



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 8, 2012

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Dear Dr. Wolfe:

Thank you for your letter regarding the legal and ethical questions related to pediatric anthrax vaccine clinical trials. At present, the Department has no plans to conduct clinical trials to test anthrax vaccine in children. As a parent, I understand the concerns you raise and agree that children should not be exposed to unnecessary risk. Protecting the health of our children is paramount, and I am committed to it.

Because of our concern surrounding the complexities of studying any type of medical product for children and the challenge this particular situation presents, my Assistant Secretary for Preparedness and Response asked the National Biodefense Science Board (NBSB), a federal advisory committee, for objective and expert advice on how best to obtain scientifically valid safety and immunogenicity data about anthrax vaccine as a medical countermeasure for children. The NBSB debated the risks and benefits of attempting to perform a study for children before, versus after, an event. The NBSB's recommendation stated that the ethical considerations of such a study should adequately be addressed by an appropriate review board of experts, before considering a pre-event study to gather sufficient safety and immunogenicity data on pediatric use of anthrax vaccine in advance of an event.

On January 6, 2011, I asked the Presidential Commission for the Study of Bioethical Issues to convene a panel to conduct a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures in children. I also asked that the Commission include in its review the ethical considerations in conducting a pre- and post-event study of Anthrax Vaccine Absorbed (AVA) Post-Exposure Prophylaxis (PEP) in children.

Given the complexity and sensitivity of this issue, I asked that the Commission consult with a range of experts within and outside the United States Government, to include the medical and scientific communities, in addition to non-profit organizations and other public constituencies. I asked that the Commission provide me with a report of its findings, as well as any recommendations and suggestions the Commission deems appropriate.

I enclose the roster of the NBSB Anthrax Vaccine Working Group at your request. As you will see, the NBSB Anthrax Vaccine Working Group consists of top experts from public health agencies, board members, and pediatricians. The final report with recommendations approved

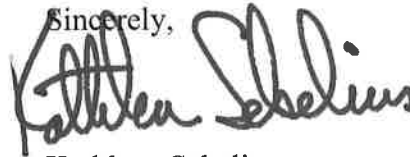
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by the NBSB is posted on the NBSB Web site, <http://www.phe.gov/nbsb>. I hope that many of your concerns are addressed in the report. I appreciate and certainly share your commitment to the health and safety of America's children. I also provide this response to the cosigner of your letter.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is written in a cursive style with a large, stylized initial "K".

Kathleen Sebelius

Enclosure

National Biodefense Science Board Anthrax Vaccine Working Group Roster

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