

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 [Amplix 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