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HEALTH

Department of Global Health

EMORY

March 2, 2005

Food & Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

I am writing in reference to "Docket Number 1980N-0208, Final Rule & Final Order Involving Bacterial Vaccines and Toxoids" and specifically about the human anthrax vaccine. In the study that I conducted in the late 1950s evaluating human anthrax vaccine developed by scientists at Fort Detrick, Frederick, Maryland, we selected as our volunteer group of subjects, employees at four textile mills in the northeastern part of the United States who volunteered for this double-blinded evaluation. The four selected mills had a high risk of anthrax infections among its employees due to the processing of imported contaminated goat hair. The volunteers were divided into two groups, one group receiving a placebo inoculation, and the other group the anthrax vaccine according to the published schedule. I personally gave every dose of vaccine and placebo, and additionally, looked at the site of inoculations at 24 and 48 hours after giving each dose. At the time of my evaluation of reactions, I was not aware as to whether the employee was in the vaccinated or placebo group.

When possible cases of cutaneous or inhalation anthrax infections were reported among the employees, I was immediately notified and I flew to the mill in order to confirm the diagnosis. After several years, it was apparent that the anthrax vaccine was effective in preventing human anthrax infections. Subsequently, the vaccine was made available to all employees in these four mills as well as in other mills who requested the vaccine.

In analyzing the data, we felt that since the pathophysiology of human anthrax is the same whether the organisms gains entrance through the skin or through the lungs, and therefore, it was appropriate to combine the data from the field trial. The pathophysiology of anthrax is the result of a toxin produced by the organism causing local or

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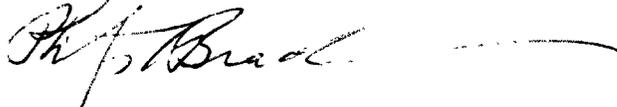
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systemic reactions regardless of the route by which the organisms entered the body. In our statistical analyses, we did omit cases of anthrax that occurred in employees that did not volunteer to participate in the study. However, if these cases are included in the analyses, the vaccine efficacy is not changed

Thus, I feel that the vaccine is appropriate for active immunization against *Bacillus anthracis* regardless of the route of exposure. If I can be of any further assistance to you in considering this conclusion, do not hesitate in contacting me.

Sincerely,

A handwritten signature in cursive script, appearing to read "Philip S. Brachman", followed by a horizontal flourish line.

Philip S. Brachman, M.D.
Professor

PSB/bf