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

January 6, 2012

Amy Gutmann, Ph.D.
Commission Chair
Presidential Commission for the
Study of Bioethical Issues
U.S. Department of Health and Human Services
1425 New York Ave, NW
Suite C100
Washington, DC 20005

Dear Dr. Gutmann:

The U.S. Department of Health and Human Services is responsible for developing and stockpiling safe and effective medical countermeasures to protect the nation from bioterror attacks. While it has made significant progress toward this goal for adults, the development of appropriate medical countermeasures for children lags, in part due to challenges in collecting basic dose and immunogenicity studies in pediatric populations.

On October 28, 2011, the HHS's National Biodefense Science Board (NBSB) released its report and recommendation on the "Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis (PEP)." The NBSB debated how best to obtain scientifically valid safety and immunogenicity data about AVA PEP for children, a complex issue with ethical, scientific, medical, legal, regulatory, and administrative challenges. In its recommendation, the NBSB concludes that it would be in the best interests of children to gather safety and immunogenicity data about AVA PEP in children prior to an anthrax event, rather than during a future crisis when the vaccine may be needed. The NBSB also recommends that such data be obtained only after the ethical considerations are adequately addressed and reviewed by an appropriate body.

To address this issue and the broader question of how best to obtain clinical data on medical countermeasures in children, I ask you, as the Chair of 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 ask that the Commission include the ethical considerations in conducting a pre- and post-event study of AVA PEP in children as part of its review.

Given the complexity and sensitivity of this issue, I ask 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 ask that the Commission provide me with a report of its findings, as well as any recommendations and suggestions the Commission deems appropriate.

I would welcome the opportunity to further discuss a timeframe for this project that is mutually agreeable, taking into consideration both the urgency and complexity of the issue. The safety of our children is paramount, and it is vital that we thoroughly address any and all ethical considerations relative to having adequate and available safety and immunogenicity data on our medical countermeasures to protect them before, during, or after an event.

I look forward to reviewing the Commission's recommendations on this critical component of improving and advancing our nation's resilience, preparedness, and response efforts.

Sincerely,

Kathleen

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Thank you for your continued leadership