

The Honorable Joseph R. Biden, Jr.  
1401 Constitution Avenue, N.W.  
Washington, DC 20230

December 16, 2020

Dear President-elect Biden:

The undersigned organizations, representing clinicians, scientists, public health, veterinary professionals, hospitals, patients, advocates and the pharmaceutical and diagnostics industries, thank you for your leadership as Vice President alongside President Barack Obama in launching the *National Action Plan for Combating Antibiotic-resistant Bacteria*. This roadmap paved the way for important progress, but significant challenges remain. We urge you to prioritize and strengthen the national response to antimicrobial resistance (AMR), which poses both national security and public health threats. We recommend a comprehensive, One Health approach to combating AMR through prevention, surveillance, stewardship, research and innovation.

In the United States, there are 2.8 million antibiotic-resistance infections each year, causing more than 35,000 deaths.<sup>1</sup> As modern medicine advances, we heavily rely on antibiotics to combat infections and address life threatening complications in procedures such as cancer chemotherapy, transplants, cesarean sections, joint replacements, other surgeries and care of complex patients. While antibiotic resistance poses a threat to everyone, cancer patients and others with compromised immune systems are particularly at risk. In the last decade, we have witnessed significant progress in cancer care; however, AMR limits the potential of these advances, as cancer patients are highly susceptible to infections due to their compromised immune systems. This results in the use of combinations of different antibiotics, longer intensive care unit and hospital stays, and increased health care costs.

While we are still learning about COVID-19, secondary infections complicated by AMR have challenged our response. One study has shown that 1 in 7 patients hospitalized with COVID-19 has acquired a secondary infection and 50 percent of patients who have died had such infections.<sup>2</sup> According to data presented by the Centers for Disease Control and Prevention, 12% of hospitalized patients with COVID-19 had a secondary infection.<sup>3</sup> Further, high levels of antibiotic use 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. COVID-19 has illustrated the importance of having a strong foundation of antibiotics as we consider how to better prepare our nation for future pandemics and national security threats.

While AMR poses increasing challenges to patient care and public health, our antibiotic pipeline is in crisis. Antibiotics must be used judiciously to preserve their effectiveness, making it very difficult for antibiotic innovators to earn a reasonable return on investment. Nearly all large

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<sup>1</sup> CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019.

<sup>2</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30566-3/fulltext#tbl2](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2)

<sup>3</sup> <https://www.hhs.gov/sites/default/files/srinivasan-covid-and-amr-overview.pdf>

pharmaceutical companies have been driven away from antibiotic research and development (R&D) and small companies in this space struggle to stay in business. In 2019, two small companies with new antibiotics on the market filed for bankruptcy. Current federal investments are critical to help bring new antibiotics to market, but they must be matched with new policies to provide a return on investments in order to sustain antibiotic R&D.

We are delighted that regulations proposed by the Obama-Biden administration requiring all hospitals and long-term care facilities to establish antimicrobial stewardship programs are in effect. Stewardship programs have been found to reduce inappropriate antibiotic use, improve patient outcomes and lower health care costs. Many health care facilities require new federal resources to implement their stewardship programs, however, and much work remains to ensure diagnostics are effectively leveraged as a core part of these programs and robust stewardship is extended to outpatient settings.

We also acknowledge that, as more medically important antibiotics are used in *any* setting, the less effective they become. This includes the use of antibiotics in animals and environmental applications. To help preserve antibiotics' effectiveness, our organizations urge you to assess federal agencies' progress in advancing the agenda outlined in [Executive Order 13676](#) to promote stewardship nationwide. The new administration should support FDA to accelerate its implementation of the agency's five-year animal antibiotic stewardship action plan in collaboration with relevant stakeholders, prioritizing clear, science-based duration limits for all medically important antibiotics used in animals, and direct FDA and USDA to expand on-farm data collection and use reporting nationwide. We must also increase U.S. investments in agricultural research and cooperative extension to improve our understanding of antibiotic use and resistance and deepen our commitment to One Health principles and partnerships to strengthen farmers' and veterinarians' efforts to reduce the need for use of medically important antibiotics in agricultural production settings.

We urge you to prioritize the federal response to AMR and reinvigorate efforts to sustain antibiotic R&D. We appreciate the second iteration of the CARB National Action Plan, issued in October 2020, though it does not include sufficiently meaningful incentives needed for antibiotic R&D. We urge you to build on its goals and objectives to align federal activities with the recommendations of the Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB). We call for a One Health approach with bold policies and investments to advance the implementation of antibiotic stewardship and optimal use of diagnostic tests, prevent infections, strengthen surveillance, boost research and sustain innovation in human medicine and agricultural science. We thank you for your attention and look forward to working with you.

Sincerely,

Accelerate Diagnostics  
AdvaMedDx  
American Academy of Pediatrics  
American Society for Microbiology  
American Society of Transplant Surgeons

American Society for Tropical Medicine & Hygiene  
American Thoracic Society  
Amplix Pharmaceuticals  
Antibiotic Resistance Action Center, George Washington University  
Association for Professionals in Infection Control and Epidemiology  
Association of Public Health Laboratories  
Association of Public and Land-grant Universities  
Association of State and Territorial Health Officials  
bioMerieux, Inc.  
Biotechnology Innovation Organization (BIO)  
Center for Biological Diversity  
Center for Disease Dynamics, Economics & Policy  
CIMAR  
CommonSpirit Health  
Consumer Reports  
Cystic Fibrosis Foundation  
Duke Center for Antimicrobial Stewardship and Infection Prevention  
Food & Water Watch  
Food Animal Concerns Trust  
Health Care Without Harm  
Immune Deficiency Foundation  
Infectious Diseases Society of America  
Making-A-Difference in Infectious Diseases  
Michigan Antibiotic Resistance Reduction Coalition  
Microbion Corporation  
National Athletic Trainers' Association  
Natural Resources Defense Council  
ONCORD, Inc.  
Pediatric Infectious Diseases Society  
Peggy Lillis Foundation  
Qpex Biopharma, Inc.  
Research!America  
Sepsis Alliance  
Small World Initiative  
Social Innovation on Drug Resistance, Boston University  
Society of Critical Care Medicine  
Society of Hospital Medicine  
Society of Infectious Diseases Pharmacists  
Spero Therapeutics  
Stop TB USA  
The Antimicrobials Working Group  
(Amplix 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 Emory Antibiotic Resistance Center

The Gerontological Society of America  
The Johns Hopkins Center for a Livable Future  
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