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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement for Request for Comment for: 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 seek public comments regarding the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered.

DATES: Submission Period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], 9:00am EST. Submission Period ends 5PM EST [INSERT DATE 45 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments can be sent to **https://www.challenge.gov**.

FOR FURTHER INFORMATION CONTACT: Robert W. Eisinger, Ph.D., National Institutes of Health, Division of Program Coordination, Planning, and Strategic Initiatives, Telephone: 301-496-2229, E-mail: Robert.eisinger@nih.gov.

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_antibotic-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, 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.

At this time, HHS is seeking comments on the topics identified below 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_antibotic-resistant_bacteria.pdf). The comment period will be open for 45 days from the

publication of this request for information (RFI). Input received during this 45-day comment period and during the subsequent 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. Comments can be submitted to the discussion board for this Challenge accessible on https://www.challenge.gov

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 RFI. 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.

Comments may include, but are not limited to, the following topic areas:

1. **Purpose.** The purpose(s) or function(s) a rapid, point-of-care in vitro diagnostic test that would be of significant utility to the clinical and public health communities in combating antibiotic resistance. Comments may reflect considerations about in vitro diagnostic tests that distinguish between bacterial and viral infections, or that identify specific bacterial pathogens and/or their drug susceptibility in patients.
2. **Characterizing drug susceptibility.** The development of an effective in vitro diagnostic test that can identify whether bacterial pathogens are resistant and/or sensitive to certain clinically relevant antibiotics, and thus would be of significant utility in combating antibiotic resistance. Examples may be provided.
3. **Sample matrix.** The development of an effective in vitro diagnostic test that identifies pathogens by testing human samples (e.g., blood, urine, sputum, tissue fluid, multiple or

other sample specimens). Comments may include what type or types of samples would be most relevant in identifying pathogens and/or antibiotic susceptibility.

4. **Speed.** The development of an effective in vitro diagnostic test that rapidly produces results. Comments may reflect considerations about what would be the maximum acceptable time-to-result for an in vitro diagnostic test to be of significant utility (i.e., from the time that a sample is collected from a patient to the time that the result is available to the healthcare provider).
5. **Setting.** The settings or venues in which the proposed point-of-care in vitro diagnostic test may be most needed for combating antibiotic resistance.
6. **Ease-of-use.** The development of an effective in vitro diagnostic test that is easy to use. Recognizing that diagnostics often require specialized equipment for sample storage, processing and/or analysis, comments also may include considerations about how such specialized equipment may affect an in vitro diagnostic test's ease of use or otherwise limit its utility. Comments also may include considerations about the nature and extent of training that would be necessary to operate and obtain results from the proposed in vitro diagnostic test.
7. **Diagnostic performance.** The performance characteristics (e.g., sensitivity, specificity, positive predictive value, and negative predictive value) required of the proposed in vitro diagnostic test in order for it to have significant utility in combatting antibiotic resistance.
8. **Tradeoffs.** Any inherent tradeoffs associated with the performance characteristics/parameters described in connection with your previous comments and priority of the characteristics/parameters, if applicable.

9. **Cost.** The development of an effective in vitro diagnostic test that is not cost prohibitive for its intended purpose. Cost and cost considerations may include what price or price range would be desirable to support the widespread adoption of an in vitro diagnostic test that will be effective in combating antibiotic resistant bacteria.
10. **Other characteristics.** Additional characteristics of the proposed in vitro diagnostic test that would be of significant value.
11. **Key technologies.** The specific technologies or disciplines, current or nascent, which would lend themselves to the development of a successful in vitro diagnostic test including, for example, what special considerations, advantages, and disadvantages may be associated with each technology/discipline. Comments on what timeframe would be considered reasonable for the development and licensure of a successful in vitro diagnostic test are also welcome.
12. **Interest.** Major factors that may influence a person's decision to compete in the prize competition described in this information request.
13. **Use.** Identification of who is likely to purchase and/or use the type of in vitro diagnostic tests being targeted by this prize competition and how or where such a purchaser or user is most likely to use the in vitro diagnostic test. Examples may be provided (e.g., patient/self-diagnosis, guiding prescriptive decisions, etc.).

14. **Barriers.** Major barriers that may impede development of the proposed in vitro diagnostic test (e.g., technical or research driven; financial or regulatory; infrastructure or resource based). Comments may reflect considerations about what potential solutions, if any, may be available to overcome such barriers and the level of difficulty associated with implementing any such solution in the U.S. and/or globally.

Dated: May 26, 2015.

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Lawrence A. Tabak, D.D.S., Ph.D.

Deputy Director

National Institutes of Health

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