



JAN 26 2010

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 Secretary of Health and Human Services has asked me to conduct a major review of the issues and challenges facing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) - the national program responsible for providing medical countermeasures to the U.S. population in response to public health emergencies, encompassing chemical, biological, radiological, and nuclear (CBRN) events, emerging infectious diseases (EIDs) and pandemic influenza. The intent is to optimize the PHEMCE and all aspects of the Enterprise will be examined.

There are a number of activities involved in this review. I have commissioned a set of white papers to capture pertinent information on the strategic management, leadership and accountability structure of the Enterprise; methods used to create a robust pipeline of candidate products for advanced development; the market forces and incentives that contribute to or detract from the government's ability to meet its preparedness goals; and an analysis of stockpiling, distribution, dispensing and use strategies. I am also contracting with the Institute of Medicine (IOM) to sponsor a two-day workshop in mid-February to examine in further detail the latter two issues.

I would like the NBSB to take a leadership role in this review given that you are in the unique position of more fully understanding the complexities of the issue as a result of the Board's sustained involvement with this program, and its record of achievement in advising the Department on related issues. The Board's Medical Countermeasures Research and Development Working Group as well as the Medical Countermeasures Markets and Sustainability Working Group have been developing background on these issues since early 2008 and there is a robust Pandemic Influenza Working Group that has proven invaluable as we have readied the nation for a pandemic and responded to 2009 H1N1 flu. Because of this expertise and experience, I would like to request the Board take on two activities:

- First, convene a workshop to examine the strategic management, leadership and accountability structure of the PHEMCE. There are significant successes in the PHEMCE mission but also ample opportunity to make improvements in efficiency and effectiveness. This workshop should identify these opportunities, particularly as they relate to how the Enterprise is conceptualized, organized, managed and led. I have commissioned a white paper, organized by cases studies, which will help inform the proceedings.

- Second, by March 26, 2010, generate a written report for the Secretary of Health and Human Services synthesizing the issues and challenges facing the PHEMCE and at your discretion, suggesting policy options to optimize it. The white paper series and the IOM and NBSB-sponsored workshops, combined with the valuable insight NBSB members will bring to this subject matter, should allow for a robust analysis of the issues.

All of this work, which will culminate in the NBSB written report, will guide my development of final policy recommendations or other proposed actions for the Secretary, to be completed in the second quarter of 2010.

As always, I look forward to the work that we will accomplish together. Thank you for your diligence in ensuring the public health of our nation.

Sincerely,

/s/ Nicole Lurie

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