Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. form	re: Correspondence routing slip (Personal) (1 page)	05/12/1997	b(6)
001b. letter	Individual living with AIDS to Dianne Feinstein re: Ricky Ray Hemophelia Relief Fund Act (Personal) [partial] (2 pages)	05/07/1997	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office

OA/Box Number: 19394

FOLDER TITLE:
Correspondence - SLT - Incoming - 5/97 [Folder 1] [3]

2018-0764-F
jm2039

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3745

Date Rcvd: 05-12-97

From: Jerald A. Braudman

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

n:\corresli

Jerald A. Breitman
15 Innisfree Drive
Durham, North Carolina 27707

May 7, 1997

Sandy Thurman
Director
National AIDS Policy Office
808 17th Street NW
Eighth Floor
Washington, DC 20006

Dear Sandy:

Congratulations on your appointment as Director of the National AIDS Policy Office, although I prefer the title of "Czar." What a wonderful opportunity to make a difference in this modern day scourge. While I know that you are leaving the "best job in government" to take on this new assignment, there is no doubt that you will make this the best job in government. I, for one, am immensely pleased that you are there and have renewed confidence that we will meet the challenges of the future effectively.

This is such a dynamic and important time in the pandemic. As therapies advance and the potential for improved outcomes offer new hope for many, it will be important to help the nation focus on the realities that the war is far from won. In many ways, your challenge is made even greater by hope than your predecessors was from despair.

I am confident that you are more than equal to the challenge. If I can help in any way, I know you will feel free to call on me. In the interim, good luck.

Sincerely,

Jerald A. Breitman

15 Innisfree Drive
Durham, NC 27707-5069

Personal (919) 493-5443
Business (919) 419-1441
Fax (919) 419-0494

e-mail: jabreitman@aol.com

PROCEPT

Procept, Inc.
840 Memorial Drive
Cambridge, MA 02139
TEL: 617-491-1100
FAX: 617-491-9019

Contact: Stanley C. Erck
President and CEO
Procept, Inc.
(617) 491-1100

Karen M. Goldman (media)
INFOCUS, Inc.
(609) 683-9055

For Immediate Release

PROCEPT'S TOPICAL MICROBICIDE AGAINST HIV SHOWN TO BE CONTRACEPTIVE

Data Complement Anti-STD Activity Of PRO 2000 Gel

Cambridge, MA, May 8, 1997 -- Procept today announced preclinical results demonstrating the contraceptive efficacy of its PRO 2000 topical microbicide gel. In a program of late-breaking discoveries presented at the National Conference on Women and HIV in Pasadena, CA, Procept scientists described the results of studies recently conducted with PRO 2000.

The *in vivo* results showed that PRO 2000 was contraceptive when rabbits were dosed intravaginally with a gel containing a 4% concentration of PRO 2000. At a concentration about 10 times lower, PRO 2000 did not appear to effect the rabbit pregnancy rate. Results of preclinical tests have indicated that both concentrations prevent HIV infection, suggesting that contraceptive and non-contraceptive formulations of this drug may be developed.

"The potential of this compound as an advancement in the area of women's health is significant", said Stanley C. Erck, president and CEO of Procept. "We believe that the contraceptive properties demonstrated by PRO 2000 Gel will compliment the anti-HIV/STD activity we will be evaluating in clinical trials."

More than 70% of all HIV infections worldwide follow heterosexual intercourse. A major problem confounding efforts to prevent AIDS in women has been the lack of effective, female-controlled barrier methods. PRO 2000 Gel has been identified as a topical microbicide well suited for use by women to prevent HIV infection. In laboratory studies, PRO 2000 blocked infection by a wide variety of HIV strains and also was active against herpes simplex virus.

Clinical studies are currently underway to assess the safety of PRO 2000 Gel in healthy female volunteers. Assuming the results of these studies are positive, additional studies will be conducted to demonstrate safety and efficacy in populations at high risk for HIV infection.

Procept, Inc. is engaged in the discovery and development of small molecule therapeutics for the prevention and treatment of chronic and life-threatening immune system disorders. The Company's research is based upon its understanding of critical cell receptors responsible for modulating immune responses. Procept is developing therapeutics for the treatment of arthritis, diabetes, organ transplant rejection and infectious diseases, including AIDS and tuberculosis. Procept was founded in 1985 and is traded on the Nasdaq National Market System under the symbol PRCT.

POSTAL UPDATE

May/June 1997

From The Postmaster's Desk . . . .

Help Us - Take a Bite Out of Crime

Almost every day of the year U.S. Postal Service Letter Carriers visit your neighborhood and deliver important pieces of mail which assist you in your financial transactions. Unfortunately, criminals sometimes target the Letter Carrier for robbery of their personal funds. When this happens the letter carrier as well as the neighborhood is traumatized.

It is a Federal crime for a letter carrier to be assaulted or robbed while delivering mail in your neighborhood. The likelihood of a Letter Carrier being robbed while delivering mail is small, but unfortunately, it can happen.

The Postal Service delivers millions of valuable items every day. Criminals know this and are ready and waiting to steal your mail when the time is right. They break into mailboxes, collection boxes, and postal vehicles.

Never send cash or coins through the mail, always send a check or money order. Make sure your mailbox is in good condition. Mailboxes in poor condition often expose mail to theft or bad weather. Collect mail from your mailbox as promptly as you can. If you can't be home when checks or other important mail is expected, ask a trusted friend or neighbor to pick up your mail. Also, contact your local post office about holding your mail for you during vacations or other long absences from home.

The Postal Service works hard to make sure your daily mail gets to you safe and sound. But we need your help. By following a few tips, you can make life a little harder for mail thieves.

If you notice any suspicious activity in your neighborhood, contact the local Police and also the Washington Division, Postal Inspection Service at (202) 636-2323.

David A. Clark
Postmaster

Loose Dogs and Letter Carriers Don't Mix

Whatever the reasons for them, dog bites are a serious problem for letter carriers trying to deliver your mail.

The Humane Society estimates that between two and three million dog bites are reported to local authorities each year.

Dog bites range from painless nips to fatal maulings. Children are most often the victims. Dog attacks are the most commonly reported childhood public health problem in the United States. Dog bite victims account for up to five percent of all hospital emergency room admissions.

You may feel confident that your dog won't add to these statistics, and it is probably true that your trusty companion will never seriously harm anyone.

However, if your dog attacks or bites someone, including your letter carrier, you could be liable for the victim's pain, suffering, and medical costs. There are several ways you can reduce that liability. Reducing the likelihood that your dog will ever bite someone helps protect you, your canine companion, and everyone else in the community.

Unfortunately, our employees still face dangerous incidents. Nationally, last year, over two thousand letter carriers were attacked by dogs, many of which, according to their owners, "wouldn't hurt a fly".

Please be a responsible pet owner. Keep your dog inside, away from the door, or restrained when your letter carrier arrives.

Dog bites are a serious problem, and the solution is in your hands. Help the United States Postal Service deliver safely for you!

Lamond-Riggs Opens Window Service Operations

The Lamond-Riggs Station, located at 6200 North Capital, Street, NW, which serves the 20011-20012 Zip Code areas, now has full retail service.

The station, which has been undergoing renovations to include a retail lobby that can provide full window services, is now open for business.

The hours of operation are 8:30 am until 5:00 pm, Monday thru Friday, and Saturday 8:30 am to 2:00 pm.

We would like to thank the residents of the Lamond-Riggs area for their patience during the renovation period.

Postal Stores Open For Business

Project Fix-Up has brought a new look to postal lobbies in Washington, D.C. Most of the post offices have the Postal Store concept. This concept was piloted in the late 1980's, and is designed with customer convenience in mind.

Postal Stores feature open merchandising, where customers can browse and purchase prepackaged stamps and philatelic products from wall displays.

In the QuickPost self-service area, vending equipment allows customers to weigh items, purchase postage and mail items without ever having to stand on-line.

Northwest Station - Grand Opening Celebration

On Friday, May 23 at 11:00 am, the Washington, D.C. Post Office, along with the Mr. Beasley Stamp Club, and the residents of the surrounding neighborhoods, will celebrate the opening of the newly renovated Northwest Station, located at 5632 Connecticut Ave., NW.

In conjunction with the opening of the station, the issuance of the Bugs Bunny Stamp will be commemorated.

We will offer a special pictorial postmark for the grand opening, and for the Bugs Bunny stamp.

Come out and join the celebration, light refreshments will be served.

Postal Update
Vol. 6 Issue 3

David A. Clark
Postmaster
Luvenia Broussard
Editor

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Send comments to:
Postal Update
900 Brentwood Rd NE
Washington DC 20066-9998

Postal Update
WASHINGTON DC POST OFFICE
900 Brentwood RD NE
Washington DC 20066-9998

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2018-0764-F
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Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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COLLECTION:
Clinton Presidential Records
National AIDS Policy Office

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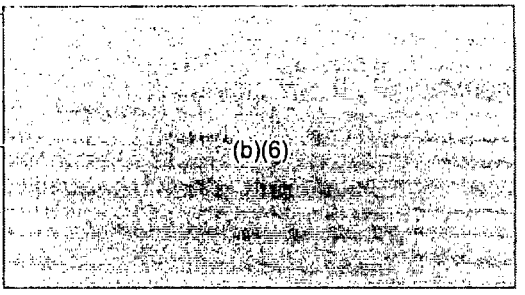

5-7-97

Senator Dianne Feinstein
11111 Santa Monica Blvd.
Ste. 915
Los Angeles, CA 90025

Dear Senator,

I am writing to ask for your support of "The Ricky Ray Hemophilia Relief Fund Act of 1997" – S.358/H.R. 1023.

The following is a very brief personal history:

47 year old hemophiliac (Severe "A") male, married with one son, aged 14. I have been HIV positive since 1984 (My current "T-Cell" count is only 55!) I contracted the HIV virus through contaminated "Clotting factor" given as routine treatment for hemophiliacs. Even though I am a California licensed optician the HIV virus has caused me to sell my practice and due to my weakened state I am unable to work. This leaves my wife as sole support of our family.

My family and I desperately need your help and

support on this matter. We keep asking for help and yet none comes!

Every month that is delayed puts us further into debt!

Please, please help us pass "The Ricky Ray Hemophilia Relief Fund Act of 1997" - S. 358 / H.R. 1023

Thank you for your time and help.

Sincerely,

(b)(6)

cc: President Bill Clinton
Vice President Al Gore
Speaker of the House Newt Gingrich
Senator Barbara Boxer
Representative Elton Gallegly
Director of AIDS policy Sandy Thurman

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3774

Date Rcvd: 05-20-97

From: Various Signatures (Edward M. Kennedy)
Ltr. adressed to David Satcher cc: Sandra Thurman

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

_____

Recommendations/Instructions:

_____

_____

_____

To Support Staff:_____

Date of Response:_____

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(12)

CONGRESS OF THE UNITED STATES
WASHINGTON, D. C. 20515

David Satcher, M.D.
Director, Centers for Disease Control and Prevention
1600 Center Road, NE
Atlanta, Georgia 30333

May 15, 1997

Dear Dr. Satcher:

We are writing to express our grave concerns with the decision of the Centers for Disease Control and Prevention, and the process by which this decision has been reached, to cut the HIV prevention funding for six small minority community-based agencies in Massachusetts. This cut represents a 75 percent reduction (a reduction of $1.5 - $1.8 million) of the CDC's support to these important organizations in the Commonwealth.

As you know, these cuts were announced in two stages. Four programs were notified one month ago that defunding seemed likely. At that time, two other agencies -- Hispanic Office of Planning and Evaluation (HOPE) in Jamaica Plain and Massachusetts Alliance of Portuguese Speakers (MAPS) in Somerville, Lowell and New Bedford -- were informed that they were among the finalists for continued funding. In spite of positive feedback about these organizations from the Massachusetts Department of Public Health, high-ranking in the application review process and a seemingly optimistic message during a CDC site visit, these two agencies suddenly were moved to the list of the defunded as well.

Federal and state support for these agencies is vital to their existence. In addition to paying for important prevention efforts to high-risk populations of color, these agencies used the indirect and administrative portions of their CDC grants to support general operational costs, such as rent and the salary of the executive director. In fact, for each of these six agencies, the CDC funding represented between 25 - 33 percent of total agency funding. Each was given 60 days notice that this support was going to be eliminated.

We have concerns about this process of defunding small agencies which provide vital services to hard-to-reach communities. The ill-effects of these sudden cuts have already been experienced in our state: funding for a Haitian-oriented agency in Cambridge, the Haitian American Cultural Center, was cut by the CDC three years ago. The cuts put the organization into a financial tailspin from which it never recovered, and within six months, the agency was closed. The Haitian community in Cambridge -- which has been affected by AIDS in disproportionate numbers -- now has no indigenous organization to conduct HIV-prevention and education activities. Limited activities to target the Haitian community were begun at Cambridge Cares About AIDS, but this agency's funding was cut in the most recent round. In addition, this round will see an end to funding for the Boston-based Haitian American Public Health Initiatives. Funding for three Latino organizations -- two in Boston and one in Springfield -- was also cut at a time when cases of HIV-infection among Latinos in Massachusetts are soaring.

The Massachusetts Health Department and the CDC-mandated Massachusetts Prevention Planning Group have both expressed their displeasure with the decision-making process and their exclusion from meaningful participation. We urge your office to work with these agencies and us to ensure a smooth transition process when federal funds are reduced: clearly, the current process is not in the interest of the good public health policy, the credibility of the CDC, the financial status of the Massachusetts Department of Health and especially the eradication of HIV infection among at-risk communities. The current short time frame of the notifying small agencies of defunding is undermining their financial viability.

We propose an alternative approach that would cap the loss to any state in a given year while CDC prevention funds are reallocated throughout the country. At this juncture we would also call upon CDC to reverse the decision on the two most recent agencies just added to the defunding list and to lengthen the phase-out period from 60 days to 6 months.

The CDC and you personally have provided heroic leadership in the efforts to prevent HIV transmission. We strongly urge the CDC not to undermine such efforts.

Sincerely,

Edward M. Kennedy

John F. Kerry

Richard E. Neal

John F. Tierney

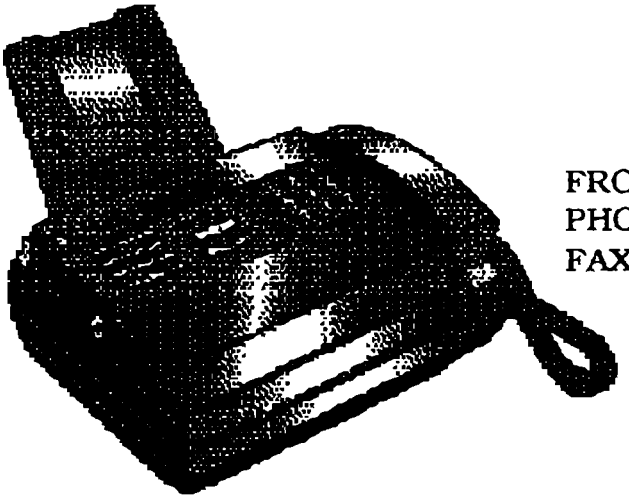
Barney Frank

Joseph P. Kennedy II

William Delahunt

cc: Dr. Helene Gayle, Director of National Center for HIV, STD &TB Prevention
Sandra Thurman, Office of National AIDS Policy

FROM GENEVIEVE'S FAX TO



FROM: Geneviève M. Clavreul
PHONE: (818) 398-8585
FAX: **(818) 398-5664**

YOUR FAX

May 19, 1997

TO: Ms. Sandy Thurman **c/o Mr. Daniel Montoya**
PHONE: (202) 632-1090
FAX: **(202) 632-~~1615~~** 1090

25 Pages including this header.

Message:

PLEASE DELIVER TO MS. THURMAN

PO BOX 867
Pasadena, CA 91102-0867

C3

Geneviève M. Clavreul
PO Box 867
Pasadena, CA 91102-0867
(818) 398-8585

May 19, 1997

Ms. Sandy Thurman
Office of National AIDS Policy
808 17th Street NW
8th Floor
Washington DC 20006

Via Facsimile

Dear Ms. Thurman:

I am writing to you today at the request of your scheduling staff. I received your response to my request for an appointment while I was in Washington DC last week, and I can understand that given the short notice for you and your already growing list of obligations and meetings that last week just wasn't the best of times. However, when I called this morning to attempt to schedule a meeting for my next trip to Washington DC, I was surprised to be given instructions that my request should be in writing with an explanation of my reason for the meeting.

I will be in Washington DC to attend a meeting on June 5th, so as your staff person request I would like to requested an appointment for either Wednesday, June 4th or Friday, June 6th. As we discussed at AIDSWatch '97 and at the National Women's Conference in Pasadena, it would be advantageous for the two of us to set aside some time to meet and continue our discussion.

I have attached some articles and letters regarding my work and involvement in the fight against HIV/AIDS. Please do not hesitate to call me if you have additional questions.

Sincerely,

Geneviève M. Clavreul, Ph.D.

GMC/cme

encl.: letter from Dr. Gallo (2)
articles (11)
- AIDS Experts and Clinicians are Settling in for the Long Haul
- Health Experts Share Research Findings at AIDS Summit
- WIN-AIDS Creates Hi-tech Network for Linking Researchers, Clinicians
- Who Do You Trust?: Self-Apointed Experts Further Confuse the Issues Surrounding HIV
- Lesbians and AIDS – The Overlooked Statistics
- Minimizing the Impact of AIDS on the Nursing Shortage
- Battling the Body Snatchers
- Are Women and Children Expendable? -- The Untold Dangers of HIV and Breastmilk
- A Future with AIDs: Prolonging the Quality of Life -- A Treatment Tool for RNs, Part 1
- AIDS Workers Going for Computer Link
- Misdirection: AIDS Research, the Government and AmFAR
- AIDS -- Has the Human Species Met Its Match?

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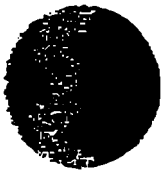
INSTITUTE OF HUMAN VIROLOGY



Medical Biotechnology Center
University of Maryland Biotechnology Institute
University of Maryland at Baltimore
725 W. Lombard Street, Fifth floor
Baltimore, MD 21201
(410) 706-8614; FAX (410) 706-1952

Dr. Robert Gallo
Professor and Director

May 8, 1996

To Whom It May Concern:

This letter is to introduce Dr. Geneviève M. Clavreul, International Consultant for the International Cancer and AIDS Research Foundation, ICARE. In addition, she is the designated representative and project developer for the Institute of Human Virology, West Coast.

When needed she will arrange for members of the Institute team or myself to attend meetings that will further the cause of the Institute. She is also the individual to contact in order to organize meetings and conference calls for me vis a vis the West Coast.

If you have any questions please do not hesitate to contact me at (410) 706-8614 or Dr. Clavreul at (818) 398-8585.

Sincerely,

Robert C. Gallo, M.D.

cc: Dr. Geneviève M. Clavreul
The Honorable Robert K. Gray
Mr. Jim Jennings

COPY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Bldg. 37, Room 6A11
37 Convent Dr MRC 4255
Tel: 301/496-6007
Fax: 301/402-1338

November 29, 1994

TO WHOM IT MAY CONCERN:

There are very few persons who know the history of the discovery of HIV, the scientific background prior to the discovery, and the subsequent work which led to our understanding that HIV is the cause of AIDS, and who know as well the people who made these discoveries, and the surrounding details of these events. There are still fewer who know these things from both sides of the Atlantic. Genevieve Clavreul is one such person. Ms. Clavreul has known both Profs. Montagnier and Gallo virtually from the start of this research and I believe she can and will contribute to a truthful and interesting history.

Sincerely yours,

Robert C. Gallo, M.D.
Chief
Laboratory of Tumor Cell Biology

News Analysis

AIDS Experts and Clinicians are Settling in for the Long Haul

This year's conference was marked by gritty determination and the epidemic's human side. Researchers have more pieces of the puzzle in hand—but not the grand design.

Stockholm, Sweden—As tenacious and as entrenched as the virus they combat, the investigators who gathered here for the Fourth International Conference on AIDS are already planning their summer itineraries through 1994.

The researchers will span the globe during the next six years—traveling from Montreal in 1989 to San Francisco; Florence, Italy; Boston; a city in Germany; and, in 1994, a country in Asia—to synthesize their experience in fighting the human immunodeficiency virus in its many manifestations.

Faced with a virus that eludes immune surveillance by finding shelters in the brain and bone marrow, travels silently via macrophage, and coats itself to evade targeted attacks, AIDS researchers and patient advocates have committed themselves to the long haul.

Progress now is "incremental," say veterans like Dr. James Curran, the CDC's director of AIDS programs. The era of "dramatic advances is over," Dr. Robert Gallo said at the opening ceremony of this year's conference. The pace has become more typical of science—slow and steady.

Dr. Gallo, head of the National Cancer Institute's tumor cell biology laboratory and co-discoverer of the AIDS virus, did not foresee any major announcements at the Stockholm meeting "unless [there's] a secret."

His prediction held true. But there were intimations of new directions for drug treatments based on increased understanding of viral structure, reasons to be more optimistic about immunomodulatory efficacy, and hints that viral takeover can be aborted even after infection occurs.

This year's sessions started to target practical clinical concerns as the quilts reminded attendees of the disease's human toll.

On a more discouraging note, researchers warned that vaccines could raise antibodies that activate HIV infection, and no reports of clinical success with any vaccine approach were presented.

Altogether, more than 7,000 delegates from 140 countries elucidated pieces of the AIDS puzzle in more than 3,000 oral and poster presentations, making the Stockholm meeting the largest of the international AIDS gatherings to date. And there were signs everywhere that scientific "secrets" and competition are giving way to global information networks.

Cooperation. The World Immunological Network (WIN) AIDS data base and hot line was officially launched during the conference. It already boasts more than 60 subscribers throughout the world and can link academic, commercial, and federal research laboratories in the U.S. with one another and with their counterparts abroad.

Earlier this year, France's Luc Montagnier expressed his desire to participate in the network. Dr. Montagnier, co-discoverer of the AIDS virus with Dr. Gallo, noted that researchers in France and elsewhere in Europe are eager to "exchange scientific information with our American colleagues, especially Dr. Gallo and his team."

During the course of the conference, researchers scoured another electronic communications network in order to arbitrate a clinical discrepancy. British researcher Anthony Pinching, of St. Mary's Hospital Medical School in London, reported what he called an "unpredicted" finding of precipitous myopathy among 10% of patients on long-term therapy—defined as more than 100 days—with zidovudine (Re-

continued

evolved into a "conference within a conference" during program planning, according to Dr. Kallings, who also is chairman of the Swedish National Bacteriological Laboratory.

Each day, the "Face of AIDS" sessions took place at a time that was allotted for poster viewing but did not conflict with the nine simultaneous workshops or roundtables that also took place each afternoon. The "Face of AIDS" sessions could also be viewed on dozens of closed-circuit television sets scattered throughout the poster areas.

The only formal complaint lodged against the organizers—by a gay and lesbian caucus formed during the conference—related to the absence of HIV-infected persons from the speakers' rostrum, an oversight that planners said would not be repeated next year in Montreal.

The main conference's sessions represented virtually all AIDS-related interests, encompassing both the "harder" science and the "softer" prevention and psychosocial issues.

At various points in planning the meeting, Dr. Kallings noted, some suggested that the conference be split in two to reflect these "hard" and "soft" issues. But the prevailing philosophy was that neither half could do without the other.

The sessions were divided into nine categories, with the greatest number of abstracts falling under the clinical management category. This reflected the need for clinicians to dig in and deal realistically with HIV-infected patients' everyday and emergency health problems despite the lack of any imminent vaccine prospect or a surefire and nontoxic drug regimen.

Coming coverage. The incremental accumulation of knowledge of how the virus works and potential strategies to subdue it—including vaccine prevention of initial infection, chemoprophylactic prevention of viral takeover after infection, and specific regimens for symptomatic patients—will be reported in the next issue of MWN.

—FRAN POLLNER

Southern California
NURSING
News, Continuing Education and Career Guide
NEWS

COPY

Health experts share research findings at AIDS Summit

By Genevieve M. Clavreul, RN, PhD

The June International Conference on AIDS held in Stockholm, Sweden was not characterized by any fantastic breakthroughs. A total of 3,100 abstracts were accepted for presentation, and 140 countries were represented by participants. As of the 1st of June 1988, a total of 96,433 cases of AIDS have been reported.

Compared with the last international AIDS conference (held in Washington), there was less of a Patients with AIDS (PWA) presence at Stockholm and less camaraderie among the participants (perhaps due to the more scattered hotels and the conference center being outside of the city). In addition, gay activists perceived a level of homophobia that had not been present at previous conferences. However, the scientific community demonstrated a renewed commitment to meet the challenge of the AIDS retrovirus. For this writer, the most rewarding part of the conferences was the informal, unplanned evening networking, where scientists willingly shared the results of their research. The collaboration between Drs. Gallo and Montagnier and other leading scientists was notable. As was stated by Dr. Luc Montagnier, "In implementing programs, we are learning lessons that need to be learned. We are seeing the inadequacies of existing systems. AIDS is a danger, but it is also an opportunity . . . to see where in the past we have failed, to gain new insight into circumstances, to find the way to succeed." Dr. Robert Gallo stated, "While we know little about the origin of the virus, we know even less about the pathogenesis and practically nothing about the therapy of the disease. And yet the pressure is on us to

See *AIDS Update* on page

Left to right: Drs. Luc Montagnier, Genevieve M. Clavreul, and Robert Gallo

SOUTHERN CALIFORNIA NURSING NEWS AUGUST 1988

AIDS Update

COPY

WIN-AIDS creates hi-tech network for linking researchers, clinicians

Continued from page 1

move in this direction."

Primary concerns addressed at the conference included the spread of AIDS into the heterosexual community via IV drug users and bisexual males, as evidenced by the more studies focusing on AIDS in women and infants; the neurological effects of AIDS; and extreme emphasis on AIDS and minorities and upon prevention.

The situation in Africa continues to be a serious one. Dr. Bosenge N'Galy of the Department of Public Health in Zaire described the distribution of HIV-1 and the emerging epidemiology of HIV-2 in his country. Each country in Africa appears to have a distinct epidemiological history. For example in Zaire the data shows that women had a 50% higher rate of infection than men. The data also demonstrates the evidence of potential spread of HIV-1 amongst prostitutes and persons with tuberculosis. Dr. N'Galy presented several hypotheses to explain why Zaire, in particular, had the highest rate of heterosexual transmission of AIDS in contrast with other developing countries. The higher rates of transmission were attributed to:

- the higher incidence of promiscuity
- the relatively common practice of anal intercourse in Africa
- a high prevalence of sexually transmitted diseases in Africa which increases the risk of viral susceptibility.

More disturbing new studies indicate the probability that 99% of those now seropositive will, given enough time, eventually develop ARC and/or AIDS.

The impact of AIDS in Europe is steadily growing. Dr. Jean Baptiste Brunet of Hospital Claude Bernard in Paris, stated that in December 1989, the impact of AIDS will be as great as it is in the U.S. today. Even if the projected 56,400 cases for 1989 are overestimated, as of March 1988, 12,231 cases of AIDS were reported from 30 European countries. Countries most widely affected are Switzerland, France, and Denmark. This increase in reported AIDS cases has been predominately among drug users.

"AIDS is a danger, but it is also an opportunity . . . to see where in the past we have failed, to gain new insight into circumstances, to find the way to succeed."

—Dr. Luc Montagnier

Early diagnoses is crucial for disease prevention. Dr. Robert Redfield of Walter Reed Army Hospital shared survey statistics which revealed that over 5,000 military personnel had been given an early diagnosis. It is considered standard practice in medicine to evaluate infected spouses. The correlation between the time of diagnosis and the risk of the spouse being infected is dramatic: 50% risk of infection as opposed to 15% risk if the diagnosis was made at Stage 6 versus Stage 1 (on the Walter Reed scale). Results from this study definitely indicate that *early diagnosis* should be our top priority in providing quality care.

Promising drug therapies that were discussed included AZT (presently the most effective drug, although its high toxicity was noted), DDC (now in trials at the National Institute of Health), dextyran sulfate (now in trials at S.F. General Hospital), and aerosolized pentamadine which appears effective in both treating and preventing PCP). More disturbing new studies indicate the probability that 99% of those now seropositive will, given enough time, eventually develop ARC and/or AIDS. In addition, it was reported that the macrophage cells are capable of harboring the AIDS retrovirus for long periods of time before attacking lymphocytes, thus giving a false negative on the antibody test. A new test will be commercially available soon to test the presence of the virus in the macrophage.

AZT, although the most effective drug therapy to date, has its drawbacks. Due to severe toxic side-effects, it has been suggested that AZT be administered less frequently. Dr. Markus Vogt from the Department of Medicine at the University Hospital in Zurich, Switzerland has conducted experiments in vitro in which infected cells were exposed to AZT for one hour once daily or at pulsed intervals. The results were the same in both experiments, both for the reduction in viral replication and toxicity levels. Dr. Vogt, therefore, suggests that AZT dosages can be reduced without reducing its benefits. Also Dr. Vogt noted that AZT doesn't seem to be as effective against HIV-2.

"Of all the issues surrounding the AIDS health crisis, few are of more central concern . . . than the challenge of coordinating and disseminating the vast amount of research information that is generated."

—Robert C. Gallo, MD

As is known, the first step of HIV infection is the attachment to the target cell receptor. Dextran Sulphate, which has

been administered orally to humans for more than 20 years as an anticoagulant or antilipemic agent, can also block the binding of HIV-1 virion to various target T cells. The implications are both clinical and theoretical for the development of new anti-HIV drugs. H. Mitsuya and his colleagues have found that dextran sulphate exerts a potent inhibitory effect against HIV-1 in vitro at levels that are acceptable to humans. HTLV-1 was also suppressed in vitro by dextran sulphate.

A field of interest for AIDS research has been that of *peptide synthesis*. Since their discovery in the 1960's by Merrifield, there has been continuous improvement in the synthesis techniques so that, today, they can be synthesized reliably with the help of automated instrumentation. Synthetic peptides compare favorably with virus proteins which have been isolated and purified from a culture or genetically engineered polypeptides. The most obvious advantage is that synthetic peptides can be produced (1) in very large quantities, (2) with very high purity, and (3) with excellent reproducibility.

Synthetic peptides are remarkably specific tools, and therein lies the benefits as an antigen to detect antibodies directed against a specific epitope to elicit antibodies against well-defined regions of the proteins from which they originate. And lastly, they are not hazardous to work with.

Promising vaccines that were discussed include three different theories. One utilizing a killed virus as in the vaccine proposed by Professor Jonas Salk who is a proponent of the control of AIDS by immunizing seropositive individuals. The second theory proposed was one utilizing the entire envelope such as the vaccine of Zagury, Lurhuma and Salaun. The third theory discussed is the use of viral subunit of the virus envelope: GP 160, or portion of subunit GP 120 or GP 41. But according to the scientists, we are still far from the miracle vaccine.

The World Immunological Network Project Foundation (WINPF) announced during the conference the start-up of a worldwide computerized data network and hotline, known as WIN-AIDS. WIN-AIDS connects researchers and clinicians using electronic mail, specific computer software programs and data bases. The IBM Corporation provides technical support to WIN-AIDS.

In its initial phase, WIN-AIDS involves nearly 50 researchers and clinicians from 12 countries: Africa, Austria, Belgium, Brazil, England, Finland, France, Italy, Japan, Switzerland, the United States and West Germany. The purpose of WIN-AIDS is to provide rapid and widespread dissemination of information concerning AIDS programs. In the event of a crisis, or when a significant finding occurs, all WIN-AIDS subscribers will quickly receive the information. WIN-AIDS is technologically possible through linkage with established computer networks such as EARN (Europe, Israel, Africa), BITNET (United States, Mexico, Brazil, Chile, Japan, Taiwan, Singapore), NETNORTH (Canada), and JANET (England). Scientists and physicians treating AIDS patients will be able to exchange information without leaving their laboratories or hospitals. Time and money spent on travel to and from costly seminars, where the most current information is often not available, will be saved.

Participants in the WIN-AIDS network include the acknowledged co-discoverers of the AIDS virus, Luc Montagnier, MD, of the Institute Pasteur in Paris, France, and Robert C. Gallo, MD, of the U.S. National Institutes of Health. According to Gallo, "Of all the issues surrounding the AIDS health crisis, few are of more central concern to the scientific community than the challenge of coordinating and disseminating the vast amount of research information that is generated. As scientists worldwide work around the clock in their laboratories, they are often frustrated by the inability to communicate freely with their colleagues in other countries or even adjacent institutions. Scientists are often unaware of what others are doing, so they cannot ask questions or seek to compare, cross-validate or collaborate."

The WIN Foundation is one of the means by which nurses could begin to take a larger role, including RN representation on the organizing board of next year's international AIDS conference.

Another WINPF project is the World Immunological Network (WIN), which has received significant funding from HSN and DuPont for its start-up costs. The satellite delivered TV network allows international scientific participation in conferences and round tables dealing specifically with immunological disorders. WIN will cover topics of importance to fundamental researchers, medical specialists, general practitioners, nursing and allied health personnel as well as individuals with AIDS and their families.

There was a notable lack of RN participation in terms of abstracts presented. An RN caucus drew less than 20 participants, many of whom were from San Francisco. A recommendation worthy of vigorous follow-up was made to include RN representation on next year's conference organizing board. Although to date nurses have not developed a leading role in the AIDS epidemic, they are in an excellent position to do so in as much as they generally have more contact with the patient than does the physician and other members of the health team.

The WIN Foundation is one of the means by which nurses could begin assuming a more prominent role, including RN representation on the organizing board of next year's international AIDS conference. WIN is currently developing its nursing level. In addition, WIN would be pleased to provide further specific information on abstracts presented at the Stockholm conference. (Please contact Dr. Cavreul at 213-663-0088). ■

About the Author: See "Reporting from the Ranks" on page 4.

Who Do You Trust?: Self-Appointed Experts Further Confuse the Issues Surrounding HIV.

GUEST COMMENTARY

Recently I attended an informational session on the management of HIV infection which was billed as an "Amsterdam Update." This special session was to give people living with HIV, their families, friends and care partners a clinical overview and update from the VIII International Conference on AIDS. The panelists were Drs. Marcus Conant of San Francisco, and Jeffrey Rollins, Steven Oppenheim, Douglas Richman and moderator Brett Cassens, all of San Diego. Publicity indicated the program was "supported by an educational grant from Burroughs-Wellcome Company."

Sadly, the information given was spotty at best, and misleading at worst. It's not that many of the answers were not helpful but that too many of the responses betrayed a disturbing lack of objectivity about promising developments and an equally disturbing support for others unrelated to growing bodies of evidence. Many responses implied an insider's knowledge but betrayed an appalling lack of up-to-date information. And, as in everything related to the complex politics of AIDS — so saturated with hidden issues of profit and professional rivalry for funds — beneath the surface were issues shaped as much by unspoken agendas as by science.

This was most apparent in the attitude of the presenters to the drug AZT, a product (surprise) of the event's sponsor, Burroughs-Wellcome. Despite disclaimers to challenges to the objectivity of the panel regarding the sponsor's best-selling product, minimal reference was made to the drug's well known negative side effects. AZT was clearly the star of the show. One could easily come away with no sense of the risks involved in its use or of the serious reservations many have regarding its potentially deleterious effect on bone marrow. ddI and ddC were mentioned mainly as enhancers of AZT. There was no mention of feared connections between AZT use and the high incidence of non-Hodgkin's lymphoma as reported by Richard D. Moore, et al., 1991 in the Journal of the American Medical Association.

More troubling was the clear message that people who are HIV-positive begin AZT early, long before progression of the disease. Earlier this year, the U.S. Veterans Administration released a study comparing early vs. late treatment of AZT. It found that while the group receiving early treatment did experience a reduction in progression to AIDS, by no means had AZT improved the rate of overall survival. In fact, the study's secondary findings indicated that once AIDS developed in persons who had received early AZT treatment, more of them seemed to have multiple infections; a slightly higher proportion died; and the median survival time was slightly shorter than in patients who received late AZT therapy. These findings confirm early work of Dournon et al., released in 1988 in France. Early AZT use is not necessarily wise and it is certainly not universally recommended. Burroughs-Wellcome's balance sheet notwithstanding.

This all-too-cozy relationship between doctors and drug companies is not limited to AIDS, but experiencing it in this context — many years into this struggle — underlined for me the danger of relying on corporate giants as the major source of information on the drugs they market. The pressure on the panelists to present the hosts' bread-and-butter products in the most favorable — even the least unfavorable — light is too strong, even if not conscious. Few physicians show themselves willing to offend such a magnanimous host as Burroughs-Wellcome. The firm has sought to muffle criticism even within the activist community by offering its "educational grants," including a one million dollar gift to ACT-UP/ New York.

Let me address some of the audience questions to correct the information given and, where they exist, to point out some of the underlying issues:

1. DRUG EFFECTIVENESS TRIALS:

In response to questions about reports at the conference on two drugs which had shown early promise — Tagamet (also known as cimetidine) and Amsilogen (double-helix interferon), panelists indicated that no new studies had been done, implying the drugs had been disappointing.

This is not accurate. Tagamet, a prescription medicine licensed in 1977 for peptic ulcers and stomach bleeding, has shown widespread indications that it acts as an immune modulator, tending to strengthen immune response by blocking histamine receptors on immune system cells. It is currently available, gives every appearance of being non-toxic and has demonstrably increased CD4 cells in many individuals. No current studies are planned — not because of the inherent merits or effectiveness of the drug — but because the manufacturer's patent will run out next year, making it financially unprofitable for further research investment. Ampligen has shown promising results when used in connection with AZT — contrary to Dr. Oppenheim's claim no new work had been done on this drug. It enhances the effects of the AZT without additional toxic reaction when employed to suppress outbreaks of AZT-resistant strains of the virus, as documented by Dr. David H. Gillespie of Hahnemann Hospital in Philadelphia. The study results were available at the Conference. Again, lack of funding has slowed progress in our understanding of Ampligen's possible benefits.

2. MYCOPLASMA AS A CO-FACTOR:

Professor Luc Montagnier, the French researcher from the Pasteur Institute in Paris, has developed a theory that tiny bacterial agents known as mycoplasma are an infectious co-factor in the evolution of HIV-infection into full-blown AIDS. This research may be critical in finding a way to save the lives of millions currently infected but who remain healthy, as the presence of mycoplasma in HIV-infected individuals is thought to accelerate the progression to AIDS. If mycoplasma fermentans is treated it could slow or stop the progression of the disease. Virologist Doug Richman of UCSD Medical Center indicated that Montagnier had recanted from his earlier statements because he had found no compelling evidence to support his hypothesis. As evidence, he noted that Montagnier had not presented any new papers in Amsterdam. He went on to indicate that an agent he referred to as mycoplasma pneumoniae is relevant only to non-AIDS-related pneumonia and is meaningless when it comes to HIV.

The facts tell a different tale. Indeed, Montagnier presented no new papers — because an entire conference about the relationship of AIDS and mycoplasma had been held in Scottsdale, Arizona in October of 1991. And the agent he has been researching is not *mycoplasma pneumoniae* but *mycoplasma fermentans*, a different entity altogether. In a telephone conversation Dr. Montagnier indicated to me that he still considers mycoplasma to be of crucial importance in understanding how HIV activates and may even be a relevant factor in the cases of the so-called AIDS-like disease — recently the subject of so much media attention — a fact he noted in a paper published as long ago as 1990.

Indeed, Dr. Montagnier believes that it may be the spread of a hardy new strain of mycoplasma in the '70s colliding with HIV, which until then had lain dormant in Africa, that triggered the epidemic. He believes mycoplasma is still a mystery and may yet yield many keys to understanding that could translate into real progress in the fight to end the epidemic. Dr. Richman's dismissal of this line of research — like that of his fellow virologist Anthony Fauci, head of the National Cancer Institute in Bethesda — may reflect a concern that if the focus shifts away from virus-borne to mycoplasmologists, so will the research grants which mean money and influence.

3. WOMEN AND AIDS:

It was disturbing that the issue of women and AIDS was presented by a male physician and the individuals on the podium were all white males, since there are many competent women clinicians who attended the Amsterdam Conference. Nor am I merely engaging in feminist nit picking since, twice, information given about women and HIV was suspect.

Dr. Oppenheim stated that studies indicate that there is no change in the menstrual flow of women with HIV-infection. Having personally interviewed hundreds of women with HIV/AIDS, I find it impossible to accept such a statement and I question the validity of studies that reach such a conclusion. Over 90 percent of the women I interviewed report that a change in menstrual flow was the first indication of a problem. Perhaps this is a case in which the results of data collection are directly affected by the techniques and the expertise of the interviewers.

Dr. Jeffrey Rollins, an OB-GYN, answering a question about transmission of HIV through breast milk, minimized a risk that many feel to be as potentially deadly for infants as is unprotected sex for adults. For years we have known that breast milk was a possible means of transmission, but the information was inadvertently not released at the request of Pan American Health Organization (PAHO) which receives its funds from the World Health Organization. PAHO spokesperson Dr. Lydia Bond reasoned that in underdeveloped countries, specifically in Africa, infants would die of starvation in any case if denied breast milk. Hiding this mode of transmission from mothers where other alternatives nourishing the child are abundantly available, strikes me as criminal. Every mother deserves to know the risks to her child so she can be tested and proceed according

4. NEOPTERIN:

Asked whether more had been discovered about the usefulness of monitoring Neopterin levels of an HIV-positive individual as an early predictor of disease progression before the outbreak of actual symptoms, the panel dismissed the possibility rather cavalierly as if the notion had been discredited.

Again, the weight of scientific evidence flies in the face of their dismissal. Neopterin is now considered "a marker of immune activation" (Dr. Ecienvarria LaBarge, Spain). This means that Neopterin production is stimulated as soon as the body perceives itself under attack from a foreign substance. This response is triggered by all sorts of viruses, not just HIV; what is important is that elevated Neopterin levels can indicate trouble before other means of detection will give any evidence. Mark Gompels of London found "Neopterin was the most significant overall predictor of disease progression." There is a "consistently increased level of Neopterin in the more advanced stages of HIV," according to Aristo Kanoulidou of Athens. "In neurological disease, elevated Neopterin levels in cerebrospinal fluid usually indicated a patient with HIV encephalitis or cerebral toxoplasmosis," says Dr. Armand Pierre Lhuder of the Laboratoire de Biochimie France. Alfred Saah of Baltimore considers Neopterin to "provide ... more sensitive prognostic information than Beta microglobulin."

My experience at the "Amsterdam Update" — reminding of a misnomer, since much of what was up-dated was old news for those involved in AIDS research — convinced me that current information from a clear, informed and objective source or current knowledge uncontaminated by the agendas either of the drug companies or the various factions within medicine is lacking. Another problem we must address: the lack of clear channels of communication between busy clinicians, often overwhelmed with the needs of their own patients and the researchers in their laboratories doing cutting-edge work to discover new medical initiatives that could save these patients' lives. I do not mean to point out for special criticism those clinicians who spoke; I wish only to appeal for the creation of better, more objective channels to disseminate the facts — to doctors as well as concerned persons outside the medical profession.

LESBIANS AND AIDS — COPY
THE OVERLOOKED STATISTICS

How and Why Lesbians Should Protect Themselves

by GENEVIEVE CLAVREUL, PH.D.

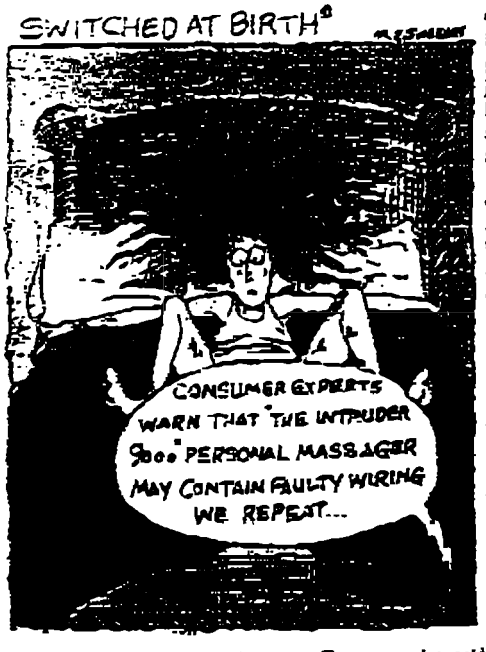
My visit to the VIII International AIDS Conference in Amsterdam last month revealed yet another oversight in the already tragic history of the epidemic, as a quick glance at the book of scientific abstracts presented to participants at that conference makes clear. Of the 9,199 *abstracts* (reports of research projects) listed there, *only ten concerned lesbians.* And three of these focused on lesbians who are also IV-drug users, thus adding that risk variable to the possible routes of transmission, and further illustrating the inescapable point: little or no serious scientific study of AIDS among lesbians is currently taking place.

There are many reasons for this, including the fact that figures accurately detailing the incidence of the disease among lesbians have not been accurately kept. Workers at HIV test sites in San Diego report, for example, that there is no place on the report forms for the category "Women having sex with other women," despite the fact that there is a whole column of other descriptive categories. The reporting of AIDS cases among lesbians has mostly been lumped together with that concerning heterosexual women, not only because of homophobia within officialdom, but because of the ways women do or do not disclose the details of their intimate lives to doctors and researchers. In this as in every area, HIV feeds on our silence.

The time has come to end that silence. Research shows that — just as women in general are conditioned socially to suppress our awareness of our sexuality and our comfort with frank discussion about it — lesbians are often highly reticent to talk about what we do and what we enjoy sexually. This includes talking with each other. Equally disturbing, we seem to be no better than condom-resistant men when it comes to protecting ourselves and our lovers with safer sex practices like dental dams for oral sex. (In fact, according to Joyce Hunter of the HIV Center for Clinical and Behavioral Studies in New York City, "97 percent ... of women who identify themselves as 'butch' ... have never used a dental dam and 41 percent refused to do so ever.")

First and foremost, we must demand more research into woman-to-woman transmission. Some of the complications come because of the long incubation period of the virus, leading many to discount cases of AIDS that occur in lesbian women because of a tendency to attribute cause to earlier heterosexual contact, often engaged in prior to coming-out. Some lesbians are sex workers who continue to be exposed in the course of practicing their trade. Some do use intravenous drugs. But, contrary to the widely-held belief that lesbian sex is no risk sex, there is an increasing number of cases with no other apparent mode of transmission. I have involved blood-to-blood contact, and perhaps oral sex. Many assert that levels of the virus high enough for transmission can be found in vaginal fluid of infected women, especially when sharing sex toys that penetrate the vaginal opening. It is assumed that the risk of HIV transmission is particularly high during the menstrual period as both vaginal fluid and blood are present.

Obviously we must move beyond assertions and speculations when it comes to AIDS. Pressing for more research directed toward discovering how easily the virus can be passed by women to one another is critical. Equally important, we must also do a better job of supporting and treating lesbians already infected. Accessible care must be made available, including psychological and social services, and medical care that includes both traditional and alternative therapies. And we must learn more in a focused way about how the virus affects women, since it is already in our bodies.



In addition, there is an urgent need to train and educate health care providers about the specific needs and risks of lesbian women. Current, comprehensive, and correct information concerning all issues about women living with AIDS must be readily available to them, as to the community at large. But a special effort is needed to reach out to those in the health care professions who have little or no access at this time to such information.

It has been stated time and again in article after article that lesbians are not at risk of contracting AIDS. This is simply not the case, though indeed, *under certain conditions* we seem to be less at risk. Emphasizing these, however, at the expense of warnings about the conditions under which *we are as vulnerable as any other group* is dangerous and destructive and can lead to a false sense of security that could have disastrous consequences.

Every woman, of course, sets her own limits in regard to what she will and will not do. *The basic rule of thumb to lower its safest is that blood-to-blood, or vaginal fluid-to-blood contact is needed to transmit the virus, not an open cut or sore. Do not forget that the menstrual period is the time of highest risk and vulnerability.*

Mutual masturbation or any other sort of external body contact with unbroken skin is okay. Any open cuts or sores should be thoroughly cleaned, dressed, and covered. If you have no sores or cuts on your hands, fingers inserted inside your lover are probably okay but the use of a thin latex glove — especially if your partner is menstruating — can decrease the risk even further.

Oral sex has generally been presented as low risk unless the woman doing it has open cuts or sores in her mouth, or the woman receiving her attentions has such sores or cuts on her labia, i.e. Herpes lesions or canker sores due to HPV (Human Papilloma Virus), or if she is menstruating or bleeding from her sex organs in any way. This is due to the probability that the digestive juices kill the fragile virus before it can reach the bloodstream. This however, is speculative: there is no hard evidence to allow complete certainty that this is the case, and responsible women must be made aware that when dealing with AIDS, we are still operating largely in a twilight zone wherein all dogmas are to be held in question, and there is *no* such thing as "a little mistake." The safest way to reduce risk during oral sex with another woman is by using a "dental dam," a square of latex originally designed for use by dentists. It is about 15 square centimeters and very stretchy, though a little bit tougher than a condom. The latex is stretched across the sexual organs which are then stimulated through it — it is often a good idea to mark one side so that you don't inadvertently use the wrong one. Dams can be cleaned with warm soapy water and should never be left in direct sunlight. As with condom use, *only* water-based lubricants like KY Jelly can be used *safely* as petroleum or oil-based products (such as Vaseline, lotions, or elbow grease) may weaken the latex dental dam. If no dam is available, Saran Wrap can also be used effectively to prevent direct contact with the genital area and thus reduce the risk of infection.

Using sex toys with your partner, or in lieu of a partner, also involves some risk, especially if they are shared. Just because you are using an inanimate object does not mean that there are no risks. If you do share a dildo or other stimulator that penetrates the vagina, put a condom on it between uses or wash it in very hot soapy water, being careful not to immerse it if it is an electrical device. Cleaning toys after each use is a must. Having your own individual supply is highly recommended. Do be aware that putting *any* large things inside you — including fists — vaginally or anally, or using them roughly can stretch the vagina or anus too far and cause bleeding which adds greatly to risk. Any such penetration should always be accompanied by the use of latex gloves and plenty of water-based lubricant, preferably one that includes Nonoxynol-9, an approved spermicidal jelly with anti-viral properties.

A word here about drugs. All drug use — *and this includes the use of alcohol* — is highly suspect if for no reason other than the ways it tends to alter perceptions and increase our sense of personal invulnerability. The ego-loss that accompanies the ecstatic states that drugs encourage, especially in highly-charged erotic encounters, can also result in the loss of inhibition and common sense that often leads even very well-informed people into behaviors and practices that can be highly compromising from the point of view of HIV transmission. This is not a moral argument; it is a matter of simple, and sometimes tragic, fact. Therefore, the ingestion of any substance which alters consciousness must be considered a risk factor in and of itself, regardless of the method by which it is ingested. That said, of course it is *less* risky to smoke, snuff, eat or drink such substances than it is to use needles to shoot them up; and it is less risky to use needles which are never shared with others, as sharing needles is a route of transmission just as dangerous as unprotected sex. Cocaine injection seems to be particularly associated with HIV infection; and while further research into why lesbian intravenous drug users are at increased risk, one study reported on at Amsterdam considers it possible that it is because they share needles with infected gay male friends.

If you are attempting to get pregnant from a donor, or by donor insemination, it is of course essential that the fertilizing sperm be fully tested for HIV. All reputable insemination clinics now do this as a matter of course, but if you make your own arrangements, with or without actual intercourse, you must be sure that your donor is fully tested for HIV, preferably having had two negative tests several months apart while practicing only safe sex during that time. It would be worth your while to pay for him to have a PCR (Polymerase Chain Reaction) test rather than the standard ELISA antibody test because this will detect the actual shedding of the virus rather than just the antibodies to the virus, giving an extra measure of security. Of course, it goes without saying in this as in all instances that seeing the actual printed record of a person's test is preferable to accepting verbal assurances, given the unfortunate ways that deception or denial can still enter into our relationships in this darkest of times.

Early testing is a must. If you test HIV-positive, seek immediate guidance in order to take control over your life and your treatment. Beware of fad treatments that may harm you. Be wary of "The Cure" — no silver bullet exists, only well thought-out, multi-faceted therapy to allow you survival and the actualization of a full life.

REMEMBER:
Knowledge is power.
Low risk isn't no risk.
Safer sex isn't safe sex.

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SOUTHERN CALIFORNIA NURSING NEWS SEPTEMBER 1988

AIDS Update

Minimizing the impact of AIDS on the nursing shortage

By Genevieve M. Clavreul, RN, PhD

Health Care Professionals are aware of the current critical nursing shortages. Many are aware of the likely causes of the shortages. Some are conscious of the possible solutions. Few are willing to implement long-term organizational changes to effectively deal with the shortages. How many are cognizant of the potential dangers that the health care industry will have to face will only be revealed by time.

$$\frac{\text{Nursing Shortage} + \text{AIDS Crisis}}{\text{Demotivation} + \text{Stress}} = \text{Poor Patient Care/Death}$$

In our studies *Demotivation in the Nursing Profession: Its Signs and Symptoms*, Genevieve M. Clavreul, PhD, and Sue Caviness, PhD, ICU Forum Volume IV, No. 2, 1984, we were able to identify four stages of the demotivation process which impact on the nursing shortage problem:

DETERMINED

At this stage the "initiate" has come to the facility fresh out of nursing school. S/he is highly stimulated to seek out both peers as well as superiors to discuss duties, suggestions for improvement, and, in general, to enjoy a professional dialogue. S/he feels free to experiment with new ideas (despite previous training) and is willing to commit to a joint practice with the physicians. S/he feels that s/he is contributing well within the parameters of her/his professional obligations.

DISTRAUGHT

At this stage the inconsistencies and fragmentation of the communication process, as well as the general resistance of the organization to accept her/his free participation and overall interaction, is beginning to take effect. As a result s/he focuses more narrowly on those persons who have positively responded to her/his questions and needs and, therefore, with whom s/he feels most comfortable. Although s/he maintains the same standards of patient care as before, s/he does so with the increasing recognition that the policies and procedures by which s/he must operate are either rigid, confusing, or non-existent. S/he is not yet alienated nor yet feeling victimized by the organization, but her/his frustration level is increasing.

DEBILITATED

At this stage the alienation process is well under way. A heightened sense of anger and powerlessness is manifested in her/his behavior, and s/he can no longer dismiss her conscious thoughts and feelings. S/he has, in short, become frustrated as her/his need for achievement within they system remains unfulfilled. S/he exists now only on the periphery of her/his mandated involvement with both staff and patients. S/he tends to care for her/his patients more on an "8 hour shift" basis rather than being committed to their total recovery. Although s/he is conscious of her/his instructions, patient charts, responsibilities, etc., s/he now functions in her/his role as nurse only on a superficial level.

DETACHED

At the final state in the progression toward total demotivation, the nurse has experienced the full gamut of helplessness. S/he has, in effect, "dropped out." S/he has withdrawn from concerns over patients, her/his career, others and her/himself. These concerns have now been replaced by how many days s/he has to work to financially survive. It is at this point that the signs of the demotivated nurse are most observable. It is a warning sign that a solution must be found to salvage not only the staff and its professional viability but also the very management system that aggravates it.

The needs of nursing personnel must be an issue of prime importance, especially when faced with the seriousness of AIDS.

When dealing with a deadly disease such as AIDS, you require highly motivated and caring individuals. The best method of recruiting such personnel is through the use of specialty units where the nurses are aware and prepared to work with AIDS patients. Also, when you have specialty units, there is a tendency to have individuals who genuinely care and are willing to deal with

This fear of working with AIDS and seropositive individuals more than any other factor will prove critical in the eventual revamping of our present health care delivery system at all levels.

AIDS Update . . .

these patients rather than to express their fear through neglect and poor patient care, which may be found on regular wards out of fear and lack of knowledge of the disease. With other serious illnesses, i.e., TB, neonatal, oncology, etc., no real progress was made in treatment until specialty units were created. In such a setting, not only does the staff become more skilled, but the opportunities for observation and research are greatly enhanced. With greater consistency on the part of the staff, patient monitoring is likely to be more consistent, while greater familiarity with the disease process enables the staff to become more quickly aware of subtle changes in patient condition. In a specialized unit, the creation of a team approach, or joint practice, is more likely to occur. This not only provides better support to the patient but to the team members themselves (San Francisco General, where such a specialized AIDS ward has been in existence for five years, has lost approximately 1/3 of their patients while Los Angeles County has lost 1/2, is extremely suggestive of the value of this form of health care delivery), and at the same time addresses one of the causes of nursing dissatisfaction: their perceived low impact on the health team.

The current critical nursing shortage has several well-known causes: lack of job satisfaction due, in part, to the traditionally low impact of nursing on the health care profession, the availability of other career options to women; the closure of nursing training facilities; and, today, fear of working with AIDS patients. This fear of working with AIDS and seropositive individuals more than any other factor will prove critical in the eventual revamping of our present health care delivery system at all levels. One other factor which is emerging is the pressure exerted on nursing personnel by their family, friends, and significant others (as well as AIDs researchers) not to work with AIDS patients.

These fears must be addressed. In the words of Gerald Hughes, a medical administrator, "It's important for all employees to have the sense that they are being protected. They need to know that management is aware of the disease and is keeping informed." We are continuing to struggle to reach the proper balance between protecting the patient's, as well as the health care personnel's rights to confidentiality and wellness. The existing California law states that, once a person has been diagnosed with AIDS, all members of the treatment team are entitled to be informed. However, this is not the case with those that are seropositive but have not yet developed the signs and symptoms as stipulated by the CDC diagnostic criteria of AIDS or ARC. Currently, each individual health care personnel involved in the care of a seropositive patient can be informed only with the expressed written consent of the patient, legal guardian, parents, or conservator for the particular individual health care professional. Violation of these confidentiality laws by individuals exposes them to certain criminal and civil penalties under Section F, Criminal/Civil Penalties. At the present, there are approximately one hundred fifty bills before the California legislature which pertain to AIDS.

Meeting this challenge will require a systematic, proactive approach, rather than stop-gap measures. Existing employee assistance programs must be strengthened, and inservice education expanded to include training in the care of AIDS patients. Several factors need to be taken into consideration in the training of any personnel who will be in contact with AIDS patients.

1. The health care professionals' fear of being put at risk when treating an AIDS patient
2. Working with co-workers who are contaminated with AIDs
3. Dealing with the knowledge of the certain death of the patient (at the present time)
4. Pressure of family, friends, and significant others not to work with AIDS patients
5. The patient's fear of discrimination, stigma, and lack of confidentiality
6. The patient's need for psychological and social support
7. The possible health care personnel's fear of already being contaminated due to previous social and sexual experiences, i.e., alcoholism, drug abuse and high-risk sexual behavior, etc.

AIDS Update . . .

As the AIDS crisis continues to worsen, the strategies which health care organizations will need to develop have to be flexible and adaptable, and the people selected to spearhead them must be not only knowledgeable but sensitive to the needs of the patients, the employees, and the organization. For example, in dealing with an employee suffering ARC/AIDS and possible AIDS dementia, they will need to consider: (a) Is s/he able to continue working? (b) If so, in what capacity? (c) Could adjustments in working hours or tasks assigned keep the employee on the job? (d) If such adjustment cannot resolve the problem, what combination of severance pay and/or continued insurance coverage would be appropriate to provide for the needs of the disabled employee? and (e) The perceived threat felt by the patients who are being cared for by health care professionals who are infected with AIDS or are seropositive.

It may well be necessary for organizations to utilize consultants knowledgeable in the medical, psychological, social and legal fields in order to keep up to date on strategies dealing with AIDS in the workplace. . In this way, health care organizations can be made aware of and comply with existing legislation and judicial decisions regarding discrimination and confidentiality—if only to avoid costly litigation.

It may be good public policy to form a credentialing body for consultants on AIDS issues and nursing shortages to assure a high level of quality, knowledge and confidentiality. Also the consultants will be required to educate employees about dealing with their fears of working with individuals with ARC or AIDS. Other professions such as psychology, sociology, etc. will need to develop well rounded programs for dealing with the stress and concerns of both the health care professionals and the patients.

Hospital/health care professionals, nursing school administrators, professors and policy makers must now synchronize their efforts and establish long-term goals and procedures to address the nursing shortage problem. Nursing leaders must have input into this process. We do not need stop-gap or Band-aid measures. We need a cure for the problem of nursing shortage and a vaccine to prevent its recurrence. Similar to the AIDS crisis, the nursing shortage has become the state of emergency it is now because our leaders thought that if they ignored it, it would go away. ■

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AIDS Update

Battling the Body Snatchers

By Genevieve Clavreul, RN, PhD

There is no magic silver bullet yet when we are dealing with AIDS and its sequela. There has been some steady progress towards palliative treatments, as well as preventive therapies, for opportunistic infections for the seropositive, ARC or AIDS patients.

AIDS, as you well know, is caused by a virus consisting of a mass of genetic material (in the case of HIV, RNA), hidden in glycoproteins and lipids. HIV cannot replicate on its own: it must find a host organism and invade that host's genetic pattern in order to reproduce itself, a body snatcher in the truest sense of the word. During the active phase of reduplication it is very difficult to distinguish between the viral proteins of the virus that interact with the host cell and the normal proteins of the host cell. An agent must be found that can selectively inhibit viral reduplication with as little damage as possible on the host organism. This is no easy order. Treatment strategies must integrate minimal side effects and toxicity on the host while still yielding effective results.

CLINICAL TRIALS

The different stages of clinical trials are as follows:

Phase I: usually implies a small number of patients and is designed to establish *toxicity* levels, (the maximum dose acceptable) and the drug mechanism in vivo.

Phase II and Phase III: involve a larger number of patients and are designed to assess the *effectiveness* of the drug. Several drugs have been found to hold some success in the treatment of AIDS and are in various stages of clinical trials, including:

ALPHA INTERFERON

May reduce viral binding, could also have other actions. It has a direct antitumor activity against Kaposi's sarcoma. At the present time, phase II trials are in progress alone or in conjunction with AZT.

AMPLIGEN

Is an interferon inducer, could also have other actions. So far little toxicity has been observed in patients. At the present time, large scale phase II and phase III trials are in progress.

COSTONOSPERMINE

Action: focuses on enzyme inhibition. Specific inhibitor of glycoprotein processing. Shows reduction of syncytium formation and infectivity of the virus. This drug is in the early stages of development.

AZT

The first approved drug effective in inhibiting HIV replication is AZT (also called azidothymidine). AZT binds to reverse transcriptase and prevents HIV DNA synthesis. The effectiveness of AZT lies in non-mutation or alteration of the viral transcriptase. This could indicate that an AZT-resistant mutant may occur in patients. AZT has been the drug most extensively submitted to clinical studies. Still many questions remain unanswered, such as the best method of administration: keep AZT at a constant level or allow the levels to fluctuate. AZT levels decline by 50 percent over the course of one hour. The present dosage is one dose every four hours to maintain constant circulating levels. AZT appears to increase the survival time of patients. A decrease in opportunistic infections is observed as well as a decrease in HIV-induced dementia. The main side effect is toxicity to the bone marrow.

ddA and ddI

These are also transcriptase inhibitors and chain terminators. Very little is known at this stage about either drug. Phase I trials are now in progress. These two drugs appear to have less toxicity in vitro to T-helper cells than either AZT or ddC. Both also show less bone marrow toxicity. The preliminary findings have been encouraging.

ddC

(2' 3' -dideoxycytidine) is also a transcriptase inhibitor and a chain terminator. This drug has demonstrated even at low dosages strong antiviral properties. However, patients on ddC after a few weeks of treatment developed extremely painful peripheral neuropathy, primarily in the lower extremities. After cessation of the treatment the peripheral neuropathy slowly subsided. The other toxic effects appear to be dose-related such as cutaneous eruptions, fever, mouth sores, thrombocytopenia, and neutropenia. DdC is actually in phase II studies both alone and in conjunction with AZT. Peripheral neuropathy seem to be reduced when ddC and AZT were on alternate regiments.

DEXTRAN SULFATE

In vitro Dextran Sulfate (Mw 34X 10 (3], xylofuranan, and ribofururanen, as well as sulfated counterparts demonstrated cytopathic effect on HIV. Dextran Sulfate is thought to inhibit viral binding, and has been used orally only outside of the United States for the following purpose: to reduce cholesterol levels. Phase I trials of UA001 (Dextran Sulfate) utilized doses ranging from 900 to 5400 mg/day increased by 900 mg increments for a period of 8 weeks. Some of the toxic effects included neutropenia and diarrhea. No coagulation abnormalities have been noted. Dextran Sulfate is in Phase II clinical trials at San Francisco General Hospital.

PHOSPHONOFORMATE

Appears to be a reverse transcriptase inhibitor. Appears also to be effective against cytomegalovirus (a frequent opportunistic infection in AIDS patients). Phase II trials are in progress and show evidence of some effectiveness against HIV.

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PHOSPHOROTHIOATE OLIGODEOXYNUCLEOTIDES

Appears to have several mechanisms of action, one of them includes the arrest of protein synthesis. This drug is still at a very early stage of development. Specific and non-specific activities are still not known.

RIFABUTIN

Demonstrates a possible reverse transcriptase inhibitor. The action of Rifabutin appears to be through action on the RT enzyme since the enzyme activity was reduced in vitro experiments. Further studies are needed to evaluate the therapeutic value in vivo. Unlike AZT, it appears to have very low toxicity level. In vitro studies also show activity against mycrobacteria (one of the possible opportunistic infections incurred by AIDS patients). Phase I clinical trials are in the last stage of completion.

SOLUBLE CD4 (rsT4)

CD4 is the T-cell surface glycoprotein. It is the anchored membrane receptor for HIV. The progression of AIDS in HIV infected individuals is correlated with the depletion of CD4+ T lymphocytes. Soluble CD4 acts as a soluble viral receptor and inhibits viral binding. Soluble CD4 is a genetically engineered form of CD4. Phase I clinical trials are ongoing. Also some studies in vitro are evaluating the possible synergy with concurrent AZT therapy.

Innovative approaches must be developed in all phases of the health care delivery system to meet the increasing needs of individuals infected with AIDS. These innovations will have implications worldwide and include some of the following: inpatient and outpatient AIDS treatment and research units, hospices, home care health providers, more extensive community service organizations, AIDS information hot lines, confidential testing sites and reporting procedures and better communication between the different disciplines in the health care/medical/scientific fields.

Extraordinary challenges are posed by an HIV diagnosis. We must face the challenge of dealing with nursing shortages and a decrease in enrollment in nursing programs, a severely overtaxed public health care system, the staggering cost of health care, and the reluctance on the part of insurance agencies and organizations to absorb the cost of health care. However, we are starting to see a significant change in the role of AIDS in our health care system. We are accepting the challenge of AIDS research and care; we are beginning to accept AIDS as part and parcel of our role as health care professionals. We have some of the technology and more advances are being made every day. Now we need to reintroduce the nurturing for which the health care profession is known. This is a disease of devastating proportions. As it stands today, people with a diagnosis of AIDS must be prepared to die, but the due date can be postponed. It is up to the patient and the entire health care team to delay the grim forecast.

Genevieve M. Clavreul, RN, PhD

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Are Women and Children Expendable? -
The Untold Dangers of HIV and Breastmilk ©1993
By
Geneviève M. Clavreul, Ph.D.

We have been inundated in recent years - and rightly so - with information about the dangers of HIV-transmission through body fluids -- blood, semen, and vaginal discharge. The educational outreach to people at risk of contracting AIDS through unsafe sexual practices or through any blood-to-blood procedure, medical or otherwise, continually emphasizes the importance of shielding one's self from concentrations of the virus contained in these substances.

And yet there is another route of transmission which endangers the most helpless and vulnerable "risk group" of all, rarely mentioned when the litany of unsafe behaviors and practices is repeated and in fact actively covered up for years by no less a body than the World Health Organization! The culprit in this case is breastmilk and the risk group are newborn infants, the children of HIV/AIDS-infected mothers who pass on HIV as they breastfeed. In yet another of the cruel ironies that accompanies this most insidious of diseases, the act that should epitomize the sustaining of life within the primary bond between mother and child, instead becomes an act with potentially deadly consequences.

How has this situation come to exist? Surely, as the AIDS epidemic has spread and widened over the last dozen years, the fact of transmission from mother to infant through breastfeeding must have come to light. Why has there not been sounded a more general alarm that would warn mothers that they should be tested for HIV before deciding to nurse their babies? Why have nurses in Obstetric wards and Neonatal Intensive Care Units, most of them women, not been taught to treat expressed milk with the same caution that they now must treat blood samples or other patient excretions? And why does there continue to be a veritable blackout of information about the subject which, though decidedly a smaller risk -- in statistical terms -- than other means of HIV transmission, yet constitutes a very real danger that a growing body of evidence suggests affects a growing number of children?

To understand the troubling answer to these disturbing questions, one must go back to the early days of the epidemic when all of the research studies being done on HIV-transmission among heterosexual people was taking place in Africa where large numbers of women were among the infected. Because AIDS in the developed world of Europe and North America first showed up in the gay communities among homosexual men, concerns there were not focused at all on dangers to women or their children. And in Africa, where infant mortality rates soar for all

sorts of reasons unrelated to AIDS, public health workers, particularly those associated with the World Health Organization (WHO), saw the problem of HIV transmission through the filter of other concerns.

Routinely, when asked about screening mothers for HIV before encouraging them to breastfeed, WHO briefing leaders, as a matter of policy, have told audiences of international gynecologists and obstetricians that the practice would be counterproductive because no alternative sources of nourishment exist in the desperately-poor, drought-plagued, Third World environments of Africa. The fear, clearly a legitimate one in that environment, is that untold numbers of newborns would starve to death if mother's milk were to be denied them; therefore, the potential risk of breastfeeding is to be downplayed. As the epidemic has widened, the policy has been adopted as well by the Pan American Health Organization (PAHO) that is dealing with the AIDS problem in Latin and South America.

The dilemma with this approach of course is that, while it may make sense not to cut off the only food supply for millions of children in starving Africa or Brazil despite the risk to some of them, in the industrialized World -- where ample resources exist to provide infants with formulas -- it makes no sense at all. In fact, here and in Europe, the "downplaying" of the evidence of HIV-transmission via breastfeeding amounts to a cover-up which some might call criminal negligence. It highlights the greater problem arising from the lack of a truly global strategy to deal with the AIDS epidemic that would take into account different conditions in different parts of the world, and then sets policy accordingly.

So much for origins. The question now is, at a time when attempts to monitor and protect the blood supply are being extended, what is being done to alert women to the risks associated with breastfeeding?

The answer, frightening as it may be, is that little or nothing is being done, despite the increasing evidence and the highly-publicized personal tragedies of some highly visible women. A case in point is that of Elizabeth Glaser, the founder of the Pediatric AIDS Foundation, who contracted the virus as the result of a blood transfusion at the time of delivery and then passed the infection of her uninfected newborn daughter through her milk. Despite the fact of the Foundation and of having been a speaker at the Democratic Convention in New York that nominated Bill Clinton for the Presidency, Mrs. Glaser's story has not created an awareness of the need for more education or for more precautionary procedures that would apply routinely to all pregnant women and nursing mothers.

COPY

Just how easy is it for an infant to contract HIV/AIDS through its mother's milk? Breastmilk is highly susceptible even to subtle shifts in the biochemistry of the mother; recent studies at Indiana University in Bloomington indicate that babies are significantly more fussy about accepting milk expressed after their mothers exercised because the increased lactic acid content affects the taste! More to the point, many cases have been documented that are similar to that of Elisabeth Glaser in which it can be demonstrated that the mother was infected after delivery. One such case involves a French mother from Limoges, a woman with no risk factors for HIV who, because of blood loss during the birth of her second child, received two units of transfused blood. (This was at a time previous to the screening of blood donors.) Twenty-seven months later, she was readmitted to the hospital with *pneumocystis* pneumonia and diagnosed with AIDS; her daughter was also HIV positive, though her husband and older child were not. A sample of her blood from the fourth month of pregnancy was tested retrospectively and was found to be without any trace of the virus. Records existed that enabled officials to trace the blood donors, one of whom did test positive. Obviously, even during the primary stages of infection in the breastfeeding mother, HIV can be transmitted to her infant.

As early as 1988, numerous studies presented at the Fourth International Conference on AIDS in Stockholm clearly demonstrated the transmissibility of HIV via breastmilk. These studies have been confirmed over and over again at subsequent conferences, though they have failed to attract much attention and have remained outside the media spotlight reserved for sensationalistic reports about high-profile celebrities with AIDS and the like. Risk of transmission seems especially high during the colostrum period and up to two weeks after delivery. Colostrum is the liquid secreted for a few days after birth that is characterized by high protein and immune body content; in normal circumstances, it is a kind of booster for the immune system that gives the infant the benefit of greatly enhanced immune capability. Unfortunately, this highly condensed substance also appears to contain high concentrations of HIV in an infected mother and thus represents enhanced risk.

One of the most puzzling aspects of this dilemma concerns the seeming unconcern of experts and organizations that normally advocate for women and children. Dr. Benjamin Spock, the noted baby expert, appeared in September, 1992 at a press conference for the Physicians Committee for Responsible Medicine, an animal rights organization that is against the human consumption of cow's milk, and advocated the use of breastmilk during the child's first year making no mention of potential risk. Tipper Gore, the wife of the new Vice-president, has been a strong advocate of lactation. Even La Leache League, the group that has as its

mission the resurgence of breastfeeding among western women -- which one might think would be in the forefront of any effort to insure the safety of the activity that they so passionately advocate -- has so far remained, at best, silent; at worst, actively resistant to a clear assessment of genuine risk, as if so used to having to defend its pro-breastfeeding position that it has blinded itself to the dangers brought on by the worldwide AIDS epidemic.

Recently, during my research for this article, I contacted chapters of La Leache in many states throughout the country, in order to find out what information is being presented to prospective mothers. These included chapters in Iowa, Florida, Ohio, Oklahoma, Louisiana, Texas, Minnesota, Alabama, Tennessee, Georgia, Missouri, California, Michigan, Illinois, Kentucky, Wisconsin, and Pennsylvania. Not one encourages screening of prospective mothers for HIV. Not one mentioned HIV as a risk to the infant. And not one was able to give me any further information, even after I specifically asked about the risk of such transmission. This is the rough equivalent of a fertility clinic that advocates artificial insemination not screening potential sperm donors or mentioning the risk to potential recipients. To my mind, at this point in our knowledge of the facts about AIDS, such an omission is evidence of negligence in the extreme.

A further concern relative to the potential danger of infection involves those health professionals who must deal daily with breastmilk -- the nurses who work with mothers and newborns on hospital units around the country. OSHA, the Occupational Safety and Health Association responsible for establishing safe standards for workers in their work environments, has a series of guidelines and procedures that cover HIV-related risks called the ***OSHA Bloodborne Pathogens Final Standard***. Breastmilk is not included on the list though theoretically it is just as dangerous to express HIV-infected milk as to come into contact with HIV-infected blood. To my knowledge, no nurses to date have been shown to have been infected by contaminated breastmilk. The possibility, however, exists and should be taken into consideration by hospitals, obstetricians -- and OSHA.

What, then, is to be done? In addition to the inclusion of breastmilk in the OSHA guideline, it seems to me that all women who become pregnant or are considering pregnancy should be tested for the HIV virus, much as couples wishing to engage in unprotected sexual contact. Women who wish to breastfeed should be tested both at the beginning of the pregnancy and at delivery, as the first test could result in a false-negative result in infection occurred close to the time of the test, before the antibodies measured by the standard ELISA test for infection could be produced. It goes without saying that -- from the time of the first test

to the second -- the woman should not engage in any unsafe sexual practices or in procedures that involve the exchange of blood or blood products. In this way, the second test will be a more trustworthy indicator of health: and the activity of breastfeeding can be what nature intended -- an act of deep nurturance that develops in the child a sense of primal trust in the world and in the mother a profound sense of her ability to care for and protect the new life that she has brought into it.

AIDS Update

A Future with AIDs

Prolonging Quality of Life— A treatment tool for RNs, Part 1

By Genevieve Clavreul, RN, PhD

Only a few years ago, the implication of a seropositive/AIDS diagnosis meant a rapid, painful and irrevocable decline of one's health, ceasing only in death. The moments, hours and days began ticking away at life in a cruel and final countdown, removing even the last ray of hope. The unique integration of characteristics which are "You" will determine the ultimate course of your survival. Now the odds are changing slowly and steadily. As health care providers, we must treat an AIDS-infected person as a "normal" patient/individual with a severe chronic long-term debilitating health care problem, rather than as someone who is "FTD" (fixin' to die).

AIDS SURVIVORS

There is a growing group of individuals who, once diagnosed, are outliving their expected survival rate. Up to 8 percent of all people diagnosed with AIDS in 1983 are still alive (Grady, American Health, September, 1988). These statistics are encouraging for the many individuals afflicted with AIDS.

Diagnosed four years ago, Bruce Zachar was told he would probably not live to see the results of a study for which he volunteered. "I thought to myself," said Zachar, "maybe you'll get run over by a cab on your way home." (Grady, American Health September, 1988.)

As physicians and health care providers become more skilled in treating the various cancers and opportunistic infections which are part and parcel of AIDS, this can only help increase the odds. Those treating AIDS patients have agreed that immediate and aggressive use of drugs such as AZT and aerosol pentamidine is imperative.

Many physicians and researchers agree that the survival success of some AIDS-diagnosed individuals is due to their "will" to live, their ability to cope with stress and adversity, and their level of assertiveness and drive. We are finding that individuals who are surviving longer, and enjoying a substantial "quality of life" are those who assume control over their lives, maintain a positive attitude, exercise regularly, have an internal locus of control, and practice sound nutrition. In short, those taking an active role in their own treatment.

FAVORING THE ODDS

■ *Nutrition:* Although sensitivity varies among individuals, foods that further damage your immune system—such as those that cause sores in the mouth, fruits, acidic foods and hard crusts—should be avoided.

■ *Exercise:* aerobic exercise training resulted in a significant increase in CD 4 lymphocytes (> cells over baseline) in the anti-HIV negative subjects. There was a modest increase of about 50 CD cells over baseline in the anti-HIV positive subjects. Data also reveal that exercise can act as a buffer for anxiety, confusion and depression, emotional reactions elevated by a positive HIV diagnosis. (Mary Ann Fletcher, Ph.D., Abstract: Stress and aerobic Exercise. Effects on Immune Functions and Psychosocial Variables in an AIDS Risk Group (Healthy Gay Men)).

■ *Regular Hours and Environment:* avoid overcrowded and unsanitary places. Lack of sleep has been found to depress the immune system.

■ *Smoking:* alters and suppresses the immune system.

■ *Alcohol:* depresses the immune system, causes depression and vitamin deficiency.

■ *Drugs:* the use of IV drugs and the sharing of needles has been proven to lead to a seropositive/AIDS diagnosis. Using a simple and cheap disinfectant such as bleach to cleanse needles can eliminate contamination.

■ *Physician Knowledge:* assess the knowledge of your physician so that you feel that he is equipped to diagnose and counsel regarding AIDS, competent to carry out a treatment plan and committed to saving your life.

■ *Positive Attitude:* maintaining a positive attitude is one of the most important interventions to implement in your fight against AIDS. Learning to cope with your fear, stress and anxiety will go a long way toward improving your prognosis and longevity.

■ *Support Groups:* have someone you can talk to honestly about your feelings and what you are going through.

Drug Therapy: there should be aggressive use of available drugs (i.e., AZT, Pentamidine, etc.) by your doctor.

■ *Sexual Practices:* make responsible and mature decisions about your sexual life. Get counseling. When deciding on the brand of condom to use, take into account the different brands available, the brands that contain nonoxynol-9, shelf life, susceptibility to deterioration by heat, etc.

A FUTURE WITH AIDS

It is very evident among AIDS professionals that we are now settling in for the long-haul and we must think in terms of long-term treatment strategies. Although not cures, new drug treatments on the horizon may prove significant as palliative treatments. Even more promising is the impact of personality traits on the survival rate among individuals with AIDS.■

Next Month: Seropositivity and Reinfection: Pending off AIDS

Genevieve M. Clavreul, RN, PhD

NATURE VOL. 332 17 MARCH 1988

AIDS workers going for computer link

Washington

THE World Immunological Network Project Foundation — an organization which promotes hospital videoconferencing — has ambitious plans to link all AIDS researchers worldwide together in computer networks, according to Genevieve Clavreul, the foundation's director.

Clavreul scored her first big success last week by persuading Robert Gallo of the US National Cancer Institute and Luc Montagnier of the Institut Pasteur in France to activate accounts with BITNET — a widely used scientific network in the United States — and the European Academic and Research Network (EARN). Members of Gallo's and Montagnier's laboratories will now be able to communicate electronically, through an interface between the two networks.

By tying together electronically two of the leading centres of AIDS research Clavreul hopes to stimulate increased use of data-sharing and communication networks among the biomedical scientific community. Her ultimate plans are to create a 'subset system' on AIDS research that would allow the exchange of electronic mail, and provide access to AIDS-specific databases and software. Clavreul is working with IBM to encourage biological researchers to tap into electronic mail networks. Most researchers studying AIDS work at institutions already have accounts on major networks such as BITNET and EARN, but biologists have been slower than other scientists to communicate electronically because their work involves less computing.

But despite Clavreul's enthusiasm, the idea of a specialized computer network for the exchange of AIDS information among researchers is not new. The US Presidential Commission on the HIV Epidemic recommended the creation of a computer network for AIDS research in its preliminary report (see *Nature* 332, 3; 1988). Recently, the American Foundation for AIDS Research convened a meeting of AIDS researchers to discuss whether or not such a network would be useful. The consensus was that communication by facsimile machine and telephone was filling current needs, and that frequent meetings were more beneficial. **Carol Ezzell**

Misdirection: AIDS Research, the Government and AmFAR

ACTING UP
A GENERAL ALLIANCE FOR DEALING WITH AIDS

The World Health Organization estimates that 40 million of us will be infected with the HIV virus by the year 2000. The estimates of a recent Harvard University study are twice this number. People are dying in large numbers. The White House is inaccessible and President Bush is totally unresponsive to the recommendations of the National Commission on HIV/AIDS. In reality, the American Foundation for AIDS Research (AmFAR), AIDS service agencies and commissions have accomplished very little.

During the past seven years, AmFAR has appointed itself to raise private funds for AIDS research. We have remained silent in our criticisms in an effort to protect AmFAR and its chief fundraiser, Elizabeth Taylor, because no other organization has stepped forward to spearhead private AIDS research. So, AIDS activists intolerant of the government and corporations, have allowed AmFAR to remain unaccountable for its behavior and utilization of over $40,000,000 received in donations to date. We did not demand an explanation when AmFAR started replacing directors. Many past directors typically refuse to give exact reasons for their decisions to leave except for a vague allusion of some philosophical problem with the AmFAR board of directors. Celebrity fundraisers and socialites are either leaving or cutting back their involvement with the organization and the process perpetuates itself. This comes at a time when government cutbacks are on the horizon and few real breakthroughs in the treatment of HIV/AIDS have emerged. AmFAR has failed to achieve its original claim that it would become a leader in AIDS research initiatives. Several AIDS researchers, community advocates and former staffers charge that AmFAR has repeatedly misdirected its funds to education instead of research.

Now is the time to challenge the status-quo and initiate a new organization for international private AIDS medical research. As Larry Kramer stated in his article to the *Village Voice* in December 1991: "The numbers are marching faster than we can ever stop them by education alone. The only thing that is going to make the plague go away is a cure at the most and successful treatments at the least. And research has been ignored. Because of this there is not one drug that is any good. We are in the middle of a huge war and there is no general. The American Foundation for AIDS Research should be a watchdog, but it isn't."

You've got to want to end all of this! You've got to fight for science, research, treatments, vaccines, and a cure! Many leading scientists are in favor and would support such an international think tank, including Professor Montagnier and Dr. Gallo. We must unite now and take action. Leading scientists in the United States and Europe have publicly committed to work together to improve the coordination and dissemination of AIDS research information. With financial backing and organizational structure, this is achievable.

"AIDS is a danger, but it is also an opportunity ... to see above in the past we have failed, to gain insight into circumstances, to find the way to succeed."

— Dr. Luc Montagnier

ACT UP/SAN DIEGO RESOLUTION

WHEREAS:

- No strategic plan is in place to coordinate national and international efforts in AIDS research.
- No scientific structure to guide the systematic study of potential treatments and cures for AIDS is in place.
- No formal educational plan exists to educate all physicians in current practice or in medical schools to recognize, treat and make appropriate referrals for patients with AIDS.
- The process for scientific publication is antiquated, inadequate and impedes the timely dissemination of research and clinical data.
- The governments of the developed world, particularly the United States, are devoting only a fraction of the resources to AIDS that are merited by the potential for nationwide and worldwide devastation from this epidemic as it continues.
- The unabated gravity of the existing AIDS crises requires a logical, collaborative and immediate response, and no agency involved in AIDS research funding, whether public or private, has used its influence to help build any significant, cooperative effort between scientists and research institutions addressing this problem.
- The American Foundation for AIDS Research (AmFAR), which has collected over $40,000,000 since its founding in 1985, has allocated those resources in a wasteful and unproductive manner, generally giving grants to institutions already receiving public funding for AIDS research and duplicating government-funded research instead of funding innovative projects; therefore be it

RESOLVED:

- That AmFAR no longer be allowed to claim unquestioned primacy in the collecting and dispersing of funds for the purpose of ending the AIDS epidemic; and that a campaign be mounted to alert the public as to the incompetence of much of its effort.

ACT UP does hereby call upon AIDS activists, AIDS researchers, AIDS clinicians, academic institutions, the biomedical and pharmaceutical industries and the governments of the United States and other countries with significant populations affected by AIDS, to join together NOW to develop a new international research project in fundamental and, clinical AIDS medicine, to be a "Manhattan"-like project known as "Project Attila."

ACT UP demands that a call to implement this project be incorporated into the national platforms of all presidential candidates in the 1992 United States presidential election.

This resolution passed unanimously at an ACT UP meeting during June 1992 in San Diego. Join us in our efforts to battle AIDS. For specific information about "Project Attila" contact Genevieve Clavreul at (619) 597-0707. If you would like more information about ACT UP contact us at: PO Box 5341, San Diego, CA 92165. We meet at 7pm each Friday evening at Being Alive in Hillcrest. The address is 720 Robinson Avenue.

ACT UP! FIGHT BACK! FIGHT AIDS!

COPY

AIDS — Has The Human Species Met Its Match?

The revelation this week that Arthur Ashe, the tennis great and sports historian who disclosed his HIV status late last year, is now planning to raise five million dollars to create his own AIDS-related foundation has filled me with great sadness and despair. One might think that my response would have been quite different, since the fight against this disease occupies so much of my time and my energy. One might think that I would have been heartened by the news that yet another high profile media personality has joined the battle. One might think that I would welcome Arthur Ashe, as a couple of months ago, I might have been enthusiastic about the Magic Foundation started by Magic Johnson or the new Family Coalition founded by Body by Fisher heiress Mary Fisher, or the Ryan White Foundation, the Dionne Warwick Pediatric Foundation or the New York-based Gelpi Foundation (which created the concerned parents of children with AIDS). So one might think.

In actuality, however, each of these new announcements causes me to question anew our capacity to respond to the challenge of AIDS. It appears that each new celebrity or person of means who discovers that he or she has an HIV infection or AIDS feels the need to create a new foundation or organization in his or her name to focus on the segment of the population he or she feels the most drawn to protect or support. In so doing, each violates a basic axiom: *the less you splinter, the more power you have.* Rather than strengthening our chances of defeating AIDS, each new splinter organization actually weakens us because the united effort we need is further eclipsed. It is as if a huge fire, burning out of control, were being fought by separate groups of individuals armed with coffee cups of water with no one noticing that there are no fire trucks, no hoses and no chief.

Worse yet is the fact that each organization, in addition to funneling dollars away from the creation of a more focused point of attack, also wastes so much energy and time. Each organization creates more bureaucracy that adds reams of paper to the effort but no new treatments. Communication is enormously difficult between people working in the labs and those seeing PWAs in clinical settings. In any case, this plethora of tiny Davids with their slingshots only adds more strain to an already dilapidated health care delivery system struggling as it is just to take care of the ordinary load of the nation's sick. This results in just what we do not need: more duplicated effort, more money spent on health-care managers, less on clinicians, and, most crucially, less on researchers.

This is a high price to pay to assuage the egos of the high-profiled. No doubt the reasons for many of them are both diverse and complex, but that does not erase the fact that everyone wanting THEIR foundation to take care of THEIR special-interest risk group has now gone beyond the point of absurdity. No doubt, faced with the awful uncertainty of HIV, many wish to keep control of their lives by means of an executive position astride an organization. Many, celebrities and socialites by vocation, think automatically of philanthropic contribution as a way to make one's mark for both altruistic and self-aggrandizing reasons.

GUEST COMMENTARY

Why can we not ally? Against no other disease is the research effort so fragmented though no other one can name has such a potentially devastating effect on our planet. Say what you will about Jerry Lewis, who periodically comes under fire for his sometimes maudlin appeals for funds on his annual Labor Day Muscular Dystrophy telethons. The fact is that his efforts are enormously successful in accomplishing what they set out to do — raise awareness and necessary funds. This year he raised $34 million in a single weekend. Why has AIDS not found someone with that dedication to produce such striking results? Elizabeth Taylor's AmFAR is a highly visible giant that, amoeba-like, sucks up all the money it raises and uses it to fund educational programs of increasingly questionable effectiveness while promising efforts to find new treatment methods die on the vine for lack of research funds. Beyond that, we have only a castrated AIDS commission that can make recommendations with no power to implement them as it struggles to retain what little funding it has to pay its own staff. If we as a species were consciously attempting to commit mass suicide we could do so no more effectively than by this supposed effort to stave off global disaster. Forget global warming and the death of the oceans and the dissemination of nuclear weapons throughout the developing world. A few more years of this and AIDS will do us in quite nicely, thank you, especially given some of the more disturbing implications of the ways it is creating further public health dilemmas like the rise in tuberculosis. We are like Dorothy locked in the witch's castle with the hourglass running out, but to date no coalition of scarecrow, tin woodsman and cowardly lion is on the way to bust us out. They are each holding individual press conferences announcing a new "Free Dorothy Foundation."

> " Even in Hollywood, no one would think of making 10 movies in one season on the same subject; in AIDS research such overlapping happens all the time because no attempt at coordination has yet been successful."

It seems to me that the time has come in the progression of the AIDS epidemic to ask a simple but chilling question: Is the Human Immuno-deficiency Virus (HIV) a more intelligent life form than the human species? I am not speaking medically here. It is a crafty organism to be sure and researchers are well aware of its ability to mutate and the many strategies it employs to defy those searching for ways to destroy it or predict its moves. I am speaking here about the will of our species to respond with a coherent and coordinated plan that will give the search for a cure the [illegible] it must have if our species is to [illegible] this global crisis and the related [illegible] to our continued existence on [illegible]

What could be the reason [illegible] denial? [illegible] In addition to its ability [illegible] blood/brain barrier in some [illegible] AIDS dementia, [illegible]

Disease or a threatened outbreak of cholera. It is the price we are paying for the homophobia that has dictated the response of officialdom since the onset of the epidemic, one reason for the fragmentation is, self-evidently, that no one wanted to be lumped with gays, the "guilty victims" of the virus, like IV drug-users; as opposed to the innocent ones like children and hemophiliacs. The snarling "let 'em die" attitude of the Helmses and the Buchanans on the right and the reactive responses of many of our own politicians and activists that made health issues into civil liberties issues are two manifestations of this tragic waste of energy and time.

Another related issue has to do with the issue of sexuality in general, without regard to the specifics of gender. The fact that AIDS is sexually-transmitted has meant that denial was already a built-in part of the response to its appearance, given the high degree of repression and shame that surrounds sexual issues in this puritanical culture where the choices still seem to be between pornography and rigid suppression, with little in between. Psychologists tell us that when deeply-repressed material threatens to become conscious, splitting can occur within the self that fragments the personality into myriad sub-personalities — a kind of inner version of the external situation I've been discussing here.

Furthermore, the lack of leadership on the highest levels that has led to the [illegible] at the center of the effort so far has created a situation in which no one is assigning priorities, managing resources or assessing results. This has led to total chaos. Research in some areas is being duplicated while needed studies in other areas are being totally neglected. Critical decisions are being dictated by egos rather than by good scientific judgment. Even in Hollywood, no one would think of making 10 movies in one season on the same subject; in AIDS research such overlapping happens all the time because no attempt at coordination has yet been successful.

Perhaps we need to look again at the later writings of Professor Freud, whose final musings on the human dilemma [illegible] him to posit the existence of a force he called thanatos, the death wish, the [illegible] kind of longing for extinction — within the species as within the individual. Regardless of the particulars, the question that [illegible] over us and demands that we rise to the challenge of this epidemic is the [illegible] preoccupied him.

"The fateful question for the [illegible] species," he wrote in *Civilization and [illegible] Discontents* (1931), "seems to be [illegible] and to what extent their cultural development will succeed in mastering the [illegible] bance of their communal life by the [illegible] instinct of ... self-destruction. It may [illegible] in this respect precisely the present [illegible] deserves a special interest ... Now it [illegible] expected that the other of the two '[illegible] powers,' eternal Eros, will make [illegible] effort to assert himself in the struggle [illegible] his equally immortal adversary — [illegible] can foresee with what success and [illegible] what result?"

Who indeed? And in the case of [illegible] disease that already has [illegible] the time for that unifying effect had [illegible]

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3753

Date Rcvd: 05-14-97

From: Daniel Jongale

Ltr sent to Dexina Stalala cc: Sandra Thurman

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

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Recommendations/Instructions:

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To Support Staff:_____

Date of Response:_____

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AIDS Action council

May 5, 1997

The Honorable Donna Shalala, Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Room 615-F
Washington, DC 20201

Dear Secretary Shalala:

We are writing to express our deep concern regarding clinical trials presently being conducted by CDC, NIH, and UNAIDS. These trials are designed to develop an inexpensive, short-course protocol to reduce the incidence of perinatal transmission of HIV in developing countries. A recent study published by Public Citizen raises important ethical questions regarding the conduct of these studies which appear to rely on non-treatment or ineffective treatment, such as vaginal washing or Retin-A, as placebo arms in the trials in spite of the availability of the 076 regimen as a proven standard of care. We request your leadership in discovering whether guidelines protecting human subjects who participate in clinical trails are being violated by these trials, and, if they are, to assist in altering the re-design of the trials so that they comply with accepted ethical standards.

Our central concern is that there is an appearance that clinical trails in the developing world are being conducted in a manner which would not be permitted in the United States or Europe. While we understand that the 076 protocol is far too expensive for widespread use in countries where such a regimen is unsustainable, we firmly believe that the search for a short-course regimen must not be provided at the cost of refusing to use standard of care as the baseline for determining the efficacy of any modified treatment regimen. Since other clinical investigations have proven that alternative treatments or other interventions including vaginal washing are not effective in stopping vertical transmission, there is no point in subjecting additional women to such interventions.

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300

The International Ethical Guidelines in guideline #15, states that "...the ethical standards applied [in clinical trials carried out in foreign countries] should be no less exacting than they would be in the case of research carried out in [the sponsoring] country." The employment of a placebo arm in a study of perinatal transmission seems not to be consistent with this guideline due to the availability of a proven regimen, 076. Although the host countries have cooperated in these efforts to design simpler preventive therapies, your agencies must comply with an ethical baseline that is consistent with existing standard of care.

It is our hope that none of the principles of the Nuremberg Code or other internationally accepted ethical standards were violated by this research. We ask that you meet with concerned community groups to discuss your plans for assuring that these trials conform to international ethical standards.

As you know, there exists widespread suspicion in the AIDS community -- especially among African-Americans and women -- regarding the ethical treatment of participants in research studies. It would be unfortunate, especially at a time of increased optimism in treating HIV, for an incident like this to make our work in reaching out to communities of color even more difficult.

We look forward to your comments and cooperation in dealing with this important matter. If we can be of assistance, please call on us. Thank you for your time and consideration.

Sincerely,

Daniel Zingale

Daniel Zingale
Executive Director

cc: Mr. Kevin Thurm
Mr. Bill Corr
Dr. Helene Gayle
Dr. Jack Killen
Dr. William Paul
Ms. Sandy Thurman

SOCIAL SECURITY

Office of the Commissioner

May 12, 1997

MEMORANDUM FOR SANDRA THURMAN

FROM: Brian D. Coyne
Chief of Staff

SUBJECT: Interagency Task Force on AIDS

The Social Security Administration (SSA) would like to appoint Lisa Peoples as the liaison from SSA to the Interagency Task Force on AIDS. Charlie Brittian previously served in this position for SSA. Please begin forwarding all material concerning the Interagency Task Force on AIDS to Lisa Peoples. She can be reached at (202) 358-6093 and the fax is (202) 358-6077.

If you have any questions, please do not hesitate to contact me at (202) 358-6013.

Check this out!

Ranael,
look/skim at these letters, before they go out.

THE WHITE HOUSE
WASHINGTON

May 22, 1997

Seth Berkley, MD
International AIDS Vaccine Initiative
c/o The Rockefeller Foundation
420 Fifth Avenue
New York, NY 10018-2702

Dear Dr. Berkley:

Thank you for your letter to the President in support of his recently announced vaccine initiative. We share your excitement about this new initiative!

I wanted to let you know that we will definitely take you up on your effort to work with us as we put the initiative together. Our shared goal of developing a vaccine (or vaccines) to stop HIV is a worthy one, but one which will demand a great deal of effort and coordination.

I look forward to working with you on this effort. Thank you again for your kind letter of support!

Very truly yours,

Sandra Thurman
Director
White House Office of National AIDS Policy

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3766

Date Rcvd: 05-20-97

From: Seth Berkley, M.D.

Ltr Sent to The President cc: Sandra Thurman

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

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Recommendations/Instructions:

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To Support Staff:_____

Date of Response:_____

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(C1)

May 19, 1997

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

The International AIDS Vaccine Initiative strongly supports your call for an urgent increased and time-bound effort to develop safe and effective HIV vaccines. We agree that an HIV vaccine is possible and with nearly 10,000 new infections occurring a day worldwide, time is of the essence.

We also applaud your plans to call for the leaders of the G-7 countries and Russia to join the U.S. in a global effort to create a vaccine. HIV is the first large global epidemic of an emerging infectious disease in this era of global interconnectedness. How we deal with this epidemic portends how we will contend with future, yet undiscovered infectious diseases. Your leadership on this issue internationally will intensify recognition of the impact of HIV/AIDS on international health and development, and bring together the strengths and commitment of national and international agencies and organizations to address and solve the impact of HIV/AIDS on worldwide human and economic development.

We concur that the U.S. government must continue to support or even enhance the excellent basic scientific research that serves as the essential underpinning of vaccine development. In addition, we need to enhance applied vaccine development efforts. Without good animal models and without clear correlates of protection, there is no substitution for clinical testing of promising safe candidates in humans at an early stage. Results (whether positive or negative) from clinical testing will drive the basic science agenda as much as findings in basic science will inform the product development process.

We support the creation of a new vaccines effort at the NIH which will facilitate the important linkage between basic and clinical research. As you have acknowledged, however, industry is the best source of applied work. Unfortunately, as you are aware, there currently are not the market incentives for industry to invest substantial resources in HIV vaccine development. A new initiative needs to be considered. This initiative should be a directed research effort which

IAVI

Interim Secretariat • c/o **The Rockefeller Foundation** • 420 Fifth Avenue • New York, NY 10018-2702 • USA
phone (212) 852-8349 • **fax** (212) 852-8279

is goal oriented with clear benchmarks using the world's most experienced HIV/AIDS researchers and vaccinologists. Vaccines cannot be developed by researcher oriented mechanisms. Vaccines need to be developed by an experienced team of vaccinologists and other scientists that will, step by step, solve the problems encountered during the development process.

In addition, vaccines need to be designed for testing and use in international settings where the epidemic is spreading most rapidly and where testing can be efficiently accomplished. Use in international settings may require special characteristics such as simplicity, stability and cost that may require different vaccine designs than are being evaluated for the U.S. market.

The International AIDS Vaccine Initiative was established with just this purpose in mind -- to ensure the development of safe, effective, preventive HIV vaccines for use throughout the world. IAVI has established a partnership of international agencies (UNAIDS and the World Bank) to work directly with those in the private sector without the constraints of government funding mechanisms to accelerate vaccine development. We would welcome the opportunity to work with your staff to assure the completion of your noble and just target of a safe and effective HIV vaccine by the end of the decade.

With best wishes.

Sincerely yours,

Seth Berkley, M.D.
Interim President

cc: Sandra Thurman

SFB/pb

IAVI

Interim Secretariat • c/o **The Rockefeller Foundation** • 420 Fifth Avenue • New York, NY 10018-2702 • USA
phone (212) 852-8349 • **fax** (212) 764-3468

FOR IMMEDIATE RELEASE
CONTACT: BETSY KOVACS, 212-852-8377

IAVI Applauds Clinton Action; Suggests Next Steps for Vaccine Development

NEW YORK, N.Y., May 19, 1997 -- President Clinton's establishment of a national goal to develop vaccines for AIDS by the year 2007 and creation of a vaccine research center at the National Institutes of Health is a major new step in the effort to halt the AIDS pandemic which is now sweeping the globe, according to Dr. Seth Berkley, president of the interim board of directors of the International AIDS Vaccine Initiative (IAVI). It is imperative that the effort to create safe, effective AIDS vaccines be a comprehensively international effort and one that focuses on catalyzing the efforts of the commercial vaccine industry.

Dr. Berkley, head of the two-year-old organization established by the Rockefeller Foundation and the Sloan Foundation, further said that IAVI's panel of distinguished AIDS scientists from around the world believes that development of such vaccines is possible and that work is proceeding to intensify current efforts of private pharmaceutical companies in the United States and France to achieve such a breakthrough.

Dr. Berkley said that the President's announcement that he would seek cooperation from other nations in the Group of Seven is especially gratifying. "IAVI has been seeking such action since the organization was formed," Dr. Berkley said, "because it is only through a co-operative international vaccine effort that we can halt the advance of this global epidemic." Given the enormous number of currently infected persons, it is vital that work continue on improving AIDS therapeutics and making them more available. Due to their expense, complicated dosing regimen, unintended side-effects and the likelihood of developing antimicrobial resistance, however, these new therapies will not stop the epidemic, especially in developing nations where the HIV disease is spreading at the rate of 8,000 to 9,000 new infections each day.

"Without good animal models or an understanding of the correlates of immunity, it is only though human trials of safe vaccines that we will gain the knowledge necessary to succeed in developing a vaccine appropriate for use. It is, therefore, essential to move as quickly and aggressively as possible to stimulate vaccine development. It is within industry that the expertise for vaccine development lies. Therefore, this new effort will not only require the support of governments, but also a broad coalition of private interests and involvement of leaders within the non-governmental and philanthropic community," Dr. Berkley said.

- more -

Dr. Berkley said that if President Clinton can muster financial and political support from the leaders of the industrialized world, it should be directed at two areas.

"In addition to adequate funding for promising but underfunded vaccine research, private pharmaceutical companies must be provided with incentives to accelerate vaccine development and some provision must be made for ensuring that such vaccines will be tested to determine their efficacy.

"Basic research certainly is vital to determine the mechanisms whereby vaccines may work, but simultaneously, a directed, targeted vaccine development effort led by experienced vaccinologists is imperative to accelerate and initiate phase I testing of a variety of vaccine approaches if this disease is to be halted" Berkley said.

"Attention to the international aspects of the epidemic must also be considered. The subtypes of HIV viruses found in developing countries are substantially different than those found in the United States. Although the ultimate significance of this finding is unknown, prudence dictates creating vaccines from strains where they will be tested. In addition, vaccines for use in developing country settings may require special characteristics such as simplicity of delivery, stability and cost that may entail different vaccines designs that are being developed for the U.S. market."

Berkley said that IAVI has assembled a Scientific Advisory Committee with scientists from nine countries who are some of the most respected scientists in fields germane to HIV vaccine development to provide counsel on vaccine development. Under the leadership of IAVI's Scientific Director, Peggy Johnston, Ph.D. the panel recommended and the Initiative is supporting three priority areas for stimulating vaccine development: DNA vaccine development, research on live-attenuated vaccines, including safety studies in animals and the development of viral clones from developing regions that can be used in animal testing.

Dr. Berkley urged that the new vaccine research center and any organization established by the Group of Seven to stimulate vaccine development consider ways to create a more enabling environment for private pharmaceutical companies to develop novel products and in testing and delivering these vaccine products particularly in developing countries.

"Hopefully, the challenge issued by President Clinton to the scientific community and soon to the G-7 will lead to involvement and commitment of the CEOs of the world's vaccine and biotechnology companies -- a true public-private initiative in the spirit of Sematech or Airbus," Dr. Berkley said.

IAVI works with various other AIDS-related organizations to achieve its mission of ensuring the development of safe, effective, preventive HIV vaccines for use throughout the world. Among its partners are AmFAR, the Until There's A Cure Foundation, the Sabin Vaccine Foundation, the National AIDS Trust, the Marcel Mérieux Foundation, and others. Major funders of IAVI, in addition to the Rockefeller and Sloan Foundations, are the Until There's A Cure Foundation, UNAIDS, and the World Bank.

# # #

(Editor's Note: To schedule interviews with Dr. Seth Berkley or with Dr. Peggy Johnston, please call Ms. Betsy Kovacs at 212-852-8377.)

THE WHITE HOUSE
WASHINGTON

May 22, 1997

Ronald B. Moss, MD
Medical Director
The Immune Response Corporation
5935 Darwin Court
Carlsbad, CA 92008

Dear Dr. Moss:

Thank you for taking the time to talk with me about the Salk Immunogen and for sending along the information.

I also appreciate the offer to provide an informal presentation on the Salk Immunogen to our staff here. At the moment, we are working to build a staff here! Please allow us a few weeks to get this office in order, and then we will take you up on your kind offer.

The President's recent announcement of a new AIDS vaccine initiative is truly exciting. Now we have the hard work of making his vision a reality, and making the promise to this nation and to the world a reality. Thank you for all that you do to that end!

I look forward to speaking with you again soon.

Very truly yours,

Sandra Thurman
Director
White House Office of National AIDS Policy

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3767

Date Rcvd: 05-20-92

From: Ronald B. Moss, M.D.
Re Immune Response Corporation

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

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Recommendations/Instructions:

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To Support Staff:_____

Date of Response:_____

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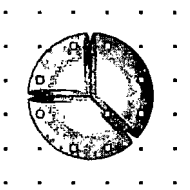


The Immune Response Corporation

May 19, 1997

VIA FEDERAL EXPRESS

Ms. Sandy Thurman, Director
Office of National AIDS Policy
808 17th Street, NW
8th Floor
Washington DC 20503

Dear Ms. Thurman:

It was a pleasure talking to you today regarding the clinical development of the Salk Immunogen.

I have included a copy of my presentation to the PACHA as well as a transcript for your review. In addition, regarding our most recent meeting at the FDA, please feel free to contact the following individuals who were also at that meeting in order to get an objective idea of the content of the meeting: Dr. Robert Gallo, (410) 706-8614; Dr. Fred Valentine, (212) 263-6565; Dr. Bruce Walker, (617) 724-8332.

The main issue that we are dealing with is the threshold for considering immunological markers as surrogate markers for HIV infection. We, and many others, are beginning to realize that complete immune reconstitution is not being demonstrated, even with optimal antiviral drug therapy (viral load to undetectable). Therefore, if immune-based therapies such as ours are to continue to develop as an adjuvant therapy to enhance HIV-specific immunity, there must be a clear regulatory pathway for this approach, as there has been for antiviral drugs. In light of the President's recent commitment to the expedited development of AIDS vaccines the goal of enhancing immunity in infected individuals is increasingly important. I would be happy to give you an informal presentation on the Salk Immunogen at your convenience in the near future as I am in Washington very frequently.

If you require any additional information, please do not hesitate to contact me.

Sincerely,

Ronald B. Moss, MD
Medical Director

RBM/mlh

The Immune Response Corporation 5935 Darwin Court Carlsbad, CA 92008 (619) 431 7080 FAX (619) 431 8636

Dr. Ron Moss
Presidential Commission on AIDS

OK, does everybody have a copy of my presentation; was that distributed? OK, great, well, thank you very much. I want to thank everybody for the opportunity to give a presentation to the committee today. The title of my talk is "Incentives and Disincentives for Vaccine Development: A Biotech Perspective". And I want to give the committee a perspective that we have had in the development of our whole-kill product, in terms of its therapeutic use because I think there are potential parallels to vaccine development of a preventative vaccine as well.

The product that we have been involved in is a whole virus gp120-depleted inactivated HIV antigen in incomplete Freund's adjuvant. And if you turn to Figure 1 in your handout, you can see a schematic, basically diagramming what we are using as a therapeutic immunogen. And essentially this is an HIV virus which was actually taken from a Zairian woman in 1976 and the virus has been inactivated using Cobalt ^{60} and ß-propiolactone. During the purification of the immunogen, the gp120 is depleted. It essentially falls off during the purification. And finally, it's put in Incomplete Freund's Adjuvant.

The concept that Dr. Salk proposed to use this immunogen was to focus the immune system on more of conserved protein of the virus. So, except for the gp120 which is depleted in this product, all of the other epitopes of the HIV virus are there.

In terms of the subtype of this virus, the gag subtype is probably more relevant than the envelope since it is depleted in the envelope and it's gag subtype G. And as I mentioned, no surprise that this gag region, the p24 region, is very homologous to virtually every HIV subtype gag that's found.

We presently are in a number of different clinical trials and actually I think that this vaccine at this point has probably been injected into more seropositives than any other vaccine. If you look at Figure 2 of your handout, there is a schematic there of all the ongoing clinical trials. Moving counter-clockwise I'll just briefly review what trials are ongoing. There is a pediatric phase I trial being conducted at the National Cancer Institute looking at safety and immunogenicity of this product in children with HIV infection. Within two weeks, a trial will begin combining this immunogen with AZT 3TC and Indinovir, a protease inhibitor. This trial is a collaboration with Merck and Glaxo and the focus of this trial is really looking at HIV-specific immunity, something that we believe we have had some impact on in the past and asking the question whether or not using a potent antiviral combination one can further enhance HIV-specific immunity by combining these drugs with our immunogen. A Phase I trial in Thailand was completed about a month and a half ago. This trial looked at individuals, 99% of which had subtype E virus and confirmed the safety and immunogenicity of the product in individuals with subtype E, which as you know is a different subtype than the predominant subtype in the US. The

phase II trial is continuing in Thailand where individuals will continue to get immunizations and we will be looking at viral loads, CD4 and, of course, immunogenicity.

A phase II trial has just begun in Spain, combining the immunogen with AZT and ddI and this trial, unlike the US trial, is focused on the effects of immunization and the antirviral drugs on viral load.

Finally, we have a phase III study which began last March. The phase III study is a clinical endpoint study and we are presently at over 70 medical centers in the United States and this trial is enrolling very rapidly, we are beyond 1500 patients already enrolled and we envision that the trial will be completely enrolled by March or April of this year.

So, overall this particular therapeutic vaccine has been injected into thousands of individuals at this point and most of those individuals coming out of the phase III study which is currently ongoing.

In terms of what we have seen so far in these trials, the phase I and phase II trials, and Figure 3 gives you a nice synopsis of the effects we have had on markers of disease progression. If you look at Figure 3, in the left hand side is a data from a placebo controlled study looking at the effects of immunization on a healthy cohort of individuals who were predominantly not on antiviral drugs. You can see differences there in the number of infected cells. On the left hand side differences in the middle of the slide, in terms of CD4 changes, and also on the right hand side, changes in terms of weight.

Most importantly, though, if you move to Figure 4, the activity of this product is really focused on developing HIV-specific immune responses against the virus. This is something that has not been shown to be affected by even the most potent antiviral drug. And, in fact, at the Retrovirus Meeting the results of AZTG Study 315 will be revealed showing no effect on HIV-specific immunity of a potent triple drug therapy combination.

If you look at Figure 4 in your handout you can see HIV-specific immune responses induced by this immunogen in terms of lymphocyte proliferation. And then if you move ahead to Figure 5, you can see the inducement of Beta chemokines by the particular immunogen and to our knowledge this is the first report of any therapeutic or prophylactic vaccine inducing the Beta chemokines. And I understand from some of your members that you 've heard from Bob Gallo and that everybody has been following the Beta chemokine story. In addition to the Beta chemokines, we have also seen an enhancement of gamma interferon. Once again, these are all responses in response to HIV antigens so we are looking at HIV-specific immune responses.

---Discussion about whether or not everybody has handout ---

Sure. Since I spoke so quickly through Figures 3 and 4 - or 3,4 and 5, does anybody have any questions they would like to ask any particular questions now before I continue or should I continue and we can come back for questions later?

Committee member: I think that's probably best.

Dr. Moss: In terms of our experiences with the development of this immunogen, there has been incredible disagreement over the correlates of protective immunity in terms of therapeutic immunogens and we believe this has impeded the expedited testing of various products. To give you an example, ten years ago when Dr. Salk proposed this concept and really focused on cell mediated immunity, most of the scientific dogma was that neutralizing antibodies were really the main correlate of immunity and therefore products that were focused on different correlates were not embraced. And we have seen a flip-flop on that. Presently cell mediated immunity has come into vogue including CTL lymphocyte proliferative responses, delayed type hypersensitivity responses, cytokines, and most recently the Beta chemokines. And I think it's important to note, on Figure 7, actually Figure 6... in the handout it should say Figure 7 after the discussion of cell mediated immunity. If you look at Figure 7 you will see that Dr. Salk had proposed a theory back in 1993 really embracing cell mediated immunity and I think the scientific community has come around from really focusing on neutralizing antibodies to more cell mediated immunity as being the predominant potential correlate of immunity.

Most recently as you know the Beta chemokines have been embraced and perhaps one fact related to the Beta chemokines which is important is that they appear to be suppressive for macrophage tropic or early HIV viruses, regardless of the subtype of the virus. So, this appears to be a cell mediated marker that appears to suppress virus irrelevant of particular virus subtypes that you are talking about.

So in our experience, scientific orthodoxy has really impeded the development of not only preventative vaccines and immune-based therapies, but also with our experience with our own product. And, clearly, applied research is undervalued. There is a great concern for detailed mechanisms rather than good clinical studies.

The history of this, as I mentioned, was that envelope based vaccines for therapeutic use were pursued within government sponsored trials while empirical approaches have been largely left to private industry - at great cost to private industry with little government support. Our company for example has pursued this whole virus gp120 inactivated immunogen and it has spent over 100 million dollars on the development of this product. And we believe that an empirical approach which include many vaccine designs really offers an incentive for companies to produce a prophylactic vaccine.

Now I have read a brief transcript of some previous discussions about whole killed viruses and some difficulties with manufacturing, I am presently on page 4 of my handout. And large scale manufacturing capabilities obviously must be considered when evaluating a vaccine candidate. I can tell you that our experience that we are able to manufacture the whole killed product in large scale quantities and we've very well characterized and shown to the FDA the appropriate safety killing of this product to go on to phase III studies. So the technical hurdles have been overcome for large scale production of this product. If

you look at Figure 6 you can see an example of the type of characterization we have done with this product. Figure 6 is a profile called a HTLC profile with all of the proteins in one lot of this product and you can see the sequencing of all of the bands basically showing the characterization, what are the components of this product. And as you would expect, they are all of the components found in the HIV virus. We have also had to show that there is not lot to lot variability in these components and also had to show that there is adequate safety killing of this particular product.

Moving on to page 5, obviously the safety parameters for a preventative vaccine must be determined with risk/benefit ratios taken into consideration before large scale preventative vaccines are begun. And as I have mentioned before, the experience we have had with our product in seropositive individuals is that at this point in time over a 1,000 HIV positive individuals have been injected with this product with no serious treatment-related adverse event. So, in the seropositive population this product has a very good safety profile.

Moving on to the issue of liability on page 6, one of our concerns is that many companies because of the liability issue have focused mainly on therapies for seropositive patients rather than a preventative vaccine. Obviously, we think it may be a good idea and it sounds like others do as well that some sort of insurance fund, similar to the one for pediatric vaccines, could potentially be enacted by the Federal government and this would potentially encourage companies to pursue the development of an AIDS vaccine without the major concern of the liability issue.

Finally on page 7 are my conclusions. I have given you an overview of what we have done with this whole killed product in seropositive individuals. A whole killed gp120 depleted product can be manufactured for large scale testing of a potential preventative AIDS vaccine. Should many of the disincentives be addressed, this product could be considered empirically a prime candidate for AIDS vaccine testing.

And obviously you are all aware that there is a tremendous public health need for an AIDS vaccine and the testing of AIDS vaccines. So, I have very briefly and very quickly gone over a lot of information, and I now want to open it up and see if there are any questions about the Figures and we can go over those again, if need be.

Question: What would you envision us doing, or what would you expect from us as a council that might help your goals and objectives in your work.

Dr. Moss: Well, quite frankly, I think that we have had a lot of discussions with outside scientists, with activists, with people who have asked us regarding the whole killed virus and why this is not being focused on or at least included in the discussions on preventative vaccines. And I think that one of the things that would be very helpful to us is at least opening up the doors of the people who are powered in developing the preventative trials to consider taking a look at the whole killed virus approach. There is a lot of dissent regarding the narrow focus of the current preventative vaccine trials - or the plans for the current vaccine trials. I think that our immunological data with regard to

HIV-specific immunity in seropositives has a direct correlation to the potential of this product as a preventative vaccine and I think more recently getting more sophisticated immunologically in terms of the cytokine and chemokine data has really aroused a lot of individuals who had written off this product just because of not really being completely objective and looking at our data. And I think that now people are taking a second look at this and saying there may be some possibilities here, not only is it therapeutic, but also preventative. And I think our company is interested in pursuing this if some of these disincentives could be addressed.

PACHA Presentation

Given by Ronald B. Moss

January 17, 1997

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

- Whole virus gp120 depleted inactivated HIV-1 antigen in incomplete Freund's adjuvant (Figure 1).
- Contains multiple conserved proteins.
- Product uses HZ321, gag subtype G.
- Presently in Phase I, II, and III clinical trials in US and abroad (Figure 2).
- Positive Impact on immunological and virological markers (Figures 3, 4, 5).

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

- Disagreement over correlates of protective immunity has impeded expedited efficacy testing of products.
- Scientific dogma relating to protection has changed over the years.
  - » Ten years ago neutralizing antibody was embraced.
  - » Presently CMI (CTL, LP, DTH, β chemokines, T_H1) are believed to be important (Figure 6).
  - » β chemokine suppression of HIV is virus subtype independent
- Scientific orthodoxy has impeded the development of preventive vaccines and immune based therapies.
- Applied research is undervalued.

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

- Envelope based HIV-1 vaccines were pursued within government sponsored trials while other empirical approaches have been left to private industry at great cost with little government support.
- The company pursuing this whole virus gp120 depleted inactivated immunogen has spent over $100 million dollars on the development of this product.
- An empirical approach which includes many different vaccine designs offers an incentive for companies to produce a prophylactic vaccine.

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

Manufacturing

- Large scale manufacturing capability must be considered when evaluating a vaccine candidate.
  - » The technical capabilities for manufacturing large scale cGMP quantities of a well characterized, whole killed, gp120 depleted product have been established (Figure 5).
- Technical hurdles have been overcome for the large-scale production of this product.

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

Safety

- Safety parameters must be determined, with risk/benefit taken into consideration before large scale clinical trials of a preventive vaccine are begun.
- A whole gp120 depleted inactivated virus vaccine has been injected into over 1,000 HIV seropositives with no serious treatment related adverse events.

Incentives and Disincentives for Vaccine Development: A Biotech Perspective

Liability

- Due to liability concerns many companies have focused mainly on therapies for seropositive patients, rather than vaccine.
- An insurance fund sponsored by the Federal Government similar to one for pediatric vaccines could be enacted to encourage companies to pursue development of AIDS vaccines.

Conclusions

- A whole killed gp120 depleted HIV product can be manufactured for large-scale testing as a preventive AIDS vaccine.
- Should many of the disincentives be addressed, this product could be considered a prime candidate AIDS vaccine for testing.
- There is a tremendous public health need for a preventive AIDS vaccine.

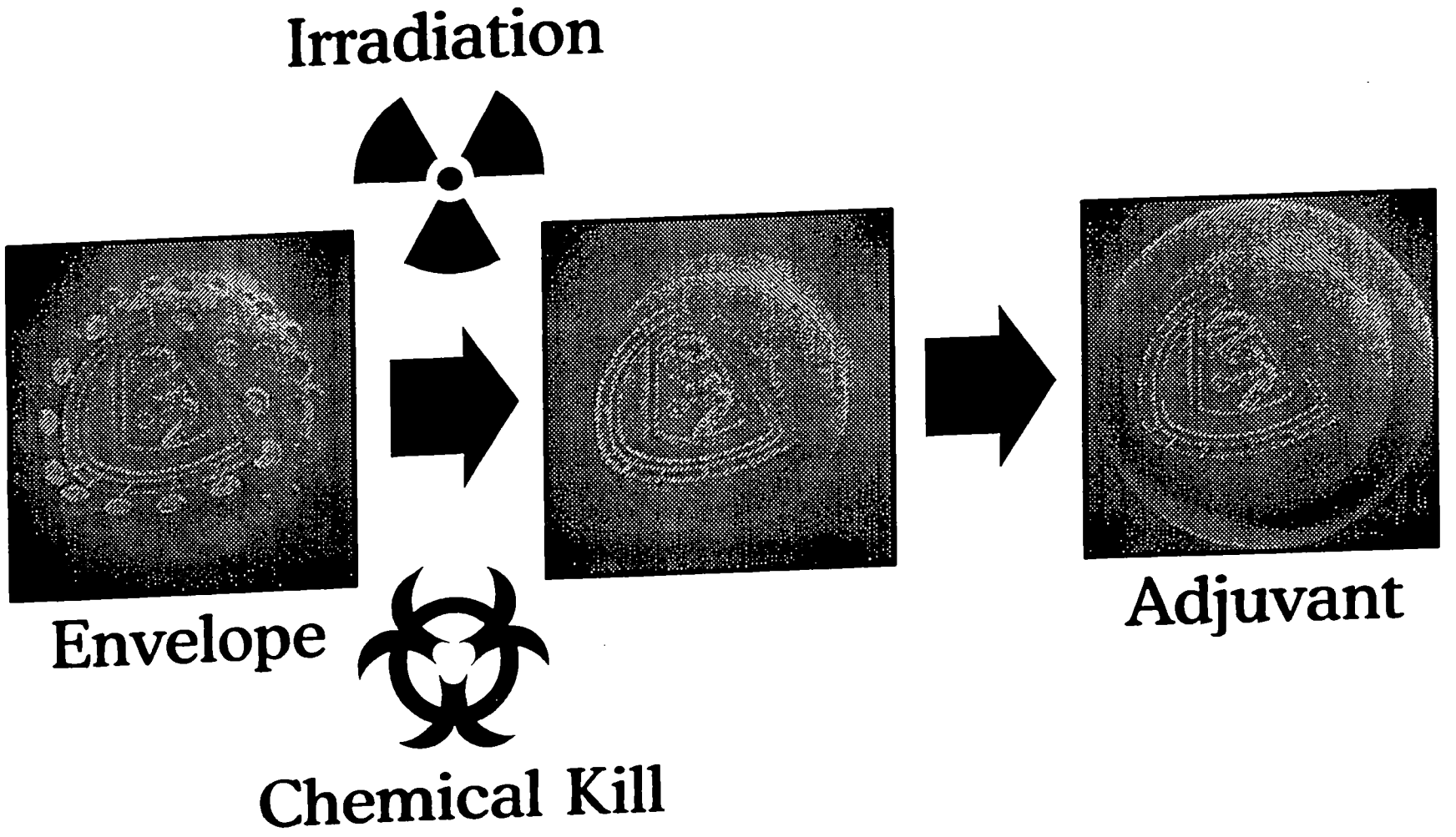


Figure 1.

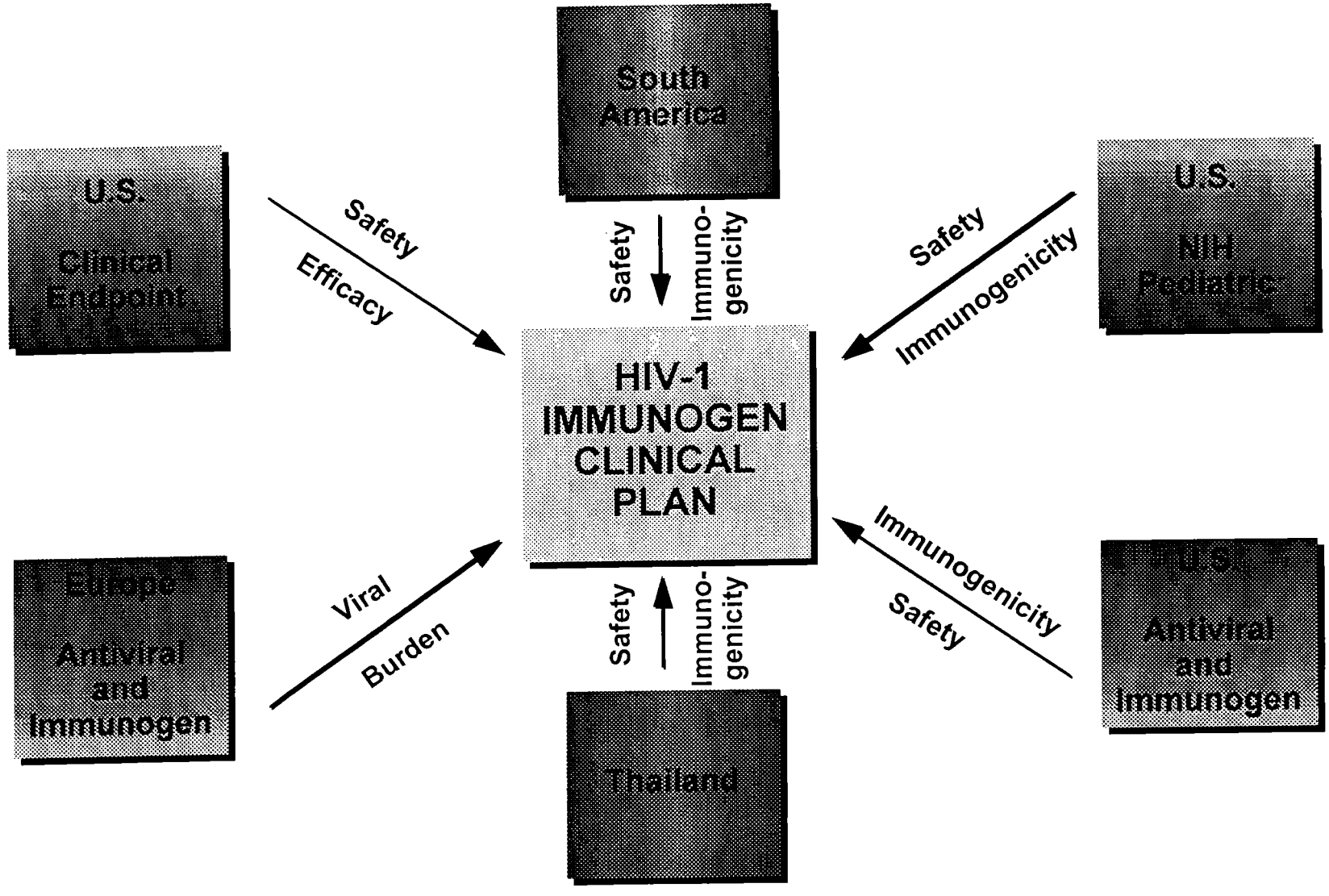
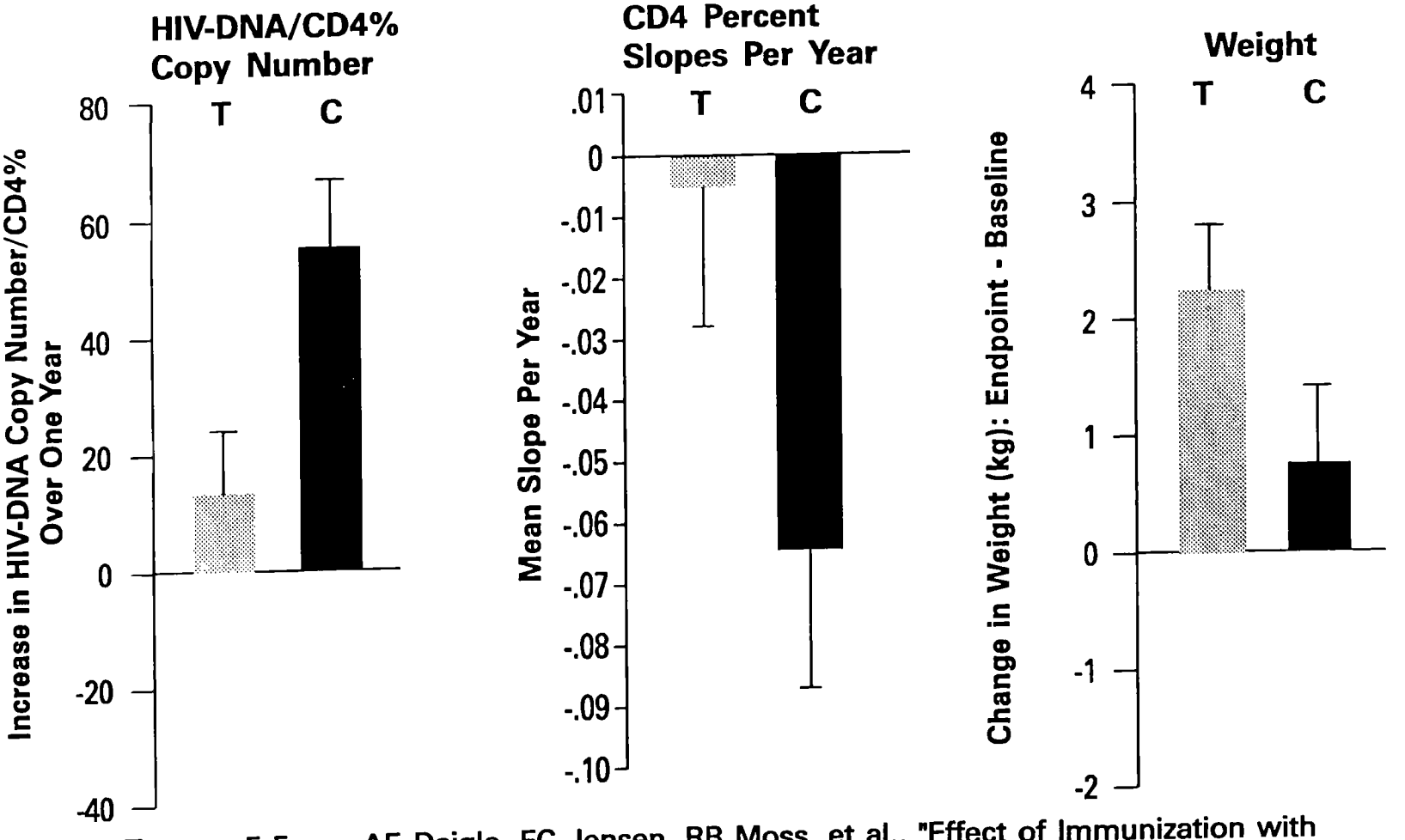

South America
U.S.
Clinical Endpoint
Safety
Efficacy
Safety
Immuno-genicity
U.S.
NIH Pediatric
Safety
Immunogenicity
HIV-1 IMMUNOGEN CLINICAL PLAN
Europe
Antiviral and Immunogen
Viral
Burden
Safety
Immuno-genicity
Thailand
Immunogenicity
Safety
U.S.
Antiviral and Immunogen

Figure 2.

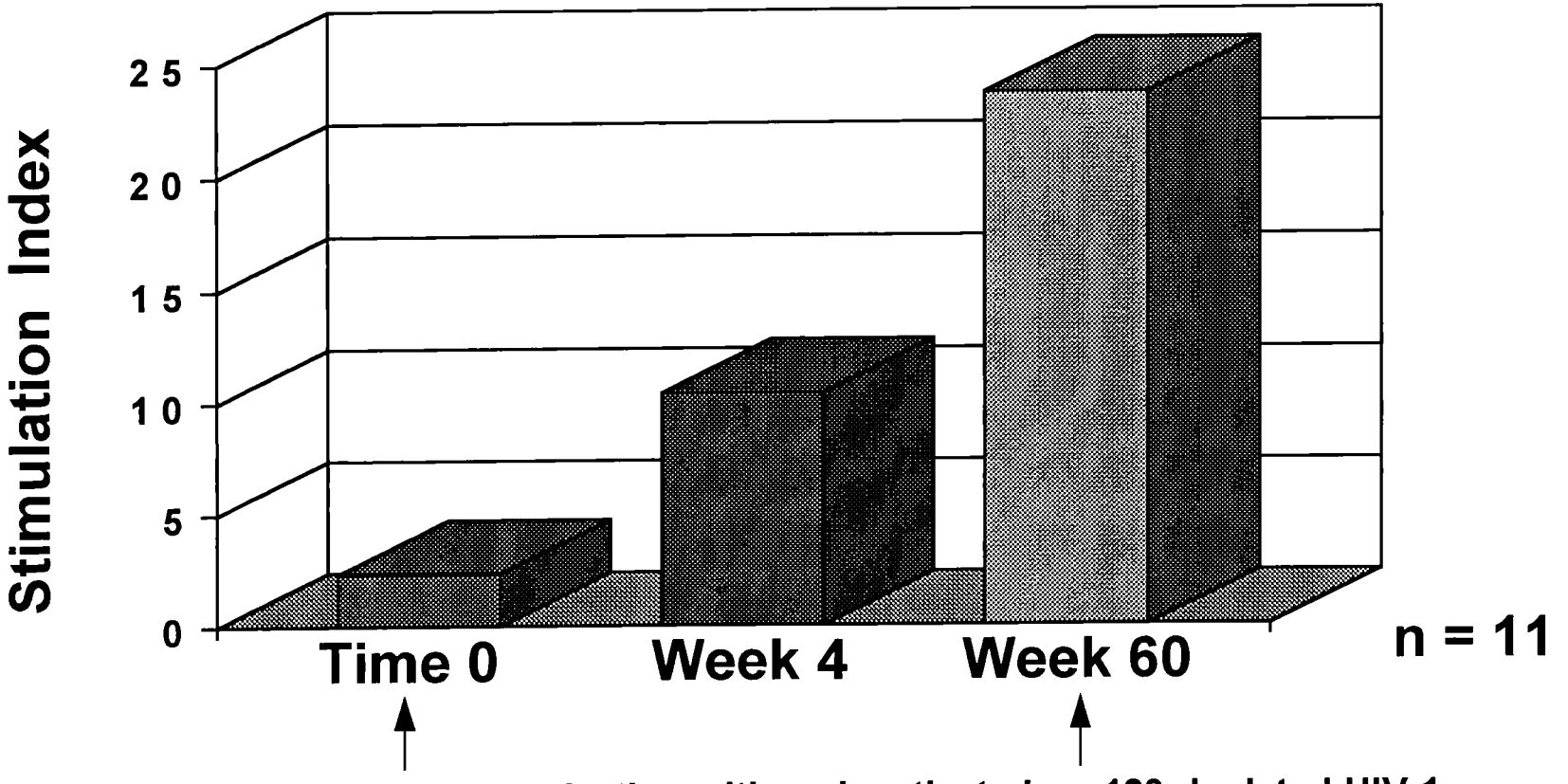
Clinical Study 103
Virologic, Cytologic and Clinical Effects of Immunization
Treated (T) vs Controls (C)



RJ Trauger, F Ferre, AE Daigle, FC Jensen, RB Moss, et al., "Effect of Immunization with Inactivated gp120-Depleted Human Immunodeficiency Virus Type 1 (HIV-1) Immunogen on HIV-1 Immunity, Viral DNA, and Percentage of CD4 Cells." *JID* 1994; 169:1256-1264.

Figure 3.

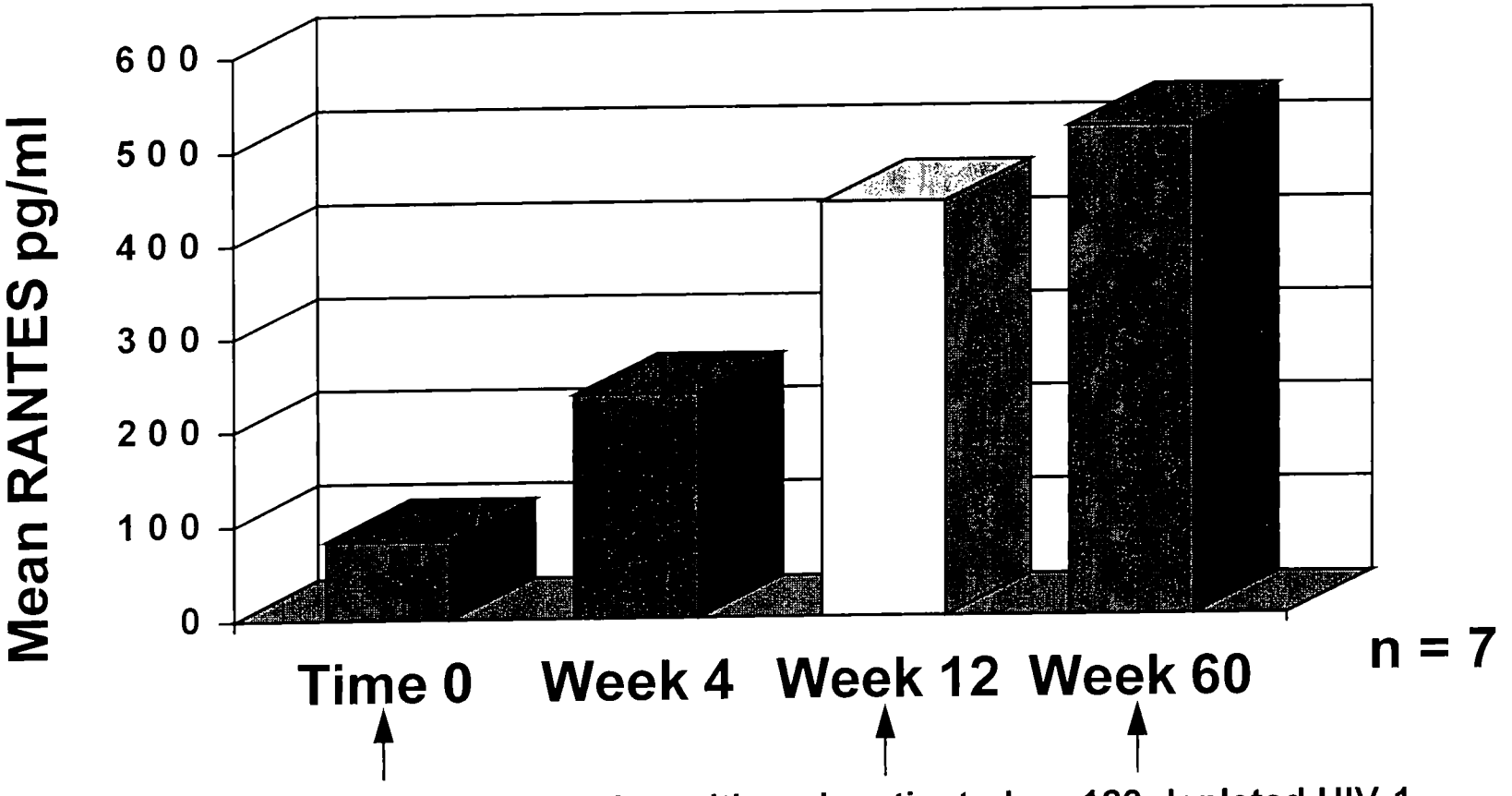
In Vitro Lymphocyte Proliferation to HIV-1 Antigen



Moss, RB, et al., Effect of immunization with an inactivated gp 120 depleted HIV-1 Immunogen (REMUNE™) on β chemokine and cytokine production in subjects with HIV-1 Infection. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* (IN PRESS).

Figure 4.

Long Term RANTES Production After Immunization



Moss, RB, et al., Effect of immunization with an inactivated gp 120 depleted HIV-1 Immunogen (REMUNE™) on β chemokine and cytokine production in subjects with HIV-1 Infection. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* (IN PRESS).

Figure 5.

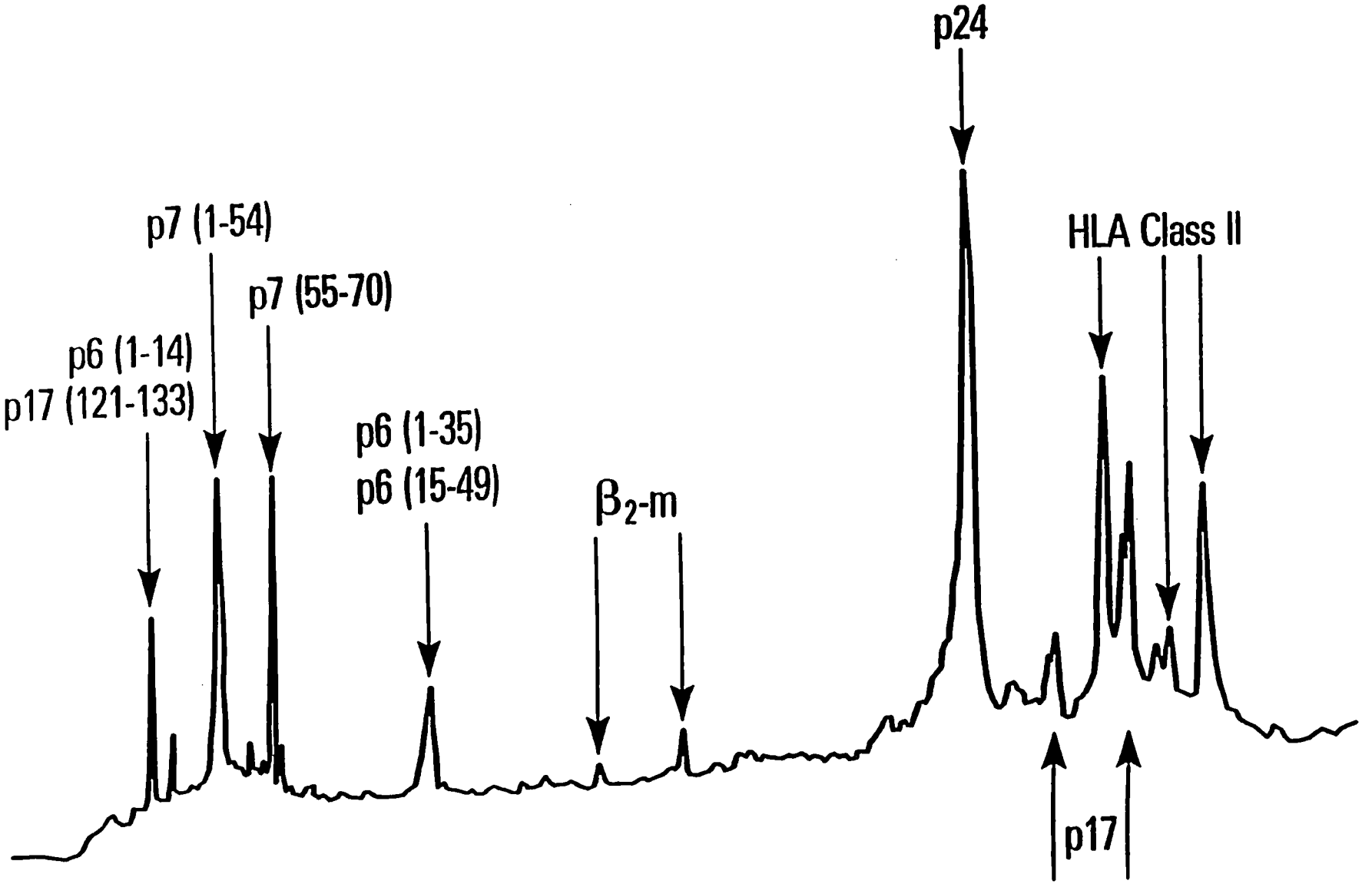
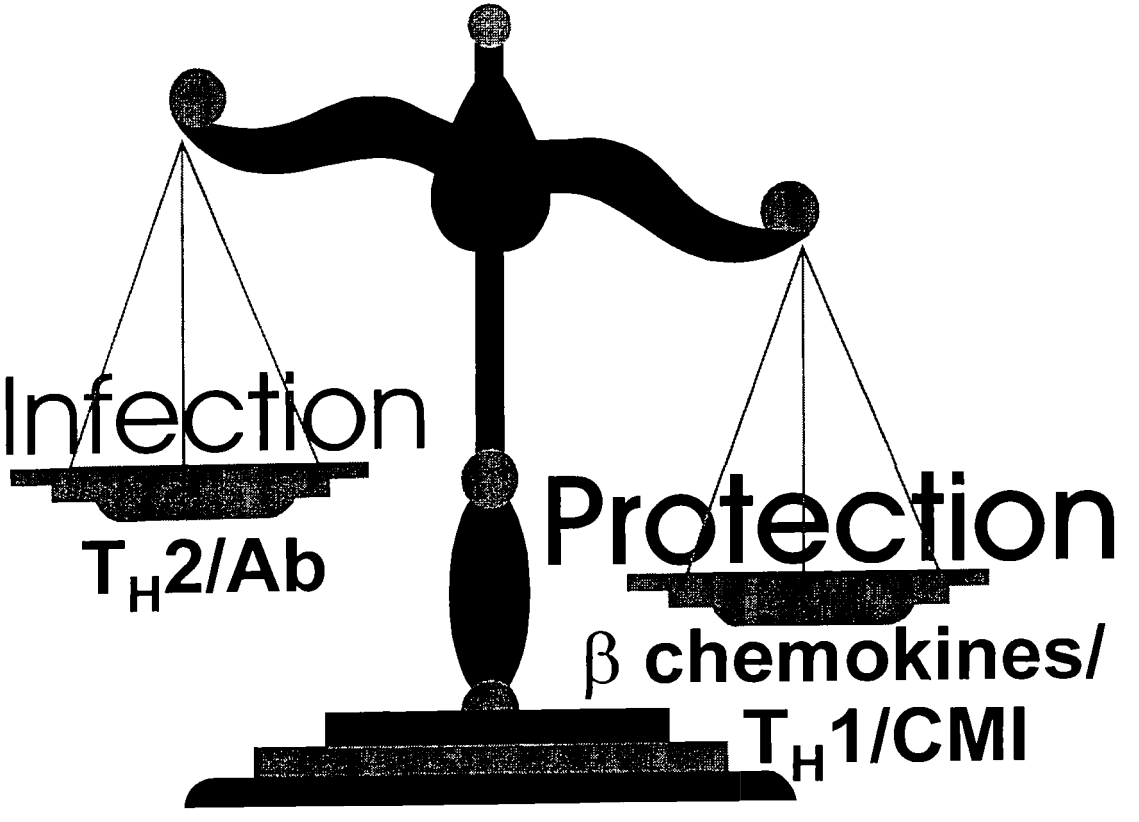

p24
p7 (1-54)
p7 (55-70)
p6 (1-14)
p17 (121-133)
p6 (1-35)
p6 (15-49)
β2-m
HLA Class II
p17

Figure 6.

A Strategy For Prophylactic Vaccination Against HIV



Jonas Salk, Peter A. Bretscher, Peter L. Salk, Mario Clerici, and Gene M. Shearer, A Strategy For Prophylactic Vaccination Against HIV. *Science* 1993; 260:1269-1271.

Figure 7.

THE WHITE HOUSE
WASHINGTON

May 22, 1997

Les J. Leibow
18-27 Hillery Street
Fair Lawn, NJ 07410

Dear Mr. Leibow:

Thank you for your recent letter to the President expressing your comments on the issue of patents in relation to non-traditional care for HIV/AIDS.

We appreciate your expressing your concerns on this issue. It is clear that you have devoted a considerable amount of energy working on it! As you are aware, the use of non-traditional care for pain alleviation, symptom management, and treatment of HIV-related illnesses for persons living with AIDS has been substantial.

We will certainly keep your concerns in mind as we look at meeting all of the needs of those living with HIV and AIDS, and in providing a thoughtful national response to the epidemic. Again, thank you for all the work that you do on behalf of those living with HIV/AIDS.

Very truly yours,

Sandra Thurman

Sandra Thurman
Director
White House Office of National AIDS Policy

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3758

Date Rcvd: 05-15-97

From: Les J. Leibow

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

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CS

Les J. Leibow
18-27 Hillery Street
Fair Lawn, New Jersey 07410

Sandra Therman
Office of National AIDS Policy
808 17th Street N.W.
8th Floor
Washington, D.C. 20006

Dear Ms. Therman:

There are several situations which hinder medical research in the United States. One of those situations involves products that cannot be patented. There are also procedural difficulties involved in certain types of studies. As a result, some products may be overlooked or bogged down in controversy despite preliminary evidence indicating they may have medical uses. I will outline these situations in general terms but I will not argue the merits of any specific products/treatments. Please note I am not a doctor or a health professional, and I do not have HIV. *

Some products cannot be patented including foods; nutritional supplements (vitamins, minerals, and various others); herbs; homeopathic products, among others. If a product cannot be patented, there would be no limit to the number of companies that are permitted to sell the product. With the sales spread thin among many companies, each company would make only a relatively small amount of money by selling the product. Therefore no company could pay for the expensive research and development (R&D) to prove to the Food and Drug Administration that the product will treat or prevent an illness.

> A hypothetical example comparing two products may illustrate the point. ... Suppose a pharmaceutical company invents "Drug X" and obtains a patent on it. The pharmaceutical company suspects that Drug X might be useful to treat a particular illness. The company spends $100 million for R&D. The research proves that Drug X is useful to treat the illness. The side effects are within acceptable limits. Drug X is approved by the FDA to treat the illness. The company sells $500 million of Drug X (since Drug X is patented, no other company can sell it until the patent expires). The company makes a profit of $400 million on Drug X (I am using the term "profit" to indicate the sales of Drug X by that particular company, minus the cost of R&D. For simplicity I am ignoring the cost of advertising, taxes or other factors). ... In contrast suppose that Drug X

* I have sent a similar letter to President Clinton, Hillary Rodham-Clinton and other Government officials.

> had never been invented. Instead there is preliminary evidence from a university study indicating that "vitamin Z" - which cannot be patented - might be useful to treat the same illness. A pharmaceutical company notices the evidence and spends $100 million for R&D. The research proves that vitamin Z is useful to treat the illness. The side-effects are within acceptable limits. Vitamin Z is approved by the FDA to treat the illness. Since vitamin Z cannot be patented, many companies - let us say 125 companies - would sell it. If the total sales of vitamin Z equal $500 million (the figure would probably be lower since competition would keep the price down) then the average sales for each company would equal $4 million. Thus, the company that did the R&D would lose $96 million.

It is easy to see that no pharmaceutical company, or any other type of company, will do the expensive R&D on a non-patented product. Each company knows that it will inevitably lose money if it does the R&D, regardless of whether the product works or not.

This situation has not entirely halted research. There is preliminary evidence that dietary modifications or nutritional supplements might be useful to treat or prevent a variety of illnesses or injuries, or to reduce the harmful side-effects of certain other types of medical treatments. The evidence comes from studies by the U.S. Department of Agriculture; other government agencies; some universities; and some anecdotal reports. There may also be evidence on the possible medical usefulness of other non-patented products (herbs and homeopathic remedies among others), although I am less familiar with that evidence. However, the money for such research is usually doled out only a little at a time within the government or universities. The research often proceeds in a slow erratic manner. The evidence is often not extensive enough for the FDA to approve the product for a specific medical use.

It is legal to sell many non-patented products; however, if a product is not approved by the FDA for a specific medical use, insurance companies generally will not pay for the product. Government programs that pay for medical treatments generally will not pay for such products either. The label or the advertising for such products cannot claim that they have any specific medical use. Most doctors and other health professionals know little or nothing about such products, or if they hear about such products at all, they may refer to them as "unproven", "alternative", or similar terms. They are almost always unaware of the financial obstacle stemming from the lack of a patent, which hinders the research. ... There have been a

few examples in which prominent doctors have advocated a dietary modification, nutritional supplement, or other non-patented products. These are the exceptions, not the rule. There are dozens, perhaps hundreds, of other potentially useful products which remain almost entirely overlooked or entangled in protracted controversy. (Furthermore, even in the rare case in which prominent doctors notice some evidence about dietary modifications, nutritional supplements, or other non-patented products, they often reach hasty conclusions, since they are only aware of a narrow portion of evidence. In some cases, they have made dietary recommendations to their patients or to the public which later were shown to be incorrect or misleading.)

One possible way to overcome such difficulties is with increased government spending for research on dietary modifications, nutritional supplements, herbs, homeopathic products, or other non-patented products. I realize there will be howls of protest at any suggestion to increase government spending. There is widespread concern about high deficits, high taxes, the need to streamline government, etc. I would point out that government spends far more to treat patients (programs such as Medicaid and Medicare, among others) than it spends for research in medicine and/or nutrition. Unfortunately, doctors do not have useful treatments for many illnesses today. Thus, a large portion of the money that government spends to "treat" patients, is actually spent to keep patients in a hospital or nursing home or other care - at very high cost - for an extended period of time, while doing little or nothing to improve the health or longevity of the patients. It is possible that a relatively modest increase in spending for research on non-patented products might lead to the development of better treatments or preventive measures for a variety of illnesses or injuries. This might improve the quality of care for many patients. Interestingly, it might also reduce the cost of healthcare (prevention is often less expensive than treatment; effective treatment is often less expensive than ineffective treatment and long-term care). ... Conceivably, there may be other ways for government to promote research on non-patented products, perhaps including tax incentives or financial subsidies to pharmaceutical companies or other appropriate companies that are willing to do such research. Keep in mind, however, that the "Orphan Drug Law" is not designed to solve this problem.

Increasing awareness is also important. Some doctors/researchers would probably be willing to do research on dietary modifications, nutritional supplements, or other non-patented products. First, however, doctors/researchers must become aware that evidence exists on the potential medical usefulness of such products. The fact that some products are certain to lose money for the company that does the R&D, whether or not the products

are useful, seems contrary to common sense. This may explain why most doctors, researchers, and public officials are apparently unaware of this situation.

There are some other situations which also hinder research in medicine and/or nutrition. For example: Many medical studies today are expected to be "double blind placebo controlled" studies. Some patients receive the real product to be tested, but other patients receive a placebo (look-alike); however, the patients are not told which is which. The placebo is intended to resemble the real product in all outward respects (same appearance, etc.), but to have no physical effects on the human body. If some patients are given a product and they are told that it is medicine, the patients will sometimes say that they feel better, even if the product is a phoney. Giving some patients a placebo provides a basis for comparison, so that doctors can distinguish between the physical effects of the real treatment that they are testing, and the possibility of such psychologically induced effects. This may seem straightforward, but a problem arises when a product to be tested is easily accessible to the public. Some patients, especially if they are seriously ill, will simply obtain the real product and refuse to take a placebo. The patients realize that the real product might do them some good, but the placebo will have no effect, either good or bad. However, if some patients do not receive a placebo, there will be doubt about the reliability of the study. This situation hinders research on a wide variety of potential medical products: Foods, nutritional supplements, herbs, homeopathic products, over-the-counter medications, even some prescription medications if they are already on the market (i.e. if they were previously approved for a different medical use); and a wide variety of other products. ... There is also another obstacle: Some products have telltale characteristics, such as color, shape, size, taste, aroma, texture, or other characteristics which might be very difficult to duplicate in a placebo (remember the placebo is intended to have no physical effect on the human body). This situation hinders research on most foods, some herbs, and a variety of other products.

Fortunately, these obstacles involving placebo controlled studies are not insurmountable either. Placebo controlled studies have been done on some nutritional supplements or other "alternative" medical products despite these difficulties. Furthermore, there are a variety of other types of studies which can also be useful in some situations. This includes prospective epidemiological studies; retrospective epidemiological studies; studies in which some patients receive the new product to be tested, while other patients receive the best existing treatment (if any) for the same illness (this still provides a basis for comparison but none of the patients will feel that they are

entirely deprived of treatment); animal studies; test tube studies; possibly others. Nonetheless, it is important to recognize that the difficulties in doing placebo controlled studies have hindered research on some potentially useful medical products.

There may be various other obstacles which hinder research in medicine and/or nutrition. This includes several common misconceptions which can cause doctors/researchers to overlook the potential medical usefulness of some products/treatments, or otherwise hinder research. Such misconceptions are often bewildering, convoluted, or contradictory. To avoid being tedious or confusing the issue, I will not attempt to explain such additional misconceptions or other obstacles in this letter.

Caution - although they are usually less risky than most prescription medications, surgeries, or other medical treatments that doctors routinely employ, it is important to remember that dietary modifications, nutritional supplements, herbs, or other "alternative" products can sometimes have side-effects, including in rare cases, serious side-effects or fatalities. Some types of dietary modifications, nutritional supplements, or herbs may be harmful when used in combination with certain medications or other types of medical treatments, or when used by people with certain types of illness*; very large overdoses of certain nutritional supplements or herbs can be harmful (among nutritional supplements doctors usually caution people against taking very large overdoses of vitamin A, vitamin D, vitamin E, iron, or vitamin B6; however, other supplements can also be harmful if the dose is too extreme); certain types of dietary modifications if carried to extreme may be harmful (for example: For a number of years many prominent doctors recommended that pregnant women severely minimize their weight gain. They thought this would prevent a medical problem which occasionally occurs during pregnancy. Instead, this advice caused thousands of low birth weight babies before the doctors realized that they were mistaken. There are other examples in which prominent doctors have made dietary recommendations that later were shown to be mistaken, perhaps even harmful, but I will not try to list them all here); certain foods, nutritional supplements, or herbs may cause misleading results on certain types of medical tests; and there are various other reasons why side-effects can sometimes occur. There are many types of "alternative" medical

* As you may know, some studies indicate that a large intake of certain nutrients (either in food or supplements) by HIV infected patients may reduce the likelihood that they will develop symptoms of AIDS within a given period of time. However, large intake of certain other nutrients (either in food or supplements) might hasten the onset of the symptoms of AIDS. Clearly, more research needs to be done. Please see American Journal of Epidemiology Volume 138, Page 937-951, 1993. There may be other articles on this topic.

products/treatments and their risks may vary widely. Caution is always advisable. For personal advice, individuals should consult with a well-informed doctor or other licensed healthcare professional. Doctors and other health professionals should probably do a thorough search of the medical, nutritional, or other scientific literature for details on possible side-effects, proper dosage, contraindications, or other important details.

In this letter, I have tried to describe in general terms how the lack of a patent and the difficulties involved in doing placebo controlled studies have hindered research on some potentially useful medical products. I have tried to describe such situations only in general terms. There are dozens, perhaps hundreds of products which have potential medical uses, but have not received enough research. It would not be practical to attempt to list all such products in this letter. Such evidence is scattered among a long list of medical, nutritional, and other scientific journals. Some of the evidence is recent, but some goes back a number of years, in some cases decades. I do not want to imply that every "alternative" product will treat or prevent a medical problem; however, if even a modest percentage of such products eventually proves to be useful, it might lead to improvement in the prevention or treatment of a variety of medical problems. I hope you will investigate these situations and discuss them with your colleagues, to consider possible ways to promote additional research on non-patented products or other "alternative" medical treatments.

Please note, I have no professional association to products mentioned or implied in this letter. Thank you. I look forward to your reply.

Sincerely,

Les J. Leibow

Les J. Leibow May 8, 1997

P.S. I have sent a similar letter to several Government officials. Aside from some "form letter" replies, I received a reply from a senior official at F.D.A. She explained that the Office of Alternative Medicine at N.I.H. is conducting research on "Alternative" medical treatments. However, she neglected to explain that the OAM Budget is minuscule.

Memorandum

TO: Sandra Thurman
CC: Daniel Montoya

From: Michael Diz, Sarah Holewinski

Date: May 21, 1997

Re: Congressional Task Force on International HIV/AIDS: Briefing on HIV Vaccine Research and Development.

Congresswoman Morella's remarks were brief, centering on the goal of the Congressional Task Force on HIV/AIDS to include a 9% increase in funding for vaccine research as opposed to the President's suggested 2.3%.

Subsequent remarks were given by:

Dr. Anthony Fauci:	National Institute for Allergy and Infectious Diseases, National Institute for Health;
Seth Berkley:	Associate Director, Health Sciences, The Rockefeller Foundation, International AIDS Vaccine Initiative;
Margaret Johnston:	Scientific Director, International AIDS Vaccine Initiative;
Dr. Gordon Douglas:	President, Merck Vaccines, Merck & Co. Inc.

Dr. Fauci

Dr. Fauci gave his remarks before a crowded briefing room; unfortunately, representatives from the ONAP were not yet in that room.

Seth Berkley

Mr. Berkley began by listing various facts regarding an HIV Vaccine: first, such a vaccine is urgently needed; second, development is possible; third, presently allocated resources dedicated to vaccine research are inadequate; and finally, the current international environment does not meet the expansive needs for the development of vaccines that would serve all populations.

He then went on to assert that HIV is the largest killer in the world and that the cost of providing current drugs to all of those in need would be between $300 and $400 billion per year. Obviously, drug treatment is not the most cost-effective or feasible way to attack this epidemic. Therefore, the focus of funding and research should shift toward the development of a vaccine.

Mr. Berkley also stresses how improbable it is that any one vaccine will be effective on all strands of HIV. This means that vaccine research must be focused on multiple sub-types, not just those which plague the United States and other industrialized nations. In the face of almost sure non-profitability, creating incentives for private industry to develop such vaccines becomes a governmental imperative. One suggested incentive is to award grants for research on a wide range of vaccines that would meet international demands.

Mr. Berkley concluded by advocating President Clinton's vaccine initiative (and insisted that the IAVI suggested similar measures long before the President's announcement). IAVI believes it was important to set the specified ten year time period for the development of a vaccine, recruit leaders from the vaccine industry, and bring together researchers and governments from around the world in the struggle to overcome HIV/AIDS.

Margaret Johnston

Ms. Johnston also discussed the need for breaking down barriers to vaccination for those populations which cannot afford it. The budget process may be burdensome to the NIH, other government-funded researchers, and many smaller companies that have developed technologies which may be helpful in vaccine research, but lack the funding to utilize these new discoveries. Finding a way to utilize that technology while making it cost-effective for these companies is an enormous barrier to the development of a vaccine which cannot be overcome without government involvement.

Ms. Johnston emphasized the need for a combination of Empirical and Basic research, and stress such goals as making vaccines safe for those participating in trials and developing vaccines which are not only effective, but easily reproduced.

Dr. Douglas

Dr. Douglas spent a good deal of time discussing the history of Merck Vaccines- it's accomplishments and failures especially pertaining to the area of vaccine research. He then discussed exciting possibilities for the development of a vaccine, stemming from new evidence. suggesting that the immune system can handle HIV (at least for a time) and promising results from animal trials testing vaccines. Furthermore, new technologies using of "naked" DNA in vaccines offer hope in the fight against HIV.

Dr. Douglas then discussed the barriers to vaccine development and use. He suggested that government agencies should take steps now to develop delivery mechanisms for populations which cannot afford to import medicines on their own. In addition, governments must create better protections for intellectual property, establish quality control systems, and develop health care systems infrastructures.

Barriers:

It is important to highlight the topic of barriers to the development and distribution of an

Q: Can the government do anything to increase the world-wide effort?
A: (Dr. Douglas) Yes. A collaborative effort must begin immediately, with its goal to break down the barriers to vaccine development and distribution.

Q: Is a decade a realistic time frame for developing a vaccine?
A: (Dr. Douglas) It is impossible to say for sure, but yes, that is a reasonably good figure-- 5 years would have been too short, 20 too long.

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G31-34

Date Rcvd: 05-09-97

From: Theresa Wildman

Resume

Staff Action:

Reviewed By Sandy:_____ **Reviewed By:** _____

Assigned To:_____

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

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Teresa Wildman
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(202) 456-2861 (work)
(202) 328-8104 (home)

May 8, 1997

Sandra Thurman
Director
Office of National AIDS Policy
808 17th St. NW 8th Floor
Washington, DC 20006

Dear Ms. Thurman:

David Chai suggested that I contact you. For the past year, I have been working for the Assistant to the President for Management and Administration at the White House. I am interested, however, in focusing more on public policy as opposed to internal policy, and in expanding the use of my communication skills.

I have a strong background in debate, research and professional communications, and I am skilled at managing personnel details. As an Executive Assistant in the Office of Management and Administration, I juggle a number of responsibilities from writing senior staff correspondence to motivating individuals and encouraging a "team" mentality. Previously, I was working as Deputy Chief of Staff Evelyn Lieberman's Special Assistant. Both of these experiences have led me to understand that the effort I invest in every project and presentation demonstrates my personal abilities, as well as my level of commitment to the policies of this Administration.

I am looking for a position that would capitalize on my government experiences, as well as my management and leadership skills. I would like to discuss any opportunities that you might know of, or have in your office. I have attached my resume, and I will call you this week to discuss the possibility of setting up an appointment. Thank you for your time. I look forward to meeting you.

Sincerely,

Teresa Wildman

Teresa Wildman

2456 20th Street, N.W. # 106 Washington, DC 20009 (202) 456-2861 (W) (202) 328-8104 (H)

EDUCATION

Southeast Missouri State University (Cape Girardeau, MO)
B.S. Degree in Political Science. Minors: Forensics & History (8/91 - 5/95)
Honors: Graduated Magna Cum Laude (GPA: 3.76)- Honors Scholar and Departmental Distinction
Scholarships: Hattie Eicholtz Memorial , President's and Missouri Leadership Award
Research: Presented theses at Missouri Political Science Association and Conference at Southeast Missouri State

EXPERIENCE

The White House (Washington, DC) **4/96 - Present**
Executive Assistant to the Assistant to the President for Management and Administration

- Manage all information flow to the Assistant to the President for Management & Administration.
- Assist in development of internal policies for Executive Office of the President.
- Liaison to United States Secret Service, the White House Military Office and the Office of Administration to strengthen connections between political and non-political offices.
- Evaluate requests for non-reimbursable DoD aircraft by comparing request to guidelines set forth by the Chief of Staff. Provide background information to Assistant to the President for Management and Administration, White House Counsel and the Deputy Chief of Staff.
- Write weekly report to the Chief of Staff on all Management and Administration operations.
- Serve as "help desk" for all staff the Executive Office of the President on policies and procedures of the White House and United States Secret Service.

The White House (Washington, DC) **12/95 - 4/96**
Special Assistant to the Deputy Chief of Staff for Operations

- Managed all daily activities in the Deputy Chief of Staff's Office.
- Conducted research and brief's for meetings with the Chief of Staff, Members of Congress, and the President.
- Responsible for writing all correspondence for the Deputy Chief of Staff.
- Provided logistical support and coordinated meetings for senior level White House staff.

Center for the Study of the Presidency (New York, New York) **1994 - 1995**
Fellow

- Conducted major research thesis on the politics of national health care.
- Participated in Leadership Conference and Student Symposium.
- Served as moderator for issue panels of scholars and public policy professionals.
- Recruited and assisted in selection of next class of fellows.

Psychology Department, Southeast MO State University (Cape Girardeau, MO) **1/93 - 3/94**
Student Worker

- Communicated with students about policies of campus, schedules and student records.
- Assisted professors with grading, data entry and administrative support.

COMMUNITY INVOLVEMENTS AND ACTIVITIES

SafeHouse for Women (Cape Girardeau, MO) **1/95 - 6/95**
Volunteer Mentor / Advocate
Office of Senator John Danforth (R - MO) **6/94 - 8/94**
Legislative Intern
Clinton/Gore ' 92 Victory Campaign (Cape Girardeau, MO) **8/92 - 11/92**
Volunteer
Activities: University Players; Debate Team; Model United Nations (Secretary General); Volunteer tutor/mentor for grade school children with behavioral problems.