



October 26, 2007

Mr. Garrick Groves,
Policy Analyst
Office of the Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
330 Independence Ave., SW, Room G640
Washington, DC 20201

REF: Draft HHS BARDA Strategic Plan for Medical Countermeasure Research, Development and Procurement

Dear Mr. Groves:

The American Association for the Advancement of Science (AAAS), the world's largest multi-disciplinary scientific society and the publisher of the prestigious peer-reviewed journal *Science*, has for many years engaged in programs related to the role of science in national security. The development of a strategic plan to address future and potential chemical, biological, radiological and nuclear (CBRN) threats is a critical step in protecting our nation.

We are pleased that the HHS Office of Biomedical Advanced Research and Development Authority (BARDA) incorporated AAAS's comments (submitted on October 10, 2006) on the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategy and also considered our recommendations for scientific experts to participate on the National Biodefense Science Board (submitted July 2007). We respectfully offer the following comments on the draft BARDA strategic plan.

BARDA Funded Research and Development. The Pandemic and All-Hazards Preparedness Act (PAHPA) authorizes \$1.07 billion to BARDA for advanced development of medical countermeasures against material threats, as determined by the Department of Homeland Security, and emerging infectious diseases. The draft strategic plan indicates that BARDA would fund research and development of top-priority medical countermeasures if alternative funds are not available as well as facility design, construction, and validation for product development and vaccine manufacturing surge capacity.

AAAS believes that BARDA should restrict its funding activities to be consistent with the PAHPA, which is to fund advanced development only. BARDA should not duplicate the National Institute for Allergy and Infectious Diseases' (NIAID) critical role in basic research and pre-clinical development. Rather, the two agencies should work in collaboration toward bridging the development gap between early clinical development and procurement.

Given the limitations in authorized funding levels, AAAS suggests that BARDA encourage partnerships between academic institutions and industry, and small biotechnology firms and large pharmaceutical companies to address support functions for product development and surge capacity. BARDA should also consider technologies that would allow companies to maintain "warm-based manufacturing" of related products for commercial use. In addition, the BARDA office should consider funding additional antimicrobials and vaccines to combat pathogens resistant to procured medical interventions. Finally, BARDA should consider funding projects establishing animal testing standards for different categories of threat.

Evaluation for Medical Countermeasure Funding. In the Advanced Development section on page 8, the draft strategic plan states that BARDA would work closely with private sector developers and academic collaborators as well as other federal agencies “to select and transition medical countermeasures that may be considered for acquisition.” In addition, the draft plan states that BARDA would also consider new technologies, presented by industry representatives, for advance development.

AAAS strongly recommends that BARDA seek an external oversight mechanism to ensure that decisions are made equitably and transparently. We encourage BARDA to share information about new technologies and medical countermeasures with the Centers for Disease Control and Prevention, first responders, health care workers, and other relevant individuals. We hope that these information-sharing and disclosure concerns will be adequately addressed in the final BARDA strategic plan or a BARDA implementation plan. Finally, we suggest that BARDA create a committee dedicated to evaluating any new technology that could support the goals of the PHEMCE and HHS Pandemic Influenza Plan.

Medical Countermeasure Development and Dual-Use Research Guidelines. The National Science Advisory Board on Biosecurity (NSABB) has drafted criteria and oversight guidelines for dual-use life sciences research of concern. Many, if not all, federal agencies that fund life sciences research will incorporate the NSABB guidelines into their funding regulations. Much of the research and development of medical countermeasures against material threats, projects BARDA could fund, could fall within the NSABB’s criteria for dual-use research.

AAAS urges BARDA to foster a culture of scientific responsibility by encouraging contractors to adhere to final NSABB recommendations and to establish an oversight body for evaluating biosecurity concerns related to their research. We believe that if this is done from the start, the transition to compliance with HHS or DoD regulations on dual-use research will be both easier and consistent with the requirement of responsible scientific research.

Overarching Principles. We continue to support the following principles as essential to the medical countermeasure enterprise:

- PHEMCE should take a multi-layered approach that includes distinct procedures for evaluating and prioritizing categories (based on dispersion method, incubation period, virulence, and rate of transmission and disease onset) of CBRN threats, regardless of origin, as well as their corresponding medical countermeasures
- The new National Biodefense Science Board should, in addition to evaluating new technologies and countermeasures, conduct risk-benefit analysis on procured medical countermeasures to determine their retention or destruction
- Plans for deployment and prioritization of distribution of medical countermeasures should be created and tested for each category of CBRN threat.

Should you have any questions or require further information, please contact Kavita Berger, Ph.D., at 202-326-7027 or kberger@aaas.org.

Sincerely,



Alan I. Leshner
Chief Executive Officer