



# IDSAs

Infectious Diseases Society of America

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### IDSAs 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

May 1, 2019

The Honorable Robert Kadlec, MD

Assistant Secretary for Preparedness and Response

Department of Health and Human Services

200 Independence Avenue SW

Washington, DC 20201

Dear Assistant Secretary Kadlec:

On behalf of the Infectious Diseases Society of America (IDSAs), I am writing to urge swift federal government action to address the dire state of the antibiotic pipeline and the growing crisis of antimicrobial resistance (AMR) that, together, are causing loss of life and threatening to undo decades of medical advances.

The recent bankruptcy of a small antibiotics company with a recently launched antibiotic has significantly heightened our concerns. Without rapid action, the already fragile antibiotic pipeline will thoroughly crumble with devastating impacts for patients, public health and national security. I am grateful that you will be meeting with representatives from IDSAs, large and small pharmaceutical companies, and venture capitalists on May 10 to discuss meaningful solutions. We hope this letter will illustrate our perspective on the urgent need for action. The Biomedical Advanced Research and Development Authority (BARDA) plays a lifesaving role in supporting antibiotic development, but its current investments will fail to achieve their goals without a plan to secure the sustainability of the antibiotics market.

Data from November 2018 indicate that as many as 162,000 people in the US die every year from antibiotic-resistant infections, making these infections the third leading cause of mortality in the US. Without safe and effective antibiotics, hospital stays are lengthened, and complications increase. As the opioid epidemic drives increasing numbers of severe infections such as endocarditis, skin and soft tissue infections and bone and joint infections, antibiotic resistance is further impacting an even larger number of patients. Many face significant surgeries, amputations and even death because we lack the antibiotics to treat them successfully. Some patients with multidrug-resistant infections can only be treated with toxic antibiotics like colistin that can cause severe kidney damage and require patients to rely upon dialysis—at significant expense. In fact, it is estimated that antibiotic resistance costs the healthcare system an additional \$20 billion every year. Some patients have infections resistant to every single available antibiotic, even colistin. The current antibiotic pipeline is insufficient to meet patient needs.

Antimicrobial resistance also poses a threat to our national security. Resistant pathogens complicate our soldiers' combat wounds, increasing the risk of limb loss and death, and compromise our military's combat readiness and effectiveness. Alarming, resistant pathogens are also a prime candidate for weaponization by our nation's enemies. Studies have concluded that the aerosolized release of a weaponized, resistant pathogen in just a single incident of bioterrorism in the Washington, DC area would result in a death toll of over 3 million. The death toll from a coordinated bioterrorist attack using a weaponized resistant pathogen would be many magnitudes higher. Further, wounds and burns resulting from a mass casualty event can also become quickly infected, and AMR would make those infections much more challenging to treat.

The antibiotic market is unique, and uniquely broken. Antibiotics are used for a short duration, and new antibiotics are held in reserve, used as infrequently as possible, to protect their clinical utility from the development of antibiotic resistance. These factors lead to very low sales of new antibiotics, making it challenging for companies to earn a return on their investment.

Since 2015, IDSA has successfully advocated for increased federal investments across multiple federal agencies to combat AMR. We deeply appreciate the federal commitment to this issue, and are encouraged that these investments are beginning to deliver results. In particular, funding provided by BARDA has been essential to the survival of the antibiotic pipeline and has supported the successful development of two new FDA-approved antibiotics for hard-to-treat infections. Unfortunately, the two small companies who developed these drugs are no longer in the antibiotics market—The Medicine's Company shuttered its infectious diseases division and Achaogen filed for chapter 11 bankruptcy protection. Many companies currently receiving support through the BARDA Broad Spectrum Antimicrobials program and CARB-X are likely to face a similar fate without action to ensure sustainability.

The lessons of Achaogen and The Medicines Company have demonstrated that federal investment in the research and development of new antibiotics in the form of "push" incentives must be matched with opportunities for industry to earn a fair and reasonable return on its investments in antibiotic R&D through novel "pull" incentives. Without this approach, federal investments in antibiotic R&D will be wasted as companies are unable to sustain economic returns that allow for continued manufacturing of the recently approved antibiotics or to develop new ones.

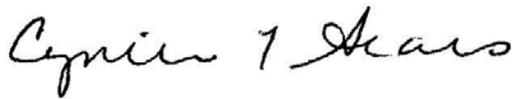
The loss of Achaogen not only poses concerns about the availability of its antibiotic but sends a chilling ripple effect across an antibiotic market that is already in a tenuous position with other small companies that have recently launched new antibiotics facing plummeting stock prices. There is a substantial concern that the Achaogen news will make investors even less likely to support antibiotic research and development at a time when innovation is desperately needed.

IDSA represents over 11,000 physicians, other health care providers, scientists and public health practitioners who are on the front lines of efforts to combat AMR—caring for patients with serious infections caused by multidrug-resistant pathogens; conducting research to discover and develop new antibiotics, diagnostics, vaccines and novel therapeutics; leading antimicrobial stewardship and infection prevention programs; and driving public health interventions. Our

members see firsthand the urgent need for new antibiotics to care for patients now, and for a robust and renewable antibiotic pipeline to meet future patient needs.

Antibiotics underpin many of the advances in modern medicine. Cancer chemotherapy, organ and bone marrow transplants and other complex surgeries are not possible without safe and effective antibiotics. The growing threat of antibiotic resistance coupled with inadequate antibiotic innovation put the future of medicine at risk. New federal policies are urgently needed to stimulate antibiotic research and development and to promote appropriate antibiotic use through stewardship.

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