

January 28, 2020

The Honorable Alex M. Azar II
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

As organizations representing health care providers, patients, public health, scientists, and industry, we are writing to alert you to the latest significant evidence that the antibiotic market is in jeopardy —the December 27, 2019 Chapter 11 bankruptcy filing and restructuring of Melinta Therapeutics —a biotech company with four products on the market. While Melinta’s products remain available during this process, this is yet another sign that will drive investors away from this space. We implore you to take swift action to stabilize and strengthen the antibiotics market and make the investments necessary for a comprehensive response to antimicrobial resistance, including stewardship, diagnostics, surveillance, prevention and research.

The antibiotics market is in a state of crisis. Melinta is not an outlier—it is the second small antibiotics company, following Achaogen, to file for bankruptcy in 2019. The stock prices of the remaining small antibiotics companies with approved antibiotics make clear that additional bankruptcies are likely in 2020 unless federal action is taken. Small companies are particularly important in the antibiotic space as they are developing the majority of new medicines to address antimicrobial resistance (AMR). Many of these companies are struggling to secure private investment to bring these medicines to the market and patients. Additional failures of companies following successful approval will sap what little investment remains in this space with catastrophic consequences on an already inadequate pipeline.

Allowing the antibiotics market to collapse endangers modern medicine, public health and national security. Antibiotics underpin modern medicine—making interventions like cancer chemotherapy, organ and bone marrow transplants, and surgeries safe to perform. Without antibiotics, simple cuts can once again lead to amputations and even deaths. The death tolls of mass casualty events—whether natural or human-made—will increase substantially as we become unable to treat secondary infections that complicate wounds and burns.

We appreciate the initial steps taken by the administration to address antimicrobial resistance, including the new Medicare Condition of Participation requiring hospitals to implement stewardship programs, efforts to improve antibiotic reimbursement, strides in surveillance and infection prevention, and support for antibiotic development from the Biomedical Advanced Research and Development Authority and the National Institutes of Allergy and Infectious Diseases.

However, the magnitude of the problem requires far greater investment to ensure the sustainability of the antibiotics market. While current incentives have been successful at bringing important new antibiotics to market, they alone are insufficient and a package of incentives are needed to ensure new antibiotics can remain available to patients and to further strengthen the pipeline to bring about the innovation needed to meet current and future patient needs. New resources are also urgently needed

to support stewardship, surveillance and other public health activities to address antimicrobial resistance.

We appreciate your attention to the serious issue of antimicrobial resistance and the urgent need to save the antibiotics market in order to protect our national security, public health and modern medicine.

Sincerely,

Accelerate Diagnostics

Aequor

American Gastroenterological Association

American Thoracic Society

Association for Professionals in Infection Control and Epidemiology

Association of Public and Land-grant Universities

bioMerieux

Biotechnology Innovation Organization (BIO)

Cystic Fibrosis Foundation

Emory Antibiotic Resistance Center

HIV Medicine Association

Infectious Diseases Society of America

Making-A-Difference in Infectious Diseases

Merck

National Coalition of STD Directors

ONCORD, Inc.

Peggy Lillis Foundation

Peptilogics

Qpex Biopharma

Shionogi, Inc.

Society of Critical Care Medicine

Society of Infectious Diseases Pharmacists

Spero Therapeutics

Summit Therapeutics

The Antimicrobials Working Group (Amplix Pharmaceuticals, Cidara Therapeutics Inc., Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc, VenatoRx Pharmaceuticals Inc. and X-Biotix)

The Foundation to Combat Antimicrobial Resistance

The Gerontological Society of America

The Pew Charitable Trusts

Trust for America's Health

Tufts Center for Integrated Management of Antimicrobial Resistance (CIMAR)

Venatorx Pharmaceuticals

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