



NEW YORK METRO AREA POSTAL UNION, APWU AFL-CIO

350 WEST 31st STREET NEW YORK, NY 10001 (212) 563-7553 Fax (212) 239-9142

A Democratic Trade Union

WILLIAM SMITH
President

JONATHAN SMITH
Executive Vice President

DANIEL R. ZACHMAN, JR.
*Director of
Industrial Relations*

ELEANOR C. JENKINS
Executive Secretary

J. RENEE BOST
Secretary/Treasurer

BURNEY O. FREEMAN
Director of Organization

December 31, 2001

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

I am President of the New York Metro Area Postal Union, American Postal Workers Union, AFL-CIO. My union represents over 14,000 postal workers in the New York metropolitan area.

I am writing to express deep concern about the anthrax vaccination plan for my members employed at the Morgan Parcel and Distribution Center in New York City. I am also deeply concerned about the quality of the informed consent being provided by the Centers for Disease Control and Prevention ("CDC") and the HHS in justifying this "investigational" use of the anthrax vaccine. This decision to make available the anthrax vaccine to postal workers has significant implications regarding the Department's willingness to uphold a law you are charged to enforce -- the Food, Drug, and Cosmetic Act.

As you must be aware, the problems with this anthrax vaccine are not new. The House Government Reform Committee and its National Security Subcommittee have held at least nine hearings on the anthrax vaccine since early 1999. The House and Senate Armed Services Committees have also held two hearings each. This unprecedented series of hearings was necessitated by the controversy surrounding the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP). Among the issues identified in these hearings were:

- Adverse reactions (including possible deaths) far more serious than DoD or Food and Drug Administration (FDA) have acknowledged.

- A contractor to the Federal Government that for over a decade has demonstrated a persistent inability to comply with the law.
- A breakdown in contract management by Pentagon acquisition officials.
- An unwillingness by FDA to enforce the law that protects all Americans from adulterated vaccines.

Finding the best way to protect those exposed to anthrax is an important priority for all of us. Under the law, anthrax vaccine used for post-exposure treatment is “experimental,” since the vaccine has never demonstrated efficacy in humans for this indication. The current question is whether this treatment is truly warranted for patients who are asymptomatic and who have already undergone at least 60 days of antibiotic prophylaxis. **The fact is that because of the ethical difficulties associated with researching biodefense drugs, your experts do not know whether this post-exposure use of the anthrax vaccine will offer any benefit or not.** Thus, it is important to provide patients and their doctors all the facts about what we do and do not know to prevent a less-than-fully-informed decision.

Therefore, I am particularly disturbed by the statement made by a participant at the December 15, 2001 anthrax vaccine meeting at the CDC that “it’s also our duty to take advantage of the opportunity” to study the anthrax vaccine. **Is protecting postal workers who have been exposed to anthrax spores the priority of the CDC or is experimenting with the health and safety of workers as guinea pigs the real reason for the distribution of the vaccine?** My members will not countenance another Tuskegee.

I am also concerned that some public health officials may wish to use the vaccine, whether medically indicated or not, to justify an expansion of the vaccine’s license to include post-exposure use. Without proof that test subjects remain at risk for anthrax infection, such a conclusion, based on giving healthy individuals the vaccine and later observing an absence of anthrax infection, is scientifically suspect. A similar attempt at an efficacy trial of anthrax vaccine in a mill in Talladega, Alabama in the late sixties was noted by NIH reviewers to be scientifically invalid because zero cases of anthrax following vaccination is meaningless if the level of exposure cannot be measured.

The post-exposure rationale, given its uselessness as a scientific test, further begs the question: **Is this an experimental post-exposure use of the vaccine, or is it pre-exposure prophylaxis for postal workers who must continue to work in contaminated buildings?** The United States Postal Service’s inability to thoroughly clean the Morgan facility raises serious questions about residual anthrax contamination in Morgan and other postal facilities.

New York Metro insists the “informed consent” offered to postal workers must be truly informed. During your conference call announcement on December 18th, Dr.

Kathryn Zoon, director of the FDA Center for Biologic Evaluation and Research, cited data from the Vaccine Adverse Event Reporting System (VAERS) and characterized the reactions of military personnel from the anthrax vaccine as minor and temporary. This statement is deliberately misleading, and cannot suffice as informed consent about the real and serious adverse reactions associated with this vaccine. **To provide inadequate risk/benefit data to prospective recipients is medical malpractice.** I therefore request that you make all VAERS reports filed on the anthrax vaccine immediately available on the CDC and FDA websites so that the physicians and patients, on whom you have placed the burden of recommending or using this vaccine, are truly informed.

The VAERS reports on the anthrax vaccine document a high rate of systemic reactions. This was one of the reasons foregoing manufacturer in 1999 into changing the systemic reaction rate on the FDA-approved product label from 0.2% to a range of 5-35%, or 25-175 times greater than was originally claimed. In 1999, former Army Surgeon General Ronald Blanck testified that these are some of the possible conditions that followed vaccination: Guillain-Barre' syndrome, multiple sclerosis, angioedema, aseptic meningitis, severe injection site inflammation, bipolar psychiatric disorder, diabetes mellitus and systemic lupus erythematosus. Since Lieutenant General Blanck's testimony two years ago there has been an eight-fold increase in the number of VAERS reports, making the anthrax vaccine statistically the most frequently reported vaccine based on the number of shots given.

Further, the HHS Anthrax Vaccine Expert Committee, while denying any causal connection between anthrax vaccine and the maladies that follow its use in otherwise healthy soldiers, does not conduct continued monitoring of those who have reported adverse reactions. **While the Army continues to publicly assert that there are no adverse long-term health affects, we have received information that establishes that the Walter Reed Army Medical Center has a protocol to treat servicemembers specifically for a wide range of serious or chronic anthrax vaccine adverse reactions.** Yet, CDC officials have not informed us about these possible side effects, and appears not to have received this information from the Army.

Additionally, we have been informed by military servicemembers of anaphylactic shock, gastroparesis, primary testicular failure, chronic fatigue syndrome, fibromyalgia, Steven Johnson's syndrome, deep vein thrombosis, and other problems. Women appear to be adversely affected at twice the rate of men. We suspect there are many more adverse reactions than those identified in the VAERS system. Servicemembers who have testified before the House Government Reform Committee have consistently reported a reluctance or unwillingness on the part of DoD medical officials to submit VAERS reports for adverse reactions. **Further, the General Accounting Office has reported that the adverse reactions are likely underreported and understated, given the pressure by Pentagon leaders to enforce the vaccine with courts-martial and imprisonment.**

Beyond the immediate issue of experimental post-exposure use of the anthrax vaccine is its legal status. The fact is that a proposed rule on the legal status of the

anthrax vaccine, published 16 years ago, had never been finalized. **The proposed rule, written by an FDA expert committee, recommended that the vaccine be categorized as safe and effective. But the committee also noted that, “no meaningful assessment of its value against inhalation anthrax is possible.”** The lack of human efficacy data against inhalation anthrax was the rationale for an Investigational New Drug application submitted by the manufacturer to FDA on September 20, 1996. The FDA subsequently allowed the IND research to go forward, but has never approved a change based on new scientific evidence obtained through the IND protocol. Further, the fact that FDA has never finalized its 1985 proposed rule is a fundamental issue addressed in a Citizen Petition filed with FDA on October 15, 2001. That petition questions whether the vaccine was ever licensed in accordance with the law.

At the December 15th CDC meeting, Dr. Zoon said that “this is the same vaccine that was used in the Brachman studies,” referring to a trial conducted in New England textile mills in the late 1950’s that demonstrated efficacy for cutaneous exposure. Her statement is contravened by the FDA’s own expert committee in 1985, which stated, “the vaccine manufactured by the Michigan Department of Public Health [now BioPort] has not been employed in a controlled field trial.” Investigation by the General Accounting Office has revealed substantive differences between the vaccine used in the Brachman study and the BioPort vaccine in the manufacturing process, the strain of anthrax used, and the ingredients used to increase the yield of the protective antigen.

These differences were the reason BioPort’s predecessor attempted a new efficacy trial in Talladega, Alabama (ten years after the Brachman study) when it sought licensure in the late sixties. Had the two vaccines been the same, no efficacy trial would have been necessary. The FDA’s predecessor, the Public Health Service, clearly documented the failure of the Talladega efficacy trial in a series of 1969 letters contained in the FDA’s own files on the anthrax vaccine. **Further, the anthrax vaccine manufacturing process was modified a decade ago with a change that the Army believes may increase the potency of the vaccine by up to 100 times (not percent). But FDA was not aware of this change until it was brought to their attention by the General Accounting Office last summer, at which point Dr. Zoon approved the change ten years after-the-fact.**

For the past four years, Dr. Zoon and the Army have asserted that data from the Brachman study of a different vaccine justified licensing the BioPort anthrax vaccine for inhalation anthrax. However, if this leap of faith were legally sufficient, why did six members of Dr. Zoon’s CBER Division participate in a planning session on July 2, 1996, to assist the manufacturer and the Army in preparing an IND application specifically to obtain an indication for pre-exposure use for inhalation anthrax? The FDA personnel could have simply told the manufacturer and the Army that such an IND was not necessary. So, while I applaud your decision to deem use of the BioPort anthrax vaccine for post-exposure use as experimental, perhaps it is time for this same standard to be applied to pre-exposure use as well.

Dr. Zoon also has termed one lot of vaccine to be used for experimental post-exposure use, Lot 63, as “licensable”. But no such term exists in the Food, Drug, and

Cosmetic Act; either the vaccine is licensed or it is not. The manufacturer has been operating under an FDA Notice of Intent to Revoke (NOIR) its license to produce all biologic products since March 11, 1997. On February 20, 1998, FDA inspectors found that "the anthrax vaccine manufacturing process is not validated." The exact same observation has been made on every subsequent inspection since and the manufacturing facility is still not certified to produce vaccine nearly four years after it was shut down. If the manufacturing process is not validated, then the vaccine produced by BioPort under those circumstances is, according to the law, adulterated, and cannot be considered "licensable", even if such a term exists.

Finally, on December 15th Dr. Zoon justified use of another lot produced in 1992, Lot 15, for experimental post-exposure use because "BioPort was not under an intent to revoke or any of the conditions that we currently have" that still preclude licensed production. In fact, having for decades allowed the Army to do their job for them, FDA inspectors did not begin physical inspections of the Michigan facility until a year after this lot was manufactured – and 23 years after the vaccine was first licensed. So, inferring that this lot of vaccine is not adulterated because of an absence of FDA regulatory sanctions against the manufacturer is specious since no inspections had even taken place at that time. On the contrary, when it began inspecting, the FDA discovered significant deviations from federal regulations that resulted in the prohibition against the manufacturer from producing vaccine for the past four years. These deviations and the failure of this lot to pass supplemental testing ordered by former Secretary of Defense Cohen, are why the FDA withheld Lot 15 from distribution. **I am very disturbed that Dr. Zoon now believes this quarantined lot should be used on my members.**

The anthrax vaccine's possible link to Gulf War Illness (GWI) is another issue that must be part of a physician's informed consent of those patients considering this vaccine. Yet no researchers on this subject were invited to attend the CDC meeting on December 15th. DoD asserts that there is no connection between the anthrax vaccine and GWI, but they have never conducted a study to determine whether this is true. DoD bases its opinion on findings by the Defense Science Board, the Institute of Medicine and the President's Commission on Gulf War Illness even though none of these entities ever conducted a study. They simply based their findings on "expert" testimony by Army medical corps officers who are proponents of this vaccine, and then recommended against further study.

While the Army frequently cites its 18 safety studies that the National Academy of Sciences Institute of Medicine found unpersuasive in their March 30, 2000 review of the safety of the vaccine, the Pentagon ignores independent studies that indicate a possible connection between anthrax vaccine and Gulf War Illness. In particular, the Steele study of Kansas Gulf War vets, the Goss-Gilroy study of Canadian Gulf War vets, and the Unwin study of British Gulf War vets (which was funded by DoD) all found a positive correlation between non-routine immunization for biowarfare threats and Gulf War Illness symptoms. Yet, despite having spent \$180 million on research, DoD has not studied the impact of anthrax vaccine on US veterans of the Gulf War. The French military, which did not use an anthrax vaccine and experienced

a much lower incidence of illness than US, British and Canadian Gulf War veterans, apparently is convinced that the higher rate of illness in U.S. veterans was due to biowarfare drugs or vaccines. Yet, CDC briefers have not informed us of these concerns.

Mr. Secretary, the complex issues I have raised are why you have a career civil service staff on which to rely. Unfortunately, the recent comments by Dr. Zoon, who is responsible for understanding the science and following the law, lead me to believe you have received poor advice by regulators who apparently do not understand their obligation to enforce the Food, Drug, and Cosmetic Act. Because postal workers may always be on the front-line of any bioterrorism attack, it is critical to that the government get it right this time.

In closing, consider the May 2000 decision of the highest judge in the Canadian military, who dismissed court-martial charges against a Canadian military airman who refused the BioPort anthrax vaccine. **The judge stated that the military "could never be justified to impose inoculation of soldiers with an unsafe and dangerous vaccine as a limit of their rights" under the Canadian Charter of Human Rights.**

Until my members are fully informed of the risks associated with the anthrax vaccine discussed above, I cannot recommend use of this vaccine. If you or your staff would like to contact me about the matters discussed in my letter please feel free to do so.

Sincerely,



William Smith
President

New York Metro Area Postal Union

cc: William Burrus, President, APWU
John E. Potter, Postmaster General of the United States
Louie Nikolaidis, Esq., General Counsel for the
New York Metro Area Postal Union
Senator Hillary Clinton
Senator Charles Schumer
Senator Thomas Daschle
Attorney General Elliot Spitzer
Representative Richard Gephardt
Mayor-Elect Michael Bloomberg