

October 27, 2014

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Donovan:

The undersigned organizations representing healthcare providers, patients, scientists, veterinarians, industry, and public health are deeply concerned with the growing crisis of antibiotic resistance (AR). This crisis is a serious threat to public health, national security, and patients—particularly immunocompromised patients including chemotherapy and transplant patients, the elderly, preterm infants, individuals with HIV/AIDS, and others. We write to urge the Office of Management and Budget (OMB) to help provide the resources necessary to implement the President's Council of Advisors on Science and Technology (PCAST) recommendations to combat antibiotic resistance. A comprehensive, well-coordinated federal response should include prevention and control activities, enhanced data collection and surveillance, antibiotic stewardship, as well as greater investment in research and development (R&D) for antibiotics, diagnostics, vaccines and other therapeutics. We support the PCAST recommendation to significantly increase federal investments dedicated to addressing AR. Such commitments can save lives and help reduce healthcare expenditures associated with AR. Specifically, we request:

- 1. The final budget agreement for Fiscal Year (FY) 2015 should include at least a down payment on the new resources needed to address AR.**
- 2. The FY 2016 President's Budget Request (PBR) should include significant new resources sufficient to carry out the activities recommended by PCAST and included in the Combating Antibiotic Resistant Bacteria (CARB) National Strategy and Executive Order.**

Improved prevention, surveillance and data collection are central to the federal effort to address antibiotic resistance. We support the PCAST recommendation of \$90 million in new funding to the Centers for Disease Control and Prevention (CDC) to support grants to states and major cities for public health efforts for detection of antibiotic resistance, outbreak response, and aggressive prevention activities including stewardship of existing antibiotics. We also support the PCAST recommendation of \$190 million per year to establish and maintain a national capability for pathogen surveillance based on genome analysis. Surveillance activities should include both human and animal health. The proposed CDC Detect and Protect Against Antibiotic Resistance initiative (included in the FY2015 PBR at \$30 million) could be a first step toward these investments.

Recognizing the need to promote the appropriate use of antibiotics and preserve these precious drugs' utility, the PCAST report also recommends that the Centers for Medicare and Medicaid Services (CMS) take a number of steps to improve antibiotic stewardship, including gathering data on antibiotic use and resistance. These data are critical to fully understand the problem and evaluate the effectiveness of our interventions. The increase of \$14 million proposed for the National Healthcare Safety Network (NHSN) in the FY2015 PBR is critical to increase the number of facilities reporting these data.

We agree that more fundamental research is needed to better understand and overcome antibiotic resistance. We support the PCAST recommendation of an additional \$150 million per year for the National Institutes of Health (NIH), the Defense Advanced Research Projects Agency (DARPA), and the Defense Threat Reduction Agency (DTRA) to support this research. In addition, we recognize that developing alternatives to antibiotic use in agriculture is another important component to efforts to limit the development of resistance. We support the PCAST recommendation of \$25 million per year in new funding for a USDA multidisciplinary Innovation Institute to support research in this area.

The urgent need for new antibiotics, diagnostics and vaccines has been clearly articulated by leading public health authorities. The antibiotic pipeline remains extremely fragile, and many patients are succumbing to infections for which there are no satisfactory treatments. New rapid point-of-care diagnostic tests are needed to improve patient care, guide appropriate antibiotic use, and help identify patients eligible for antibiotic clinical trials. Given the significant economic, scientific, and regulatory barriers to antibiotic and diagnostic R&D, public private partnerships are critical. We support the PCAST recommendation of \$25 million per year to begin, with additional funds in the future, to establish the necessary infrastructure for a public private partnership and to pursue the development of a master clinical trials protocol. Further, we support the PCAST recommendation of increased funding to the Biomedical Advanced Research and Development Authority (BARDA) to support partnerships with industry for antibiotic and diagnostic development. Specifically PCAST suggests an additional \$400 million for BARDA to support antibiotic development and an additional \$400 million for BARDA to provide advance market commitments (AMC) and milestone payments as incentives for bringing a new antibiotic to market. We also support the PCAST recommendation of federal awards in the range of \$25 million each for the development of rapid point-of-care diagnostics. Lastly, we recognize that additional economic incentives for antibiotic and diagnostic development will be needed.

Following the release of the PCAST report, CARB National Strategy, and Executive Order, it is now time for our nation to take action. We ask that OMB serve as a ready partner to facilitate the strategy articulated by the Administration by helping to provide federal agencies with the resources necessary to implement the strategy. The lives of our citizens depend on a comprehensive and swift federal response to antibiotic resistance. We welcome the opportunity to further discuss these issues with you and your staff.

Sincerely,

Accelerate Diagnostics, Inc.
AdvaMedDx
Alere, Inc.
Alliance for Aging Research
Alliance for Natural Health-USA
Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Association of Avian Pathologists
American Association of Bovine Practitioners
American College of Physicians
American College of Preventive Medicine
American Public Health Association
American Society for Microbiology
American Thoracic Society
American Urological Association
American Veterinary Medical Association

Antibiotics Working Group (Cempra, Durata Therapeutics, Optimer Pharmaceuticals, Melinta, The Medicines Company and Theravance)

Antimicrobial Innovation Alliance (Actavis-Forest Labs, Achaogen, Astellas US, AstraZeneca, Actavis-Forest Labs, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Tetrphase and The Medicines Company)

Association for Professionals in Infection Control and Epidemiology

Association of American Veterinary Medical Colleges

Association of State and Territorial Health Officials

BD

bioMérieux

Biotechnology Industry Organization (BIO)

Cempra, Inc.

Center for Disease Dynamics, Economics & Policy

Council of State and Territorial Epidemiologists

Cubist Pharmaceuticals

Food & Water Watch

Health Care Without Harm

HIV Medicine Association

Infectious Diseases Society of America

International Centre for Migration, Health and Development

Making-A-Difference in Infectious Diseases

March of Dimes

National Association of County and City Health Officials

National Association of Pediatric Nurse Practitioners

National Coalition of STD Directors

National Foundation for Infectious Diseases

ONCORD, Inc.

Pediatric Infectious Diseases Society

Premier Healthcare Alliance

Renal Physicians Association

Research!America

Society for Healthcare Epidemiology of America

Society for Women's Health Research

Society of Critical Care Medicine

Society of Infectious Diseases Pharmacists

Tetrphase Pharmaceuticals, Inc.

The Peggy Lillis Memorial Foundation

The Pew Charitable Trusts

Theravance Biopharma

Trust for America's Health

UPMC Center for Health Security

Organizations added following initial distribution:

Consumers Union

Health Watch USA