



APR 27 2011

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

Patricia Quinlisk, M.D., M.P.H.
Chair, National Biodefense Science Board
State Epidemiologist and Medical Director
Iowa Department of Public Health
321 East 12th Street
Lucas State Office Building
Des Moines, IA 50319-0075

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

The U.S. Government (USG) has stockpiled Anthrax Vaccine Adsorbed (AVA) to provide post-exposure prophylaxis (PEP) for at-risk populations following an anthrax attack. National-level exercises regarding government response following an anthrax attack conducted over the years, and most recently the Dark Zephyr Senior Officials exercise, have highlighted the continuing policy and response challenges we face in addressing the potential for vaccine prophylaxis of special populations, such as children. We have no safety, immunogenicity, or efficacy data in pediatric populations that would permit the U.S. Food and Drug Administration to evaluate the product for use under an Emergency Use Authorization (EUA). This signifies that any policy decision to use AVA as a public health measure after an attack would require some form of investigational protocol in pediatric populations while adults would receive the vaccine under less stringent EUA status. This scenario presents an array of logistical, clinical, and communication challenges. While on the surface it would appear that a simple solution is to gather the safety and immunogenicity data in pediatric populations in advance of urgent need, there are legitimate countervailing concerns regarding subjecting children to risk with no clear benefit at the time of the study.

The NBSB has the expertise, experience, and demonstrated ability to deliberate on difficult issues such as these. Therefore, I would like the Board to consider particular issues around the use of AVA, primarily in pediatric populations, but also considering other special populations who would not otherwise be covered under an EUA, or under current product approved uses. I would like the Board to address the following questions and ultimately to provide a recommendation on best course of action to prepare for a potential use of AVA vaccine in a pediatric population:

1. What are the risks and benefits of attempting to perform an AVA vaccine safety and immunogenicity IND research protocol study in children pre-event vs. after an event?
2. What are the challenges for administering this vaccine under an Investigational New Drug (IND) research protocol after an event and how do these challenges compare with ethical considerations for attempting to gather sufficient data to permit use under an Emergency Use Authorization.

3. What pre-planning should the U.S. government have in place to optimally perform an investigational protocol post-attack
4. How should the U.S. Government communicate these issues with parents, pediatricians, public health officials and political officials before and in response to an anthrax attack?

In performing your deliberations, I encourage the Board to obtain Stakeholder views on these issues using whatever means is deemed most appropriate. I look forward to learning of your recommendations at the next NBSB public meeting on September 22 – 23, 2011. Thank you for your diligence in ensuring the public health preparedness of our nation.

Sincerely,

/s/

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