December 14, 2021

The Honorable Rosa DeLauro Chair Committee on Appropriations United States House of Representatives Washington, DC 20515

The Honorable Patrick Leahy Chair Committee on Appropriations United States House of Representatives Washington, DC 20515 The Honorable Kay Granger Ranking Member Committee on Appropriations United States House of Representatives Washington, DC 20515

The Honorable Richard Shelby Ranking Member Committee on Appropriation United States House of Representatives Washington, DC 20515

Subject: Antimicrobial Resistance Funding in FY2022 Appropriations Bill

Dear Chair DeLauro, Ranking Member Granger, Chair Leahy and Ranking Member Shelby:

The undersigned organizations representing clinicians, scientists, patients, public health, animal agriculture and the pharmaceutical and diagnostics industries urge you to finalize a Fiscal Year (FY) 2022 omnibus appropriations bill that significantly increases 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.

AMR is a significant and growing threat that jeopardizes modern medicine and undermines our preparedness for public health emergencies. Advances from cancer chemotherapy to transplantation, from cesarian sections to joint replacements and other surgeries all come with increased infection risks and rely upon the availability of safe and effective antibiotics. Secondary infections complicate our responses to pandemics and other emergencies that involve high levels of hospitalization, underscoring the need to invest in a comprehensive approach to AMR, including the investments outlined below.

Labor, Health, Human Services, and Related Agencies Appropriations (LHHS)

Centers for Disease Control and Prevention

Antibiotic Resistance Solutions Initiative

We urge at least \$192 million in funding for the Antibiotic Resistance Solutions Initiative in FY2022, as provided in the Senate-released bill. AMR negatively impacts patients, including individuals hospitalized with COVID-19. A study published in August 2021 reviewed data from 148 hospitals across 17 states and found that COVID-19 surges negatively impact rates of antibiotic resistant infections. Specifically, from March-September 2020, the study found a 24% increase in hospital-onset multidrug-resistant infections, including an additional 30% hospital-onset methicillin-resistant *Staphylococcus aureus* (MRSA), 44% hospital-onset vancomycin-resistant enterococci (VRE), and 27% hospital-onset multidrug-resistant Gram-negative pathogens, that were associated with COVID-19 surges. If we do not act now, by 2050 antibiotic resistant infections are expected be the leading cause of death globally. Increased funding at the level provided in the Senate bill 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 Prevention Epicenters, and increase public and healthcare professional education and awareness activities.

Advanced Molecular Detection

AMD strengthens CDC's epidemiologic and laboratory expertise to effectively detect and respond to the ever-expanding universe of resistant pathogens. FY2022 funding of \$40 million, as provided in the Senate LHHS bill is required to ensure AMD is able to further enhance federal, state, and local laboratory capabilities and spur innovation, including through further integration of genomics and other advanced laboratory technologies into AMR surveillance. Increased funding would help CDC apply the work of the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance program (SPHERES), a national genomics consortium led by AMD that coordinates large-scale, rapid SARS-CoV-2 sequencing across the U.S., to bolster AMR surveillance, detection, and response.

National Healthcare Safety Network

FY2022 funding of \$26 million for the National Healthcare Safety Network (NHSN) as provided in the House LHHS bill will help enable CDC to expand data collection on antibiotic use and resistance in healthcare facilities as outlined in the 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria. In 2020, many additional healthcare facilities began reporting COVID-19 data to NHSN, and new funding will help expand that reporting to include antibiotic use and resistance data. The House funding level would help us 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 Antimicrobial Use Option. These data help measure and drive progress toward optimizing antibiotic use and preventing the development and spread of resistance. Additionally, increased funding would provide access to technical support for more than 65,000 users of NHSN.

Division of Global Health Protection

We recommend \$448.2 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. The 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)

Biomedical Advanced Research and Development Authority

IDSA urges \$823 million as provided in the House and Senate LHHS bills for BARDA, which will help support increased funding for BARDA's broad spectrum antimicrobials program and <u>CARB-X</u>. These programs leverage public/private partnerships to advance novel products to combat AMR and have supported the development of new FDA approved antibiotics. Despite the progress made, the pipeline of new antibiotics in development is insufficient to meet patient needs, and increased funding is needed to help 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.

Increased overall funding for BARDA also bolsters the Project BioShield Special Reserve Fund (SRF), which is positioned to support the response to public health threats, including AMR. BARDA and 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 small company following approval of its antibiotic—a phase in which small antibiotic-focused biotech companies are particularly vulnerable. Additional funding at the House level is needed to expand this approach to better support the antibiotics market.

National Institutes of Health

National Institute of Allergy and Infectious Diseases

Within NIH, NIAID should be funded at \$6.342 billion, including \$550 million for antimicrobial resistance research, as included in the Senate LHHS bill. Funding at this level 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 the suggested resources, FDA can accelerate its 2018 five-year antibiotic stewardship action plan, including continuing its commitment 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). We support the \$4.5 million increase for AMR activities funded through APHIS as included in the House Agriculture appropriations legislation, including additional funding for academic partnerships and surveillance conducted by the National Animal Health Monitoring System (NAHMS). Increased USDA 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 NAHMS and other initiatives. Expanded funding for agricultural research at UDSA'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 Appropriations (SFOPs)

U.S. Agency for International Development

Global Health Security

\$1 billion is needed in FY2022 for Global Health Security, as provided in the House bill. USAID's global health security program provides technical assistance to partner countries to prevent and respond to rising rates of AMR in resource-limited settings, and requires increased resources to strengthen efforts to address the impacts of COVID-19 on AMR.

Tuberculosis Program and the Global Fund to Fight AIDS, TB and Malaria

IDSA urges FY 2022 funding of \$469 million for USAID's TB program as provided in the House bill, and \$1.56 billion for the Global Fund as provided in both the House and Senate bills. Recommended funding for USAID's TB program and the Global Fund will not only allow continued reductions in malaria and TB, but help staunch the growth of drug-resistant forms of these infections, particularly of drug-resistant forms of tuberculosis, which is the only airborne drug resistant disease and the second biggest infectious disease killer globally, just behind COVID-19. Drug-resistant forms of TB drive rising rates of antimicrobial resistance in many parts of the world, particularly in resource-limited countries with underdeveloped healthcare infrastructure, and poses a significant threat to health security in the U.S. and globally.

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.

Sincerely,

Accelerate Diagnostics

AdvaMedDx

Alliance for Aging Research

American Academy of Allergy, Asthma & Immunology

American Academy of Pediatrics

American Association of Avian Pathologists

American Association of Bovine Practitioners

American Association of Veterinary Medical Colleges

American Society for Microbiology

American Society of Tropical Medicine & Hygiene

Association for Professionals in Infection Control and Epidemiology

Association of State and Territorial Health Officials

Biotechnology Innovation Organization (BIO)

Center for Disease Dynamics, Economics & Policy

Clarametyx Biosciences, Inc.

Coalition for Improving Sepsis and Antibiotic Practices

Cystic Fibrosis Foundation

Emory University Antibiotic Resistance Center

Food Animal Concerns Trust

Global Health Technologies Coalition

Health Care Without Harm

HIV Medicine Association

Infectious Diseases Society of America

Johns Hopkins Center for a Livable Future

Michigan Antibiotic Resistance Reduction Coalition

Novo Holdings

NTM Info & Research

ONCORD, Inc.

Partnership to Fight Infectious Diseases

Pediatric Infectious Diseases Society

Qpex Biopharma

Sepsis Alliance

Society of Infectious Diseases Pharmacists

Spero Therapeutics

The Gerontological Society of America

The Joint Commission

The Pew Charitable Trusts

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

Treatment Action Group

Trust for America's Health