

August 7, 2018

The Honorable Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Commissioner Gottlieb and Administrator Verma:

The undersigned organizations representing health care providers, patients, public health, researchers and industry are deeply concerned about the public health crisis of antimicrobial resistance (AMR). There is an urgent need to adopt meaningful antibiotic stewardship programs nationwide and to incentivize the research and development of desperately needed new antibiotics and diagnostics. We greatly appreciate that Commissioner Gottlieb's June 2018 statement on AMR reflected a deep understanding of the gravity of the crisis, while committing to action. We are encouraged, from that statement, to learn that the Food and Drug Administration and Centers for Medicare and Medicaid Services are exploring new payment models for antibiotics to help stimulate their research, development and appropriate use. We would appreciate the opportunity to further engage with FDA and CMS on these important issues and are pleased to offer some recommendations below.

We wholeheartedly agree that the antibiotic pipeline is fragile and insufficient to meet the needs of the increasing number of patients suffering from serious or life-threatening infections caused by multidrug resistant pathogens. We greatly appreciate your recognition that further investment in antibiotic R&D is needed and look forward to hearing more details about your proposal.

We also emphasize that meaningful antibiotic stewardship is equally essential to addressing AMR. Bringing new antibiotics to market, while necessary, will only have limited impact if we do not simultaneously advance policies to protect those antibiotics from the development of resistance. Antibiotic stewardship programs have been found to reduce inappropriate antibiotic use, healthcare costs, and adverse events associated with antibiotic use such as *C. difficile* infection. Studies indicate that 30 to 50 percent of antibiotics prescribed in hospitals are unnecessary or inappropriate, and new rapid diagnostic tests are important to help inform clinicians and reduce the overuse and misuse of antibiotics that is undoubtedly driving the development of antibiotic resistance.

We ask FDA and CMS to build upon the Joint Commission requirement since 2017 that hospitals establish stewardship programs for accreditation. The Centers for Disease Control and Prevention has reported that in 2016, 69.5 percent of general acute care hospitals had implemented stewardship programs aligned with the CDC core elements for stewardship. This is an increase from 53.1 percent in 2015 and 44 percent in 2014. While this progress is encouraging, we remain deeply concerned about those facilities that have not yet implemented robust stewardship programs and the safety of the patients they serve.

Specifically, we strongly support requiring stewardship programs that align with the CDC core elements as a Condition of Participation in Medicare for all acute care hospitals and long-term care facilities. While this policy is in place for long term care facilities, the status of its enforcement is unclear. Revisiting the current, CMS draft CoP that would require stewardship in acute care hospitals – a

proposal supported in official comments by a wide array of stakeholders in health care and public health – would be an effective way of ensuring stewardship programs were in place, universally.

Lastly, we believe it is essential to monitor antibiotic use and resistance patterns in order to evaluate the impact of new antibiotic payment models or other policies on prescribing and resistance. The CDC National Healthcare Safety Network offers an antibiotic use and resistance module through which healthcare facilities may report these data. As of January 1, 2018, over 616 facilities from 48 states are reporting antimicrobial use data and over 231 facilities from 27 states submitted at least some antimicrobial resistance data. This represents a 40 percent increase for hospitals reporting use data and a 27 percent increase for resistance data over the previous past six months. While the upward trend is encouraging, there are still significant gaps in reporting which hinder our understanding of antibiotic prescribing and resistance trends and how to best improve them. We strongly encourage you to require all hospitals participating in a new antibiotics payment model to report data to NHSN on antibiotic use and resistance, allowing for the effective tracking of antibiotics use. These data would be essential in tracking how policy changes impact antibiotic use and resistance.

Once again, we thank you for your attention to the crisis of antimicrobial resistance and your commitment to improving patient safety and public health.

Sincerely,

Abbott

Accelerate Diagnostics

AdvaMedDx

Alliance for Aging Research

Alliance for the Prudent Use of Antibiotics

American Public Health Association

American Thoracic Society

Antimicrobials Working Group (Amplify Pharmaceuticals, Aridis Pharmaceuticals, Arsanis Inc., Cidara Therapeutics Inc., ContraFect Corporation, Entasis Therapeutics Inc., Iterum Therapeutics Ltd., Melinta Therapeutics Inc., Motif Bio plc, Nabriva Therapeutics US Inc., Paratek Pharmaceuticals Inc., SCYNEXIS Inc., Spero Therapeutics, Inc., T2 Biosystems Inc., Theravance Biopharma U.S. Inc., Viamet, Vical Incorporated, and Zavante Therapeutics Inc.)

Association of American Veterinary Medical Colleges

Association of Public Health Laboratories

bioMerieux

BD

Emory Antibiotic Resistance Center

The Fecal Transplant Foundation

GlaxoSmithKline

The Gerontological Society of America

Infectious Diseases Society of America

Making-A-Difference in Infectious Diseases

National Association of County and City Health Officials

National Association of Pediatric Nurse Practitioners

National Athletic Trainers Association

Octagon Therapeutics
Peggy Lillis Foundation
The Pew Charitable Trusts
Spero Therapeutics
Trust for America's Health