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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Ethical Issues Associated with the Development of Medical Countermeasures for Children

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Presidential Commission for the Study of Bioethical Issues.

**ACTION:** Notice.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the ethical issues associated with the development of medical countermeasures for children, including ethical considerations surrounding clinical research with children, ethical considerations surrounding pediatric medical countermeasure research, and ethical considerations surrounding emergency access to and use of medical countermeasures.

**DATES:** To ensure consideration, comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments received after this date will be considered only as time permits.

**ADDRESSES:** Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to [info@bioethics.gov](mailto:info@bioethics.gov) or by mail to the following address:

Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW, Suite C-100, Washington, DC 20005.

**FOR FURTHER INFORMATION CONTACT:** Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. E-Mail: [hillary.viers@bioethics.gov](mailto:hillary.viers@bioethics.gov). Additional information may be obtained at <http://www.bioethics.gov>.

**SUPPLEMENTARY INFORMATION:** On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that ensure ethically responsible conduct of scientific research and healthcare delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

On January 6, 2012, HHS Secretary Kathleen Sebelius asked the Commission to “conduct a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures in children,” including the ethical considerations of conducting a pre- and post-event pediatric study of Anthrax Vaccine Adsorbed (AVA) as a component of post-exposure prophylaxis, in order to address “how best to obtain clinical data on medical countermeasures in

children.” Accordingly, the Commission is examining ethical issues surrounding the development of medical treatments to keep children safe in the event of a public health emergency. While significant progress has been made in the development of medical countermeasures for adults, the development of similar products for children has lagged, in part because of challenges in conducting safety and immunogenicity studies. In the 2011 report, “Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis,” the National Biodefense Science Board recommended that the Department of Health and Human Services move forward with testing AVA before a public health emergency but only after the ethical considerations are adequately addressed and reviewed.

The Commission is requesting public comment on the ethical issues associated with the development of medical countermeasures for children, including ethical considerations surrounding clinical research with children, ethical considerations surrounding pediatric medical countermeasure research, and ethical considerations surrounding emergency access to and use of medical countermeasures. To this end, the Commission is inviting interested parties to provide input and advice through written comments.

The Commission is particularly interested in policies, practices, research, and perspectives on ethical issues associated with pre- and post-event studies testing the safety, dose, and/or immunogenicity of medical countermeasures for and with children. Among other issues, specifically:

- how to conceptualize and consider risk and societal value when reviewing pediatric clinical research in general and for medical countermeasures in particular;
- the types of information, data, or facts needed to ensure evidence-based decision-making for conducting pediatric medical countermeasure research;
- possible criteria, if any, that might classify proposed studies testing medical countermeasures for pediatric use as minimal risk;
- ethical issues related to access to and allocation of medical countermeasures previously studied within pediatric populations in a public health emergency;
- scientific and public health strategies that could minimize the risk or ethical concerns associated with pediatric medical countermeasure research;
- strategies for communicating risk to prospective participants and their families; and
- the role communities play in the design and support of pediatric research and pediatric medical countermeasure research.

Please address comments by e-mail to [info@bioethics.gov](mailto:info@bioethics.gov), or by mail to the following address:  
Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW, Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain.

Trade secrets should not be submitted.

Dated: June 15, 2012

Lisa M. Lee

Executive Director, Presidential Commission for the Study of Bioethical Issues

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