March 29, 2005

Lester Crawford, Ph.D., D.V.M.
Acting FDA Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane, Rockville MD 20857-0001

Dear Acting FDA Commissioner Crawford, Ph.D., D.V.M.:

The Alliance for Human Research Protection has opposed the forced use of anthrax vaccine on military service-members between 1990 and 2004, because it was never properly tested, never proven safe or effective, and improperly licensed. We are even more concerned about future mandatory anthrax vaccinations.

When a federal judge ruled the vaccine to be an "investigational drug and a drug being used for an unapproved purpose" on December 22, 2003, FDA hurriedly issued a Final Rule for anthrax vaccine. The agency submitted its Final Rule just eight days after a federal court injunction, having failed to do so for 19 years. In a January 7, 2004 court hearing the same judge called FDA's actions "highly suspicious." On October 27, 2004 FDA's arbitrary and capricious promulgation of this Final Rule resulted in a permanent injunction, remanding the license to your agency to complete according to the law. The injunction also halted what the judge called DoD's "illegal" mandatory anthrax vaccination program.

Since late December 2004 FDA took two major steps to bring back the use of this experimental vaccine. First, FDA complied with the Defense Department and the Department of Health and Human Services to issue rules for an Emergency Use Authorization that would permit use of the vaccine despite its lack of a license. Since the court injunction allowed voluntary immunization with informed consent, the sole purpose of the EUA is to deny military service-members knowledge of deaths, chronic autoimmune disorders, and birth defects known by FDA to be associated with this BioPort anthrax vaccine.

Second, FDA opened a ninety-day comment period as a prerequisite to consideration of licensure of the vaccine, having been sanctioned by the court for not having opened the license to comment before issuing a final rule.

We are very concerned by FDA's actions, which ignore the significant departures from Food, Drug and Cosmetic Act standards in all aspects of this vaccine’s licensing process.

Accordingly, we have prepared the accompanying detailed comments to make perfectly clear the many regulatory failures in this vaccine’s history. The quality of the data supporting licensure is very poor, and almost all of the human data was obtained using very different vaccine formulations. No valid bridging studies exist to allow FDA

to extrapolate data from these studies. FDA has used animal studies to justify licensure when no valid correlate of immunity exists. There is a high degree of product variability. The BioPort anthrax vaccine has never demonstrated efficacy in humans for any route of infection, and the very different protoype vaccine used in the Brachman study did not demonstrate inhalation efficacy. We understand that the vaccine is associated with a high rate of chronic, serious illnesses.

We have provided FDA with a large number of facts about the vaccine, and have footnoted relevant documents so your staff can substantiate the scientific basis of our comments. We believe there is abundant evidence to recategorize BioPort's anthrax vaccine as a Category II biologic, "determined to be unsafe or ineffective or to be misbranded and which should not continue in interstate commerce." We have asked FDA to respond to a number of questions posed in our comment, and we await your answers.

Human beings -- including military service-members -- deserve to make informed choices about vaccines and drugs. Unfortunately, FDA's past actions have repeatedly undermined informed consent and have aided and abetted the military's unlawful cover-up of the very real risks of this vaccine. We implore you to insure that the agency's future regulatory actions place respect for both the law and and the dignity of all American citizens before the demands of the Department of Defense.

Our organizations appreciate this opportunity to comment and to provide the agency our expertise with anthrax vaccines. If the FDA follows the law and the science, your licensing decision should be very simple.

Sincerely yours,

Meryl Nass, M.D., Director
Vera Sharav, President
Alliance for Human Research Protection.

Barbara Loe Fisher, President
National Vaccine Information Center

Steve Robinson, Executive Director
National Gulf War Resource Center