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The Honorable Barbara Lee
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The Honorable Hal Rogers
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The Honorable Betty McCollum
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March 18, 2021

Dear Chairs and Ranking Members of the Labor-HHS-Education, Agriculture, State and Foreign Operations, and Defense Appropriations Subcommittees:

The undersigned organizations, representing clinicians, scientists, patients, public health, animal agriculture and the pharmaceutical and diagnostics industries, urge you to significantly increase federal investments in domestic and global programs to address antimicrobial resistance (AMR). We call for a comprehensive One Health approach that encompasses human, animal and environmental health with increased funding for surveillance, prevention, stewardship, research and innovation.

Antibiotic resistance is one of the greatest public health threats of our time. Drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people in the United States each year. Antibiotic resistance accounts for direct health care costs of at least \$20 billion. Globally, over 700,000 people die each year, accounting for a cost as high as \$1.2 trillion. If we do not act now, antibiotic resistant infections will be the leading cause of death by 2050 and could cost the world \$100 trillion.

Addressing AMR is central to strengthening our preparedness for future public health emergencies, as patients with respiratory infections, serious wounds or burns, or other conditions requiring hospitalization are all at risk for secondary resistant infections. For example, seriously ill COVID-19 patients particularly those requiring mechanical ventilation, are at heightened risks for secondary resistant infections. Very high levels of antibiotic use among patients with COVID-19 may also have created new resistance threats we have not yet identified.

Unfortunately, the pipeline of new antibiotics in development is insufficient to meet patient needs. Small companies that are responsible for nearly all current antibiotic innovation are struggling to stay in business. Factors unique to antibiotics, including the need for their judicious use, make it challenging

for companies to earn a return on investments in antibiotic research and development. Additionally, new diagnostic tools are needed to help guide appropriate antibiotic use and enable surveillance.

A deeper federal investment commensurate with the gravity and importance of AMR is urgently needed. We recommend:

Labor, Health and Human Services, Education and Related Agencies

The Centers for Disease Control and Prevention (CDC)

Current CDC resources are not sufficient to address AMR. We recommend \$672 million for the **Antibiotic Resistance Solutions Initiative** to achieve the goals outlined in the 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria. Increased funding would help expand antibiotic stewardship across the continuum of care; double grant awards at the state and local level, expand the AR Laboratory Network globally and domestically to strengthen the identification, tracking and containment of deadly pathogens; support AMR research and epi centers, and increase public and health care professional education and awareness activities. This funding is vital to achieving the Plan's goals, including a 20 percent decrease in health care-associated antibiotic-resistant infections and a 10 percent drop in community-acquired antibiotic-resistant infections by 2025.

The **Advanced Molecular Detection (AMD) program** strengthens CDC's epidemiologic and laboratory expertise to effectively detect and respond to the ever-expanding universe of emerging diseases and deadly pathogens. We recommend \$60 million to ensure AMD has updated cutting-edge technology to allow CDC to more rapidly determine where emerging diseases come from, whether microbes are resistant to antibiotics and how microbes are moving through a population. Additional funding in FY2022 would enhance laboratory capabilities and spur innovation, including through further integration of genomics into AMR surveillance. Funding would also help CDC apply the work of the national genomics consortium, Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES), led by EMD that coordinates large-scale, rapid SARS-CoV-2 sequencing across the US.

We recommend \$100 million for the **National Healthcare Safety Network (NHSN)** to meet its current and projected demands. This funding would expand data collection on antibiotic use and resistance in health care facilities as outlined in the 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria. In 2020, many additional health care facilities began reporting COVID-19 data to NHSN, and new funding will help expand that reporting to include antibiotic use and resistance data. FY2022 funding would help achieve the National Action Plan goal for 75 percent of acute care hospitals and 25 percent of critical access hospitals, reporting to the NHSN Antibiotic Resistance Option. Increased funding would also help achieve the National Action Plan goal of 100 percent of acute care and 50 percent of critical access hospitals reporting to the CDC NHSN Antibiotic Use Option. These data help measure and drive progress toward optimizing antibiotic use. Additionally, increased funding would provide access to technical support for more than 65,000 users of NHSN.

Finally, we recommend \$465.4 million for CDC's **Division of Global Health Protection**. In light of the COVID-19 pandemic, increased resources for this vital CDC program are needed to improve global health capacity to stop threats before they reach domestic soil as well as address growing drug resistance in developing countries. This Division works to enhance infectious disease surveillance

systems, strengthen laboratory capacity, train health care workers and disease detectives and support emergency operations centers. CDC experts provide technical assistance to 30 countries and work to detect resistant threats; prevent and contain resistance germs; and improve antibiotic use. Public health experts address more than 400 diseases and health threats in 60 countries.

Assistant Secretary for Preparedness and Response (ASPR)

We recommend funding of at least \$300 million to support **Broad Spectrum Antimicrobials and CARB-X at the Biomedical Advanced Research and Development Authority (BARDA)**. The BARDA Broad Spectrum Antimicrobials program and CARB-X leverage public/private partnerships to develop products that directly support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria and has been successful in developing new FDA-approved antibiotics. Additional funding is needed to help achieve the Plan's goals to accelerate basic and applied research for developing new antibiotics and other products. This funding will prevent a post-antibiotic era in which we lose many modern medical advances that depend upon the availability of antibiotics, such as cancer chemotherapy, organ transplants and other surgeries.

We recommend \$200 million in funding for the **Project BioShield Special Reserve Fund (SRF)**. The SRF is positioned to support the response to public health threats, including AMR. BARDA and National Institute of Allergy and Infectious Diseases (NIAID) efforts have been successful in helping companies bring new antibiotics to market, but those companies now struggle to stay in business and two filed for bankruptcy in 2019. In December 2019, SRF funds supported a contract for a company following approval of its antibiotic – a phase in which small biotechs are particularly vulnerable. Additional funding is needed to expand this approach to better support the antibiotics market.

National Institutes of Health (NIH)

Funding of \$6.520 billion for NIAID, including \$600 million for AMR research, would allow NIAID to address AMR while carrying out its broader role in supporting infectious diseases research. Increased FY2022 funding would support the training of new investigators to improve AMR research capacity; enhance basic, translational and clinical research on mechanisms of resistance, therapeutics, vaccines and diagnostics; and support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections as outlined in the 2020-2025 National Action Plan to Combat Antibiotic-Resistant Bacteria.

Agriculture-FDA

Food and Drug Administration

We recommend an increase of at least \$20 million for the **Combating Antibiotic Resistant Bacteria program** at FDA. FDA requires support to advance antibiotic stewardship in animals and to protect antibiotic effectiveness for human and animal populations. With suggested resources, FDA can accelerate its 2018 five-year antibiotic stewardship action plan, including continuing to strengthen the **National Antimicrobial Resistance Monitoring System (NARMS)** and other initiatives by the **Center for Veterinary Medicine** to transition the remaining over-the-counter antibiotic products to veterinary supervision, promptly update product labels to fully reflect judicious use principles, identify new ways to encourage the development of antibiotic alternatives, assist academic institutions and other partners in the development of veterinary educational materials, rapidly develop strategies to collect and analyze antibiotic use data on farms and in other agricultural settings, and support

surveillance capacity-building through FDA's **Veterinary Laboratory Investigation and Response Network (Vet-LIRN)**.

US Department of Agriculture (USDA)

We recommend an increase of at least \$85 million for antimicrobial resistance priorities at USDA, including support for the **Animal and Plant Health Inspection Service (APHIS)**, the **National Agricultural Statistics Service (NASS)** and the **National Animal Health Laboratory Network (NAHLN)**. Funding allows the agency to continue to promote agricultural stewardship, including gathering and evaluating valuable information on antibiotic use practices and identifying and characterizing injudicious use on farms and other agricultural settings through the **National Animal Health Monitoring System (NAHMS)** and other initiatives. Expanded funding for agricultural research at USDA's **Agricultural Research Service (ARS)**, the **National Institute of Food and Agriculture (NIFA)** and **Food Research Initiative (AFRI)** will enable USDA investigators and scientists working at public universities, veterinary colleges and other research settings to better understand the factors driving the emergence of resistant pathogens. Funding will also help producers find new vaccines and antibiotic alternatives and develop improved animal management and husbandry practices that can be shared directly with farmers and livestock growers through USDA's **Cooperative Extension Service**.

State and Foreign Operations

US Agency for International Development (USAID) and Department of State

We recommend \$975 million for **USAID global health security efforts** to strengthen the agency's capacity to invest in health systems strengthening in low-income countries to combat the spread of AMR. We also recommend \$1 billion for **USAID's Tuberculosis Program**, which supports high-quality screening, diagnosis and treatment services for patients affected by multidrug-resistant TB. USAID also leads efforts to expand treatment to more patients infected with MDR-TB, strengthen diagnostic and surveillance capacities globally, and accelerate basic and applied research and development to combat MDR-TB. Finally, we recommend \$1.56 billion for the **Global Fund to Fight AIDS, TB, and Malaria** to allow continued reductions in malaria and TB and help staunch the growth of drug-resistant forms of these infections.

Defense

Department of Defense (DoD)

We recommend increased support for AMR research and development under the **Defense Health Program** and the **Research, Development, Test & Evaluation (RDT&E)**, which address key military medical challenges including AMR. Funding supports strategies to prevent, mitigate and treat antibiotic-resistant bacteria. The Defense Health Program also supports a **Multi-Drug Resistant Surveillance Network (MRSN)** program that including projects for Army service level support.

Conclusion

We greatly appreciate your leadership in providing strong investments in AMR in FY2022. We urge you to continue to place a high priority on AMR to continue making strides to protect patients and public health and spur needed innovation.

Signed,

Accelerate Diagnostics

AdvaMedDx

American Academy of Allergy Asthma and Immunology

American Academy of Pediatrics

American Association of Bovine Practitioners

American Public Health Association

American Society for Microbiology

American Society of Transplant Surgeons

American Society of Tropical Medicine & Hygiene

Antibiotic Resistance Action Center, George Washington University

Antimicrobial Innovation Alliance

Association for Professionals in Infection Control and Epidemiology

Association of American Veterinary Medical Colleges

Association of State and Territorial Health Officials

BIO

Center for Disease Dynamics, Economics & Policy

Center for Science in the Public Interest

Cystic Fibrosis Foundation

Emory University Antibiotic Resistance Center

Food & Water Watch

Food Animal Concerns Trust

Health Care Without Harm

Health Watch USA

HIV Medicine Association

Infectious Diseases Society of America

Johns Hopkins Center for a Livable Future

Making-A-Difference in Infectious Diseases

National Association of County Health Officials

National Association of Pediatric Nurse Practitioners

National Athletic Trainers' Association

Natural Resources Defense Council

Novo Holdings

ONCORD, Inc.

Partnership to Fight Chronic Disease

Partnership to Fight Infectious Disease

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Sepsis Alliance

SIDR Program at Boston University

Small World Initiative

Society for Healthcare Epidemiology of America

Society of Critical Care Medicine

TB Alliance

The Antimicrobials Working Group

(Amplix Pharmaceuticals, Cidara Therapeutics Inc., Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Nabriva Therapeutics US Inc., Melinta Therapeutics, Paratek Pharmaceuticals Inc., Qpex Biopharma Inc., SCYNEXIS Inc., Summit Therapeutics plc, UTILITY therapeutics Ltd, Venatorx Pharmaceuticals Inc. and X-Biotix)

The Gerontological Society of America

The Pew Charitable Trusts

The Society of Infectious Diseases Pharmacists

The Stuart B. Levy Center for Integrated Management of Antimicrobial Resistance at Tufts

Trust for America's Health

U.S. Public Interest Research Group