

September 23, 2020

The Honorable Rosa DeLauro
U.S House of Representatives
2413 Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Cole
U.S House of Representatives
2207 Rayburn House Office Building
Washington, DC 20515

The Honorable Sanford Bishop Jr.
U.S House of Representatives
2407 Rayburn House Office Building
Washington, DC 20515

The Honorable Jeff Fortenberry
U.S House of Representatives
1514 Longworth House Office Building
Washington, DC 20515

The Honorable Nita Lowey
U.S House of Representatives
2365 Rayburn House Office Building
Washington, DC 20515

The Honorable Hal Rogers
U.S House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

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

The undersigned organizations, representing health care providers, scientists, patients, public health, animal agriculture, and the pharmaceutical and diagnostics industries, thank you for support for investments in domestic and global programs to address antimicrobial resistance (AMR). We thank you for your leadership in advancing FY2021 funding legislation and for your support for investments in domestic and global programs passed in the House LHHS, Ag-FDA, and SFOP appropriations bills needed to address this urgent public health threat. We urge you to work with your colleagues in the Senate to ensure this funding is included in any final FY2021 appropriations bill.

While there is still much to learn about COVID-19, there is already some evidence of secondary infections among coronavirus patients. It is unclear exactly how significant secondary bacterial infections will be in this pandemic, but serious viral respiratory infections typically pose some risk that increases when patients need to be hospitalized or placed on a ventilator. One study of 191 patients found that 50 percent of those who died had a secondary infection. Further, high levels of inappropriate antibiotic use among COVID-19 patients is likely driving the development of new resistance threats for which we are unprepared.

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

Additionally, the pipeline of new antibiotics in development is insufficient to meet patient needs. The imminent collapse of the antibiotic market is exacerbating this threat, and small companies that are responsible for nearly all current antibiotic innovation are struggling to stay in business because

factors unique to antibiotics, including the need for judicious use, make it challenging for companies to earn a return on investments in antibiotic research and development. New diagnostic tools are needed as well to help guide appropriate antibiotic use and enable surveillance

We believe that a deeper federal investment commensurate with the gravity and importance of AMR is urgently needed, and we urge final passage of the following funding requests:

Labor-HHS-Education Appropriations

Assistant Secretary for Preparedness and Response (ASPR)

We applaud emergency supplemental funding in the bill of \$500 million to support AMR research and development at the Biomedical Advanced Research and Development Authority (BARDA), and \$230 million in funding for the BARDA Broad Spectrum Antimicrobials and CARB-X efforts. 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. Despite this progress, the pipeline of new antibiotics in development is insufficient to meet patient needs. \$500 million in emergency funding, and \$230 million in regular appropriations speaks to the urgency of the dwindling antibiotic pipeline and will help to 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 that the emergency funding be targeted to provide support in the post-approval phase, as this is where antibiotic innovators are struggling the most. We further urge that this funding be allowed to support all AMR threats, and not limited to traditional biotreats.

Additionally, we are deeply grateful for \$140 million in regular FY2021 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 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.

The Centers for Disease Control and Prevention (CDC)

Our organizations are very grateful for increased funding of \$175 million for the Antibiotic Resistance Solutions Initiative in FY2021. Antibiotic-resistant infections sicken at least 2.8 million and kill at least 35,000 people annually in the United States, and this deeper investment will help state and local health departments to prevent, detect, contain and respond to multi-drug resistant infections. Funding in the House bill will also support implementation of antimicrobial stewardship programs (newly required by the Centers for Medicare and Medicaid Services at hospitals) to reduce inappropriate antibiotic use and improve patient outcomes.

While we appreciate continued funding of \$30 million for the Advanced Molecular Detection (AMD) program, and \$21 million for the National Healthcare Safety Network, we urge you to work with the Senate Appropriations Committee to provide deeper investments for both programs in the final bill, at a time when the tragic global and domestic impacts of COVID-19 have underscored urgent needs to detect and respond to emerging pathogens and to protect our health providers.

AMD strengthens CDC's epidemiologic and laboratory expertise to effectively detect and respond to the ever-expanding universe of emerging diseases and deadly pathogens and additional funding is

needed to help ensure CDC, state and local health departments have enhanced expertise to harness DNA sequencing of pathogens to ramp up detection and response to COVID-19 and other disease outbreaks.

Additional resources are also needed to enhance National Healthcare Safety Network (NHSN) which is the most widely used healthcare associated infections tracking system in the country and provides facilities, states, regions, and the nation with data needed to identify problem areas and best practices, and to measure and drive the progress of prevention and stewardship efforts. NHSN is playing a central role in the COVID-19 response, spurred by new Centers for Medicare and Medicaid Services nursing home COVID-19 case reporting requirements.

While we were appreciative of \$2 million in increased overall funding for the CDC's Center for Global Health, additional investment in global health is needed to prevent resistant infections from becoming the leading cause of death by 2050. Additional resources are needed for programmatic efforts at the CDC's Division of Global Health Protection to improve health security, capacity and outcomes. This program helps strengthen laboratory capacities, disease surveillance and field epidemiology in the developing world to stop health threats overseas before they reach the US. CDC is a key implementor of the Global Health Security Agenda (GHSA), which includes preventing AMR as its first action package.

Finally, we acknowledge the House bill's robust report language expressing support for CDC's National One Health Framework initiative and encouraging CDC, USDA and other federal agency stakeholders to strengthen intra-agency coordination and advance One Health priorities that address zoonotic disease threats and the interconnections between human, animal and environmental sectors that contribute to the emergence, evolution and spread of antibiotic resistance.

National Institutes of Health (NIH)

We are appreciate that the House bill provides \$6.013 billion in funding in FY2021 for the National Institute of Allergy and Infectious Diseases (NIAID), and continued funding of \$511 million for vital research on AMR, and we welcome the opportunity to work with you and the Senate to provide recommended funding of \$6.345 billion overall and \$600 million for AMR funding in a final funding package. This funding will help advance valuable studies into how to combat the ever-evolving threat posed by resistant microbes, and speed the discovery novel antimicrobials, diagnostics and vaccines that are urgently needed to address multi-drug resistant organisms.

Agriculture Appropriations

US Department of Agriculture (USDA)

We are pleased that the House bill provides \$2 million for USDA's Animal and Plant Health Inspection Service (APHIS) to explore opportunities to develop an antimicrobial resistance data dashboard tool to enhance public health and stakeholder understanding of the emergence and spread of antimicrobial resistant pathogens in livestock production systems. We also appreciate the House bill's continued support for robust increases in agricultural research funding at USDA's Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA), including the Agriculture and Food Research Initiative (AFRI). ARS and NIFA's efforts to expand our scientific knowledge base and deepen producers' and food-animal veterinarians' understanding of antibiotic alternatives, including pre- and probiotics, vaccines, and animal husbandry, is crucial to driving the expansion of good antibiotic stewardship throughout animal production. Moreover, small and rural

growers in particular rely on the professional extension agents and veterinarians, land-grant institutions and veterinary colleges associated with the USDA Extension Service and its work to validate and disseminate stewardship best practices to farms and ranches nationwide, and we appreciate the House bill's support for these investments.

Food and Drug Administration (FDA)

We are pleased that the House bill includes \$1 million for FDA's Center for Veterinary Medicine (CVM) to support the implementation of FDA's 5-year plan for supporting antimicrobial stewardship in animals, which includes steps to mitigate antibiotic resistance by ensuring that medically important antibiotics for use in food-producing animals have clearly defined durations of use. Congress' focus on FDA's five-year plan and additional funding will help FDA prioritize and advance the activities needed to achieve its 2018 commitment to shift the remaining over-the-counter antibiotic products to veterinary supervision, update animal biomass methodologies, continue to strengthen and modernize the National Antimicrobial Resistance Monitoring System (NARMS), expand data collection and surveillance capabilities to better understand antibiotic use and resistance on the farm, and ensure that medically important animal antibiotic drug labels fully meet FDA's judicious use standards with well-defined and scientifically grounded duration of use information.

State and Foreign Operations Appropriations

Department of State and United States Agency for International Development (USAID)

While we are pleased that the House State and Foreign Operations bill provides \$800 million in emergency funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria, for the organization's efforts to fight COVID-19 in resource-limited countries, more resources are needed to address growing drug resistance that can result from TB and malaria service disruptions due to the pandemic. We recommend \$1.56 billion in regular appropriations for the Global Fund to allow continued reductions in malaria and TB and help staunch the growth of drug-resistant forms of these infections.

We also recommend \$197.5 million for USAID global health security efforts to strengthen USAID's capacity to invest in health systems strengthening and implement One Health principles in low-income countries to combat the spread of AMR. We recommend \$400 million for USAID's global 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.

Conclusion

Once again, we greatly appreciate passage of the House Labor-HHS-Education, Agriculture, and State and Foreign Operations appropriations bills for FY2021 and your leadership in providing strong investments in AMR in FY2021. 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, Inc.

AdvaMedDx

American Academy of Allergy, Asthma & Immunology

American Academy of Pediatrics

American Association of Avian Pathologists

American Society of Transplant Surgeons

American Society of Tropical Medicine and Hygiene

Antibiotic Resistance Action Center, George Washington University

Association of American Veterinary Medical Colleges

Association for Professionals in Infection Control and Epidemiology

Association of Public and Land-grant Universities

Association of State and Territorial Health Officials

Center for Disease Dynamics, Economics & Policy

Center for Science in the Public Interest

Cystic Fibrosis Foundation

Food Animal Concerns Trust

Infectious Diseases Society of America

National Athletic Trainers Association

National Institute of Antimicrobial Resistance Research and Education

ONCORD, Inc.

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Sepsis Alliance

Socially Responsible Agricultural Project

Society of Infectious Diseases Pharmacists

Spero Therapeutics

The Antimicrobials Working Group

(Amplify 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,
VenatoRx Pharmaceuticals Inc. and X-Biotix)

The Center for Integrated Management of Antimicrobial Resistance

The Emory Antibiotic Resistance Center

The Gerontological Society of America

The Johns Hopkins Center for a Livable Future

The National Association of Pediatric Nurse Practitioners

The Pew Charitable Trusts

Treatment Action Group

cc: The Honorable Nancy Pelosi
The Honorable Kevin McCarthy