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Infectious Diseases Society of America

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March 21, 2016

Presidential Advisory Council  
on Combating Antibiotic-Resistant Bacteria  
Office of the Assistant Secretary for Health  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201  
Submitted via email to: [CARB@hhs.gov](mailto:CARB@hhs.gov)

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSAs) thanks the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) for this opportunity to provide comments on ongoing federal efforts to address the public health crisis posed by antibiotic resistance. IDSAs, which represents over 10,000 infectious diseases physicians and scientists, has been sounding the alarm for over a decade about the danger of antibiotic resistance that is sickening and killing patients and jeopardizing our ability to conduct both routine and life-saving medical care, including surgery, transplants, chemotherapy, and the care of preterm infants. Since publishing its [Bad Bugs, No Drugs report](#) in 2004, IDSAs has promoted a set of multipronged policy solutions to address the complex problem of antibiotic resistance. ID physicians have been and continue to be at the forefront of this battle, caring for patients with serious and life-threatening infections caused by multi-drug resistant organisms; leading antibiotic stewardship programs in health care facilities; running clinical trials to develop urgently needed new antibiotics, diagnostics, and vaccines; and advancing public health efforts to strengthen surveillance, data collection, and infection control and prevention.

IDSAs applauds the PACCARB for its work so far on the five goals of the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB), and offers its continuing support in the effort to turn the tide against the threat of these superbugs. IDSAs would like to take this opportunity to highlight our specific recommendations to advance each of the goals of the National Action Plan:

### Goal 1: Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections

IDSAs has long advocated for the judicious use of antibiotics to slow the emergence of resistance and extend the lifetime of antibiotics. Specifically, IDSAs led the effort to urge the Centers for Medicare and Medicaid Services (CMS) to require all healthcare facilities to implement an antibiotic stewardship program as a Medicare condition of participation (COP). In our [comments](#) on the proposed rule for stewardship programs in long term care facilities, IDSAs underscored the importance of ID physician leadership for stewardship programs to ensure appropriate expertise and optimal patient care and outcomes, and we urge the PACCARB to support this

policy as well. We continue to look forward to a proposed rule requiring stewardship programs in acute care hospitals.

IDSA also continues to lead advocacy in support of federal funding for the Centers for Disease Control and Prevention (CDC) antibiotic resistance activities, namely through the new Antibiotic Resistance Solutions Initiative that will soon establish prevention programs based on best practices in all 50 states and major U.S. cities. The CDC program will also include a regional laboratory network allowing for faster detection of outbreaks of antibiotic-resistant bacteria. We urge the PACCARB to highlight the importance of sustained federal funding to support these activities.

### Goal 2: Strengthen National One-Health Surveillance Efforts to Combat Resistance

IDSA has long asserted that collecting and making publicly available data regarding antibiotic use and resistance patterns is critical to help guide and evaluate efforts to combat resistance. Earlier this year, IDSA provided [recommendations](#) to the PACCARB Working Group on One Health Surveillance on how best to organize a national public health network responsive to the need for identifying resistance as well as the development and utilization of specimen repositories in order to support measures to combat resistance.

IDSA continues to actively engage in discussion with the [U.S. Food and Drug Administration](#) (FDA), [U.S. Department of Agriculture](#) (USDA), and others to provide recommendations on how best to collect antibiotic use and resistance data in agricultural settings.

IDSA continues to advocate for the necessary funding levels for data collection and surveillance activities on antibiotic use and resistance through the CDC, USDA and FDA.

### Goal 3: Advance Development and Use of Rapid Diagnostic Tests for Identification and Characterization of Resistant Bacteria

IDSA has stressed the importance of innovative diagnostics in guiding appropriate antibiotic use, including in our 2013 policy report “[Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#).” The report makes a number of policy recommendations to help spur the development of new and more rapid diagnostic tests and encourage their use in patient care and public health, and we hope the PACCARB will endorse these recommendations, including:

- Provide robust funding for diagnostics research through National Institute of Allergy and Infectious Disease (NIAID), Biomedical Advanced Research Development Authority (BARDA), and tax credits to incentivize diagnostics investment;
- Reduce regulatory barriers to diagnostics R&D, specifically working with the FDA Center for Devices and Radiological Health (CDRH) to facilitate development of point of care tests;
- Ensure appropriate levels of reimbursement for diagnostics; and
- Provide funding for the Agency for Healthcare Research and Quality (AHRQ) and the Health Resources and Services Administration (HRSA) to assist healthcare institutions and professional societies with educational programs about the utility of diagnostic tests.

IDSA [supports](#) recent efforts by NIH and BARDA to sponsor a prize for rapid, point-of-care diagnostics that can identify antibiotic resistance, and [led advocacy efforts](#) in support of federal funding for these agencies as well as for the bipartisan Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act, which is modeled after the highly successful Orphan Drug Act, and would help reduce the significant economic barriers to diagnostics R&D. IDSA also provided [comments](#) to CMS to assist the agency in gathering data to appropriately set reimbursement rates for diagnostic tests.

Goal 4: Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines

Antibiotic research and development (R&D) faces significant economic and regulatory hurdles. While progress has been made in recent years to stimulate antibiotic R&D, additional economic incentives and regulatory approaches are needed to bring to market the new antibiotics that patients urgently need. Existing regulatory pathways pose significant challenges to the development of new antibiotics that are active against some of the most deadly, highly resistant pathogens. Currently, many of these superbugs are infecting relatively small numbers of critically ill patients; thus, it is extremely difficult to enroll sufficient numbers of patients to fill traditional, large clinical trials. As a result, despite some recent progress in antibiotic approvals, significant unmet needs remain and must be addressed before these multi-drug resistant pathogens become epidemic. To address this problem, IDSA continues to advocate for legislation to establish a new limited population approval pathway for antibiotics to treat infections caused by drug resistant pathogens for which there is an unmet medical need. Such a mechanism would allow the most urgently needed new antibiotics to be studied in smaller human clinical trials. This Limited Population Antibacterial Drug (LPAD) concept was approved by the House of Representatives in 2015 as part of the 21<sup>st</sup> Century Cures Act. IDSA continues to [urge the Senate](#) to advance its LPAD bill, the Promise for Antibiotics and Therapeutics for Health (PATH) Act. We hope the PACCARB will endorse this approach, which has also been recommended by the President’s Council of Advisors on Science and Technology (PCAST).

Additional economic incentives are also needed to spur needed antibiotic R&D. IDSA continues to advocate strongly for the READI Act, which would provide tax credits to support phase 2 and 3 clinical trial expenses for new antibiotics that treat a serious or life-threatening infection and address an unmet medical need. This “push” incentive is an important complement to “pull” incentives that have already been adopted or are being considered (such as the increased exclusivity provided by the Generating Antibiotic Incentives Now Act or alternative reimbursement strategies). We encourage the PACCARB to support additional economic incentives, including the READI Act, and to urge the Administration to release recommendations regarding antibiotic incentives, as promised in the CARB National Action Plan. .

While stewardship, surveillance, and prevention activities are critical, we must recognize that even our best efforts can only slow the development of resistance—it cannot be stopped entirely. New antibiotics are needed now for treatment of existing infections with unmet need and a strong pipeline of antibiotics to combat future threats.

Goal 5: Improve International Collaboration and Capacities for Antibiotic-resistance Prevention, Surveillance, Control, and Antibiotic Research and Development

Infectious diseases do not respect national borders, and it is only through global collaboration that we will effectively control the threat of antibiotic resistance. IDSA strongly supports efforts to strengthen global public health infrastructure, surveillance and data collection systems and activities. We also support efforts to strengthen antibiotic stewardship globally. Many IDSA leaders are already involved in multinational efforts to spur antibiotic research and development, such as through the European Union's Innovative Medicines Initiative (IMI) and we look forward to similarly productive public private partnerships in the U.S.

Once again, IDSA thanks you for requesting our input on these important topics and we look forward to future opportunities to work with the Advisory Council. Should you have any questions, please contact Amanda Jezek, IDSA Vice President for Public Policy and Government Relations, at 703-740-4790 / [ajezek@idsociety.org](mailto:ajezek@idsociety.org).

Sincerely,

A handwritten signature in black ink that reads "Johan S. Bakken MD, PhD". The signature is written in a cursive, slightly slanted style.

Johan S. Bakken, MD, PhD, FIDSA  
President, IDSA