

THE WHITE HOUSE

WASHINGTON

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M-14-13

MEMORANDUM FOR THE DEPUTY SECRETARY OF STATE
THE DEPUTY SECRETARY OF DEFENSE
THE DEPUTY SECRETARY OF AGRICULTURE
THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
THE DEPUTY SECRETARY OF VETERANS AFFAIRS
THE DEPUTY SECRETARY OF HOMELAND SECURITY
THE DEPUTY ADMINISTRATOR OF THE ENVIRONMENTAL
PROTECTION AGENCY
THE DEPUTY ADMINISTRATOR OF THE UNITED STATES
AGENCY FOR INTERNATIONAL DEVELOPMENT
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF

SUBJECT: Fiscal Year 2016 Budget Guidance for Combating
Antibiotic Resistant Bacteria Resource Priorities

The President has stated that combating antibiotic resistance bacteria (CARB) is an Administration priority and actionable recommendations to advance this priority are in development through the process established in Presidential Policy Directive-1. The list of CARB priorities (Tab A) was developed by the National Security Council staff, Office of Science and Technology Policy, and the Domestic Policy Council in coordination with the Office of Management and Budget (OMB) and is consistent with the goals and objectives approved by Deputies on May 29, 2014.

The purpose of this resource guidance for the Fiscal Year (FY) 2016 budget process is to enable your department or agency to allocate appropriate resources implementing United States Government CARB priorities. When developing budget submissions, your department or agency should focus on programs and activities highlighted in the priorities paper.

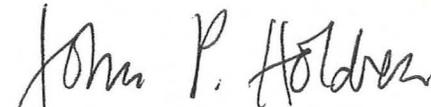
In your FY 2016 budget submissions to OMB in early September 2014, please identify which programs, projects, and activities align to each of the priorities in the attached guidance. The submission to OMB should also include a brief

narrative that explains how the CARB activities of your department or agency support the FY 2016 policy priorities. We all have a critical role in fulfilling these priorities, and each department and agency is responsible for budgeting for relevant priorities within available resources in FY 2016.

In this time of constrained resources, departments and agencies should continue to direct resources to high-priority activities and identify potential reductions or eliminations in less-effective, lower quality, or lower-priority programs. In their budget submissions, departments and agencies should explain how they are redirecting available resources from lower-priority areas to CARB activities that address the priorities described in the attached guidance. It is also important that departments and agencies engaged in complementary activities consult with each other during the budget planning process so that resources are coordinated to maximize their impact and avoid unnecessary duplication. Where appropriate, and consistent with the law, departments and agencies should consider leveraging programs with other public and private-sector institutions. Department and agency submissions should meet the requirements outlined in the FY 2016 Budget Guidance memorandum from OMB, titled "M-13-14."



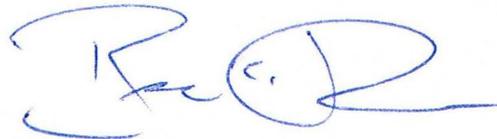
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Attachment

Tab A Fiscal Year 2016 Budget Guidance for Combating
Antibiotic Resistant Bacteria Resource Priorities

CC:

Assistant to the President and Counsel to the President
Assistant to the President and Deputy Chief of Staff for
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Assistant to the President and Director of the Office of
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Deputy Assistant to the President and National Security Advisor
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TAB A

FISCAL YEAR 2016 BUDGET GUIDANCE FOR COMBATING ANTIBIOTIC
RESISTANT BACTERIA (CARB) RESOURCE PRIORITIES

The discovery of antibiotics in the early 20th century fundamentally transformed the medical approach to bacterial infections and now saves hundreds of thousands of lives annually in the United States. Antibiotic resistant bacteria, recognized by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) as one of the greatest threats to human health worldwide, cause significant human mortality and economic costs in the United States and globally. According to the CDC, there are more than 2 million illnesses annually caused by antibiotic resistance, resulting in about 23,000 deaths in the United States.

- Antibiotics are among the most commonly prescribed drugs used in human medicine. CDC estimates that up to 50 percent of all the antibiotics prescribed for people are not needed or are not optimally effective as prescribed. Enhancing and improving antibiotic stewardship programs are a demonstrated method for reducing unnecessary antibiotic use in humans and animals.
- Antibiotics are also commonly used in food animals to prevent, control, and treat disease and to promote the growth of food-producing animals, which some argue is accelerating the emergence of antibiotic resistant bacteria in humans. Enhanced surveillance into the use of antibiotics in humans and animals is needed to inform evidence-based decisions on antibiotic stewardship for humans and improve animal management practices.
- The principal drivers of increased antibiotic resistance are not completely clear - some contend it is exclusively the result of antibiotic overuse in livestock and poultry; others attribute it largely to inappropriate medical use in humans; and others believe that both factors are important contributors. More basic and epidemiological research concerning humans, animals, food, the environment, and the microbes themselves is warranted to understand the complex interactions that contribute to the emergence of resistance.
- Vital to effective antibiotic stewardship programs are rapid diagnostic assays to give health providers the information they need to make evidence-based decisions regarding the proper antibiotic to treat a specific pathogen. The development of and easy availability of diagnostic technologies to identify and characterize bacterial strains

and resistance patterns are needed in laboratory settings for humans, animals, and food-borne pathogens.

- Although infectious diseases cross all medical specialty boundaries, the antibiotic research industry has not kept up with the advancing state of antibiotic drug resistance. Novel public-private partnerships and incentives to encourage a return to drug discovery are needed for the development of new antibiotics, vaccines, and other therapeutics to combat antibiotic resistant bacteria.
- Antibiotic resistance is a growing global threat, and the United States should work with global partners to improve international surveillance capacity; research and development partnerships; and cooperation to address the drivers of this threat. Accelerating progress to address antimicrobial resistance, including antibiotic resistance, is a key component of the Administration's Global Health Security Agenda and should be prioritized.

Departments and agencies need to consider the following priorities to enhance domestic and global CARB efforts in developing their Fiscal Year (FY) 2016 budget requests as they responsibly budget for relevant priorities within available resources in FY 2016:

1. **Minimize the Development of Resistant Bacteria and Preserve the Efficacy of New and Existing Antibiotics**
 - 1.1 Implement programs and policies in all U.S. healthcare settings to promote: (1) antibiotic resistance prevention across healthcare settings and communities; and (2) implement stewardship programs and strategies.
 - 1.2 Eliminate use of medically important antibiotics for growth promotion (production use) and bring remaining therapeutic use (treatment, control, prevention) under veterinary oversight.
 - 1.3 Identify and implement measures to foster stewardship of existing antibiotics in animals.
2. **Strengthen National One-health Surveillance Efforts to Combat Resistance**
 - 2.1 Develop a nationwide regional laboratory network with expanded capability to detect antibiotic-resistant strains and maintain a specimen repository suitable for use in diagnostic and therapeutic development and evaluation.
 - 2.2 Expand and integrate the national data reporting infrastructure to incentivize the reporting of instances

- of antibiotic resistance and antibiotic use within civilian and military health care settings.
- 2.3 Develop, expand, and maintain domestic veterinary diagnostic and food safety laboratory infrastructure to conduct testing and disseminate results from standardized antibiotic susceptibility testing and bacterial characterization for select zoonotic and animal health pathogens.
 - 2.4 Enhance monitoring of: (1) antibiotic drug resistance trends at multiple points in the production chain in food-producing animals and in retail meat; (2) antibiotic sales, antibiotic usage, and management practices in food-producing animals; and (3) antibiotic resistance trends in food-borne pathogens from humans through the National Antimicrobial Resistance Monitoring System.
3. **Develop and Promote Use of New, Rapid, One-health Diagnostic Technologies to Identify and Characterize Bacterial Resistance**
 - 3.1 Develop and approve new diagnostics that can easily be implemented in a wide range of laboratory settings.
 - 3.2 Expand the availability and uptake of these appropriate diagnostics to improve successful treatment at the patient-level, through training and the consideration of reimbursement, to enhance infection-control interventions to prevent transmission, improve successful treatment, and enhance outbreak detection and response in healthcare settings.
 4. **Accelerate Scientific Research and Facilitate the Development of New Antibiotics, Other Therapeutics, Vaccines, and Diagnostics**
 - 4.1 Conduct research that enhances our understanding of the ecology and other factors leading to the development, dissemination, and function of antimicrobial-resistant microorganisms and associated resistance genes that are common to animals and humans.
 - 4.2 Intensify research and development of new therapeutics and vaccines, first-in-class drugs, and new combination therapies for the treatment of infections caused by Gram-negative bacteria.
 - 4.3 Develop non-traditional therapeutics and innovative strategies to minimize effects of the emergence of resistant bacteria in animals and humans.
 - 4.4 Leverage and expand the United States Government's array of core service programs and capabilities to provide key

- data and materials to support the development of promising antibacterial candidates.
- 4.5 Enhance opportunities for productive public-private partnerships consistent with law and regulations by expanding the use of innovative partnering mechanisms, such as cost-sharing contracts or Other Transactional Authority to support antibacterial drug and diagnostic development.
 - 4.6 Create a biopharmaceutical incubator consistent with law and regulations - for example, a consortium of academic, biotechnology and pharmaceutical industry partners funded by public-private partnership(s) to promote innovation and stimulate the antimicrobial product pipeline by supporting translational research from proof-of-concept to preclinical or clinical development.
5. **Improve International Collaboration and Capacities for Prevention, Surveillance, and Antimicrobial Research and Development.**¹
- 5.1A Promote laboratory capability to identify at least three of the seven WHO priority antimicrobial resistant pathogens using standardized, reliable detection assays.
 - 5.1B Collaborate with WHO, Food and Agriculture Organization of the United Nations, World Organization for Animal Health, and other international efforts focused on the development of harmonized, laboratory-based surveillance capacity to monitor antibiotic resistance in relevant animal and foodborne pathogens.
 - 5.2 Develop a mechanism for international communication of critical events that may signify new resistance trends with global public and animal health implications.
 - 5.3 Promote the generation and dissemination of information needed to effectively address antibiotic resistance by: (1) promoting consistent international standards for determining whether bacteria are resistant to antibiotics; and (2) developing international collaborations to gather country-specific and regional information on drivers of antibiotic resistance, identify evidence-based interventions, adapt these strategies to new settings, and evaluate their effectiveness.
 - 5.4 Establish and promote international collaboration and public-private-partnerships, consistent with law and regulations, to advance drug development to counter

¹ Priority 5 is consistent with the Global Health Security Agenda and should be synchronized with budget priorities for FY 2016 outlined for Presidential Policy Directive-2.

antibiotic resistance, as well as complementary research on new and next generation antibacterial agents, vaccines and other alternatives to antibacterials, affordable, rapidly deployable, point-of-care diagnostics, and encourage the sharing of information or data results in the public domain.

- 5.5 Support countries to develop and implement national plans to combat antibiotic resistance and strategies to enhance antimicrobial stewardship.
- 5.6 Partner with other nations to promote quality, safety, and efficacy of antibiotics.
- 5.7 Partner with other nations to strengthen pharmaceutical supply chains.