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[AIDS Cure Project] [loose]

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# THE AIDS CURE PROJECT

**A detailed plan,
inspired by the work of
Barbara McClintock,
for an all out
research effort
to find a cure for AIDS.**

**The AIDS Cure Project was developed with input from the entire membership of ACT UP/New York City and other ACT UP chapters nationwide.**

*This longer document was a collaborative effort by members of the AIDS Cure Working Group, including:*

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# THE AIDS CURE PROJECT - QUESTIONS & ANSWERS

**What is the AIDS Cure Project?**

**The AIDS Cure Project** is *NOT* "The Manhattan Project to Cure AIDS." It *IS* a nationwide call for an intensive research effort to find a cure for AIDS. During his campaign, Bill Clinton promised a "Manhattan Project," but no one ever defined that term. **The AIDS Cure Project,** which has been introduced into Congress as The AIDS Cure Act by Jerrold Nadler (D-NY), would assemble a team of researchers from a broad range of fields at a primary location. Primary research staff would be required to suspend all conflicts of interest and work exclusively for the Project. Their mandate would be to find a cure for AIDS, by exploring a diverse range of theories, even ones outside the mainstream, and by studying all affected populations. The Project would have powers of "eminent domain" to ensure full cooperation from all drug companies.

**Why a whole new project? Can't we just improve the NIH?**

No. The history of the NIH is riddled with conflicts of interest, excessive influence from the pharmaceutical industry, and a pattern of stifling creative, non-mainstream research. Also, the granting processes of the NIH drastically slow research, and divert money to university overhead costs, etc. rather than to the search for a cure.

**Why force scientists to move to a central location? Isn't that asking a little much?**

They've done it before, for the Manhattan and Apollo Projects. And **The AIDS Cure Project** wouldn't be in the middle of the desert. It would be in an area with a high incidence of AIDS, maybe even New York City, so researchers could study people with AIDS, not just a virus. If the Project is conceived as being on the cutting edge of research, many would be eager to participate; if only to free themselves from the continual pain of grant-writing, which can consume up to 40% of their time.

**Isn't it crazy to ask researchers to suspend all conflicts of interest? Why not just require full disclosure?**

President Clinton has asked for similar suspensions from his Cabinet, why not from AIDS researchers? Full disclosure will not rectify the bias inherent in research done by investigators who hold stock in the involved drug company or who are paid to promote the drug they are researching.

**How much will it cost?**

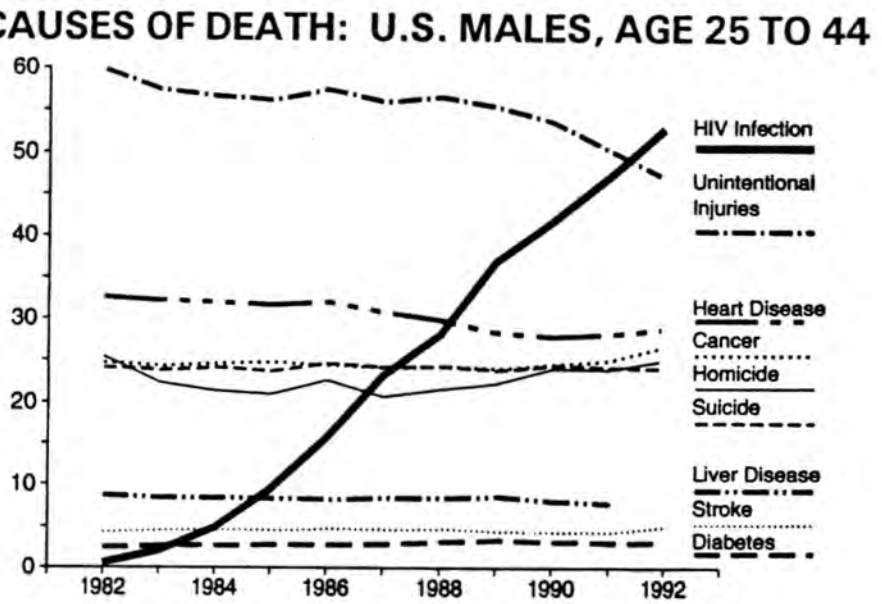
$1.84 billion over 5 years.

**Isn't that a pipe dream in today's political climate?**

If we only ask for what we *think* we can get, we'll get even less than that! We must demand what we *know* is right. If we can spend $3 billion a year on "Star Wars", we can afford this much to cure the world's deadliest plague. If we build a national demand for this, it can happen. $6 billion appeared *immediately* for Midwest flood relief, and that didn't save a single life.

**Why a Project just for AIDS? Why not one for cancer and heart disease?**

This chart says it all:




**What is eminent domain?**

Eminent domain is the government's right to seize private property for the public good, with just compensation. While it is usually used for highways and other public land uses, it has been used in times of war, as well as in peace, by the Department of Defense, to procure patents. The Manhattan Project had this power, and **The AIDS Cure Project** would need it to ensure that drug companies can't stop all research into a compound simply because it doesn't "fit into their corporate agenda."

**Won't that drive drug companies from research?**

The pharmaceutical industry has always said that any government intervention will drive them from research. They predicted disaster when the FDA was formed in 1938. **The AIDS Cure Project** will most likely *never* seize any patents, but use the threat of eminent domain to ensure that drug companies cooperate and do not stall research into vital compounds. Actually, any company making a good faith effort to research a drug would receive little interference from the Project.

**What's the next step?**

A groundswell of grassroots support is needed to get something as ground-breaking as **The AIDS Cure Project** through Congress. Endorsements for the Project are continuously being received, and it has received broad support from AIDS and non-AIDS organizations alike.

Congress must respond to AIDS as they do to other national emergencies: quickly. We'll do whatever it takes: demos, letter and phone zaps, civil disobedience, visits to Congresspeople, etc. We believe this is the best way to find a cure, so we must push for it no matter how difficult the battle seems. Bringing the relevant issues to the fore will be an added benefit in our struggle to make **The AIDS Cure Project** a reality.

# THE AIDS CURE PROJECT

**The AIDS Cure Project** has been introduced as legislation in Congress as the AIDS Cure Act, by Representative Jerrold Nadler (D-NY). The Project is an intense research effort with the single goal of finding a cure for AIDS. These are a few of the features needed if honest, creative research is to be done in the shortest possible time:

The Project would bring ***a team of researchers together in a primary location*** in an area with a high incidence of AIDS. These researchers would come from backgrounds as diverse as virology, immunology, nutrition, clinical practice, etc., and would interact regularly, for maximum creativity and "cross-pollination" of ideas. It is essential that the primary research staff work at one location in order to encourage innovative thinking. It is well known that the best exchange of information at scientific conferences happens not at the formal presentations, but in the hallways between sessions. While the primary staff would interact with researchers world-wide through computer links and teleconferences, nothing can replace the "what if?" conversations that happen spontaneously when great minds are brought together.

The Project would have two main goals: to do ***basic research*** into the pathogenesis of AIDS (how AIDS actually happens in the body), and to ***identify potential curatives***, either new or existing. Current research efforts have focused primarily on the study of HIV itself, and knowledge about the actual course of disease is still in its infancy. The Project would be required to study people with AIDS, not just a virus.

The Project would ***examine diverse theories*** about the development of AIDS, not just the current NIH model, and be open to new ideas. The current research structure forces out scientists who offer "radical proposals" and instead funds those who submit safe, "mainstream" ideas. The Project would actively encourage new theories.

In order to insure an honest, all-encompassing approach, ***researchers would rescind all conflicts of interest*** for the duration of the Project, and receive payment only from the AIDS Cure Project. When researchers receive thousands of dollars from a drug company whose compound they are investigating, the possibility for bias is clearly present. The Project would match the strict conflict of interest guidelines that the President's cabinet requires.

The Project would have the ***power of "eminent domain"*** to ensure that all promising approaches are pursued as quickly as possible. AIDS drug development has a history of treatments either stalled or stopped outright due to the "corporate agenda" of the patent-holder. Currently the NIH is powerless to force a drug company to cooperate if they choose otherwise. Abbot's HIVIG and Roche's tat inhibitor are two examples. The Project would work cooperatively with all drug companies, and would not interfere with any company that was developing a compound with due speed. Only if a company refused to cooperate or adhere to an approved timetable would the Project buy the patent and develop it itself.

***All curatives*** released primarily due to the AIDS Cure Project ***would be made available to everyone***, regardless of ability to pay. An international cooperative effort would be established to ensure that all curatives released primarily due to Project research would be available worldwide.

# A RATIONALE FOR THE AIDS CURE PROJECT

"Listen to your material." - Barbara McClintock*

Due to years of grassroots pressure from AIDS activists nationwide, President Clinton, in his campaign for the White House, promised to implement a "Manhattan Project for AIDS". The Manhattan Project was a multi-billion-dollar crash program at the Presidential level in World War II to develop an atomic bomb. Based on the premise that such a concept was possible, it proved the premise and produced the product. If such skills and resources could be assembled for the purposes of destruction, surely AIDS, and its accompanying devastation, deserves a similar all-out effort. A project designed to cure AIDS is essential for a sound global future: economically, culturally and - most crucial - ethically.

A number of proposals for such a project have been put forward. Unfortunately, none of these plans fundamentally questions the relationship between pharmaceutical companies and the slow pace of AIDS research, or the research establishment's refusal to study diverse theories of pathogenesis. And none provides real power - rather than merely an advisory role - for people with HIV and AIDS of diverse communities in the running of the project.

Any new initiative on federal AIDS research must be based on a comprehensive critique of the current system. After 11 years and several billion dollars of spending, NIH has a track record on AIDS that parrots some of the worst aspects of the National Cancer Institute's (NCI) "War on Cancer". That program (much longer-running and more generously-funded) has resulted in:

1. an "early detection" model with a minimum of available treatments;

2. an emphasis on the development of toxic, debilitating and expensive chemical therapies (individual and combination) of limited efficacy;

3. claims of "survival" when a patient lives two years after diagnosis.

The NCI remains unable to detail a coherent model for the pathogenesis of the disease and has come up with frightfully few effective long-term cancer therapies, yet has systematically neglected (and sometimes attacked) promising experimental treatments not sponsored by large pharmaceutical companies.

Like NCI, the NIH's AIDS programs are becoming self-perpetuating research machines which contribute only marginally at best to uncovering effective treatments, while gobbling billions in tax monies. Among the reasons for this:

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* In order to reflect the values necessary to end the AIDS crisis, the Project takes its inspiration from the work of Nobel laureate Barbara McClintock, a research geneticist who, without advanced technology and bucking the then-prevailing orthodoxy, discovered a revolutionary premise underlying DNA replication. Though her findings were shunned by her colleagues, she continued her work. It was only years later, after the discovery by others of the structure of DNA, that her work was finally acknowledged. Her approach - intense commitment and a focus on divergence rather than the norm - is a model for AIDS research.

**1. Corporate domination of research agenda.**

Priorities in both basic and clinical research are inordinately influenced by the interests of major pharmaceutical companies. Research directions are thought of in terms of drug outcomes, rather than understanding an illness in a way which could lead to a broad range of effective treatments. Government research priorities become tied to corporate profit interests primarily through direct and indirect conflicts of interests by members of NIH policy-making committees and rank-and-file Principal Investigators (PIs), via either consulting fees or stock ownership.

Other channels of influence are campaign contributions to, or lobbying of, Congresspeople who control the NIH budget. University programs are influenced by the widespread grants and endowments bestowed upon them by drug companies, as well as by personal financial ties of research faculty to those companies.

The result of this entrenched system is a research agenda - both public and private - skewed towards drugs likely to receive FDA approval (or occasionally, for which a Congressional sponsor can be found), a closed-loop process favoring companies rich enough to afford the huge expenses required. Thus, promising treatments are ignored or rejected because:

1. they threaten the markets for already-approved or in-development products of large companies;
2. they are backed by small companies with inadequate funds to navigate the exhaustive FDA approval process; or
3. they are unpatentable (or already on the market for other purposes), making FDA approval uneconomical to the sponsors.

As a result, over 100 treatments (including drugs, vitamins, herbs and no-cost health practices) not backed by large pharmaceutical companies have been reported through medical literature and/or clinical experience to improve the health of people with HIV or AIDS to some degree, yet virtually none has had a large-scale clinical study which could either show its ineffectiveness or move it ahead towards broad recognition and, where relevant, FDA approval.

Furthermore, the corporate focus on profits promotes the development of treatments which are extremely expensive and require indefinite use. When these are the primary treatments investigated by NIH, the mentality created is one of accepting a few more years of life of dubious quality, rather than a striving for a cure. In fact, a therapy from outside the major companies which shows curative promise is viewed as a competitive threat, often provoking moves in academic or government circles to discredit it.

**2. Stifled investigation of divergent pathogenesis theories.**

Understanding pathogenesis - the origin and development of disease - is the key to finding cures. Through every level of the current AIDS research system, a very narrow band of pathogenesis theories are promoted and well-funded. All posit HIV as the unquestioned necessary and sufficient cause of AIDS, and examine only a few possible biological mechanisms by which the virus could cause immune system damage. Some theories consider viral co-factors (such as

cytomegalovirus and various herpes viruses) as "initiators" or "promoters" of HIV's action.

Meanwhile, what remain virtually ignored by mainstream researchers are such alternative theories as auto-immunity (the idea that AIDS results from the immune system turning on itself) or such proposed co-factors as non-viral infections (bacterial, fungal, parasitic or mycoplasmic), side effects of medicinal drugs, nutritional deficiencies, environmental toxins or psychological stress. Shunned completely are those suggesting that HIV may not play a causative role.

Contrary to the claims of mainstream scientists, this set of priorities is not, in most cases, the result of either inadequate credentials by the "dissidents" (many have distinguished backgrounds) or a lack of sound scientific bases for their theories (many have written well-researched papers, although some are unpublished or appear in obscure journals). Rather, the near-exclusive focus on viral causes, particularly new viruses, is a by-product of both pharmaceutical company domination of AIDS research and academic research "trends" of what is deemed the "new frontier" of scientific knowledge (a determination heavily influenced by the former).

Since the 1980s, antiviral drugs - particularly those developed by genetic engineering - have become the medical industry's "hot commodities" (as antibiotics were in the 1950s and 60s) because they involve the highest technology (thus justifying the expensive corporate staff and facilities) and offer high profit margins. In addition, academic and government researchers are pressured by their department heads to seek recognition through publishing and winning grants (both controlled by a "peer review process" in which a small elite sets trends for favored scientific fields).

The result of these factors is stark: scientific work on AIDS, whether basic science or drug development, which could lead to a new antiviral, gains funding and prestige in academic and NIH research circles. In contrast, any theories which significantly differ from those propounded by "leading" (i.e., well-connected) researchers are scorned and funding for investigating them is often rejected. This creates a climate which influences many researchers to steer clear of all but the safest, most conventional approaches. Some with theories outside the mainstream continue to pursue their work with extremely limited funds and no (or only obscure) publishable outlets for their information, guaranteeing a longer than necessary research schedule and the absence of their approaches and findings from the thinking of others in the field.

**3. Uncoordinated and competitive research.**

The NIH's AIDS research projects are funded through an uncoordinated and competitive system of investigator-initiated research, leaving vital areas unexplored. Within the NIH and in the private sector, many researchers remain compartmentalized within their university, agency or company - or even a department thereof - and do not communicate, much less collaborate, with colleagues working on identical problems. This is especially true in terms of cross-disciplinary contact (e.g., virologists rarely speak to immunologists or nutritionists). An inordinate emphasis in both public and private agencies on secrecy and glory-seeking discourages researchers from challenging this isolation. Further, the location of AIDS research in 21 separate NIH institutes and centers has prevented a concerted, comprehensive and multidisciplinary approach to understanding and thus treating this disease.

The newly enhanced powers of the NIH Office of AIDS Research will help somewhat in reducing the most obvious inefficiencies and in highlighting, through the construction of a "strategic plan", some areas of neglected research. But the absence of a single unified research project (rather than separate programs coordinated by one office) and the lack of a multidisciplinary approach will prevent that strategic plan from being complete or from being implemented quickly.

Furthermore, while coordination and multidisciplinary teamwork (rather than competition and isolated research efforts) would do much to advance our knowledge, these are not the only problems with the current organization of the research effort. The NCI is more coordinated bureaucratically and financially than the AIDS programs, yet it has not fared any better in its cancer research.

**4. Closed circuit of researchers focused on empire-building rather than creative investigations.**

An "old-boy-network" of researchers, most working for either large pharmaceutical companies, major universities or private research institutions, gets the lions-share of the funds. Due to the structure of academic institutions and the requirements for career advancement, many academically-based researchers (regardless of their good intentions) submit proposals aimed more at enhancing their institution's prestige, facilities or budgets than at creatively probing for solutions to this urgent crisis.

One outcome of this system is the waste produced by university research departments receiving multiple grants, each including indirect (overhead) costs. Some grants provide greater overhead than substantive research funds. Another outcome is that a single researcher can be the Principal Investigator (PI) on numerous grants (17 in the case of one prominent AIDS researcher). Regardless of a PI's individual skill or reputation, one person cannot possibly attend to the research content of these projects in any concerted or creative way. This is a factory model of research, reaping large amounts of overhead for one institution and pushing out more of the same product rather than taking new paths.

**5. Other problems with current AIDS research priorities include:**

- a focus on the similarities or "norms" among people with HIV or AIDS, rather than the differences, resulting in the systematic neglect of populations whose pathogenesis and manifestations of the disease may be significantly different (such as women, people of color from diverse national/cultural backgrounds, injection drug users, and people with inadequate medical care and/or nutrition).

- the relative neglect of the need for developing treatments towards the end of the disease spectrum (people viewed as "near death") and the beginning (people recently infected and asymptomatic).

- the lack of meaningful power by people with HIV or AIDS from diverse communities in determining the federal research agenda.

For all these reasons, it is imperative that Congress immediately enact an intensive AIDS research initiative to cast a broad net which will unravel the pathogenesis and lead to the cures for this disease. The same government that could find the resources to set up a unified command and transport, feed and shelter 400,000 troops to wage a war in the Persian Gulf can certainly quickly create a powerful, well-funded project to pursue a life-giving struggle to end the suffering and deaths from AIDS.

## Endorsements for The AIDS CURE PROJECT

*as of April 28, 1994*

**Dr. Mike Alcalay**, AIDS IN FOCUS, Pacifica Radio
**George Barnhart**, AIDS ALLIANCE OF THE BAY AREA, Clearlake, TX
**Prof. Susan Bassein**, Chair, Math Department, Mills College, Oakland CA
**Michael Carr**, MIDDLE GEORGIA PEOPLE WITH AIDS, Macon GA
**Yvonne Chambers**, WOMEN AND AIDS RESOURCE NETWORK, NYC
**Alex Conchola**, K.C. FREE HEALTH CLINIC, Kansas City, MO
**Robert Darrow**, THE PHILADELPHIA CENTER, Shreveport, LA
**Rev. William M. Davis, ULC Ambassador**, San Francisco, CA
**Jerry DeJong**, Director, CENTER FOR AIDS SERVICES, Oakland, CA
**Rep. Ronald V. Dellums**, 9th District, California
**Lalia Docty**, EAST ORANGE V.A. MEDICAL CENTER, NJ
**Brian Donoghue**, The LEARNING ALLIANCE, NYC
**Ivy Dumeier**, MOTHERS' VOICES
**Eileen Durkin**, HOWARD BROWN HEALTH CENTER, Chicago IL
**Jack Godby**, ODYSSEY HOUSE, INC., NYC
**Maryanne Guiney**, FAXTON HOSPITAL, Utica, NY
**Loni Hancock**, Former Mayor of Berkeley, CA
**Mayor Elihu Harris**, Oakland , CA
**Mayor Frank Jordon**, San Francisco, CA
**Morris Kight**, Commissioner on Human Relations, Los Angeles
**Quincy Kirks**, UPPER ROOM AIDS MINISTRY, NYC
**Ulle Kolv**, ST. MARKS WOMEN's HEALTH COLLECTIVE, NYC
**Kevin Langely, R.N.**, SAN FRANCISCO GENERAL HOSPITAL, CA
**Rep. Barbara Lee**, California State Legislature, Oakland, CA
**Mayor Jefferey Leiter**, Berkeley, CA
**Gerald Lenoir**, Executive Director, BLACK COALITION ON AIDS, SF, CA
**Sharon Lerner & Nancy McKenzie**, HEALTH POLICY ADVISORY CENTER, NYC
**Ann Magnuseon**, Performer/actress
**Gwen Martinez**, PROMESA, INC., Bronx, NY
**Marie C. McCann, M.D.**, President, Board of Directors, CHASE-BREXTON HEALTH SERVICES , Baltimore,
**Supervisor Carol Midgen**, SAN FRANCISCO BOARD OF SUPERVISORS
**Rep. George Miller**, 7th District, California
**Rep. Jerrold Nadler**, 8th District, New York,
**Fr. Bill O'Donnell**, St. Joseph the Worker RC Church, Oakland, CA
**Rep. Major R. Owens**, 11th District, New York
**Eva Jefferson Patterson**, LAWYER'S COMMITTEE FOR CIVIL RIGHTS, SF, CA
**Douglas Paul**, Metropolitan Assistance Corp., NYC
**Thayer Quoos**, AIDS PROJECT NEW HAVEN, CT
**Sylvia Racca**, VERMONT CARES, Burlington, VT
**Arlene Rakoncay**, CHICAGO ARTISTS' COALITION, Chicago, IL
**Cliff Scott**, DOWNTOWN ART COMPANY, NYC
**Tim Sherman**, LET ME BE ME, Glens Falls, NY
**Joey Tajonera**, CONFERENCE ON JUSTICE & PEACE, Brooklyn, NY
**Mabrey Russell Whigham III**, PHYSICIANS ASSOCIATION FOR AIDS CARE, Chicago , IL

**The AID$ Cure Coalition seeks endorsements for the "Demand for the AIDS Cure Project" on pages 7 & 8, not for this entire document. Questions? Phone 212-631-4251.**

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☐ **Yes, I endorse The AIDS Cure Project.** ☐ **Hay otro panfleto disponible en español.**

Name

☐ **For my Organization.** ☐ **List Organization for identification only.**

Address

City, State Zip

**The AIDS Cure Working Group**
**ACT UP/New York**
135 W. 29th Street, 10th Floor
New York, NY 10001

☐ **I've enclosed a check to support ACT UP's work.**

# Endorsement for The AIDS CURE PROJECT

*as of April 28, 1994*

AIDS ACTION NOW!, Toronto, OT
AIDS ROCHESTER, Rochester, NY
AIDS FOR AIDS OF NEVADA
ALTERNATIVE TREATMENTS / ONGB NOW!, San Francisco, CA
AMERICAN CIVIL LIBERTIES UNION OF NEW JERSEY
AMERICAN FEDERATION OF STATE, COUNTY & MUNICIPAL EMPLOYEES, LOCAL 3211, UC
ASCME DISTRICT COUNCIL 16, Oakland, CA
BELLEVUE HOSPITAL COMMUNITY BOARD, NYC
BERKELEY CITY COUNCIL, Berkeley, CA
BERKELEY HIGH SCHOOL NOW
BODY POSITIVE, NYC
BODY POSITIVE, Houston, TX
CALIFORNIA PEACE & FREEDOM PARTY
CHARLOTTE HIV/AIDS NETWORK, Port Charlotte, FL
CENTRAL CITY AIDS NETWORK, Macon, GA
CENTRAL NEW YORK HIV CARE NETWORK, Syracuse, NY
COMMUNITY BOARD NO. 3 MANHATTAN, NYC
COMMUNITY HEALTH PROJECT, NYC
DOWNTOWN UNITED PRESBYTERIAN CHURCH, Rochester, NY
EARLY ADVOCACY & CARE FOR HIV PROGRAM, San Francisco, CA
EAST BAY LESBIAN/GAY DEMOCRATIC CLUB, Oakland, CA
EAST BAY NOW, Oakland, CA
EAST END NOW, Hampton Bays, NY
EPISCOPAL DIOCESE OF ROCHESTER
THE GALAXI PROJECT, Philadelphia, PA,
GAY ALLIANCE OF GENESSEE VALLEY, Rochester, NY
GAY & LESBIAN AMERICANS, USA
GAY & LESBIAN RESOURCE CENTER OF VENTURA COUNTY, CA
GAY HUMAN RIGHTS LEAGUE/QUEENS COUNTY, NY
GRAY PANTHERS OF BERKELEY
GRAY PANTHERS OF SAN FRANCISCO
GREATER HOUSTON AIDS ALLIANCE, Houston, TX
GREEN PARTY U.S.A.
GREEN PARTY OF ALEMEDA COUNTY, CA
GOOD SAMARITAN PROJECT, Kansas City, MO
GULF STATES HEMOPHILIA CENTER, Houston, TX
GULF COAST LEGAL SERVICES, Houston, TX
HAIGHT ASHBURY FREE CLINICS, INC, San Francisco, CA
HIGH SCHOOL HIV/AIDS RESOURCE CENTER, NYC
IBERO AMERICAN ACTION LEAGUE, Rochester, NY
JEFFREY GOODMAN SPECIAL CARE CLINIC, Los Angeles, CA
LATINO HEALTH INSTITUTE, Boston MA
LATINos/as CONTRA SIDA, Hartford, CT
MIDDLE EAST CHILDREN'S ALLIANCE, Oakland, CA
METROPOLITAN COMMUNITY CHURCH OF SAN FRANCISCO
MOBILIZATION AGAINST AIDS
NATIONAL ORGANIZATION FOR WOMEN - NYC Chapter
NORTHERN LIGHTS ALTERNATIVES, NYC
NORTHEAST OHIO COALITION FOR NATIONAL HEALTH CARE, Cleveland, OH
OAKLAND CITY COUNCIL, Oakland, CA
ORLEANS COUNTY AIDS TASK FORCE, NY
OHIO AIDS COALITION, Columbus, OH
PEACE & FREEDOM PARTY OF ALEMEDA COUNTY
PEOPLE WITH AIDS COALITION, Baltimore, MD
PEOPLE WITH AIDS COALITION, Houston, TX
PEOPLE WITH AIDS COALITION OF MINNESOTA
PEOPLE WITH AIDS COALITION OF NEW YORK, NY
PEOPLE WITH AIDS COALITION, Provincetown, MA
PEOPLE WITH AIDS COALITION OF TAMPA BAY, FL
THE PHOENIX SHANTI GROUP, Phoenix, AZ
PROJECT RETURN FOUNDATION, NYC
THE RAINBOW CENTER, Macon, GA
REPUBLICANS FOR INDIVIDUAL FREEDOMS, Atlanta, GA
ROCHESTER AREA TASK FORCE ON AIDS
ROCHESTER AIDS INTERFAITH NETWORK
ROCHESTER FAMILY SERVICE, NY
ROCHESTER PEACE & JUSTICE EDUCATION CENTER
RUTH HOME, INC., Buffalo, NY
SAN FRANCISCO BOARD OF SUPERVISORS
SOCIAL JUSTICE FOR STREET YOUTH, San Francisco, CA
STRONG MEMORIAL HOSPITAL, Rochester, NY
THURSDAY'S CHILD, INC. Westhampton Beach, NY
WOMEN IN CRISIS, NYC
WOMEN'S HEALTH EDUCATION PROJECT, NYC

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ACT UP / Baltimore
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ACT UP / Houston
ACT UP / Idaho
ACT UP / Ithaca
ACT UP / Kailua-Kona
ACT UP / Kansas City
ACT UP / Los Angeles
ACT UP / Louisville
ACT UP / Madison
ACT UP / Miami
ACT UP / Milwaukee
ACT UP / Minnesota
ACT UP / New Haven
ACT UP / New Orleans
ACT UP / New York
ACT UP / Philadelphia
ACT UP / Rhode Island
ACT UP / Rochester
ACT UP / San Diego
ACT UP / Seattle
ACT UP / Shreveport
ACT UP / Washington, DC
ACT UP / West Palm Beach
ACT UP / Western New York

# DEMAND FOR THE AIDS CURE PROJECT

**The present U.S. AIDS research effort is incapable of bringing the AIDS crisis to an end. Therefore, the federal government must take extraordinary steps to remove all barriers to the development of cures. President Clinton has called for a "Manhattan Project for AIDS." We demand that Congress enact legislation to implement such an all-out effort as follows:**

**I. A declaration of the dire urgency of the international AIDS pandemic and the need for immediate, rapid, focused steps towards curing AIDS.**

**II. The establishment of the AIDS Cure Project, jurisdictionally separate from the National Institutes of Health (NIH) and reporting to but not directed by the President through a special liaison.**

**The Project shall have the following mandates:**

**1. The Project's goal will be to find a cure for AIDS, with cure being defined to include "any and all approaches which will ensure a well-functioning immune system and a normal life span with a reasonable quality of life." To that end, it will have two missions: [see page 9 for details]**

**a. to pursue comprehensive basic science investigations, based on diverse theories and schools of thought which elucidate the pathogenesis of AIDS,**

**b. to identify, based on this work, all promising curatives and to oversee their timely and adequate testing through the extraordinary powers detailed in section 4 below.**

**2. In order for the Project to achieve its goals, its work must be carried out in the most efficient and cooperative manner possible, free of private interests and bureaucratic red tape. To this end,**

**a. The Project shall establish a primary location for its work. All primary research staff will work at that location; contributing researchers located around the world will interact via video teleconferencing, an international computer network, and regularly scheduled face-to-face meetings. [see page 9]**

**b. The NIH's existing AIDS research programs will be maintained. All NIH basic science research supplementary to that done by the Project will be performed cooperatively with the Project.**

**c. All primary research staff and administrators shall be financially compensated only by the Project and may not have conflicts of interests with private organizations (including but not limited to universities, pharmaceutical companies, private research organizations, etc). [see page 12]**

**d. The Project shall be funded by public - not private - monies. Appropriations for the Project shall not be diverted from other health care or human service programs.**

**e. The Project will be governed by, not merely advised by, a council composed of scientists and clinicians representing divergent approaches, and people with AIDS and HIV, and their advocates, from all affected communities. This council will set policy and oversee research priorities, ethical standards, conflict of interest rules and hiring of researchers, consistent with 3a below. [page 13]**

**f. The project shall, in addition to basic research investigations, operate an on-site clinic to conduct small scale research trials with human participants in such trials are crucial for testing hypotheses related to its basic research.**

3. To ensure that the most open and productive research paths are pursued, and to produce a cure accessible to and usable by all affected people:

a. Thorough consideration shall be given to both conventional and other medical approaches and scientific theories, and researchers representing divergent approaches shall be on the primary research staff as well as be contributing researchers. [see page 15]

b. The Project's study of AIDS pathogenesis and manifestations must focus on all populations of people with AIDS and HIV. Equal consideration shall be given to the differences between these populations as to their similarities or "norms." This includes women, children, gay men, lesbians, people of color (of various affected national-cultural groups), injection drug users, prisoners, hemophiliacs and people with inadequate medical care and/or nutrition. [see page 17]

c. Basic science investigations and therapeutic results will be geared to people at every point on the spectrum of AIDS and HIV - form the sickest to the healthiest. Saving people considered "near death" must be considered as important as early intervention.

d. Information generated by the Project shall be made freely available to researchers, health care providers, people with AIDS and HIV and their advocates as soon as it is available, without being inhibited by professional publication practices.

e. Curatives ultimately released due primarily to project research shall not result in financial gain to any private organization, and shall be made available to all affected people regardless of ability to pay. [see page 18]

4. In order to accomplish its goals, the Project shall have extraordinary powers to:

a. direct the utilization of any and all existing U.S. government funded research entities and their facilities to clinically test promising cures developed on the basis of its research and to direct the manner in which such research shall proceed, including staffing, participants, location and timing. Such research will be funded by the AIDS Cure Project. [see page 19]

b. exercise the right of eminent domain to: [see page 20]

- obtain from public and private organizations - with just compensation - samples of all potential curatives and all data regarding their development (including safety and efficacy data) as well as other information, materials or products deemed crucial to the Project.

- implement clinical testing for potential curatives owned by private companies, whether under development or not, only if said companies refuse to either adhere to an approved time frame (and are forthcoming with their data as such work proceeds) or to develop such compounds in cooperation with the Project.

- use existing pharmaceutical company facilities (with just compensation) for the production of promising curatives to be utilized in Project research and, if effective, to produce such curatives in sufficient amounts to be disseminated to all people needing them.

5. A seed budget must be allocated immediately to be used for project planning (including creating facilities, selection of staff, funding, structure and schedules), so that the Project can begin functioning as soon as possible.

# THE AIDS CURE PROJECT

## A Detailed Explanation

**1. The Project's goal will be to find a cure for AIDS, with cure being defined to include "any and all approaches which will ensure a well-functioning immune system and a normal life span with a reasonable quality of life."**

The AIDS Cure Project will purposely define "cure" in very broad terms, to avoid focusing all research on a "magic bullet". While the Project would most likely speed the research needed to find a one-time treatment, it would also fully explore all the other approaches to healing that have heretofore been ignored in the NIH's current research effort, including those that utilize the body's own systems to fight disease, long-term therapies (drug-oriented or not) to keep the virus in check, and treatments that may eventually rid the body of the virus.

The current approach, based on the cancer model, has led to three approved treatments for HIV - AZT, ddI and ddC - all of which are actually old cancer chemotherapy medications abandoned after they proved too toxic for cancer patients or were ineffective. The Project will seek approaches with a minimum of toxicity that result not only in a normal life span, but also a reasonable, and hopefully high, quality of life.

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**2a. The Project shall establish a primary location for its work. All primary research staff will work at that location; contributing researchers located around the world will interact via video teleconferencing, an international computer network, and regularly scheduled face-to-face meetings.**

> "The mainspring of progress in science is the free interplay of creative minds that had to be brought together and allowed to talk to each other. Only through their unrestricted exchange could they make speedy headway [during the Manhattan Project]...*We needed a central laboratory devoted wholly to this purpose, where people could talk freely with each other, where theoretical ideas and experimental findings could affect each other, where the waste and frustration and error of the many compartmentalized experimental studies could be eliminated; where we could begin to come to grips with [the diverse] problems that had so far received no consideration.*" [Stoff, M.B., A Documentary Introduction to the Atomic Age]

Three issues need to be addressed concerning the creation of a primary facility for the Project:

*1. Is it necessary?*

Current AIDS research efforts, particularly basic science and pathogenesis research, are not only fragmented and compartmentalized, but also are conducted by researchers from a variety of disciplines. A good part of this research is not funded by the government or is done by researchers not considered part of the "AIDS network." While they may not be aware of each others' efforts, their theoretical and experimental findings could profoundly affect one another.

The reporting and discussion of the basic science of AIDS research is currently conducted at meetings around the world throughout the year, including the International AIDS Conference, Gallo Conference, Keystone Conference, AIDS Clinical Trials Group Meetings, Biological Response Modifiers Meetings and the Antimicrobial Agents in Chemistry Conference, to name only a few. Researchers in one field, eg. molecular biology, usually do not attend conferences in other fields, i.e., virology; researchers from related fields whose work may be relevant often do not even attend conferences focused on AIDS.

Basic science research has minimal coordination even within one institution in the U.S., let alone within the country or across the world. Since the complexity of AIDS requires that a diverse group of scientists, including immunologists, virologists, molecular biologists, biochemists, nutritionists, herbologists, etc., interact on a regular basis, a central location is essential to facilitate the cross-fertilization of ideas. The inclusion of sophisticated global telecommunications equipment will allow affiliated researchers from around the world to be contacted quickly for the dissemination and sharing of information and ideas.

2. *Will researchers be willing to relocate to be part of the Project?*

Currently many scientists do exactly this -- sometimes for better pay, more opportunity, or to be part of more interesting research projects. It is not unusual for scientists to seek out visiting professorships, post-doctoral fellowships and the like, which can require several years of commitment. One year sabbaticals are common, with scientists moving their families to other parts of the country or to another part of the world. For many scientists, the opportunity to focus their work in a concerted effort and to dialogue with other creative minds, using the best equipment and facilities available, would be extremely enticing.

In the past, scientists have even been willing to relocate under trying circumstances. During the Manhattan Project, for example, entire families were moved to a central location which, for security reasons, was physically remote (a precaution not needed for the AIDS Cure Project, which would be located in an area with a high incidence of AIDS). Living conditions were strictly regulated: people were put under surveillance, their travel restricted, and so on. Similarly, during the Apollo project, "When the Space Task Group in Hampton, Virginia was required to move to Houston, Texas, here was a reaction: 'I was so upset about going to Texas. I wouldn't even let them send me the free subscriptions to their goddanged newspaper. It was my intention never to go to Houston.'...[In the end]...Houston it was, and off they went, 700 engineers and their families. Almost everyone in the Space Task Group did ." [Murray, C. and Cox, C.B., Apollo, The Race to the Moon].

Robert Oppenheimer had similar experiences when recruiting for the Manhattan Project. Travelling across the country, he relied on researchers' "sense of interest, the urgency and feasibility of the Los Alamos mission. It aroused great misgivings because of the very severe restrictions...But there was another side to it. Almost everyone realized that this was a great undertaking. Almost everyone knew it was an unparalleled opportunity to bring to bear the basic knowledge and art of science for the benefit of his country. Almost everyone knew that this job, if it were achieved, would be part of history. The sense of excitement, of devotion...in the end prevailed." [Stoff]. Surely this would also apply to the task of finding a cure for AIDS.

*3. Is such a facility feasible in terms of the time and money it would take to create?*

Existing AIDS research facilities most likely could not physically support the AIDS Cure Project. More importantly, these facilities do not have the needed equipment for research and communications, and have no priority for obtaining it. While it will take time and effort to build the laboratories, office space and communications facilities needed, this can occur in parallel with the planning and recruiting for the project.

Quick construction is possible: "In mid-November 1942, Los Alamos was little more than a large ramshackle main house and a group of log cabins set among the poplars just below the timberline. By July 1945...more than 4,000 people -- mostly scientists, engineers and their families were living there." The Pentagon, intended as a "temporary structure" was built in only 16 months. It has an outside circumference of one mile, the world's largest telephone system, and a staff of 32,000. It follows that physically creating a central facility for the Project is feasible within a short amount of time.

Research spending for AIDS in the past decade has been roughly $3 billion. Compared to this, the Apollo Project cost $94 billion in 8 years, the Osprey (a vertical take-off aircraft) optimistically budgeted at $22 billion, will more likely cost 3 to 4 times more, and the "Star Wars" program currently costs $4 billion a year. A fraction of these funds could find a cure for AIDS.

The Project would require adequate funding and the same top purchasing priority that the Manhattan and Apollo projects enjoyed; that is, the Project would receive the first specialized machines out of manufacturing lines, and would be the first to get the raw and semi-worked materials it needs. This type of priority can only work for a "project" with an intended goal, a project which will terminate after the goal is achieved. It cannot be employed indefinitely by any "institute".

In truth, it is neither feasibility nor cost that is the issue. If the U.S. government could find the funds for the Manhattan and Apollo projects, and for the war in the Persian Gulf, to "serve the national interest", it can do the same to find a cure for AIDS, which is most certainly in the national interest. All that is missing is the will and the vision to make it happen.

**2c. All primary research staff and administrators shall be financially compensated only by the Project and may not have conflicts of interests with private organizations (including but not limited to universities, pharmaceutical companies, private research organizations, etc).**

> "The pharmaceutical industry is criticized for spending money on promotion. What is promotion? It involves sending young scientists and clinicians to national meetings to present research, giving textbooks to residents and medical students...[funding] scholarship endowments for clinical investigators, [and] subsidy of clinical journal publication...*Most importantly, it involves paying for the vast majority of basic and clinical research in U.S. medical centers.* This results in the training of graduate students, post doctoral fellows, clinicians...*and the creation of a forum for the pharmaceutical industry to carry out its clinical studies.*" - Richard Blackwell, M.D., Univ. of Alabama

Perhaps no other provision of the AIDS Cure Project raises as many eyebrows as the strict conflict of interest regulations. Yet it is this concept that is at the core of the Project; without it, the Project would be doomed to failure, as was the "War on Cancer" in the 1970's.

Conflicts of interest in biomedical research have always existed on some level. Government-funded researchers are often consultants, employees or even heads of companies developing major pharmaceutical products, or are large shareholders. Yet, they do not disclose their financial interest when submitting papers for publication or when presenting their findings at professional conferences. These papers often demonstrate the superiority of their product or technique over competitors.

But this is only part of the problem. After attending training sessions given by a pharmaceutical company, researchers appear at research symposia, also often supported by that same company, to present the latest information about an illness and the company's treatment. A well-respected researcher can earn $2,000 for a 45-minute presentation, and be booked many times a year across the country. Several major researchers earn up to $100,000 per year for such work. Some researchers have become identified as proponents for a particular drug, while receiving fees from the drug's manufacturer.

Another example includes the large number of clinical newsletters, AIDS and otherwise, published by not-for-profit medical foundations, yet funded by major pharmaceuticals. The editors of these publications, often prestigious university-based researchers, can earn $2,000 per issue. Clinicians can earn $1,500 for a published article.

There are no requirements that researchers disclose these relationships, and it is questionable if such disclosure would be sufficient to guarantee objective research. We propose that, as in other areas of government, it is essential that there be no conflicts of interest, to avoid the continuation of a basic science research agenda for AIDS that superimposes the desire for future pharmaceutical profitability on the decision making process for research priorities.

Therefore, strict conflict of interest regulations will be applied to the primary research staff,

administrators and members of the Policy Council of the AIDS Cure Project. All primary research staff and administrators will be required to suspend their relationship with any private organizations for the duration of their association with the Project. Policy Council members will be required to suspend their relationship with for-profit organizations which represent a conflict of interest.

These requirements will include full-time, part-time or consultant positions with a private organization or other government agencies, and the suspension would include employment, consulting or board membership fees, and stock or business ownership.

Although this standard is significantly more stringent than that currently applied by the NIH, it is similar to the code of ethics imposed by the Clinton administration on its political appointees. The rationale is identical: governmental decisions on vital matters of public needs cannot be even slightly influenced by the possibility of personal financial gain. For too long, the domination of the NIH peer review and advisory committee process by scientists with direct financial ties to drug companies has skewed decisions on which theories and treatments to study, and led to the extreme narrowing of promising research directions.

Some have expressed concern that such strict conflict of interest regulations will discourage leading AIDS researchers from joining the Project. But the primary focus of the Project will be to bring together many of the scientists who, despite excellent credentials and/or important investigative work, have been excluded from most existing private organizations funding AIDS research, due either to the unpopularity of their theories or the lack of interest in their academic disciplines. And for more "mainstream" researchers who would have to suspend their financial interests, the excitement of being part of a cutting-edge project that hold the possibility of major breakthroughs - combined with the time-limited goal of the project and competitive salaries - should be more than adequate to lure those who are genuinely devoted to finding a cure, rather than a career.

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**2e. The Project will be governed by, not merely advised by, a council composed of scientists and clinicians representing divergent approaches, and people with AIDS and HIV, and their advocates, from all affected communities. This council will set policy and oversee research priorities, ethical standards, conflict of interest rules and hiring of researchers, consistent with 3a below.**

*1. The Governing Council*

For overall policy-making and accountability, the Project will be governed by a Governing Council composed of scientists representing divergent approaches, clinicians with both research and community-based experience and people with AIDS and HIV and their advocates. The following structural guidelines are suggested:

Such a council should have at least twenty-one (21) members in order to adequately represent diverse communities, opinions and disciplines. Whatever the final number of Council members,

people with AIDS and HIV from diverse communities will be in the majority to insure that Project staff are ultimately accountable to people directly affected by the course and outcome of the research. Council members will step down and be replaced by new members on a regular basis.

The Council will set policy for and oversee research priorities. It will develop guidelines for and oversee the hiring of primary research staff, ensuring both high quality (scientific credentials and experience) and a diversity of disciplines and perspectives. While certain staff will have pursued specific AIDS theories, this cannot be a necessary prerequisite for hiring; indeed, it will be important to have some primary research staff members who approach the subject freshly. The Council will have the power to create new research positions when necessary and to remove scientists from their positions after due process and appropriate review of their work.

The Council will be charged with evaluating the work of the Project, as well as the pace of the research, to insure that it matches the urgency of the epidemic. Initially, and throughout the life of the Project, the Council, in cooperation with the primary research staff, will solicit and evaluate all new theories developed outside the Project. It will direct the Project scientists to evaluate and respond to deserving proposals and to devise new research plans where desirable.

The Governing Council will adopt strict, detailed codes governing medical ethics and conflicts of interest (according to 2c) and will monitor compliance with these codes. Project scientists will report directly to the Council about the progress of their work in a manner to be determined by the Council. The Council will report directly to the President about the progress of the Project.

Council meetings, including those at which all decisions are made, will always be public and will be held at least quarterly, with time allotted for public comment. In addition, the Council will hold an annual public hearing on its priorities and progress. A complete report of the Project's goals and accomplishments will be updated by the Council, submitted to the President and released to the public at least once quarterly. The Council will evaluate its structure and process at least once per year and make changes which allow it to function more effectively.

*2. The Coordinating Committee*

In addition to an overall Governing Council, there must be day-to-day leadership in the Project. It cannot be governed by research bureaucrats or a single person who might create an entrenched research agenda. Therefore, the community of scientists selected for the Project will elect three of their members to serve as the Coordinating Committee for the Project, and determine whether these positions should be permanent or rotating. It is here that the AIDS Cure Project must differ from the structures and process of military projects such as the Manhattan and Apollo projects. The development of an AIDS cure requires an open and cooperative research environment with scientists from different disciplines and perspectives interacting in a creative and free manner yet focused on a set of shared goals.

The Coordinating Committee will be responsible for facilitating communication among the different scientists working on the Project, for evaluating the progress of its work, and for

convening the entire staff on some regular schedule (or when necessary) to evaluate the progress of the Project as a whole, re-evaluate its direction, and to consider newly developed theories emanating from both within and outside the Project.

The Coordinating Committee will be also be responsible for keeping the Governing Council informed of the progress of the Project's work, at times and in a manner to be determined by the Governing Council. The coordinating Committee will also make decisions regarding the hiring of research associates, technical staff, purchases of equipment and other day-to-day needs.

The first task of the Coordinating Committee will be to facilitate an intensive preliminary review, lasting no more than three months, of all existing pathogenesis hypotheses, as well as other relevant information about AIDS pathogenesis. At the end of this review, the primary research staff will collectively develop plans for evaluating and testing each of the viable hypotheses, including timelines for evaluating the progress of this work.

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**3a. Thorough consideration shall be given to both conventional and other medical approaches and scientific theories, and researchers representing divergent approaches shall be on the primary research staff as well as be contributing researchers.**

The key to the AIDS Cure Project's success will be its ability to provide a venue for scientists with diverse - even conflicting - approaches and theories about AIDS pathogenesis to fully pursue their hypotheses. It is particularly important that approaches and theories previously under- or unfunded by large institutions be given a chance to be tested. These approaches include unconventional theories within both conventional and "alternative" medical disciplines (which not only have entire systems of medical interventions, but also complex theoretical paradigms explaining the pathogenesis of disease). This applies to both the basic science work and the uncovering of potential cures.

*Pathogenesis* refers to the actual course of a disease. We still have precious little knowledge of what happens to the bodies of people with AIDS, apart from the eventual loss of CD4 cells. AIDS Cure will aggressively pursue research into all areas of AIDS pathogenesis. Two broad categories of theories to be researched, among others, by the Project include:

**1. Virological/immunological theories about how immune system damage occurs, including understudied approaches.**

The NIH has focused almost exclusively on one model of pathogenesis: the destruction of CD4 cells due to viral replication. Study of the virus' effect on macrophages, Langerhans and dendritic cells, CNS and GI involvement, etc. is sorely lacking. In truth, we do not have a clear understanding of HIV's effect on any body system, much less the immune system.

Many researchers have, however, presented information on the pathogenesis of AIDS, including theories of *autoimmunity* (the body's tendency to attack its own tissue after seroconversion, whether of not HIV is directly involved), *apoptosis* (programmed cell death that seems to occur more extensively in people with HIV), the presence of a *superantigen*, *chronic inflammation* of mucosal tissues (including the gut, rectum, vagina, nasal passages, mouth and throat), the role of *cytotoxic T-lymphocytes* in suppression of HIV, *cytokine disregulation* (people with HIV have elevated levels of IFN-$\alpha$, IL-6, TNF, and IL-10, to name a few), and effects of HIV on the *endocrine system* (particularly with regard to cortisol and testosterone levels).

All these hypotheses must be studied in depth, in order to determine their role in damaging the immune system. Such research is not now pursued by the NIH unless it appears likely it will lead to a marketable drug.

**2. Theories about co-factors which may precede, activate or even substitute for HIV in the process of immune system damage leading to AIDS.**

Up until now, the sparse research on co-factors has clustered around a very few viruses (CMV, EBV, HHV-6), and has not even been adequate to establish or disprove these theories. Still to be adequately explored are the role of several micro-organisms for which strong presumptive evidence has been developed: other viruses (hepatitis-B, African Swine Fever virus); mycoplasmas; bacteria (those causing syphilis and gonorrhea); yeast (Candida); and parasites (malaria, amoebiasis, giardia). Investigations must also be done of the possible immuno-suppressive role (suggested in numerous non-AIDS studies) of many medications for the above conditions, several of which are common in the medical histories of people with AIDS and HIV.

Likewise, further work must be done on the potential role of recreational drugs (including alcohol) in progression. A huge area with substantial - but usually small-scale and uncoordinated - evidence for co-factorial role are micro-nutrient deficiencies. Given the widespread use of nutritional interventions by people with AIDS and HIV, nutritional research must be included in the Project. Current evidence also suggests a possible role for several chemical and heavy-metal toxins (including cigarette smoke) which must be explored. Finally, a vast body of knowledge grouped under psychoneuroimmunology - some of it now specifically based on people with AIDS and HIV - demonstrates connections between psychological stress, lack of social support, and immune compromise, and must also be studied.

Equally important as exploring each individual theory will be the integration of these into proposed interactive models. This multi-disciplinary, integrative approach, so rare in AIDS research, may hold the key to devising the most effective curatives. Here, too, diversity in approach should be the guideline in hiring staff and setting priorities. Examination should be given to the full spectrum of pathogenesis theories, from those maintaining that HIV is the sole and sufficient cause to those considering HIV a primary cause together with co-factors to those believing that HIV does not necessarily play a causative role.

Diversity of perspective should also be applied to methodology. Theories should be developed and tested through both laboratory experiments and epidemiological research, including careful examination of existing medical records of people with HIV and AIDS. Another key method involves epidemiological and blood studies of long-term survivors from diverse populations to attempt to isolate the factors that have sustained them. Overall, so-called "subjective" evidence - i.e., asking people with AIDS and HIV and their care providers what factors they think may be playing a role, and how the factors may have interacted - should be collected to supplement, and possibly help to synthesize, the more "quantifiable" data.

International cooperation must also be maximized, meaning both the open-minded consideration of hypotheses and results obtained in other countries, and the implementation of an aggressive effort to recruit the best and brightest researchers from other countries. This could include agreements by another country to reassign particular researchers to the Project for an indefinite commitment. But since speed is of the essence, the Project's progress would not await the conclusion of such international agreements.

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**3b. The Project's study of AIDS pathogenesis and manifestations must focus on all populations of people with AIDS and HIV. Equal consideration shall be given to the differences between these populations as to their similarities or "norms." This includes women, children, gay men, lesbians, people of color (of various affected national-cultural groups), injection drug users, prisoners, hemophiliacs and people with inadequate medical care and/or nutrition.**

The inclusion of a diverse range of people in AIDS research, and a focus on the differences among them, is basic to sound scientific research. It is not just a vague call for inclusion nor an attempt to deal with what some have called "social issues." In fact, almost all research on AIDS thus far has focused on white men, most of them gay. Conclusions drawn from this research are generalized to all people with AIDS.

This cannot continue if we are to unravel the complexity of AIDS pathogenesis and develop a cure that will be usable by all affected people. Despite the dearth of scientific research on diverse groups of people with AIDS, the little we do know points to significant differences in not only the manifestations of AIDS, but also in immunological markers and routes of transmission.

For example, while it is generally believed that there is a direct relationship between CD4-cell depletion and the occurrence and severity of infections, differences in that relationship have been found for different groups of people. People with hemophilia, as a result of years of infusions of other people's proteins in their clotting factor, have lower T-cell counts in comparison to other people. Yet, they are less likely to get opportunistic infections at these low levels compared to non-hemophiliacs with HIV.

Healthy children have higher CD4 counts than adults, yet infected children deteriorate more rapidly than adults; 20% die within the first year after birth. And, we know virtually nothing about normal CD4 counts in women or about CD4-Cell depletion and severity of illness in

women. We do know that compared to HIV negative women, HIV positive women with invasive cervical cancer have lower CD4 counts and are more likely to die. Yet, their CD4 counts average around 340, while 200 CD4 cells is considered the marker of severe immunosuppression.

With regard to infections, cervical cancer is one manifestation of AIDS in women which of course does not appear in men, bacterial pneumonia is more common in former and present injection drug users, and proportionately more women than men get MAI.

Finally, even the possibility of HIV transmission appears to be related to overall health at the time of exposure - a European study found that, with good prenatal care, the rate of perinatal transmission was only 15-20% without pharmaceutical interventions, compared to the findings of 30-50% in the U.S.

Routes of transmission can also affect the course of disease. A recent report showed that white babies with AIDS suffer more and earlier oral symptoms than black infants; researchers suspect the difference may be linked to whether the mother was infected through vaginal intercourse or injection drug use. Most importantly, differences in route of transmission may be crucial in finding a cure usable by all people. Most vaccines currently being tested are designed to confer humoral immunity (immunity through the blood stream). Yet HIV is found in the mucosa and humoral vaccines do not confer mucosal immunity. This may be especially significant for women infected vaginally since HIV has likely entered the body through the mucosa.

Each of these differences, and the many more which undoubtedly exist but remain unresearched, indicates that the inclusion of diverse populations and a focus on their differences is the only way to understand the complexity of AIDS.

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**3e. Curatives ultimately released due primarily to project research shall not result in financial gain to any private organization, and shall be made available to all affected people regardless of ability to pay.**

> "Industry representatives say they are in the business of making medicine and making money, and that it is for society to decide, through its government, what social needs should be met. If society wants drugs for rare diseases or vaccines for public health programs or medicines for Third World countries, then it is for society to find a way to pay for this work. People should not expect a private industry to do it for them, they say." (Drake, Donald C. and Uhlman, Marian. "'Me-too' drugs boost profits", The Tampa Tribune, Feb. 93)

The key phrase here is, "due primarily to the Project's research." That is, any curatives developed by the Project, resulting exclusively from its own work or work begun by a private company and completed predominately by the Project, should not create opportunities for private gain. The same logic applies to the use of existing pharmaceutical facilities for production of promising curatives. Since just compensation will be provided, it is reasonable that the affected company should not reap gains from Project-supported research.

Conversely, this provision will in no way prevent private companies from continuing to see profits from compounds developed on their own, even if AIDS Cure assisted in identifying their usefulness, as long as the company developed them independently and quickly, requiring no use of eminent domain (as described in 4c).

The principle of no private gain from public financing means that Project-developed curatives will not be licensed to for-profit companies. This stands in stark contrast to current NIH practice. Government funded research has led to FDA approval of many drugs, including AZT, ddI, ddC, ganciclovir, foscarnet and others licensed to private companies, resulting in substantial profits and exorbitant prices, thus seriously limiting access to those who need the drugs.

Making curatives available to all affected people, regardless of ability to pay, is predicated on the simple idea that it is immoral to allow people to die because they can not afford to pay for something which would save their lives. This is in line with President Clinton's stated intention to make vaccines available free to all children who have not been vaccinated (some 40%). But adopting this principle implies nothing about how it is accomplished. That is left for later determination by Congress, when it becomes relevant.

Keeping financial gain out of AIDS Cure and guaranteeing that a cure be available to all affected people regardless of ability to pay will not slow basic scientific research nor will it prevent drug companies from making profits. It will however, ensure that the basic research necessary to find a cure will be done under circumstances in which saving lives, rather than producing unnecessary and ineffective products, is the primary motivation. Finally, lack of ability to pay for a cure will not be a death sentence for someone with AIDS.

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**4. In order to accomplish its goals, the Project shall have extraordinary powers to:**

**a. direct the utilization of any and all existing U.S. government funded research entities and their facilities (such as the ACTG) to clinically test promising cures developed on the basis of its research and to direct the manner in which such research shall proceed, including staffing, participants, location and timing. Such research will be funded by the AIDS Cure Project.**

To avoid duplicating the NIH's efforts in establishing a nationwide program for the testing of new compounds, the AIDS Cure Project will direct the use of the AIDS Clinical Trials Group (ACTG) and other clinical trials programs for large-scale testing of compounds identified or developed by the Project. The Project will design its own protocols and work with these existing clinical trials programs to develop research designs and methods appropriate to the Project's goals, assuring that data gathered by the NIH would accurately reflect the use of these compounds in the "real world", i.e. all populations and stages of illness. The Project will provide funding for these clinical trials of its own compounds. The AIDS Cure Project's goal is to work cooperatively with these existing programs, albeit free from the numerous roadblocks described earlier. However, in areas of conflict, the Project will have the power to implement its goals.

**4b. The Project shall have extraordinary powers to exercise the right of eminent domain to:**

- **obtain from public and private organizations - with just compensation - samples of all potential curatives and all data regarding their development (including safety and efficacy data) as well as other information, materials or products deemed crucial to the Project.**

- **implement clinical testing for potential curatives owned by private companies, whether under development or not, only if said companies refuse to either adhere to an approved time frame (and are forthcoming with their data as such work proceeds) or to develop their compounds in cooperation with the Project.**

- **use existing pharmaceutical company facilities (with just compensation) for the production of promising curatives to be utilized in AIDS Cure research and, if effective, to produce such curatives in sufficient amounts to be disseminated to all people needing them.**

Research into potential curatives and treatments for AIDS has been hampered on numerous occasions by the economics of drug development. While the conflicts of interest inherent at the NIH may result in faster development of treatments sponsored by major pharmaceutical companies, the self-concern of these same companies can stall or even prevent a drug's development. Examples include Abbott's HIVIG, (the trial of which was delayed by a year while the company sold the drug to avoid liability problems) and Hoffman LaRoche's tat inhibitor, the development of which was stopped for a year while Roche sought a buyer for the compound.

The AIDS Cure Project must be able to research all potential curatives, unencumbered by the secrecy produced by marketplace competitiveness. Therefore, the Project will forge a new alliance with the pharmaceutical industry; an alliance unlike that which currently exists at the NIH. Rather than allowing it staff to profit from consulting agreements with drug companies, the AIDS Cure Project will objectively examine patented compounds currently owned by the various pharmaceuticals, and gauge the company's development plan. In order to assess the current state of the numerous drugs being developed or sitting "on the shelf", the Project will require access to samples of these drugs, as well as data, published or not, relating to them. Such data will be kept in strict confidence within the Project, although researchers associated with the Project will have access to such information as deemed necessary.

If a drug company is found to be impeding or halting the development of a promising compound, the Project will first attempt to work with the company to develop the needed timetable for research and trials. A company lacking the resources to develop a compound will have the option of selling the compound to the Project for a just compensation, or allowing portions of its development to be undertaken by the Project, thereby reducing the company's later profits from the marketing of the drug.

If, however, a company refuses to cooperate with the Project by not releasing needed data, or

by withholding samples of requested compounds, the AIDS Cure Project will be empowered by Congress to use powers of eminent domain to procure samples and data. Ultimately, the Project will have the power to obtain the patents of such compounds if, after reasonable attempts at cooperation, it finds that a company will not develop a promising compound in an accelerated fashion. After notification by the Project that this power will be used, a company will have thirty (30) days in which to develop, for the Project's approval, a plan for accelerated development of the compound to avoid losing its patent.

*Eminent domain*

Eminent domain is defined as "the power of the nation or a sovereign state to take private property for a public use without the owner's consent, conditioned upon the payment of just compensation". This power, while generally used to obtain land and buildings, also extends to "intangible and corporeal rights, such as contracts...franchises...and patent rights." The U.S. government has used this power to obtain various patents in peacetime as well as wartime. (For example, a number of Buckminster Fuller's patents for geodesic domes were taken by the Department of Defense in peacetime. Mr. Fuller initially resisted and then realized that his patents would be developed more swiftly with government assistance.) The urgency which will be the hallmark of the AIDS Cure Project warrants the use of these powers in this health crisis.

With regards to patents, "Most of the case law dealing with the provision addresses the issue of compensation. A patent holder's claim under the section is treated as an 'eminent domain taking of a patent license.' Drawing on precedents...courts have repeatedly stated that the appropriate measure of damages is to be based on what the owner has lost and not on what the taker has gained." [Mary Griffin, "AIDS Drugs & the Pharmaceutical Industry: A Need For Reform", American Journal of Law & Medicine]

Idealistically, such powers would not need to be invoked. During the Manhattan Project, certain companies "divulged the processes covered by [their] patents to the United States, and...they were widely used." The research frenzy which drove the search for an atomic bomb led private companies to surrender their patents voluntarily to the government. Unfortunately, this same urgency has been sorely lacking in the AIDS research effort.

In another example of swift action, Congress passed the Atomic Energy Act of 1946, which, in "revoking all existing patents useful exclusively in production of fissionable materials and prohibiting issuance of new patents insofar as they were useful for such purposes, government exercises constitutional powers of eminent domain and must render just compensation." Here not only existing patents, but all possible future patents regarding atomic energy were commandeered by the federal government.

*Will the threat of eminent domain deter needed private research?*

Since the late 19th century, the pharmaceutical industry has threatened that any government interference will result in an end to drug development and prevent the saving of lives. This argument caused the Federal Pure Food and Drug Act of 1906 to lead to negotiations with

pharmaceutical companies, and accusations of collusion between the industry and the federal agencies set up to oversee it. The pharmaceutical industry also opposed the Food, Drug, and Cosmetic Act of 1938, claiming that "requiring proof of safety would greatly slow, even cripple," research efforts. Yet, the following two decades were a heyday for the industry, producing dozens of new drugs that reaped profits in the millions.

The pharmaceutical industry (the most profitable legal business in America) claims its high profits are appropriate because of the high risk research and development work involved. Yet, a review of historical and recent data shows that these profits, contrary to its claims, are not based on investments in basic science, but on producing unnecessary variations on already existing products, on taking the least risk possible (by using research funded largely by the government or by small companies), and by manipulating pricing so that government attempts at price controls do not make a dent in their profits.

In truth, the goal of the pharmaceutical industry, and the reward system for its scientists, is not to find useful drugs; it is to find profitable drugs. Pharmaceuticals spend more than $10.9 billion per year on research and development ($1 billion more than the entire NIH budget). But more than half of that is spent on "me-too" drugs (versions of drugs already on the market). 53% of the drugs approved in the U.S. from 1981-1991 were "me-too" drugs. Only 16% represented significant improvements over drugs already on the market, and these were not necessarily for diseases for which new treatments were desperately needed.

Actually, commercially motivated drug companies seldom do the kind of basic research the AIDS Cure Project will focus on and which could produce a cure for AIDS. The Nobel Prize in Medicine, given for significant discoveries in basic science, has been awarded to seventy-four scientists funded by the government, compared to only three who have worked for drug companies. The existence of AIDS Cure will not threaten industry profits, since their profits are not based largely on basic scientific research.

To refuse to take the bold steps needed to find a cure for AIDS rapidly because of industry-fed fears, is a smokescreen. It is clear that when the U.S. had the will to remove roadblocks to research and development, as in the Manhattan and Apollo projects, it did so swiftly and broadly. No less commitment from both government and industry is acceptable in the search for a cure for AIDS.