January 13, 2017

Donald J. Trump President-elect Washington, DC

Dear President-elect Trump:

Congratulations on your election to the presidency of the United States. As you prepare to take office, the undersigned organizations look forward to working with your Administration to address antimicrobial resistance (AMR), an acute threat to patient safety, public health, and national security.

The Centers for Disease Control and Prevention (CDC), President's Council of Advisors on Science and Technology (PCAST), World Health Organization (WHO) and other expert bodies have well documented the urgent threat posed by antibiotic resistance. Over time, bacteria develop resistance to existing antibiotics, leaving patients with increasingly fewer, and in some cases no treatment options. By CDC estimates, each year antibiotic resistant bacteria sicken at least two million Americans and claim the lives of at least 23,000. Antibiotic resistant infections annually account for an additional 8 million hospital days and costs in excess of \$20 billion to the U.S. healthcare system. The actual human and financial costs are likely far higher, as our surveillance and data collection capabilities cannot yet capture the full disease burden.

While anyone can develop an antibiotic-resistant infection, we know that specific populations are disproportionately impacted – including our active-duty military and veterans, the elderly, preterm infants, and immunocompromised individuals, such as patients with HIV/AIDS. Antibiotic resistance also complicates a variety of important medical procedures, including cancer chemotherapy, solid organ and bone marrow transplants, joint replacements, and other complex surgeries. The safety of these procedures depends upon the availability of effective antibiotics. Antibiotic resistance could also significantly diminish our nation's ability to respond to a bioterror attack, should highly resistant pathogens be weaponized.

Antibiotic resistance has been exacerbated by the inappropriate use of existing antibiotics. According to the CDC, at least 30 percent of the antibiotics prescribed in the United States are unnecessary. The use of antibiotics in animals is also a factor driving the development of resistance in human and veterinary medicine.

As resistance escalates, antibiotic research and development (R&D) has lagged—further limiting treatment options. Antibiotic R&D poses unique scientific, regulatory and economic challenges. It can often take dozens of lead antibiotic compounds in the early discovery phase to generate one FDA-approved product; other drug classes have considerably lower failure rates during development. Antibiotics become less effective as soon as they are used, because bacteria develop defenses to resist them and then transfer these defenses to other bacteria. As a result, new antibiotics are often held in reserve to protect their long-term effectiveness, severely limiting antibiotics' profitability. Antibiotics also are typically inexpensive and used for short durations and, therefore, can rarely successfully compete for R&D dollars against more profitable drugs including those that treat chronic diseases. What's more, it can often prove difficult or even impossible to identify a sufficient number of patients for clinical trials for the most desperately needed new antibiotics, as the infections occur in relatively small populations at any given period in time.

Antibiotic resistance is a complex problem that will require strong federal leadership of a multi-faceted solution. Specifically, we offer the following recommendations:

Antibiotic Stewardship and Infection Prevention: Antibiotic stewardship refers to using the right antibiotic for the right patient at the right time. Antibiotic stewardship programs have been demonstrated to reduce inappropriate antibiotic use and reduce health care costs. We recommend that all hospitals be required to establish these programs. In addition, we recognize that the best way to limit antibiotic use is to prevent infections in the first place, and urge support for efforts infection prevention and control activities.

Surveillance: Robust surveillance and data collection are vital to help us understand the scope of the problem, track emerging threats, and evaluate interventions. Information on antibiotic use, in both human and animal health, and resistance patterns is essential.

Incentives for Antibiotics, Diagnostics, and Vaccines: Our best efforts can, and must, limit the development and impact of antibiotic resistance, but we cannot stop it entirely. We need a robust and renewable pipeline of new antibiotics to address current and future threats. We will not achieve this goal without significant economic incentives for antibiotic R&D. In addition, we urge the creation of incentives for the research, development, and appropriate use of rapid diagnostic tests, which are essential to guide the optimal use of antibiotics. Lastly, we support research to fill vaccine gaps to support infection prevention.

The above recommendations are reflected in several reports by expert bodies, including the CDC, PCAST, and WHO. They are also embedded in the *National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan)*, which was issued in March, 2015 and engages state and local government partners, academia, industry and other stakeholders to directly respond to the threat AR poses to patients, public health, and national security. In Fiscal Year 2016, Congress—with broad bipartisan support—provided \$380 million in new funding to begin implementing the Action Plan, with activities across CDC, National Institute of Allergy and Infectious Diseases, Biomedical Advanced Research and Development Authority, and the Food and Drug Administration. We hope your administration will maintain and build upon these investments. We also strongly encourage you to advance policies to promote antibiotic stewardship and incentivize R&D.

In September 2016, the U.S. also joined the U.N. General Assembly in a political declaration aimed at addressing AMR around the world. These efforts must be sustained and built upon to prevent a post-antibiotic era in which common infections prove fatal.

Once again, we look forward to working closely with you and your Administration to address antibiotic resistance. We believe the existing Action Plan provides a thoughtful roadmap for progress, and are also eager to collaborate with you on new opportunities to enhance our nation's response to this public health crisis. We welcome the opportunity to serve as a resource to your administration as it considers how to move forward in this area.

Sincerely,

Accelerate Diagnostics, Inc. AdvaMedDx Alliance for Aging Research Alliance for the Prudent Use of Antibiotics American Academy of Allergy, Asthma & Immunology American Association of Bovine Practitioners American Association of Immunologists American College of Preventive Medicine American College of Rheumatology American Gastroenterological Association American Society for Microbiology American Thoracic Society American Veterinary Medical Association Antibiotic Resistance Action Center, The George Washington University Antimicrobials Working Group [Amplyx Pharmaceuticals, Arsanis, Cempra, Cidara Therapeutics, ContraFect, Iterum Therapeutics, Melinta Therapeutics, Nabriva Therapeutics, Paratek, Scynexis, Theravance, Viamet, Zavante Therapeutics] Association for Professionals in Infection Control and Epidemiology Association of American Veterinary Medical Colleges Association of Public Health Laboratories Association of Public and Land-grant Universities BD Clinician Champions in Comprehensive Antibiotic Stewardship **Consumer Federation of America** Council of State and Territorial Epidemiologists Emory Antibiotic Resistance Center, Emory University Food Animal Concerns Trust GlaxoSmithKline Health Care Without Harm HIV Medicine Association Infectious Diseases Society of America Keep Antibiotics Working Making-A-Difference in Infectious Diseases Merck Microbion Corporation Musculoskeletal Infection Society National Association of County and City Health Officials National Association of Pediatric Nurse Practitioners Pediatric Infectious Diseases Society Peggy Lillis Foundation Pure Cultures LLC Research!America Society of Infectious Diseases Pharmacists **Spero Therapeutics** The Foundation to Combat Antimicrobial Resistance The Gerontological Society of America The Pew Charitable Trusts The Society for Healthcare Epidemiology of America Theravance Biopharma Trust for America's Health