FOIA Number: 2018-0756-F

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001. letter	Mahlon Johnson to Kristine Gebbie; re: Working on Manuscript; [Personal] (Partial) (2 pages)	06/15/1994	b(6)
002. letter	Rodney H. Clurman to Dr. Paul; re: Appointment; [Personal] (Partial) (1 page)	06/02/1994	b(6)
003. letter	To: Nancy Sanford; re: Information; (4 pages)	05/23/1994	b(6)
004. letter	Nancy Sanford to Kristine Gebbie; re: Your Difficult Task (2 pages)	06/06/1994	b(6)
005. list	re: Medicines (2 pages)	05/21/1994	b(6)

COLLECTION:
Clinton Presidential Records
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Kristine Gebbie
OA/Box Number: 3770

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PLEASE READ BEFORE PROCEEDING INTO FOLDER

THE WHITE HOUSE

WASHINGTON

July 19, 1994

MEMORANDUM FOR LORI ABRAMS
PRESIDENTIAL CORRESPONDENCE

FROM KRISTINE M. GEBBIE
NATIONAL AIDS POLICY COORDINATOR

SUBJECT LETTER TO SIGMA ALPHA MU FRATERNITY FROM POTUS

I have attached a draft letter to members of Sigma Alpha Mu fraternity from POTUS. Sigma Alpha Mu is the first fraternity to incorporate AIDS training into its annual leadership conference. Additionally, Sigma Alpha Mu has adopted the Pediatric AIDS Foundation as its national philanthropy.

I believe it is important that their actions to help AIDS awareness be recognized. The letter will be copied and distributed to individual fraternity chapters. If you have any questions or concerns please contact me at 632-1090.

DRAFT LETTER TO SIGMA ALPHA MU FRATERNITY

July 19, 1994

Men of Sigma Alpha Mu:

I would like to commend you for your leadership in the battle against HIV infection. By adopting the Pediatric AIDS Foundation as your national philanthropic endeavor, you are setting an example for other fraternal organizations. The truth is that all Americans need to be involved in this fight. Your actions show that not only is it necessary to care, it is all right to care.

Raising money for the Pediatric AIDS Foundation is a noble cause. But, by providing AIDS education at the national and local level to all fraternity members, Sigma Alpha Mu is striking the biggest blow in this fight, because education is the key to reducing the spread of this virus. Unlike cancer or heart disease, HIV is an infection that people acquire by making uninformed choices. Thank you for making the effort to inform your members how to protect themselves and others.

Together, all Americans can win the war against AIDS. Thank you, Sigma Alpha Mu, for doing your part.

Sincerely,

B.C.

THE WHITE HOUSE
WASHINGTON

July 19, 1994

Mr. Neal Arthur Dickerson
c/o Monument Press
Las Colinas, Texas 75014

Dear Neal:

Thank you for sharing a copy of A Prescription for Preventing AIDS: Curing the Body Politic of Prejudice with me. I certainly agree that prejudice in its many forms has contributed to the spread of HIV. We must combat both the virus and the attitudes.

Thank you again.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Mahlon Johnson, M.D., Ph.D.
Vanderbilt University Medical Center
Vanderbilt University School of Medicine
C-3321 Medical Center North
Nashville, TN 37232-2561

Dear Mahlon:

I'm looking forward to seeing your manuscript about living with HIV. As you may know, I should have time to read it as I am leaving this position shortly.

One of the highlights of this year has been the opportunity to meet, talk with, correspond with individuals such as you who are struggling to live with HIV, and to contribute to our effort to stop the epidemic.

The national effort in research, service and prevention continues to improve, with a much-strengthened AIDS research office at NIH, the hopes of health reform to finance care for all, and community planning for prevention. All of these will continue, and I hope you will continue to be a part of the action.

I also hope that we will not lose touch, and that you will keep me informed of your progress and activities. This office will have a forwarding address, once I know where I am headed. My best wishes.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

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Vanderbilt University Medical Center

Vanderbilt University School of Medicine
Department of Pathology

C-3321 Medical Center North
Nashville, TN 37232-2561
(615) 322-2102
Fax (615) 343-7023

June 15, 1994

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Kristine:

Thank you for taking the time to respond to my letter.

Last October, I did begin working on a article about the heros in our battle against AIDS, particularly the nurses. After eight months and many long weekends, it has now become a 220 page, 24 chapter manuscript about living with HIV. The first revision is in progress. Perhaps the manuscript will help the public learn about HIV, the people with it, and the soldiers that fight it. Five people have read this fledgling effort which will eventually exceed 300 pages and require four or five major revisions. I'll send you the rough draft or final version if you'd like. (But I can't imagine you having time to read it.)

[001]

Once finished with the second revision, I hope to write shorter articles profiling nurses and social workers fighting AIDS.

(b)(6)

(b)(6)

[redacted]

(b)(6)

As always, I look forward to seeing you again and wish you continued success orchestrating drug company efforts in streamlining clinical trials.

Sincerely,

Mahlon

Mahlon Johnson, M.D., Ph.D.

MJ:ls

[001]

Mahlon Elaine
HS

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Mr. Rodney H. Clurman
General Delivery
San Francisco, CA 94102

Dear Rodney:

As you no doubt know by now, I am soon to be leaving the position of National AIDS Policy Coordinator. This year of creating a new position from nothing in the face of 12 years of expectations, conflicting definitions of the role, and the continuing growth of the epidemic has been an incredible experience. I believe the groundwork has been laid for much effective action, though there is no doubt that whomever my successor is, the job will be done differently.

I have appreciated your interest, ideas and encouragement over the year. I hope that your activities continue to go well.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

General Delivery
SF, CA 94102
415-776-3485

Dear Kristine,

Always nice to talk to you.

We must stem the rising tide directee at the WH.

What is needed id positive action with funded legislation with $ 1,000 for each person with AIDS not much for the care-direct issue.

Also SSA must speed up not the process of SSI approval. I believe I can Senators Pell, Moynihan Kennedy etc., to sponsor and Gerry Studds, Syd Yates and Waxman on house thoughts.

Pls share these thoughts with MacLarity who is aware of my interest

When you are next in NYC visit my brother Dr. Groge Popkin's NYU Skin cancer clinic. They do ~~zboy~~ with KS.

Enclosed to new NIH chief.

Best,

Rodney M. Clurman

ps- you my resume and govt personnel form on file. If not call, pls ~~pls~~ send along any papers.

MISSIONARIES OF CHARITY
+LDM 54/A, A. J. C. Bose Road.
Calcutta - 700016 India

Dear Rodney H. Clurman,

Thank you very much for your letter. Enclosed is a medal for your friend Jacqueline Onassis.

My prayer for her is that she allow Jesus to live His life in her. May His passion that He shares with her be a sign of His tender love, and through it grow in His likeness and compassion.

You are most welcome to come and share in our humble works of love for the poorest of the poor.

God bless you.

Mc Teresa me

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Genedral Delivery
San Francisco,CA 94102
June 2, 1994

Dear Dr. Paul,

Congratulations on your appointment at NIH, as one wh has toiled in the AIDS crisi as a volunteer here and on [redacted] (b)(6) your appointment would appear to be the only substantive [redacted] (b)(6) by our government to date.
One of your nice assistants told me you were distressed by the tone of Gina Kolata's piece in the NYT. Do not-be. I come from a long line of journalists--NY Times,Time Life, NBC News--me etc., We cannot all be Scotty Reston Chet Huntley, Howard Rusk of Larry Altman--all friends.

Gina's reporting on the AIDS mess has often been opinionated and therefore supect. As for Larry KRAMER, forget it. He spends his time knocking others. He put down wonderful friend Elizabeth Taylor and AMFA when Elizabeth and nice Berthild Krim havewraised more money for AIDS than anyone else. I judge you not spent to much time in the public arena as I have- NBC News, President's Eisenhower, Kennedy and Johnson and Martin Luther King and more.

There are lots of people who pend there time putting others time. To them I say"Angels swearing I am right or wrong, it makes no difference, it is how it brings me out in the end". A. Lincoln. Amen!

I would hope you might gwet to SF to dee our excellent AIDS model and I would be pleased to introduce you to those than run the system, public and priva-t,e some of whom, like Dr. Don Francis I am sure you know.

They are a great, caring tireless bunch. I was prviliged to ehlp Paul Volperding, SFGH AIDS Chief organize the 6th Intl AIDS Conference a few years back and got to meet and talk with people worlwide.

After finishing a long overdue autobigraphy Mother Theresa has asked me to join her in her work in Calcutta, which for an aging jewish, Quaker journalist will ne anj honor and a privilite

Finally, one of our greatest helpers in the LBJ Poverty progrqam was Dr. Leonard Duhl-Psychiatrist now retired and practicing here n n Berkley.

Take care and all the best-

Sincerely,

Rodney H. Clurman

cy, Dr. Don Francis
Dr. Paul Volperding
Dr. Marcus Conant
Bishop Bill Swing

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Rafael H Pagán, M.D.
Executive Director
Puerto Rico CONCRA
Box 30, One Stop Station
103 Avenue Universidad
San Juan, Puerto Rico 00925

Dear Dr. Pagán:

It was a pleasure to have met with you last May. Thank you writing and summarizing the concerns raised about funding of AIDS services for Puerto Ricans.

I am sorry that we will not be able to meet before I leave the position of the National AIDS Policy Coordinator. The information from our meeting will be waiting for my successor so that he or she may take appropriate action.

The Office of National AIDS Policy was created out of the commitment of the President to take positive steps to provide services to people living with HIV/AIDS. I am confident that the office will continue to be a focal point for the discussion of important issues such as the ones you have identified.

Thank you again for sharing your concerns with me. I wish you continued success with your endeavors.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Tim— help!

Andrew / Tim —
please collaborate on
draft reply
Carlos fyi

Radisson
PLAZA LORD BALTIMORE

20 West Baltimore Street
Baltimore, Maryland
21201-3285
Telephone: (410) 539-8400
Facsimile: (410) 625-1060

May 17, 1994

Kristine Gebbie, RN, MN
National AIDS Policy Coordinator
Executive Office of the President

Dear Ms. Gebbie:

Thank you for meeting with us this morning to discuss our concerns regarding the funding of AIDS services for Puerto Ricans residing in the mainland and in the Commonwealth of Puerto Rico.

We would like to use this opportunity to summarize the concerns we expressed to you so that you may utilize the information to investigate further the situation that we described this morning. From our perspective, the issues that we believe deserve your review are the following:

- That more funds be made available for AIDS services and programs in Puerto Rico in order to reduce the need for residents to travel to the mainland to obtain services and medication not available in the Commonwealth;

- That other health care island and mainland institutions; i.e. hospitals and community health centers, be selected to participate in the Air Bridge Project that have more Puerto Rican patients actually flying between the two jurisdictions than the two institutions currently in the Air Bridge Project;

- That the current Medicaid cap in Puerto Rico be eliminated so as to equalize disbursement of funds and to reflect the inordinate need in the island for more Medicaid funded services; and

- That funds be increased to be allocated directly to community based AIDS organizations in Puerto Rico that provide prevention, education, primary care, and research services.

We would welcome the opportunity to meet with you personally to discuss these concerns in greater detail. It would be advantageous if we could schedule meetings both on the island and in the mainland to facilitate greater participation of the frontline providers.

Please feel free to contact Maria Lago of the Bureau of Primary Health Care who has indicated her willingness to make all necessary arrangements for such a meeting. Maria can be reached at (301) 594-4442. I am signing on behalf of the Puerto Rican Ryan White Title III(b) representatives who met with you this morning.

Sincerely yours,

Rafael H. Pagan, Executive Director
Puerto Rico CONCRA

Enclosure: List of participants

Meeting of Puerto Rican HIV Program Administrators

1. Julio Rivera, Jr
Administrator, AIDS Center
Lutheran Medical Center
150 55th St
Brooklyn. NY 11215
(718) 630-8234

2 CAMILA JUSINO, MD, FAAP
MEDICAL DIRECTOR
Lares HEALTH Center, INC
P.O. Box 379
Lares, P.R. 00669 Tel(809) 897-2727
HIV Consortium Program Providing Services to 14 RURAL TOWNS.

3- Rafael H. Pagán MD.
P.R. CONCRA / Executive Director
Box 30, One Stop Station
103 Ave. Ponce de León, San Juan, P.R 00925
(809) 753-9443 fax (809) 753-2894

4- Dr. Awilda García
Box 10009
Ponce, P. Rico 00732
(809) 843-9393

or CDT Playa Ponce
#216 Avenida Hostos
Ponce, P.R
00731.

Table of Contents

(5) Donna Rivera, Greater Lawrence Family Health Ctr,
130 Parker St. #14, Lawrence, MA 01843 (508) 685-7663 fax (508) 685-1561

(6) Eileen Godreau M.D.
C.D.T. Playa Ponce
Ponce, P.R. 00731

(11) Norma Iris Villanueva, M.D.
Acting Medical Director
Boriken Neighborhood Health Center
2253 Third Avenue
~~Bronx~~, N.Y., N.Y. 10035

(7) Paul Ramos
Betances Health Unit Inc.
281 East Bway
NYC 10002 — (212) 227-8408

(8) Cynthia Flores, Adm.
Lower ~~NY~~ New York Consortium for Families with HIV
550 First Ave.
NY, NY 10016 - 212-263-6954

(9) Neftalí Cotto M.D. MPH
~~Epidemiology~~ Clinical Director
Bayamón Epidemiology Center
Box 1588, Bayamón P.R. 00969
Tel- 740-5215

(10) Tamara Behar M.D.
Executive Director
Bo Ty Amon
P.O. Box 1588 Bayamon P.R. 00960
EPIDEMIOLOGY CENTER

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Ms. Rebecca Denison
Founder/Executive Director
Women Organized to Respond to
Life-threatening Diseases
P. O. Box 11535
Oakland, CA 94611

Dear Ms. Denison:

Thank you for sharing with me the many touching letters from women infected with the HIV virus. I have forwarded copies of the letter to President Clinton so that he may reply to you directly.

Our Administration is working hard to prevent the continued spread of HIV, while at the same time insuring that we continue to provide services to persons with AIDS and their families. Since President Clinton was elected there have been substantial increases in funding for prevention, services and research. The creation of the Office of AIDS Research at the National Institutes of Health will help us to better coordinate the efforts to find a research solution.

I appreciate your efforts on behalf of people living with HIV/AIDS and helping to keep this important issue on the front burner. Keep up the good work!

Thank you.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

July 5, 1994

Ms. Rebecca Denison
Founder/Executive Director
Women Organized to Respond to
Life-threatening Diseases
Post Office Box 11535
Oakland, California 94611

Dear Rebecca:

Thank you for writing to me. I was deeply moved by the letters written by HIV-positive women that you enclosed.

I want to reassure you that my Administration remains committed to fighting AIDS and to revitalizing AIDS prevention efforts. Since 1993, we have made significant increases in AIDS prevention, research, and services, including full funding for the Department of Housing and Urban Development's AIDS Housing Programs. I have also required all federal employees to be trained in AIDS prevention education and am working to get businesses to follow suit with their own employees.

In addition, my comprehensive health plan will ensure that all people, including those with HIV/AIDS, have health benefits that can never be taken away. Under my plan, more people with HIV/AIDS will be able to continue working and contributing to society without worrying about losing their jobs or benefits.

I stand with you in the effort to reach out to those affected by AIDS and educate all Americans about HIV/AIDS. Working together, we can stop the spread of HIV and help those infected with AIDS to receive the services they need for the highest possible quality of life.

We will continue the fight against AIDS until we find a cure.

Sincerely,

BILL CLINTON

BC/MHM/ps (Corres. #1635276)
(7.denison.r)

cc: Andrew Barrer, Office of AIDS Policy

JUL 19 1994

THE WHITE HOUSE

Dear Pastor Miller -

It was a real pleasure to learn something about the South Florida Pastoral Care Network. I believe that spiritual care & support are critical parts of our response to the HIV epidemic and am encouraged by the development of local resources - My best wishes to you & your colleagues ~~Justus Ge~~

Dr. Roger P. Miller
Director-Chaplain
HIV Pastoral Care Network
Spiritual Support for South Florida
4520 West Park Road
Hollywood, FL 33021

THE WHITE HOUSE

Dear Bob —

Thank you for setting up the visit at your S.S. branch office — I will use my experience with you & your colleagues in my upcoming conversation with Dr Chester — all the best to you —

K. McClure

JUL 19 1994

Mr. Robert Tomasulo
633 N.E. 9th Avenue, Unit 6
Fort Lauderdale, FL 33304

JUL 19 1994

THE WHITE HOUSE

Dear Skip —

Thank you (and everyone at Hope House) for the chance to visit last week ... you're doing great work and it is a pleasure to be a little part of it. My continuing best wishes for the agency, and for you personally —

Hillary

Mr. Skip Ciotti
P.O. Box 6905
West Palm Beach, FL 33405

NOV 19 1991

THE WHITE HOUSE

Dear Jeff—

Thank you again for your contribution to the fight against HIV and AIDS. Your home was a wonderful setting for Saturday night's event — my best wishes in all that you do —

Christine

Mr. Jeff Scott
295 Granada Road
West Palm Beach, FL 33410

JUL 19 1994

THE WHITE HOUSE

Dear Mark –

It was a pleasure being in your county yesterday – the work underway to build a true community response is indeed encouraging. We look forward to future progress. I also hope you're fully recovered from the allergic response ... All best wishes

Hillary

Mark S. Rapoport, M.D., M.P.H.
Commissioner of Health
Westchester County Department of Health
19 Bradhurst Avenue
Hawthorne, NY 10532

JUL 19 1994

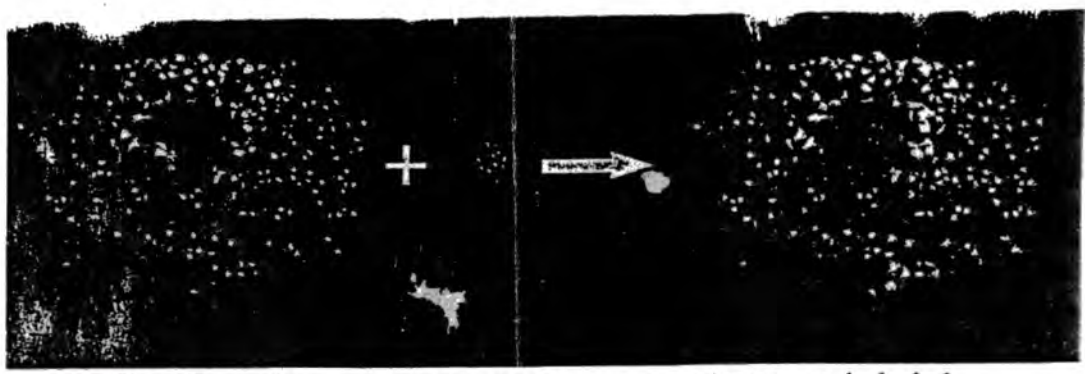
THE WHITE HOUSE

Dear Joyce —

Thank you for the article on buckyballs — I appreciate it. You may know by now that I have resigned my position — it has been a great year but it's time for someone else ... I'll keep my eyes on Montana & cheer you all on in your efforts wherever I end up — all the best — Christine

Ms. Joyce M. Galster
1016 California Street
Butte, MT 59701

Buckyballs and HIV



BUCKYBALLS AND HIV SEEM AN UNlikely combo: one is the soccer ball–shaped molecule that is intriguing chemists around the world; the other, the deadly virus that causes AIDS. But believe it or not, researchers at the University of California at San Francisco have recently discovered that buckyballs can disable the enzyme machinery the AIDS virus needs to reproduce. Whether buckyballs will ever be made into a practical AIDS drug remains to be seen.

A buckyball does its bit of monkey-wrenching on HIV protease, an enzyme produced by the virus. Initially part of a long chain of proteins called a polyprotein, HIV protease folds around and clips itself free. Then it cleaves the other proteins so they can build new viruses. The protease knows where to snip because the parts of the polyprotein that it cuts fit into an "active site"—one of the enzyme's several nooks and crannies. When a segment of the protein chain snuggles into the site, it triggers reactions that cut the chain. A buckyball sabotages this process by squatting in the active site and blocking the polyprotein from entering.

It was a casual remark made during a late-night conversation that caused Simon Friedman, a chemistry graduate student in George Kenyon's lab at UCSF, to realize buckyballs might work. "A friend and I were talking about projects in the department that are trying to find inhibitors for the protease," Friedman recalls. "She said, 'What are they going to try next, buckyballs?' And I realized that a buckyball could potentially fit because it has a circular cross section just like the active site."

After a computer simulation showed that a buckyball was also the right size to slip into the site, Friedman put actual molecules to the test. He used modified buckyballs, called fulleroids, that had a short chain of molecules attached to the sphere's surface. The chain makes the fulleroids soluble in water, a necessity for working in the aqueous environment of a living cell. Friedman mixed a solution of fulleroids with HIV protease and a short protein in a test tube. After 30 minutes or so, he looked for the smaller proteins that should have been present if HIV protease had been clipping the original protein in two. He didn't find any.

Researchers at Emory University in Atlanta have since taken the experiment a step further. They have found that fulleroids actually block HIV from reproducing in cultures of infected white blood cells, without killing healthy cells. On the other hand, many things have been found to disable HIV in lab cultures. The important question is whether buckyballs can do so, and do so safely, in the body of a person with AIDS. The answer to that question is years of experiments away.

I thought this was interesting. This is about the "buckyballs" I mentioned to you at the May HIV/AIDS conference in Helena MT.

It was a pleasure meeting you but I feel you will never last in D.C. as you are logical, insightful, intelligent, HONEST and truly caring. Don't be surprised to find yourself turned into mincemeat!

Respectfully
Joyce

Thanks too for the nice note you sent to me. Me me proud.

JOYCE M. GALSTER
1016 CALIFORNIA ST.
BUTTE, MT 59701

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Michele M. Ginsberg, M.D.
Chief, Division of AIDS & Community Epidemiology
Department of Health Services
Public Health Services
Post Office Box 85222
San Diego, California 92186-5222

Dear Dr. Ginsberg:

Thank you for writing and for sharing the results of the T-cell testing program. It was indeed a pleasure to meet with you during my trip to San Diego.

The T-cell testing program you implemented in San Diego County demonstrates an innovative and cost effective method for linking diagnosis with treatment. The figure of 87 percent for kept appointments is very impressive. This sounds like a program that should be considered for replication nationwide.

As you may know, I have resigned my position as the National AIDS Policy Coordinator, effective August 2, 1994. I enjoyed and learned from my experiences with dedicated individuals, such as you, who are so committed to the welfare of those living with HIV/AIDS. Keep up the good work.

Again, thank you for writing. I wish you continued success with your endeavors.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

County of San Diego

Robert K. Ross, M.D.
DIRECTOR

DEPARTMENT OF HEALTH SERVICES

Community Health Services
AIDS & Community Epidemiology
(619) 236-3598

May 9, 1994

Khristine Gebbie, R.N., M.N.
AIDS Coordinator
750 17th Street N.W., Suite 1060
Washington, D.C. 20500

Dear Ms. Gebbie:

It was a pleasure to meet you during your visit to San Diego. During your brief tour of our programs, an innovative program that has been initiated in San Diego County was mentioned. The accompanying attachment describes the results of patients seen during 1993.

The goals of this program are two-fold: To expedite the entrance of HIV infected people into appropriate services and at a community level to characterize the picture of individuals recently learning of their HIV infected status. Thus far, the program has been very successful. Eighty-seven percent of individuals who accept referrals for medical assessment and early intervention have kept those appointments.

It is important to know that this clinic was established and is maintained at a minimal cost. A half-time nurse fully trained and knowledgeable in HIV schedules intake, provides phlebotomy and individual counseling upon return for result and assessment of TB skin test.

It will be my pleasure to discuss this or other aspects of our HIV related services that may be of interest to you and hope you might visit with us again when your travels bring you back to Southern California.

Sincerely,

Michele M Ginsberg MD

Michele M. Ginsberg, M.D., Chief
Division of AIDS & Community Epidemiology

MMG:aa

T-CELL PROGRAM

San Diego County

Throughout the country people who engage in behaviors that put them at risk of exposure to HIV are encouraged to seek HIV antibody testing to determine if they have been exposed to the virus. Testing is available in many settings including clinics providing services for sexually transmitted diseases, family planning, general medical clinics, and anonymous testing sites. After persons make the difficult decision to be tested and learn they are infected with the HIV virus, they often delay seeking medical evaluation which will provide further education, intervention services, and needed and appropriate medical attention, including medication. This delay can be costly in terms of quality of life and survival. Since the beginning of the AIDS epidemic it was not uncommon for HIV infected individuals to delay medical assessment for months or even years until symptoms of illness occurred.

In San Diego County, a program was initiated to assist people in taking the first step towards their evaluation. Determination of CD4 count or T-cell testing has been identified as a most reliable predictor, assisting clinicians to determine the status of the HIV infected individual. The T-cell testing program makes available a one time opportunity for HIV positive persons to have T-cell testing performed and, in addition, testing for syphilis, tuberculin reactivity and provision for individual interpretation and counseling by a public health nurse with referral for needed services. When necessary, an immediate appointment for further medical evaluation is made. Ideally, the length of time elapsing between learning of a positive HIV test and referral for physical examination with T-cell results, syphilis serology, and tuberculin skin test results may be as little as two weeks.

During 1993, 266 HIV positive persons were evaluated in this program. Sixty percent of participants were White, 26% Hispanic, 9% Black, 5% Other; 93.6% Male, 6.4% Female. Ages ranged from 18-68, mean 33.5. Seventeen percent met the new AIDS case definition having CD4 count below 200. Counselors must be prepared for client reactions upon receiving this information. Prior to T-Cell program these persons would have been seen at the Early

Intervention Program (EIP). Initial intake, laboratory and psychosocial assessment would have been initiated before it was determined that the client was ineligible for the program. Currently, all potential clients have T-cell testing prior to EIP enrollment. This directs enrollment and EIP activities to appropriate populations.

A major goal of the T-cell program was linking HIV infected persons with medical services. Eighty-seven percent of clients accepting referrals kept their appointments with community medical care providers. Copies of laboratory results are provided to the client and are available for practitioners to review at the initial visit.

HIV infection is a chronic disease requiring different interventions as symptoms develop. New and available therapies may reduce symptoms, transmissibility and prolong survival and improve quality of life. After HIV positivity is recognized the essential step is regular medical evaluation. In San Diego, the T-cell testing program has been successful in expediting medical assessment and establishing medical care relationships by eliminating barriers for the HIV infected individual.

The establishment of this clinic has closed the gap between diagnosis and treatment with a minimum of initial expense and a maximum benefit to the client. Early intervention permits notification of potentially exposed partners, health maintenance efforts, and medication with subsequent reduction in hospital days, improving quality of life and longer survival. Evaluation and referral from the clinic may be accomplished on an outpatient basis. A further benefit is avoidance of expensive emergency room visits and other costs as the individual's health deteriorates.

Tcell-#977

THE WHITE HOUSE

WASHINGTON

July 19, 1994

Mr. Bud Schindler
9901 Mercedes Avenue
Arleta, CA 91331-5226

Dear Bud:

Nancy Sanford was kind enough to send along your letter, and the materials about your treatments. I appreciate your interest in contributing to our national efforts to better serve those already infected with HIV, and to stop the spread of the virus.

You may already know that I will be leaving my position at the end of this month, but I want to be certain that your interests and ideas are available to my successor, and to the national policy staff. Most of the issues you raise, better therapy for the conditions arising from living with the chronic infection of HIV, more complete research on alternative and nutritional therapies, and more aggressive approaches to prevention education for gay youth, are being considered already at the national level. I have shared your letter, and attachments, with staff working on research, services, and prevention. You may be hearing from one of them directly.

I encourage you in your continued struggle to live with this disease. As is often the case, your personal decision to become an informed partner of your care-givers is a critical part of the success you are experiencing. While I will not be in this position longer, I will certainly remain in touch with Nancy. If there is anything I can do for you, please let me know.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

cc: Nancy Sanford

Withdrawal/Redaction Marker
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. letter	To: Nancy Sanford; re: Information; (4 pages)	05/23/1994	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Kristine Gebbie
OA/Box Number: 3770

FOLDER TITLE:
July Chron Files 1994 [4]

2018-0756-F
jp4825

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]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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RR. Document will be reviewed upon request.

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b(1) National security classified information [(b)(1) of the FOIA]
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b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
004. letter	Nancy Sanford to Kristine Gebbie; re: Your Difficult Task (2 pages)	06/06/1994	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Kristine Gebbie
OA/Box Number: 3770

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. list	re: Medicines (2 pages)	05/21/1994	b(6)

COLLECTION:
Clinton Presidential Records
National AIDS Policy Office
Kristine Gebbie
OA/Box Number: 3770

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July Chron Files 1994 [4]

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Drug Treatment Suggestions*

Immune Modulators	Dosage	Rationale
Naltrexone	2/50 mg tablets dissolved in 100cc(ml) of water, dispensed with a 3cc syringe. 3cc's of solution mixed with 3-4 ounces of water or juice daily at bedtime. Keep refrigerated	increases production of beta endorphin and metenkaphalin, immune regulating hormones usually low in PWA's.
Cimetidine (Tagamet)—Zantac (Ranitidine) may be substituted if Tagamet causes impotence—ask doctor for dosage.	400 mg 3 times/day (supplement with 1 or 2 hydrochloric acid tablets before meals--suggest Nuradyn or Acydidyn)	blocks histamine receptors/elevated histamine levels impair lymphocyte functions and reduce T-helper cell count
Antabuse (disulfiram) [no longer recommended]	500 mg 2 times/week (upset stomach can be prevented by ingestion of 2 tablespoons of olive oil and/or Alka Selzer one hour before ingestion of the drug)	same active ingredient as imuthiol—stabilizes immune function and seems to prevent clinical progression in 60% of patients
Antivirals	**Dosage**	**Rationale**
Hypericin For information call (800) 869-8783. Also, check Buyer's Club.	dosage still in trials 10-40 mg/day	prevented infected cells from releasing HIV and prevented free-floating virus from infecting healthy cells in vitro and murine tests/very low toxicity—also effective against CMV, Herpes Simplex, and Influenza A
Protease inhibitors, Merck "L" drugs, TIBO derivatives, Tat gene inhibitor, BI-RG-587	dosages still in trials	antivirals—ask your doctor about availability or call 1-800-TRIALS-A
AZT (ddI or ddC if AZT is not tolerated)	as directed	treats fatigue, weight loss, night sweats not associated with a particular OI; also effective against HIV encephalopathy

* Extracted from "Management of HIV Disease: One Physician's Approach," by Bernard Bihari, MD; *Bulletin of Experimental Treatments for AIDS* (BETA), November 1991, published by the San Francisco AIDS Foundation.

Management of Cofactors	**Dosage**	**Rationale**
Acyclovir (Zovirax)	800 mg 3 times/day; *if T-helper cells drop below 150, increase to 800 mg 5 times/day or 1000 mg 4 times/day*	suppresses herpes viruses; may suppress Epstein Barr virus; also may suppress CMV at higher dosages, 4000 mg/day
Doxycycline (Prescribe only if above treatments do not arrest decline or if there is a sharp, rapid drop in T-cell count without an opportunistic infection)	200 mg 2 times/day	suppresses mycoplasma
Prophylaxis of Opportunistic Infections	**Dosage**	**Rationale**
Bactrim[†]	1 double-strength tablet/day	prevents systemic PCP and possibly toxoplasmosis
Aerosolized Pentamidine	300 mg inhaled 1 time/month	prevents PCP in lungs
Fluconazole (Prescribe only if T-helper cells drop below 150.)	100 mg/day	prevents fungal infections
Pyrimethamine (Prescribe only if high toxoplasmosis antibody titres are present and if T-helper cells drop below 150)	25 mg/day or 50 mg 3 times/week	prevents toxoplasmosis
Clarithromycin (Prescribe only if monthly MAC blood culture is positive and if T-helper cells drop below 75)	250 mg 1 or 2 times/day	prevents MAC/MAI
Ciprofloxacin plus clofazimine or ethambutol (Prescribe only if monthly MAC blood culture is positive and if T-helper cells drop below 75)	as directed	prevents MAC/MAI
Isoniazid (Prescribe only if TB skin test is positive or if patient's lifestyle is likely to create exposure to infection , e.g .IV drug use or alcoholism)	300 mg/day indefinitely regardless of T-cell count	prevents tuberculosis

[†] Desensitization schedule: 2cc pediatric suspension on the 1st day. Increase dosage by 2cc/day for nine days. On day ten switch to regular double-strength tablets.

Management of Symptoms (weight loss, diarrhea, fatigue)	Dosage	Rationale
Megesterol acetate (Megace)	800 mg/day	increases appetite and reverses weight loss
°Azithromycin, Erythromycin, Spiramycin, Clarithromycin, 566C80, Humatin, Clindamycin/Primaquin	as directed	may cure cryptosporidiosis, microsporidiosis, or other parasites that cause diarrhea
Somatostatin or analog	as directed	treats severe, chronic diarrhea
N-Acetyl Cystein (NAC)	as directed—this is a non-prescription dietary supplement available at many health food stores 500 mg 3x/day	blocks effects of TNF; aids in assimilation of lipids and blocks TNF's tendency to stimulate HIV replication
hydrocortisone acetate	15 to 20 mg morning and 10 mg in the late afternoon	may reduce fatigue that is not caused by depression and is not a side-effect of high dose acyclovir

Anti-diarrhea Protocol—Use each treatment for 10 days one after the other in the order shown.

Treatment	Dosage
Humatin (Paromomycin)	250 mg 8Xday or 500mg 4Xday
Vermox	100 mg 2Xday
Azithromycin (Zithromax)	250 mg 2Xday
Flagyl	250 3Xday
Qin Hao (Chinese herb pronounced "chin hao," a.k.a. Artemesia)	As directed by herbal practitioner.

° These experimental treatments for cryptosporidiosis were taken from Project Inform's discussion paper on cryptosporidiosis dated December 1991.

Management of HIV Disease: One Physician's Approach*

Bernard Bihari, MD
29 West 15th Street
New York, NY 10011
(212) 929-4196

Bernard Bihari has served as the principal investigator of several clinical trials of HIV/AIDS therapies, including naltrexone, lentinan and rifabutin. He is currently the national principal investigator for the Phase II trials of metenkaphalin, and endorphin that may have immune-enhancing activity. In recent years, Dr. Bihari has divided his time between a private medical practice directed to the care of people with HIV infection and to the above-mentioned clinical trials. The following article is a description of the various treatments he uses in his private practice to manage HIV disease, and the rationale involved for each.

Much of the material presented by Dr. Bihari reflects his personal experience rather than scientific fact. For this reason, we urge readers to interpret his conclusions with caution. The views expressed here are those of the author, and do not necessarily represent the opinions or recommendations of **BETA**, *the San Francisco AIDS Foundation or the San Francisco Department of Public Health.*

As the AIDS epidemic enters its 11th year, the paucity of FDA-approved treatments and their limited value have left many people with HIV disease confused and searching for other treatments. In the past several years, dozens of treatment approaches have been explored in preliminary clinical trials. In the course of these trials, some agents that looked promising early on have failed to obtain funding for further study because they lacked commercial potential, or because of skepticism in the research community about their mode of action. One example of a treatment which has not been pursued in clinical trials because is lacked commercial potential is the use of acyclovir (Zovirax) in high doses as prophylaxis for cytomegalovirus infections such as CMV retinitis or CMV colitis. Efforts by myself and 2 colleagues to convince Burroughs Wellcome to fund such a study failed, primarily because of the short time remaining on the Burroughs Wellcome acyclovir patent; the company would not have recouped the substantial investment the study would have required before its patent expired.

Skepticism about the whole class of non-cytokine immune modulators has made it difficult for interested investigators to raise funds to develop these agents, even when preliminary studies look promising.

Since many of the drugs that fall in the above categories are available by prescription for other FDA-approved purposes, I have used a number of them in my private medical practice to assist in the management of HIV infection and its complications. It is my belief, based on my experience in private practice, that HIV

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* Copied from the *Bulletin of Experimental Treatments for AIDS* (BETA), November 1991 issue, published by the San Francisco AIDS Foundation.

disease has already become a chronic manageable disease, and that many, if not most, patients can be stabilized and their disease progression arrested. It is also my belief, based on my own research experience and on my knowledge of new antiviral and immune modulating agents in early stages of clinical development, that we may soon have the tools to allow the process of recovery to begin.

The purpose of this document is to describe the interventions I recommend, with the scientific rationale for each, and to describe what I have observed with their use.

Although I generally counsel patients about diet, aerobic exercise, meditation, avoidance of alcohol and recreational drugs, and recommend vitamin and mineral supplements, Chinese herbs, acupuncture and other adjunctive interventions, this article will focus primarily on medications.

Immune Modulators

Although many AIDS researchers have suggested that the ideal treatment for HIV disease would involve a combination of antiviral and immune modulating agents, little of the national research effort has focused on the means to enhance or stabilize immune function. All of the drugs on the NIH-ACTG research menu identified as "immune modulators" are in fact cytokines, substances produced by immune cells to influence other immune cells. These include alpha interferon, tumor necrosis factor, interleukin-2 and gamma interferon. Although it is possible that some of the substances in this class may have immune-enhancing value in small doses, in fact, the first 2 are generally present in the body in abnormally high level in people with AIDS and appear to contribute to the disease process when elevated. Alpha interferon does so by lowering T-helper cell counts and depressing T-helper cell function, and tumor necrosis factor by increasing HIV replication and impairing the metabolism of lipids.

NIAID has been skeptical of the possible merit of the "non-specific" or broad-spectrum immune modulators. This skepticism has its history in American cancer research, which has generally ignored such an approach, even though cancer in part is a disease involving immune failure. In fact, most clinical immunologists believe that the immune system(unlike all other systems in the body) act autonomously, not under significant influence by the brain or endocrine glands. This belief is held despite the extensive basic immunology literature that demonstrates considerable external hormonal influence on the immune system.

This skepticism has led the cancer research establishment to ignore the Japanese success with lentinan as an immune-enhancing adjunct to cancer chemotherapy. Lentinan, an approved drug in Japan for several years, has tripled the 5-year survival rate for patients with several common types of cancer. Despite this, the only U.S. trial of lentinan was a small Phase I trial in people with ARC, conducted by myself at the Community Research Initiative (CRI) in New York and by Donal Abrams, MD, at San Francisco General Hospital.

[Editor's Note: Both trials showed no benefit from lentinan among HIV-infected individuals at the doses tested. A Phase II Open Label study of lentinan plus AZT is underway at UCSF.]

The skepticism about non-cytokine immune modulators has kept several possibly useful agents off of the NIAID high priority list. These include metenkephalin,

imuthiol, antabuse, imreg, levamisole, naltrexone, cimetidine, transfer factor and several thymic hormones.

There is sufficient evidence of immune-stabilizing/enhancing activity from clinical trials of 3 of the above agents, which are non-toxic prescription drugs approved by the FDA for other purposes, to provide a basis for physicians and patients to begin immune modulating treatment while waiting for further clinical trials to more fully address this class of drugs. A description of these 3 drugs and my clinical experience with them follows.

Naltrexone

A placebo-controlled trial with small doses of the opiate antagonist, FDA-approved in high doses for treatment of heroine addicts, was carried out from 1985 to 1986 at Downstate Medical Center by my colleagues and myself in people with an AIDS diagnosis. Its use was based on the considerable evidence suggesting that the most important systemic hormones involved in regulating immune function are the endorphins (especially metenkephalin and beta endorphin) and a study showing that beta endorphin levels are low in people with AIDS. Small doses of naltrexone taken by mouth once a day a bedtime induce the body to substantially increase production of beta endorphin and metenkephalin during the night.

Significant blood levels of beta endorphin are sustained for at least 18 hours, while the small dose of naltrexone is excreted in 2 or 3 hours. In the trial, 5 of 16 patients on placebo suffered major opportunistic infections while non of the 22 on the drug did so.[1] In addition, patients on drug had no deterioration in T-helper cell functions while those on placebo did. Finally, most patients on drug had a gradual decline in their toxic levels of serum alpha interferon to low, physiological antiviral levels.[2]

Based on this study and the lack of toxicity of the dose used, I began giving naltrexone to all of the individuals in my practice in mid-1985 at a dose of 3 mg every night at bedtime. Over the following 2 years, when no other treatment was available but PCP prophylaxis I found that, as in the Downstate trial, about 75% of the patients on naltrexone stabilized, with no further drop in T-helper cells and no clinical disease progression.

Naltrexone is prepared by a pharmacist by dissolving two 50 mg tablets in 100 cc(ml) of water, and dispensed with a 3 cc syringe. The patient measures 3 cc of the liquid, mixes it in 3 or 4 ounces of juice or water and drinks it once a day at bedtime. It should be taken no earlier than 9 pm, as it works in large part by boosting beta endorphin production, which peaks in the early morning hours. When the 50 mg tablets are dissolved, the compound in the tablet that ordinarily keeps it from crumbling will not dissolve, but will settle to the bottom of the bottle. Since the naltrexone itself is all in solution, it is not necessary to shake the bottle. When mixed in water without sugar, the

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[1] Bihari B, Drury F, Ragone V et al. Low dose naltrexone in the treatment of AIDS. IV International Conference on AIDS. Poster 3056. Stockholm, June 1988.

[2] Bihari B, Drury F, Ragone V et al. Low dose naltrexone in the treatment of AIDS: long term follow up results. V International Conference on AIDS. Poster M.C.P.62. Montreal, June 1989.

dissolved naltrexone is table for at least 3 months. It should in general be refrigerated, but can go 2 or 3 weeks without refrigeration without spoiling.

Antabuse (disulfiram)

In mid-1987 a paper was published reporting the results of a placebo-controlled trial of imuthiol in France, showing relative protection against clinical progression. [3] Trials since have demonstrated that imuthiol also stabilizes about 60% of patients on a long term basis, thereby significantly reducing the incidence of opportunistic infections.[4] When I became aware that imuthiol is in fact diethyldithiocarbamate (DTC), the active metabolite of antabuse that is responsible for the efficacy of the latter drug in controlling impulse drinking by alcoholics, Tom Hannon, Dr. David Seaman and I publicized this fact among community physicians and organized an antabuse monitoring project at CRI. This study, although it was not a prospective placebo-controlled trial, nonetheless suggested that antabuse had a similar spectrum of activity as imuthiol.[5] I then added antabuse to my standard regimen in private practice, and during the 4 years since, I have followed more than 250 patients on the combination of naltrexone and antabuse.

Of those who have been on the combination more than 3 months, and who have stayed on it, only a few have shown a drop in T-helper cells, and fewer have evidenced significant clinical progression. When I encounter people who were started on this combination 2 or 3 years ago and are not doing well now, they invariably turn out to have stopped both drugs within the first few months, either because their T-helper cell count did not increase, or because their physicians expressed skepticism about the value of the drugs. Unfortunately, many people with HIV disease overlook the value of T-helper count stabilization, which in fact can prevent disease progression.

The antabuse should be taken at a dose of 500 mg twice a week on a full stomach. Eighty percent of patients have no side effects, except for the necessity to avoid alcohol completely. About 20% get nausea or cramps and loose stools for a few hours after each dose. This can generally be prevented by ingesting either 2 tablespoons of olive oil, or an Alka Seltzer, or both, if necessary, an hour before each dose. Occasionally, the regimen must be changed to 250 mg every other day to avoid these side effects if the olive oil/Alka Seltzer regime does not provide adequate protection.

In late July of this year, Merieux Institute announced that it was withdrawing imuthiol from development based on a "preliminary analysis" of a recently completed trial. Many people with HIV infection and Chronic Fatigue Syndrome (which also frequently responds to this drug) were deprived of supplies of the Merieux product. Others who had been taking "underground" DTC or disulfiram became concerned about whether they should continue to do so, since their use of these substances was

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[3] Lang J, Oberling F et al. Immuno modulation with diethyldithiocarbamate in patients with AIDS-related complex. *The Lancet* 2:1066. 1985.

[4] Hersh E, Brewton G, Abrams D et al. Ditiocarb Sodium (diethyl dithiocarbamate) therapy in patients with symptomatic HIV infection and AIDS. *Journal of the American Medical Association* 265:1538. 1991.

[5] Bihari B, Seaman J. Disulfiram in the treatment of AIDS related illness. IV International Conference on AIDS. Poster 3042. Stockholm, June 1988.

based on earlier Merieux clinical trials of imuthiol. Taking into account this history, the positive benefits demonstrated in published clinical trials of imuthiol and the apparently similar benefits seen in clinical practice with disulfiram, I have continued to recommend the latter drug to my patients.

[Editor's Note: The Merieux Institute, manufacturer of imuthiol, suspended trials of the drug after a large study showed that more people taking imuthiol progressed to ARC and AIDS than those taking a placebo.]

Cimetidine (Tagamet)

Recently, some clinicians have added cimetidine, a prescription drug, to their treatment regimen as an immune modulator. Like the other 2 drugs described above, cimetidine is FDA-approved for another purpose, in this case for treating peptic ulcers. This has been based on the anecdotal experience of patients put on cimetidine for treatment of ulcers whose T-helper cells counts have unexpectedly risen, and a German trial showing a marked rise in T-helper cell count and reduction in symptoms in 33 ARC patients on cimetidine.[6] The German study showed a rise in T-helper cells from an average of 360 to 690 within 3 months, accompanied by a reduction in ARC symptoms. This was not a prospective, randomized placebo-controlled trial, but since the drug is relatively non-toxic, I have recently added it to my standard regimen (400 mg 3 times/day). In the 140 patients in whom I have seen 3-month follow-up T-cell counts, about half have had T-helper cell count rises of more than 30% (220 to 420, 50 to 130, 300 to 580 and, in one case, from 156 to 684). In a few patients, T-helper cell count rises did not occur until 4 to 6 months after starting cimetidine. Many of the patients with rises in T-helper cell counts have improved energy and appetite and sense of well being, and in some, I have observed a reduction in the size and number of swollen lymph nodes.

Cimetidine works as an ulcer treatment by blocking the histamine receptor that regulates stomach acid secretion. Histamine receptors have been demonstrated in lymphocytes, and a number of studies have shown enhanced lymphocyte and macrophage function in the test tube when cimetidine is added.[7,8,9] Presumably, normal or high levels of histamine impair lymphocyte function (which it does in the test tube) and reduce T-helper cell count numbers in patients with HIV disease. The frequency of hives, rashes, allergy and itching in people with HIV/AIDS suggests that histamine blood levels may be chronically or frequently elevated. Cimetidine may work by blocking the negative effect of such elevated histamine levels on T-helper cells. *Patients on dapsone for PCP prophylaxis who are started on cimetidine should have their dapsone dose increased by 50%, since dapsone absorption is partially dependent on stomach acid.* Patients on cimetidine may wish to take 1 or 2 hydrochloric acid tablets before each meal to assure that the drug will in no way reduce the efficiency of digestive processes. Two such products are Nuradyn and Acydidyn.

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[6] Brockmeyer N et al. Immunomodulatory properties of cimetidine in ARC patients. *Clinical Immunology and Immunological Pathology* 48:50. 1988.

[7] *International Journal of Clinical Pharmacology.* Therapeutics and Toxicology 458. 1989.

[8] Lee I, Starr A, Rheiu S. *Proceedings of the Reticulo Endothelial Society.* 26:47. 1979.

[9] Friedman H, Immunomodulating effects of cimetidine, in *Augmenting Agents in Cancer Therapy*, by E Hersh et al. Raven Press, New York, p417. 1981.

It is of interest that at least 2 of the above 3 drugs appear to work on immune cell hormone receptors, naltrexone on the opiate receptor and cimetidine on the histamine receptor. At least 3 of the other broad-acting immune modulators in development also act on opiate receptors. Metenkaphalin (MEK), for which I was recently the principal investigator of a Phase I placebo-controlled trial at CRI, clearly does so. In fact, the CRI MEK Phase I trial results as presented at the VII International AIDS Conference in Florence in June 1991, showed that the higher dose (125 micrograms/kg intravenously once a week) induced a significant increase in total lymphocytes, T-helper cells, natural killer cell activity, interleukin 2 receptors, lymphocyte blastogenic responses to cytomegalovirus and pokeweed in CD56 (leu 19) receptors, as compared with low dose MEK and placebo.[10] The difference in T-helper cell count between high dose and placebo at 12 weeks was 20%. The CD56 increase may be of particular interest, as it represents the lymphocyte-activated killer cells that destroy HIV-infected cells.

Some thymic peptides have been used for the treatment of chronic pain and thus may also act on opiate receptors. Transfer factor and Imreg apparently include endorphins in regulating immune function should be of particular interest in efforts to develop immune modulating agents.

Antiviral Drugs

The Nucleoside Analogues

Clearly, antiviral agents are crucial in the management of an illness in which viruses play a major role. Unfortunately, the antiviral agents currently available, the nucleoside analogues AZT, ddI and ddC, are toxic to many patients, have a limited span of activity because of the tendency of HIV to develop resistance to this class of drugs, and finally, may have limited long-term value because of their potential carcinogenicity. A significant percentage of people started on AZT cannot tolerate it because of persistent nausea, fatigue or depression, and some patients develop intolerable abdominal pain, severe headaches, agitation and/or psychosis. The toxic effects of AZT on the bone marrow with consequent anemia and a low white blood count have been less problematic since it became clear that 500 mg/day, and possibly 300 mg/day, are as effective as 1,200 mg/day.

When AZT was first marketed for people with and AIDS diagnosis and/or fewer than 200 T-helper cells, I found that it was useful in 2 groups of patients. One was those who developed severe fatigue and weight loss, accompanied by fevers, night sweats and other constitutional symptoms, without a causative opportunistic infection. On AZT, many such patients gained weight and had considerably improved energy and mood. Some patients in my practice sustained such AZT-related improvements for as long as 18 months.

The other group of patients who frequently benefited from AZT were those who developed signs of HIV encephalopathy. In my experience (confirmed by clinical trials),

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[10] Bihari B, Plotnikoff N. Freeman K et al. Methionine enkephalin in the treatment of ARC. VII International Conference on Aids. Florence, June 1991 (Poster WB 2137).

about 75% of such patients show considerable improvement on AZT. Unfortunately, when I see such patients now, they generally have been on AZT long enough in the past, while asymptomatic, to have developed resistance to the drug, and they rarely respond. The widespread use of AZT in asymptomatic patients has thus been responsible, in my opinion, for depriving AZT of its 2 major clinical uses.

This is one of the reasons that I do not encourage asymptomatic patients, in particular those with more than 200 T-helper cells, to start AZT. Another is that the NIAID/ACTG trial that led to the FDA approval of the use of AZT in early stages of HIV infection, in my opinion, *did not demonstrate any value* in patients with more than 200 T-helper cells. The paper reporting the results of this study (ACTG 019) included patients with fewer than 200 T-helper cells in its statistics.[11] Although only 15% of the patients in the trial (162 of 1339) had fewer than 200 T-helper cells, 38% of the ARC symptoms and opportunistic infections (29 of 77) that developed during the trial were in this small subgroup. If this subgroup is eliminated from the statistical analysis, the differences between the 2 patient groups with more than 200 T-helper cells on AZT, (one group on 1,500 mg and on 500 mg) and the group on placebo are not significant. The study therefore does not appear to prove that AZT prevents major OI and ARC symptoms in patients with *more than* 200 T-helper cells. It raises the possibility that AZT *may* reduce such events in patients with *fewer than* 200 T-helper cells, but the data are insufficient to prove this.

The results of the Veterans Administration study of AZT in asymptomatic patients and information available about the as yet unpublished results of the "Concorde" study in England and France also raise serious questions about the validity of the conclusions drawn by the investigators involved in ACTG 016 and 019.

For the above reasons, I do not recommend AZT in patients who are asymptomatic and/or have more than 200 T-helper cells. However, since the FDA has approved AZT use in such situations, I do prescribe it when it is requested. In addition, when I see a patient with more than 200 T-helper cells who has been on AZT for some time and has done well, I recommend that it be continued. In fact, a subset of patients with more than 200 T-helper cells seem to do extremely well. This group, representing in my experience between 10% and 15% of patients taking AZT, show sustained rises in T-helper cells that may last as long as 18 months.

There are some physicians who do not routinely recommend AZT to asymptomatic patients with more than 200 or 300 T-helper cells, but who do so if the T-helper cells suddenly drop. This makes little sense to me, since in all of the AZT studies T-helper cells have dropped as much on drug as on placebo a year after study entry, despite a transient rise the first few weeks averaging about 10%. This indicates that AZT has no effect in stopping the usual decline in T-helper cells of 80 to 100 per year.

The use of rising p24 antigen levels as a basis for starting AZT theoretically makes somewhat more sense, since AZT has consistently been shown to reduce p24 antigen levels. The p24 antigen, however, has turned out to have little or no value as a prognostic marker for disease progression.

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[11] Volberding P, Lagakos S, Koch M et al. Zidovudine in asymptomatic human immunodeficiency virus infection. *New England Journal of Medicine* 322:941. 1990.

Regarding ddI, which was approved by the FDA on October 9, 1991, its use at present may make sense for some patients, since its FDA approved use is restricted to patients who are doing poorly on AZT. It does, however, occasionally cause death from drug-induced pancreatitis, and a painful peripheral neuropathy that may not immediately clear when the drug is discontinued.

[Editor's Note: ddI manufacturer Bristol-Myers Squibb reported the following major adverse side effects from ddI in the Expanded Access program and in the adult Phase I trials: potentially fatal pancreatitis (5 to 9 percent), peripheral neuropathy (16 to 34 percent) and diarrhea (18 to 34 percent).]

The recommendation in late July by the FDA antiviral Advisory committee that ddI should be licensed unfortunately did not clarify much about the value of the drug for the community of people with AIDS. According to the reports of many people who attended the meeting, and the media interviews of the committee members, *the data presented on the clinical benefit was quite limited.*

Other Antivirals

There are several classes of antiviral drugs in various stages of development that, if they prove to work in patients, would have many advantages over the nucleoside analogues. None of these work by breaking the DNA chain. All act at points in the HIV life cycle that make them unlikely to be carcinogenic, unlikely to trigger resistance in HIV and much less likely than the AZT family to have major side effects.

Thus, any of these that turns out to be effective may be taken by patients for many years. These include the protease inhibitors, TIBO derivatives, the Merck "L" drugs, hypericin and related alkaloids, the Hoffman La Roche tat gene inhibitor and the new Boehringer Ingelheim reverse transcriptase inhibitor, BI-RG-587. The protease inhibitors may ultimately have limited value since human cells have similar enzymes. Unpublished information that I have obtained from the Phase I trials of the Hoffman La Roche tat gene inhibitor at Johns Hopkins sounds quite promising. It appears to completely stop HIV replication as low doses (50 mg/ 4 times a day). This finding has apparently led to a redesign of the Phase I study to omit testing the higher doses of the drug that had been identified in the original protocol.

Hypericin, in addition, looks quite promising. It was tested for antiviral activity by New York University scientists after extraction from the St. John's Wort plant, in use for thousands of years in Caribbean and Mediterranean countries as an anti-infective agent. It is dramatically effective in the test tube against HIV, acting to prevent infected cells from releasing virus, and it prevents free-floating HIV from infecting healthy cells. It does both at concentrations that are much lower than those that are toxic to the cells. Of interest as well is the effectiveness of hypericin in treating mice infected with the murine retrovirus. In this mouse illness, which is similar to AIDS, and which is widely used in screening new antiviral agents, mice live only 30 days after being infected. Appropriate hypericin blood levels restore the mice to a normal clinical state and to a normal life span of 240 days, *with no apparent toxicity.*[13] In addition, hypericin appears to

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[13] Dan Meruelo, private communication.

be active against the hepatitis virus, and the Epstein Barr and other herpes viruses, some of which may be cofactors in HIV disease progression.

The Phase I ACTG trial of hypericin is expected to begin soon at NYU and hospitals in Boston and Minneapolis. The Phase II trial is unlikely to begin before the Fall of 1992, but if the Phase I trial shows little toxicity and suggests some efficacy, and expanded access program will hopefully be instituted.

The development of hypericin has unfortunately been marked by several delays. A highly purified extract of the St. John's Wort plant, more than 98% of which was hypericin, was used in the test tube and mouse studies. Unfortunately, the effort required to synthesize pure hypericin delayed the start of the Phase I trial by more than a year. In addition, according to reliable sources, the synthetic drug is less potent than the purified extract. Because of these delays, St. John's Wort extracts have been prepared with much higher concentrations of hypericin and the closely related alkaloid pseudo-hypericin (which has a similar spectrum of activity). Pacific Bio Logic in Oakland, California, has agreed to eventually distribute the product, which contains 10 mg of a hypericin/pseudo-hypericin combination per capsule, after a clinical trial to evaluate its safety/toxicity. This trial, which will being in November or December of 1991, with myself as the principal investigator, will be an open label study, conducted with 100 patients in the private practices of several community physicians across the country who have had significant experience in conducting clinical trials. The dose will be increased slowly over a 12-week period to 140 mg/week to evaluate safety/toxicity. Patients will be stabilized at this dose for 24 weeks to look for evidence of efficacy, with particular regard to T-helper cell numbers, p24 antigen levels and alpha interferon levels. Once the first 50 patients have been in the study for 12 weeks, and the data to that date evaluated for safety/toxicity, the decision will be made about distribution of this concentrated extract. If the toxicity is limited and manageable, Pacific Bio Logic will then make the concentrated extract available through physicians' offices and/or buyers clubs. Hopefully, the decision can be made by March or April of 1992. Information can be obtained by calling 415-548-8616 or 800-869-8783.

The currently available St. John's Wort extract probably has little value as an anti-HIV agent, short of taking massive and probably toxic doses. It may have some value, however, in suppressing some herpes viruses and the hepatitis virus. In the planning stages for the study described above, we collected information from 3 physician/research groups that have done open label studies of currently available St. John's Wort extracts. The 3 studies included 10 patients (of a total of 25) with abnormal liver function studies due to chronic hepatitis before starting on a St. John's Wort extract who showed dramatic improvement in liver function. In the 15-patient study at CRI, the 2 patients with chronic hepatitis both showed considerable improvement in liver chemistries within 3 months. In addition, one patient in my practice with symptomatic chronic hepatitis showed a dramatic improvement in both symptoms and liver chemistries after 2 months on St. John's Wort (using 9 tablets/day of the Yerba Prima product).

It should be emphasized that this anecdotal information about hepatitis does not represent a study. In addition, we will not know how toxic the concentrated extract is until the spring of 1992. Evidence of efficacy will be much more difficult to obtain from a small open label such as this, unless the drug is dramatically effective. Information

about the study as it progresses will be available through AIDS newsletters. Ultimately, the results will be analyzed and submitted to a medical journal.

Management of Cofactors

Although it seems clear to me that HIV is necessary for the development of AIDS-related immune suppression, it is not as clear that HIV alone is sufficient to do so. Many cofactors have been postulated as contributing to or as necessary for HIV infection to lead to progressive immune suppression and/or AIDS. There are 2 cofactors for which the evidence is, in my judgment, significant enough to consider in making treatment decisions: the herpes family of viruses and the mycoplasma organism. The evidence and treatment implications briefly are as follows.

Herpes Viruses

This family of viruses includes herpes simplex 1 (HSV-1), the virus that causes cold sores; herpes simplex 2 (HSV-2), which causes genital herpes; herpes zoster (HZV), the chicken pox/shingles virus; the Epstein Barr virus (EBV); the cytomegalovirus (CMV); and the newly discovered human herpes virus 6 (HHV-6). Most adults are chronically infected with 3 or more of these viruses, which remain latent. There is significant evidence suggesting that, in the test tube, HIV replication, HIV induced cell destruction and HIV spread to other cells is markedly accelerated when a herpes virus is added. Studies of high doses of the anti-herpes drug acyclovir plus AZT compared to AZT use alone suggest that the acyclovir helps to reduce the number of opportunistic infections and possibly to improve survival.[14,15] The acyclovir benefit may be due to its ability to control the contribution of herpes viruses to HIV replication. The acyclovir dose used in these studies was 3,200 to 4,800 mg/day.

Because of the studies, and the relatively low toxicity of acyclovir, I generally recommend that patients take 800 mg of acyclovir 3 times a day. On this dose approximately 10% of patients have side effects, mostly involving fatigue, headaches and/or light-headedness, generally controlled by lowering the dose to 1,600 or 1,800 mg/day. Rarely, someone on chronically high doses of acyclovir may develop mild abnormalities of kidney or liver function. I therefore obtain monthly blood chemistries (which include liver and kidney function tests) for the first 3 months in patients on these doses, since if such a side effect is to occur it will do so within this time. I recommend this intervention for all patients, regardless of T-helper cell count levels, since it may help to prevent progressive T-helper cell loss, particularly when combined with the immune modulators described above.

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[14] Collier A et al. IV International Conference on AIDS. Abstracts 3137-3138. Stockholm, June 1988.

[15] Fiddian A et al. Zidovudine Plus or Minus Acyclovir in Patients with AIDS or ARC. European/Australian Collaborative Study Group. Abstract, 28th Interscience Conference on antimicrobial Agents and chemotherapy. Los Angeles, October 1988.

Mycoplasma

Dr. Luc Montagnier and Shyh-Ching Lo have published considerable evidence suggesting that this odd organism, which resembles a bacterium but has no cell wall, is a major cofactor in the progressive T-cell destruction in patients with HIV disease.[16, 17] Two widely used broad-spectrum antibiotics, doxycycline and ciprofloxacin, are effective in the test tube in suppressing mycoplasma growth and in inhibiting its apparent proclivity to accelerate HIV replication, HIV-caused cell destruction and HIV spread from cell to cell. A prominent physician treating AIDS in Paris told me recently that she has treated more than 30 people with AIDS with long-term doxycycline therapy, with more than half showing symptom reduction and clinical stabilization, and none showing serious side effects. In addition, I have seen or talked to 5 patients, who were started on chronic doxycycline therapy by the late Dr. Steven Ciazza between 2 and 3 years ago, based on his belief that the syphilis spirochete was the cause of AIDS. All 5 report long-term clinical and T-helper cell count stabilization with no side effects.

Although I am impressed with Dr. Montagnier's and Dr. Lo's findings, I have concerns about the potential long-term consequences of broad-spectrum antibiotic therapy. I have thus far been reluctant to add 1 of these 2 antibiotics to my standard treatment regimen until a good clinical trial with one of these antibiotics has been carried out. I do, however, recommend doxycycline 200 mg twice a day for patients who are doing poorly despite aggressive treatment with a regimen like that described herein. In addition, I occasionally suggest it for a patient who has had a marked drip in T-helper cells in a relatively short time period without a triggering opportunistic infection. Such a sharp drop always raises in my mind the possibility that a silent cofactor is involved. Unfortunately, no clinical trial of long-term doxycycline treatment has yet been organized.

Prophylaxis of Opportunistic Infections (OI)

It is presently standard practice to begin prophylaxis again *Pneumocystis carinii* pneumonia (PCP) in people with fewer than 200 T-helper cells with aerosolized pentamidine (AP), 300 mg inhaled once a month, or Bactrim, one double-strength tablet daily or 3 times/week, or dapsone 100 mg per day. I prefer, as do many clinicians, to begin prophylaxis at a T-helper level of 250, perhaps erring on the side of caution. I also prefer to use oral systemic medication (Bactrim or dapsone) rather than AP, since clinical experience and clinical trials have both shown considerably more break-through episodes of PCP with the latter. Bactrim and dapsone also have the advantage of preventing non-pulmonary pneumocystis infections (in the eye, pancreas, etc.), but the disadvantage of frequently producing allergic rashes, drug fevers or both. If both Bactrim and dapsone have caused an allergic reaction, I generally resume Bactrim with the use of a desensitizing schedule in order to bypass the allergic reaction. This involves

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[16] Lo S et al. *American Journal of Tropical Medicine (and Hygiene)* 41:601. 1988.

[17] Montagnier L et al. *Research in Virology* 141:5. 1990.

gradually increasing doses of the liquid pediatric suspension of Bactrim over a 10 day period, until the equivalent of one double-strength tablet is achieved, then switching to the double-strength tablets.

Twenty cc of the pediatric suspension is equivalent to 1 double-strength Bactrim tablet. The patient is dispensed a 2cc or 3cc syringe, and takes 2cc the first day on the drug. The dosage is increased by 2cc per day so that the dose on the 9th day is 18cc. On the 10th day, the switch to the tablets is made. Approximately two-thirds of the patients with a previous allergic reaction to Bactrim can complete this schedule, and take double-strength tablets daily or 3 times/week without the reappearance of allergic symptoms.

The most important experimental agent for PCP treatment and prophylaxis is 566C80, a Burroughs Wellcome drug now in clinical trials for the treatment of acute PCP. It is available under a Compassionate Use IND for patients with *acute* PCP who are resistant to or intolerant of standard treatment regimens (the phone number for the physician to call is 800-755-2020). Efforts to obtain 566C80 as a Compassionate Use *prophylactic* treatment for patients who cannot tolerate the standard regimens have thus far been unsuccessful, but individual requests can be pursued through the same phone number.

Although it is not standard medical practice or an FDA recommendation to do so, a growing number of AIDS clinicians have begun to initiate prophylaxis against other OI. The decision concerning when to begin prophylaxis should be based on the individual's T-helper cell count. Since we rarely see cryptococcal meningitis or esophageal candidiasis (both fungal OI), toxoplasmosis or CMV retinitis, gastritis or colitis in people with T-helper cells counts above 150, I use that T-helper cell number as a guide to begin prophylaxis for these OI. Similarly, since infection with MAI *(Mycobacterium avium intracellulare)* is rare with T-helper cells above 75, I use that number and the duration of time the patient has been at or below that T-helper cell level as the basis for recommending MAI prophylaxis. The drugs recommended and rationales for their use to prevent these OI follow.

Fungal Infections

HIV-related fungal infections include cryptococcal meningitis, esophageal/gastric candidiasis, vaginal candidiasis, histoplasmosis and aspergillosis. Since fluconazole (Diflucan) 100 mg/day is the standard drug of choice for "secondary" prophylaxis of fungal OI (prevention of relapse after a successfully treated episode), it's reasonable that it would be highly likely to prevent the first episode of fungal OI. Since this drug has minimal toxicity, I recommend it for all patients with fewer than 150 T-helper cells for this purpose. It has the additional value of clearing minor fungal infections of the skin, nails and mucous membranes including oral and vaginal candidiasis, thereby reducing the possible contribution of such a chronic low-grade infection to stimulation of HIV replication.

Toxoplasmosis

Toxoplasma encephalitis in people with AIDS, unlike most OI, generally represents reactivation of an old silent infection, which usually occurred in childhood or adolescence, in which the *Toxoplasma gondii* parasite was isolated and sealed off in a cyst in the spleen, liver, lung or brain. Almost all cases of toxoplasma encephalitis occur in patients who have high levels of antibodies representing an old silent infection. It is estimated that about 20% of people with AIDS/HIV infection in the U.S. have such toxoplasma antibodies, with considerable geographic variation.[19]

Of patients with high antibody levels, approximately 30% will eventually develop toxoplasma encephalitis without prophylaxis. The principle involved in toxoplasmosis prophylaxis is similar to that described above for fungal OI. Acute toxoplasmosis is generally treated with pyrimethamine (Daraprim) and sulfadiazine, with the former drug continued after successful treatment of an episode to prevent relapse. It makes medical sense that a drug that is successful for secondary prophylaxis will also be highly likely to be effective for preventing the first episode. I therefore currently routinely test all patients for toxoplasma antibodies and recommend pyrimethamine, 25 mg per day or 50 mg 3 times/week for prophylaxis in patients with high antibody titres and fewer than 150 T-helper cells. Pyrimethamine may occasionally cause a sharp drop in the white blood count. This can be prevented by using folinic acid (leucovorin), which I generally prescribe with it.

If the patient cannot tolerate pyrimethamine, 2 presently available alternatives are clindamycin (300 mg twice a day) or doxycycline (100 mg twice a day). There are 2 promising experimental drugs with low toxicity and significant activity against toxoplasmosis, Pfeizer's azithromycin and Burroughs Wellcome's 566C80. The former is now available, under a Compassionate Use IND, for treatment of acute toxoplasmosis in patients resistant to or intolerant of pyrimethamine and sulfadiazine. 566C80 for toxoplasmosis is currently available to a few individuals in clinical trials and on a Compassionate Use basis from Burroughs Wellcome (physicians may call 800-722-9292).

Cytomegalovirus (CMV) Retinitis, Gastritis, Colitis and Systemic Infections

These CMV OI are generally treated with DHPG (ganciclovir), an effective, but highly toxic drug that must be given intravenously every day, indefinitely, requiring the insertion of an indwelling intravenous catheter. The catheter tends to be the site of repeated bacterial infections, and the DHPG, by frequently producing a marked drop in the white blood count, can simultaneously increase the patient's vulnerability to bacterial infections. Thus treatment of CMV OI, while successful in arresting the disease at least 75% of the time, is nonetheless itself a major cause of serious illness and death. Intravenous foscarnet has recently been shown to be as effective as DHPG for CMV retinitis and to increase survival rates in patients using the drug. Patients on foscarnet can also concurrently use AZT, which is rarely an option for those taking DHPG, since the AZT/DHPG combination causes severe bone marrow suppression.

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[19] Luft B, Remington J. *Journal of Infectious Diseases* 157:1. 1988.

Although it has not yet been confirmed by prospective randomized double-blind clinical trials, there is mounting anecdotal evidence that high doses of acyclovir (1,000 mg 4 times a day for a total of 4,000 mg/day) considerably reduce the incidence of CMV OI. In particular, as of 20 months ago, Metroka and Josefberg had followed 120 patients with 150 T-helper cells or less for an average of 15.5 months on this dose, with only 2 patients developing CMV retinitis rather than the expected number of 15 to 20.[20] Their experience with a larger number of patients and over a longer period of time has supported these findings, as has the cumulative experience of a number of physicians in New York, including myself.

Although high-dose acyclovir lacks the rationale of efficacy for secondary prophylaxis upon which the use of flucanazole and pyrimethamine are based, and has not been tested with prospective randomized double-blind trial, it is my judgment that the difficulty and danger involved in treating CMV OI provides reason enough for recommending high-dose acyclovir. This recommendation is supported by the fact that CMV replication is suppressed in the test tube by high concentrations of acyclovir, and by studies showing that high-dose acyclovir effectively reduces the incidence of CMV pneumonitis in patients with kidney and bone marrow transplants who have immunosuppression caused by the drugs used to prevent transplant rejection. [21, 22] Since HIV-related lymphomas are generally of B cell origin, and have been linked to Epstein Barr virus infection of B cells, it is possible that high-dose acyclovir may also have some value in helping to prevent this opportunistic disease.

I therefore routinely recommend that patients with less than 150 T-helper cells take 1,000 mg of acyclovir 4 times a day or 800 mg 5 times a day, making use of the new 800 mg capsules. Side effects and laboratory monitoring for high-dose acyclovir were previously described in MANAGEMENT OF COFACTORS.

Mycobacterium Avium Intracellulare (MAI)

This infection, caused by a bacterium closely related to the organism that causes tuberculosis, is a major cause of serious illness in people with fewer than 50 T-helper cells. The organism was present without symptoms in the blood cultures of 7% of people with AIDS in one study.[23] There is some evidence that it begins as a non-infectious pathogen in the gastrointestinal tract, then becomes an asymptomatic blood stream and bone marrow infection for some time, perhaps several months, and then may become a serious symptomatic clinical illness. Clinically evident MAI infection is characterized by fevers, weight loss, swollen glands, anemia, diarrhea and wasting, and is often accompanied by an enlarged liver and spleen. Physicians treating clinical MAI infection generally use 3 or 4 drugs simultaneously. These usually include ciprofloxacin,

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[20] Metroka C, Josefberg H. Usefulness of high-dose acyclovir as prophylaxis for CMV. VI International Conference on AIDS. Abstract 2111. San Francisco, June 1990.

[21] Meyers J, Reed E, Shepp D et al. Acyclovir for prevention of cytomegalovirus infection and disease after allogenic marrow transplantation. *New England Journal of Medicine* 318:70. 1988.

[22] Balfour H, Chace B, Stapleton J et al. A randomized placebo-controlled trial of oral acyclovir for the prevention of cytomegalovirus disease in recipients of renal allografts. *New England Journal of Medicine* 320:1381. 1989.

[23] Steve Nightingale, private communication.

clofazimine and ethambutol with intravenous amikacin, a highly toxic drug, sometimes added for the first 4 weeks of treatment. Ethionamide, rifampin and isoniazid are occasionally used as well.

In general, only 20 to 30 percent of patients respond with relief of symptoms to these multi-drug regimes, and many who do eventually develop recurrence despite maintenance on oral medication. (Ciprofloxacin plus clofazimine is the usually preferred maintenance regime). More recently, clarithromycin has shown considerable promise in the test tube and in clinical anecdotal reports in improving the management of this terrible infection.[24, 25, 26] I have seen 2 patients who were not responding to standard therapies dramatically improve in 3 to 7 days after adding clarithromycin, 1,000 mg twice a day to their regime. Recently, I've had one patient with MAI who responded to clarithromycin alone. In late July, clarithromycin became available under a Compassionate Use IND from Abbott for patients with active MAI (physicians may call 800-352-6661).

Although it is available in Ireland and Italy, clarithromycin is not an FDA-approved prescription drug in the U.S. It is presently available from buyers clubs but, because it lacks FDA approval, its cost is not covered by insurance policies. The Compassionate Use IND does not cover its use for prophylaxis.

Since MAI eventually develops in about 30% of people with AIDS and is so difficult to treat, I suggest that most patients with fewer than 75 T-helper cells consider one of several approaches to MAI prophylaxis. One simple approach is to get an MAI blood culture monthly, and if it turns positive, begin treatment with 2 drugs until it turns negative. The 1 or both drugs are maintained on a long-term basis (ciprofloxacin with ethambutol or, if obtainable and affordable, clarithromycin). Since it may take as long as 6 to 8 weeks for MAI to appear in blood cultures, this has the drawback of delaying preventive treatment. It may nonetheless facilitate early intervention, since it may take many months for people with positive cultures to become symptomatic. An alternative is to begin prophylaxis with ciprofloxin or clarithromycin with the hope that these drugs may have some efficacy in preventing MAI. This is likely to be the case particularly with clarithromycin, but only controlled prospective clinical trial will determine whether this is so with either drug. Since, unlike the case with the 4 OI discussed above, there are no prospective studies to provide even an inferential basis for choosing 1 of these regimes, I do not strongly recommend which to follow, but I do urge those patients with fewer than 75 T-helper cells to choose . I suggest monthly MAI blood cultures as a minimum regime in order to allow early intervention, and clarithromycin 250 mg 1 or 2 times a day for patients who can afford it.

As one of the principal investigators in the large nationwide Adria placebo-controlled trial of rifabutin as prophylaxis for MAI, I was notified in late September 1991 that the trial was stopped by the DATA Safety Monitoring Board (DSMB) after an interim analysis of the data. The DSMB directed Adria to offer open label rifabutin to all participants in the trial, and we have begun to do so. Although the data will not be

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[24] Fernandez P, Hardy D, McDaniel D et al. In vitro and in vivo activities of clarithromycin against *Mycobacterium avium intracellulare. Antimicrobial Agents and Chemotherapy* 33: 1531. 1989.

[25] Franke-Ruta G. Guerillamycin! *Notes from the Underground* 4. September 1990.

[26] *AIDS Treatment News* 122. March 1, 1991.

available for several months, the DSMB would presumably not have stopped the trail unless the drug showed statistical evidence of efficacy. According to preliminary reports, toxicity was minimal. Hopefully, rifabutin will become available under a treatment IND reasonably soon, increasing the options available for MAI prophylaxis.

As MAI prophylaxis becomes more common, the question whether to use multiple or single agents will have to be addressed. The reason for this is that the mycobacterium responsible for the infection has a history of developing resistance to many of the drugs used to treat it in the past. The simultaneous use of 2 drugs to which the bacterium is sensitive considerably reduces the risk of the development of resistance. Thus a combination of rifabutin (300 mg once a day) and clarithromycin (250 mg twice a day) may ultimately represent an effective prophylaxis. It should be mentioned that the development of clinically significant resistance has not been noted with the pneumocystis and toxoplasma organisms, nor with fungi or cytomegalovirus. MAI and tuberculosis, caused by related mycobacteria, are the 2 opportunistic organisms most likely to develop drug resistance.

[Editor's Note: The San Francisco Community Consortium study of clofazamine (50 mg day) as a single agent prophylaxis for MAI has been discontinued. The drug showed no evidence of effectiveness in preventing onset of the disease.]

Tuberculosis (TB)

TB is not considered an opportunistic infection in most HIV negative people who are symptomatically infected with it, although it is most common in people who are chronically ill and malnourished, in particular in alcoholics, drug addicts and the long-term homeless. Like toxoplasmosis, many people are silently infected with it early in life, forming a walled off lesion or scar, generally in the upper area of the lungs. Approximately 10% of adults in New York City have such a healed TB lesion, documented by the presence of a positive skin test for TB (the PPD or the Tine test). It has long been the recommendation of public health authorities that people with a positive PPD or Tine test be treated with isoniazid, 300 mg.day, for 12 months, to reduce the risk of future TB. However, for people with HIV infection and a positive skin test, some clinicians recommend treatment with 300 mg/day isoniazid indefinitely.

People with immune suppression are at much greater risk of developing TB through reactivation of an old healed tuberculosis lesion than people with normal immune function. The TB rate in the United States has increased considerably in the last 8 years, largely related to the AIDS epidemic.

The patient with HIV infection who has a positive PPD or Tine test should be treated with isoniazid (INH) on a long-term basis, with supplemental pyridoxine (Vitamin B6) to 150 mg/day to prevent a toxic neuropathy secondary to INH, for prevention of this OI, whatever the T-helper cell level. The fact that antigen skin test reactivity is T-cell based, however, often presents a problem in determining which patients have previously suffered a silent TB infection, since the skin reactivity disappears when the T-helper cells drop somewhere below 400. (The toxoplasma titre as a reflection of old infection does not disappear with increasing immunosuppression, as it depends on antibody production, which is B cell dependent and is not lost as T-helper cells drop.)

As a result, it may not be possible to determine whether the patient with low T-helper cells and a negative PPD is carrying an old healed tuberculosis scar unless it is apparent on a chest x-ray. A past history of a positive TB skin test, previous treatment for tuberculosis and/or significant personal exposure to someone with the disease should be considered indications for long-term prophylaxis with isoniazid. Some physicians feel that patients in groups at high risk for TB who fall in this category (a T-helper cell count too low to assure reactivity to a TB skin test), should all be given prophylaxis, in particular present or former IV drug users with HIV disease. I generally make this decision on an individual basis, based on history and chest x-ray findings. I generally recommend INH for former or active injection drug users with HIV infections because of the particularly high incidence of TB in this group of patients.

Human Papilloma Virus (HPV) and Genital Neoplasis

A number of studies have shown a significantly increased incidence of HPV-associated cervical dysplasia and cervical cancer in women with HIV disease.[27, 28] One study has demonstrated, in addition, premalignant changes in mucosal tissues in the vagina, the vulva and the perianal region among HIV positive women.[29] From the clinical perspective, it is clear that HPV-associated cervical cancer should be included by the Centers for Disease Control (CDC) as an AIDS-defining opportunistic disease in women with HIV infection.

The only prophylactic regimen currently available for this cluster of genital-associated cancers is close and frequent clinical surveillance, in particular frequent Pap smears, to permit early surgical intervention.

Treatment of Kaposi's Sarcoma (KS)

Since the treatments for KS, both local and systemic, are well described in AIDS newsletters and elsewhere, I would like to particularly focus here on the indications for treating KS, i.e., determining *when* it should be treated. It has long been clear the *KS is not a cancer;* lesions arise independently of each other rather than representing metastases from a primary source. KS appears to represent a distinct disorder. It was first described in the 1870s as a very slowly evolving disease in elderly men of Mediterranean origin. The KS associated with AIDS appears to be the same disease, although it is sometimes slow and *indolent* in development and sometimes more aggressive and rapid in spread than classical KS. AIDS-associated KS is primarily found in gay men with HIV infection. The aggressive form has appeared in the last few years in a number of gay men who are *not* HIV positive and are *not* significantly immune

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[27] Bradbeer C. Is infection with HIV a risk factor for cervical intraepithelial neoplasia? *The Lancet* II:1277. 1987.

[28] Byrne M, Taylor-Robinson D, Harris J. Cervical dysplasia and HIV infection. *The Lancet* I:239. 1989.

[29] Byrne M, Taylor-Robinson D, Munday P. The common occurrence of human papilloma virus infection and intraepithelial neoplasia in women infected with HIV. *AIDS* 3:379. 1989.

suppressed, raising the possibility that it is a distinct disease that is often linked to AIDS, but not necessarily a manifestation of AIDS.

KS lesions appear to represent excessive growth of endothelial cells, the cells that line blood vessel walls. Evidence from several studies suggest that the abnormal endothelial cell growth is stimulated by the excessive production of several hormones that regulate growth of these cells normally, including interleukin 6, endothelial growth factor and fibroblastic growth factor, and possibly by the HIV tat gene.[30, 31] The most sensible way to treat KS would involve the development of substances to block these growth stimulating factors, thereby avoiding the highly toxic alternatives of injected alpha interferon or chemotherapy. In fact, Dr. Robert Gallo of the National Cancer Institute (NCI) announced more than 2 years ago that he was working on such a treatment approach and about 18 months ago casually commented to a journalist that he had developed a successful treatment for KS. Although he has since refused to discuss this subject publicly, a number of other NCI researchers have apparently acknowledged privately that such a treatment has, in fact, been tested in patients at NCI with dramatically successful results and that "we have licked KS." Dr. Gallo's work appears to be tied up by patent and legal problems, but clinical trials have begun elsewhere testing agents one at a time based on the same premises.[32, 33]

Until these agents become available (if, in fact, they work), the patient with KS and his/her physician must exercise careful judgment about whether and when to treat it. The current systemic therapies, in particular alpha interferon, are quite toxic. Chemotherapy is a general bone marrow depressant, lowering the white blood count, including the lymphocytes, and therefore T-helper lymphocytes. Alpha interferon, besides the acute symptomatic toxicity associated with each dose (mostly flu-like symptoms), is also specifically toxic to T-helper cells,[34, 35] although this side effect of interferon has not been much discussed in relation to its use in treating KS (and more importantly, its questionable non-FDA sanctioned use as an antiviral adjunct to AZT).

It is my judgment that, aside from local treatment of lesions for cosmetic purposes, *KS should not be treated with the present system therapies unless it begins to interfere with functioning or is life-threatening.* Patients in whom the disease is slowly spreading should postpone systemic therapy until the newer non toxic therapies described above become available, or until functional impairment requires more immediate intervention.

When this does happen, chemotherapy appears to be a less toxic and more reliable intervention. Oncologists have discovered that KS can be stabilized with much smaller doses than are traditionally used to treat cancer. In such a situation it is

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[30] Weiss R. The conundrum of Kaposi's sarcoma. *European Journal of Cancer* 26:657. 1990.

[31] Vogel J, Hinrichs S, Reynolds R et al. The HIV tat gene induces dermal lesions resembling Kaposi's sarcoma in transgenic mice. *Nature* 335:606. 1988.

[32] Ingber D, Fujita T, Kishimoto S et al. Synthetic analogues of fumagillin tat inhibit angiogenisis and tumor growth. *Nature* 348:556. 1990.

[33] Miles S, Rezai A, Martinez-Maza O et al. Recombinant platelet factor 4 and a non-heparin binding derivative inhibit AIDS-Kaposi's sarcoma cell lines. VII International Conference on AIDS. Poster WA 1066. Florence, June 1991.

[34] Taylor-Papadimitrious. Effects of interferons on cell growth and function. In *Interferon*, ed. by I Gresser. New York: Academic Press. 1982.

[35] Heron I, Berg K, Cantell K. Regulatory effect of interferon on T cells in vitro. *Journal of Immunology* 117:1370. 1976.

important to find an oncologist with enough experience in treating KS to understand this issue, involving balancing the need to treat the KS against the need to minimize bone marrow toxicity in patients with HIV disease.

Considerations in the Management of Some Signs and Symptoms in Patients with Low T-Helper Cell Counts

Weight Loss

Weight loss, if not caused by a specific treatable opportunistic infection, is sometimes due to high blood levels of tumor necrosis factor (TNF, cachetin), a hormone of macrophage origin that is sometimes elevated in patients with low T-helper cell counts. TNF interferes with the metabolism of fats and is probably responsible in part for the low serum cholesterol and high serum triglyceride levels seen in some people with low T-helper counts.[36] TNF also stimulates increased HIV replication.[37] N Acetyl Cysteine (NAC) blocks the latter effect of TNF and is non-toxic. It can be obtained from buyers clubs. *[Typist's Note: It is also available from many pharmacies and vitamin sources.]* Pentoxyfilline, a prescription drug used for leg pain caused by hardening of the arteries ("intermittent claudication"), may lower TNF levels. Beth Israel Hospital in Boston is conducting a clinical trial of this drug to determine its value in patients with elevated TNF levels, including its value in preventing weight loss. Another prescription drug, megesterol acetate (Megace), has been shown in a recently completed CRI trial to significantly increase appetite and weight in two-thirds of patients, *but only at a dose of 800 mg/day or higher*. Trials are also underway to test the effectiveness of Dronabinol, a form of cannabis found in marijuana, as a treatment for poor appetite and weight loss in people with low T-helper cells.

Diarrhea

Diarrhea can be caused by cryptosporidiosis (or the related parasite microsporidiosis), CMV infection of the colon, MAI, or parasites such as amoeba, giardia or B. Hominis. A specific diagnosis to permit specific treatment may require repeated stool cultures, blood cultures and/or a colonoscopy with a biopsy. Each of the above infectious agents can be treated with specific interventions. When all of these tests are negative, the diarrhea is usually attributed to HIV and considered untreatable. In at least half of cases in the latter category I have found treatment with Humatin, 1,000 mg twice a day for 7 to 14 days, to be successful. This is a drug used for treating some

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[36] Lahdevirta J, Maury C, Teppo A et al. Elevated levels of circulating cachectin/tumor necrosis factor in patients with acquired immune deficiency syndrome. *American Journal of Medicine* 85:289.1988.

[37] Israel N, Hazan U, Alcami J et al. Tumor necrosis factor stimulates transcription of HIV-1 in human T-lymphocytes, independently and synergistically with mitogens. *Journal of Immunology* 143:3956. 1989.

intestinal parasites. It also appears to be effective in about two-thirds of cases of chronic cryptosporidiosis which is also not generally considered to be treatable. Presumably the response to Humatin in patients whose stool cultures are negative reflects the presence of a parasite that has escaped laboratory detection (possibly microsporidiosis).

For patients in whom the cause of diarrhea cannot be determined, and who fail to respond to Humatin, somatostatin, (available in New York City through a clinical trial at Albert Einstein College of Medicine) is sometimes effective. In addition, nonsteroidal anti-inflammatory agents such as indomethacin, aspirin and ibuprofen may help to reduce diarrhea.

Fatigue

The clinical context is essential in identifying treatable causes of fatigue. In a significant percentage of patients with little or no other systemic symptoms, fatigue is a symptom of depression. Depression-related fatigue is not uncommon in patients the first few months after a positive HIV serology test, and is often mistakenly identified as an HIV-related physical symptom. Clearly, in such situations, individual or group psychotherapy, and if necessary and anti-depressant drug, may be appropriate. Frequently the provision of accurate information about prognosis and treatment options makes people more hopeful and less depressed.

Occasionally, in patients with low T-helper cell counts and other system symptoms, fatigue may be the consequence of mild adrenal cortical insufficiency, which is common in people with AIDS. It is not uncommon for the serum cortisol response to adrenocortocotrophic hormone (ACTH) stimulation to decrease with disease progression, paralleled by a drop in endorphin levels.[38] (ACTH, which regulates adrenal production of cortisol, and beta endorphin, both derive from the same prohormone in the pituitary gland, proopiomelanocorten. ACTH and beta endorphin levels are both low in people with AIDS). Low-dose naltrexone may restore beta endorphin levels and, in parallel, ACTH and cortisol levels in some patients; in fact, it sometimes reduces fatigue in people with an AIDS diagnosis. When it doesn't do so, and ACTH cortisol stimulation test should be done. If it is low, supplementation with small doses of hydrocortisone acetate may be useful; 15 to 20 mg in the morning and 10 mg in the late afternoon may be sufficient. If cortisol levels are low, hydrocortisone will also aid the patient in coping with the physiological stress of the disease. Its use at this dose is not immune suppressive since this is less than half the normal amount normally produced by the adrenal gland each day and is serving as replacement therapy.

Fatigue as a side effect of high-dose acyclovir should also be ruled out by taking a one-week vacation from the drug.

Diet

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[38] Membreno L, Irony I, Dere W et al. Adrenocortical function in acquired immuno deficiency syndrome. *Journal of Clinical Endocrinology Metab* 65:482. 1987.

Nutritionists and holistic practitioners from various disciplines have been telling us for decades that Americans would be much healthier with a diet much lower in animal fats, cholesterol and refined sugar, and higher in fiber, fresh fruits and vegetables and whole grains. In recent years, epidemiological studies and prospective controlled trials have convinced most of mainstream medicine that this advice is sound, with particular regard to reducing the incidence of cancer and heart disease. Many patients with HIV disease, as part of a broader effort to improve their general well-being and thereby their ability to cope with the disease, are following this advice, either on their own counsel or on the advice of nutritionists and other holistic practitioners.

Unfortunately, one element of such a dietary change may be particularly harmful: the reduction in dietary animal fat. People with HIV infection have a varying and sometimes profound impairment in the ability to absorb and metabolize fats. This may be in part due to impaired pancreatic and small intestine function and, in patients with T-helper counts below 200, exacerbated by TNF levels. As a result, cholesterol levels are frequently low, sometimes markedly so in patients with HIV infection. A diet that is low in cholesterol and other animal fats will lower serum cholesterol even further. Cholesterol is an essential ingredient of all cell membranes; its ratio to phospholipids determines membrane fluidity. An appropriate degree of membrane fluidity is essential for normal membrane and cell function. This has been shown to be true for lymphocytes. Since nerve fiber insulation in the central nervous system and peripheral nerves is primarily cholesterol, the body will tend to protect brain function by lowering cholesterol levels in cells elsewhere first. Thus, a diet low in animal fats may contribute to immune deficiency and to impaired function of other organs, particularly if the serum cholesterol is less than 130. Eggs are an excellent source of cholesterol, as are whole milk, cheese, butter and red meat.

The other aspects of the "nutritionally ideal" diet described above are likely to be helpful, including the generally associated advice to reduce the intake of caffeine and refined sugars.

Cognitive Impairment

Difficulties with memory and concentration sometimes represent early HIV encephalopathy, although depression may cause the same symptoms and frequently leads to a mistaken diagnosis of HIV encephalopathy. If depression is ruled out as the cause, and true cognitive impairment is present, this represents in my opinion one of the few specific indications for treatment with AZT (or if the patient is AZT resistant, with ddI). Cognitive impairment in patients without previous AZT treatment will improve significantly two-thirds to three-fourths of the time with AZT treatment. The improvement is so specific, rapid and dramatic in some cases that it seems unlikely that the AZT is directly affecting HIV replication in the brain cells that are infected, the glial cells that support nerve cells. It may possibly work instead by lowering levels in the blood and brain of free-floating gp120, the envelope glycoprotein that with gp41 provides the shell of HIV. Gp120 has been shown in the test tube to impair nerve cell

function.[39] The group of calcium channel blocking drugs, marketed for treating heart disease (e.g., Procardia), may sometimes improve cognitive function as well, with minimal toxicity.

In addition, treatment with deprenyl, 5 mg twice a day may be helpful. This is a drug that is FDA approved for the treatment of Parkinson's disease, and it works by increasing levels of dopamine in the brain. Dopamine has been shown to be quite low in the cerebrospinal fluid of patients with HIV encephalopathy,[40] and some of the symptoms are clinically consistent with a dopamine deficiency. I have thus far treated one AZT-resistant patient with deprenyl with considerable improvement and no toxic effects.

Drug Interactions

People who follow the recommendations I've described, in particular those with less than 150 T-helper cells, may be taking many more medications than they otherwise would be. Patients often raise questions about the risks of taking too many "foreign" chemicals and the risks of drug interactions.

It is important in this regard to be aware that taking 6, 8 or even 10 drugs is not in itself, apart from the individual toxicities, an abnormal stress for the liver, kidneys or other organ systems. In fact, the liver detoxifies hundreds of substances every day, including toxins ingested in food and water, and in particular toxic byproducts of metabolic processes in the body. The additional detoxifying load produced by drugs such as these represents only a small fraction of the detoxifying work the liver does every day.

With regard to drug interactions, the possible tendency of cimetidine to decrease the absorption of dapsone is mentioned above. In addition, both dapsone and Bactrim my increase the tendency of pyrimethamine to produce bone marrow depression, making leucovorin essential in patients on the latter drug to prevent this side effect. Disulfiram may decrease the metabolism and excretion of isoniazid, requiring close monitoring for toxic effects of isoniazid on the central nervous system and peripheral nerves. Finally, AZT may increase the toxic effects of dapsone, alpha-interferon and chemotherapy.

These represent the major potential interactions *between* drugs mentioned in this document, all of which can be easily managed. In addition, some of the drugs I've mentioned may interact with other agents commonly used by patients with HIV disease. Naltrexone blocks the pain-relieving effects of opiate drugs such as codeine, morphine, demerol and percodan, for 2 to 4 horse after the (3 mg) naltrexone dose is taken. There are, however, no dangerous interactions between naltrexone and these opiates. In addition, naltrexone cannot be used by patients on maintenance methadone, as it will trigger a brief, but intense opiate withdrawal syndrome. Cimetidine may slow the liver breakdown and excretion of tricyclic antidepressants such as imipramine,

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[39] Brenneman D, Westbrook G, Fitzgerald S et al. Neuronal cell killing by the envelope protein of HIV and its prevention by vasoactive intestinal peptide. *Nature* 335:639. 1988.

[40] Elyse Singer, private communication.

amitriptyline, nortriptyline, etc., sometimes requiring a reduction in the antidepressant dose. It may also slow the excretion of benzodiazepine tranquilizers, such as valium, ativan, halcion, xanax, dalmane, etc., sometimes making smaller doses of these drugs appropriate. Cemetidine, Bactrim and disulfiram may all slow the excretion of dilantin and barbiturates, both used in patients with seizures. Disulfiram should be temporarily discontinued in patients treated for parasitic infections with flagyl, as the 2 drugs in combination may occasionally cause a psychotic reaction.

Acyclovir should be used with caution in patients who have previously had toxic neurological reactions to chemotherapy for KS or lymphoma. Ciprofloxacin may increase plasma levels of bronchodilators, used by patients with asthma, sometimes requiring smaller doses of the latter. Tricyclic antidepressants, such as those mentioned above, should be used with caution in patients taking St. John's Wort, as some of the substances in the plant, including hypericin, have monoamine oxidase (MAO) activity. The MAO inhibitors are another class of drugs used to treat depression and may have serious adverse interactions with tricyclic antidepressants.

These lists of drug interactions are provided to allow physicians prescribing the drugs I've described to minimize adverse reactions. I am presently following at least 200 patients taking naltrexone, disulfiram and high-dose acyclovir, another 150 with cimetidine added to these 3 drugs, and 90 to 100 who are, in addition, taking diflucan and dapsone or Bactrim. I have at least 30 patients who are taking clarithromycin or doxycycline in addition to these drugs, and 20 who are in addition taking pyrimethamine and leucovorin, without a singe serious drug interaction. All of the adverse reactions have been the predictable minor toxic reactions to individual drugs, managed in the ways I've described above.

The "Cure"

Some of the scientific community involved in AIDS research is expecting the eventual cure for HIV disease to come in the form of a "magic bullet," a drug that would eliminate HIV directly from the body. The ultimate cure is, I believe, likely to be available to us much sooner than such a drug, which we are not likely to have the technology to develop for 10 to 20 years. In addition, this concept of cure overlooks the very real issues of the role of cofactors, the need for immune stabilization and/or reconstitution, and, for patients with AIDS and/or very low T-helper counts, the need for multiple OI prophylaxis.

I expect that the ultimate cure will be simpler, and is closer at hand. I believe that it will involve specifically designed combinations of the interventions outlined above for each patient, with the addition of at least one antiviral drug with certain properties. These properties must include the following:

- The ability to *completely* stop cell-to-cell spread of HIV, from infected to presently uninfected cells.
- Mechanisms of action that are not highly susceptible to the development of drug resistance by HIV.
- Low toxicity with, in particular, a minimum of long-term toxic effects (including no carcinogenicity).

Two and possibly 3 of the anti-HIV drugs currently far enough alone in development to be out of the lab and imminently in patient trials have a reasonable likelihood of meeting these criteria, in particular hypericin, BI-RG-587 and the tat gene inhibitor. I will use hypericin as an example to describe my notion of the "cure." Unlike the nucleoside analogues, hypericin *completely* stops HIV release from infected cells in the test tube, at concentrations that are considerably below those that are toxic to cells.[13] Its modes of action are to block release of HIV at the cell membrane and to prevent free-floating HIV from being infective, possibly by altering its envelope glycoprotein structure. These mechanisms are much less likely to trigger resistance in HIV than are drugs that interfere with DNA synthesis. It also is dramatically effective in the treatment of mice infected with the murine retrovirus, which produces an AIDS-like illness and an early death. It extends life expectancy in these mice from 30 days after infection to a normal life span of 240 days.[13] (AZT and related nucleoside analogues extend life in these mice by only 10 to 20 days). Finally, it is completely non-toxic to mice in the doses and blood levels required. We will not know whether hypericin works the same way in patients as in the test tube or whether it is as non-toxic to humans as mice until we see the results of the Phase I and Phase II clinical trials.

Assuming that it is as effective in patients as in the test tube and in mice, or that BI-RG-587 or the tat gene inhibitor is similarly effective, one of these 3 drugs could provide the one currently missing piece that is needed for a "cure" as I envision it. Since all of the cells in the body (except for the neurons in the brain and spinal cord, which do not become infected with HIV) die and are replaced approximately every 5 to 7 years, a combination of an antiviral with the above-described properties with immune stabilizing and/or reconstituting agents and agents to control cofactors, would allow the body to completely shed all HIV in 5 to 7 years. Patients who have more than 250 to 300 T-helper cells would need only the currently available immune stabilizers with the antiviral. Patients with a AIDS diagnosis and/or T-helper cell counts below 200 would also need aggressive OI prophylaxis, and might need more effective immune-enhancing agents than are now available, to remain stable and healthy during the time it would take to shed all of the body's HIV-infected cells.

Since most of the HIV in the body is in tissues with a cellular turnover rate of 3 to 6 months (the bone marrow, skin, intestinal linings), a large percentage of HIV in the body would be shed within a few months. This would reduce some of the secondary causes of immune suppression such as production of free-floating gp160, and excessive levels of TNF, IL1 and alpha interferon, making immune reconstitution easier to achieve. Although several immune-enhancing drugs besides those now available by prescription are moving slowly through underfunded clinical trials, an increased effort by NIAID to develop such broadly acting agents and to further test the 3 immune-modulating prescription drugs described above is critical if people with very low T-helper cells are to have the tools necessary to survive and recover.

If the scenario I've described turns out to be accurate, *then a large percent* of people who currently have HIV disease will have access to interventions that give them a good chance of surviving and recovering, once the missing antiviral piece is available

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[13] See page 8.

[13] See page 8.

to them. In my opinion, it is crucial for patients to aggressively pursue the currently available immune stabilizing agents and other interventions described above *now*, to maximize the possibility of benefiting from this scenario once the appropriate antiviral is available to complement these therapies.

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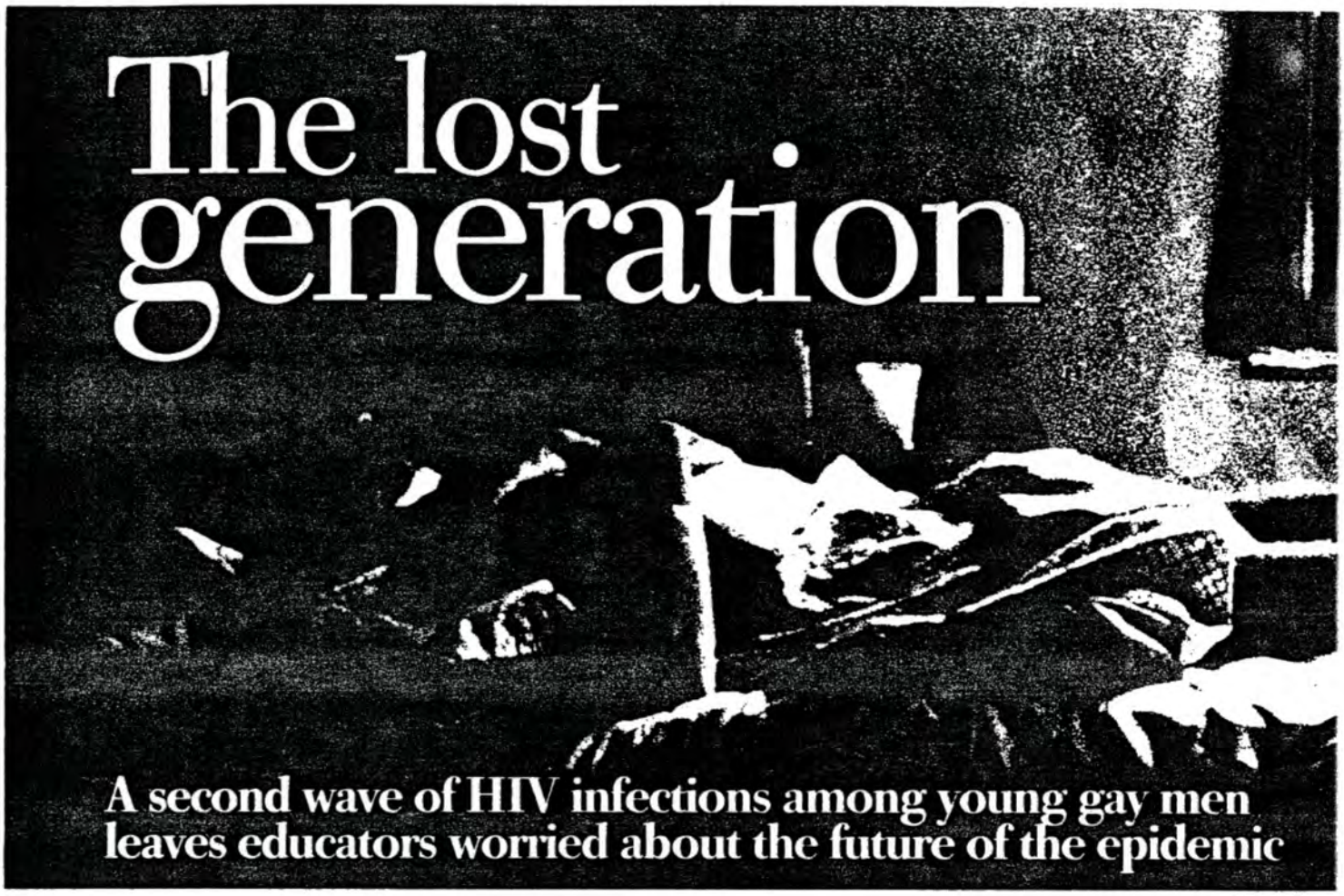
AIDS 1994

HAS STILL A SPECTER OF DEATH to most people. And indeed, since AIDS was first reported by the Centers for Disease Control and Prevention 13 years ago, more than 200,000 Americans have died because of it. But over the years the disease has become more than just a death sentence. Appalled by government inaction in the early '80s over the growing epidemic, gay men and lesbians learned to empower themselves—to an extent that has cumulatively surpassed the activism sparked by the Stonewall riots. In a real sense, AIDS has shaped our community as we know it. In the following section *The Advocate* uncovers why AIDS prevention measures are failing a new generation of gay men. Leaders of community service groups tell how they're battling to come back from near-failure. Finally, we report on the latest evidence about HIV and how it is related to the disease—still a point of contention after all these years. Obviously—and unfortunately—AIDS continues to shape our lives.

The lost generation



A second wave of HIV infections among young gay men leaves educators worried about the future of the epidemic

By Chris Bull and John Gallagher

When Kevin received the results of his HIV antibody test last year, he wasn't surprised to learn he had tested positive. The 27-year-old gay man, who says he became sexually active six years ago in Washington, D.C., recalled several instances of unprotected intercourse and feared the worst. "I'd made my mistakes," he says, "and it was time for my reckoning."

Kevin is hardly alone. According to recent surveys and anecdotal reports, a sizable number of young gay men who became sexually active well after the onset of the AIDS epidemic are testing HIV-positive despite a barrage of educational messages. A 1993 survey of gay men aged 17 to 22 in San Francisco, for example, found that nearly one third had engaged in at least one instance of unprotected anal intercourse—the riskiest form of sexual activity—in the prior six months.

For these young men, testing HIV-positive may be even more devastating than for those who contracted the virus before scientists had even identified its existence. "All I could think of was how I had done something terribly wrong and thrown my life away, like all those nasty things conservatives have been saying about us were true," Kevin says. "I remember my mom, who has always been really cool about my being gay, saying, 'How could you have been so stupid?' I was asking myself the same question."

More than a decade into the epidemic, educators are frantically reevaluating prevention strategies in the wake of what public health officials have dubbed the "second wave" of HIV infections among gay men, many even younger than Kevin. A 1993 report from the San Francisco Health Commission found that almost 12% of 20- to 22-year-old gay men surveyed were HIV-positive, as were 4% of 17- to 19-year-olds. If those figures are not quickly reversed, health officials say, the current generation of young urban gay men will have as high an infection rate by the time they reach their mid 30s as middle-aged gay men are thought to have today—close to 50%.

"The data is absolutely unacceptable," says Columbia University professor of public health Ronald Bayer, author of *Private Acts, Social Consequences: AIDS and the Politics of Public Health*. "AIDS education has failed an entire generation of gay men who are going to be wiped out if the current trajectory continues. The challenge is to put a renewed emphasis on prevention campaigns that work."

Although the epidemic has killed more than 100,000 gay men, educators still lack basic demographic and psychological information about the sexual behavior and attitudes of gay men that would allow for the design

ALAIN McLAUGHLIN/IMPACT VISUALS

of effective prevention campaigns. Even worse, educators often can't agree on how best to design prevention campaigns based on what they do know.

"AIDS has been marked by a search for a technological—with a heavy emphasis on biomedical—solution when there may well be none," says Harvard University history of science professor Allan M. Brandt, author of *No Magic Bullet: A Social History of Venereal Disease in the United States Since 1880.* "As a result, we don't know nearly enough about sexual behavior change, which is the only sure way to save lives."

Further compounding the problem is opposition from conservatives in Congress and right-wing groups, which are using the high infection rates as one of their primary arguments against government funding for sexually explicit AIDS education campaigns. In its final report before it closed its doors in 1993, the National Commission on AIDS blamed antigay conservatives for the lack of a serious national prevention campaign that it said could cut the annual rate of new infections in half. "The specter of male homosexuality has repeatedly been used to circumscribe prevention efforts," the report maintained. "Continuation of this situation is morally indefensible."

In many ways AIDS education is the victim of its own success. After annual new infections of gay men in San Francisco and other major urban areas declined from a rate of close to 25% in 1983 to less than 1% by 1987, some AIDS educators declared victory, closed up shop, and went home. Public health experts were widely quoted in the media lauding the gay community's AIDS prevention campaign as one of the most successful examples of behavior modification in the history of public health. The accomplishment was even more impressive because it involved sex, which public health experts have long identified as perhaps the most difficult behavior to change because it is linked to deep-seated emotional and social taboos.

"What is true is that by 1987 in San Francisco, people honestly believed that the battle had been won," says Dan Wohlfeiler, education director of STOP AIDS Project San Francisco, an HIV prevention group that briefly closed its doors three years after its founding in 1984. "The feeling at that time was that we could shut down and allow our resources to be used at other agencies that really needed them. We had no idea how difficult our task really was."

Those optimistic projections proved to be a fatal miscalculation. The annual rate of new infection among gay men is now almost 3%—a far cry from earlier figures but still alarming to educators. "By 1989 it was apparent that a couple of things were happening," Wohlfeiler says. "The community is not under a bell jar. A lot of new people moved in, and younger people

came out. These people were not part of the community that was mobilized against AIDS in the '80s."

The early optimism was based in part on the mistaken assumption that AIDS was a temporary affliction that scientists would eventually learn to cure or prevent with a vaccine. "It was ten years ago that [health and human services secretary] Margaret Heckler stood up and said that we have discovered the virus and would have a cure by the end of the decade," says David L. Kirp, a professor at the graduate school of public policy at the University of California, Berkeley. "It was seen as just a matter of having a little less sex with fewer partners and learning how to make safe sex sexy. The understanding now is that some form of HIV will be around as long as there are human beings on this planet. All of a sudden gay men have to learn how to change the way they relate to one another permanently."

In the case of young gay men, educators say the key is getting them started practicing safe sex as soon as they become sexually active. But if the experience of older gay men—some of whom are reverting to unsafe practices—is any indication, establishing a lifetime commitment to safe sex is easier said than done. Moreover, the heavy prevalence of HIV infection among gay men in major urban areas makes every unprotected sexual experience fraught with risk.

"In the early '80s you really did need to have a lot of partners to acquire a partner with HIV infection," says Jeffrey A. Kelly, director of the Center for AIDS Intervention Research (CAIR) at the Medical College of Wisconsin. "Now in the big cities, if you have sex with two men, you have a 50% chance of meeting someone who is HIV-positive."

Researchers have identified many reasons gay men of all ages engage in unsafe sex, including depression, alcohol and drug use, survivor guilt, and sexual shame. Lack of knowledge about how to prevent transmission, though, is not one of them. "Typically, knowledge about how HIV is transmitted and about condoms is very high," says Roger Roffman, director of Project ARIES, an AIDS prevention service developed by the University of Washington's School of Social Work. Instead, the problem is "feeling kind of lonely and kind of horny on a Friday night, drinking too much, feeling attracted to someone, and fearing rejection if you take out a condom."

But educators disagree—often sharply—about whether AIDS prevention should focus narrowly on safe-sex practices or on larger issues of communal and personal responsibility. Walt Odets, a clinical psychologist in Berkeley, Calif., who has written extensively about sexual behavior and HIV prevention, contends that many AIDS education campaigns have failed by not taking into account the emotional content of gay men's sex lives.

"Some educators forget that sex often takes place on a sensual and irrational level," Odets says. "We try to pretend there's no reason gay men would want to have unprotected sex with each other, because sex is just a big game. But people practice unsafe sex for emotional reasons—it brings you closer to your partner. The exchange of semen is one way of displaying affection for one another."

Contrary to what some conservative critics believe, research indicates that lust is not the only factor that incites unsafe sex among gay men. "When love and affection come into the picture, people tend to forget what they know," says Kelly. "Finding someone special can make you feel an illusion of safety."

That illusion is especially troubling in the case of young gay men, who often engage in what educators describe as serial monogamy. "With the younger guys what we observe is a pattern," says Tom Coates, director of the Center for AIDS Prevention Studies at the University of California, San Francisco. "They are doing OK, then they get into a relationship and practice unsafe sex, and that relationship may not last very long. People who are just starting to date have a more rapid turnover, but it's a situation that's perceived as safe. In a desire to be more intimate with a partner, safety is dropped. That can lead to infections."

The problem is further complicated by the inability of educators to reach a consensus on what constitutes safe sex, leaving gay men unsure of exactly how to protect themselves. Studies indicate that unprotected anal intercourse is by far the most dangerous activity, but research is inconclusive about anal sex with condoms and unprotected oral sex. As a result, safe-sex guidelines often vary from city to city.

But as some educators turn their attention to the emotional aspects of sex, others fear that prevention efforts are becoming too squeamish just when gay sex clubs are reemerging across the country. Most clubs mandate that patrons engage only in safe sex, but public health officials in New York City complain that the mandates are often poorly enforced and have periodically threatened to shut the clubs down. In San Francisco the Coalition for Healthy Sex, a group of sex club owners, has established a system to monitor the clubs.

"A lot of times you will hear educators say things like 'When you go to bed with a man, use condoms,' implying a one-person-per-night kind of thing when the reality is that a lot of people are out leaning against a tree in a park having sex with lots of people," says Christopher Wittke, public-sex outreach coordinator for Boston's AIDS Action Committee. "We're telling people to protect the one they love rather than to love and protect

"THE UNDERSTANDING NOW is that some form of HIV will be around as long as there are human beings on this planet. All of a sudden gay men have to learn to change the way they relate to one another permanently."

—David L. Kirp of the University of California, Berkeley

the one they're with."

Wittke's view is bolstered by some preliminary research. In an unpublished study conducted by Bayer and his associates at Columbia University, gay men surveyed were more likely to practice safe sex in committed relationships than during anonymous sexual encounters. "In sexual encounters in bars, parks, or bathrooms, there is a tendency for people to care less about one another," says Bayer. "The unspoken calculus is that one's partner is dispensable because he is engaging in casual sex. In an ongoing relationship we found that the idea of not telling a partner about HIV infection is usually considered morally outrageous."

In an article in a forthcoming edition of *American Journal of Public Health*, Bayer argues that this evidence demonstrates that AIDS educators should stress the positive role personal and communal responsibility can play in HIV prevention. "For a long time," Bayer says, "AIDS campaigns have stressed protecting yourself, but a sense of moral responsibility would indicate that you should be concerned about your partner as well."

But Steve Humes, director of HIV prevention at New York City's Gay Men's Health Crisis (GMHC), the country's largest AIDS service group, says he fears that many gay men don't care enough about themselves to care about others. Educational messages, he argues, fall short when they fail to address the intense psychological burden of living in the midst of an epidemic. "You can hardly put an entire community in therapy," Humes says, "but we have to find ways for gay men to value themselves enough to protect themselves. The question for educators today is, How do we build up gay men's self-esteem?"

Indeed, the widespread despair among gay men caused by the overwhelming horror of AIDS has itself become an obstacle to AIDS prevention. Many have seen their entire community of friends decimated by the disease and wonder how long they themselves may be able to hang on. To combat this situation several AIDS groups are featuring an educational campaign titled "Be Here for the Cure," an attempt to remind gay men that, despite the toll AIDS has taken, there is hope for the future.

"For many people this does feel like a hopeless period," says Coates. "We've reached a wave of the epidemic where lots of people are dying, so it's hard to pay attention or even want to pay attention to protecting yourself. So now AIDS education is going to have to deal with issues of hope, caregiving, and survival beyond AIDS."

This approach is a far cry from early prevention efforts, many of which used fear as a motivator. One notorious advertising campaign in San Francisco, for instance, depicted a man's legs covered with Kaposi's sarcoma lesions. "Fear was very motivating," says Tom Lindsay, a STOP AIDS Project educator. "But at this point in the epidemic, it doesn't work. People who have AIDS are around long enough so that AIDS is now part of the milieu. They don't want to be presented with the downside of it. They want to have a productive and fun life. Prevention can't be a downer."

But activists' switch to make campaigns more upbeat was tempered by the changing face of activism itself. Young gay men today lack some of the political and social support groups—ACT UP and Queer Nation in particular—that dominated the gay community's early activist response to the epidemic and helped establish safe-sex practices among their older counterparts by fostering a sense of purpose and belonging. ACT UP's New York chapter, for instance, designed its own educational materials as a way of making safe sex fashionable. One celebrated poster depicted an erect penis over the words MEN: USE CONDOMS OR BEAT IT.

"Some young gay men don't even know what ACT UP and Queer Nation are anymore," says Kirp, who is the author of *Learning by Heart: AIDS and Schooling in America's Communities*. "The assumption was that for gay men who came into gayness in the age of AIDS, safe sex would be a way of life. But that's not based on the reality of their lives."

Race further complicates AIDS education. According to a February report by the Centers for Disease Control and Prevention (CDC), gay and bisexual men of color constitute 20% of the total number of people with AIDS in this country. And because many minority gay men travel in different circles than their white male counterparts, educators are designing new methods of reaching them. In the New York City borough of Queens, which has a large population of Latino gay men, educators from GMHC have established a program to identify and train community leaders to serve as peer educators.

But Ernest Andrews, an educator at the National Task Force on AIDS Prevention, a minority AIDS group, says GMHC's efforts are too little, too late. "I'm glad they're finally dealing with black and Latino gay men, but it's been a very long time coming," he says. "For too long gay men of color have faced racism from white-dominated gay AIDS organizations and homophobia from AIDS organizations run by people of color."

Racial barriers are not the only target of the peer-education approach. The tack has also worked well in smaller cities, where AIDS prevention campaigns have often been less intensive, says Kelly. Since 1985 CAIR has been using peer-education and community-building techniques to educate gay men in more than 20 cities with populations of less than 250,000.

"We're finding a lot of high-risk behavior in the smaller cities because AIDS is perceived as a big-city problem," Kelly says. "We identify people who are key to a community and quite popular; we call them opinion leaders. We have bartenders watch the crowd in their bar for ten days and tell us who is popular. We approach these people and teach them ways they can personally endorse the desirability of risk aversion among their friends and acquaintances. You can change the attitudes of the entire gay community in a city this way."

At times, though, peer education may actually be too successful for its own good. Acknowledgment of engaging in unprotected sex became tantamount to admitting to criminal behavior, increasing the difficulty educators already faced identifying trouble spots among gay men. "Some say we did too good a job at promoting a peer norm for safe sex," says Wohlfeiler. "It put unsafe sex in the closet, a dirty little thing you can't talk about."

Indeed, the unspoken idea that the risk of HIV infection is itself erotic and one of the motivations for unsafe

sex underscores the difficulty facing AIDS educators. "Sex and risk have long been linked together even when it involves death," says Bayer.

Securing the massive resources necessary to effectively take on such issues, though, ultimately depends mainly on the larger political climate, over which AIDS educators have little control. With the rate of increase of new AIDS cases among heterosexuals exceeding that of gay men for the first time last year, federal, state, and local governments are shifting already limited prevention resources toward heterosexual transmission. In California, for instance, the state is spending just 10% of its prevention funds on gay men even though they still make up close to 80% of the total number of AIDS cases. Nor has the Clinton administration delivered on its promise to significantly increase funding for prevention. The biggest increase in this year's AIDS budget was for medical research, while AIDS prevention remained unchanged.

But James Curran, associate director of HIV prevention at the CDC, insists there is light at the end of the tunnel. Since 1991 federal regulations have required that two thirds of the CDC's AIDS prevention funds go toward HIV testing and surveillance. Starting in 1995 those regulations expire, freeing up millions of dollars for direct outreach to high-risk groups. "What we have to do is get young gay men to age 25 safely," Curran says. "More than half the gay men who are becoming infected are infected by the time they are 25. If we can get them to 25 safely, they are not home free, but it gets much easier. The new regulations will help make this happen."

Activists maintain, however, that these relatively minor changes in the CDC's AIDS prevention program are not nearly enough, given the current political climate. Despite a new administration with a professed sympathy for AIDS prevention efforts, right-wing groups and conservatives in Congress continue to exert pressure to curtail government funding for gay-friendly educational efforts. In March the House narrowly turned back legislation that would have denied federal funding to local school districts if their curricula portray gays and lesbians in a positive light.

Such attacks on AIDS prevention make it more difficult for gays and lesbians to acknowledge that it is not the success it once appeared to be, says Benjamin Schatz, executive director of the American Association of Physicians for Human Rights, a gay group that is organizing a summit on AIDS prevention in Dallas in July. "The way we have been able to get prevention funding—indeed, any funding—for AIDS services at all was historically to say that prevention is working fine: 'We're all being really good boys and deserve funding,'" Schatz says. "It's considered deeply embarrassing to admit that is not always the case. There's a fear that it will make us look bad or jeopardize our funding."

Humes agrees that politics and public health are a deadly mix. "Gay men have been able to make changes that are unique in the history of public health, but they are still subject to a barrage of messages that they are responsible for the epidemic," he says. "Gay men have the weight of the world on their shoulders. This is no way to build the kind of self-esteem gay men need to maintain safe sex."

But the self-esteem of gay men has never been a particular concern of right-wing groups. In fact, many of these groups are stepping up their efforts to use AIDS as a component of their antigay campaign. For instance, an April report by the American Family Institute, an antigay research group, alleged that as a result of AIDS, the life expectancy of gay men is just 42.

Although public health officials immediately denounced the study as inaccurate and biased, potential Republican presidential candidate William Bennett said on a conservative cable-TV talk show that it provided evidence that homosexuality is unhealthy. "If I gave you a subset of the population that died at the age of [42], you would say, 'Stop these three-pack-a-day-smokers,'" he said. "When gays talk about the joys of the gay lifestyle, they are lying. We know they are lying, and they know they are lying."

But Brandt says Bennett's analogy underscores the depth of the public's ignorance about the emotional and psychological complexity of AIDS prevention. As a former smoker himself, Bennett "should understand how difficult behavior modification is for some people," Brandt says. "If the press reports I read were correct, Bennett had enormous difficulty giving up smoking, which could have proved as fatal as unsafe sex. Here's an intelligent and well-educated man who had trouble modifying his own destructive behavior. Imagine the difficulty when you bring sexuality, not to mention race and class, into the equation. Changing people's behavior, especially when it comes to sex, is an enormously complex task, and blaming people only makes things more difficult."

Meanwhile, educators in the trenches say they have little choice but to make the best of a climate dominated by prejudice and ignorance. "The metaphor in public health is a river," Wohlfeiler says. "You're standing on the side of the river, and people are screaming for help as they're swept away by the waters. You go in and pluck them out. You keep pulling people out of the water. Finally, you have to go upriver and figure out why people fell in. We've got a lot of people downriver helping folks, but we have to get people to go up the river and stop people from falling in." ●

"THE WAY WE HAVE been able to get prevention funding—indeed, any funding—for AIDS services was to say that prevention is working fine. It's considered deeply embarrassing to admit that is not always the case."

—Benjamin Schatz of the American Association of Physicians for Human Rights

THE WHITE HOUSE

WASHINGTON

RECEIVED

JUL 20 1994

July 20, 1994

Dr. Stanley Abramowitz
Advanced Technology Program
National Institutes of Standards and Technology
U.S. Department of Commerce
Administration Building, Room 409
Gaithersburg, MD 20899

Dear Dr. Abramowitz:

As promised, enclosed are labels of biomedical researchers and other interested parties, largely drawn from private industry researchers with a special focus in HIV/AIDS.

We would greatly appreciate it if you could mail all of these individuals your most up-to-date materials about the Advanced Technology Program and any announcements about upcoming workshops or application deadlines which may be of interest.

Also, as I mentioned over internet, if you would be willing to participate in an educational workshop about the ATP focused program model, targeting the HIV/AIDS research industry, we would be very appreciative.

I look forward to hearing from you soon. My contact information:

E-mail: tbeswick@oash.ssw.dhhs.gov.
(202) 690-5560
Fax (202) 690-7560

Thank you very much for your time and assistance.

Sincerely,

Terry Beswick
Senior Research Specialist
Office of National AIDS Policy

cc: Kristine Gebbie, RN, MN ✓
Paul Tran, PhD

JUL 20 1994

THE WHITE HOUSE

Dear Muriel -

Thank you for the info on the CDC position. I'm not sure it's up my alley, but I certainly appreciate the interest. I hope all is well for you —

Ken Lane

NATIONAL IMMUNIZATION PROGRAM
Centers for Disease Control
Program Development and Coordination Activity

Facsimile Transmission

TO: Kristine Gebbie AIDS Program	FROM: Muriel A. Hoyt National Immunization Prog CDC Atlanta
FAX NO: (202) 632-1096 PHONE NO: (202) 632-1090 DATE: 7/14/94 NO. PAGES: 2 (Not Including This Form)	Corporate Square Mail Stop E52 1600 Clifton Road, N.E. Atlanta, GA 30333 USA FAX NO: (404) 639-8616 PHONE NO: (404) 639-8257

SUBJECT:
Position Announcement for ASSOCIATE DIRECTOR FOR SCIENCE

You may be interested in this position. Note that the closing date is July 29th.

Muriel

JUL 20 1994

THE WHITE HOUSE

Dear Joycelyn

This has got to be a very tough week for you ... just want you to know I'm thinking of you and your family as it goes on. If a concerned friend can help, let me know.

Hillary

JUL 20 1994

THE WHITE HOUSE

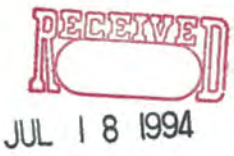
Dear Jim –

Thanks for the info on Practice Sights. If my slot on the committee is still open, I'll be available again soon! And wherever I land, I'll be watching the primary care developments with interest –

PRACTICE SIGHTS

STATE PRIMARY CARE DEVELOPMENT STRATEGIES

July 13, 1994



Ms. Kristine M. Gebbie, RN, MN, FAAN
National Aids Coordinator
750 17th Street, N.W.
Suite 1060
Washington, DC 20500

Dear Kristine:

I wanted to take this time to thank you again for the excellent work you accomplished for *Practice*. Your evalations of the written proposals were conducted professionally and with great care, and we greatly appreciated your efforts.

I have enclosed a short summary of each of the 10 projects selected. We are currently in budget negotiations with these projects and are using your suggestions from the evaluations and June meeting to guide our negotiations.

Staff both with the Robert Wood Johnson Foundation and here in the National Program Office greatly enjoyed working with each of you, and we wish you well in your continued work in primary care. We also plan to keep you informed regarding the progress of these 10 sites and ask that you feel free to contact us if you have any questions or concerns.

I read in the newspaper of your decision to leave your job.

Sincerely,

James D. Bernstein
Director

JDB:jh

enclosure

NORTH CAROLINA

FOUNDATION FOR

ALTERNATIVE HEALTH

PROGRAMS, INC.

P.O. BOX 10245

RALEIGH, NC 27605

(919) 821-9991

(919) 821-9993 FAX

JAMES D. BERNSTEIN
PROGRAM DIRECTOR

CHRISTINE KUSHNER
DEPUTY DIRECTOR

PRACTICE SIGHTS IS A NATIONAL PROGRAM SUPPORTED BY THE ROBERT WOOD JOHNSON FOUNDATION WITH DIRECTION AND TECHNICAL ASSISTANCE PROVIDED BY THE NORTH CAROLINA FOUNDATION FOR ALTERNATIVE HEALTH PROGRAMS, INC.

Summary of Fifteen Grantee States: Phase I (Development)

Practice Sights: State Primary Care Development Strategies
The Robert Wood Johnson Foundation

The ten states selected to participate in Phase II of Practice Sights *have each proposed a varied set of strategies to address the primary health care needs of their state. The states will receive grants, on average $800,000, for a three-year implementation phase that will focus on the four program areas of* Practice Sights*: needs assessment, recruitment, retention, and health finance and policy. The primary goal of* Practice Sights *is to improve the distribution of physicians, physician assistants (PAs), nurse practitioners (NPs), and certified nurse-midwives (CNMs) in underserved communities of the nation. To achieve their goals, each state lead agency will work with an Interagency Working Group, representing a multitude of health care interests in the state, including primary health care associations, Area Health Education Center (AHEC) programs, medical schools, professional associations, hospital associations, private nonprofit groups, and state government agencies.*

Idaho
Lead agency: Idaho Rural Health Education Center (Mountain States Group, Inc.)
Project Director: Jim Przybilla, Director, Office of Community Health Development

Through the leadership of the Idaho Rural Health Education Center, the state's AHEC, an Interagency Working Group has developed both state-level strategies and local-level interventions in a program titled "Target: Practice—Rural and Underserved Idaho," its initiative under *Practice Sights.* Comprised of state government agencies, training programs, private sector health care providers, and nonprofit, statewide agencies, the Group has defined a community-based strategy that will train local residents as "community encouragers" and "community recruiters" to develop grassroots solutions to the shortage of physicians, CNMs, NPs and PAs in the state's rural communities. During the first phase of the project, the coalition obtained unprecedented financial support from the state, in the form of an expanded loan repayment program, an expanded NP training program, a primary care grant program, and an increase in state funding for the Family Practice residency program. The state also has strengthened its needs assessment methodology. To improve retention of providers in underserved communities, the lead agency will develop a *locum tenens* service and offer practice management assistance to community-based providers as well as increase their access to capital financing by developing a targeted loan fund.

Kentucky
Lead agency: The Center for Rural Health, University of Kentucky
Project Director: Wayne Myers, M.D., Director

The University of Kentucky Center for Rural Health will lead Phase II interventions that focus on providing labor-intensive technical assistance to at-risk communities and their providers through the training and use of Primary Care Systems Specialists. These specialists will conduct in-depth analysis and work with communities to develop financially-viable practice sites for primary care providers. The Center also will implement a community decision-making model. The project will expand the state's current Physician Placement Service to include non-physician primary care providers, emphasizing the primary care team approach involving NPs, PAs, and CNMs, and will develop and maintain a statewide data base on primary care providers. The state assembly also approved health reform legislation that implements significant health insurance and provider workforce reforms. The project is also working in collaboration with Kentucky Economic Development Financing Authority to develop a loan pool to increase access to capital for providers in the targeted communities. During Phase I of the project, the University of Kentucky's School of Nursing led planning efforts and forged partnerships, including work with the Department of Health that strengthened the state's needs assessment system.

Minnesota
Lead agency: Minnesota Office of Rural Health, Department of Health
Project Director: Chari Konerza, Director, Minnesota Office of Rural Health

As the lead agency, the Minnesota Office of Rural Health, through a cooperative public/private partnership with the Minnesota Center for Rural Health, has developed a multi-tiered approach to strengthening the practice environment for providers in rural and underserved areas of the state. The ORH will tie its *Practice Sights* project to its state-initiated community health center program, which receives funding from the state Department of Health. The ORH also has identified a need to augment their ability to conduct management and reimbursement analysis to local communities in need of assistance. The ORH plans to devise a loan fund strategy to build on the state's health reform efforts to develop Community Integrated Service Networks. The project emphasizes regional and locally-derived strategies through recruitment and retention strategies that help communities define their needs. As a partner, the Minnesota Center for Rural Health will receive funding to build on their existing resources to recruit providers to the state. During Phase I, staff established a system for on-going collection of practice-related data on health care professionals, published and distributed a retention and recruitment manual, conducted practice recruitment feasibility studies in

numerous communities, and established stronger linkages to the state's primary care residency programs and medical schools.

Nebraska
Lead agency: Nebraska Department of Health
Project Director: David Palm, Ph.D., Director, Bureau of Health Planning and Data Management

The Nebraska Office of Rural Health will use its Phase II funding to further their strategy to develop three Community Health Care Networks of previously competitive providers in three multi-county, underserved areas—one in the western panhandle, another in the south-central region, and a third in the central region. These networks will receive in-depth technical assistance, and as a condition of receiving assistance, must address issues of managed care and provider recruitment. The project also will investigate the feasibility of a statewide *locum tenens* program. The team has secured strong legislative funding and executive support from the Governor and Lieutenant Governor. During Phase I, the project team selected the three network plans from a field of seven applicants and made steady progress to remove practice barriers for PAs, NPs and CNMs. Using RWJF loan funding, the project also will work with four regional economic development agencies that will administer regional loan funds, which will help the networks upgrade facilities and use other strategies to advance their consolidation. A sophisticated data base, combining state and private insurance data, will be used to target underserved populations, assess the supply of health providers and provide analytical data concerning the three multi-county networks.

New Hampshire
Lead Agency: Division of Public Health Services, Department of Health
Project Director: Susan Epstein, Acting Director, Division of Public Health Services

During Phase I of *Practice Sights*, the New Hampshire Division of Public Health Services used a partnership with the Primary Care Association, Medical Society, Hospital Association, NP Association, and PA Association to establish the New Hampshire Primary Care Recruitment Collaborative, which has had early success in recruiting providers to underserved communities. In Phase II, the Division will build on the recent unprecedented progress made through its community-based primary care project, *Partnerships in Primary Health Care Delivery*. This project will create a Community Health Institute, a nonprofit entity that will direct and administer provider retention

strategies, such as practice management, loan repayment, reimbursement analysis, and a revolving loan fund, and will incorporate the recruitment collaborative in the project's third year. The state's initiative has called new attention to providing primary health care services to the state's medically underserved populations, both urban and rural. The project also has developed plans to improve to the practice environment for all primary care providers in underserved areas. During Phase I, state health reform efforts expanded primary care services, including funds for a state loan repayment program, added technical assistance capacity, and $1 million annually for community-based primary care system development. The Division will continue to work cooperatively with the Generalist Physician Initiative site at Dartmouth Medical School as well as the new family practice residency program through Dartmouth and Concord Hospital.

New Mexico
Lead agency: New Mexico Office of Rural Health
Project Director: Charles Alfero, Director

During its 1993-94 session, the New Mexican legislature committed more than $13 million to the Office of Rural Health to expand primary care service delivery in the state, as well as one-time funding for loans and facility development. During Phase I, the project provided leadership on non-physician primary care provider issues, as PA regulations were strengthened and training programs will be expanded. The project also improved their data capacity and ability to identify at-risk communities. *Practice Sights* Phase II funding will allow the state agency to provide in-depth technical assistance to at-risk communities, with an emphasis on frontier communities. Under a plan for establishing a loan fund, the project will be able to leverage state moneys that will be lent to private physicians unable to access capital markets for facility and practice improvements. Technical assistance under Phase II will include financial incentives for primary care providers, community organizing, *locum tenens* services, regulatory changes, and the development of support systems. Both market-based and public/not-for-profit interventions will be developed, and the Family Practice residency program will be decentralized into nonmetro sites, including Roswell, Las Cruces, and Santa Fe. The Office of Rural Health will be reorganized as the Division of Community Health Systems with expanded staff and duties as well as stronger authority within the Department of Health. The *Practice Sights* project leaders have worked in concert with other RWJF initiatives in the state, including the Generalist Physician Initiative, State Initiatives in Health Financing Reform, and Medical School Curriculum Reform.

New York
Lead agency: Department of Health (Health Research, Inc.)
Project Director: Steve Schrieber, Bureau of Health Resources Development

The Primary Care Advisory Committee, convened by the lead agency (the New York State Department of Health), has developed an extensive Phase II plan to address primary health care shortages in both rural and urban communities of New York. During Phase I, the Department of Health developed an improved needs assessment methodology to target new and existing resources; examined practice issues related to PAs, NPs and CNMs; and worked to secure strong state financial support through the state's prospective hospital and clinic payment system. That system will provide a substantial funding stream for training increased numbers of physician and non-physician primary care providers and for developing community-based centers and other service delivery sites that receive assistance through *Practice Sights.* During Phase II, the state Department of Health will form a Primary Care Resource Team, based in Albany, Buffalo and New York City, which will provide direct technical assistance to 40 of the state's neediest communities and their providers. Support from the Resource Team will be augmented by a pool of experts from state agencies, local technical assistance networks, and electronic information systems. The project also plans to develop a capital loan fund for private practitioners and health centers. The project will continue to work in close coordination with the two RWJF Generalist Physician Initiative sites at the State University of New York at Buffalo and New York Medical College.

Pennsylvania
Lead agency: Pennsylvania Department of Health
Project Director: Joseph May, Deputy Secretary, Office of Community Health Systems Development

The Pennsylvania Department of Health, the lead agency, has established a new Bureau of Primary Care Resources and Systems Development, which will become a statewide advocate for primary care. Staff from the new Bureau will provide long-term state assistance to both urban and rural underserved communities. Coupled with gubernatorial efforts to increase access to health care services, under Phase II, the Department aims to further develop a statewide recruitment/placement program; work to remove barriers to practice for NPs, PAs and CNMs; and establish new practice sites in medically underserved communities. The Department will continue to work in coordination with the two RWJF Generalist Physician Initiative sites at the Pennsylvania

State University College of Medicine and the Hahnemann University School of Medicine. In addition, the state has funded its own version of the Generalist Physician Initiative, providing grants to six other medical schools and challenging them to graduate more primary care physicians. During Phase I, the state developed a grant program to help expand the numbers of CNMs, PAs, and NPs trained in the state and established a grant program for the development of primary care practice sites, funded demonstration telemedicine projects, and supported the development of a statewide AHEC system.

South Dakota
Lead Agency: South Dakota Office of Rural Health
Project Director: Loren Amundson, M.D., Director

During Phase I, the South Dakota Office of Rural Health developed its strategy to establish the Regional Coordinated Care Networks, expanded state scholarships for health professionals, completed a statewide needs assessment of the provider workforce, and published a guidebook for community recruitment and retention. The focus of the Phase II strategy for the South Dakota Office of Rural Health will be the formation of Regional Coordinated Care Networks. These networks will establish viable, stable practice sites that ensure adequate support systems, access to capital financing options, and continuing medical education opportunities. For Phase II, three interventions will be carried out: 1) creation of primary care linkages through the networks; 2) modification of the current state financing structure to enhance reimbursement and reduce disincentives for rural practice; 3) and creation of a revolving loan fund to enhance the viability of primary care practices in network communities. The project's key partners include the University of South Dakota School of Medicine and the Dakota Association of Community Health Centers.

Virginia
Lead Agency: Joint Commission on Health Care
Project Director: Jane Norwood Kusiak, Executive Director

The Joint Commission on Health Care of the Virginia General Assembly, the lead agency, will work closely in partnership with several statewide organizations during Phase II—the Virginia Department of Health, the Virginia Health Care Foundation, the Virginia Primary Care Association, Blue Cross/Blue Shield, and the state's Area Health Education Center program. During Phase I, the Department of Health developed a sophisticated primary care data system, dubbed PriCAM, which focuses on assessing the statewide distribution of

primary care physicians and nonphysician providers. Targeted underserved communities will be the focus of intensive technical assistance from the partnership agencies, including assistance regarding the recruitment and retention of providers and practice support. Also working within the partnership, the Department of Health will establish a centralized recruitment clearinghouse, the Center for Health Professions Recruitment and Retention. The Commission will continue to work in coordination with the Generalist Physician Initiative coalition of the state's three medical schools: the University of Virginia, the Medical College of Virginia and the Medical College of Hampton Roads.

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Herbert W. Perry, LPA/EA
6442 Bristlecone Circle
Las Vegas, Nevada 89102-6618

Dear Herbert:

I'm sorry this has been slow in coming. I wanted to send you some details on D.C. area HIV/AIDS organizations (enclosed). They are all crying "tight budget" just now, so I really don't know what's possible. You might also wish to contact some of the national HIV/AIDS organizations based in D.C. such as AIDS Action Council at (202)986-1300, The National Association of People With AIDS at (202)898-0414, the National Minority AIDS Council at (202)544-1076, and the National Pediatric HIV Resource Center at (202)289-5970.

As you probably know, I will be leaving my position at the end of this month. I will remain interested in HIV and AIDS from wherever I land. You can reach me at (202)387-0015.

Thank you for your continuing enthusiasm and efforts.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

Enclosures

THE BELLEVUE HOTEL

5-21-94

Kristine Gebbie -

I would like to discuss two items with you.

#1 - Could you come to Las Vegas some time this fall, to be involved in a AIDS advocacy fund raiser?

#2 - What a person have to do to find a position in AIDS advocacy in the DC area?

Thanx

H

Andrew
Would you or Tonya
give me names/#'s of
DC based advocacy
grps so I can
pass along to
Herb ?

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HERBERT W. PERRY, LPA/EA
ENROLLED TO PRACTICE BEFORE THE INTERNAL REVENUE SERVICE
6442 BRISTLECONE CIRCLE
LAS VEGAS, NV 89102-6618
(702) 253 - 1969 FAX (702) 253 - 7306

June 22, 1994

Office of the National AIDS Policy Coordinator
750 17th Street, NW - Suite 1060
Executive Office of the President
Washington, DC 20503

Dear Kristine Gebbie:

As you may recall, I gave to you a letter when I was at your reception on May, 23rd. Since I had not heard from you, I am writing this letter.

We are planning a fund raiser this fall and would like very much for you to participate. This would give you a very good opportunity to see our ever growing community an you will be able to visit some of the excellent AIDS provider facilities.. We are leaving the date open in order to fit your schedule.

I await hearing from you.

Together we can make a difference.

Sincerely,

Herbert W. Perry, LPA/EA

HWP:dbh

From the Desk of
H. W. PERRY

I would like to be more involved on a national level. If you are aware of anything, please let me know!
Thanx

HERBERT W. PERRY, LPA/EA

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6442 BRISTLECONE CIRCLE
LAS VEGAS, NV 89102-6618
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BIOGRAPHY OF HERBERT W. PERRY, LPA/EA

Mr. Perry graduated from college with a Degree of Master in Business Administration, and over twenty years experience in the small business bookkeeping and individual income tax return preparation profession. He handles all phases of the various required accounting needs for his small and medium sized business clients. He is retained by many clients to assist them in budget and financial planning, as well as income tax planning. He has represented many of bis clients before the Internal Revenue Service as an Enrolled Agent.

LICENSES AND CREDENTIALS

Licensed Public Accountant by the State Board of Accountancy - Minnesota (LPA)
Enrolled to practice Before the Internal Revenue Service as an Enrolled Agent (EA)
Accreditation Council of Accountancy Certificate
Accreditation Council of Taxation Certificate
Licensed Real Estate Broker in three states
Licensed Mortgage Broker in Minnesota
Licensed Private Pilot - SEL

PROFESSIONAL AND BUSINESS ORGANIZATIONS (member)

Minnesota Association of Public Accountants
National Society of Public Accountants
Nevada Society of Accountants
National Association of Enrolled Agents
Minnesota Association of Enrolled Agents
Nevada Association of Enrolled Agents
National Association of Tax Practitioners
Accreditation Council of Taxation
Accreditation Council of Accountancy

PUBLIC SERVICE AND VOLUNTEER ORGANIZATIONS

Board of Trustees member of Aid for AIDS of Nevada (AFAN)
Holds the offices of First Vice President and Assistant Treasurer for AFAN
Serves as a member of the volunteer Speaker's Bureau of AFAN
Member of the National Speaker's Bureau of the National Association of People With AIDS (NAPWA)
Listed by Corporate Wellness as a recommended speaker on AIDS awareness
Member of and an active AIDS advocate on Capitol Hill in D.C. for AIDS Action Council
Former Development Director for Reach Out, pediatrics care center for children with AIDS, and a member of the Advisory Committee
Guest speaker on numerous occasions covering many subjects on small business operations and HIV/AIDS in the workplace, including many radio and television shows
Legislative Chair for Nevada Society of Accountants
Former member and officer of the Network and Executive Leads Clubs, which are business and professional organizations
Former member of the National Leadership Coalition of AIDS
Active in many other community affairs and volunteer organizations
Guest Host on Southern Nevada Perspective aired on KFBI, 107.5 FM

PERSONAL

Married. Two daughters, one son -in-law and two granddaughters.
Hobbies, include bowling, watching football and reading time permitting.

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Mr. Jesse Matney
1575 Woodbridge Lake Circle
West Palm Beach, FL 33405

Dear Mr. Matney,

Thank you very much for organizing the "White House Reception of Hope" on July 16, 1994. I understand that you dedicated a lot of time and put forth a tremendous effort to make this event successful. It is this level of commitment that has become the hallmark of HIV/AIDS advocates and caregivers.

Together, we can continue our progress on increasing awareness, pursuing research, and extending the hand of compassion.

We must maintain hope alive.

Sincerely,

Kristine M. Gebbie
National AIDS Policy Coordinator

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Thomas and Betty Guthrie
796 Williams Hollow Road
Pulaski, Tennessee 38478

Dear Mr. and Mrs. Guthrie:

Thank you for your comments on the Prevention Marketing Initiative sponsored by the Centers for Disease Control and Prevention (CDC). This Administration is committed to stopping the spread of HIV, especially among our youth. The age group with the greatest increase of new cases of AIDS is the 18-24 year old group; the majority of these infections occurred during adolescence. Best information indicates that 72 percent of all high school seniors have engaged in sexual activity and 19 percent of those have had 4 or more sexual partners.

Although abstinence is the most effective way of preventing transmission, the campaign is also aimed at those who, because of personal decisions or circumstances, have chosen to be sexually active. The decision to promote safer sexual practices through the use of condoms is supported by research released in 1993 showing that when condoms are used correctly and consistently, they are extremely effective in preventing transmission. The research showed that transmission occurred primarily in those instances where the condoms were used incorrectly or were not used for every sexual act. To obtain more information on this research, please contact the CDC National AIDS Clearinghouse at (800) 458-5231.

The CDC initiative is intended to reinforce young people who have not become sexually active to postpone sexual activity as long as possible. It will encourage young people who engage in sex but have not tried condoms to try them and it will encourage those who use condoms to do so correctly. A national task force will analyze the effectiveness of the various components of the initiative, including the public service announcements.

As a parent, I understand the concerns you may have about our young people being at risk for HIV/AIDS. I am concerned that our young people are not receiving the information about changing behaviors that may place them at risk. For those who have chosen to be sexually active, it is our responsibility as adults to provide the means necessary for young men and women to protect their lives. I believe this Prevention Marketing Initiative is a necessary step in our endeavor to end the HIV/AIDS epidemic.

Again, thank you for your input. I hope that you will continue to communicate your concerns with me.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

Standards

7-5-94

To Whom It May Concern:

I am writing this to voice my concern about the television commercials that are being broadcast.

I do not appreciate this type of commercial in my den with my children watching. It is totally disgusting and way off track of what we should be teaching. Abstinence.

God gave us a book of rules and guidelines which people seem to be ignoring. We wonder why we have the problems and troubles that we have in our nation and all we need to do is pick up the Bible and find the answers. The answer is certainly not condoms but abstinence.

The stations which are airing these are off-limits in my house & will be until they are removed. My children will not watch such things.

Thank you for your time and I pray you will consider and then act on removing these ads and commercials.

Sincerely,
Betty Guthrie

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Mr. Marvin Rosen
Apartment 2108
253 West 72nd Street
New York, New York 10023

Dear Mr. Rosen:

Thank you for taking time to write me.

While it is true that in the United States more men than women have HIV infection, worldwide the distribution by gender is approximately equal. While it is also true that anal intercourse is a practice which efficiently transmits this infection, and that men transmit the virus more efficiently to women than women to men, the worldwide epidemiology makes it clear that transmission is associated with **any** sexual activity in which there is direct contact with blood, semen or vaginal secretions, regardless of gender or sexual orientation.

This administration will continue to advocate for prevention programs based on good public health science, and will support making information available in culturally appropriate ways. If you want more information on HIV prevention, you can contact the National AIDS Clearinghouse at 1-800-458-5231.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

I WILL BE OUT OF THE COUNTRY
FROM 7/27 TO APPR. 9/10/94 —

June 27, 1994

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
The White House
Washington, DC

I am not a doctor and I am in no way connected to or involved in medicine. For that matter I am not much of a writer. But I would like to share some of my observations and thoughts, a few posed as questions, with you. Some may seem outrageously gross and at first sight, outlandishly ridiculous. Nor do I mean to be flippant. Please bear with me and hopefully some useful information will be found or new ideas developed.

By now we know, ar at least we should know, that other than direct blood contact, be it transfusion or injection or being born of an infected mother or other exchange, the only other definitely known means to become infected with AIDS, be it male or female, is to be anally penetrated by an infected male. I don't believe there is any "magic" way.

When giving statistics on the spread of AIDS it would make sense to indicate if the sex practices involved were vaginal, anal, oral, manual or whatever, rather than simply hetero- or homosexual.

Bisexuals who have sex with women often prefer anal intercourse. The danger should be evident if the male is infected.

Very possibly AIDS is transmitted to some women as a direct, almost immediate, aftermath of vaginal sex with an infected male via seepage from the vagina to the anal area. Obviously, a condom and/or an effective spermicide could help prevent this.

I believe this is more apt to occur if certain conditions are present: hemorroids, polyps, fistulas, parasites, recent proctological examination or enema or suppository use, abrasions caused by scratchy paper or rough towel and, in general, wiping "from front to back" as little girls are taught to do. Further the missionary position lends itself to this happening. The use of a bidet could possibly aggravate the situation.

Oral sex? Probably safer but keep in mind such things as bleeding gums, recent dental work, canker sores, bitten tongues and inner cheeks, scratches caused by things like good pizza crust or even hot spicy food. Dental dams? Somebody's just got to be kidding!

Sex à deux or more always has risks of one kind or other. There is no safe sex. Condoms and spermicides can make it safer. Other than total abstinence, autoerotic, or if you wish self-service sex is the safest (without ropes, chains, drugs, dildos, vibrators, etc.). A water soluble lubricant, a kleenex or two and you're in business. No strain and no stain.

When I was younger, I spent a number of years in Latin America, mostly in Mexico, Panama and the Caribbean and my observations are probably still valid and pertinent to many parts of the third world. While a middle-class, middle-aged monogamous couple, as anywhere else would just roll over and go to sleep after sex, lower down the economic, educational and social scale, things would become quite different. It was, and probably still is, usual

for the woman to wash the man's organ after sex. The lower you went the more prevalent it was: among prostitutes it was a given, whether or not a condom was used. Generally a basin was used and often the woman would then use the same basin, sometimes the same water, to "clean" herself. At best the basin is rinsed before its next use. Often there is no running water and usually no hot water for such purposes. If the man is HIV positive, with or without condom, infection for the woman could easily follow.

While I know that the *New York Times* obituaries do not represent the general public, it does strike me as strange that during the course of a year, there are hundreds of men noted as AIDS victims while only two or three women are (the last I remember was Tina Chow). Similarly, male ice skaters and dancers are victims but not their female counterparts.

I don't believe that prostitutes (nor for that matter, women in general) spread AIDS to men. Nor is there any real evidence that the virus enters through the penis (as does gonorrea) unless there is a cut or lesion of some sort present. Of course, anyone with contaminated fingers could infect a sex partner anally via digital foreplay.

Is the virus present in prostatic fluid before it forms part of the ejaculate? Or is it only in the sperm itself? Can a man who has had a vasectomy sexually transmit the disease? Or someone who has had prostatic surgery that causes the ejaculate to back up into the bladder?

I know that many cases involving various ways to get AIDS have been "documented" but I believe that means noted or recorded and not authenticated. Statistics are meaningless, confusing and misleading, intentionally or otherwise. Many efforts are time, effort and money wasteful. The distribution of condoms to high school students may cut the teenage birth rate but if I remember correctly, other than homosexuals, bisexuals and drug users, the rate was virtually nil in this group.

Speeches, quilts, marches and movies will not change the situation. Nor are pink ribbons any more efficacious than wearing garlic or crosses. The main advance has been to identify the cause. All other progress is at a standstill and I doubt that any effective vaccine will be developed in our lifetime. AZT? Switch the "before" and "after" photos and the true believer will still have a vision of hair growth.

I don't have any answers. Hopefully, there will be some forthcoming soon. Again, my thanks for your consideration and patience.

Sincerely,

Marvin Rosen
253 West 72nd St., Apt. 2108
New York, NY 10023

THE WHITE HOUSE
WASHINGTON

July 20, 1994

Harvey J. Makadon, M.D.
Co-Director
Division of General Medicine
and Primary Care
Beth Israel Hospital
330 Brookline Avenue
Boston, Massachusetts 02215

Dear Harvey:

Thank you for your kind letter about the June 30 meeting. You did the work, and I'm glad I was able to help.

Wherever I end up for my "next life", I'll be happy to do what I can on the follow up actions. Please keep me posted.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

cc: Thomas Coates, Ph.D.
Mark Smith, M.D.

Beth Israel Hospital **Harvard Medical School**

Beth Israel Hospital
330 Brookline Avenue Boston, MA 02215

6 July 1994

Harvey J. Makadon, M.D.
Co-Director
Division of General Medicine and Primary Care

Medical Director
Ambulatory Services
Beth Israel Hospital

Assistant Professor of Medicine
Harvard Medical School

(617) 735-3996
(617) 735-2885 FAX

Kristine M Gebbie RN MN
National AIDS Policy Coordinator
Executive Office of the President
750 17th Street NW Suite 1060
Washington DC 20500

Dear Kristine,

We would like to thank you for convening our session *Enhancing the Clinician's Role in HIV Prevention*. We would not have been able to hold such a session had it not been for your encouragement and support. We would also like to thank you for making your staff so available in planning this effort.

As for specific outcomes, we have made plans to move ahead and work with clinical groups in several areas. These include:

1) Development of clinical guidelines and standards for practice

2) Further consideration of how to incorporate HIV prevention within constraints of contemporary clinical practice

3) Development of educational materials which will allow practicing physicians and students to understand how to deal with the complexities of the substance of HIV prevention

4) Development of collaborative efforts which will continue the discussions of June 30

Finally, we will be talking with you further about how to work with these organizations in order to incorporate HIV prevention as part of an annual meeting and as a part of World AIDS Day. We welcome your input in any of these areas and look forward to continuing our work together.

Sincerely,

Harvey J Makadon MD

cc: Thomas Coates PhD
Mark Smith MD

Beth Israel Hospital

Harvard Medical School

Beth Israel Hospital
330 Brookline Avenue Boston, MA 02215

Harvey J. Makadon, M.D.
Co-Director
Division of General Medicine and Primary Care

Medical Director
Ambulatory Services
Beth Israel Hospital

Assistant Professor of Medicine
Harvard Medical School

(617) 735-3996
(617) 735-2885 FAX

6 July 1994

Carlos Velez JD
Director, HIV/AIDS Prevention
Office of National AIDS Policy
Hubert H Humphrey Building
200 Independence Avenue SW Room 738G
Washington DC 20201

Dear Carlos

I would like to thank you for all your time and effort in helping us prepare for our meeting on June 30. I am enclosing a letter I wrote to Kristine, summarizing what we saw as some of the major areas that call for further work. I welcome your input and suggestions with respect to how to develop these and/or your thoughts about other areas that we should pursue.

Your help over the past several months has been invaluable. I hope to see you soon and wish you an enjoyable summer.

Sincerely,

Harvey J Makadon MD

Encl

cc: T Coates
K Gebbie
M Smith
J Stryker

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Ms. Ruth L. Juhlin
Apartment 505-B
820 West Mill
Carbondale, Illinois 62901

Dear Ms. Juhlin:

Thank you for your comments on the Prevention Marketing Initiative sponsored by the Centers for Disease Control and Prevention (CDC). This Administration is committed to stopping the spread of HIV, especially among our youth. The age group with the greatest increase of new cases of AIDS is the 18-24 year old group; the majority of these infections occurred during adolescence. Best information indicates that 72 percent of all high school seniors have engaged in sexual activity and 19 percent of those have had 4 or more sexual partners.

Although abstinence is the most effective way of preventing transmission, the campaign is also aimed at those who, because of personal decisions or circumstances, have chosen to be sexually active. The decision to promote safer sexual practices through the use of condoms is supported by research released in 1993 showing that when condoms are used correctly and consistently, they are extremely effective in preventing transmission. The research showed that transmission occurred primarily in those instances where the condoms were used incorrectly or were not used for every sexual act. To obtain more information on this research, please contact the CDC National AIDS Clearinghouse at (800) 458-5231.

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As a parent, I understand the concerns you may have about our young people being at risk for HIV/AIDS. I am concerned that our young people are not receiving the information about changing behaviors that may place them at risk. For those who have chosen to be sexually active, it is our responsibility as adults to provide the means necessary for young men and women to protect their lives. I believe this Prevention Marketing Initiative is a necessary step in our endeavor to end the HIV/AIDS epidemic.

Again, thank you for your input. I hope that you will continue to communicate your concerns with me.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

Ruth L. Juhlin
820 W Mill Apt 505B
Carbondale, IL 62901

May 10, 1994

Christine Gebbie
Director of the Office of AIDS Policy
750 17th St. NW
Washington, DC 20050

Dear Ms. Gebbie,

I am writing in regard to CDC's latest TV ads which promote condoms as a means of preventing, among other diseases, AIDS. The ads include a condom character that jumps out of a drawer, tiptoes across a bedroom floor and jumps into bed with a couple. These ads give a false sense of security in regard to the effectiveness of condoms.

My major complaint about these ads is the information that is painfully absent from your campaign. What you fail to communicate are the statistics established by studies which indicate that condoms are only 67% effective in preventing leakage of HIV-sized particles. (R.F. Carey, Sexually Transmitted Diseases, Vol. 6, 1993.) Specific researchers such as the late Bruce Voeller, M.D. of the University of Southern California, Dr. Susan Weller of the University of Texas Medical Branch in Galveston and Isabelle de Vincenzi, M.D. of France's Hopital National de Saint-Maurice have all published significant writings indicating that condoms do not consistently prevent transmission of the HIV virus, even when used as directed in a monogamous relationship.

Why have we the public not heard this from CDC? How can you in good conscience promote a product as a means of AIDS prevention that has such a poor success rate? You are misleading the public by not giving all the facts. If people knew about the risks in using condoms they might abstain from intercourse all together. If your goal is to prevent the spread of AIDS perhaps you should promote other means beside condoms, namely abstinence. It's the only 100% sure method of preventing AIDS and STDS. In spite of the "Safe Sex" campaign, high school pregnancies are on the rise. Kids are not using condoms more, just having intercourse more. If married adults, as documented in Isabelle de Vincenzi's research, cannot use condoms properly, how can you expect uncommitted teenagers to use them properly?

With all due respect for the work the CDC has done in the past, it seems that the CDC is being overrun by activists who promote condom use. Please present facts to the public about the ineffectiveness of condoms, rather than skewing statistics to support the liberal point of view. People's lives are at stake.

Sincerely,

Ruth L. Juhlin

Ruth L. Juhlin
Nursing Program
Southeast Missouri State University

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Ms. Alice Brown
P.O. Box 29774
Lincoln, Nebraska 68529-0774

Dear Ms. Brown:

Thank you for sharing your thoughts on HIV/AIDS prevention with me. As you may know, over 360,000 Americans have been diagnosed with AIDS as of December 31, 1993. Over 218,000 have died. The statistics also suggest that a substantial number of persons that have been diagnosed with AIDS became infected during their teenage years. That was the reason why I attended the meeting in New York, to share with the young people that attended the meeting.

The materials that were brought by a volunteer of Gay Men's Health Crisis, the largest and oldest AIDS-specific non-governmental organization in the country, were intended for an audience not in attendance at the meeting in question. Due to this oversight, that organization has been barred from distributing information to young people in New York City schools.

Although we have been fighting AIDS for twelve years, there is still no vaccine and no cure is in sight. The best tool we have to combat this epidemic is education. Although some of the prevention information may be less appropriate for certain audiences, it is critical that we reach those who are at risk in the most effective way possible, and that we target our effort. What I and others mean by linguistically specific materials, is that information being given on HIV prevention must specifically address those behaviors that place individuals at risk. With almost two-thirds of all infections due to unprotected sex and one third due to injecting drug use, in order to prevent HIV transmission we must specifically tell individuals what behaviors place them at risk.

Prior materials and campaigns that did not even mention what causes AIDS (i.e., Federal campaigns carried an awareness message about how anyone could get AIDS but did not specify how) have

been ineffective in changing those behaviors that put people at risk. We must also be realistic in our approach and understand that young people today are bombarded with messages about sexuality that are very confusing. Most confusing are the messages from a society that wants young people to refrain from sex but uses sex to sell everything from clothing to cars. That confusion causes 80% of young people to engage in sex by age 20, and 25% of sexually transmitted diseases to occur in individuals 18-25.

This administration is committed to protecting the lives of young people by delivering messages on the most effective way to protect themselves. All of this administration's messages stress that abstinence is the best way of preventing HIV transmission. We are also aware that 4 of every 5 young adults are sexually active by age 20, and we need to assist them in making the right choice that will save their lives.

Thank you again for sharing your concerns with me.

Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

Carlos - draft typed to last 4 pp -

June 28, 1994

Ms. Gebbie -

I had written to you some time ago, objecting to your participation in a conference held in New York City, at which materials advocating Sodomy (same sex and with animals) were available and/or actively disseminated.

You make reference to an anonymous "sponsoring agency" that brought these objectionable materials "by mistake", and that this organization has acknowledged its error. What agency that "sponsors" a youth conference on sexuality and AIDS would carry such graphic and obscene materials advocating even sex with animals? Why would you not name "the organization"?

No, I am not aware that "the current administration is committed to taking the steps necessary to stop the spread of HIV". To the contrary, I am aware that the current administration has gone out of its way to encourage the perverse,

↓

and protect

sodomite behavior that has been the chief cause of the spread of HIV - I am also aware that Bill Clinton sought actively to permit HIV-positive individuals to immigrate into this country. I am also aware that almost any statements issued by "the White House" are as likely to be false as true.

In your reply to my letter, you mention "linguistically specific" materials - can you give me an example, or a sample of these materials?

Thank you.

Alice Brown

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Mr. Michael Kegley
317 S.W. Alder
Suite 1100
Portland, OR 97204

Dear Michael:

Please excuse the slow response to your letter, written after our conversation at the Ecumenical Ministries of Oregon dinner. The letter has been on my desk, and I have given considerable thought to the answer. By now, you also know that the reply is sent in the context of my departure from this job.

You ask for the roar of thunder. In responding to this disease, the issue has always been how to tell mere noise, no matter how loud, from real communication and progress. As I think I said to you, shouting has no impact if people are not working together to resolve the issues. Too many people have heard only an angry noise, which they attribute to disgruntled and disposable people, about a disease which is assumed to be "fringe" to society. The critical issue in long-term success in stopping the spread of the virus, and in serving well those who are living with it, is to have community ownership of solutions. That ownership does not come by fiat from above, but must be nurtured. It is, regrettably, not the stuff of which headlines are made!

The label "czar" for the position I have held has been one of the most persistent areas of misunderstanding about the national effort. It may well be that my departure opens the door for the President and others to more clearly define what is to be done. However that plays out, know that I will continue to add my voice to the effort. My concern for those living with this disease, and for those whose infection should be prevented, continues very high.

I send you my personal best wishes. Perhaps we will have opportunity to talk or correspond again.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

May 9, 1994

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
Office of National AIDS Policy
Executive Office of the President
Washington, DC 20500

Dear Kristine:

PLEASE LET ME HEAR THE ROAR OF THE THUNDER!! This was the request I attempted to make in my brief encounter with you last evening at the HIV Honor Awards Dinner at the Hilton Hotel in Portland, Oregon. Enough could not be said in our five minute visit -- my entire message was not received. My memory is not as keen as it once was (AIDS has a way of doing that), so I don't recall all we talked about. I find that when I reduce my thoughts to writing, I can review and recall much easier. So please, allow me to express my opinions.

What this country needs in response to the AIDS crisis is a real storm -- the likes of which have never been recorded before. This storm, unlike natural disasters, MUST be created and planned and implemented by the people appointed to head up the AIDS crisis -- namely YOUR TEAM AND YOU.

Recent history would dictate that only storms of a catastrophic nature are responded to swiftly in terms of "people power" and money. Our government has proven itself extremely capable of mobilizing thousands of people overnight in response to a national tragedy. Our President has approved the allocation of billions of dollars to restore the destruction left by the storms. It appears obvious to me that the AIDS epidemic, for whatever the reason, does not fall into the same "catastrophic category." It has not and is not being responded to in the same manner as Hurricane Andrew or the midwest floods or the California earthquakes. It has not been treated as the international disaster it is. THIS MUST CHANGE!! The time is NOW . . .

This change will begin to occur with the appointment of a true AIDS Czar. Webster defines czar as one having great power and authority. I take that one step further -- one MUST be capable of exercising efficiently and expediently that power and authority.

You MUST have the courage and insight to brave the elements -- you MUST not fear the unknown, you MUST not allow yourself to be intimidated by anyone -- you MUST lay ego and political expediency aside and know that both will be bruised as the storm develops and runs its course.

We MUST repackage the message to renew interest -- the message we hear is old and tired. We need to consistently keep AIDS issues on the "front page" through proper packaging of the message. An AIDS czar should have the knowledge and where-with-all to accomplish this. The message MUST be accurate and informative -- not sensationalistic. AIDS issues today only make prime time news when a toddler sticks his finger with a potentially contaminated needle, or some rapist terrorizes victims with infected semen.

What a sad commentary -- our message MUST change.

If we do it effectively, the calm that will follow, surely will provide the reward that millions of people throughout the world will enjoy as we will have found a lasting solution to the AIDS epidemic.

I've mentioned a lot of MUSTS, and I know the task is a formidable one. But, it can be done, and it has to be done!! Our lives depend on it. Only you know if you are capable of meeting this challenge -- only you know if you have been "called" to accomplish this task. If the MUSTS appear to overwhelm you, then you MUST have the grace and dignity to allow someone else to assume control.

We MUST have success!! Millions of people are waiting and watching. ***PLEASE, LET ME HEAR THE ROAR OF THUNDER***....

Sincerely,

Michael Kegley
317 S.W. Alder, Suite 1100
Portland, Oregon 97204
(503) 295-5916

THE WHITE HOUSE

WASHINGTON

July 20, 1994

TO: James D. Shelton, USAID
Judy Manning, USAID
Carol Roddy, OSG
Burt Peterson, CDC
Jack Whitescarver, NIH
Nancy Alexander, NIH
Randy Wykoff, FDA
Bruce Burlington, FDA
Elizabeth D. Jacobson, FDA

FROM: Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator

SUBJECT: Rescheduling Meeting on Plastic Condoms

Please accept my apologies for the last minute cancellation of the Wednesday, July 13 interdepartmental meeting on the subject of plastic male condoms. Unexpected scheduling conflicts for the FDA representatives made it impossible to convene the meeting as planned.

It is important that discussions of this issue continue. I am attaching for your information a two-page outline prepared by the USAID on some of the public health issues related to plastic male condoms. I encourage others of you to circulate any other materials on this subject.

Again, my apologies to those of you who were inconvenienced by this cancellation. The ONAP staff will be working to reschedule the meeting as soon as possible.

Attachment:

New Plastic Male Condoms - Public Health Perspective

Basic Premises:

- HIV and unintended pregnancy epidemic.
- Time is of the essence in preventing HIV spread.
- Latex male condoms best current technology against HIV.
- Acceptability/Behavior most important determinant of successful use and attractiveness of condoms.
- Consumer needs/preferences highly multifactorial and individual. For OTC methods, consumers self select methods most acceptable to them that suit their own preference.
- Many men/couples dislike condoms → no use, improper use.
- Best strategy - large diversity of condom products to match large range of needs/preferences.

Advantages offered by new plastic male condoms:

- **esthetics/feel** (major advance, esp. loose fit - like "skin" condoms)
- compatible with any lubricant
- strength? - (esp. important for anal intercourse)
- slower deterioration
- non-allergenic
- smell/taste
- cheap cost?

Conclusion: New plastic male condoms offer a major improvement in technology to prevent AIDS, indeed their introduction would be arguably the *most important single action* near at hand to stem HIV transmission in this country. Additional benefits include prevention of other STDs and unintended pregnancy.

What's needed is a means to make a wide array of such condoms available *as quickly as possible* to meet the varying needs of the consumer and foster competition. This needs to done while maintaining a reasonable level of regulatory requirement.

Points on Regulatory Approval

• 510K rationale can be applied based on materials testing, permeability studies, actual human use slippage/breakage (S/B) studies and the common sense judgement on face validity.

• Randomized comparative clinical trials are of relatively little value for a number of reasons but especially because they don't reflect actual use conditions and largely destroy the self-seletion, adaptation process that occurs in the real world. They may be especially misleading in deriving a pregnancy use-effectiveness "rate".

• Clinical trials are difficult, expensive, and time consuming. Prototype "6 month" comparative study costs $2-3 millions and takes 2-3 years.

Possible Options:

• 510K approval based on materials testing and S/B clinical testing alone.

• USG funded "sentinel" postmarketing studies X2.

• Postmarketing clinical trial requirement.

• Grace period for postmarketing "grandfather" treatment.

• Accumulate data from 2-4 clinical trials, relate to S/B data. Then, handle other plastics as latex is currently handled.

THE WHITE HOUSE

WASHINGTON

July 20, 1994

Ken South
110 Maryland Avenue, N.E.
Suite 504
Washington, D.C. 20005

Dear Mr. South:

Thank you for your five years of service at ANIN.

Your contributions are felt all across the country, and continue to aid our collective effort to end the HIV epidemic and serve all of those affected by it.

It's been a pleasure working with the Network, and I encourage you to continue the good work.

Sincerely,

Kristine M. Gebbie
National AIDS Policy Coorinator

THE WHITE HOUSE

WASHINGTON

July 20, 1994

The Honorable Suzanne Jacobs
Florida House of Representatives
302 House Office Building
Tallahassee, Florida 32399-1300

Dear Suzanne:

It was good to talk with you about HIV testing, mothers, and newborns on Saturday. As I indicated, this is a complicated area in which access to appropriate services and thoughtful care providers are more important than mandates.

As you consider how to proceed with your concerns in the future, Fran Page of this office may be of assistance. She can be reached at (202)690-5560.

My best wishes and my thanks for your interest in the health of mothers and infants.

Sincerely,

Kristine

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

JUL 21 1994

THE WHITE HOUSE

Dear Debbie –

Thank you for your phone call – and words of support. I look forward to seeing you again at some point – and thanking you for your continuing efforts

Hillary

Ms. Debbie Runidns
2600 Hillboro Pike
Apt. H-1
Nashville, TN 37212

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Joanne M. Johnson, RN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

Dear Ms. Johnson:

Thank you for your input on the need to protect nurses and other health care workers who may be exposed to HIV in occupational settings. As you know, this has been a subject of intense debate since the beginning of the epidemic, especially since the documented cases of transmission from a dentist to his patients in Florida a few years ago.

As a nurse, I understand the concerns of fellow nurses and health care workers about the dangers of getting exposed to HIV at work while caring for others. I have been a longtime proponent of universal precautions to prevent the spread of HIV from patient to practitioner and vice versa. The guidelines developed by the Occupational Safety and Health Administration (OSHA) have been instrumental in limiting the risk of exposure in health care settings. However, it is also critical that all health care workers implement these guidelines on a consistent basis for all medical interventions.

The items that you mention in your communication do not guarantee that HIV exposure will be eliminated. I am not in favor of implementing measures that may give practitioners and the public a false sense of security when it has been proven that universal precautions, and the use of currently-available technology in all instances will protect those who have to engage in invasive procedures.

Finally, I also believe that we shall continue to search for new and better ways to provide first class health care to all while protecting health care workers.

Thank you again for your input. I hope that you will continue sharing your concerns with me.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

Dear Ms. Gebbie,

Along with other registered nurses, I am growing increasingly alarmed at the degree to which nurses are not being adequately protected — particularly in the clinical setting — from people who carry the HIV virus or have AIDS. There is now persuasive evidence that "universal precautions" are not adequate.

We urge you to put the full force of your office into insuring that: (1) HIV becomes a reportable disease, in keeping with sound preventive and treatment policies; (2) definitive studies about the potential of HIV to be spread by aerosol are completed and publicized; (3) operating rooms be equipped with special air filters and O.R. nurses be provided with special face shields and other impenetrable protection; (4) premarital, prenatal, and neonatal testing be mandatory; (5) routine testing of all patients and healthcare workers be mandatory.

I am concerned that the rights of nurses are being abrogated in the name of "political correctness" and call upon you to respect the health and lives of America's frontline healthcare workers, the 2.4 million registered nurses in the United States.

Sincerely,

Joanne M Johnson RN

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Mattie Washington, RN, BSN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

Dear Ms. Johnson:

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Sincerely,

Mattie Washington, RN, BSN

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Sue Anne Graham, RN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

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Sincerely, Sue Anne Graham, R.N.

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Geraldine Pleasant, RN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

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Sincerely, Geraldine Pleasant RN

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Anna Willith, RN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

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Sincerely,

Anna Willette RN

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Deborah A. Hudel, RN
P.A.C.U. Staff
c/o 9332 Moorish Road
Swartz Creek, MO 48473

Dear Ms. Johnson:

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Sincerely,

Deborah A. Hudak RN

THE WHITE HOUSE

WASHINGTON

July 22, 1994

Mr. Henry Moran
Executive Director
Mid-America Arts Alliance
912 Baltimore Avenue
Suite 700
Kansas City, MO 64105

Dear Mr. Moran:

Thank you for the invitation to the "Access to the Arts: Beyond Compliance" conference on July 27, 1994. Unfortunately, my schedule does not permit me to participate. I am pleased that Bob Hattoy will be able to attend. I wish you the best of luck with your event.

Sincerely,

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator

JUL 22 1994

THE WHITE HOUSE

Nigel—
great work getting the pharmacy - HIV education initiative launched! We'll be watching the process in Alabama, and hoping for positive results. Relax a bit before climbing the next mountain—you've earned it— Kristine

Nigel L. Gragg, R.Ph.
President
Foundation of Pharmacists &
Corporate America for AIDS Education
700 Thirteenth St., N.W.
Suite 950
Washington, D.C. 20005

JUL 22 1994

THE WHITE HOUSE

Dear Bill —

Thank you for the copy of Experiences in Environmental Institution - I look forward to reading it —

Best Wishes

Kirsten

William B. Culham
17128 Eldorado Dr. S.W.
Tigard, OR 97224