The Honorable Thad Cochran Chairman Committee on Appropriations United States Senate Washington, DC 20510

The Honorable Harold Rogers Chairman Committee on Appropriations United States House of Representatives Washington, DC 20515 The Honorable Barbara Mikulski Vice Chairwoman Committee on Appropriations United States Senate Washington, DC 20510

The Honorable Nita Lowey Ranking Member Committee on Appropriations United States House of Representatives Washington, DC 20515

Dear Chairman Cochran, Vice Chairwoman Mikulski, Chairman Rogers, and Ranking Member Lowey:

The undersigned organizations representing healthcare providers, patients, scientists, veterinarians, industry, and public health are deeply concerned with the growing crisis of antimicrobial resistance (AR). This crisis is a serious threat to public health, national security, and specific populations—such as immunocompromised individuals including chemotherapy and transplant patients, the elderly, preterm infants, individuals with HIV/AIDS, and others. The rapid rise of AR, along with other crises such as the recent outbreak of Ebola, demonstrates the need to increase and sustain federal investments in biomedical research and public health.

The development of antimicrobial resistance is occurring at an alarming rate and far outpacing the struggling research and development of new antibiotics. Last fall, the President's Council of Advisors on Science and Technology (PCAST) made recommendations to combat antibiotic-resistant bacteria. The PCAST report to the president held that a comprehensive, well-coordinated federal response must 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, and vaccines. These activities are advanced in the administration's National Strategy to Combat Antibiotic-Resistant Bacteria and Fiscal Year (FY) 2016 budget request. Congress has already demonstrated strong, bipartisan leadership in addressing AR through enactment of the Generating Antibiotic Incentives Now (GAIN) Act, which provides additional exclusivity for new antibiotics that treat a serious or life-threatening infection. But we must build upon that initial step. As consideration of the FY 2016 budget moves forward, we urge you to provide the resources necessary to implement the PCAST recommendations to combat antibiotic-resistant bacteria. Specifically, we ask that the agencies and programs that follow receive the support requested in the FY 2016 budget.

Centers for Disease Control and Prevention (CDC)

• <u>Antibiotic Resistance Solutions Initiative</u> (\$264 million): The CDC Antibiotic Resistance Initiative builds prevention programs in all 50 states and 10 large cities, utilizing evidence-based approaches to stop the spread of drug-resistant bacteria and preserve the effectiveness of existing

- antibiotics. The initiative also supports a new network of regional labs to improve tracking of and response to outbreaks of serious and potentially deadly bacteria.
- National Healthcare Safety Network (NHSN) (\$32 million): The requested funding allows CDC to expand the National Healthcare Safety Network to more than 17,000 facilities. Expanded activities include providing real-time data about antibiotic use and trends, targeting health care facilities that need additional assistance using NHSN data, and implementing prevention strategies.
- Advanced Molecular Detection (AMD) Initiative (\$30 million): Continuation of this initiative allows CDC to more rapidly determine where emerging diseases come from, whether microbes are resistant to antibiotics, and how microbes are moving through a population. The AMD initiative strengthens CDC's epidemiologic and laboratory expertise to effectively guide public health action.

### *National Institutes of Health (NIH)*

• National Institute of Allergy and Infectious Diseases (NIAID) (\$4.615 billion): Within the NIAID budget, an increase of \$100 million is proposed to spur R&D for new rapid diagnostics to help ensure that antibiotics are prescribed appropriately, develop a national database of genome sequence data of all reported human infections with antimicrobial-resistant microorganisms, launch a large-scale effort to better understand drug resistance, and create a rapid-response clinical trial network to test new antibiotics on individuals infected with highly resistant strains.

# Assistant Secretary for Preparedness and Response (ASPR)

• Biomedical Advanced Research and Development Authority (\$522 million): Funding requested for BARDA includes \$192 million dedicated to antimicrobial R&D, which is a step towards the PCAST recommended level of \$800 million annually. BARDA utilizes novel public-private partnerships to address the market failure in antibiotic R&D.

#### Food and Drug Administration (FDA)

• Combating Antibiotic Resistant Bacteria (\$47 million): Funding requested supports phasing out the use of medically important antimicrobials for growth promotion in food-producing animals, development of a system for monitoring antimicrobial drug use in food-producing animals, evaluation of new antibacterial drugs for patient treatments, and streamlining of clinical trials.

## Department of Agriculture (USDA)

• Antimicrobial Resistance (\$77 million): Proposed funding allows the USDA to support research on the relationships among microbes and livestock, the environment, and human health, as well as alternatives to antibiotic use. Funding would also support expanded dissemination of science-based knowledge to veterinarians and producers, plus use of voluntary surveys to measure antibiotic use in agriculture.

The PCAST report on antibiotic resistance was preceded by similar warnings and recommendations from public health authorities such as the <u>CDC</u> and <u>World Health Organization</u>. There is no dispute that the lives of our citizens depend on a comprehensive and swift federal response to antimicrobial resistance. It is now time for our nation to take action. We urge you to appropriate the resources necessary to implement the *National Strategy* and offer our groups as resources to help inform your

deliberations. You can obtain additional information by contacting Jonathan Nurse at the Infectious Diseases Society of America (703) 299-0202 or <a href="mailto:jnurse@idsociety.org">jnurse@idsociety.org</a>. We thank you for your leadership and working with us to prevent a post-antibiotic era where common infections prove fatal.

### Sincerely,

**Accelerate Diagnostics** 

AdvaMedDx

Alliance for Aging Research

Alliance for the Prudent Use of Antibiotics

American Academy of Pediatrics

American Association of Bovine Practitioners

American College of Preventive Medicine

American Gastroenterological Association

American Public Health Association

American Society for Microbiology

American Society of Transplant Surgeons

American Thoracic Society

American Veterinary Medical Association

Antimicrobial Innovation Alliance (Actavis-Forest Labs, Achaogen, Astellas US, AstraZeneca, Actavis-

Forest Labs, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Microbion Corporation, Spero

Therapeutics, Tetraphase, The Medicines Company, and Zavante Therapeutics)

Association for Professionals in Infection Control and Epidemiology

Association of American Veterinary Medical Colleges

bioMérieux, Inc.

Biotechnology Industry Organization (BIO)

California Tuberculosis Controllers Association

Cempra Inc.

Center for Disease Dynamics, Economics & Policy

Center for Foodborne Illness Research & Prevention

Council of State and Territorial Epidemiologists

Da Volterra

Dignity Health

Health Watch USA

**HIV Medicine Association** 

Infectious Diseases Society of America

International Centre for Migration, Health and Development

Johns Hopkins Center for a Livable Future

Keep Antibiotics Working

Making a Difference in Infectious Diseases

March of Dimes Foundation

Microbion Corporation

National Association of County and City Health Officials

National Association of Pediatric Nurse Practitioners

National Foundation for Infectious Diseases

National TB Controllers Association

Natural Resources Defense Council

NovaDigm Therapeutics, Inc.

Continues on the next page

ONCORD, Inc.

Pediatric Infectious Diseases Society

Premier Safety Institute

RPS Diagnostics, Inc.

Renal Physicians Association

Society for Healthcare Epidemiology of America

Society for Women's Health Research

Society of Critical Care Medicine

Society of Hospital Medicine

Society of Infectious Diseases Pharmacists

Stop TB USA

The Medicines Company

The Pew Charitable Trusts

Theravance Biopharma

Trust for America's Health

**UPMC** Center for Health Security

Zavante Therapeutics Inc.

CC: Senators Roy Blunt, Patty Murray, Jerry Moran, Jeff Merkley Representatives Tom Cole, Rosa DeLauro, Robert Aderholt, Sam Farr