we urge you to work with Congress to add a provision to include a logo or other such visual means to clearly mark drugs approved under this pathway.
- The [Strategies to Address Antimicrobial Resistance \(STAAR\) Act](#) would promote prevention, improve surveillance and data collection of resistant infections and antibiotic use, strengthen antibiotic stewardship efforts, encourage research, and enhance federal leadership and accountability. As the federal government provides incentives to spur new antibiotic R&D, it is critical to protect that investment and the utility of current and new antibiotics by addressing resistance through these public health activities.
- Targeted tax credits are needed to overcome the economic barriers associated with antibiotic and diagnostic R&D.
- Funding to support the ITFAR and key federal agencies including the National Institute for Allergy and Infectious Diseases (NIAID) (specifically the new Clinical Research Network on Antibacterial Resistance), the CDC, the Biomedical Advanced Research and Development Authority (BARDA) and others.

New diagnostic tools are also crucial for combating resistance and developing new antibiotics. Diagnostic tests help guide appropriate use of antibiotics and decrease inappropriate antibiotic use by lessening the need for clinicians to treat patients empirically. Diagnostics can also help identify eligible patients for antibiotic clinical trials. IDSA's recently released report, [Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#) makes policy recommendations to help spur the development of new and more rapid diagnostic tests and encourage their use in patient care and public health. Key priorities where your leadership can have a significant impact include:

- Provide robust funding for diagnostics research through NIAID and BARDA.
- Reduce regulatory barriers to diagnostics R&D, specifically working with the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) to facilitate development of point of care tests.
- Ensure appropriate levels of reimbursement for diagnostics.
- Provide funding for the Agency for Healthcare Research and Quality (AHRQ) and the Health Resources and Services Administration (HRSA) to assist healthcare institutions and professional societies with educational programs about the utility of diagnostic tests.

Once again, we thank you for highlighting antibiotic resistance during the State of the Union address. Calling attention to this public health crisis is important, but action is now needed to protect public health and save patients' lives. We hope these recommendations can assist your Administration in devising and implementing a strategic national plan to combat antibiotic resistance.

Sincerely,

A handwritten signature in black ink that reads "Barbara E. Murray M.D." The signature is written in a cursive style with a large, stylized initial 'B'.

Barbara Murray, MD, FIDSA
President, IDSA