September 13, 2019

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:

We, the undersigned organizations representing health care providers, scientists, patients, public health, veterinary medicine, industry and advocates, write to thank you for recent Department activities to combat antimicrobial resistance (AMR) and to express our desire to work with you on additional efforts to address this serious threat to patient safety and public health. As you know, AMR kills up to 162,000 people in the US every year and threatens to undo decades of medical progress, including organ and bone marrow transplants, cancer chemotherapy, and care of preterm infants and other immunocompromised patients. The antibiotic pipeline is in grave danger of collapse, as the small companies currently responsible for the majority of antibiotic innovation struggle to stay in business.

Urgent, well-coordinated efforts across human health, animal health and the environment including stewardship, infection prevention, surveillance, research and innovation will be essential, and we greatly appreciate the Department's recent steps forward in many of these areas. The FY2020 Inpatient Prospective Payment System (IPPS) final rule aims to improve reimbursement for new antibiotics to help improve patient access to these lifesaving new medicines. Public statements from the Centers for Medicare and Medicaid Services Administrator indicate a willingness to consider stronger payment reforms and stewardship policies. Statements from the Biomedical Advanced Research and Development Authority Director signaling a greater role from BARDA in supporting antibiotic R&D have provided much needed encouragement. Research supported by the National Institute of Allergy and Infectious Diseases generates an important foundation for the development and optimal use of new antibiotics, diagnostics and vaccines. Ongoing Food and Drug Administration efforts to implement the Limited Population Antibacterial Drug (LPAD) pathway and modernize clinical trial approaches should improve the regulatory environment for antibiotic development. The AMR Challenge launched by the Centers for Disease Control and Prevention and soon to celebrate its one-year anniversary is bringing together partners across the globe to fulfill commitments to address all aspects of this issue. We are grateful that these and other efforts demonstrate that AMR is a clear priority across the Department and across other cabinet level departments as well.

Despite these welcome advances, new investments and policies are quickly needed to stabilize the antimicrobial market, ensure a robust, diverse antibiotic pipeline, and stem the tide of AMR. Below we outline key areas in which we hope to work with you for continued progress.

**Stewardship**
Antibiotic use in all settings—including healthcare, livestock farming, and horticulture —requires careful stewardship to minimize the likelihood that bacteria exposed to the drugs will become resistant to them. Antibiotic stewardship optimizes antibiotic use and patient outcomes, limits the development of resistance driven by overuse and misuse of antibiotics, and reduces healthcare costs. We greatly appreciate that CMS extended the draft Medicare Condition of Participation that would require

hospitals to implement stewardship programs, and we strongly encourage CMS to finalize this rule as quickly as possible. It will be essential to ensure that diagnostic tools and tests, critical to the success of stewardship programs, are effectively leverage by our hospital partners. In addition, we encourage the Department to seek universal hospital reporting of antibiotic use and resistance data to the CDC National Healthcare Safety Network (NHSN) to allow for evaluation of stewardship efforts. Lastly, we encourage HHS to provide funding for hospitals who may require initial support to establish stewardship programs and to begin reporting to NHSN, particularly rural hospitals and critical access hospitals.
We support the U.S. Food and Drug Administration (FDA) five-year roadmap to enhance stewardship in veterinary settings and food-animal production and look forward to working with FDA on key goals such as transitioning all animal antibiotics with human medical importance to veterinary oversight and establishing scientifically-based durations of use for all medically important antibiotics. Better data about on-farm antibiotic use are needed to guide future policy actions. We therefore strongly support FDA's commitments to enhance this information, and to work closely with the U.S. Department of Agriculture (USDA) and other stakeholders on these and other important issues, such as spurring the development of new antibiotic alternatives.

**Additional policies to create a robust and sustainable antimicrobial pipeline**
We greatly appreciate the steps your Department has taken to help address the market challenges of antimicrobial development. However, we must urgently advance an additional package of incentives policies that will both further stabilize the pipeline and the certainty needed for investment into the antibiotic pipeline.

We are hopeful that new policies in the FY2020 IPPS rule to boost antibiotic reimbursements and reimbursements for patients with resistant infections will allow Medicare reimbursement to come closer to covering the cost of new antibiotics for patients who need them. However, we believe it is likely that a gap in coverage will remain, which may still pose a challenge for patient access. We look forward to working with HHS to explore additional reimbursement solutions, including both the DISARM Act as well as additional CMS-lead reimbursement solutions, that ensure that reimbursement levels for new antibiotics pose no hurdles to appropriate prescribing.

While reimbursement reforms are essential, they are likely insufficient to sustain the antibiotic pipeline capable of meeting current and future patient needs. Because new antibiotics must be used judiciously to preserve their effectiveness, traditional business models focused on high sales volume are often infeasible for new antibiotics. A new approach—a significant pull incentive—is needed to spur the development of novel antibiotics for urgent unmet needs. We look forward to engaging with HHS to explore how we can develop and implement this policy. We also note that existing investments in antibiotic research and development, such as BARDA and NIAID efforts, must be maintained.
We thank you for your commitment to combating AMR and look forward to continued collaboration this fall on this issue.

Sincerely,
Accelerate Diagnostics, Inc.
Alliance for Aging Research
American Academy of Allergy, Asthma, and Immunology
American Association of Avian Pathologists
American Gastroenterological Society of America
American Thoracic Society
American Veterinary Medical Association

Animal Health Institute
Antibiotic Resistance Action Center, the George Washington University
Association for Professionals in Infection Control and Epidemiology
Association of American Veterinary Medical Colleges
Association of Public and Land-grant Universities
Becton Dickinson and Co. (BD)
bioMerieux
Biotechnology Innovation Organization (BIO)
Cepheid
Clinician Champions in Comprehensive Antibiotic Stewardship
Coalition for Improving Sepsis and Antibiotic Practices
Council of State and Territorial Epidemiologists
Emory Antibiotic Resistance Center
Food Animal Concerns Trust
Health Care Without Harm
Immune Deficiency Foundation
Infectious Diseases Society of America
Johns Hopkins Center for a Livable Future
Making-A-Difference in Infectious Diseases
Melinta Therapeutics, Inc.
Michigan Antibiotic Resistance Reduction Coalition
National Athletic Trainers' Association
National Institute of Antimicrobial Resistance Research and Education
National Tuberculosis Controllers Association
ONCORD, Inc.
Peggy Lillis Foundation
Qpex Biopharma, Inc.
Roche Diagnostics Corporation
Sepsis Alliance
Small World Initiative
Spero Therapeutics
The Antimicrobials Working Group (Amplyx Pharmaceuticals, Aridis Pharmaceuticals, Cidara Therapeutics Inc., Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc, VenatoRx Pharmaceuticals Inc. and X-Biotix)
The Fecal Transplant Foundation
The Foundation to Combat Antimicrobial Resistance
The Gerontological Society of America
The Pew Charitable Trusts
The Society of Infectious Diseases Pharmacists
Trust for America's Health
Tufts Center for Integrated Management of Antimicrobial Resistance (CIMAR)

Cc:
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Norman Sharpless, MD, Commissioner, Food and Drug Administration
Rick Bright, PhD, Director, Biomedical Advanced Research and Development Authority
Garrett Grigsby, Director, HHS Office of Global Affairs