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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Public Consultation on Antimicrobial Resistance Rapid, Point-of-Care Diagnostic Test Challenge

AUTHORITY: 15 U.S.C. 3719

SUMMARY: The U.S. Department of Health and Human Services (HHS) intends to hold a prize competition in which up to \$20 million will be made available, subject to the availability of funds, for the delivery of one or more successful rapid point-of-care diagnostics that may be used by health care providers to identify bacterial infections. The National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) are sponsoring the prize competition and will convene a public consultation to seek comments regarding the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered.

DATES: The public consultation will be held on October 7, 2015, 8:30 AM to 3:30 PM PDT. Written comments can be submitted to the <https://www.challenges.gov> website for this competition beginning on October 1 at 8:30 AM EDT to October 6, 2015 at 5:00 PM EDT.

ADDRESSES: The public consultation will be held at the Marriott Marquis San Diego Marina, 333 West Harbor Drive, San Diego, California, 92101.

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SUPPLEMENTARY INFORMATION: On September 18, 2014, the President issued Executive Order 13676 on Combating Antibiotic-Resistant Bacteria (<https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria>) and the Antimicrobial Resistance Challenge was called for in the accompanying White House Fact Sheet (<https://www.whitehouse.gov/the-press-office/2014/09/18/fact-sheet-obama-administration-takes-actions-combat-antibiotic-resistan>). The development and use of rapid, point-of-care, and innovative diagnostic tests for identification and characterization of resistant bacteria was a goal identified in the National Strategy for Combating Antibiotic-Resistant Bacteria released in September 2014 (https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf) and addressed in the National Action Plan for Combating Antibiotic-Resistant Bacteria released in March 2015 (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf).

In conformance to the above documents, the NIH and BARDA are sponsoring a prize competition, and the Food and Drug Administration (FDA) and the Centers for Disease Control

and Prevention (CDC) are contributing technical and regulatory expertise to develop the award evaluation process.

The aim of the prize competition is to incentivize the development of one or more in vitro diagnostic tests that would be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria. For example, such a diagnostic test could be used by health care providers to identify bacterial infections in patients to help guide their decisions about the necessity of prescribing antibiotics, and if so, which antibiotics may be effective – thus promoting antibiotic stewardship. Another important diagnostic use could be to facilitate clinical trials for new antibacterial products by allowing for the enrichment of patient populations with specific infections, thus advancing the development of new antibacterial agents. The prize-winning diagnostic(s) must exhibit a set of predefined technical criteria and performance characteristics based on the intended use(s).

When exercising prize authority under the America COMPETES Act (<http://www.gpo.gov/fdsys/pkg/PLAW-111publ358/html/PLAW-111publ358.htm>), agencies are to “consult widely both within and outside the federal Government” when developing prize competitions. As such, HHS is seeking input from the medical, public health, and scientific communities; the pharmaceutical and medical diagnostic sectors; patients and other advocacy groups; and the public at-large in order to receive broad input on the type(s) of diagnostic(s) that may be developed in an appropriate time frame to be of significant utility in combating the development and spread of antibiotic resistant bacteria.

HHS has previously issued a Request for Information (RFI) to obtain comments on several topics as they pertain to a rapid, point-of-care diagnostic test(s) that could be developed in an appropriate time frame to be of significant clinical and public health utility in combating the development and spread of antibiotic resistant bacteria. A prioritized list of 18 bacteria of

highest concern can be found in Table 3 of the National Action Plan

(https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf). Input received from the RFI and during the public consultation will be used by HHS to develop the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered. The design of the Challenge will take into account previous guidance obtained in the aforementioned National Strategy and National Action Plan to combat antibiotic resistant bacteria.

The agenda of the public consultation meeting will be devoted to presentations and discussions on the objectives and criteria for the antimicrobial diagnostic challenge competition. Presentations will focus on the need for rapid diagnostics to address antimicrobial resistance; development and use of rapid diagnostics for drug resistant microorganisms; pathogen/resistance markers identification versus phenotypic susceptibility; antibiotic stewardship in the clinical setting; and regulatory perspectives on rapid diagnostic development.

Any interested person may submit written comments to be considered during the public consultation to the discussion board for this Challenge accessible on <https://www.challenge.gov>. This statement should include your name, address, telephone number and when applicable, the business or professional affiliation. Written comments can be submitted from October 1, 2015 at 8:30 AM EDT to October 6, 2015 at 5:00 PM EDT.

This web-based discussion board also provides an open forum for discussion of this prize competition. The online community is open to the public and will allow for a broad and interactive discussion of the topics covered by this public consultation. This platform will allow users to submit ideas about a desired diagnostic test and to comment on the ideas that have been submitted by others.

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