Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President November 17, 1994

William Perry
Secretary, Department of Defense
Pentagon
Room 3E880
Washington, DC 20301

Dear Secretary Perry:

We write to request that you immediately investigate the diversion of $10.3 million in AIDS vaccine research funds by the Department of Defense (DOD) to the Henry M. Jackson Foundation, with which DOD works in close collaboration. When asked why the diversion had occurred, Neal Boswell, deputy director of DOD's AIDS research program, told the journal Science that its purpose was to prevent a potential shortfall in DOD's AIDS research budget. However, because the Congressional Conference Committee later increased the DOD's AIDS research funding by $10.2 million (see Attachment 1), there is in fact no shortfall. The DOD should, therefore, have no objection to returning these funds for appropriate disbursement. We ask that you take whatever action is necessary to ensure that this occurs.

This diversion skirted the recommendations of the DOD's own peer review committee, set up specifically to decide how the funds were to be allocated, and violated the most basic tenets of the scientific research process. An Army memorandum that we have obtained (see Attachment 2) establishes for the first time how the funds will be spent. First, ongoing therapeutic vaccine trials ($7.8 million, including indirect costs) that would otherwise be funded by the manufacturer and through existing DOD funding streams. Second, developing alternative vaccines ($2.6 million, including indirect costs). These awards were made despite recommendations by the peer review committee established by DOD to judge research proposals that the funds go to other researchers. DOD has thus been caught with its fingers in the till, brazenly disregarding the peer review process for the second time in two years and denying AIDS research funds to potentially more deserving scientists.

The first time the peer review process was evaded was in October 1992 when the Meriden, CT-based biotechnology firm MicroGeneSys, the manufacturer of a gp160 therapeutic AIDS vaccine called VaxSyn, strongarmed Congress into earmarking $20 million for the Army to test VaxSyn. AIDS researchers, activists and government regulators protested the appropriation. Eventually, Dr. Edward D. Martin, Acting Assistant Secretary of Defense, wrote to Representative William H. Natcher, Chairman of the House Committee on Appropriations, on January 4, 1994 (see Attachment 3) and proposed using the $20 million to fund a vaccine therapy development program. "Submissions will be judged by peer review," promised Martin, "and selections will be based on scientific excellence and potential for clinical impact."

Although the DOD has funded five projects recommended by the peer review committee at a cost of $9.6 million, the majority of the funds ($10.3 million) has been skimmed off the top for the Henry M. Jackson Foundation, which collaborates closely with DOD researchers on scientific matters and receives a substantial proportion of its budget from the DOD. $4.4 million will be spent for ongoing clinical trials of VaxSyn. The $10.3 million would otherwise have been used to fund the following four additional proposals that were highly rated by the peer review committee:

•The Scripps Research Institute, San Diego, CA: To develop a therapeutic AIDS vaccine based on cloned neutralizing antibodies obtained from HIV-infected individuals.

•Progenics Pharmaceuticals, Inc., Tarrytown, NY in collaboration with the Southwest Foundation for Biomedical Research, San Antonio, TX/University of Oklahoma Health Sciences Center, Oklahoma City, OK: To develop novel therapeutic AIDS vaccines by conjugating portions of the viral envelope from U.S. and international viral strains to highly immunogenic carrier proteins.

•Public Health Research Institute, New York, NY: To develop a vaccine containing portions of the vaccine envelope from multiple U.S. and foreign HIV strains.

•United Biomedical, Inc., Hauppauge, NY: To develop a global HIV vaccine that could be administered orally.

Twice in two years DOD has been the beneficiary of these under-the-counter subversions of the peer review process. It is high time that the individuals responsible be made to account for their actions in full view of the tax-paying public. We urge you to fully investigate these issues and, particularly because the potential shortfall used to justify the diversion never transpired, to ensure that these scarce AIDS vaccine research funds are awarded to their rightful recipients.

Yours sincerely,

Peter Lurie

Peter Lurie, MD, MPH
Research Associate

pl for sw

Sidney M. Wolfe, MD
Director

cc: Henry Waxman, Chair, House Health and the Environment Subcommittee
Ronald Dellums, Chair, House Armed Services Committee
Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Patricia Fleming, National AIDS Policy Director

HOUSE APPROPRIATIONS COMMITTEE REPORT 103-562	*SENATE APPROPRIATIONS COMMITTEE REPORT 103-321*	*APPROPRIATIONS CONFERENCE REPORT 103-747*
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) The Committee recommends an increase of $20,000,000 to the budget request for Acquired Immune Deficiency Syndrome research (P.E. 0603105A). The increase is provided for general research of vaccines and treatment therapies. The Committee is aware of research in the field of irradiation of cells and in particular the development of a unique bioreactor that utilizes ultraviolet light in the prevention and treatment of AIDS. The Committee directs the Department of the Army to explore the feasibility of funding additional research in the area of cell irradiation and to provide the Committee with a report on its recommendations.	**ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)** "Acquired immune deficiency syndrome [AIDS] research.--The Committee adds $30,225,000 to continue the Army's efforts to characterize all strains of the AIDS virus, to develop and test vaccines, and to define prevention measures. The proposed funding of $33,410,000 continues this program at the fiscal year 1994 level. The House allowance is $10,225,000 below the Senate recommendation." (RDT&E, ARMY, COMMITTEE RECOMMENDED ADJUSTMENTS)	**ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)** The Senate recommendation was of $33,410,000 was adopted. (See Medical Research)

ATTACHMENT 1

1. HMJFAMM received $10,333K of the $19,969K appropriated for gp160 vaccine studies. All funds are to be used to support of HIV vaccine research.

2. The following projects are being supported by the HMJF:

a. Complete ongoing gp160 vaccine therapy trials

(1) Completion of ongoing gp160 vaccine therapy trial in military volunteers. $4.4M

(2) Conduct analysis of viral load parameters in cells, plasma and serum of vaccine therapy recipients. 1.0

(3) Perform assessment of the functional status of the immune system and its relationship to cellular phenotypes and viral load in vaccine therapy recipients. 0.4

(4) Determine the depth and breadth of the T-cell response to HIV envelope epitopes. 0.6

(5) Perform in vitro assessment of humoral and cellular immune pressure on the induction of viral mutations. 0.3

b. Develop alternative vaccines

(1) Develop conformationally effective envelope and whole virus vaccines. 1.1

(2) Map in vivo T-lymphocyte epitopes by DTH skin testing. 0.6

(3) Evaluate in vivo/in vitro the immunogenicity of inactivated whole virus vaccine. 0.5

$8.9M

3. Summary:

Total Direct Costs	$8,900,000
Indirect Costs	1,433,000
Grand Total	$10,333,000

ATTACHMENT 3 SENT 4 JANUARY 1994

THE ASSISTANT SECRETARY OF DEFENS

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

The Honorable William H. Natcher
Chairman, Committee on Appropriations
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Pursuant to the ninth proviso of the first paragraph of Title IV of the Defense Appropriations Act, 1993, as amended by section 8005A of the Defense Appropriations Act, 1994, on behalf of the Secretary of Defense, I hereby certify that, a large-scale Phase III clinical investigation of the gp160 vaccine should not proceed. Similar certifications are being made by the Director of the National Institutes of Health (NIH) and the Commissioner of the Food and Drug Administration (FDA).

The reason for this determination is that based on available data, it is premature at this time to initiate a large Phase III therapeutic efficacy trial of gp160 or any other vaccine therapy product. The U.S. Army Medical Research and Development Command continues to believe the MicroGeneSys gp160 has potential as a therapeutic vaccine against the Human Immunodeficiency Virus (HIV), and accordingly, plans to complete its current Phase II trial of gp160. Decisions on further clinical trials of this product will be based on the Phase II results.

The Department of Defense (DoD) continues to believe that this novel approach to therapeutics, aimed at boosting the patient's own immune defenses against the HIV, merits intense exploration. Accordingly, the fiscal year 1993 special appropriation, available under the statute for other AIDS research needs of DoD, will be used to fund a vaccine therapy development program. The purpose of the program will be to accelerate development of new HIV vaccine therapy strategies and products. Research proposals on this topic will be solicited in the public domain from universities, industry, and others. Submissions will be judged by peer review, and selections will be based on scientific excellence and potential for clinical impact. DoD, FDA, NIH, and non-government scientists will be invited to participate in the peer review process.

A similar letter has been sent to the Chairman of the Senate Committee on Appropriations.

Sincerely,

Edward D. Martin

Edward D. Martin, M.D.
Acting Assistant Secretary of Defense

As cary