

Docket Management Comment Form**Docket: 1980N-0208 - Biological Products; Bacterial Vaccines and Toxoids;
Implementation of Efficacy Review****Temporary Comment Number: 14780**

Submitter: Dr. Muhiuddin Haider	Date: 03/28/05
Organization: The Partnership for Anthrax Vaccine Education	
Category: Health Professional	
Issue Areas/Comments	
General	
<p>The Partnership for Anthrax Vaccine Education (henceforth, the Partnership), a coalition of public and private organizations, submits this comment to Docket No. 1980N-0208 in support of the Category I classification of the Anthrax Vaccine Adsorbed (AVA) manufactured by BioPort Corporation. The Partnership and its member organizations agree with the Panel finding that AVA is safe, effective and properly labeled. The Partnership further supports the Panel's decision to classify AVA based on the body of scientific knowledge summarized in detail by the Institute of Medicine report "The Anthrax Vaccine: Is It Safe? Does It Work?? (cited in the docket as reference 2). The Institute of Medicine report is the current definitive exploration of the safety and efficacy of the Anthrax Vaccine Adsorbed. Drawn from case reports, research studies, and the expert testimonies from stakeholders, the IoM report is an exhaustive survey of the questions and answers that surround AVA. Having pulled together the vast array of data, facts and opinions on the vaccine, the committee was ultimately able to conclude with confidence that AVA was an effective vaccine against all forms of anthrax. The committee also found the vaccine to be reasonably safe in adults and that there was no evidence to suggest that vaccination increased the risk of life-threatening or permanently disabling events as compared with the general population. Furthermore, the labeling has remained consistent with what is widely regarded as a safe and effective immunization schedule. On these grounds, the Partnership firmly supports the Panel in classifying the Anthrax Vaccine Adsorbed as a Category I product. The Partnership, an organization that advocates for vaccine education and promotion based on sound science, lends its support to the Panel finding on behalf of its many member organizations. The Partnership is a broad coalition of organizations including military and security personnel, law enforcement, first responders, consumer and patient groups, vaccine manufacturers, educational institutions, public health officials and health care providers. These organizations include the American Medical Association, American Nurses Association, American College of Emergency Physicians, Society for Public Health Education, and the George Washington University's School of Public Health and Health Services, among many other distinguished private and public institutions. The primary goals of the Partnership are to clarify myths and correct misinformation regarding anthrax and anthrax vaccines using current science-based information, raise awareness and knowledge about anthrax and anthrax vaccines, and advocate for the development of a comprehensive national anthrax preparedness plan. Further information about the Partnership can be found online at http://www.anthraxinfo.org/.</p>	
Attachments	
No Attachments	

80N-0208

CAS



THE PARTNERSHIP FOR ANTHRAX VACCINE EDUCATION

Who are we?

Established by the George Washington University School of Public Health and Health Services, *the Partnership for Anthrax Vaccine Education* is a coalition of public health, medical, and anti-bioterrorism organizations that have united to provide the public with the most comprehensive and current information on anthrax and its vaccine. The Partnership provides on-going anthrax education insights and collaborative research findings.

Anthrax Education Mission

1. Clarify misconceptions regarding the anthrax vaccine by providing a comprehensive source of accurate, user-friendly, and timely information.
2. Educate and inform the public on anthrax and anthrax vaccines using science-based information
3. Raise public awareness of the facts regarding the anthrax vaccine.
4. Advocate for an adequate National Preparedness plan to protect against future anthrax attacks.

What can the Partnership do for you?

- Clients and consumers remain up-to-date on the latest developments surrounding the anthrax vaccine and related issues.
- Members of the Partnership exchange valuable information and resources, and contribute to the understanding of the anthrax vaccine - including its challenges and impact on public health.

What is Anthrax?

Anthrax is an often deadly disease caused by a spore (microscopic organism), called *Bacillus anthracis*. Anthrax is a threat to the public's health and security.

Methods of Infection (3 ways)

1. Skin (cutaneous)
2. Inhaled (inhalational)
3. Ingestion (gastrointestinal)

Symptoms of Anthrax Infection

Cutaneous: swelling at the site of contact; small fluid blisters, black scabs; malaise; low grade fever; swelling of lymph glands

Inhalational: malaise; cough/sore throat; fatigue; fever/chills; breathing problems/shock

Gastrointestinal: nausea; vomiting; bloody diarrhea; abdominal pain.

Prevention of Anthrax Infection

- Anthrax Vaccine Adsorbed is given in six doses over 18 months.
- Studies indicate that protection is achieved after as few as three doses.
- Per current CDC recommendations, anthrax vaccine was used under an IND following the 2001 anthrax attacks.
- Rates of side effects from the anthrax vaccine were no different than those of other regularly administered adult vaccines.

Facts about the Anthrax Vaccine

- The anthrax vaccine has been approved by the U.S. Food and Drug Administration (FDA) since 1970
- The Institute of Medicine concluded that FDA-licensed anthrax vaccine is safe and effective.
- A 1962 study using mill workers found that AVA was 92.5% effective in protecting against all forms of anthrax disease.
- The FDA-licensed anthrax vaccine does not contain any anthrax cells, dead or alive, so there is no risk of infection or death by the pathogen when receiving the vaccine.

Additional prescribing information can be found at <http://www.fda.gov/cber/label/biopava0131022LB.pdf>

Current Members

The George Washington University School of
Public Health and Health Services

The George Washington University Center for
Emergency Preparedness

American Medical Association

American Nurses Association

American College of Emergency Physicians

American Association of Occupational
Health Nurses

American Council on Science and Health

Society for Public Health Education

Global Health Council

To Request More Information:

Please Contact the Partnership for Anthrax Vaccine
Education at:

THE GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER
WASHINGTON DC

The George Washington University Center
for Global Health

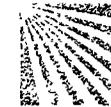
2175 K Street, NW, Suite 820
Washington, DC 20037

Our office is located near the Foggy Bottom-GWU
(Blue Line) Metro Station in NW D.C.

Phone: (202) 416-0424 or (202) 416-0427

Email: anthraxinfo@gwu.edu

www.anthraxinfo.org



THE PARTNERSHIP FOR
ANTHRAX VACCINE EDUCATION

THE GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER
WASHINGTON DC

Every day...

The threat of bioterrorism compromises the world's security and health. The anthrax attacks of 2001 were successful at terrorizing people - largely due to the public's lack of accurate information. An effective vaccine to protect against anthrax is available. Unfortunately, so are myths regarding the vaccine. To promote a greater awareness of the facts, the Partnership for Anthrax Vaccine Education (the Partnership) developed the following website:

www.anthraxinfo.org