

The Honorable Dr. Eric S. Lander
Assistant Secretary to the President for Science & Technology
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20501

The Honorable Jacob J. Sullivan
Assistant Secretary to the President for National Security Affairs
1600 Pennsylvania Avenue, NW, 1st Floor, West Wing
Washington, D.C. 20500

October 12, 2021

Dear Dr. Lander and Mr. Sullivan:

The undersigned organizations, representing clinicians, scientists, patients, public health, animal agriculture, and the pharmaceutical and diagnostics industries appreciate the Biden Administration's leadership on efforts to strengthen public health infrastructure and pandemic preparedness. We urge you to more fully integrate antimicrobial resistance (AMR) as a core principle of the "American Pandemic Preparedness: Transforming Our Capabilities" plan by not only primarily focusing on viral pathogens, but also prioritizing other microbial threats identified by the [Centers for Disease Control and Prevention](#). AMR represents a critical and growing threat to the nation's biopreparedness and requires a comprehensive approach that advances economic solutions to the current market challenges that impact antimicrobial drug development, while strengthening infection prevention, antimicrobial stewardship, surveillance, and basic and applied research at the federal, state and local levels.

Antibiotic resistance is one of the greatest public health threats of our time. In the United States alone, drug-resistant infections sicken at least 2.8 million people and kill at least 35,000 people annually; and, both of these figures are likely undercounts. Antibiotic resistance also accounts for direct health care costs of at least \$20 billion. Globally, over 700,000 people die each year, and if we do not act now, antibiotic resistant infections will be the leading cause of death by 2050.

Even during viral pandemics, strengthening our ability to combat AMR is central to our nation's public health and pandemic preparedness. Secondary resistant infections have challenged our COVID-19 response and increased mortality among patients. A recent study shed light on the adverse impact of COVID-19 on AMR in US hospital settings: higher-than-expected rates of hospital-onset bloodstream

infections and multidrug resistant organisms – including methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococcus (both classified as ‘Serious Threats’ by the US Centers for Disease Control & Prevention) – as well as Gram-negative organisms which are extremely difficult to treat, were all significantly associated with COVID-19 surges. Furthermore, high levels of antibiotic [overuse among COVID-19 patients](#), particularly earlier in the pandemic, may have driven the development of new resistance threats which we have not yet identified and for which we are unprepared.

As you may know, in October 2020 the Department of Health and Human Services (HHS) released the new National Action Plan for Combating Antibiotic Resistant Bacteria (CARB) 2021-2025. Our national strategy for pandemic preparedness should align with its many important goals and objectives and build on progress that CDC and other agencies have already made to strengthen antibiotic stewardship, infection prevention, surveillance, and research, while targeting key gaps that still persist in all these areas. In particular, antibiotic stewardship programs, now required in hospitals and long-term care facilities, remain sorely under-resourced and have been forced to reduce activities during the pandemic to prioritize administration of COVID-19 therapies.

Finally, despite the pressing need for new antimicrobials, the market for these essential drugs is fundamentally broken. Innovation to advance the rapid development of new antimicrobials is critical to address the AMR threat and secure the nation’s biopreparedness against an uncertain future, but new solutions are urgently needed to address the market failures that have led to an insufficient pipeline of novel antibiotics and must be included in any national strategy to strengthen our public health infrastructure and preparedness efforts.

In spite of its important stewardship objectives, the National CARB Action Plan notably lacks recommendations surrounding the type of novel financing mechanism necessary to sustain antibiotic research and development (R&D). This is troubling because the pipeline of new and innovative antimicrobials in development worldwide is woefully insufficient to meet patient needs of today and those of the future. Factors unique to antibiotics, including the need to use these drugs sparingly, make it challenging for companies to earn a reasonable return on investment. As a result, many companies have either closed their antibiotics research programs voluntarily or gone bankrupt, posing a health security risk as clinicians run out of options to treat new infections. New incentives, particularly those that address post-market challenges through stable, upfront revenue commitments, are urgently needed to spur antibiotic R&D, revitalize the pipeline, and ultimately curb the spread of AMR, a solution that the HHS Assistant Secretary for Planning and Evaluation recently acknowledged¹. One such incentive is the Doyle-Ferguson-Bennet-Young PASTEUR Act (H.R. 3932 / S. 2076).

Integrating antibiotic resistance into the national pandemic preparedness plan is critically important to ensure that the nation adequately combats AMR, and we hope the Administration’s final strategy on

¹ See, HHS, ASPE, Report to the White House Competition Council, Comprehensive Plan for Addressing High Drug Prices, September 9, 2021. The report notes: “It is also important to foster innovation in the antimicrobial market by developing novel payment mechanisms that delink volume of sales from revenue for selected products. This is especially true for therapies aimed at drug resistant pathogens for which there is a critical unmet societal need as a direct result of large externalities from infection transmission and evolved resistance. Creating such a delinked payment mechanism has the ability to simultaneously restore a robust pipeline and supply chain of new antimicrobial therapies, as well as maintain and enhance stewardship efforts to limit the rate of evolved resistance.”

biodefense and pandemic readiness will recognize the threat of AMR and develop commensurate plans to address this global threat. We thank you for your attention and look forward to working with you on this vital national priority.

Sincerely yours,

Accelerate Diagnostics, Inc.

Alliance for Aging Research

The American Academy of Allergy, Asthma & Immunology

American Association of Veterinary Medical Colleges

American Society of Transplant Surgeons

The American Society of Tropical Medicine & Hygiene

Antimicrobial Innovation Alliance

bioMerieux

The Biotechnology Innovation Organization

Center for Biological Diversity

Clarametyx Biosciences, Inc.

Coalition for Improving Sepsis and Antibiotic Practices

Cystic Fibrosis Foundation

Genentech, Inc., a member of the Roche Group

The Gerontological Society of America

Global Antibiotic R&D Partnership, North America

Global Health Technologies Coalition

Infectious Diseases Society of America

Johns Hopkins Center for a Livable Future

Making a Difference in Infectious Diseases

Merck & Co.

Microbion Corporation

National Association of Pediatric Nurse Practitioners

National Athletic Trainers' Association

Novo Holdings

NTM Info & Research

ONCORD, Inc.

The Pew Charitable Trusts

Professor Kevin Outterson, Boston University

Sepsis Alliance

Shionogi Inc.

The Society for Healthcare Epidemiology of America

Society of Infectious Diseases Pharmacists

Spero Therapeutics

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

Venatorx Pharmaceuticals