

December 14, 2021

Deputy Director Shalanda Young
Office of Management and Budget
725 17th St NW
Washington, DC 20503

Dear Deputy Director Young:

The undersigned organizations representing health care professionals, patients, scientists, public health, advocates and the pharmaceutical and diagnostics industries write to encourage you to prioritize antimicrobial resistance (AMR) in the President's Budget Request for Fiscal Year 2023. AMR is a growing crisis that jeopardizes modern medical care and undermines our preparedness for public health emergencies. Additional investments are urgently needed to support the research and development of novel antimicrobial drugs, antimicrobial stewardship, prevention and surveillance.

Secondary antimicrobial resistant infections hamper our ability to care for patients with COVID-19, while at the same time COVID-19 is worsening our AMR crisis by driving an increase in inappropriate antimicrobial prescribing. A large study of 148 hospitals across 17 states that 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.¹ At the same time, another study found that over 77% of patients with COVID-19 were prescribed antibiotics, despite most of these patients not having a secondary bacterial infection.² More broadly, outside of the context of COVID, any event involving mass hospitalizations - and especially high levels of ventilator use, would carry significant risk of secondary infections, particularly for patients with weakened immune systems. Also, while COVID-19 was a viral public health emergency, the next pandemic could be bacterial or fungal in nature, and we are woefully unprepared. This set of complex, multi-faceted challenges must be addressed to strengthen our preparedness. These threats require deeper investments in new innovations that improve upon all aspects of our response to AMR immediately to ensure we have the necessary arsenal of novel antimicrobial drugs as well as the resources to ensure they are used appropriately and to prevent and track infections.

A stronger approach to combating AMR is needed to protect modern medicine. 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. A recent study reported that infections are one of the most frequent complications seen in cancer patients and a cancer patient has a three times greater risk of dying from a fatal infection than those without cancer.³

We applaud the initial steps that the Administration has taken to strengthen our federal response to AMR, particularly the announcement in September 2021 that \$385 million in American Rescue Plan funds would be allocated to support infection prevention and combat AMR, including laboratory capacity to strengthen testing of resistant pathogens in every state, stewardship, and reporting

¹ <https://pubmed.ncbi.nlm.nih.gov/34370014/>

² <https://academic.oup.com/ofid/article/8/6/ofab236/6291836>

³ <http://doi.org/10.3322/caac.21697>

antibiotic use and resistance data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network. However, while a one-time infusion of resources is extremely helpful, sustained adequate funding is necessary to effectively confront AMR, especially as the challenges posed by resistant pathogens evolve over time. Further, this allocation of funding only supports some aspects of the federal response to AMR, and notably does not address significant challenges facing the antimicrobial drug pipeline.

We greatly appreciate the Administration's recognition in its Comprehensive Plan for Addressing High Drug Prices that, "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."⁴

We agree with this assessment regarding antimicrobial innovation and believe that the bipartisan, bicameral Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act would achieve the delinked payment mechanism and deliver on the promise of a robust antimicrobial drug pipeline. This bill would allow the federal government to enter into contracts with antimicrobial developers to provide set payments for truly novel antimicrobials, regardless of the volume of drugs used. The bill would also provide new resources to support stewardship programs, with priority given to rural, critical access and safety net hospitals. PASTEUR, while vital, is only part of the broader solution to address AMR. No AMR policy option is a panacea, and additional actions, such as reimbursement reform, will also be necessary to stabilize and sustain the antimicrobials ecosystem.

We encourage the Administration to prioritize AMR in the President's FY23 Budget Request, including expressing support for the PASTEUR Act and requesting significant increases in funding for AMR activities at the Biomedical Advanced Research and Development Authority (BARDA), CDC and National Institutes of Allergy and Infectious Diseases (NIAID).

Sincerely,

Accelerate Diagnostics

Alliance for Aging Research

American Academy of Allergy, Asthma & Immunology

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

⁴ <https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf>

Association for Professionals in Infection Control and Epidemiology
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
HealthyWomen
HIV Medicine Association
Infectious Diseases Society of America
Johns Hopkins Center for a Livable Future
Merck
Michigan Antibiotic Resistance Reduction Coalition
Novo Holdings
NTM Info & Research
ONCORD, Inc.
Partnership to Fight Infectious Diseases
Pediatric Infectious Diseases Society
Peggy Lillis Foundation for C. diff Education & Advocacy
Sepsis Alliance
Society of Infectious Diseases Pharmacists (SIDP)
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
Trust for America's Health
Venatorx Pharmaceuticals