DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

MAY 22 2013

John S. Parker, M.D., Major General (Retired)
Senior Vice President
Scientific Applications International Corporation
656 Lynn Shores Drive
Virginia Beach, VA 23452

Dear Dr. Parker and Members of the National Biodefense Science Board (NBSB):

The 2012 U.S. Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan states that the Office of the Assistant Secretary for Preparedness and Response (ASPR), by the end of Fiscal Year 2013, will lead PHEMCE agencies in defining Strategic End States for all PHEMCE capabilities, based on a clear description of the preparedness goals for addressing particular threats and/or medical countermeasure needs. The PHEMCE is an interagency coordinating body, chaired by the HHS ASPR, and its membership includes the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and interagency partners at the Departments of Veterans Affairs (VA), Defense (DoD), Homeland Security (DHS) and Agriculture (USDA). The PHEMCE coordinates the development, acquisition, stockpiling and use of medical products needed to respond to a variety of potential high-consequence public health threats.

Preparedness goals are overarching goals that define the ability to limit adverse health impacts from a particular threat. These goals are derived from the requirements process, which is a needs-driven assessment of the types and quantity of medical countermeasures that would be needed to treat all affected populations in the plausible, high consequence scenario(s) used for planning. Strategic End States, then, encompass these goals in the context of available resources. In a resource constrained setting, it may not be possible to achieve the full requirement. In order to meet Strategic End State outcomes, an acceptable balance is sought across a wide range of threats, conditions of financial constraint, and other major operational considerations. The ASPR must assess tradespace for strategic decisions to efficiently allocate finite resources as well as identify acceptable levels of risk.

Although the PHEMCE Implementation Plan has stated goals and objectives for preparedness, the identification of the gaps between these goals and objectives and what can actually be addressed due to finite resources must be considered. So while the perfect end state equals mitigating against all threats, this is not a likely reality. The ASPR is contemplating methodologies to achieve a suitable balance across these diverse needs, i.e., an adequate answer to what is an acceptable level of preparedness in light of constraints. In addition, the ASPR would like to determine how to best communicate levels of preparedness in a way the public could comprehend.

The NBSB has provided a comprehensive review of the 2012 HHS PHEMCE Strategy and Implementation Plan. I call upon the NBSB to again provide support and expertise to this ongoing project to ensure that our nation has appropriate medical countermeasures to counter any unanticipated threat. I would like the NBSB to assist the ASPR in examining the following questions:

- What methodology or process should be used for assessing the requirements for Strategic End States versus real resource capacity?
- How should we think about what levels of risk are acceptable given the tradeoffs?
- How do we effectively communicate the levels of preparedness versus the level of risk tolerance to the public?
- What do we need to know in order to make decisions on future investments to achieve the next level of preparedness?

Given the NBSB's expertise, I believe that the NBSB can offer great insight on this issue as an independent scientific body. I look forward to receiving the NBSB's recommendations by December 15, 2013.

Thank you for your continued support in ensuring the public health preparedness of our nation.

Sincerely,

Nicole Lurie

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response