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Infectious Diseases Society of America

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May 1, 2019

The Honorable Norman Sharpless, MD  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

The Honorable Amy Abernethy, MD, PhD  
Principal Deputy Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Acting Commissioner Sharpless and Principal Deputy Commissioner Abernethy:

On behalf of the Infectious Diseases Society of America (IDSAs), I write to urge swift federal government action to address the dire state of the antibiotic pipeline and the growing crisis of antimicrobial resistance (AMR). Together, they cause loss of life and limb—threatening to undo decades of medical advances. IDSAs has sounded the alarm on AMR for over a decade, but recent events—namely the bankruptcy of a small antibiotic-manufacturing company with a recently launched and needed antimicrobial—have significantly heightened our concern that without rapid action, the already fragile antibiotic pipeline will crumble, with devastating impacts for patients, public health and national security. **We request a meeting at your earliest convenience to discuss opportunities for a rapid response to save the antibiotic pipeline. We recognize that you are uniquely well suited to champion this issue within the federal government.**

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 occur. As the opioid epidemic drives increasing numbers of infections such as endocarditis, skin and soft tissue infections and bone and joint infections, antibiotic resistance is now impacting an even larger number of patients who are facing major surgeries, amputations and even death because we lack the tools to successfully treat them. Some patients with multidrug-resistant infections can only be treated with toxic antibiotics like colistin, which can cause severe kidney damage and require patients to rely upon dialysis—a significant expense. We have even seen patients with infections due to pathogens resistant to ALL available antimicrobials—including colistin. It is estimated that antibiotic resistance costs the healthcare system an additional \$20 billion every year. The current antibiotic pipeline is insufficient to meet patient needs.

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 have greatly appreciated the federal commitment to this issue, and are encouraged that these investments are beginning to deliver results. Increased willingness from the Food and Drug Administration (FDA) to consider more flexible approaches to clinical development has made it possible for a few new antibiotics to reach the market. Funding provided by the Biomedical Advanced Research and Development Authority (BARDA) 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.

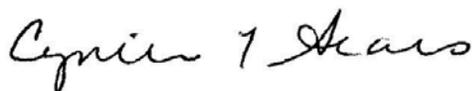
The lessons of Achaogen and The Medicines Company have demonstrated that federal investment in the research and development of new antibiotics in the form of “push” incentives must be matched with opportunities for industry to earn a fair and reasonable return on its investments in antibiotic R&D through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

The loss of Achaogen not only poses concerns about the availability of its antibiotic, but could send 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 strong 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 of 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