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November 1, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Proposed Clinical Trials Testing the Anthrax Vaccine on Children

Dear Secretary Sebelius:

Public Citizen, representing more than 225,000 members and supporters nationwide, urges you to reject the National Biodefense Science Board's (NBSB) recommendation to conduct pre-event clinical trials of the anthrax vaccine in children. Such trials would be unethical and are prohibited under the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations for the protection of human subjects.

The proposed research would be unethical, because the research does not present any prospect of direct benefit to the children who would be the subjects of the research, and the vaccine poses significant known risks of potentially serious harm. The most serious known risk of anthrax vaccine is anaphylactic shock. Other potential risks identified in either clinical tests or postmarketing surveillance include:[1]

- Serious allergic reactions, including angioedema, rash, urticaria, pruritus, erythema multiforme, anaphylactoid reaction and Stevens-Johnson syndrome;
- Nervous system disorders, including headache, paresthesia, syncope, tremor, ulnar nerve neuropathy;
- Musculoskeletal, connective tissue, and bone disorders, including arthralgia, arthropathy, myalgia, rhabdomyolysis, alopecia;
- General disorders and administration site conditions, including injection site reactions (including pain, nodule, edema, induration, erythema, warmth, pruritus, cellulitis), fatigue, pyrexia, flu-like symptoms; and
- Multisystem disorders defined as chronic symptoms involving at least two of the following three categories: fatigue, mood-cognition, and musculoskeletal system.

Furthermore, such research could only be supported by HHS if both you, in accordance with the requirements of HHS human subject protection regulations at 45 C.F.R. 46.407, and the commissioner of the FDA, in accordance with the requirements of FDA regulations at 21 C.F.R. 50.54, consult with a panel of experts in pertinent disciplines

(for example, science, medicine, education, ethics, law) and, following an opportunity for public review and comment, determine that:

> (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious health problem affecting the health or welfare of children;
> (b) the research would be conducted in accordance with sound ethical principles; and
> (c) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

Regarding determination (a), anthrax currently is not "a serious health problem affecting the health or welfare of children" in the U.S., and the extremely remote chance of children being exposed to anthrax is not sufficient justification for testing the anthrax vaccine in children, particularly since there are antibiotics approved by the FDA for use in children to treat post-exposure cutaneous or inhalation anthrax, including penicillin and doxycycline.

Regarding determination (b), as we have noted above, the proposed research would not be consistent with sound ethical principles, because exposing vulnerable children, who lack autonomy to make an independent decision about participation in research, to a high-risk experimental intervention is not justified given the lack of any direct benefit to the subjects and the fact that anthrax is not a serious health problem affecting the health and welfare of children.

Finally, regarding determination (c), it is highly unlikely that parents who are truly informed about the nature of the anthrax vaccine, the absence of benefits to the subjects, the availability of FDA-approved antibiotics for post-anthrax exposure treatment, and the highly unlikely possibility of anthrax exposure to children would give permission for their children to be in such research.

Millions of taxpayer dollars currently are being spent to maintain a national stockpile of anthrax vaccine. Exaggerating the risk of an anthrax bioterrorism event for both adults and children may help justify such expenditures, but should not be used to justify unethical research in children.

In closing, we urge you to immediately reject the NBSB's recommendation to conduct unethical pre-event clinical trials of the anthrax vaccine in children.

Thank you for your prompt attention to this matter.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

cc: Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response

[1] Emergent BioDefense Operations Lansing Inc. Biothrax Label. Revised December 2008. Available at http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM074923.pdf. Accessed October 31, 2011.