June 22, 2021

The Honorable Patty Murray
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, D.C 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, D.C 20510

Dear Chair Murray and Ranking Member Burr:

We, the undersigned organizations representing clinicians, researchers, public health, hospitals, patients, and the pharmaceutical and diagnostics industries, thank you for launching a bipartisan effort to strengthen our national preparedness for public health emergencies. Antimicrobial resistance (AMR) and secondary infections threaten our ability to respond effectively to domestic and global crises. We urge you to address the AMR crisis as part of your pandemic preparedness efforts and specifically include the *Pioneering Antimicrobial Subscriptions to End Upsurging Resistance* (PASTEUR) *Act* in pandemic preparedness legislation.

The Centers for Disease Control and Prevention estimate that at least 2.8 million individuals in the U.S. suffer from antibiotic-resistant infections each year, and at least 35,000 die. Six resistant pathogens lead to national health care costs exceeding $4.6 billion each year, according to a January 2021 CDC report. Patients with COVID-19 are susceptible to secondary infections at a similar frequency to patients with influenza-like illness, and patients who require mechanical ventilation are most at risk. Since April 2020, CDC has responded to 20 outbreaks of antibiotic resistant pathogens in COVID-19 treatment and observation units. In addition, high levels of antibiotic use, particularly early in the COVID-19 pandemic, may have led to the development of additional resistance highlighting the need for stewardship programs and diagnostics to guide optimal antibiotic use.

The COVID-19 pandemic demonstrates that a robust antibiotic pipeline is a crucial component of preparedness. Unfortunately, it is incredibly challenging for antibiotic developers to earn the return on investments necessary to sustain antibiotic innovation, in part because antibiotics must be used judiciously to preserve their effectiveness. In 2019 alone, two small biotech innovator companies filed for bankruptcy, and in 2021 another announced that it was exiting this area of work. Economic barriers have driven nearly all large pharmaceutical companies from antibiotic research and development and have left smaller companies struggling to stay in business.

The PASTEUR Act would establish a subscription program that provides a predictable return on investments for critically needed new antibiotics through federal payments delinked from antibiotic sales and use. The bill will also incentivize the development of antibiotic and diagnostic stewardship guidelines to encourage appropriate use of antibiotics and includes critical transition measures to stabilize the fragile antibiotic ecosystem in the near-term.

Many authoritative thought-leaders, reports, and commissions have identified the need for economic "pull" incentives, like subscription models and prize funds, to stimulate urgently needed antibiotic

development. Aaron Kesselheim and Kevin Outterson noted over a decade ago that prize proposals "may represent a substantial evolution in the thinking behind global pharmaceutical development, especially for fighting high-priority disease-causing microorganisms and where existing drug development pipelines are weak."[1] Former FDA Commissioner Scott Gottlieb has also expressed support for incentives for antibiotics , including new payment models that "delink" revenue from use.[2] The PASTEUR Act is one important piece of the resolution, but this crisis will need a package of policies.

We are also pleased that you plan to consider policies to strengthen medical preparedness and responses systems and ensure medical capacity to provide critical health services during emergencies. Antibiotic stewardship programs have been proven effective in improving patient outcomes, reducing inappropriate antibiotic use, limiting antibiotic resistance and lowering health care costs. During the COVID-19 pandemic, stewardship programs were critical in efforts to successfully launch novel therapies for patients with COVID-19. However, many stewardship programs lacked sufficient resources to sustain stewardship activities during the pandemic. Even prior to the pandemic, many hospitals lacked adequate resources to implement evidence-based stewardship practices fully. PASTEUR would provide support for hospitals to strengthen their stewardship programs and encourage hospitals to report data on antibiotic use and resistance to the CDC National Healthcare Safety Network to enhance our national understanding of antibiotic resistance and evaluate our interventions.

We look forward to working with you on public health preparedness and the challenges facing the antibiotic drug pipeline at the foundation of modern medicine. With your leadership, we can avoid a 'post-antibiotic' era with cost-effective incentives and careful stewardship and ensure that future generations have access to these vital medical tools.

Sincerely yours,

American Academy of Allergy, Asthma & Immunology

American Association of Bovine Practitioners

American College of Clinical Pharmacy

American Society for Microbiology

American Society of Plastic Surgeons

American Society of Tropical Medicine & Hygiene

Antibiotic Resistance Action Center, George Washington University

Antimicrobial Innovation Alliance

BIO

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[1]https://www.researchgate.net/publication/46158450_Fighting_Antibiotic_Resistance_Marrying_New_Financial_Incentives_To_Meeting_Public_Health_Goals

[2] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-efforts-foster-discovery-and-development-new-toolshttps://twitter.com/scottgottliebmd/status/1214140637022498821

bioMerieux

BEAM Alliance

Bridge the Gap - SYNGAP Education and Research Foundation

Center for Disease Dynamics, Economics and Policy

Clarametyx Biosciences, Inc.

Coalition for Improving Sepsis and Antibiotic Practices

COPD Foundation

Cystic Fibrosis Foundation

Emory Antibiotic Resistance Center

Emory University School of Medicine/Atlanta VA Medical Center

Genentech, Inc., a member of the Roche Group

Global Coalition on Aging

Health Care Without Harm

HealthyWomen

HIV Medicine Association

Immune Deficiency Foundation

Infectious Diseases Society of America

Integrated Biotherapeutics

Johns Hopkins Center for a Livable Future

Making-A-Difference in Infectious Diseases

Mass Medical Angels

Michigan Antibiotic Resistance Reduction Coalition

Microbion Corporation

National Association of Pediatric Nurse Practitioners

National Athletic Trainers' Association

Novo Holdings

NTM Info & Research

Partnership to Fight Infectious Diseases

Pediatric Infectious Diseases Society

Peggy Lillis Foundation

Revagenix, Inc.

Sepsis Alliance

Shionogi Inc.

SIDR Program, Boston University

Society of Critical Care Medicine

Spero Therapeutics

The Gerontological Society of America

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

The Pew Charitable Trusts

Venatorx Pharmaceuticals

Vizient, Inc.