

# ACT UP

ACT UP

AIDS Coalition To Unleash Power

496A Hudson Street, Suite G4, New York, NY 10014 212 533-8888

# NGLTF

GAY & LESBIAN  
TASK FORCE

1517 U Street, N.W. • Washington, D.C. 20009  
202-332-6483

PRESS ADVISORY

Release Date: April 7, 1988

FOR FURTHER INFORMATION:

Urvashi Vaid (202) 332-6483

David Corkery (212) 219-9261

REAGAN ADMINISTRATION LAME DUCK CAMPAIGN  
AGAINST CIVIL RIGHTS TARGETS PEOPLE WITH AIDS

Contrary to reports that the Justice Department's conservative agenda has been hurt by the controversy surrounding Attorney General Meese, two recent developments illustrate the Reagan Administration's attempts to target the civil rights of people with AIDS for renewed attack.

These developments are:

(1) a Justice Department memorandum urging government officials to counter and "confront" those who advocate for the civil rights of people with AIDS (see attached story from the New York Times; and

(2) hearings called by the U.S. Commission on Civil Rights on May 16-18 that would, the Commission says, "gather information with respect to the view that according civil rights protections to AIDS carriers jeopardizes the public health." (See attached previously unreleased internal memorandum and Congressional correspondence pertaining to hearings).

Justice Department Memo

The recently released Justice Department memorandum calls upon Administration officials to "polarize the debate" on AIDS and other legal issues. The memo says "AIDS is not a civil rights or privacy issue but one of public health and safety."

The memorandum ignores the broad consensus within the public health community for civil rights protections for people with AIDS (see for example, U.S. Department of Health & Human Services, Public Health Service, Centers for Disease Control "Recommended Additional Guidelines for HIV antibody counseling and Testing in the Prevention of HIV Infection and AIDS", April 30, 1987). It ignores the fact that in most situations, such as employment, housing, equal access to services, there is no conflict between protecting the civil rights of persons with AIDS, and protecting the public health.

The Department's memo also confirms the criticism of many in the gay and lesbian and AIDS activist communities that the Administration is playing a murderous political game with a crisis that is destroying thousands of lives.

#### U.S. Commission on Civil Rights Hearings

The previously unreleased internal memorandum proposing that the Commission report on the "Civil Rights Aspects of Public Health Policies and Initiatives to Control AIDS" (attached hereto) outlines the bias underlying the upcoming Commission hearings. The memorandum identifies the purpose of the project as gathering "information on the transmissibility of AIDS, thereby facilitating an examination of the related civil rights issues" (p.4).

The memorandum says "Those act generally responsible for transmitting the virus are often illegal and have traditionally been morally proscribed." The memorandum then quotes extensively from the Bible. The attached memorandum and correspondence clearly show the Commission's strong bias against the recognition of civil rights protections for people with AIDS.

The concern within the gay/lesbian and AIDS activist communities about these hearings is twofold:

(1) That after nearly eight years of inaction and silence on the issue, the U.S. Commission on Civil Rights newfound interest in AIDS is suspect and bodes ill for people with AIDS. The Commission has no credibility among civil rights activists and has been overtly hostile to gay/lesbian issues throughout the Reagan years. (Please contact Urvashi Vaid for further documentation on this point).

(2) That the Administration seeks to counteract the growing consensus for non-discrimination protections and a compassionate AIDS policy among sources as diverse as the Presidential Commission on AIDS, the public health community, the mainstream civil rights community and Congress.

While groups such as NGLTF will testify at the U.S. Civil Rights Commission hearings, we have no illusions about the hostile agenda which pervades the last days of this Administration, and we share an ongoing commitment to challenging that agenda.

ACT UP (AIDS Coalition To Unleash Power) is a diverse non-partisan group of individuals united in anger and committed to direct action to end the AIDS crisis.

NGLTF works for full civil rights rights for gay men and lesbians through lobbying, grassroots organizing, public education and action.

NYT 2/26

## Memo Urges Justice Department 'To Polarize Debate' on Key Issues

WASHINGTON, Feb. 25 (AP) — An internal Justice Department memorandum urges officials to "polarize the debate" on key legal issues such as drugs, AIDS, obscenity and the death penalty and to seek confrontation instead of consensus in the remaining months of the Reagan Administration.

The memo says that such issues should be discussed not as questions of someone's rights but as "public health or safety issues."

The document was sent to various Justice Department officials Monday under the initials of William Bradford Reynolds, the counselor to Attorney General Edwin Meese 3d, and the Assistant Attorney General in charge of the Civil Rights Division.

"We must polarize the debate," it says. "We must not seek 'consensus,' we must confront. Of course, we must confront sensibly, in ways designed to win the debate and further our agenda."

### Bid to Stimulate Discussion

The memo was adopted from a document written by Terry Eastland, the department's director of public affairs, several months ago. Mr. Eastland said he wrote it to stimulate discussion on how to approach various issues.

The contents of the memo were disclosed in The Baltimore Sun on Thursday and subsequently confirmed by Mr. Eastland.

The document recommends that the death penalty be defended as necessary for "deterrence, retribution and incapacitation (i.e. decapitation)."

Mr. Eastland said the department did not favor decapitation as a method of capital punishment, but that he used the word to make "incapacitation"

seem "less abstract and professorial."

The memorandum says "AIDS is not a civil rights or privacy issue, but one of public health and safety." It recommends the department press lawsuits that seek to counter "the privacy advocates who challenge AIDS testing."

Regarding obscenity, it says that the department "must attack the idea that those trafficking" in it "have a right to practice their trade." It suggests that public health laws, building codes, and health and safety rules be used to attack obscenity, along with laws making sale of obscene items a crime.

Titled "A Strategy for the Remaining Months," the document says the drug issue should be confronted by ad-

**'We must not  
seek  
"consensus," we  
must confront.'**

vocating a "tough approach" emphasizing strong law enforcement and drug testing, as opposed to "the soft, easy way that emphasizes drug treatment and rehabilitation."

The memo supports building more prisons instead of alternatives to imprisonment and says that "to polarize the issue we must attack those by name (such as Sen. Paul Simon) who take the other approach." Mr. Simon is a Democratic Presidential candidate from Illinois.

## U.S. COMMISSION ON CIVIL RIGHTS

PROJECT PROPOSALFY 88I. Project SummaryA. Decision Unit (Office): OGC/CREB. Decision Package (Project Title): Civil Rights Aspects of Public Health Policies and Initiatives to Control AIDS

C. Type of Project: (Check all that apply)

1. ☒ Study, including:(a) ☒ Literature Review(d) ☐ Quantitative Data Analysis(b) ☒ Field Investigation(e) ☒ Legal Research(c) ☐ Questionnaire (OMB clearance)2. ☒ Hearing5. ☐ Conference3. ☐ Factfinding Meeting6. ☐ Other \_\_\_\_\_4. ☒ Consultation

D. Program Category: (Check one only)

1. ☐ Administration of Justice4. ☐ Housing2. ☐ Economics & Employment5. ☐ Voting Rights3. ☐ Education6. ☒ Multiple and Other IssuesE. Jurisdiction: 42 U.S.C. 1978C(2) (3)

F. Purpose of Project: To gather information on the transmissibility of AIDS and the danger to the public health posed by AIDS; to gather information on allegations of discrimination against persons afflicted with AIDS; and to gather information with respect to the view that according civil rights protections to AIDS carriers jeopardizes the public health.

G. Description of Project: The project will consist of a three-day consultation/hearing in Washington, D.C., a literature review, legal research, and field investigations. The project will conclude with publication of the transcript, papers presented by experts, and a report to the President and the Congress.

- H. Anticipated Starting Date (For national office projects, this is when staff begins research for project design. For regional office projects, this is when staff began work on project proposal:)

Anticipated Completion Date (date of publication release): July 1988

Hearing/Factfinding Meeting/Consultation/Conference Date: 2/29/88-3/2/88

- I. Type(s) of Projects (Complete all that apply)

	<u>Est. No. Pages</u>	<u>Est. No. Copies</u>
<input checked="" type="checkbox"/> Statutory	<u>150</u>	<u>10,000</u>
<input type="checkbox"/> Clearinghouse	<u>          </u>	<u>          </u>
<input type="checkbox"/> Staff	<u>          </u>	<u>          </u>
<input checked="" type="checkbox"/> Hearing Transcript	<u>400</u>	<u>5,000</u>
<input checked="" type="checkbox"/> Consultation Proceedings	<u>400</u>	<u>5,000</u>
<input type="checkbox"/> Other	<u>          </u>	<u>          </u>

- J. Other Units/Offices to be Involved (indicate role): N/A

SACs to be Involved (indicate role): N/A

Project Director: Bill Howard

- K. Funding: National Office Project Costs should be calculated on the attached Budget Estimate form. A form must be completed for every fiscal year in which the project is to be conducted.

	<u>Initiating FY</u>	<u>Total Project Cost</u>
Current policy level budget:	<u>          </u>	<u>          </u>
Agency request level budget:	<u>          </u>	<u>          </u>
Reduced level budget:	<u>1988</u>	<u>200,216</u>

Funding: Regional Office Project Costs should be calculated on the Budget worksheet. Only the current budget cost level is required, but costs should be submitted in each year of the project.

<u>Initiating FY</u>	<u>2nd Year</u>	<u>Total Project Costs</u>
<u>          </u>	<u>          </u>	<u>          </u>

E. Projected by Memorandum Schedule (The tasks below are suggestive rather than inclusive. Add or delete significant steps as the project requires. See AI 1-3 for examples.):

	<u>Initiation Date</u>	<u>Completion Date</u>
Preliminary Investigation (including review of literature, regulations, statutory and case law)	10/87	12/87
Project Design		
Research/Factfinding Collection	10/87	6/88
Hearing/Factfinding Meeting	N/A	N/A
Consultation/ Conference	2/29/88	3/2/88
Data Analysis		
Draft Report	1/88	6/88
Office Director Review and Rewrite	N/A	N/A
PMD Review and Rewrite	N/A	N/A
Editorial Policy Review and Rewrite	N/A	N/A
Legal Sufficiency Review and Rewrite	N/A	N/A
Staff Director Review and Rewrite	N/A	N/A
Commission Review	7/88	
Printing	N/A	
Publication Release	N/A	
Follow-up		

F. Total duration of project (in years): 1 year

## PROJECT PROPOSAL

### CIVIL RIGHTS ASPECTS OF PUBLIC HEALTH POLICIES AND INITIATIVES TO CONTROL AIDS

#### A. Background

AIDS, or Acquired Immunodeficiency Syndrome, 1/ is a recent phenomenon in the United States. 2/ It was not until 1979 when

---

1/ What is often generically known as AIDS consists, in fact, of three different conditions of infection with the human immunodeficiency virus HIV. The first condition is asymptomatic infection. At this stage, HIV carriers appear outwardly healthy but may already be suffering from depletion of T-helper cells which will eventually leave the body's immune system open to opportunistic infections. Importantly, despite their healthy appearance, asymptomatic HIV carriers are infectious. HIV carriers may or may not progress to the second condition, called AIDS-related complex or ARC. This condition is characterized by palpably swollen glands, fatigue, and various chronic ailments which, while they can be severely debilitating, are nonetheless usually not life-threatening. On extremely rare occasions, ARC sufferers seem to have gone into remission, but in general the condition is permanent or leads to end-stage AIDS. The third condition, end-stage AIDS, may be preceded by ARC but may also develop suddenly from asymptomatic HIV infection. This stage is characterized by infection by various opportunistic diseases, often including Kaposi's sarcoma, a virulent tumor which may affect any organ of the body but usually manifests itself as purplish spots on the skin; Pneumocystis carinii pneumonia, a protozoan parasite that is the leading cause of death among AIDS patients; and various viruses, bacteria, and fungi generally unseen in nonimmunosuppressed individuals.

2/ HIV has been isolated from an African blood sample taken in 1959, but the earliest reported cases of AIDS in that continent coincided with the discovery of the earliest AIDS clusters in the United States. To date, the earliest reported AIDS case in North America dates back to 1969, when a 15-year-old boy died of a then-mysterious series of ailments including Kaposi's Sarcoma and several opportunistic diseases. His stored blood sera, tested for HIV infection in late 1987, proved positive.

the first cluster of AIDS patients began to show up in this country. While these patients were homosexuals living in metropolitan areas, New York, Los Angeles, and San Francisco, by June of 1981, AIDS was found in IV drug users who shared needles and in their female heterosexual partners. 3/ It soon became apparent that the blood supply was infected when AIDS was diagnosed in patients whose only exposure to the virus appeared to be having received either whole blood transfusions or factor VIII concentrate, which severe hemophiliacs injected intravenously to control internal bleeding. 4/

For some time, it has been feared that AIDS would become epidemic among those who did not engage in homosexual intercourse and did not receive blood products. Those predictions, however, have not been borne out. 5/ Today, as was the case five years ago, the overwhelming percentage of AIDS cases have appeared in homosexuals and IV drug users. 6/ Due to heat treatment of Factor VIII and screening of the blood supply, new infections among recipients of blood products have probably been reduced to nearly zero, although some infected blood may slip past the screening process. This is because the test used does not detect the virus itself but rather antibodies to the virus, which may take anywhere from six weeks to 14 months to develop.

---

3/ Immunodeficiency Among Female Sexual Partners of Males with AIDS, New York, 31 Morbidity & Mortality Weekly Rep. 697-8 (Jan. 7, 1983).

4/ Update on AIDS Among Patients with Hemophilia A, 31 Morbidity & Mortality Weekly Rep. 644-52 (Dec. 10, 1982).

5/ See Raspberry, AIDS: Will the 'Good' News Stop the Fight?, Wash. Post, Oct. 28, 1987, at A19, (citing remarks by HHS Secretary Otis R. Bowen, Surgeon General C. Everett Koop, and Dr. Peter Fischinger at recent meeting with reporters); and Fumento, AIDS: Are Heterosexuals at Risk?, Commentary Mag., Nov. 1987, at 21.

6/ As of September 28, 1987, of those developing AIDS since January 1, 1987, 67 percent were homosexual or bisexual males, 15 percent were IV drug users, seven percent were both homosexual males and IV drug abusers, one percent suffered hemophilia or coagulation disorders, four percent had heterosexual contact with a person with AIDS or at risk for AIDS or were born in countries in which heterosexual transmission is believed to play a major role (Haiti and Africa), three percent had received blood transfusions, and four percent of the cases could not be determined at the time.

While this bodes well for the population as a whole, it causes tremendous stigma to attach to those afflicted. This is not only because of a persistent, if unfounded, fear that HIV can be casually transmitted, but because those acts generally responsible for transmitting the virus are often illegal and have traditionally been morally proscribed. 7/ Homosexual beatings have been reported to be on the upswing in recent years, many of them reportedly a result of fear of AIDS. 8/ Children who have contracted HIV infection through blood products have had to wage court fights to be allowed to go to school, and many have been shunned while in class. 9/ In addition, many AIDS victims, be they asymptomatic or suffering from terminal or nonterminal symptoms, have claimed employment discrimination, housing discrimination, and discrimination by both health and life insurance companies. Those making these allegations charge that the discrimination is based upon unsubstantiated fear of casual contagion.

7/ Sodomy is against the law in 26 jurisdictions, and prohibitions against homosexual sodomy were recently upheld in Bowers v. Hardwick, 106 S.Ct. 2841, 476 U.S. \_\_\_\_ (1986). See also 1 Corinthians 6:9-10, "Do not be deceived . . . neither the effeminate nor homosexuals nor the thieves nor the covetous shall inherit the kingdom of God"; 1 Timothy 1:9-10, "law is not made for righteous man, but for those who are lawless and rebellious, for the ungodly and sinners, for the unholy and profane . . . and immoral men and homosexuals"; Leviticus 18:22, "You shall not lie with a male as one lies with a female; it is an abomination"; Leviticus 20:13, "If there is a man who lies with a male as those who lie with a woman, both of them have committed a detestable act; they shall surely be put to death. Their blood guiltiness is upon them"; Romans 1:26-27, "For this reason, God gave them over to degrading passions; for their women exchanged the natural function for that which is unnatural, and in the same way also the men abandoned the natural function of the women and burned in their desire towards one another, men with men committing indecent acts and receiving in their own persons the due penalty of their error."

8/ According to a report by the National Gay Task Force entitled, Anti-Gay Violence, Victimization and Defamation, "Reference to AIDS was made by the perpetrators in 14 percent or 681 of the total number of incidents, including five percent of physical assaults in 1986."

9/ The Ray family of Arcadia, Florida, successfully brought suit against the local school district to have their three hemophiliac children, infected by transfusions, allowed back in school, after which their house was destroyed by fire and they left town.

The entitlement to the protection of civil rights laws demanded by some victims of AIDS is often met with the argument that granting that protection jeopardizes the health of those who work with, attend school with, or otherwise come into contact with the carriers. Determining the extent to which AIDS is transmissible is the threshold question in resolving the many issues concerning discrimination that are arising. In other words, in examining the civil rights aspects of public health policies and initiatives to control AIDS, the Commission must begin by examining the public health issue. Having done that, among the legal issues the Commission would examine are whether persons with HIV infection are entitled to protection under Federal or State handicap discrimination laws; whether an employer should be permitted to screen job applicants for the AIDS virus; and whether the National Labor Relations Act and the Occupational Safety and Health Act, which protect employees who refuse to work in protest of a safety-threatening situation in their workplaces, are applicable in the AIDS context.

#### B. Purpose

~~The purpose of the project is to gather information on the transmissibility of AIDS, thereby facilitating an examination of the related civil rights issues. The Commission will elicit testimony from epidemiologists, legal experts, interest groups, and members of the public. Members of the homosexual community will be invited to testify, as well as persons, such as emergency medical personnel or police, who allege that their health is jeopardized through contact with AIDS victims. The Commission will also gather information from parents of HIV-positive children, representatives of the insurance industry, government officials responsible for enforcing nondiscrimination laws, representatives from the housing industry, and representatives of affected employers.~~ Independent research will also take place. prisons

Attention will be focused on the Rehabilitation Act of 1973 10/, AIDS-related legislation introduced in Congress, and on the Supreme Court decision in School Board of Nassau County v. Arline 11/, which declared that persons suffering from a

---

10/ Section 504 of the Rehabilitation Act of 1973, 87 Stat. 394, as amended 29 U.S.C Sec. 794 (Act).

11/ 107 S.Ct. 1123, \_\_\_ U.S. \_\_\_ (1987), wherein the Supreme Court held that a teacher afflicted with tuberculosis who was dismissed from her job because her employer believes her continued employment would threaten the health of others is a "handicapped individual" discriminated against "by reason of . . . handicap" in violation of section 504 of the Rehabilitation Act of 1973.

communicable illness may be considered handicapped under Section 504 of the Rehabilitation Act of 1973. The Court expressly reserved judgment on whether Arline covers those merely infected with HIV, 12/ and this too is ripe for investigation. Further attention will be given to assessing whether alleged mistreatment of AIDS victims will decline when the public understands the limited transmissibility of HIV.

### C. Scope

Specific areas to be covered include the following:

1) Should AIDS <sup>for - ARC or HIV is ~~seropositive~~</sup> be considered an occupational handicap under Section 504 of the Rehabilitation Act of 1973?

2) What rights should school age children with AIDS or HIV infection have to attend school or, conversely, what rights do parents have to keep their children insulated from infected children? *Teacher case in CA. + Prisoner case in Md. Judd - (teacher work) (state work)*

3) Should there be government-mandated mandatory or "routine" 13/ testing of individuals for HIV infection?

4) Should insurance companies be allowed to test for HIV infection?

5) Should Federal housing discrimination protections be extended to those suffering from AIDS or HIV infection?

### D. Methodology

The project lends itself to a consultation format, with a background report on the subject outlining the problem. Extensive background work is required in order to assess the nature and impact of the wide scope of this project. Background reading would assist in narrowing and focusing the issues.

---

12/ "This case does not present, and we therefore do not reach, the questions whether a carrier of a contagious disease such as AIDS could be considered to have a physical impairment, or whether such a person could be considered, solely on the basis of contagiousness, a handicapped person as defined by the Act." Id. at 1128 n. 7.

13/ While the words "mandatory" and "routine" may be confused regarding AIDS testing, the generally accepted difference is that both are to be conducted regularly on a certain class of persons but that "routine" testing allows individuals to opt out.

Staff would familiarize themselves with leading experts in the area, and interview them as necessary, in order to determine who would best be able to assist the Commissioners in considering the civil rights and public health issues in connection with the AIDS epidemic.

PROJECT SUMMARY

Office: OGC/CRE

Project Title AIDS HEARING

Project #           

Line Item	Costs	Comments
TRAVEL (staff)	15280	
INVITATIONAL	19400	
RENTALS	4650	
COMMUNICATIONS	1800	
OTHER SERVICES	45300	incl. 30,000 honoraria
PRINTING	26000	
CONTRACTUAL SERV.		
SERV. OTHER GOV'T		
SUPPLIES		
Subtotal	112430	

SALARIES		
Permanent On-Board	106420	
Permanent New-Hire		
Temporary On-Board		
Temporary New-Hire		
Consultants		
Subtotal	106420	

PROJECT TOTAL	218850
---------------	--------

EDWARD M. KENNEDY, CHAIRMAN  
CLAIBORNE PELL, RHODE ISLAND  
HOWARD M. METZENBAUM, OHIO  
SPARK M. MATSUNAGA, HAWAII  
CHRISTOPHER J. DODD, CONNECTICUT  
PAUL SIMON, ILLINOIS  
TOM HARRIS, IOWA  
BROCK ADAMS, WASHINGTON  
BARBARA A. MIKULSKI, MARYLAND  
THOMAS M. ROLLINS, STAFF DIRECTOR AND CHIEF COUNSEL  
HAYDEN G. BRYAN, MINORITY STAFF DIRECTOR  
ORRIN G. HATCH, UTAH  
ROBERT T. STAFFORD, VERMONT  
DAN QUAYLE, INDIANA  
STROM THURMOND, SOUTH CAROLINA  
LOWELL P. WEICKER, JR., CONNECTICUT  
THAO COCHRAN, MISSISSIPPI  
GORDON J. HUMPHREY, NEW HAMPSHIRE

## United States Senate

COMMITTEE ON LABOR AND  
HUMAN RESOURCES

WASHINGTON, DC 20510-6300

January 29, 1988

Clarence M. Pendleton, Jr.  
Chairman  
U.S. Commission on Civil Rights  
1121 Vermont Ave., Suite 800  
Washington, D.C. 20425

Dear Mr. Chairman:

We are writing to express our concern regarding a recently proposed project of the U.S. Commission on Civil Rights, entitled "Civil Rights Aspects of Public Health Policies and Initiatives to Control AIDS." While we agree that the Commission should be concerned with incidents of discrimination directed against individuals infected with the AIDS virus, we have some concern as to whether the scope of the proposed project represents the most effective use of the Commission's resources.

According to the proposal presented to the Commission, the purpose of the project is defined as three-fold:

- (1) to gather information on the transmissibility of AIDS and the danger to the public health posed by AIDS;
- (2) to gather information on allegations of discrimination against persons afflicted with AIDS; and
- (3) to gather information with respect to the view that according civil rights protections to AIDS carriers jeopardizes the public health.

In order to achieve these purposes, according to the proposal, the Commission would undertake a broad range of activities, including field investigations, hearings, and the taking of testimony from a large number of individuals. Among the questions to be addressed by these activities would be whether AIDS should be considered a handicap under Section 504 of the Rehabilitation Act of 1973, what rights school-age children with AIDS have to attend school, whether there should be government-mandated mandatory or routine testing and whether insurance companies should be allowed to test for HIV-infection.

We agree that the second purpose outlined in the proposal -- that of gathering information on allegations of discrimination -- falls within the responsibility of the Commission. Indeed, in the report accompanying H.R. 2763, the bill making appropriations for the Commission for Fiscal Year 1988, the Senate Subcommittee


noted, in its recommendation of continuing the Commission's funding, earmarks targeted to monitoring the enforcement of existing civil rights laws. Section 504 of the Rehabilitation Act of 1973 currently covers those who are discriminated against because they have AIDS or HIV-infection, have a record of such handicaps, or are perceived as having such handicaps, and therefore it is clearly within the responsibility and province of the Commission to monitor the enforcement of Section 504 by giving Congress and the public a sense of the extent of the discrimination that exists and of the effectiveness of efforts to redress such discrimination.

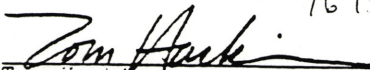
By contrast, however, it does not appear that the Commission's resources would be best used by attempting to investigate the medical, scientific and other wide-ranging questions presented in the proposal. Indeed, it is our understanding that the Presidential Commission on the Human Immunodeficiency Virus is currently expending a significant amount of time and resources investigating these very same questions. In our view, the Civil Rights Commission could best complement the effort of the Presidential Commission by targeting its resources upon monitoring whether actual cases of discrimination are being remedied under current law.


Accordingly, we request that the Civil Rights Commission reconsider any preliminary approval which may already have been extended to the proposal in its more elaborate form.


We hope these observations are useful and we look forward to your reply.

Sincerely,

  
Edward M. Kennedy  
Chairman  
Labor and Human Resources  
Committee  
24-5875  
7675

  
Tom Harkin  
Chairman  
Subcommittee on the Handicapped

  
Robert T. Stafford  
Member  
Subcommittee on the  
Handicapped

  
Lowell P. Weicker, Jr.  
Ranking Minority Member  
Subcommittee on the  
Handicapped

cc: Commissioner Allen  
Commissioner Berry  
Commissioner Destros ✓

Commissioner Friedman  
Commissioner Guess  
Commissioner Ramirez



UNITED STATES  
COMMISSION ON  
CIVIL RIGHTS

1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

February 11, 1988

HAND DELIVERED

The Honorable Edward M. Kennedy 202-2243121  
Chairman, Labor and Human Resources Committee  
428 Senate Dirksen Office Building  
Washington, D.C. 20510-8300

Dear Senator Kennedy:

Michael Iskenwitz  
202-224-  
7675

I am in receipt of your letter of January 29, in which you request that the Commission narrow the focus of its project on civil rights aspects of public health policies and initiatives to control AIDS. It is gratifying that you have taken a personal interest in the Commission's project. Your concern for civil rights and for those suffering discrimination regarding AIDS is well-known, and thus your input is extremely valuable.

Regrettably, you seem to have been misinformed on the current state of the law regarding AIDS and Section 504 of the Rehabilitation Act of 1973. It does not, as you state, currently cover those discriminated against "because they have AIDS or HIV-infection" [emphasis added]. The key court case on this issue is School Board of Nassau County v. Arline,<sup>1/</sup> which, in fact, did not involve AIDS but rather a teacher who sought to retain her employment despite being diagnosed with active tuberculosis. While the Court's decision clearly indicates that a person with full-blown AIDS would qualify under the statute as a "handicapped individual," the Court specifically reserved the question whether an asymptomatic carrier of the AIDS virus would be a "handicapped individual" within the meaning of the statute. As the Court noted:

This case does not present, and we therefore do not reach, the questions whether a carrier of a contagious disease such as AIDS could be considered to have a physical impairment, or whether such a person could be considered, solely on the basis of contagiousness, a handicapped person as defined by the Act.<sup>2/</sup>

---

<sup>1/</sup> \_\_\_ U.S. \_\_\_, 107 S.Ct. 1123 (1987)

<sup>2/</sup> Arline at 1128 n. 7

The issue of asymptomatic or apparently asymptomatic HIV infection is one that has been considered and is being considered by the lower courts.<sup>3/</sup>

Because of this lack of a solid ruling, your colleague, Rep. Henry Waxman, has introduced legislation prohibiting such discrimination.<sup>4/</sup> Conversely, Rep. William Dannemeyer has introduced legislation that would nullify Arline to the extent that it applies to persons with full-blown AIDS and clarify it to the extent that it may apply to asymptomatic seropositives, by amending the Rehabilitation Act of 1973 to exclude individuals with contagious diseases from the definition of handicapped individuals.<sup>5/</sup> Obviously, a matter which is before Congress which so clearly involves civil rights is within the jurisdiction of the Commission. Even if the issue had been clearly settled by the courts, this would not place it outside of the Commission's jurisdiction. Certainly you would agree that, had the Commission been formed a decade earlier than it was, it would have had jurisdiction to investigate the propriety of racial segregation, notwithstanding that the matter was clearly settled in the Supreme Court case of Plessy v. Ferguson.<sup>6/</sup>

Regarding potential overlap between activities of the Presidential Commission on the Human Immunodeficiency Virus and the Civil Rights Commission, we share your well-known concern for reducing redundant government services. Nevertheless, investigation of the medical and scientific questions is vital to the determination of what civil rights protections should be accorded. As you are aware, fear of contagion--either of HIV or a secondary infection common to AIDS/ARC victims--from a seropositive individual is at the root of much AIDS-related discrimination. It must be determined to what extent, if any, this is a valid fear. Finally, while the Presidential Commission may touch on areas concerning civil rights, it should be noted that while the Presidential Commission is mandated to report on the HIV epidemic in general, we are the Civil Rights Commission. I hope you would agree that if Rosa Parks were forced to sit in the back of the bus today, you would rather have her complaint investigated by a civil rights body than by the U.S. Department of Transportation.

---

<sup>3/</sup> See Local 1812, AFGE v. U.S. Dept. of State, No. 87-0121 (D.D.C. Apr. 22, 1987); Thomas v. Atascadero Unified School Dist., No. 86 6609 AHS (BY) (C.D. Cal. Dec. 31, 1986)

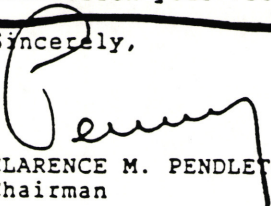
<sup>4/</sup> H.R. 1396, 100th Cong., 1st Sess. (1987)

<sup>5/</sup> H.R. 3017, 100th Cong., 1st Sess. §2341 (1987)

<sup>6/</sup> 163 U.S. 537 (1896)

Your comments and those of the Members of the Subcommittee on the Handicapped are greatly appreciated, and I hope that you will continue to take an interest in this project and offer the Commission your vital support.

Sincerely,



CLARENCE M. PENDLETON, JR.  
Chairman

cc: Senators Tom Harkin, Robert T. Stafford, and Lowell P. Weicker, Jr.

# ACT NOW ' 88

October 8 - 11, 1988, Washington, D.C.  
**ACT UP! FIGHT BACK! FIGHT AIDS!**

FOR IMMEDIATE RELEASE  
August 11, 1988

Contacts:  
Scott Sanders/ Washington, D.C.  
202/234-8801  
John Fall/Los Angeles  
213/668-2357

## AIDS ACTIVIST MOBILIZATION PLANNED FOR OCTOBER

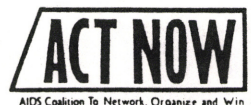
ACT NOW (AIDS Coalition To Network, Organize, and Win) is organizing a four-day, national AIDS activist mobilization, including a teach-in and conference and an AIDS-related rally and civil disobedience, October 8-11 in Washington, D.C.

The conference will begin on Saturday, October 8, with a National AIDS Activist Teach-in, featuring workshops, round-table discussions, and caucuses concerning the building of AIDS activism at the local and national levels.

ACT NOW member organizations will meet Sunday, October 9, to develop strategies and plan future actions. Both days are open to all individuals working in or interested in joining the AIDS activist movement.

A rally demanding a compassionate, comprehensive, and informed government response to AIDS will be held at the Department of Health and Human Services on Monday, October 10, 4-6 p.m..

--More--



ACT NOW/Page 2  
August 11, 1988

"Seize Control of the F.D.A.," a massive civil disobedience action will take place at 7 a.m. on October 11, at the Food and Drug Administration headquarters in Rockville, Maryland. Protesters will be demanding the release of all promising AIDS treatments and equal access to those treatments for all affected communities. Individuals not wishing to be arrested are asked to work as support for those who will risk arrest.

"It's time to show the people in power, the bureaucrats, and the nation that we will not politely accept excuses and death anymore. We want treatments released now," asserted Margie Edouardo, a member of ACT NOW's conference planning committee.

ACT NOW is a coalition consisting of over 30 AIDS activist organizations from across the nation including numerous local ACT UPs (AIDS Coalition to Unleash Power), Chicago for AIDS Rights, OUT! in Washington, D.C., and others. ACT NOW coordinated the Spring AIDS Actions, nine days of nationwide protests and education focusing on the epidemic held in May.

For more information on participating in and organizing in your community for the conference, the direct action, and joining ACT NOW, please call 202/234-8801 or write ACT NOW, PO Box 73275, Washington, DC 20056-3275.

\* \* \*

o c t o b e r 8 - 1 1 , 1 9 8 8

☐ I am interested in attending the AIDS activist teach-in on Saturday, October 8, 1988. Enclosed is my registration fee. (\$10-20 sliding)

☐ My group is interested in joining ACT NOW and in attending the conference on Sunday, October 9.

☐ I plan to participate in the civil disobedience action at the FDA on Tuesday, Oct. 11.

- ☐ I will take non-violence training in my home town.
- ☐ I will require non-violence training in Washington.
- ☐ I do not plan to risk arrest, but I would like to work to support those who do.
- ☐ I belong to a c.d. affinity group. Our group name and address are below.

ACT NOW needs your help to organize and publicize ACT NOW '88.

**I have enclosed**

- ☐ \$100      ☐ \$75
- ☐ \$50      ☐ \$25
- ☐ Other \_\_\_\_\_

to support the AIDS activist movement.

\_\_\_\_\_

n a m e

\_\_\_\_\_

a d d r e s s

\_\_\_\_\_

c i t y , s t a t e , z i p

\_\_\_\_\_

t e l e p h o n e

Return to:

**ACT NOW '88**  
PO Box 73275  
Washington DC 20056  
(202) 234-8801

# ACT

# NOW

# 88

- civil disobedience at the f d a •
- demonstration at health and human services •
- conference on aids activism •

sponsored by:

**AIDS Coalition to Network, Organize and Win**

# **AIDS ACTIVISM: A TEACH-IN**

***Saturday, October 8, 1988***

As the grass-roots AIDS activist movement grows, all of us, veterans and newcomers to the movement, need to develop skills and address issues to be effective. At the Teach-In we will pursue this process through round-table discussions, workshops and seminars.

Discussions and presentations will include:

- Coalition building • Inclusiveness • Working with AIDS service organizations •
- AIDS treatment issues • Working with the media • Locating information sources •
- AIDS in prisons • AIDS and prostitutes • AIDS among people of color •
- AIDS and women • AIDS world-wide • Planning civil disobedience actions •

**To receive complete information on the Teach-In**  
return the attached coupon to **ACT NOW**.

## **ACT NOW Conference**

***Sunday, October 9, 1988***

ACT NOW member organizations will meet to develop national strategies, plan actions, and coordinate internal operations. Participation in this conference is open to all AIDS activists. Decision-making is limited to ACT NOW organizations. Organizations involved in AIDS activism are encouraged to affiliate with ACT NOW.

Participants in the ACT Now *Teach-In* and *Conference* will have ample opportunity to **visit the NAMES Project Quilt on Saturday and Sunday at the Mall.**

## **What is ACT NOW?**

The AIDS Coalition to Network, Organize and Win (ACT NOW) is a coalition of AIDS activist groups working together to end the AIDS crisis through direct action. ACT NOW was founded on October 12, 1987 at the March on Washington for Lesbian and Gay Rights. We joined other "*Out and Outraged*" activists at the Supreme Court demanding *justice for all*. Nine days of a "Spring AIDS Action" in May 1988 demonstrated our determination to keep up the struggle to find a cure and protect all the people affected by AIDS.

ACT NOW's foundation is non-violent direct action. Conflict is a necessary part of our struggle. The strength of non-violence is our willingness to fight oppression without threatening others.

All those participating in the October 11 action at the FDA should begin non-violence training in their own communities. Additional non-violence training will be held on October 10 in Washington D.C.

## The FDA, cont.

- community-controlled AIDS treatment registry.
- Federal agencies must open all treatment trials to the range of people affected by AIDS, including gay men and lesbians, people of color, prisoners, heterosexual men and women, women of child bearing age, I.V. drug users and children.
- All government agencies must recognize that people affected by the epidemic must have complete control over all decisions concerning their care and treatment.

---

## HHS, cont.

- All agencies must include representatives from affected communities at all levels of decision making for HIV-related research, treatment, education and funding programs. E.g., AIDS education programs for women must be designed by women.
- The Federal government must end all discriminatory practices and policies against people with AIDS, people with ARC, HIV infected persons, their partners and their children. Congress must repeal all laws that contribute to the spread of AIDS through discrimination against those perceived to be at risk, such as the Helms amendment and laws prohibiting sodomy and prostitution.

- Federal, state and local governments must provide full funding for comprehensive, culturally-sensitive education programs about AIDS that are positive and explicit about sexuality including gay and lesbian sexuality.

## ACTNOW and Inclusiveness

ACT NOW is committed to supporting the work of women, people of color, people with immune system disorders, and disabled people. We are also committed to including them in our work and decision-making processes. We have established funds and committed them to caucuses of these communities. These funds will not only facilitate interaction among members but also insure that these groups have a voice in deciding the direction of ACT NOW.

## Travel and Accomodations

The Names Project has made arrangements with United Airlines and a Washington hotel reservations service to assist with travel arrangements. Travel discounts are available through these services and the Names Project will benefit directly.

### United Airlines

1 (800) 521-4041 acct. #8664N

### Hotel Reservations

1 (800) 554 2220

## Seize Control of the FDA

*Civil disobedience action*

**Tuesday, Oct. 11, 7 am**

Twinbrook Metro Station  
Rockville, MD

We are people with AIDS, ARC and HIV infection, and people who love and support those who are living with these illnesses. We are acting to take the AIDS emergency into our own hands. We have seen far too many die or face unfair treatment because the epidemic has been mishandled. We are demonstrating at the offices of the Food and Drug Administration because the FDA symbolizes the government's inaction and negligence.

We are convinced that agencies and statutes must change to create a more humane response to AIDS. The FDA, Congress and all other agencies must be held responsible in developing a coordinated, comprehensive plan to serve the people who suffer from AIDS.

- The government must provide access to treatments as a human right not a source of profit.
- The FDA and other agencies must release all promising AIDS treatments.
- The FDA must provide all information on drugs and treatments towards creation of a national

**see inside**

## Health and Human Services

*Demonstration*

**Monday, Oct. 10, 4-6 pm**

200 Independence Ave., S.W.  
Washington D.C.

The Federal government is capable of mounting massive AIDS education, patient care and treatment efforts. Instead it has responded to AIDS with underfunded and poorly planned programs riddled with prejudice and indifference. The AIDS crisis has made clear the inadequacies of this country's health care system.

We will gather on October 10 to demand that the Department of Health and Human Services mount a comprehensive and compassionate response to AIDS and that it establish a national health care system that meets the needs of all Americans.

- The Federal government must recognize universal access to health care as a human right not a source for profit. The federal government must fund a national health care system controlled by local communities.
- The Centers for Disease Control must eliminate all arbitrary and life threatening distinctions between AIDS, ARC and HIV infections. The CDC must formulate demographics based on populations rather than risk groups.

**see inside**

Act Up

Seize Control of the FDA  
Tuesday Morning  
October 11, 1988  
Civil Disobedience action

We are people with AIDS/ARC, and HIV infection, and people who love and support those who are living with these illnesses. We are acting to take the AIDS emergency into our own hands: We have seen far too many die or face unfair treatment because the epidemic has been mishandled. We demonstrate at the offices of the Food and Drug Administration because the FDA symbolizes the inaction and negligence of this government.

We are convinced that agencies and statutes must change to create a humane response to AIDS. The FDA must lead with the Congress and all other agencies in developing a coordinated, comprehensive plan to serve the people who suffer from AIDS.

1. The Food and Drug Administration must release all promising AIDS treatments.
2. Federal agencies must open all treatment trials for the range of people affected by AIDS, including gay men and lesbians, people of color, prisoners, heterosexual men and women, women of child bearing age, I.V. drug users and children.
3. The FDA must provide all information on treatment on AIDS treatments towards creation of a national community-controlled AIDS treatment registry.
4. The government must provide access to treatments as a human right not a source of profit.
5. All government agencies must recognize that people affected by the epidemic should have complete control over all decisions concerning their care and treatment.

Health and Human Services  
Rally  
Monday, October 10, 1988  
4- 6 pm  
200 Independence Avenue  
S.W. Washington, DC

The Federal government is capable of mounting massive AIDS education, patient care and treatment efforts. Instead it has responded to AIDS with underfunded and poorly planned programs riddled with prejudice and indifference. The AIDS crisis has made clear the inadequacies of this country's health care system.

We will gather on October 10 to demand that the Department of Health and Human Services mount a comprehensive and compassionate response to AIDS and that it establish a national health care system that meets the needs of all Americans.

% The Federal government must recognize universal access to health care as a human right not a source for profit. The federal government must fund a nationalized health care system controlled by local communities.

% The Centers for Disease Control must eliminate all arbitrary and life threatening distinctions between AIDS, ARC and HIV infections. The Centers for Disease Control must formulate demographics based on populations rather than on risk group distinctions.

% All agencies must include representatives from affected communities at all levels of decision making for HIV-related research, treatment, education and funding programs. Eg. AIDS education programs for women must be designed by women.

% The Federal government must end all discriminatory practices and policies against people with AIDS, people with ARC, HIV infected persons and their children. Congress must repeal all laws that contribute to the spread of AIDS through discrimination against those perceived to be at risk, such as the Helms amendment and laws prohibiting sodomy and prostitution.

% Federal, state and local governments must provide full funding for comprehensive, culturally-sensitive education programs about AIDS that are positive and explicit about sexuality including gay and lesbian sexuality.

ACT NOW, a nationwide coalition, is incurring significant costs in organizing and publicizing ACT NOW '88. We need your help to insure a successful weekend. I have enclosed

\$100	\$75
\$50	\$25
Other	

to support the AIDS  
activist movement.

Name:

Address:

City, State, Zip:

Return to: ACT NOW  
PO Box 73275  
Wash. DC 20056

AIDS ACTIVISM: A TEACH-IN  
Saturday, October 8, 1988

As the grass-roots AIDS activist movement grows, all of us, veterans and newcomers to the movement, need to develop skills and address issues to be effective. At the Teach-In we will pursue this process through round-table discussions, workshops and seminars.

Discussions and presentations will include:

% Coalition building % Inclusiveness % Working with AIDS service organizations  
% AIDS treatment issues % Working with the media % Locating information  
sources % AIDS in prisons % AIDS and prostitutes % AIDS among people of  
color % AIDS world-wide % Planning civil disobedience actions %

For further information on the Teach-In return the attached coupon to ACT NOW.

ACT NOW Conference  
Sunday, October 9, 1988

ACT NOW member organizations will meet to develop national strategies, plan actions, and coordinate internal operations. Participation in this conference is limited to ACT NOW organizations. Organizations involved in AIDS activism are encouraged to affiliate with ACT NOW.

COM:AU0810A

KEYWORDS 1

Administration: how a drug is introduced into the body: IV, oral, etc.

AIDS/ Acquired Immunodeficiency Syndrome: degenerative immune system disease probably caused by HIV, producing ~~the~~ infections (OI's) and KS.

AL-721: egg-derived food substance used by some PWA's.

Ampligen: expensive immunomodulator drug made by HEM/DuPont.

Anemia: loss of red blood-cells, can be caused by AZT or DHPG.

Antifungal: drug effective against fungus infections, e.g. Fluconazole.

Antiretroviral: drug effective against retrovirus, e.g. AZT.

Antiviral: substance that attacks a virus, e.g. DHPG.

Approval process for drugs, in the USA, regulated by FDA and consisting of pre-clinical animal & test tube studies & clinical trials in humans.

Asymptomatic seropositive: someone with HIV but without symptoms.

ATR/ Aids Treatment Registry: ACT UP project to make up an accurate, comprehensive and timely listing of all drug trials in the NYC area.

AZT: antiviral orphan drug sold by Burroughs-Wellcome; the most expensive drug ever.

Bactrim: an often toxic anti-PCP drug.

Burroughs-Wellcome: pharmaceutical making ridiculous profits on AZT monopoly.

CD4/ rCD4: a drug imitating a T4-cell protein receptor, which HIV latches on to. It is hoped HIV will dock onto the drug rather than the T-cell.

CDC/ US Centers for Disease Control, Atlanta. Federal agency which monitors the course of the epidemic and releases weekly deathcounts.

Clinical: drug trials in human subjects, regulated by FDA.

CMV/ Cytomegalovirus: a herpes-type virus which can cause blindness and colitis (diarrhea) in Aids; DHPG treats it but is unapproved.

Compassionate Use IND: FDA program to allow use of unapproved drugs because no approved drug is available; e.g. DHPG, Fluconazole.

Control: standard drug trials use two groups. The experimental group gets the test drug, while the control group gets placebo or known drug.

Cooper, Dr. Ellen: Acting Director, FDA Division of Antivirology Drugs. An obstructive and process-bound bureaucrat.

Dextran sulfate: anti-blood-clotting drug available in Japan for over 20 years and now available there to PWA's thanks to ACT-UP.

DHPG (Ganciclovir): anti-CMV drug which prevents blindness, delayed by FDA due to its own poor oversight and contradictory feedback.

Dose-ranging: drug trial in which two or more doses of a given drug are tested against each other to see which is most effective & least toxic.

Double-blind: trial procedure where doctors and subjects don't know what drug they're getting, supposed to promote objectivity.

DTC/ Iauthiol: immunomodulator drug made in France.

Efficacy: effectiveness; a drug proves efficacy in Phase II & III trials if it does what the sponsor says it does.

FDA/ US Food & Drug Administration: Federal agency which regulates drug trials; its delays in approving Aids drugs will cost 1,000's of lives.

Fisons: English pharmaceutical company (US HQ, Bedford, MA) competing with LyphoMed for FDA license to sell aerosol pentamidine.

Fluconazole: experimental antifungal drug made by Pfizer, available on compassionate use basis for thrush & meningitis.

Fungus: form of primitive vegetable life, including mushrooms, yeasts & molds. Thrush, meningitis and PCP are caused by fungi.

Gallo, Dr. Robert: head of the NCI's Division of Tumor Cell Biology, he co-discovered HIV a year after a French team first did so.

HHS/ US Department of Health & Human Services: Cabinet department including the PHS, NIH, FDA and CDC.

HIV/ Human Immunodeficiency Virus: thought to be the cause of Aids.

Immunomodulator: a drug which acts to alter or strengthen the immune system, e.g. alpha interferon, ampligen, or Imreg-1.

Imreg-1: New Orleans company's immunomodulator drug kept from PWA's by FDA badmouthing and corporate failure to apply for Treatment IND.

In vitro: experiment in the test-tube.

In vivo: experiment in animals or humans.

IND/ Investigational New Drug: After pre-clinical trials, drug companies submit IND applications; human testing can begin if FDA approves.

Indication: drug's purpose; e.g. pentamidine is indicated for PCP.

Informed consent: form signed by drug trial subjects, supposed to explain their rights and risks, but often unclear or misleading.

IRB: Institutional Review Board: hospital group which must approve drug trial protocols as safe and ethical for participants.

IVIG/ Intravenous Immunoglobulin: blood-derived drug used in unethical placebo trial on babies with Aids.

Kefauver amendments: 1962 drug law reforms which required drug companies to prove to the FDA that the drug did what they said it did.

KS/ Kaposi's Sarcoma: an Aids-related skin cancer.

Lesbians: women who have sex with women; virtually invisible to CDC epidemiologists and NYC Department of Health.

LyphoMed: Illinois drug maker, raised price of IV-pentamidine from \$25 a vial in 1984 to \$99 now, while costs dropped from \$6 to \$2 per dose.

NCI/ National Cancer Institute: part of NIH where Dr. Gallo discovered HIV & Dr. Broder discovered AZT active against HIV in test tube.

NDA/ New Drug Application: 100,000 page document submitted by drug company after clinical trials end, to gain FDA approval to market drug.

NIAID/ National Institute of Allergy & Infectious Diseases: part of NIH which runs ACTG Aids drug testing program, led by Dr. Anthony Fauci.

NIH/ National Institutes of Health. part of HHS which conducts most of the Federal government's scientific testing, includes NIAID and NCI.

OI/ Opportunistic Infection: illness occurring only in those with lowered immunity, e.g. PCP.

Orphan drug: special status granted for drugs with few potential users; gives tax credits and 7-year monopoly; e.g. AZT, IV-pentamidine,

p24: a protein found in HIV; levels of p24 antigen are one of the most-often measured markers of HIV activity in a person.

PCP/ Pneumocystis carinii pneumonia: fungal lung infection occurring in 60% of PWA's, treated w/ Bactrim, trimetrexate & pentamidine.

Pentamidine: anti-PCP drug; IV form is a LyphoMed orphan drug; LyphoMed is competing with Fisons to get license for aerosolized form.

Peptide T: drug similar in action to CD4.

Phase I: safety testing of drug in humans; under 50 take drug for short period to see how safe it is; 70% of IND's make it through.

Phase II safety & efficacy testing of drug in humans; under 1,000 take drug for 1-3 years to see if it works and if it's safe; 33% make it.

Phase III efficacy testing of drug in humans; 1-3,000 take drug for 2-3 years to see long-term side effects; 25% make it through.

PHS/ US Public Health Service: branch of HHS including FDA, NIH.

Placebo: inert substance against which test-drugs are compared. Should not be used in people with life-threatening disease or HIV.

Pre-clinical: first stage of drug testing, in test tube & animals.

Prophylaxis: Prevention. E.g. Aerosol pentamidine is effective for prophylaxis against PCP.

Protocol: IRB-approved plan stating drug trial's rationale, dose and proposed subjects.

Retinitis: CMV eye infection which can cause blindness unless treated with DHPG.

Retrovirus: a virus which replicates backwards, from its RNA onto host's DNA; HIV is a retrovirus.

Ribavirin: drug made in Mexico used by some PWA's and given a chill reception by the FDA.

Side effects: of a drug are its undesirable, harmful or toxic effects as opposed to its intended beneficial results.

T-cells: white blood immune cells attacked by HIV.

Toxicity: poisonous harmfulness, supposed to be measured in Phase I. AZT is so toxic half of PWA's can't tolerate it.

Treatment IND: FDA program for early drug release, used only once in Aids, in the narrowly designed trimetrexate protocol.

Trimetrexate: drug used against PCP; the FDA allowed only 89 PWA's to take it under Treatment IND.

Virus: primitive parasite which invades cells and hijacks their reproductive system, using it to replicate more viruses.

Women: blatantly-underrepresented group in Aids drug trials, only 5% of those in Federal ACTG trials are women.

Young, Frank. Commissioner of Food & Drugs, head of the FDA which, he says is "above economics." PWA's, unfortunately, aren't.

Zidovudine: generic name of AZT.

ACT UP



ACT NOW Conference, Sunday, October 9, 1988

All individuals participating in direct action around AIDS are welcome to attend.

The purpose of the day is to develop and move toward agreement on:

1. proposals for national actions and strategies.
2. proposals for nationally coordinated local actions and strategies.
3. the basis for ACT NOW unity.
4. the form of the continuing existence of ACT NOW and an ongoing national communications strategy.

10	- 11	Registration
11	- 11:15	Whole Group - ACT NOW Report
11:15	- 11:45	Whole Group - Brainstorm - What is ACT NOW
11:45	- 1:05	Small Groups - Consider ACT NOW Ideas
1:05	- 2:05	Lunch
2:05	- 2:50	Large Groups - Consider Reports From Small Groups
2:50	- 3:20	Whole Group - Reports From Large Groups
3:20	- 3:35	Whole Group - ACT NOW Action Report
3:35	- 4:05	Whole Group - Brainstorm - ACT NOW Actions
4:05	- 4:25	Break
4:25	- 5:45	Small Groups - Consider Action Ideas
5:45	- 6:05	Break
6:05	- 6:50	Large Groups - Consider Reports From Small Groups
6:50	- 7:20	Whole Group - Reports from Large Groups
7:20	- 7:35	Whole Group - Closure

Sunday's conference was organized to facilitate the generation and consideration of ideas for ACT NOW communications, growth, unity, and future actions.

The purpose of the small groups is to allow discussion on the ideas generated by the whole group. Individuals will decide which small group they will participate in, depending on their interests. The large groups will consist of four or five small groups and will discuss and refine the proposals/ideas generated by those groups. Finally, those proposals will be taken to the whole group for information sharing and limited feedback.

## Conference Workshops

### Track 1 -- AIDS and the Politics of Health Care

---

#### Education and Prevention

Facilitator: Chuck Stallard (ACT UP/LA)

This workshop is designed to create dialogue concerning AIDS education and prevention issues.

---

#### FDA Teach-In

Facilitators: Robert Vasquez, Jim Eigo, Margaret McCarthy (ACT-UP NY)

As we prepare for the FDA action, this session will provide in-depth information on the history of the FDA, their drug trial procedures, the inadequacies of their response to the AIDS epidemic, and the ways in which they can change to save lives.

---

#### Treatment & Research

Facilitators: John James (AIDS Treatment News, SF)

An overview of treatment options, accessibility and research.

---

#### Access, Alternative Systems & Treatments

Facilitators: Bob Lederer (ACT-UP NY), Adam Burck (C-FAR, Chicago), Terry Beswick (ACT UP/SF, Healing Alternatives Foundation, Community Research Alliance), AIDS Alternative Health Project, Chicago, Gene Fedorko (HEAL, NY)

This workshop will examine alternatives to the current profit-seeking medical/drug/industrial complex as it applies to AIDS. Topics will include holistic therapies, buyers clubs and community based clinics, particularly serving gay, black, latino and women's communities.

## Track 2 -- AIDS and the Politics of Oppression

### AIDS and the Politics of Oppression: An Overview

Facilitators: Martin Hiraga (ACT-UP, Rochester); Lourdes Lugo (VIDA SIDA, Chicago); Joanie Marquardt (ACT UP/SF), David Gilbert (political prisoner, Auburn Prison AIDS Project), and others.

This workshop will cover different aspects of "the second epidemic": AIDS in Black/Latino/Native American/Asian communities in the U.S.; women and AIDS; AIDS and targeted populations, i.e. prisoners, prostitutes, IVUDs; AIDS and differently abled communities, as well as AIDS in the lesbian & gay communities. Each of these topics will be pursued in more depth in subsequent workshops.

-----

### AIDS, Racism, and People of Color Communities

Facilitators: Lourdes Lugo (VIDA SIDA, Chicago), Victor Knox, (AIDS Action Planning Committee, Detroit)

AIDS is growing fastest in the "inner cities"--poor communities that are overwhelmingly Black and Puerto Rican. We will examine the impact that AIDS has on these communities which already face the slow genocide of: no health care, substandard housing, the drug plague, racism, etc. Workshop will also discuss racism in the AIDS movement, and why many people of color communities are organizing independently, to self-determine their own programs.

-----

### Women, AIDS, and other Immune System Disorders

Facilitators: Cathy Christeller (Women and AIDS Project, Chicago), Joanie Marquardt (ACT UP/SF), Mary Patten (C-FAR, Chicago), Alexis Danzig (ACT-UP NY, Women's Caucus)

This workshop will present an epidemiological picture of women with AIDS, and particular obstacles faced by women PWAs--the intersection of racial and sexual oppression; women and children, relationship between sex and drugs, etc. The workshop will also cover other immune system disorders which particularly affect women (i.e. Chronic Viral Fatigue Syndrome); lesbians and AIDS, and the role of women/lesbians in the AIDS movement.

## AIDS and Homophobia

Facilitators: Ferd Eggen (C-Far, Chicago); Mick Sweeney (ACT UP/SF), Connie Norman (ACT UP/LA)

Is AIDS a "gay disease"? If not, what is the significance of the fact that lesbians and gay men lead the AIDS movement? We'll discuss AIDS panic and the rise of homophobia, especially the rise of violent attacks against gay men and lesbians; AIDS work and our overall movement/identity; combatting the new sexual puritanism, etc.

-----

## AIDS and Global issues

Facilitators: Jeanne Kracher, (C-FAR, Chicago), A Representative from Alliance for Filipino Concerns, Jeff Gates and Leslie Feinberg (Nicaragua's grass-roots AIDS project, ACT-UP NY), Shanti Driver (AIDS In Africa, AIDS Action Planning Committee, Detroit)

This workshop will discuss the impact of AIDS on Africa; on women prostitutes/sex workers in the Philippines; and Nicaragua's grass-roots AIDS project. All speakers will address the responsibility of the U.S. in the worldwide epidemic of AIDS.

-----

## Coalition Building

Facilitators: David Nibblet (ACT UP/LA, No On 96/102), Steve Gradman (ACT-UP NY), Tim Powers (ACT-UP NY)

This workshop is designed to explore aspects of networking among a wide variety of AIDS-impacted communities.

-----

## Track 3 -- Organizing for AIDS Activism

### Starting A Local AIDS Activist Organization

Facilitators: Mark Kostopolous (ACT UP/LA), ACT UP/Atlanta, Dave Johnson (AIDS Action Committee, Minority Subcommittee)

This workshop will provide participants with information, ideas and methods for establishing an AIDS activist organization in

their local community. We will discuss how to publicize, network, structure and define a new organization.

---

## Publicity and Media

Facilitator: Mike Signorelli (ACT-UP NY)

How-to work with the media to get maximum coverage of your events and get the correct message out. The basics of writing press releases, making and developing media contacts, making press calls, setting up press conferences, preparing for on-site and telephone interviews, and writing press packets.

---

## Fundraising

Facilitators: Peter Stalley (ACT-UP NY) Rick Turner (ACT UP/LA)

This workshop will address how to make sure that your group has the funds to do what it needs to do. Discussion will include merchandising, direct mail campaigns, and fundraising events.

---

## Stress Management & Burnout

Facilitator: Kayeton Karowski (ACT-UP NY)

Does this even require an explanation? As activists, we often forget to take care of ourselves. This workshop will teach us how to effectively manage the stress of working in AIDS activism so that we remain (?) sane, make the most of our energy, and maintain our health. A wide variety of techniques that you can take back to all you co-workers will be discussed.

---

## Track 4 -- Tactics & Strategy

### Legal Protests

Facilitators: David Barr (ACT-UP NY, Lambda Legal Defense And Education Fund), Jim Denison (ACT UP/SF)

Protesting the limits: A discussion of pushing the limits of legal action by challenging police orders, not obtaining permits and not revealing action plans until the last minute.

## Civil Disobedience

Facilitators: Orteza Alderson (ACT-UP NY), Amy Bower (ACT-UP NY)

The nuts and bolts of how to plan for and execute civil disobedience actions.

-----

## Art and Activism

Facilitator: Margie Edouardo (ACT UP/LA, California Institute of the Arts)

This workshop is structured as a sharing of ideas and techniques of activist-oriented art. It is intended that the group create a leaflet, banner or poster in the workshop that will be used in this weeks activities.

-----

## Creative Actions

Facilitators: Abe Rybeck (United Fruit Company, Boston), Carol Leigh (COYOTE, ACT UP/SF, A Prostitute), Keith Kessler (C-FAR, Chicago), Avram Finklestein (ACT-UP NY), Linda Merideth (ACT UP/Atlanta)

Never another boring demonstration! How to get your message across with creative action to make the most effective use of your resources. Exploring non-traditional means of direct action including zaps, guerilla theater, avoiding arrest and more.



### Schedule of Events

#### Saturday, October 8

- 9:30 a.m. - 11:00 a.m. ACT NOW Steering Committee Meeting, Hine Jr. High
- 10:00 a.m. - 7:45 p.m. AIDS Activist Teach-in, Hine Jr. High, 8th St. & Pennsylvania Avenue, S.E.; Eastern Market Metro Station.
- (Check-in for participants in the FDA Action)
- 1:00 - 2:00 PISD Caucus meets over lunch
- 6:00 - 7:30 FDA Action Coordinators/ ACT NOW Action Committee

#### Sunday, October 9

- 9:30 a.m. - 11:00 a.m. Women's Caucus meets, Hine Jr. High
- 10:00 a.m. - 7:45 p.m. ACT NOW Conference, Hine Jr. High  
(Check-in for participants in the FDA Action)
- 1:05 - 2:05 Women's Caucus meets over lunch
- 4:30 - 6:30 Lawyers and Legal Observers for the FDA Action meet, Hine Jr. High

#### Monday, October 10

- 9:00 a.m. - 3:00 p.m. Non-violence Trainings, All Souls' Church, 16th & Harvard St., N.W.; Woodley Park/Zoo Metro Station. More easily accessible by bus.  
(All training sessions begin at 9 a.m. and will last until 3 p.m.)
- Check-in for participants in the FDA Action.
- 10:00 a.m. Media Team Meeting, National Gay & Lesbian Task Force, 1517 U St., N.W.

10:00 a.m. Pre-action Meeting Planning Committee Meeting, All Souls' Church

12:00 p.m. Meeting for all individuals providing general and individual support at the FDA. All Souls' Church

4:00 p.m. - 6:00 p.m. Demonstration -- "Reagan Administration on Trial"-- Department of Health and Human Services, 200 Independence Avenue, S.W. Capitol South Metro Station.

7:00 p.m. - 10:00 p.m. "Seize Control of the FDA" Pre-Action Meeting, All Souls' Church.

10:00 p.m. FDA Action Coordinators/ ACT NOW Action Committee

Tuesday, October 11

7:00 a.m. "Seize Control of the FDA," Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland, Twinbrook Metro Station.



## AIDS Activist Teach-In, October 8

Hine Jr. High School, 8th & Pennsylvania Avenue, S.E.

10	- 11	Registration
11	- 11:30	Keynote
11:30	- 1	Workshop Session 1
1	- 2	Lunch
2	- 3:30	Workshop Session 2
3:30	- 4	Break
4	- 5:30	Workshop Session 3
5:30	- 6	Break
6	- 7:30	Workshop Session 4
7:30	- 7:45	Closure

Workshops: The workshops are divided into four tracks, each with four sessions. Each track has a main issue as its theme, with each session addressing a different aspect of that issue. The issues of the various AIDS-impacted communities will be addressed in each workshop. The tracks were used as a way of organizing the conference; individuals are free to attend workshops in all of the tracks. Please see below for a schedule of workshops. A description of all of the workshops is also included.

Caucuses: There will be space available for caucuses to meet during the sessions. The caucuses that already exist are: PISD (People With Immune Systems Disorders -- including AIDS, ARC, HIV-positive status and other immune system disorders, such as Chronic Fatigue Syndrome), Women, People of Color and Differently Abled. Other caucuses are strongly encouraged.

Additional Workshops: There will be space available during each session for conference attendees to create workshops.

If you need space for a caucus, a workshop or any other meeting, please consult with the individual at the information desk to schedule a location. Please post all meetings on the information board in the lobby.

PISD Room: A room has been set aside as an R & R spot for PISD folks. The room has places to lie down and some food and beverage for refueling. Mats are also available for individuals to take to the workshops. We have an ice chest for medication that may need to stay refrigerated. \_

Workshops for the ACT NOW AIDS Activism Teach-In, October 8, 1988

Track: AIDS & The Politics of Health Care	AIDS & The Politics of Oppression	Organizing For AIDS Activism	Tactics & Strategy
Session -----			
1 Education & Prevention	Racism, Homophobia Sexism, Classism Ableism, Xenophobia	Starting a Local AIDS Activist Org.	Legal Protests
2 FDA Teach-in	Racism ----- Mandatory/Routine Testing, Quarantine	Publicity & Media	Civil Disobe- dience
3 Treatment & Research	Sexism ----- Global Issues	Fundraising	Art & Activism
4 Access, Alter- native Systems & Treatments	Homophobia ----- Coalition Building	Stress Mgmt & Burnout	Creative Actions

Note that the track, "AIDS and the Politics of Oppression" is split into two workshops for sessions 2, 3 and 4.

A Report to ACT-UP on the first meeting of  
**NCRCPANDCA / the National Committee to Review Current**  
**Procedures for Approval of New Drugs for Aids and Cancer**

NIH, Bethesda MD, 4 January 1989.

by Mark Harrington

On June 8, 1988, **George Bush** wrote to **Armand Hammer**, president of Occidental Petroleum and Chairman of the President's Cancer Panel, asking him to spearhead an effort to:

- 1) Modify approval criteria for cancer & AIDS drugs' IND's & NDA's.
- 2) Revise efficacy standards and suggest new endpoints.
- 3) Define how much flexibility PI's should have in modifying IND studies according to new developments;
- 4) Suggest institutional changes to better coordinate FDA, NCI, pharmaceuticals, etc.;
- 5) Encourage pharmaceutical companies to organize and communicate better with regulatory and research agencies.

Note that providing faster access to experimental treatments for people with life-threatening disorders is not on the Bush list of goals.

Note also that Bush initiated this panel before he charged FDA with revising its regulations late in July - this indicates, perhaps, how little faith he may have had in reforms proposed by bureaucrats.

The end result was the naming of the 9 member "NCRCPANDCA" (see above), which held its first meeting Jan. 4 at NIH.

The Panel:

**Dr. Louis Lasagna** - Dean of Biomedical Sciences at Tufts University and Chairman of NCRCPANDCA; he was a leading authority on the post-Kefauver FDA in the 1960's; Wednesday he was impatient about **Broder's** criticisms of the FDA and seemed to think it was all just a bureaucratic turf war between NCI and FDA. Lasagna asked if there was appropriate balance between antiviral and anti-infective research and seemed satisfied with **Fauci's** paeon to "basic research" (= no palliative anti-infectives and too many toxic antivirals).

**Dr. Theodore Cooper** - CEO of Upjohn Co., a major pharmaceutical, and head of the National Academy of Sciences' panel which wrote AIDS: Update '88. This panel rejected an all-out coordinated effort against Aids earlier in the Reagan years on the grounds that it was politically unfeasible. Cooper missed the morning session and dozed benignly through the afternoon one.

**Gertrude Elion** - Nobel laureate pharmacologist from Burroughs-Wellcome, she pioneered the research which paved the way for them to get AZT; she admitted she knew little about clinical trials and "has a lot of reading to do"; she seemed genuinely interested and possibly open-minded.

**Dr. Emil Frei** - Director of Harvard's Dana Farber Cancer Institute, he wrote an article last year lamenting the refusal of third-party payers (insurance companies and Medicare) to pay clinical costs associated with drug trials; he's a colleague of CD4 developer Dr. William Haseltine. Frei asked some pointed questions.

**Dr. Samuel Hellman** - Dean of Biological Sciences at U. Chicago's School of Medicine.

**Peter Hutt, Esq.** - partner in the Washington firm of Covington & Burling, he was FDA's chief counsel in 1971, and said bureaucratic tensions between them and NCI had been bad then, but apparently worsened since. Fastidious and a bit prissy, he asked many detailed questions and may know the most about the issues of anyone on the panel. He's concerned that approval of EPO (erythropoietin) is being unnecessarily delayed.

**Dr. Charles Leighton** - Sr. VP, Merck Sharp & Dohme, he was relatively quiet, suggesting there was an inadequate supply of well-trained principal investigators.

**Dr. Thomas Merigan** - head of the ACTU at Stanford, a short bow-legged impatient man, he twitched all morning and asked a few critical questions. Last year he wrote a report criticizing the earlier ATEU system, which spurred the reorganization of ATEU's into the ACTG; principal investigators were to have more input into the process. Merigan said historical controls wouldn't work because AIDS care is changing so fast HIV is "a moving target." But he suggested DHPG should now be approved without additional trials.

**Dr. Henry Pitot** - Director of Cancer Research at U. Wisconsin, he suggested animal and toxicity standards for biologics be changed since biologics are so much less toxic than synthetic drugs.

#### The Witnesses:

**Anthony Fauci**, Director of NIAID. Eager to please and anxious to avoid strife, he was boyishly earnest as he projected slides with a large cylindrical object which looked like an massive, antique vibrator. The only hint of criticism was when he admitted FDA had subjected NIAID protocols to "no real major delays ... no study was held up for an enormous period of time." He promised corporate sponsors that at NIAID, "confidentiality and property rights [are] ensured." ACTG update: 34 sites, 11 pediatric sites, 5,330 patients accrued, 24 agents under study, 44 open protocols, 9 closed, 12 pending, 28 in development, 76 concept sheets under review. He raved about the pathetically small \$6 million allocated for community trials in 1989. Fauci said researchers "must adhere to a set of scientific rules which may appear insensitive," then lied by claiming few trials use placebos anymore.

**Samuel Broder**, new Director of NCI. Brilliant and abrasive, he brutally attacked the FDA for "excessive interference and micromanagerial involvement." Posing as an ardent patient advocate, he said "those of us who treat patients speak a different language from those who make the rules."

**Dr. Bruce Chabner** - Broder's deputy, he gave the main case for NCI, with frequent interruptions from his boss. Chabner decried the requirement that nontoxic biologics and immunomodulators had to undergo the same extensive animal and safety trials as toxic drugs; he attacked the exclusion of infants from drug trials until they were proven safe in adults (particularly in an Interleukin-2 trial); said FDA must allow investigators greater flexibility in modifying trial designs as new

knowledge develops; attacked Phase 3 trials comparing test drugs vs. standard therapy as too lengthy and unnecessary; demanded simplified procedures for extending approved drugs to new indications; said third-party carriers must pay routine medical costs associated with drug trials; and demanded that FDA consider endpoints less drastic than survival vs. death.

**Dr. Ellen Cooper**, FDA's Director of Antiviral Drugs, was called down to justify FDA's refusal to allow infants into an Interleukin-2 trial. Adult Phase 1 trials have been underway for, she said, 2 months; Chabner said 8. Stiff and nervous, she said that while Frank Young may think it OK to let kids into trials before drugs are proven safe in adults, others in the FDA (implying those who know what they're talking about) don't. She blamed the delay in kids getting access to AZT on Burroughs-Wellcome. I cornered her during the morning coffee break and interrogated her about DHPG, getting the impression, once again, that FDA executives don't know the operational details of trials in the real world; she said she was "sure" Syntex would make the drug available in inner-city hospitals.

**Frank Young**, Commissioner of FDA gave a lengthy, soporific disquisition on the many wonderful things FDA had done under his enlightened guidance; he suggested all problems could be solved by monthly luncheons between the warring bureaucrats. He told me that ACT-UP was welcome meet with Ellen Cooper to vent our disgust over the DHPG fiasco.

**Dr. Carl Peck** of the FDA told the ultimate bureaucratic shaggy-dog tale about a drug which had undergone 100 clinical trial and whose NDA had been pending for 20 years.

###

The medical establishment is beginning to wake up and realize its own interests are ill-served by FDA rigidity and delays. US pharmaceuticals want more flexibility so they can handle increased foreign competition and so they can harness the scientific expertise of new, smaller biotechnology companies.

Concern for people deprived of access to experimental treatments provides a humanitarian figleaf for the scientific establishment's real aims - a striving for the dollars and honors to be won in front-line medical research. The lack of real concern for people with cancer and AIDS was dramatically shown by Bush's failure to name anyone from either of those groups to the panel.

ACT-UP should force the Committee to make the needs of people with life-threatening diseases its primary mission.

**AIDS Clinical Trial Resource: Critique of the AMFAR  
Directory of Experimental Therapies for ARC and AIDS**

James Eigo\* and Iris Long\*\*, Ph.D., March 26, 1988  
Treatment & Data Subcommittee of Issues Committee,  
AIDS Coalition to Unleash Power ACT UP  
(212) 533-2769\*, (718) 779-6684\*\*

**I. Scope:**

The AmFAR Directory (1, the "Pink Book" and its Supplements) gives the following major types of information: 1) descriptive information about antiretroviral and immunomodulator drugs: mechanism of action, trial results and toxicity/side effects. 2) tabular information about clinical trials such as: trial status, type of subjects, trial site, inclusion/exclusion criteria, etc. We are not concerned in this report with the descriptive drug information except when discussing preclinical drug information (VIII.).

**II. Background:**

Accurate, up-to-date, reliable trial information is not readily available to customers and health providers. The Presidential Commission the Human Immunodeficiency Virus Epidemic has just submitted an Interim Report to President Reagan (2) recommending that a Clinical Trial Information Registry (CTIR) be established and that all trials be registered by the sponsor within seven days of approval by the Food and Drug Administration (Exhibit A). ACT UP members consider such a Registry of prime importance. We are working to establish an electronic database for all AIDS trials underway in New York State. The database we proposed, in keeping track of existing trials, would be a repository for such information with cross reference capabilities. Physicians & PWAs & their service organizations need centralized, accessible information on the current status of AIDS drugs under research, & their progress toward government approval; they should know what trials are open & what these trials require of their participants (3,4).

The next 9 pages of this report criticize the Directory's clinical trial information in the hope that this valuable source of information can be improved as quickly as possible.

III. Unlisted Trials for AIDS-Related Opportunistic Infections and Cancers:

The preface to the October 1987 revised and expanded edition states: "This publication does not list the wide variety of Treatments being used or tested for the opportunistic infections or neoplasms associated with AIDS."

This edition, therefore, does not list the following ATEU (ACTG, 6) protocols for opportunistic infections (OI) clinical trials that were, at the time of publication, actively accruing patients:

\* ATEU 004 (PH, 7) Phase I trial of the combination of AZT and DHPG in patients with AIDS and CMV.

\* ATEU 018 (OI, 7) Escalation dose of IV trimetrexate for previously untreated PCP in AIDS, with subsequent comparison of IV and oral pharmacokinetics.

It appears that trials for drugs for opportunistic infection (OI) that also show some antiretroviral activities (eg 015 testing Foscarnet) are listed. This does not fully explain why trials similar to the unlisted 004, trials such as 010 (PH) testing AZT and acyclovir, or trial 007 (PH) testing AZT and desciclovir have been chosen for entry.

The Directory did not list the following pending ATEU protocols for which an IND had been filed for the following OI protocols. (Although it did list pending antiretroviral (AV) trials.)

\* 026 (OI) Maintenance therapy for cryptococcal meningitis after initial IV induction with amphotericin B vs fluconazole.

\* 029 (OI) Randomized study of trimetrexate + leucovorin vs TMP/SMX for moderately severe PCP (followed by prophylaxis with aerosol pentamidine

\* 030 (OI) Randomized study of trimetrexate + leucovorin and TMP/SMX + steroids in refractory PCP

By the time of the January Supplement update, trial 026 was actively accruing patients, and the following OI trials were pending 031, 033, 037, 039.

We find it inexplicable that the Directory not include trials testing antiinfectives and therapies for AIDS-associated neoplasms. There are no other sources of information for these trials (5). This means patients cannot get information that may be critical for their survival. Such a situation, because it hinders patient accrual in OI trials, hinders research on antiinfectious and cancer treatments. Shouldn't trials of these therapies be made known to doctors and their patients? There are many drug company and government trials investigating these therapies. Shouldn't information concerning the efficacy of ganciclovir (DHPG) for CMV retinitis and pentamidine aerosol prophylaxis for Pneumocystis Carinii pneumonia (PCP) be made known? Shouldn't therapies to cure life-threatening diarrhea from CMV or cryptosporidium infections be developed quickly?

#### IV. Gaps & Mistakes:

##### A. A Profile of the Ampligen Listings

Because of gaps in information or mistakes, a single trial can appear in the Directory as two different trials. Trial "Ampligen : ARC/PGL/HIV infection:" (Exhibit B, p 7 & 89) appears to be for different subjects than the trial "Ampligen : HIV+ Homosexual / Bisexual Men" listed in the January Supplement (Exhibit C). In fact both are wrong according to the criteria page from the Ampligen protocol 101, which defines the subject population as those with ARC (Exhibit D, reference 8).

Other errors and discrepancies in the ampligen listings are: manufacturer/developer, investigators, treatment duration, starting date, exclusion criteria, dosage frequency. In addition, no mention is made in the Supplement that HEM Research, Inc. went into a joint venture with Dupont Pharmaceuticals in early November 1987. This relationship could be expected to have a great effect on the drug development process. Dupont should also be listed as manufacturer/developer.

The names of the investigators vary on Exhibit B and C. The true principal investigators are given in Exhibit E. Two New York sites are listed, St. Luke's Hospital in New York City and New York Medical College, Valhalla in NY. Actually, the site of the latter trial is also in N.Y.C. and at Metropolitan Hospital which is an affiliate of N.Y. Medical College. Persons collecting trial information should know of these types of institutional relationships.

B. Trial ATEU 019

Due to discrepancies, one could easily mistake two listings of the same trial for listings for two different trials. AmFAR itself is sometimes confused: its August 1987 Directory prints information for trial 019 twice on the same page, Exhibit F. Also, the first trial, is listed under the drug AZT. The second trial is listed under the drug combination Azidothymidine & Acyclovir (August '87 Dir.). The Directory could benefit from closer editing and proofreading. Were every trial given a code number, the potential confusion we cite above could be prevented.

C. The Erythropoietin (EPO) Trials

One trial, "EPO : AIDS", is listed in the Supplement (Jan. '88, page 9). Robert Danna of Ortho Pharmaceuticals (201 218-7010) says there are two phase II trials for EPO. The first trial is for those with anemia who are on AZT, and the second trial is for those with anemia who cannot take AZT.

Errors appear quite frequently in the investigators category in the AmFAR Directory. The New York investigators of the EPO trials that are not listed in AmFAR are Donna Mildvan at Beth Israel Hospital and Barbara Starrett of the Community Research Initiative. Dr. Starrett says she is only doing the EPO and AZT protocol.

D. The Dextran Sulfate Trial

"Dextran Sulfate (UA001): AIDS/ARC" (page 27, Supplement). This trial is only for ARC not AIDS patients. This information was confirmed on March 17, 1988 by a call to the trial site (San Francisco General Hospital, Vincent Degenova). No inclusion/exclusion criteria are given for this trial (see below).

E. The Naltrexone Trial

"Naltrexone : AIDS/ARC, Trial Status: Active Recruitment" (page 42, Oct. '87 Dir.). The error is calling this closed trial an active trial; this error has persisted in June, August, October 1987 and January Supplement. A simple call to the investigator, Bernard Bihari of N.Y.C., would have determined this. No exclusion/inclusion criteria are given.

page 5

#### F. The Ribavirin Trials (Exhibit E)

Five active ribavirin trials are listed in Supplement (page 12). Only one trial lists inclusion/exclusion criteria information.

The first trial; "Ribavirin : ARC / LAS" called an active trial has been closed since January 1987. According to the drug company (Dr. Richard Schwindt, Viratek ICN Pharmaceuticals, 3/25/88). The second trial; "Ribavirin : Pediatric AIDS" is not a trial done under their IND. The trial which "holds the IND" is New Jersey School of Medicine, Newark, NJ (James Oleski). AmFAR does not list this sponsor.

The third trial; "Ribavirin : ARC / PGL" closed mid-March 1988.

The listings of the last two trials say the trial centers are ACTGs indicating that they are NIAID trials, but no NIAID protocol number is given. Trial "Ribavirin : HIV-infected" is (ACTG Protocol 035). Trial "Ribavirin : AIDS/ARC" is ACTG Protocol 034.

#### G. An AZT Trial

"AZT : HIV Ab+ or ARC (Walter Reed Stages 2-5)" is listed in the Oct. Directory (page 12). According to Dr. Michael Simberkoff this on-going trial has been modified (10-30-87). The Walter Reed Classification is no longer used, and this trial is only for HIV positive participants.

The two listed trial centers (Mt. Sinai Medical Center, NY and UCSD Medical Center, CA) for protocol 034 are incorrectly listed according to NIAID. The four trial centers are Harvard, MA; Rochester Medical Center, NY; NYU Medical Center, NY and UCSF Medical Center, CA.

#### F. Variable Inclusion/Exclusion Category Listing

Over 30 trials listed in the Directory and Supplement give no information as to what subject qualifications are required for trial entry. Many other listings of trials give some, but inadequate, information. Inclusion/exclusion criteria are part of the protocol and may comprise quite a long list of desired patient attributes. How does AmFAR decide what information should be listed?

#### V. Trials Not Listed:

We have discovered that there are New York City trials that are just not being listed. We believe that this is true elsewhere in the U. S. We established this in our October, 1987 report (5).

A trial can be considered unlisted if the investigator's name is not entered (see III. A. and B.).

A. Colony Stimulating Factor (recombinant human GM-CSF) is a phase I toxicity trial.

This trial is being carried out in N.Y.C. by Dr. Susan Krown of Memorial Sloan Kettering Hospital. This trial was not listed in the January 1988 Supplement. When Dr. Krown was contacted in December 1987, she said the trial was scheduled to begin in January 1988. Dr. Krown was contacted on March 13, 1988 and the trial was underway.

B. AZT and Interleukin-2 for AIDS patients with Kaposi's Sarcoma is a phase I trial studying the escalation dose of intravenous interleukin-2.

This trial is being carried out by Dr. Margaret Kemeny of St. Vincent's hospital in New York City (212-790-8335). A discussion of this trial can be found in the newsletter Treatment Issues (Gay Men's Health Crisis, Vol 1, #2, Dec. 31, 1987, 212- 877-7517).

#### VI. What Happens to Closed Trials:

It appears that AmFAR has made no decision about listing closed trials. Will closed trials continue to be interspersed between active trials? Will the true reasons for why a trial is closed be recorded?

#### VII. Women In Trials:

We believe (as do many other people of the scientific community and the vast majority of the American public) that women should be actively recruited to participate in trials. There are two reasons for this: 1) information should be available on how potential agents act in women; 2) women should have access to drugs that may help save their lives. We also believe (as do many experts) that proper subjects can be found in the drug user and former drug user populations.

AmFAR does not seek out information concerning the eligibility of women, IVDA, transfusion recipients and hemophiliacs. This information should appear in the trial criteria section of the AmFAR listings.

page 7

Below are nine trials which do not state in its criteria that women are excluded when in fact they are excluded.

- 1) Imuthiol (Merieux Institute, Inc.) AIDS and ARC, phase 2 (page 31, Oct. '87 Dir.), dosage/freq: 400mg/m<sup>2</sup> / once wk  
Target patient no. 200 ARC 50 AIDS

Postscript to This Imuthiol Trial: Merieux Institute, Inc. was contacted on February 10, 1988 and exclusion of women in the New York City trial was confirmed. On March 17th, 1988, Vincent Degenova of SF General Hos. (415 821-5531) said women were not excluded from this trial. The protocol may have been modified to exclude women when it opened in New York City where there are more women with AIDS or ARC.

- 2) Imuthiol (Merieux Institute Inc.) AIDS & ARC, phase 1 (page 31, Oct. '87 Dir.), dosage/freq: 200mg/m /wk, 400mg/ m /wk, 800h/ m / wk  
Target patient no. 40

- 3) Naltrexone (Dupont Pharmaceuticals) AIDS & ARC, double blind controlled (page 43, Oct. '87 Dir.), dosage/freq. 1.75mg/kg  
No target patient no. listed

- 4) D-Penicillamine (Degussa Corporation/Carter Wallace) PGL or ARC with HIV Viremia & Immune Dysfunction, phase 1 (Page 26, Oct. '87 Dir.), dosage/freq: >0.5g-2.0g / bid, 1 trial site  
Target patients no. 30

- 5) Thymopentin (Ortho Pharmaceuticals) ARC/PGL/HIV+, phase 1, 1 site (page 50, OCT. '87 Dir.)  
Target patient no. 20

- 6) Thymopentin (Ortho Pharmaceuticals) HIV AB+ Symptomatic and Asymptomatic, double blind placebo control trial (page 13 January '88 supplement), dosage/freq 50 mg tiw  
Target patient no. 60

- 7) Thymopentin (Ortho Pharmaceuticals) ARC/PGL/HIV+, phase II double blind placebo controlled study (page 13 January '88 Supplement), dosage/ freq. 50 mg tiw  
Target patient no. 100

- 8) Tumor Necrosis Factor & Gamma Interferon (Genentech, Inc.) ARC, open phase 1 trial (page 53 Oct. '87 Dir.) dosage 200mg / 3 X week  
Target patient no. not listed

page 8

9) Tumor Necrosis Factor & gamma Interferon, ARC (ATEU Protocol 025) phase 2 study<sub>2</sub> (page 53, October '87) dose 10 mcg/m<sup>2</sup>/m<sup>2</sup> rTNF / 3 X week, 10 mcg/m<sup>2</sup>/m<sup>2</sup> rIFN / 3 X week, 10 mcg/m<sup>2</sup>/m<sup>2</sup> / 3 x week  
Target Patient no. 75

Information concerning the exclusion of women from the above TNF and Gamma interferon trials was obtained from Dr. Saks of Genentech on March 3rd, 1988 (415 266-1774). He said that the company and the government are currently modifying protocol 025 to include women. The exclusion of women was confirmed on 3/17/88 by Vincent Degenova of SF General Hospital in California (see above). NIAID has previously said that women were excluded from only protocol 001 (a trial testing AZT for AIDS associated Kaposi Sacoma).

#### A. Corrections Made by AmFAR

These two protocols have been corrected in the recent Directory to show exclusion of women:

\* alpha Interferon (Schering) HIV asymptomatic, double blind placebo controlled trial (page 4, October '87), dosage / freq: 35Mu qd, trial Site: NIAID, Clifford Lane, Principal Investigator  
Target patient no. 50

\* ATEU 001, AZT in AIDS associated KS, phase 2, dosage / freq. 250, 500mg or placebo / q 4h, q 8h; q4h / q 8h (page 14, June 1987) protocol now fully enrolled  
Target patient no. 271

#### B. Recommendation Concerning Excluded Trial Subjects

Information on the exclusion of various groups from trials should be listed in the AmFAR Directory. We have yet to hear a valid reason for excluding women and other groups. We have been told by the medical officer of a major drug company that if women and other groups are excluded from phase 1 trials, most likely they will be excluded from all subsequent trials. Subject exclusion information, if widely known, can help stop such discriminatory practices against certain patient populations.

#### VIII. Listing Drugs in Pre-clinical Testing:

The preface to the October 1987 edition states: "It (the Directory) is intended to assist physicians caring for patients with HIV-related illness to obtain updated information relating to clinical trials of experimental treatments and information on agents currently in pre-clinical development."

A drug undergoing pre-clinical studies and tests may never go into clinical trials. Only drugs that have approved INDs or which are undergoing clinical trials in another country should be listed in a directory of clinical trials. The AmFAR Directory lists the following drugs which are undergoing pre-clinical testing: castanospermine, CS-85, CS-87, D4C, HGP-30 antisera, HIV-ISCOM, lentinan, monoclonal neutralizing antibodies, monolaurin, ozone, silicotungstate. Potential antiretroviral agents undergoing pre-clinical testing should be listed and their progress tracked elsewhere. The few drugs entered into the Directory are hardly representative of the hundreds of antivirals that are currently being developed. If AmFAR staff knew about them, I'm sure these drugs would be considered just as interesting as the ones they chose.

According to the FDA only 20% which go into testing ever come to the market. Far fewer drugs ever reach the stage of clinical testing in humans. Castanospermine is an example of a drug which showed interesting antiretroviral activity, and everybody was excited about it. However, the latest information indicates that it will most probably not go into clinical trial.

In a March 10th letter Dr. John Y. Killen, Acting Deputy Director, AIDS Program, NIAID states that castanospermine is undergoing pre-clinical evaluation in mouse models. "Based upon the degree in in-vitro activity and other available information, it appears likely that castanospermine itself will not go on to clinical development. However, it is certainly a very promising lead compound(,) and analogs and related compounds are being pursued (9)." The Directory's purpose should be to keep doctors and patients informed on current clinical trials of antivirals and immunomodulators. It should not raise hopes about drugs that may not be available for trials for several years. We feel it is an error in judgement to include pre-clinical testing information in a directory intended to assist practicing physicians and their patients.

#### IX. Some Recommendation to the AmFAR Editors:

- 1) If you wish to be one of the models for a National Registry of Clinical Trials, rethink all aspects of the Directory in its current context.
- 2) Hire medical editors who can really do the job.
- 3) Upgrade data collection techniques.
- 4) Work with the communities affected by AIDS around the country to implement a better system of collecting information on trials.

- 5) Immediately start to develop an active outreach program so that trial information will reach women, children, hemophiliacs, transfusion-infected individuals, black and latino people and I.V. drug users. Address and discuss the problems you have reaching people at every stage.
- 6) Enlist the cooperation of the medical establishment and drug companies. Report on problem areas to the Directory readers.
- 7) Immediately include within the Directory a complete discussion of its information gathering and storage techniques. Discuss the limitations of the Directory within it. Update this information as improvements are made.
- 8) Immediately find funding sources. (It is unacceptable for Editors to say they do not even have enough meeting-space to discuss the above matters.)

Definitions & References:

- 1) American Foundation for AIDS Research 40 West 57th St., Suite 406 New York, NY 10019-4001. Direct all inquiries to Mitchell Speer, Medical Editor (212 333-3118).
- 2) Interim Report, Presidential Commission on the Human Immunodeficiency Virus Epidemic, page 70, March 15, 1988.
- 3) "A Proposal to Collect Data for an AIDS Clinical Trial Database", Iris Long & James Eigo, ACT UP, January 28, 1988 (unpublished report).
- 4) "Toward a Proposal for an AIDS Drug Trials & Treatment Database" Iris Long & James Eigo, ACT UP, February 20, 1988 (unpublished report).
- 5) The government-run databases CLINPROT and PDQ do not give listings for all AIDS trials. Iris Long, "Non-ATEU Clinical Trials for AIDS Drugs in New York State as of October 1987", November 1987, ACT UP (unpublished report).
- 6) An ATEU protocol refers to an AIDS Treatment Evaluation Unit protocol. The ATEU protocols are administrated by NIAID. As of January 1, 1988 due to a modification of the program, the name ATEU has been changed to ACTG standing for AIDS Clinical Trial Group. Protocols for this program are now known as ACTG protocols.
- 7) The term (PH) means the protocol was reviewed by the Pharmacology Committee at National Institute of Allergy and Infectious Diseases (NIAID). The term (OI) means the protocol was reviewed by the Opportunistic Infection Committee.
- 8) Roger Morris (Dupont Pharmaceuticals) to Rebecca Cole (ACT UP member), December 1987.
- 9) Letter of March 10, 1988 John Y. Killen, M.D. Acting Deputy Director, AIDS Program, NIAID, to David Kirschenbaum (ACT UP member), New York City.

**AIDS Coalition To Unleash Power (ACT UP)  
496-A Hudson Street, Suite G4, NYC 10014  
(212) 533-8888**

**PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC**  
655 15th Street NW, Suite 901, Washington, D.C. 20005 (202) 245-2437

**CHAIRMAN**

*Admiral James D. Watkins (Retired)*

Exhibit A (page 1)

**MEMBERS**

*Colleen Conway-Welch, Ph.D.*

*John J. Creedan*

*Theresa L. Crenshaw, M.D.*

*Richard M. DeVos*

*Kristine M. Gebbie, R.N., M.N.*

*Rurton James Lee III, M.D.*

*Frank Lilly, Ph.D.*

*John Cardinal O'Connor*

*Rory J. Primm, M.D.*

*Penny Pullen*

*Cory SeVoss, M.D.*

*William B. Welsh, M.D.*

**INTERIM REPORT**

**PRESIDENTIAL COMMISSION ON THE  
HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC**

**SUBMITTED MARCH 15, 1988**

NIAID CLINICAL TRIALS: RECOMMENDATIONS

The Commission will continue its review of HIV-related clinical trials, and recommends that:

- (CT-1) Membership in the NIAID Clinical Trials Advisory Council should be increased to include at least one individual with HIV infection;
- (CT-2) The number of FTEs available to NIAID for clinical trials should be immediately increased from 47 to 120;
- (CT-3) Activities in progress at NIAID to incorporate greater participation of industry, and community physicians in protocol development and implementation should be encouraged;
- (CT-4) A direct grant program should be immediately funded to assist community-based trial sponsors to develop and implement clinical trial protocols, and to encourage increased access to these protocols by underserved populations, e.g., hemophiliacs and transfusion-exposed individuals, women, children, minorities, I.V. drug abusers, and HIV-positive asymptomatic individuals;
- (CT-5) Grants should be accompanied by Institutional Review Boards (IRB) and protocol approval by NIAID, and be constructed so as to continue private sector partnership with pharmaceutical companies;
- (CT-6) NIAID should develop means by which clinical trials can be made available to individuals in all geographic areas of the country.

CLINICAL TRIAL INFORMATION REGISTRY: RECOMMENDATIONS

- (CT-7) Information on clinical trials should be made more widely available, through the use of the CDC Clearinghouse or other mechanisms;
- (CT-8) Registration of all AIDS clinical trial information should be in one central location;
- (CT-9) All trials should be registered by the sponsor within seven days of approval by the FDA;
- (CT-10) Consider providing additional funds to the National Cancer Institute to broaden the scope of its current database, the Physician Data Query System (PDQ), to accommodate entry of AIDS clinical trials;

## Exhibit B (page 1)

Carter W, et al. Clinical, immunological, and virological effects of Ampligen, a mismatched double-stranded RNA, in patients with AIDS or AIDS-related complex. Lancet I: 1286-1292, 1987.

Heartl WG, et al. Misaligned dsRNA, poly(I)-poly(C12,U), induces accumulation of 2'-5'-oligoadenylates in mouse tissues. Biochem Biophys Res Communications 138: 40-46, 1986.

Mitchell WM, et al. Mismatched double-stranded RNA (Ampligen) reduces the concentration of 3'-azido-3'-deoxythymidine (AZT) required for the in vitro inhibition of the human immunodeficiency virus. Lancet I: 890-891, 1987.

Montefiori DC, et al. Antiviral activity of a mismatched double-stranded RNA (Ampligen) against human immunodeficiency virus in vitro. In press PNAS.

*Trial 1*

### Ampligen : ARC/PGL/HIV Infection

Study Protocol: Double Blind Placebo Controlled Trial  
Trial Status: Active Recruitment

#### Investigators:

Strayer, David: PA  
Brodsky, Isadore: PA  
Carter, William: PA  
Braude, Ron: GA

Simon, Gary: DC  
Schulof, Richard: DC  
Parenti, David: DC  
Perez, George: GA

#### Inclusion Criteria:

CD4+ Count: 60-400  
Homosexual/bisexual male  
Symptoms of AIDS associated  
Immune dysfunction

#### Exclusion Criteria:

CDC defined AIDS  
Current acute medical problem

Administration: IV  
Dosage / Freq: 200mg / 2 x wk  
Treatment Duration: 24 weeks

Number of Subjects: 200  
Duration of Trial: 24 weeks  
Start Date: June 1987

### Ampligen : AIDS/ARC/PGL

Study Protocol: Pilot Study  
Trial Status: Active, Fully Enrolled

#### Investigators:

Schulof, Richard: DC  
Strayer, David: PA

Mansell, Peter: TX  
Parenti, David: DC  
Simon, Gary: DC

#### Inclusion Criteria:

CD4+ Count: <400  
Age: >18  
Sex: male

#### Exclusion Criteria:

CDC defined AIDS  
Prior antiviral or immunomodulating  
agents within 30 days

Administration: IV  
Dosage / Freq: 200mg / 2 x wk  
Treatment Duration: 24 weeks

Duration of Trial: Ongoing  
Start Date: July 1986

### Ampligen : HIV Infection (ATEU Protocol pre68)

Study Protocol: Phase I Escalating Dose Trial  
Trial Status: Protocol Final

ATEU: University of Pittsburgh

#### Inclusion Criteria:

CD4+ count <500

#### Exclusion Criteria:

Concurrent OI

Administration: IV

Duration of Trial: 6 months  
Start Date: November 1987

### Anti-Interferon Immunoglobulin

Manufacturer/Developer: Advanced Biotherapy Concepts, Inc.  
Contact: Joseph Bellanti 202-625-7437

#### PHYSICAL DESCRIPTION:

Anti-interferon immunoglobulin is an antibody specific for interferon (IFN). It is produced by injecting alpha interferon into an animal, and purifying the antibody from the animal's blood after the animal has produced an immune response to this antigen.

#### MECHANISM OF ACTION:

The use of anti-interferon is based upon the hypothesis that acid-labile alpha interferon may down regulate the immune system (Skurkovich, et al.). It has been found that the serum of patients with frank AIDS or ARC has elevated levels of acid-labile interferon. This interferon abnormality is hypothesized to be a "fault" in the normal immune cascade, related to the HIV infection which disturbed interferon synthesis and, subsequently, the immune system. Normal functioning of the interferon system is believed to be critical for the normal functioning of the immune system. Anti-interferon immunoglobulin administered to a patient presumably binds to the hyperproduced alpha interferon and neutralizes it.

#### TRIAL RESULTS:

Bellanti and co-workers treated two AIDS patients who had recovered from PCP with three daily IM injections of sheep anti-alpha IFN immunoglobulin (1.5 to 9MU/day respectively). Before treatment both patients had detectable serum levels of acid labile alpha IFN (125 IU/ml). During the 6 day treatment period no IFN could be detected in the blood of either patient. However, 7 days after cessation of treatment, serum IFN levels in one patient increased to 630 IU/ml, which was predominantly gamma IFN.

#### TOXICITY/SIDE EFFECTS:

In the two patient study no serious adverse or toxic effects were observed following treatment, but both experienced a mild maculopapular exanthem which disappeared within a week, and both experienced a mild transient lymphopenia.

#### References:

Bellanti JA, et al. Preliminary clinical trial of anti-alpha IFN in patients with AIDS: a

3'-DEOXY-3'-FLUOROTHYMIDINE (3'-F-T<sub>D</sub>R)

Anti-HIV effect of 3'-F-T<sub>D</sub>R was evaluated in H9 cell cultures by reverse transcriptase and HIV antigen assays. 3'-F-T<sub>D</sub>R inhibited HIV replication, compared with infected controls, by 99% at concentrations ranging from 100 uM down to 1.25 uM. While *in vitro* anti-HIV activity of 3'-F-T<sub>D</sub>R appears to be comparable to AZT, it exhibits greater cytotoxicity and inhibition of lymphocyte proliferative response. A preliminary study in cats is anticipated.

Reference: Polsky B, *et al.* 3'-deoxy-3'-fluorothymidine (3'-F-T<sub>D</sub>R) inhibits human immunodeficiency and feline leukemia viruses (HIV and FeLV). ICCAC abstract, October, 1987.

PEPTIDE-T

Based on preliminary results from a study in Sweden (see page 45), an NIH pilot study of peptide-T, to be conducted by Michael Gottlieb (Los Angeles), Thomas Cotes (San Francisco) and Frederick Siegel (New York), is waiting for institutional review board approval and is projected to begin November 1987. A total of twelve AIDS/ARC patients will be hospitalized for 35 days of treatment with 1mg peptide-T infused IV drip 3 times a day (3mg/d). Patient follow-up after treatment will be on an out-patient basis.

AZT + URIDINE

Sommadossi and co-workers examined whether naturally occurring purine and pyrimidine nucleosides can reverse, *in vitro*, the toxicity of AZT to human bone marrow progenitor (HBMP) colony formation. Increasing concentrations of potential "rescue" agents were added to HBMP cells which were previously exposed to 5 uM AZT for 1 hour. Cells were cultured and colony formation was assessed after 14 days. Although all 2'-deoxynucleosides did not reverse the toxic effects of AZT, dose-dependent reversal was observed with uridine and cytidine, with complete reversal being achieved with 50 uM uridine. Anti-HIV activity, assessed by RT assays, was not decreased in the presence of uridine with combination molar ratio (uridine/AZT) as high as 10,000.

Reference: Sommadossi JP, *et al.* Enhancement of the anti-HIV activity of 3'-azido-3'-deoxythymidine (AZT) by selective rescue of human bone marrow progenitor (HBMP) cells with uridine (URD). ICCAC abstract, October 1987

DDC

Dideoxycytidine (ddC) will receive additional clinical study at doses as low as .005mg/kg/q4h, due to the primary dose limiting toxicity, peripheral neuropathy, seen at doses of .03mg/kg/q4h or greater (see page 28). Recent *in vitro* study has shown that ddC has an intracellular terminal half-life of 6-8 hours compared to 1 hour in plasma, which may provide an explanation for *in vivo* effect at doses lower than originally believed to be required. In pilot study with alternating week treatments of AZT/ddC (6 subjects enrolled - see page 16), the rise in MCV values (seen in AZT treatment prior to the detection of marrow toxicity) appears to be occurring at a slower rate; neurotoxicity associated with ddC is reported to be less severe. A pilot study of combined therapy -AZT (50mg/q4h) and ddC (.005mg/kg/q4h) - is under consideration.

AMPLIGEN

Updated trial results:

Twenty one HIV culture positive anergic patients received varying IV doses (100/200mg for ARC/LAS and 250/500mg for AIDS) of ampliten twice weekly (see page 6,7). Of the 19 patients who had lymphadenopathy at time of entry, 14 had observable decreases in lymph node size after treatment. Delayed type hypersensitivity responses >10mm was observed only in patients receiving 200-250mg. A dose of 100mg (maintenance or treatment) ampliten does not appear to be effective in patients with CDC defined stage IV AIDS.

Reference: Henriques H, *et al.* Effects of ampliten doses in HIV-infected patients. ICAAC abstract, October 1987.

Adjusted Inclusion Criteria: (see page 6)  
ARC/PGL/HIV+ Double Blind Placebo Controlled Trial  
CD4+ cell count: 60 - 300  
Additional Investigator: Michael Grieco : New York NY

Note: A combination treatment pilot study of ampliten & AZT in 30 AIDS/ARC subjects is under consideration to begin December 1987 at George Washington University using 100mg, 200mg and 400mg ampliten 2 x week with 100mg AZT q4h.

ADDITIONAL TRIALS

GM-CSF (Immunex) AIDS/ARC (leukopenia-see page 23)  
Study Protocol: Phase I Open Trial, protocol final  
Investigator: Yankovitz, Stanley: New York, NY

DTC: Double Blind Controlled Dose Response (ARC) Trial - Paris, Lyons, Strasbourg  
Double Blind Controlled Dose Response Trial (Subjects receiving AZT)

CLINICAL STUDY GROUPS (CSG's)

Under a cooperative agreement with the National Institute of Allergies and Infectious Diseases (NIAID), 17 Clinical Study Groups will begin research on AIDS treatment and basic investigations as well as conduct outreach efforts with health care providers. These groups are expected to extend access for HIV infected individuals to appropriate clinical trials and broaden information exchanges between health care professionals. The CSG's, with the principal investigators, are: Alan G. Barbour, University of Texas Health Sciences Center, San Antonio; Neil R. Blacklow, University of Massachusetts Medical School, Worcester; Edward Connor, New Jersey Medical School, Newark; M. Elaine Eyster, Milton S. Hershey Medical Center, Hershey, PA; Robert H. Fass, Ohio State University Medical College, Columbus; Peter T. Frame, University of Cincinnati College of Medicine; David J. Gocke, New Jersey Medical School, Piscataway; Michael H. Grieco, Roosevelt-St.Luke's Medical Center, NYC; Robert Jones, Indiana School of Medicine, Indianapolis; Michael Lederman, Case Western Reserve Medical School, Cleveland; Stanley M. Lemon, University of North Carolina School of Medical Chapel Hill; Kenneth McIntosh, Children's Hospital, Boston; Henry W. Murray, Cornell University Medical College, NYC; John P. Phair, Northwestern University School of Medicine, Chicago; Lee Ratner, Washington University School of Medicine, St. Louis; Richard Schulof, George Washington University School of Medicine, Washington, DC; Roy T. Steigbigel, State University of New York, Stony Brook



# **AmFAR Directory of Experimental Treatments for AIDS & ARC**

With Technical Assistance from The Professional Outreach Program  
The National Institute of Allergy and Infectious Diseases (NIAID)

**Medical Editors:**

Donald Abrams, M.D.

Michael Gottlieb, M.D.

Michael Grieco, M.D.

Mitchell Speer

Managing Editor:

Terry Biern

**Scientific Editor:**

Seymour Bernstein, Ph.D.

**Compiled By:**

The American Foundation for AIDS Research (AmFAR)

Including

**January 1988  
Supplement**

*Mary Ann Liebert, Inc. publishers*

Volume 1  
Revised & Expanded  
October 1987  
ISSN 0893-9942  
ISBN 0-913113-11-5

## Alpha Interferon (Intron-A) & AZT : AIDS-KS/ARC/HIV+ Symptomatic

Study Protocol: Phase I Dose Ranging Trial  
Trial Status: Active Recruitment

Investigators: Mullen, Michael :: Cabrini Medical Center, NY  
Davidson, Michael :: Cabrini Medical Center, NY  
Spicehandler, Deborah :: St. Clare's Hospital, NY

Inclusion Criteria:  
Platelet Count: >100000  
Hemoglobin: >9  
Creatinine: <1.5  
Granulocytes: >1000  
Age: >18

Exclusion Criteria:  
Pregnant/lactating females  
Current OI other than KS  
History of IV drug use  
Specific medications  
Past AZT treatment

Administration: SC (a-IFN) PO (AZT)  
Dosage / Freq: a-IFN qd, AZT 200mg q4h  
Treatment Duration: 4 months  
Start Date: September 1987

## Alpha Interferon (Wellferon) & AZT : AIDS-Associated KS

Study Protocol: Phase I Dose Ranging Trial  
Trial Status: Active Recruitment

Investigator: Lane, Clifford :: NIH / Bethesda, MD

Inclusion Criteria:  
Platelet Count: >100000  
Hemoglobin: >10  
Creatinine: <1.6  
Granulocytes: >1500

Exclusion Criteria:  
No chemotherapy, corticosteroids or  
experimental therapy for 6 weeks prior  
to entry.

Administration: SC (IFN) PO (AZT)  
Dosage / Freq: a-IFN 5 - 35MU qd, AZT 50 - 250mg q4h  
Treatment Duration: 3 months  
Number of Subjects: 40  
Start Date: December 1986

Exhibit C (page 1)

## Ampligen

Manufacturer/Developer: HEM Research, Inc.  
Contact: Emily Cate 1 800 251 2561

### TRIAL RESULTS:

Strayer and co-workers reported the effect of "Ampligen therapy" on patients with HIV-related immune dysfunction. 30 (25 ARC/HIV+) and (5 AIDS patients) were treated with ampligen 100-250mg IV infusion twice weekly for 2-12 months. 83% ARC/HIV+ and 75% AIDS patients demonstrated improvement in delayed type hypersensitivity (DHR) within 12 weeks of treatment. In 13/14 patients treated with 200-250mg, mean p24 decreased 39% from 776ng/ml pre-treatment to 472ng/ml after 2-8 months on study. A decrease in the ability to co-culture HIV was seen in ARC/HIV+ group treated for >2 months at 200mg. Mean CD4+ cells increased from 410 cells/mm<sup>3</sup> to 462 cells/mm<sup>3</sup> in the 10 ARC/HIV+ patients treated for >3 months. ARC patients reported a symptomatic improvement in the following: diarrhea (5/6), night sweats (11/11), fatigue (17/19). In 8/12 ARC patients, a decrease in lymphadenopathy was noted.

4 KS patients had progressive disease between 2-5 months into treatment. One OI occurred in a post-PCP patient who died at 7 weeks following a second episode of PCP. All other ARC/HIV+ patients have remained on treatment; to this point, none have progressed to AIDS. No significant side effects were observed.

### References:

Strayer D. et al. HIV-related immune dysfunction: clinical improvement and immunological/virological effects of Ampligen therapy. Abstract, American Society of Hematology, 1987.

## Ampligen : HIV+ Homosexual / Bisexual Men

Study Protocol: Phase II Double Blind Placebo Controlled Trial  
Trial Status: Active Recruitment

### Investigators:

Braude, James :: Clinical Research Facility, Atlanta, GA  
Gathe, Joe :: Park Plaza, Houston, TX  
Lefkowitz, Lou :: Vanderbilt University, Nashville, TN  
Lenox, Ted :: New York Medical Center, Valhalla, NY  
McKinley, George :: St. Luke's / Roosevelt Hospital, New York, NY  
Simon, Gary :: GWU Medical Center, Washington, DC  
Strayer, David :: Hahnemann Hospital, Philadelphia, PA

Inclusion Criteria:  
CD4+ Cell Count: 60-300  
Male

Exclusion Criteria:  
AIDS

Administration: IV (drip)  
Dosage / Freq: Twice weekly  
Treatment Duration: 9 months

Revised version:  
08/20/87

CLINICAL PROTOCOL  
AMPLIGEN INJECTION

A MULTICENTER CONTROLLED STUDY OF THE EFFICACY AND SAFETY OF  
AMPLIGEN IN PATIENTS WITH AIDS-RELATED IMMUNE DYSFUNCTION.

PROTOCOL NO. AMP101

Investigational site: Department of Neoplastic Diseases  
Hahnemann University

Principal Investigators: David R. Strayer, M.D.  
Isadore Brodsky, M.D.  
William A. Carter, M.D.

Investigational site:

Principal Investigators:

Sponsor: HEM Research, Inc.  
12280 Wilkins Avenue  
P.O. Box 2245  
Rockville, M.D. 20852

Management: Institute of Clinical Pharmacology  
HMR Medical Research  
Four Park Plaza  
P.O. Box 25049  
Nashville, TN 37202-5049

CONFIDENTIAL

Ampligen Protocol 101

3.0 Study Design

This study will be a prospective, double-blind, randomized, placebo-controlled, parallel groups, multicenter study testing the effectiveness of Ampligen versus placebo in patients with AIDS-related complex. Patients will be randomized to receive either Ampligen 200 mg. intravenously twice weekly or placebo (normal saline) intravenously twice weekly until advancement to a diagnosis of AIDS occurs, or until dose-limiting toxicity occurs, or until 9 months have passed. A total of 200 patients will be entered on the trial; 100 patients will be treated with Ampligen and 100 patients will be treated with placebo.

4.0 Patient Selection

4.1 Inclusion criteria

4.11 Homosexual or bisexual men with evidence for AIDS-related immune dysfunction including:

- a. Positive antibody serology for HIV (ELISA test with confirmation by Western Blot)

AMPLIGEN 101 CLINICAL TRIALS  
DIRECTORY OF INVESTIGATORS

As of January 1, 1988, seven clinical sites in six metropolitan areas were registered for participation in the Ampligen 101 study. With the principal investigator listed for each site, they are:

Hahnemann University  
Philadelphia

Dr. David Strayer  
215-448-8157

George Washington Medical Center  
Washington, D.C.

Dr. Gary Simon  
202-994-4200

New York Medical College  
Valhalla

Dr. Gary Wormser  
914-285-8865

St. Luke's Hospital  
New York City

Dr. Michael Grieco  
(contact Ray Roman)  
212-554-7194

Clinical Research Facility  
Atlanta

Dr. James Braude  
404-521-0785

Park Plaza Hospital  
Houston

Dr. Joseph Gathe, Jr.  
713-527-5846

Cancer Biotherapy Associates  
Miami

Dr. Sherman Kay

**Indication:**

**AIDS and some specifically designated cases of ARC**

**Study Protocol: Phase I open study**

**Trial Status: Study Completed**

**Investigators:**

Durack, David : NC  
Broder, Samuel : MD  
Yarchoan, Robert : MD  
Fischl, Margaret : FL

*Trial 3*

**Indication: HIV+ Asymptomatic**

**Study Protocol: Phase II, Placebo Controlled**

**Trial Status: Protocol Final**

**Investigator:**

Volberding, Paul : CA

**Inclusion Criteria:**

HIV+  
PGL (CDC Defined)  
Platelet Count (/cu mm): >100,000  
Hemoglobin (g/dl): >12  
Age: >18

**Exclusion Criteria:**

AIDS / ARC

Treatment Duration: 3 Years

Number of Subjects: 1500

Estimated Start Date: Fall 1987

**Azidothymidine & Acyclovir**

**Manufacturer/Developer:** (ACV) Burroughs Wellcome Co.

**FDA License Status:** NDA (AZT), NDA (ACV)

**General Description:**

(See Package Insert or PDR)

*Trial 4*

**Indication: HIV + Asymptomatic (ATEU 019)**

**Study Protocol: Randomized double blind placebo control**

**Trial Status: Protocol Development**

**Investigator:**

Volberding, Paul : CA

**Inclusion Criteria:**

HIV Antibody: + positive

**Exclusion Criteria: None**

Route(s) of Administration: PO

Dosage: 100-300 mg AZT

Frequency: Q4h (AZT) QD (ACV)

Treatment Duration: 2 years

Number of Subjects: 1600 (400 per arm)

Duration of Trial: Open

Estimated Start Date: summer, 1987

*ACV not  
in 019 from  
ATEU Wash. office  
?*

**Indication: ARC or PGL (CDC classes III or IVA)**

**Study Protocol: Open pilot trial**

**Trial Status: Protocol Final**

**Investigator:**

# PISS & Vinegar

PISS & Vinegar -- the two ingredients necessary to survive and thrive in the gay '90's -- is an occasional newsletter dedicated to polarizing, agitating and offending. Written contributions welcome at : PISS & Vinegar, P.O. Box 21303, Washington, D.C., 20009. Tel. (202) 543-1070. Michael Petrelis, editor.

Issue No. 6, April 1990

---

## A DECLARATION OF WAR!

On March 29, 1990, President George Bush finally got around to delivering his first major speech on AIDS, 14 months after being elected. During the speech, Richard Deagel, a member of ACT UP/New York, heckled and challenged him about his rotten record on AIDS. Urvashi Vaid, director of National Gay and Lesbian Task Force, stood, shouted questions at Bush, and held aloft a gay-positive placard. Both were escorted out by the Secret Service.

The rest of the audience, consisting of business leaders and heads of the major AIDS and lesbian/gay groups, responded politely to Bush. Bush audaciously claimed that the U.S. government's commitment to ending the AIDS genocide was "on a wartime footing." Yep, just like the recent "war" with the tiny island nation of Grenada which saw millions spent to send a handful of military personnel there to oust a Marxist-led government. Bush's AIDS talk is indeed cheap.

The dozens of lesbian/gay and AIDS leaders present for the speech, who ate their rare roast beef and nodded approvingly at Bush, confirmed their roles as collaborators in the AIDS genocide. By their refusal to show an iota of dissent (other than to have a pre-arranged plan to offer up one of their own, Vaid, as the sacrificial lamb), they confirmed their total lack of credibility as AIDS and gay leaders. Couldn't those fucking shitheads realize that if they had all stood defiantly together, in larger numbers than one, the community could have then looked up to them with pride and respect? Instead, the media portrayed the whole event rather coolly, because only two people refused to go silently into that good night.

The day after this shameful occurrence, I got a call from Greg King, media man for the Human Rights Campaign Fund, a euphemistically named group which brags that it is "the largest lesbian/gay and AIDS political organization in the U.S." King told me the reason he and his boss, Tim McFeeley, didn't join Vaid was because they had "to work the press." Work the press? Standing in rightful indignation while the entire press corps was recording the event would far surpass anything that could have been said after it all transpired. Work the press? What about working over Bush?

I hereby declare myself to be at war with every one of the asslicking good gay and lesbian leaders who were inside and silent at that Bush speech. I will do everything within my power to make each one of them regret that in Year Ten of the AIDS genocide, they virtually guaranteed the further annihilation of not only gays and lesbians, but every member of the planet affected by AIDS. Consider this newsletter the first shot.

## BETHESDA OR BUST

Michael Specter, medical/science writer for the Washington Post, is willing to go almost anywhere in the world for a good story. On March 27, 1990, he wrote about his search for an elderly Swedish man who may have been cured of Parkinson's disease after receiving grafts of "several thousand cells from the brain of an 8- to 9-week-old aborted fetus." The story was filed from Lund, Sweden.

Specter mentioned how the U.S. government ban on funding fetal tissue transplant research was hampering worldwide efforts to utilize fetal tissue to treat many illnesses, including juvenile diabetes and Alzheimer's disease. Specter failed to acknowledge AIDS as one of the diseases fetal tissue transplants may help alleviate, but that's par for the course. Specter is one of the worst AIDS reporters in the nation. He's up there with the New York Times's Gina Kolata when it comes to licking the assholes of government AIDS experts.

New York Native publisher Charles Ortleb believes this is because Specter "generally treat(s) government scientists with reverence and government press releases like new chapters from the Bible." (Native, April 4, 1990). I agree with Ortleb.

Other AIDS reporters working for the general press, who are not based in D.C., are doing a far better job of covering the Federal government's negligent response to AIDS. Putting all to shame is John Crewdson of the Chicago Tribune. Crewdson has been digging up damaging evidence against Dr. Robert Gallo, a top AIDS researcher at the National Institutes of Health (NIH), and Gallo's fraudulent claim of being the discoverer of HIV. French scientists may be getting ready to reopen their lawsuit against Gallo, charging him with stealing their research findings -- all because one journalist did his job and didn't accept at face value the claims of government officials.

On November 19, 1989, Crewdson wrote a 16-page special report in the Tribune detailing the tortured history of the quest to find the cause of AIDS. On March 18, 1990, Crewdson wrote a Page One story about an internal coverup at the NIH to withhold 10 pages of a document showing Gallo was not the discoverer of HIV.

The Associated Press on March 20, 1990 ran a story about Crewdson's findings. It ran that day in the Washington Times. The French newspapers Le Monde and Liberation aired the issues on March 22 and 23, respectively. Finally, the New York Times weighed in with a story on March 24. What did the Washington Post write? Nothing -- and Gallo's fraudulent behavior happened entirely in the Post's own backyard.

Many AIDS activists are dismissing the Crewdson stories as old news. They're not old news! If the Federal government is willing to go to any length to keep vital information covered up, simply to protect the ego of one man, it is reasonable to assume it is covering up even more reports and documents.

What does this have to do with Specter and his recent trip to Sweden? A lot. Specter seems uninterested in the many stories begging to be written about Federal AIDS research, or the lack thereof, happening six miles from his office. What will it take to get Specter out to the NIH campus in Bethesda to start asking some hard questions of the bumbling researchers who have managed to spend a billion dollars over the past decade and how they don't have even one drug to show for it?

## STORM THE N.I.H.!

On Monday, May 21, 1990, ACT UP/New York will descend upon the National Institutes of Health (NIH) campus in Bethesda, Maryland to protest the one billion dollars wasted by NIH in its AIDS research program. The program hasn't produced a single drug to fight AIDS.

If you are interested in bringing an end to the AIDS genocide, make plans to be there. And remember to leave your non-violent principles at home.

One suggestion for ACT UP/New York: If you plan to garner decent coverage from the Washington Post, please try to find that elderly gentleman from Sweden who may have been cured of Parkinson's disease and import him to the action. That seems to be the only way to get Post medical writer Michael Specter to leave his desk at the office. For further info on the action, contact ACT UP/New York at (212) 989-1114.

## MEET THE NEW MICHAEL HARDWICK!

Chris Farrell, editor of the North American Man/Boy Love Association (NAMBLA) newsletter was recently arrested for having consensual sex with teenage boys. Farrell thus becomes the Michael Hardwick of the gay '90's. Hardwick was arrested for breaking the Georgia sodomy laws while engaging in consensual sex. He fought his case up to the U.S. Supreme Court, where he lost.

According to the New York lesbian and gay newsweekly, OutWeek, Farrell was arrested at work. The police had a press release ready for distribution as soon as Farrell was booked and they gave advance word to news photographers who captured Farrell's arrest.

Both Farrell and Hardwick were arrested because of outdated laws criminalizing sex between consenting individuals and both faced jail time. The larger gay and lesbian community probably won't make the connection between the two cases. Indeed, a spokesman from the Lambda Legal Defense and Education Fund is quoted in OutWeek saying he thinks intergenerational gay sex "is coercive, and with the exchange of money it is inherently coercive." Farrell is alleged to have paid the teenagers.

Remove the word "coercive" from Lambda's quote and in its place use "recruitment." Does the Lambda spokesman believe gays and lesbians inherently coerce and recruit each other?

I hope that Lambda sees that political persecution is being waged against a sexual dissident group, NAMBLA, and one of its members, Farrell. If they do then they should leap forward to defend Farrell.

After all, didn't Lambda recently defend the right of gay men to have consensual sex at a public rest stop on the New Jersey Turnpike? If Lambda can defend the right of gay men to engage in sex at a public toilet, they must also defend the rights of gay men and boys to enjoy consensual intergenerational sex unfettered by the police.

## HAIL, THE GAY DAN QUAYLE!

In the March 30, 1990 Washington Blade, Tim McFeeley, executive director of the Human Rights Campaign Fund, confirmed his role as the Dan Quayle of the gay and lesbian rights movement.

In the column, "To the Point," McFeeley is quoted as saying, "I'd like to see sodomy laws repealed, but I wouldn't spend any resources on it. When you go head-on against sodomy laws, you keep sex on everybody's mind. That's the dialogue of Jesse Helms and William Dannemeyer. That's exactly the battlefield they want to take you on." Me too.

If the leader of the largest gay and lesbian political organization isn't willing to work his butt off to overturn sodomy laws, who is? How can he be sure that a head-on fight against sodomy laws isn't what the little people of the community want, regardless of whether or not it is the agenda of rabid homophobes? Witness the nearly one thousand activists who protested and focused attention on the Georgia sodomy laws this past January in Atlanta.

The same issue of the Blade contains an article about ways to fight anti-abortion and anti-gay and lesbian forces. McFeeley urges "gays to support a potato boycott (against anti-abortion Idaho) if the pro-choice forces call one." Gee, McFeeley is comfortable keeping sex on people's minds with the abortion issue, but he won't expand his agenda to include fighting sodomy laws.

I wish McFeeley would learn a lesson from the pro-choice movement and organize a boycott of Georgia peaches as a way to send the message that gay and lesbian people will not tolerate that state's sodomy laws. But like Quayle, McFeeley is mediocre and lacks vision.

The gay and lesbian community deserves better leaders in its quest for equality.

## CDC Ranks New AIDS Cases

Listed below are the twenty major metropolitan areas in the United States with the highest rate of AIDS cases in 1989. The rate indicates the number of new AIDS cases in 1989 per 100,000 population. The numbers are official figures from the Centers for Disease Control. The CDC itself estimates its numbers underestimate the true incidence of AIDS by twenty percent.

Rank	Rate	Rank	Rate
1. San Francisco, CA	109.1	11. Houston, TX	25.5
2. San Juan, PR	78.0	12. Austin, TX	24.5
3. New York, NY	57.5	13. Washington, DC	23.3
4. Jersey City, NJ	55.2	14. New Orleans, LA	22.5
5. Newark, NJ	50.0	15. Jacksonville, FL	21.6
6. Ft. Lauderdale, FL	49.9	16. San Diego, CA	21.4
7. Miami, FL	49.6	17. Dallas, TX	20.7
8. West Palm Beach, FL	40.8	18. Baltimore, MD	20.3
9. Atlanta, GA	31.2	19. Las Vegas, NV	20.2
10. Los Angeles, CA	26.8	20. Seattle, WA	19.6

## The New ACT UP Washington

call us today (202) 667-0045

ACT UP meets every Tuesday at 7:30 PM

at the AIDS Resource Center

1337 14th Street Northwest

(between N and Rhode Island)

### Committees and working groups

- \* **McClintock/Manhattan style Project**
- \* **Needle Exchange Committee**
- \* **Harm Reduction**
- \* **Treatment Activists**
- \* **Health Care Working Group**
- \* **DC Caucus**
- \* **Maryland Caucus**
- \* **Virginia Caucus**

Until there is a cure available to all, there is ACT UP Washington

## The campaign for Single Payer, single tier, Canadian style Universal Health Care

ACT UP Washington members Steve Michael and Scott MacLarty attended a series of meetings with Minnesota Senator Paul Wellstone along with other organizations throughout the fall. Senator Wellstone is the author of Senate Bill 491, the Single Payer alternative to Clinton's wretched plan (also known as the "Insurance Company Preservation Act of 1993") and the even wretcheder plans offered by Republican opponents.

Single Payer has been nearly censored from the public debate about health care reform, and the proponents of non-Single Payer plans have lied to the public about the Canadian Single Payer System, calling it a failure, when, in fact, it is extremely popular. The care Canadian PWAs receive is vastly superior to that of their brothers and sisters in the US. Dr Michael M. Rachlis, an epidemiologist from Toronto, told us that PWAs on welfare who need a catscan receive it immediately.

We met Dr Rachlis at the October 19 hearing on Single Payer before a Subcommittee of the Senate Committee on Labor and Human Resources (attending: Senators Wellstone, Metzenbaum, Jeffords, and Harkin). Michael, MacLarty, and Wayne Turner showed up and submitted written testimony in favor of Single Payer.

What we need now is a grassroots movement to push for Single Payer. The insurance and other lobbies have bought their influence, to the tune of hundreds of thousands of dollars, in Congress and the White House; all we have is our voices and votes.

We also urge people and organizations to contact Senator Wellstone's office, attend meetings, and mobilize friends and membership/dists. (Why the silence from HRCF, on record as an endorser of Single Payer? Where are our major AIDS lobbies? Isn't the health of all our people at least as important as the military ban on queers, if not more so?) One aspect of the Clinton plan which may cause many Single Payer advocates

## The Barbara McClintock Project to Cure AIDS

The McClintock Project is ACT UP's proposal for an intense research effort to find a cure for AIDS. These are some of the features essential for honest, creative and rapid research:

McClintock would bring a team of **diverse researchers together in one central location** in an area with a high incidence of AIDS. They would come from a wide variety of backgrounds, from virology to nutrition, and would interact regularly, for maximum creativity and "cross-pollination" of ideas.

The Project would have two main goals: to do **basic research** into the pathogenesis of AIDS (how AIDS actually damages the body), and to **identify and develop curatives**, either new or existing.

The Project would examine **all theories** about the development of AIDS, not just the current NIH model, and study **all affected populations**.

In order to assure an honest, objective approach, researchers would **suspend all conflicts of interest** for the duration of the Project, and be employed only by the McClintock Project.

McClintock would have the power of **eminent domain** to ensure that all promising approaches are pursued as quickly as possible. If a drug company refused to adhere to an approved timetable, the Project would buy the patent and develop it itself.

**All curatives released primarily due to the McClintock Project would be made available to everyone, regardless of ability to pay. Could we live with anything less?**

### Why the NIH will never find a cure for AIDS

**Drug companies dominate research.** Most researchers at the National Institutes of Health (NIH) are also paid consultants for drug companies or hold stock in them. They decide which drugs get tested, and what type of research is pursued. The result: profits compete with science, and we're stuck with expensive, lifelong treatments.

**No New Ideas:** Since the NIH is rife with conflicts of interest, creative thinking is stifled. Research into therapies that won't be profitable is not done. Alternative or non-drug approaches to healing are not pursued since the NIH is dominated by drug companies. Basic research to understand the course of AIDS is not done unless it's likely to lead to a marketable drug.

**The "Old Boy Network":** Research grants are awarded through a system of secret, competing proposals, submitted by investigators to the NIH, and reviewed by their colleagues. A primary goal of these proposals is to get money to pay their university's electric bill or expand the campus. Innovative proposals that may unlock the secrets of AIDS are not submitted to the NIH because they aren't assured approval and won't further careers.

**The Absolute Power of Drug Companies:** If a company wants to stall or abandon a patented drug, or even a cure, the NIH is powerless to do anything about it. That's why ACT UP targeted Hoffman-LaRoche. NIH researchers were begging for samples of Roche's important new drug, the "tat" inhibitor, but Roche refused. The Government's hands were tied. We chained our bodies to Roche's gates. We still don't have the drug.

### A brief look at the McClintock Project

The **Barbara McClintock Project to Cure AIDS** will be separate from the NIH and report to (but not directed by) the President through the "Special Assistant on AIDS", and will have the following mandates:

1. To find a cure for AIDS, with cure being defined to include "any and all..."

thousands of dollars, in Congress and the White House; all we have is our voices and votes.

We also urge people and organizations to contact Senator Wellstone's office, attend meetings, and mobilize friends and membership lists. (Why the silence from HRCF, on record as an endorser of Single Payer? Where are our major AIDS lobbies? Isn't the health of all our people at least as important as the military ban on queers, if not more so?) One aspect of the Clinton plan which may cause many Single Payer advocates to compromise and join Clinton is that it allows individual states to opt for a Single Payer system. We caution such advocates that insurance companies and other lobbies have even more power and influence at state and local levels, and we should press only for Single Payer. Don't make concessions before the battle even begins!

### Medical marijuana a demand of ACT UP's

## DC, Philly and NY unite to sponsor White House Vigil

ACT UP's Philadelphia, Washington and New York, have organized two events for the November 13-14 weekend: a candlelight vigil at the White House demanding an end to the "drug war" on Saturday, November 13, at 6 p.m.; and a rally at the FDA on Sunday, November 14, at noon, for Harm Reduction, with the following demands:

- Availability and access to clean needles.
- Equal access to experimental AIDS drugs for women.
- Availability of herbs, vitamins, and supplements.
- Availability of ibogaine, a treatment for cocaine and heroine addiction.
- Removal of marijuana, the use of which has proven beneficial in alleviating certain AIDS symptoms and other health problems, from classification as a "hard drug."
- Stop the ill-conceived and fatal drug war!

The FDA's address is 5600 Fisher Lane, Rockville, Maryland, two blocks east of the Twin Brook stop on the Metro red line. ACT UP Philly promises music and speakers. This action is extremely important, so PLEASE be there! For further information from ACT UP Philly, call (215) 731-1844.

### Activists distributing more needles than DC government

## Michael Singerman coordinates new DC Needle Exchange program

ACT UP has reinstituted needle exchange among intravenous drug users, taking over for the city's current lapse. Washington has a stunted pilot needle exchange program for thirty-five addicts who are also in rehabilitation. Someone should notify Mayor Kelly that there are a lot more than thirty-five junkies in DC.

ACT UPsters Michael Singerman, Sabrina Green, and Andrew Williams have set up tables providing the necessary works around the corner from shooting galleries and crack houses in a number of different neighborhoods. We're hoping these efforts will goad and shame the city into initiating a comprehensive program to save people's lives, as have the cities of Seattle, Tacoma, Washington and New Haven, Connecticut.

Needle exchange has been proven to diminish the rate of HIV transmission. Furthermore, the only effective needle exchange is on the street. Junkies are unlikely to travel downtown to a government building and risk exposure and arrest.

The amount of money for such programs is microscopic compared with what the costs will be to the city to care for needle users with AIDS.

## A brief look at the McClintock Project

The Barbara McClintock Project to Cure AIDS will be separate from the NIH and report to (but not directed by) the President through the "Special Assistant on AIDS", and will have the following mandates:

1. 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.
  - a. to pursue any and all basic science investigations, based on diverse theories and schools of thought, which elucidate the pathogenesis of AIDS.
  - b. to identify all promising cures and to oversee their timely and adequate testing.
2. In order to work in the most efficient manner possible, free of private interest and red tape:
  - a. All primary research staff will work at one central location, interacting with researchers around the world.
  - b. The NIH's existing AIDS research programs will be maintained, and any NIH research on AIDS basic science will be performed cooperatively with the Project.
  - c. All staff shall be employed only by the Project and may not have conflicts of interest with private organizations such as universities, pharmaceutical companies, private research organizations, etc.
  - d. The Project will be funded by public monies.
  - e. The Project will be governed by a council composed of scientists and clinicians representing divergent approaches, people with AIDS and HIV from all affected communities and their advocates.
3. To ensure that research is diverse and open:
  - a. Equal consideration shall be given to conventional and other medical approaches and scientific theories, and researchers will represent divergent approaches.
  - b. The Project will focus on all people with AIDS and HIV, at all stages of illness, including children, women, gay men, lesbians, people of color, injection drug users and people with inadequate medical care and/or nutrition.
  - c. Project results shall be freely available with being delayed by the restrictions of professional publication practices.
  - d. Curatives released primarily due to Project research shall not result in financial gain and shall be made available to all affected people regardless of ability to pay.
4. The Project will have extraordinary powers to:
  - a. direct and fund the utilization of Government research entities to clinically test promising curatives developed on the basis of its research.
  - b. exercise the right of eminent domain to:
    - obtain from public and private organizations, with just compensation, samples of all potential curatives, all data, and all relevant materials,
    - implement clinical testing for curatives under development by private companies unless they adhere to an approved time frame and are forthcoming with their data,
    - use existing pharmaceutical company facilities, with just compensation, for the production of curatives needed for Project research and, if effective, to produce such curatives in sufficient amounts for all people needing them.

To reflect the values necessary to end AIDS, ACT UP has named this project after Barbara McClintock, a research geneticist who discovered a revolutionary premise underlying DNA replication. Her approach, intense commitment, and her focus on divergence rather than the norm should be the model for AIDS research.

### Join us in implementation of the McClintock Project

McClintock was recently introduced in the US House of Representatives as HR 3310

To help implement McClintock contact ACT UP Washington at (202) 667-0054

Help us Lobby, Congress, AIDS Organizations, Gay and Lesbian Advocacy groups