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March 8, 2019

Anthony Fauci, MD, FIDSA
National Institutes of Health
Director, National Institute for Allergy
and Infectious Diseases
Building 31, National Institutes of Health
31 Center Drive, Room 7A03
Bethesda, MD 20892-2520

Dear Director Fauci:

The Infectious Diseases Society of America appreciates your commitment to combating antibacterial resistance (AR) and welcomes this opportunity to provide feedback on the NIAID strategic framework for AR research and development (R&D). Since the framework's release in 2014, NIAID has driven important progress.

Unfortunately, AR remains a major problem for patients and threatens to undo decades of medical advances. A report published in the *Journal of Infection Control and Hospital Epidemiology* in 2018 found that as many as 162,044 people die annually in the U.S. because of infections caused by resistant pathogens, making AR the third leading cause of death.

The small companies responsible for recent antibiotic innovation are in grave danger. Over the last 18 months, stock prices for antibiotic development companies have plummeted. Two companies—Achaogen and Melinta—announced massive layoffs. If these companies fail, their antibiotic R&D is curtailed, and their failures could further alienate potential investors.

Given persistent challenges, IDSAs recommends:

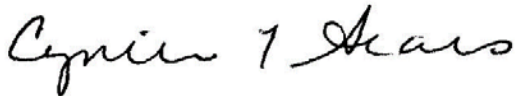
1. **Increased funding for AR research:** IDSAs appreciates increased allocations for NIAID, and specifically, AR research. We will continue advocacy for additional funding. Given the impact of AR across many areas of medicine, including cancer chemotherapy, transplantation, complex surgeries and care of the immunocompromised, IDSAs recommends pooling resources across these and other areas to increase funding for AR research.
2. **Streamlining bureaucratic processes for AR research:** Cumbersome bureaucracy can hamstring interventional clinical trials and drive away needed sponsors. IDSAs encourages NIAID to consider practices

employed with other clinical trials networks (such as the Pediatric Trials Network in NICHD and the heart failure networks in NHLBI) to provide greater efficiencies for AR research, including for the Antibacterial Resistance Leadership Group (ARLG).

3. **Prioritize the discovery and development of new antibacterial agents:** Given the fragility of the antibiotic pipeline, the need for new antibiotics, and the challenges in attracting private investment to antibiotic R&D, IDSA encourages NIAID to explicitly prioritize new antibiotic R&D, with a focus on new classes, novel mechanisms of action, and oral options.
4. **Clinical trials network:** IDSA believes a more extensive clinical trials network, built upon the foundation of ARLG, will help leverage resources to study new and existing antibiotics efficiently in well-designed trials. Such a network should be developed in cooperation with FDA and international partners.
5. **Collaboration with FDA:** As FDA works to improve clinical trial design, NIAID should work closely with FDA to drive the types of studies necessary to yield new antibiotics and understand their optimal use.
6. **Research to inform stewardship:** While great progress is underway in implementing stewardship in inpatient settings, more research to inform and support the implementation of stewardship in a variety of outpatient settings is needed. Outpatient settings are where the majority of antibiotic prescribing occurs.
7. **Diagnostics:** IDSA encourages further study and development of rapid diagnostic tests to guide more rapid pathogen-directed therapy and reduce overuse of broad-spectrum antibiotics.

IDSA looks forward to continued partnership to address antibacterial resistance.

Sincerely,

A handwritten signature in black ink that reads "Cynthia Sears". The signature is written in a cursive, flowing style.

Cynthia Sears, MD, FIDSA
President, IDSA