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NATIONAL
LEADERSHIP
COALITION
ON AIDS

RECEIVED

JAN 11 1994

January 10, 1994

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American Foundation for AIDS Research

The Rt. Rev. Douglas E. Theuner
Bishop, Diocese of New Hampshire
of the Episcopal Church

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Suite 1060
750 17th Street N.W.
Washington, D.C. 20503

Dear Kristine:

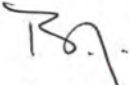
Many thanks for forwarding the letter from Enoch Prow of NationsBank to President Clinton, and for asking Andrew Barrer to coordinate planning for next steps.

President Clinton did reply to Enoch. Andrew and I've spoken, and plan to meet next week when Lee Smith is in town.

I continue to believe that a well-planned exchange between the President and business leaders in the vanguard of addressing AIDS can be very productive.

Many thanks.

Cordially,


B.J. Stiles
President

BJS/st

1730 M Street, NW
Suite 905
Washington, DC 20036
202/429-0930
FAX: 202/872-1977

Department of Health and Human Services, USA
Substance Abuse and Mental Health Services Administration



EDWIN M. CRAFT

Deputy Director
Office of Policy Coordination

Center for Substance Abuse Treatment
Rockwall II, 10th Floor
5600 Fishers Lane
Rockville, MD 20857

(301) 443-5050
FAX (301) 443-9363



January 10, 1994

JAN 12 1994

3333 University Boulevard, West, #1211
Kensington, Maryland 20895

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

Dear Ms. Gebbie:

Thank you so much for taking time out of your busy schedule to meet with me on January 4. It was very beneficial to learn the first-hand perspectives from a student just finishing the PEW Memorial Trust Program at the University of Michigan. The information you provided has encouraged me to continue with my inquiry into the program. I was also pleased (and relieved!) to know that I have started the process early - or at least in time to prepare to enter the September, 1993 class should I be accepted.

Your suggestion that I contact Rich Weston, Larry Patton, Cheryl Gelman and Charlie Huntington to secure additional perspectives on the program is greatly appreciated. I will arrange conversations with them in the order that you suggested.

Your candid discussion of your perspectives on the purpose and expected outcomes of pursuing a doctoral program has helped to crystalize my thinking in this regard. I was pleased to learn that our thinking along these lines is pretty well matched.

Finally, it was exciting to learn more about your work as National AIDS Policy Coordinator. I am grateful for your willingness to receive a copy of my SF-171 - and to keep me in mind as opportunities in your office for which I qualify become available. Let me also reemphasize my interest in working in a collaborative way with your office on projects and committees, while I am still in my current role as Deputy Director, Office of Policy Coordination, Center for Substance Abuse Treatment.

Again, many thanks for the courtesies extended. Please accept my ongoing best wishes for the challenging role you are in. I look forward to our next contact.

A handwritten signature in dark ink, appearing to read "Edwin M. Craft".
Edwin M. Craft

THE WHITE HOUSE
WASHINGTON

January 10, 1994

Lynn W. Kitchen, M.D.
CSIS
1800 K Street N.W.
Washington, D.C. 20006

Dear Dr. Kitchen:

Thank you for sharing information on DEC research. It is very interesting.

As the National AIDS Policy Coordinator, I strongly support HIV-related research and the fastest possible evaluation of promising agents.

I appreciate hearing from you, and would be interested in hearing how this is resolved.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Kristine', with a stylized flourish at the end.

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

December 26, 1993

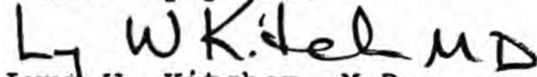
Sandra H. Bridges, Ph.D.
Senior Scientist
Targeted Drug Discovery Section
Developmental Therapeutics Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C12
Bethesda, MD 20892

Telefax: (301) 402-3211
Telephone: (301) 496-8197

Dear Dr. Bridges:

I am writing in follow-up to my October 5 letter to you because I have not yet received a reply. Given that multiple researchers currently involved in filariasis-oriented DEC research have expressed an interest in seeing the data generated in the NIAID-sponsored study examining the effect of DEC treatment in FeLV-infected cats, an update regarding the status of the manuscript of Dr. Tompkins and his associates would be helpful.

Sincerely yours,


Lynn W. Kitchen, M.D.

Mailing address (I will be going to London in early January 1994 for a period of study at the London School of Hygiene and Tropical Medicine, but my mail will be forwarded):

CSIS
1800 K Street N.W.
Washington, D.C. 20006

Telephone: (202) 966-1293 (residence)
(202) 775-3219 (CSIS)

Fax: (202) 775-3199

cc: Anthony Fauci, M.D.

bcc ✓

December 9, 1993

Dr. C.P. Ramachandran
Chief, Filariasis Control
Division of Control of Tropical Diseases
World Health Organization
CH-1211 Geneva 27
Switzerland

Fax: 011-41-22-788-08-39

Dear Dr. Ramachandran:

I appreciated very much your faxed reply to my November 30 letter, and the suggestion re possible ways of obtaining DEC for additional trials in humans. A fresh supply of clinical-grade DEC would be very helpful in enabling me and the Guatemalan researchers with whom I have been collaborating to move forward with our follow-up trial that focuses on compassionate use of DEC treatment in clinically challenging cases caused by a variety of infectious pathogens -- such as multiple-drug-resistant tuberculosis in HIV-infected persons.

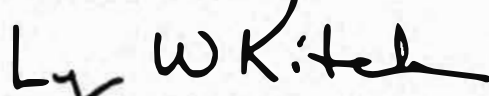
There may, however, be a problem with using Indian-manufactured DEC for a U.S. trial. My "pre-investigational new drug" discussions with FDA officials regarding conducting a clinical trial with a non-U.S./British/European-manufactured drug (particularly when conducted by the same person who has done nearly all the studies in preparation for the proposed large clinical trial) have not been encouraging. And without FDA approval, neither funding nor approval by a hospital institutional review committee for such a study is likely. And even if I could somehow get the study done despite all of these obstacles, the editors of a reputable journal would probably not publish the results without FDA record of an approved IND application. Other researchers in the AIDS field must be encountering similar gridlock, because at present no new drug applications for antiretroviral drugs are being considered by the FDA (Nature, December 2, 1993 p. 395).

I agree that the data regarding the usefulness of DEC treatment in relation to prevention/treatment of HIV infection is not conclusive at this point in time. However, I am sending you via airmail a confidential copy of another manuscript currently undergoing peer review (Kitchen L.W., Ross J.A., Turner G.J., Hernández J.E., Mather F.J., "Diethylcarbamazine enhances blood microbicidal activity") which may be of interest in considering a potential impact of DEC on HIV-related infections. Also, a copy of the as yet unpublished NIAID-sponsored trial of DEC in an animal model mentioned in my previous letter may be available to you through Dr. Fauci (address below).

Certainly it is clear that DEC is not a cure for established HIV infection. At best, DEC therapy has a modest antiretroviral effect and mitigates opportunistic infections in HIV-infected patients. But the more important question -- which cannot be answered by U.S. hospital-based studies -- is whether low-dose DEC (e.g., incorporated into table salt) can prevent horizontal and vertical transmission of HIV and associated infections (such as M. tuberculosis) in large populations in which HIV prevalence is growing despite efforts to limit HIV spread via education. This may be a particularly pertinent issue given the fact that DEC is orally bioavailable, relatively nontoxic and requires no blood parameter monitoring, concentrates in lymph node, brain and pulmonary tissue, and all available evidence indicates that the drug can be given safely during pregnancy.

As indicated in my November 30 letter, I believe that valuable data concerning HIV-related outcomes can be extracted from WHO-sponsored filarial-related studies (hopefully with relatively minor additional expense) and would be honored to assist in this process. These WHO-sponsored trials may be the only vehicle by which confirmatory evidence of DEC's non-nematodal anti-infective effects can be documented. In my opinion, expeditious research is warranted given the rise in HIV and tuberculosis cases worldwide.

Sincerely yours,

 M.D.
Lynn W. Kitchen, M.D.

Mailing address:

CSIS
1800 K Street, N.W.
Washington, D.C. 20006
U.S.A.

Telephone: (202) 966-1293 (residence)
(202) 775-3219 (office)

Fax: (202) 775-3199

cc: Eric Ottesen, M.D.
Chief, Clinical Parasitology Section
National Institutes of Health
Building 4, Room 126
9000 Rockville Pike
Bethesda, MD 20892

Michael Merson, M.D.
Director, Global Programme for AIDS
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Kenneth W. Bernard, M.D.
Associate Director
Office of International Health
U.S. Public Health Service
Department of Health and Human Services
18-90 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Anthony Fauci, M.D.
Director, NIAID
National Institutes of Health
Building 31, Room 7A-03
9000 Rockville Pike
Bethesda, MD 20896
Telephone: (301) 496-2263
Fax: (301) 496-4409

David A. Kessler, M.D., J.D.
Commissioner, Food and Drug Administration
Room 1495
5600 Fishers Lane
Rockville, MD 20857

Paul E. Simonsen, Ph.D.
Danish Bilharziasis Laboratory
Jaegersborg Allé 1 D
DK-2920 Charlottenlund
Denmark
Fax 011 45 31 62 61 21

bcc ✓

JAN 11 1994

THE WHITE HOUSE

Dear Jesse —

Thank you so much for
our meeting - I'm pleased at
the possibilities of increasing
the V.A. visibility in our national
AIDS policy, and look
forward to working with
you -

Sincerely,
Clinton

JAN 11 1994

THE WHITE HOUSE

Dear Gene -

Thank you for sending
the pictures & copy of
the Cruise. That was a great
afternoon! I do hope we
meet again

Kristine

THE WHITE HOUSE
WASHINGTON

January 11, 1994

MEMORANDUM FOR JOHN PODESTA
ASSISTANT TO THE PRESIDENT AND STAFF SECRETARY

FROM JOHN PAUL GURROLA 
OFFICE OF THE NATIONAL AIDS POLICY COORDINATOR

SUBJECT Getting us in the loop

On December 22, 1993 you distributed a memo to Cabinet Secretaries and Senior White House Staff concerning "State of the Union Address." Kristine Gebbie did not receive a copy of that memorandum.

I just wanted to double check that we are on your lists that are relevant to our office.

Thanks for your time and please call me at 202/632-1090 fax 202/632-1096 if you have any questions.

THE WHITE HOUSE
WASHINGTON

January 11, 1993

Rev. Elder Don Eastman
Second Vice-Moderator
UFMCC
5300 Santa Monica, Suite 304
Los Angeles, California 90029

Dear Rev. Eastman:

Thank you for your comments on the recently-released CDC Prevention Marketing Initiative. As you know, this campaign is intended to stop HIV infection among young adults 18-25 by encouraging the delay of sexual activity and by encouraging consistent and correct latex condom usage among those who are sexually active.

I am very encouraged to hear your positive comments about this Initiative, especially since we understand that community level organizations, in particular religious organizations, will play a pivotal role in encouraging behavior change among young people at risk. Because the Metropolitan Community Churches are an integral part of the Gay/Lesbian community, your participation in prevention efforts at the local level will be instrumental in impacting behavior among young gay men and lesbians.

Again, thank you for your comments.

Sincerely,



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

cc: Rev. Steve Pieters



1968-1993
Celebrating 25 Years of Ministry



JAN 12 1994

Ms. Kristine Gebbie
National AIDS Policy Coordinator
750 17th St., N.W., Suite 1060
Washington, D.C. 20500

January 5, 1994

Dear Ms. Gebbie:

We applaud the leadership of the Clinton Administration in the recently introduced HIV/AIDS prevention marketing program of the Centers for Disease Control. We support the approach of the program, which honors both the ideal of personal responsibility and the reality that the majority of young people in America are sexually active.

We support the recommendation that young people remain abstinent until entering into responsible relationships; we support equally the dissemination of life-saving information on the correct and consistent use of latex condoms to young people who are sexually active.

We are greatly encouraged by your leadership and initiative in this vital prevention campaign.

Sincerely,

Rev. Elder Don Eastman
Second Vice-Moderator, UFMCC

Rev. Steve Pieters
Field Director, UFMCC AIDS
Ministry

cc: Rev. Ken South, AIDS National Interfaith Network

UFMCC
5300 Santa Monica
Suite 304
Los Angeles
CA 90029 USA
Tel (213) 464-5100
Fax (213) 464-2123

THE WHITE HOUSE
WASHINGTON

January 11, 1994

Mr. Luke Adams
2130-B 13th Street, NW
Washington, DC 20009

Dear Luke,

Thank you for your memorandum regarding the status of our office. As we near the end of my first five months here, you will be happy to see that there have been some significant accomplishments and we are moving forward.

Our office has been playing a key role in many projects and programs nationally. We have played a major role in the aggressive CDC prevention marking initiative; looking at new and innovative research models; and the HHS Task Force on AIDS Drug Development to name a few.

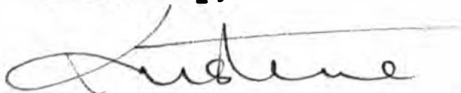
Our public affairs staff have been working at getting the message out to people about our role in coordinating national AIDS policy. In the last several weeks, we have had positive exposure on many national television news shows and newspapers including CNN Crossfire and the Miami Herald.

We currently have more than thirty staff working in our office covering research, services, prevention, global issues, liaison and Health Care Reform. At the present time, we are only interviewing for the Deputy position which is currently in the resume evaluation stage. Should other competitive positions open, which allow us to consider non-governmental employees, we shall let you know.

Your enthusiasm and desire to be a part of this office is appreciated. I wish you the best of luck in securing the type of position that would best suit your goals. However, at this time, we do not have anything here for you.

I appreciate hearing from you. Thank you for writing.

Sincerely,



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

Faxed 2/16/94

MEMORANDUM

By Telefacsimile

Post-It Fax Note	7671	Date	2/10/94	# of pages	1
To	Kristine Gebbie	From	LUKE ADAMS		
Co./Dept.	ONAP	Co.	CAF		
Phone #	632-1090	Phone #	872-5310		
Fax #	632-1096	Fax #	331-8166		

FEB 10 1994

10 February 1994

We sent it again!

Dear Kristine:

I have been told by a couple of people in your office that there supposedly was a letter sent to me to answer my note to you of 3 January.

When I faxed you the interview with Luke Sissyfag at the beginning of last week, I let you know I had still received no reply from you. As of today, I have still received no reply to the series of questions I raised. This causes me some serious unease.

If indeed this reply exists, could it please be faxed to me today at (202) 331-8166?

Let me also put in writing what I discussed briefly with Steve Lee. John Palenicek from Senator Kennedy's Committee on Health and Labor told me last week that he had discussed with you the creation of a standing list of resource people who are living with HIV that your office could put forth for hearings and the like in future. He asked that I call you and ask to be placed on such a list (if it is created). Last week I called to do so, and herewith I repeat that request.

Thank you for your attention to these matters.

With concern,

Luke Adams

Indexed

THE WHITE HOUSE
WASHINGTON

January 12, 1994

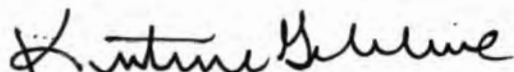
A.A. Avlicino
4205 Mariner Boulevard, Suite 202
Spring Hill, FL 34609

Dear Mr. Avlicino:

Thank you for the information regarding your thesis on sodium hypochlorite as a potential retroviral treatment. The function of the new National Task Force on AIDS Drug Development is to identify any barriers to the rapid development of therapeutic agents for treatment of AIDS and HIV-related diseases; to provide advice directly to the secretary of Health and Human Services on issues related to such barriers, to make specific recommendations for promptly eliminating such barriers; to attempt to create coalitions of those parties involved AIDS drug development; and to identify general areas of concentration for future drug development research, funding and emphasis.

Requests for consideration of specific drugs or treatments will continue to be processed through the existing system. Your proposal should be submitted through proper channels.

Sincerely,



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

To: Steve Lee

December 27, 1993



ACTION MEMORANDUM

TO: Terry Beswick *please pass along*
Jo Messor

JAN 4 1994

FROM: W. Steve Lee

SUBJECT: Action items

DATE REQUIRED: January 5, 1994

The following items need your attention:

So Letter from A.A. Avilicino (December 15, 1993) on getting research information to the drug development task force. Draft a response for KG's signature.

Information from Sherikon, Inc. (from 12/21 meeting with KG) on project/research management. Act as appropriate -- discussion. Forward to Paul Tran as well.

*Steve -
I forgot to return the
original with the letter -
copy of orig. reply attached.
Ja*

*Letter to
Dr. Jeffrey*

A. A. Avlicino

**4205 Mariner Blvd., Suite 202. Spring Hill, FL 34609
Phone: (904) 688-9669, Fax: (904) 686-0704**

December 15, 1993

~~CONFIDENTIAL~~

Ms. K. Gebbie
AIDS Advisor
750 17th St. NW
Suite 1060
Washington, DC 20500
(202) 690-5471

DETERMINED TO BE AN
ADMINISTRATIVE MARKING



INITIALS: JGP DATE: 7/25/19 DEC 21 1993
2018-0956-F

Dear Ms. Gebbie:

In April, 1994, Medical Hypotheses, the leading London-based medical publication will publish my paper, "Proposal for Experimental Studies to Evaluate Sodium Hypochlorite Dialysate in Retroviral Treatment."

This proposal, complete with 48 references, establishes the thesis that sodium hypochlorite and its related oxygen free radicals can be administered in minute quantities in vivo to achieve a reduction in retroviral titer within the infected individual and stresses that the utilization of infusion of low-concentration sodium hypochlorite dialysate for retroviral inactivation merits immediate experimental study. Chlorinated tap-water and table salt ingestion must also be among the environmental factors studied for correlation to HIV infection.

In light of the formation of the new HHS committee dedicated to exploring potential treatments for HIV infection, I believe that my thesis should be submitted for the committee's perusal, as well as derive consideration for potential research development. I would be happy to forward you and/or members of the HHS committee, advance copies of the paper upon request.

Given the innovative aspects of this research, I would appreciate if discussion of this topic be kept from the press at the present time, as we plan a formal public presentation on the publication date.

I appreciate your consideration and look forward to your reply.

Sincerely,

A. A. Avlicino
aaa/mac

Chu

THE WHITE HOUSE
WASHINGTON

January 12, 1994

MEMORANDUM

TO: Araceli Ruano, Office of Mrs. Gore

FROM: W. Steve Lee, Executive Assistant to *N. Ste L*
National AIDS Policy Coordinator

SUBJECT: AIDS prevention

Thank you for your call requesting information on the Centers for Disease and Prevention (CDC) Prevention Marketing Initiative and on Country AIDS Awareness. I hope the information is helpful. Please call me at 632-1090 if you have any questions.

Enclosures

THE WHITE HOUSE
WASHINGTON

January 12, 1994

Mr. James Joseph Treacy, Jr.
117 Roosevelt Place
Palisades Park, New Jersey 07650

Dear Mr. Treacy:

Thank you for sharing with me information on Epitepe's Orasure HIV test kit. As you know, the Office of the National AIDS Policy was created out of the commitment of the President to take positive steps to stop the HIV/AIDS epidemic. Tests to detect HIV are critical in this effort.

I want to assure you that I am in close contact with the Department of Health and Human Services and the FDA on this issue and recognize the importance of a non-blood based test for HIV. I do not agree with the statement that the FDA is "sitting" on this test. As you know, in recent years there have been many claims about products that involve HIV/AIDS. It is FDA's mission to protect the public health with regard to medical devices and to assure the safety, effectiveness, and proper labeling of these medical devices.

Thank you again for writing.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kristine Gebbie".

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

January 6, 1994

ACTION MEMORANDUM

TO: Alice Litwinowicz

FROM: W. Steve Lee

DATE REQUIRED: January 13, 1994

The following items need your attention:

Letter from James Treacy (January 4, 1994) on AIDS prevention.
Draft response for KG's signature.

Attachment

RECEIVED
JAN 5 1993

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

*Steve
please draft
reply*

January 4, 1993

Ms. Kristine Gebbie
AIDS Policy Coordinator
200 Independence Avenue SW
Room #725H
Washington, DC 20201

Dear Ms. Gebbie:

My hometown paper (Bergen Record) carried a very interesting Knight-Ridder piece about you in their January 3rd edition (copy attached.)

I think the focus you wish to put on AIDS prevention is proper. Perhaps you can get to the bottom of why the FDA seems to be sitting on a very cheap, easily distributable and effective prevention test called OraSure by Epitope. With your Pacific Northwest background you may be somewhat aware of this Beaverton, Oregon company's breakthrough product and the FDA politics they have faced trying to get a green light for distribution.

For your information, I have enclosed various correspondence concerning this very important product.

Good luck in all you do.

Very truly yours,

James J. Treacy
James J. Treacy

JJT:jf
attachments

Clinton's pick: a plain-speaking nurse with a mission

By **PATRICIA ANSTETT**
Knight-Ridder News Service

They still haven't put out the welcome mat for Kristine Gebbie — they may never.

"To the very active AIDS advocacy groups, particularly those on the East Coast, I'm an uninfected, straight white woman from the Northwest," says Gebbie, the first federal AIDS coordinator.

"How could I possibly be their hero in this epidemic?"

Gebbie, a nurse and former chief of the state health departments in Oregon and Washington, knows she wasn't President Clinton's first choice.

Still, she's excited about the possibility of changing the course of the government response to AIDS, which she says was often poorly navigated during 12 years of Republican leadership.

KRISTINE GEBBIE, AIDS POLICY COORDINATOR



Born: June 26, 1943, in Sioux City, Iowa.

Education: B.S., nursing, St. Olaf College, 1965; M.S., nursing, UCLA, 1968.

Professional career: Project director, U.S. Public Health Service training grant, St. Louis, 1972-77; coordinator of nursing, St. Louis University, 1974-76, assistant director of nursing, 1972-78; clinical professor, 1977-78; administrator, Oregon Health Division, 1978-89; secretary, Washington State Department of Health, 1989 to present; associate professor, Oregon Health Sciences, University of Portland, 1980 to present; member, Presidential Commission on HIV, 1987-88.

Other accomplishments: Distinguished scholar, American Nurses Foundation, 1989; Fellow of the American Academy of Nurses; American Public Health Association board member; Mary Tolle Wright Award for Excellence in Leadership from Sigma Theta Tau nursing society.

Sources: Washington Department of Health, Who's Who in America

KRT

"I would never have been here in the Bush or Reagan administration. They weren't interested in AIDS," she says flatly.

Gebbie's evidence that the Clinton administration is interested includes the creation of a position for AIDS research coordinator; a requirement that federal employees receive AIDS prevention and awareness training; and an initiative to get federal agencies to do more about AIDS, for example, by encouraging children to pursue research careers.

She also cites substantial increases in funding for AIDS research and treatment, and the first federally funded public service ads to mention condoms. The campaign is scheduled to kick off this week.

"The ads will be very different than See AIDS Page B-2

AIDS

Fr noPage B-1

anything you've ever seen before," Gebbie promises. "They reflect the changes we're going through here."

Gebbie heads an office of 30 people, five of whom, including herself, have White House office space. She sits in on cabinet meetings and says she has the president's ear frequently.

Ask AIDS activists how Gebbie is doing, and answers vary widely.

"She's a very wise, seasoned bureaucrat," says Randy Pope, who directs AIDS programs for Michigan's Health Department. He asks others to give her time and not blame her for "all the things not done in the last 10 years."

But Jeff Levi, director of public policy for the AIDS Action Foundation in Washington, D.C., faults Gebbie for not developing a national strategic AIDS plan or setting up a promised AIDS advisory

He was also disappointed by her comments in a recent New York Times Magazine interview that "part of her mission ... is to help people keep their expectations within reality."

Levi says, "For a community waiting so long for an appropriate and compassionate response to the epidemic, it's disappointing to hear the point person in the administration talk about lowering expectations, rather than rolling up our sleeves and doing as much as we can, as quickly as we can."

Gebbie takes the heat in stride.

She says she's making progress on setting up an advisory committee, noting that federal bureau-

crats consider starting such a committee in less than a year "something just less than a miracle."

She plans to issue a strategic plan, though she adds: "I don't want my office to turn into some place that just prints plans ... the kind that take a year to write and then they sit there."

Most recently, Gebbie, 50, headed an AIDS advisory panel for the federal Centers for Disease Control and Prevention. She seems steely enough for her present challenge, apparently unconcerned that one AIDS activist described her as "Snow White," or that peo-

ple have remarked on her "air of a head nurse."

Back in the Northwest, Gebbie earned a reputation as feisty and hardheaded, not the consensus builder she now must be.

Once she followed Oregon Gov. Neil Goldschmidt to the men's room and waited outside to give him a framed AIDS poster she had printed without his permission, though she'd been told to get his approval for all promotions. "Good boys always wear their rubbers," the caption read.

Says Pope, "You have to separate the personal attacks from the professional attacks."

"I don't think Kristine is the problem," he adds. "I think there still is a lot of denial in the cabinet" that keeps the Clinton administration from more forcefully addressing such issues as condom distribution at schools and gays in the military. "To a certain extent she's playing a difficult balancing act that's not well understood by the activists."

Gebbie, meanwhile, has high hopes for a new federal task force to coordinate AIDS research, and an inter-company pharmaceutical effort to share information on AIDS drugs. She plans to meet with church groups and others to push prevention programs.

"We've got to break through the denial," she says. "People come up with a thousand and one ways not to admit to the reality of this disease and not to admit to the reality of adolescent sexuality."



December 23, 1993

Mr. James J. Treacy, Jr.
117 Roosevelt Place
Palisades Park, NJ 07650

Dear Mr. Treacy:

This is in response to your December 2, 1993, letters to Secretary Shalala and to Surgeon General Elders concerning the approval of Epitepe's Orasure HIV test kit. We share your concerns for making new products available as soon as possible to those people who may benefit from their use.

As I am sure you know, the Food and Drug Administration (FDA) is committed to approving safe and efficacious products. Although our regulations concerning the confidentiality of information in a product license application restrict the amount of information that we can provide concerning the status of an unlicensed product, I can assure you that there are specific, product-related issues that are affecting the current application. Many of these issues were discussed at the December 1992 meeting of FDA's Blood Products Advisory Committee. These issues are being addressed by an ongoing effort on the part of the company and FDA.

FDA staff recognize the potential public health benefit of non-blood based HIV-screening technologies and are committed to working with product sponsors to expedite the review of such applications. Our evaluation of Epitepe's Orasure product, as with all marketing applications, must by law be based on the strength of the scientific data. Therefore, while we very much want to know the opinion of any affected community, our ultimate decision must be based on scientific data submitted by the product's sponsor.

I hope that this information is helpful.

Sincerely yours,

Bonnie M. Lee
Senior Policy Analyst
Office of the Executive Secretariat

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

Ms. Donna E. Shalala
Secretary of Health
and Human Services
200 Independence Avenue, SW
Suite 615F
Washington, DC 20201

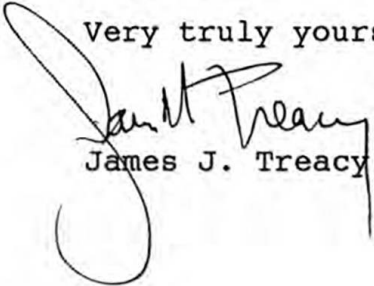
Dear Ms. Shalala:

I read about and was impressed by your news conference of yesterday concerning AIDS work. It is a plague that needs a cure and as many early prevention methods as possible.

Although there is not a drug application for an anti-retroviral AIDS drug in front of the FDA now, there is one (for at least a year) on a simple early detection device which would be a tremendous help with prevention work in the schools, military, etc. It's called OraSure by Epitepe. (details attached)

This cheap, easy-to-use and effective product plain and simple works. However, it appears for some political reasons the product cannot get out of the FDA. If President Clinton's team is serious in the AIDS fight the FDA would approve OraSure tomorrow.

Very truly yours,



James J. Treacy

JJT:jf
attachments

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

Ms. Joycelyn Elders
Surgeon General
5600 Fishers Lane
Suite 18-66
Rockville, Maryland 20857

Dear Ms. Elders:

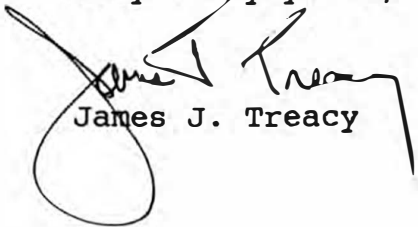
I have been closely following the events this week with regard to World AIDS Day and I was particularly taken by the statements made by Secretary Shalala during her November 30th news conference and President Clinton's December 1st address at Georgetown Medical Center.

In view of the statements made, it is somewhat puzzling that the Food and Drug Administration has been sitting on an effective, cheap, easily distributable, private, early detection device known as OraSure. Please refer to the attachments for some background.

Anything you can do to get the FDA on the move for immediate approval would appear sensible to me.

Thank you for your time and efforts.

Very truly yours,



James J. Treacy

JJT:jf
attachment

THE WHITE HOUSE

WASHINGTON

December 9, 1993

Mr. James J. Treacy
117 Roosevelt Place
Palisades Park, New Jersey 07650

Dear James:

I appreciate your taking the time to write.

It's important for me to hear the thoughts and experiences of people who care about the future of America and the world. We face many challenges ahead, and in order for us to come together and build consensus, we all must share our ideas and concerns.

I look forward to your support as we tackle the issues facing us in the coming months.

Sincerely,

Bill Clinton

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

President Bill Clinton
White House
1600 Pennsylvania NW
Washington, DC 20202

Dear President Clinton:

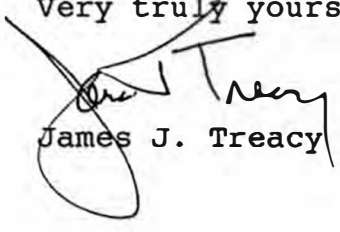
I viewed your World AIDS Day address at Georgetown Medical Center with great interest. Your speech very effectively stressed the needs for early prevention of the HIV virus. Also, your speech ended with a challenge that we the American people should continue to feel free to voice our concerns to you and to do everything we can do to fight HIV.

For my part, I am making you aware that the FDA has been sitting on a very effective, cheap, easily distributable, private, early detection device for over 2 1/2 years now. The device to which I refer is called OraSure and the attachments to this letter will give you a flavor for the red tape and foot dragging that goes on at the FDA. Plain and simple - politics is costing lives.

I have now done my part. I hope that you can do yours and get the FDA to approve this life saving product immediately.

Thank you for your time and efforts.

Very truly yours,


James J. Treacy

JJT:jf
attachments

NAE
NATIONAL
ASSOCIATION
EVANGELICAL

Office of Public Affairs

Dr. Robert P. Dugan, Jr.,
Office of Public Affairs
1023 15th Street NW, Suite 9
Washington, DC 20005
Phone: 202-789-3011
FAX: 202-942-0851

National Office
450 Gundersen Drive
Carol Stream, IL 60188
Phone: 708-665-0500
FAX: 708-665-8575

Dr. Billy A. Melvin
Executive Director

December 7, 1993

The President
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President:

I want to thank you for the wonderful opportunity to be present with you, Vice President Gore, members of your staff and other ministers for breakfast on November 29. It was the kind of privilege that will never be forgotten.

As one of the "conservative evangelicals" you referred to in your inspirational remarks at the Georgetown University Medical Center, may I respond to the invitation for input on what your Administration could do in "the quest for a better way to deal with AIDS."

You mentioned the need "to slash the rules and regulations and the bureaucracy to move drugs to people more quickly," and we say AMEN! "That is terribly important," as you recognize, but so, too, it is terribly important to slash the rules and regulations -- or whatever it is that is paralyzing the FDA with respect to testing for AIDS.

Every effort should be made to prevent the spread of AIDS, and testing can significantly contribute to that imperative. But for whatever reason, the FDA seems to be paralyzed by inertia when it comes to approving a breakthrough technology for HIV testing. I refer to a simple saliva-based test for AIDS that is not only inexpensive and easy to administer but can more effectively reach people that have been reluctant to get tested. A product of this kind has been under consideration for pre-market approval by the FDA for at least thirty months.

To ignore the potential of testing as a way to curb the spread of AIDS is criminal. We are familiar with the arguments against testing, but find them unpersuasive. So do others. See, in this connection, the attached December 13, 1993 Time essay by Amital Etzioni, an NAE friend and ally.

By their failure to act, the FDA is contributing to the needless deaths of thousands. Your intervention is urgently needed to find out why it is that the FDA can promise to act and then not do so.

DEC-09-1993 12:01 FROM

TO

1503248750055 P.03

The President
December 7, 1993
Page 2

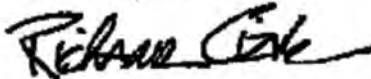
Please do not interpret our pleas as an indictment of your Administration on this score. Your compassionate remarks about AIDS at Georgetown, the superb way you handled the interruption, and your openness to new ideas for combatting this epidemic are all most welcome. We believe the FDA impasse is a matter of bureaucratic inertia or perhaps worse. Rightly or wrongly, black evangelicals involved in this issue believe that there is a "white chain of command" that has been insensitive to the need for new prevention techniques for testing HIV/AIDS.

As you undoubtedly know, HIV/AIDS is now disproportionately affecting communities of color. The Centers for Disease Control and Prevention recently reported that HIV infection was the leading cause of death for black men aged 25-44 during 1991-92. The death rate from HIV infection in 1992 for persons aged 25-44 years was three times as high for black men as for white men and 12 times as high for black women as for white women. This "second wave" of the epidemic among minorities will be catastrophic if government does not treat HIV/AIDS as a medical emergency rather than as a "civil rights" issue. Such a change would entail a policy of routine testing, reporting, and partner notification for HIV, as is done for every other sexually transmitted disease. Resistance to this idea by many of the top public health officials in our country is a tragedy.

Mr. President, we are much encouraged by your AIDS remarks and other instances where you used the "bally pulpit" to talk about the family, values, and responsibility. We want to be helpful, and certainly share your desire to take action and do whatever is necessary to cope with the sinister AIDS epidemic. We look forward to continued dialogue with you, with the thought that we can work together for good in this land we both cherish.

You and Hillary are in our prayers.

With kindest regards,



The Rev. Richard Cirik
Policy Analyst

ESSAY

Amital Etzioni

HIV Sufferers Have a Responsibility

A MAJOR DRIVE TO FIND A CURE FOR AIDS WAS ANNOUNCED last week by Donna Shalala, President Clinton's Secretary of Health and Human Services. Researchers from the private sector, gay activists and government officials were teamed up to accelerate the search for an effective treatment. Yet even highly optimistic observers do not expect a cure to be found before the end of this century. Still, as the Shalala announcement's exclusive focus on cure highlights, it is not acceptable to explore publicly the measures that could curb the spread of the disease by slowing the transmission of HIV, the virus that causes it. Indeed, before you can say what about prevention! the politically correct choir chimes in: You cannot call it a plague! You are feeding the fires of homophobic Gay basher!

Case in point: a panel of seven experts fielded questions from 4,000 personnel managers at a conference in Las Vegas. "Suppose you work for medical records. You find out that Joe Doe, who is driving the company's 18-wheeler, is back on the bottle. Will you violate confidentiality and inform his supervisor?" The panel stated unanimously, "I'll find a way." Next question: "Joe Smith is HIV positive; he is intimate with the top designer of the company but did not tell; will you?" "No way," the panel agreed in unison.

We need to break the silence. It is not antigay but fully compassionate to argue that a massive prevention drive is a viable way to save thousands of lives in the very next years. We must lay a moral claim on those who are likely to be afflicted with HIV (gays, drug addicts who exchange needles and anyone who received a blood transfusion before 1985) and urge them as a social obligation to come forward to be tested. If the test is positive, they should inform their previous sexual contacts and warn all potential new ones. The principle is elementary, albeit openly put: the more responsibly HIV sufferers act, the fewer dead they will leave in their trail.

HIV testing and contact tracing amount to "a cruel hour," claims a gay representative from the West Coast. "There are not enough beds to take care of known AIDS patients. Why identify more?" Actually, testing is cruel only in a world where captains of sinking ships do not warn passengers because the captain cannot get off. We must marshal the moral courage to tell those infected with HIV: It is truly tragic that currently we have no way to save your life, but surely you recognize your duty to try to help save the lives of others.

Warning others is unnecessary because everybody should

Amital Etzioni is the founder of the communitarian movement.

act safely all the time anyhow," argues Rob Teir, a gay activist in Washington. But human nature is such, strong data show, that most people cannot bring themselves to act safely all the time. A fair warning that they are about to enter a highly dangerous situation may spur people to take special precautions. The moral duty of those already afflicted, though, must be clearly articulated: being intimate without prior disclosure is like serving arsenic in a cake. And not informing previous contacts (or not helping public authorities trace them without disclosing your name) leaves the victims, unwittingly, to transmit the fatal disease to uncounted others.

Testing and contact tracing may lead to a person's being deprived of a job, health insurance, housing and privacy, many civil libertarians fear. These are valid and grave concerns. But we can find ways to protect civil rights without sacrificing public health.



A major AIDS-prevention campaign ought to be accompanied by intensive public education about the ways the illness is not transmitted, by additional safeguards on data banks and by greater penalties for those who abuse HIV victims. It may be harsh to say, but the fact that an individual may suffer as a result of doing what is right does not make doing so less of an imperative.

Not only that, while society suffers a tremendous loss of talent and youth and is struck with a gargantuan bill, the first victims of non-

disclosure are the loved ones of those already afflicted with HIV, even—in the case of infected women—their children.

Not cost effective, intone the bean counters. Let's count. Take, for example, a suggestion by the highly regarded Centers for Disease Control and Prevention that hospitals be required to ask patients whose blood is already being tested whether they would consent to having it tested for HIV as well. The test costs \$60 or less and routinely identifies many who were unaware they had the virus. If those who are thus identified were to transmit the disease to only one less person on average, the suggested tests would pay for themselves much more readily than a coronary bypass, PSA tests and half the pills we pop. And society could continue to enjoy the lifelong earnings and social contributions of those whose lives would be saved.

There are other excuses and rationalizations. But it is time for some plain talk: If AIDS were any other disease—say, hepatitis B or tuberculosis—we would have no trouble (and indeed we have had none) introducing the necessary preventive measures. Moreover, we should make it clear that doing all you can to prevent the spread of AIDS or any other fatal disease is part and parcel of an unambiguous commandment: Thou shalt not kill.

11 DEC 01 '93 10:22AM

NOV-19-1993 14:31 FROM

TO

1503248750035

P.12001/004

P.02

**NATIONAL
ASSOCIATION of
EVANGELICALS**

Office of Public Affairs

Dr. Robert E. Dupont, Jr., Director
Office of Public Affairs
1023 15th Street NW, Suite 500
Washington, DC 20005
Phone: 202-789-1011
FAX: 202-842-0392

November 19, 1993

National Office
490 Gundersen Drive
Carol Stream, IL 60188
Phone: 708-665-0500
FAX: 708-665-8575

Karen Groover
Consumer Safety Officer
Congressional and Consumer Affairs Branch
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Dr. Billy A. Melvin
Executive Director

Dear Ms. Groover:

Your letter of August 24 about the OraSure Collection Device for HIV-1 that has been developed by Epitope deserves an official response from our office.

You stated that "A number of people, including representatives from several AIDS activist groups, expressed concerns about [OraSure] approval at this time." Since we were not at the December 1992 FDA hearing, we asked a number of AIDS groups that were present and which offered public testimony, about the substance of that meeting. They have assured us that your appraisal of the support from AIDS groups for the OraSure product is not accurate.

However, of greater concern to us is your statement that "the review and approval of products for the prevention and treatment of AIDS has the Agency's highest priority." This is extremely hard to believe. Epitope has been waiting for FDA approval of its OraSure device since May 9, 1991. In the meantime, according to a National AIDS Behavioral Survey published in the Journal of the American Medical Association (JAMA 1993; 270: 1576-1580), a tremendous need for new strategies and means to encourage HIV testing goes unmet. "Particularly worrisome," the Survey concludes is the "low rate of testing (35%) among the largest risk group, heterosexual men and women engaging in unprotected sexual intercourse with multiple partners."

The FDA is obviously not worried about these trend lines. If it were it would have acted by now. Even a modicum of concern or compassion would have long since produced a favorable decision. Tens of thousands of people over the past two and one-half years have unknowingly become infected with the HIV virus. The consequence is an outrage: these people are going to die. This is a tragedy of immense

11DEC 01 '93 10:23AM

NOV-19-1993 14:32 FROM

TO

1503240750055

P. 2002/004
P. 03

Karen Groover
November 19, 1993
Page 2

proportions that could have been avoided. How many more lives must be lost?
Blood, alas even infected blood, is on your agency's hands.

You close your letter by stating that the matter of Epitope's application is "being given the priority and attention that it deserves." Suffice it to say that the FDA's long delay of approval for early diagnostic testing of HIV will be recorded in the history books of this epidemic as a major symbol of our government's failure to act responsibly.

Sincerely,



(The Rev.) Richard Cizik
Policy Analyst



EPITOPE

Epitope Inc.

8500 SW Creekside Place

Beverton, Oregon 97005

503.641.6115

Fax 503.643.2761

**EPITOPE REPORTS RESULTS OF STATUS CONFERENCE WITH FDA STAFF
REGARDING PENDING APPLICATION**

WASHINGTON, Nov. 10 /PRNewswire/ -- Epitope Inc. (AMEX: EPT) announced that it had a useful and constructive meeting today with FDA's Center for Biologics Evaluation and Research regarding the company's pending premarket approval application for use of its OraSure(R) oral specimen collection device.

"Certain limited issues remain under active discussion none of which would appear to prevent approval," said Adolph J. Ferro, president and chief executive officer. During the meeting, the company also learned that the application review process is considered to be complete enough so that a facility inspection is now appropriate, he added.

Epitope is a biotechnology company that develops and markets medical diagnostic products and, through its agricultural units, superior new plants and related products.

-0-

11/10/93

/CONTACT: Mary Hagen of Epitope, 503-641-6115/
(EPT)

bath
escape

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Happy-camper
cuisine! High-energy,
no-hassle meals.

SELF Magazine

SEPTEMBER

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Cover look

Bridget Moynahan looks ahead to cooler autumn days with makeup from Lancôme: *Musique* Oil-Free Liquid Makeup in *Dorée Clair*; *Poudre Majeur* Loose Powder in *Matté Beige*; and *Blush Subtil* in *Pêche*. On eyes: *Personal Eyes* in *Coquille*, *Abricot* and *Taupe Vert*; *Le Khôl Poudre* in *Carbone*; *Liner Précis* Automatic EyeLiner Pen in *Black Brun*; *Le Crayon Brow Definer* in *Ebène*; and *Carecils Excellence* Treatment Mascara in *Black*. On lips: *Rouge Absolu* Hydrating Longwearing LipColor in *Fauve* and *Le Crayon Lip Contour* in *Garnet*. Sweater by *Claude Montana*. The 1992 Jeep Wrangler belongs to Bridget's friend Andy O'Connell. Hair by *Susana Romano* for *Frederic Fekkai* at *Bergdorf Goodman*. Makeup by *Kimberly Briggs* for *Jean Owen*. Manicure by *Larissa*. Photograph by *Antoine Vergès*.

PHOTOGRAPHS, CLOCKWISE FROM TOP LEFT: ANTOINE VERGES; JEREMY SAMUELSON; NITA KALLS



New safer tests for AIDS, pregnancy, ovulation and more

Using blood or urine to test for disease has always presented problems, but it has become especially tricky of late. The threat of contracting AIDS from contaminated blood

makes some blood tests risky for clinicians, and urine tests are both messy and easily tampered with by patients. Now, a safer and more convenient technique for diagnosing all manner of disorders—from hepatitis to infertility—may soon be available. It uses saliva.

Epitope, a Beaverton, Oregon-based company, has developed a unique collection method, with which it is possible to isolate a component of saliva that can be used to test for the AIDS virus. The method, which appears to be as accurate as blood-based screens, is already being used in Thailand and Indonesia, and the FDA is considering whether saliva-based tests should be marketed in the U.S.

Meanwhile, Epitope is working on applying its system to detect hepatitis, measles and ulcer-causing bacteria. It is also developing two at-home saliva tests for pregnancy. One can be used just five days after a missed period, the other after just 24 hours.

At least four other companies are working on fertility tests that would use saliva. Like blood and urine tests, these would predict ovulation by measuring a woman's hormone levels, principally of progesterone, as they change during her cycle. Because samples must be collected as frequently as every six hours for an entire month, saliva is much easier to deal with than urine.

And, finally, related tests are in the works for monitoring drug and alcohol abuse. Since no privacy is required to collect saliva, patients would have trouble tampering with or switching samples.

—David H. Freedman

er
because of its fat-
e your rear view
work your lower
, generally don't
s of the buttocks,

One way is to do this exercise. ■ Lie on your back with your knees bent and feet together flat on the floor, a comfortable distance from your buttocks. Place your palms on the floor for balance. ■ Keeping your neck relaxed, raise your hips two to three inches off the floor. Your upper back should remain on the floor; your stomach should stay lower than your hips. Be sure you don't arch your lower back during this pelvic tilt. ■ Slowly lower your hips close to the floor (don't rest by resting your butt on the ground). Concentrate on tightening your glutes as you raise your hips up to the top position. Try 16 repetitions.

For a more intense workout, try this move next: From the same starting position, lift your right leg up in the air with the knee slightly bent and foot flexed, sole parallel with the ceiling. ■ Keeping your foot aloft, slowly raise your hips a few inches and then lower them, as before. You should feel the burn in your left leg and glute. Start with eight repetitions with your right leg raised, then switch legs and repeat. As you get stronger, increase the number of repetitions until you can do 32 raises on each side. After both moves, stretch your buttocks by lying on your back and drawing both knees in toward your chest.

—Elena Rover

Move of the month

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

Mr. David Kessler
Food and Drug Administration
5600 Fishers Lane
Suite 14-17
Rockville, Maryland 20857

As of 1/4/94
unanswered

Dear Mr. Kessler:

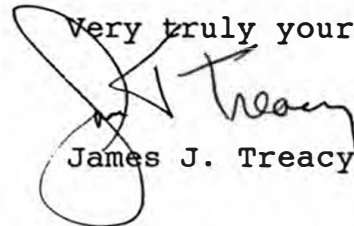
I have been closely following the events this week with regard to World AIDS Day and I was particularly taken by the statements made by Secretary Shalala during her November 30th news conference and President Clinton's December 1st address at Georgetown Medical Center.

President Clinton stressed early preventative measures and has asked the American Public what could be done to improve preventative work with regard to HIV. It appears to me that if you would take a personal interest in getting your Administration to approve OraSure immediately, it would be a great help for this cause.

It is hard to imagine why such an effective, cheap, easily distributable, private, early detection device would languish at the FDA for over 2 1/2 years. Could you please look into the circumstances covered by these attachments.

Thank you for your interest.

Very truly yours,


James J. Treacy

JJT:jf
attachments

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

Congressman Wyden
1111 Longworth
Washington, DC 20515

As of 1/4/94
Unanswered

Dear Congressman Wyden:

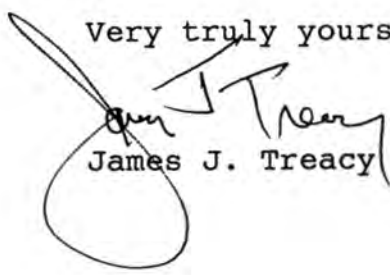
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In view of the statements made, it is somewhat puzzling that the Food and Drug Administration has been sitting on an effective, cheap, easily distributable, private, early detection device known as OraSure. Please refer to the attachments for some background.

Anything you can do to get the FDA on the move for immediate approval would appear sensible to me.

Thank you for your time and efforts.

Very truly yours,


James J. Treacy

JJT:jf
attachment

JAMES JOSEPH TREACY, JR.
117 ROOSEVELT PLACE
PALISADES PARK NJ 07650

HOME: (201) 585-1844
OFFICE: (212) 210-8033

December 2, 1993

Congressman Dingell
House Office Building
2328 Rayburn
Washington, DC 20515

As of 1/4/94
Unanswered

Dear Congressman Dingell:

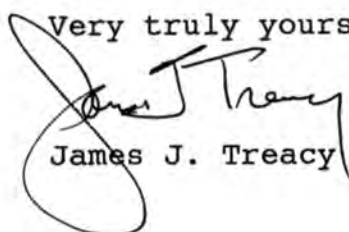
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Anything you can do to get the FDA on the move for immediate approval would appear sensible to me.

Thank you for your time and efforts.

Very truly yours,


James J. Treacy

JJT:jf
attachment

Public & Private

ANNA QUINDLEN

The Other Side

In the apartment a man and woman decorated a Christmas tree. They looped strands of lights around the branches, stood back to consider the effect, plugged them in so that colored stars danced in the darkness. From across the street we could see them, two panes of glass and a swath of asphalt away. We mourned our friend while those two strangers went about a different ritual.

Monday would have been Jeff Schmalz's 40th birthday, and he had intended to spend it dining well, as

The shadow of AIDS spreads.

was his wont, at Chanterelle. His memorial service was held at the restaurant instead. His friends and colleagues remembered him as a superb reporter and editor. And they spoke of the extraordinary work he had done, these last few years, as a gay man with AIDS covering the epidemic for *The New York Times*.

As we sat facing the restaurant window, listening to one and then another speak of Jeff, the couple across the way decorated their tree, insensible to us and our grief yet seemingly close enough to touch, framed in a rectangle of yellow lamp-light. And it came to me that they were a symbol of all of us who have gone about our business, the straight-world parallel universe, devoid of

passion and interest, that has left AIDS activism to the community of men decimated by disease.

"One day soon," Jeff wrote, "I will simply become one of the 90 people in America to die that day of AIDS." That day was Nov. 6. And one day soon you too will find yourself in the shadow of the plague, whose urgency has faded in this here-today-gone-tomorrow world. One day soon it will grip someone you know and love.

Here is the real domino theory: Gay man to gay man, bisexual man to straight woman, addict mother to newborn baby, they all fall down and someday it will come to you. The World Health Organization reports that 14 million are now infected and predicts 30 to 40 million as the millennium approaches.

"I suspect that for many of you tonight this is the first memorial service you have attended for someone who has died of AIDS," said Jeff's friend Adam Nagourney, a White House reporter for *USA Today*. "I can assure you that for me and my gay brothers and sisters here tonight, it is one of many; the most painful, to be sure, but still one of many. I also assure all of you, straight or gay, that this will most certainly not be the last one you will attend.

"You should be frightened," he added. "You should be angered — and, like Jeff, you should be driven to do something about it."

What? Anything, everything, and without the useless underpinning of Puritanism that has hobbled us the last 13 years. Yes, it is transmitted by sex. Yes, we take sexual risks. Will you care about any of that when your

son is dying, or your sister? We know what needs to be done: clean-needle exchanges, AIDS education for adolescents, money, research, agitation, information, everything.

But, as much as that, we need to care. Politicians, the people who allocate money, can scent apathy as though it were carrion. Make no mistake: The straight world's psychic remove will color how soon there is a cure. And the gay men who fight the fight grow ill and die.

In a posthumously published cover story in *The Times Magazine*, Jeff wrote, "The world is moving on, uncaring, frustrated and bored, leaving by the roadside those of us who are infected and who can't help but wonder: Whatever happened to AIDS?"

The answer is that Jeff left it to the rest of us, male and female, straight and gay, all of us who understand that the point of being human is the effort to care passionately about other human beings. The President spoke of Jeff in his speech on AIDS a week ago. "He challenged us all with these words in the article," Bill Clinton said. "'I am dying. Why doesn't someone help us?'"

If you knew Jeff, if you knew how witty and sardonic he could be, how self-sufficient and confident, you would feel those plaintive words as the rebuke they ought to be. But since you did not, I will only ask this: When it is your son's wasted face on the pillow, or your sister's, or your friend's — because for some of you it will surely, surely come to that — when they ask that question, what will you say? It is an important question. Will you have an answer? □

Administration Forms Panel To Hasten Work on AIDS

By PHILIP J. HILTS
Special to The New York Times

WASHINGTON, Nov. 30 — The Clinton Administration announced today that it would set up a working group to devise a new strategy to develop AIDS drugs.

The Secretary of Health and Human Services, Donna E. Shalala, said at a news conference that 12 years after the beginning of the AIDS epidemic "the sad fact remains that not a single new drug application for an anti-retroviral drug" is now before the Food and Drug Administration.

"It is time to refocus and re-energize our best minds for a concerted attack on this killer," she said.

Dr. David A. Kessler, the Commissioner of Food and Drugs, said: "We have never done anything like this before. We will have the Government and the industry and the AIDS community all sitting down together to develop strategy on AIDS drug development; collaboratively for the first time. We will discuss what drugs to look for, how to find them, what are the best leads now, and are we pursuing them as best we can."

Only three antiviral drugs, AZT, DDI and DDC, have been approved to fight AIDS. None of them can cure it.

Preventing Delays on Drugs

The new group, the Task Force on AIDS Drug Development, will be led by Dr. Philip R. Lee, the Assistant Secretary for Health, and will include 14 other members from drug companies, universities, the Government and AIDS groups. They will be named later by Secretary Shalala.

One goal will be to insure that the Federal Government does not delay approval of promising AIDS drugs because of outdated regulations or lack of communication among scientists, regulators and drug companies.

The announcement today, the day before World AIDS Day, was one of several the Administration has made recently to produce new momentum in combating AIDS.

On Wednesday President Clinton will speak on the disease and visit AIDS patients at Georgetown Medical Center in Washington. On Monday he had a breakfast meeting in the White House with 15 ministers, priests and rabbis from around the nation who have set up programs to help AIDS patients. Two weeks ago Mr. Clinton said that all Federal employees would be required to attend AIDS education classes.

Secretary Shalala said the Administration would soon announce a major prevention initiative, and officials have taken every opportunity to mention that the Administration has increased the AIDS research budget by more than 20 percent, to \$1.3 billion in 1994.

All of the Administration's top officials on AIDS and health care were at

the announcement of the new working group, and they fielded questions about whether a failure by the Government in combating AIDS had prompted formation of the group.

Wayne Turner, a member of Act Up, an AIDS advocacy and protest group, stood up and shouted, "Where's the Manhattan-style project that Bill Clinton promised us? Where is the action?"

Secretary Shalala replied: "We see this as taking action. None of this would be considered enough, but it is a significant step."

Derek Hodel of the AIDS Action Council, the Washington lobbying

Aiming for broad collaboration in the quest for an effective drug.

group for AIDS organizations, said: "This is an opportunity to do more. But we will hold this task force accountable for what it does or does not do."

Model in Industry Group

Dr. Lee said, "Too often in the past, needed links have been missing or relationships have been adversarial, resulting in unnecessary duplication of efforts or potential drugs not being developed and evaluated as rapidly as they might."

He said his group would be modeled on one created last April by drug companies. That group is led by the chairman of Merck & Company, P. Roy Vagelos.

Mr. Vagelos said that the group included research chiefs from several major companies and that for the first time in 50 years the companies were actually trading information with one another, on what new anti-AIDS products they were working on as well as how their testing was going.

Dr. Edward Scolnick, president of Merck Research Laboratories, said the industry group might soon lead companies to abandon one approach for another, letting one company that is far ahead take the lead on a drug while others redirect their research money to other promising projects.

The new Federal group is expected to be named and hold its first meeting by February or March.

More national news,
pages B8 to B10.

Page
A-21

NY Times

12/1/93

THE WHITE HOUSE
WASHINGTON

CM - do
what
I want
this?

January 12, 1994

Mr. Edward J. Kunuty
EUTRO Group Holding, Inc.
140 Intracoastal Pte. Drive
Suite 306
Jupiter, Florida 33477

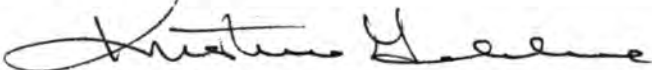
Dear Mr. Kunuty:

Thank you for sharing with me information about your HIV test. As you know, the Office of the National AIDS Policy was created out of the commitment of the President to take positive steps to stop the HIV/AIDS epidemic. Tests to detect HIV are critical in this effort.

I have forwarded the information to the Office of AIDS and Special Health Issues at the Food and Drug Administration (FDA), U.S. Department of Health and Human Services to determine the best course of action to pursue in relation to the information you provided.

Thank you again for writing.

Sincerely,



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

cc: Office of AIDS and Special Health Issues
Food and Drug Administration

EUTRO

Steve
draft reply

December 17, 1993

Ms. Kristine M. Gebbie
National AIDS Policy Coordinator
Executive Office of the President
750 17th Street N.W.
Suite 1060
Washington, DC 20503



DEC 21 1993

Dear Ms. Gebbie:

I recently saw you on a television show answering some questions about the President's position and policy on AIDS. After seeing the show, I thought I should share this with you. We are a small company that has acquired the license to produce a miniaturized HIV test. The test will significantly cut the cost of in-vitro HIV testing. There are numerous benefits to the test process, in essence, the test is simple, quick, and economical.

I'm writing because we are a small company, so capital for the next stage of development is scarce. Seeing you on TV prompted me to think in terms of a government grant to complete the project to the point where we can get a letter of equivalency from the FDA. The beauty of our process is that it uses existing technology, so it will not require a long approval process. This means we can have a low cost HIV test available in about one year. The key is for us to raise the needed funds to proceed.

We are seeking a grant that will fund us to the point of being ready to go to market with the product. I have started to write to some grant coordinators, but will need all the help we can get. Time is of the essence. The longer it takes to raise the money, the longer it takes to get the test in use.

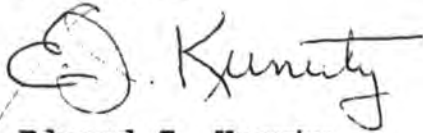
Everyone knows the first step in controlling the spread of AIDS is knowledge, this is a major step in that direction. This will make it not only possible, but economical for worldwide testing. Our analysis indicates that we can reduce the cost of a HIV test from approximate current cost of \$60 dollars to about \$10. In today's cost conscience healthcare environment, that means affordable testing for everyone.

Ms. Kristine M. Gebbie
Page 2
December 17, 1993

I've enclosed an executive summary of the Bio-Analytic product. Bio-Analytic is a wholly owned subsidiary of Eutro. Bio has the unrestricted worldwide license for the product. We are in need of funds to complete the development. If you can help us locate a grant or a strategic partner that allows us to bring this product to market, it will be a major breakthrough in controlling AIDS.

Thanks for your assistance. I look forward to hearing from you. Incidentally, I thought you handled the rather aggressive questioning on TV quite well.

Sincerely,

A handwritten signature in cursive script, appearing to read "E. J. Kunuty". The signature is written in dark ink and is positioned above the printed name.

Edward J. Kunuty

Enclosures

EXECUTIVE SUMMARY

With the increase in documented evidence being released regarding the spread of AIDS and the considerable attention being given to the skyrocketing cost of health care in the US, it's prophetic that Bio-Analytic Laboratories, Inc., a 22 year old diagnostic company stands ready to attack both problems.

Bio-Analytics a wholly owned subsidiary of Eutro Group Holding, Inc. has a license to manufacture a miniaturized *in-vitro* diagnostic test system incorporating a patented device. The system gives rise to a new branch of laboratory technology, Slide Immuno-Assay or SIA. SIA is based on the widely accepted principle of Enzyme-Linked Immunosorbent Assay (ELISA) as is Enzyme Immuno-Assay or EIA. The new process incorporates reagents that need no refrigeration or expensive electronic instruments to detect the presence of Human Immunodeficiency Virus (HIV) antibodies.

This test kit uses smaller volumes of reagents, has fewer assaying steps and shorter incubation periods than conventional methods. With its easy storage, lack of dependence on electrical energy to power support instrumentation and short assaying time requirement this product provides the company with the technology and pricing capability to supply a cost effective HIV test to the world. The second benefit comes from merely changing antibodies and antigens within the SIA test kits to create a variety of other rapid cost-effective tests e.g., hepatitis, sexually transmitted diseases and allergy testing, etc. thereby expanding SIA's potential for numerous additional mass testing but cost effective purposes.

Bio-Analytics has a long history of innovation in diagnostics. The company was formed in 1971 as a business for developing, manufacturing and selling, high quality and highly reliable, clinical diagnostic reagents, reagent test kits and supporting instrumentation for the clinical chemistry laboratory segment of the diagnostics market. Bio-Analytic is a well respected company with an established domestic and international base of business. Their facilities are adequate to develop and support the SIA program. Bio-Analytic was acquired in a reverse merger by Eutro Group Holding, Inc. in September, 1991.

Federal statisticians estimate that almost 19 percent of all HIV cases go unreported. Almost 50,000 Americans develop AIDS each year and soon 50,000 will be dying from AIDS annually. In Africa and Asia where people die from the disease even more quickly, (N.Y. times, June 28, 1992, p. E5) the infection is gaining momentum. The fact is that people who are tested and get good counseling are less likely to infect others. The only "vaccine" that is currently available is education, therefore identification is a critical element in order to deter the spread of this epidemic. For these reasons there is a need for a rapid, cost effective, screening test that can be offered worldwide.

Executive Summary

Page 2

If you look at appendix A it shows a typical microtiter plate currently in use in most laboratories. Relatively large reagent volumes are required for these tests. Also in appendix A is the SIA Technology Slide which requires reagent volumes of less than one-tenth the amount. This results in a significant reduction in the cost of expensive reagents.

The technology incorporates an enzyme-linked immunosorbent assay (ELISA) that is performed on the slide. The chemistry is similar to other commercially available ELISA tests and as such only a letter of "substantial equivalency" issued by the FDA after the 510 (k) submission is required. This should keep the approval cycle to a 90 day period. The slide technology patent is an innovation attributed to Dr. E. Conway de Macario on the staff of a prominent health research facility.

In order to complete the development and obtain the letter of substantial equivalency Bio-Analytics needs capital. We are seeking a grant that will allow us to complete the process and have this effective, easy, low cost and much needed test available for use. This is an investment that cannot be overlooked. The availability of this test will be a quantum leap toward controlling this dreaded virus. As stated earlier the only "vaccine" for this epidemic is education. The first step toward education is knowledge and this is the first step toward increasing knowledge of this disease.

For more information please contact:

EUTRO GROUP HOLDING, INC.
140 Intracoastal Pointe Drive
Suite 306
Jupiter, FL 33477

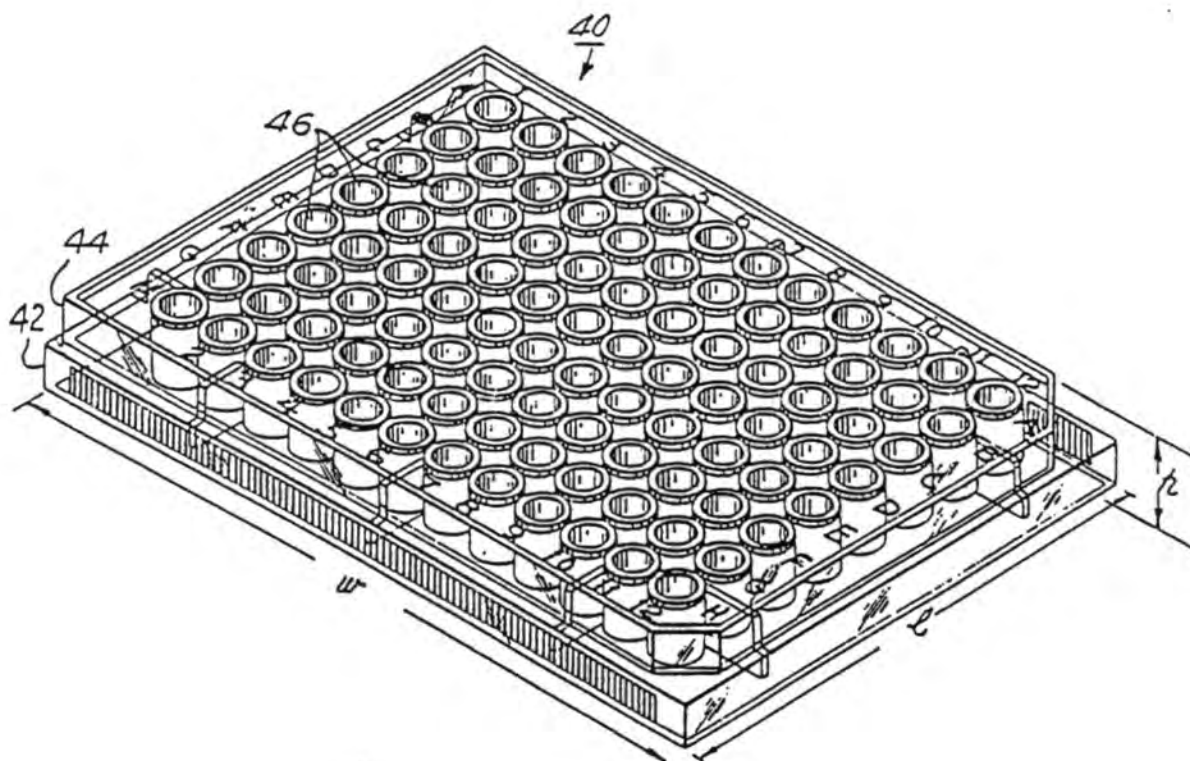
Tele: (407) 575-3520
Fax: (407) 575-0953
ATTN: EDWARD J. KUNUTY

OR

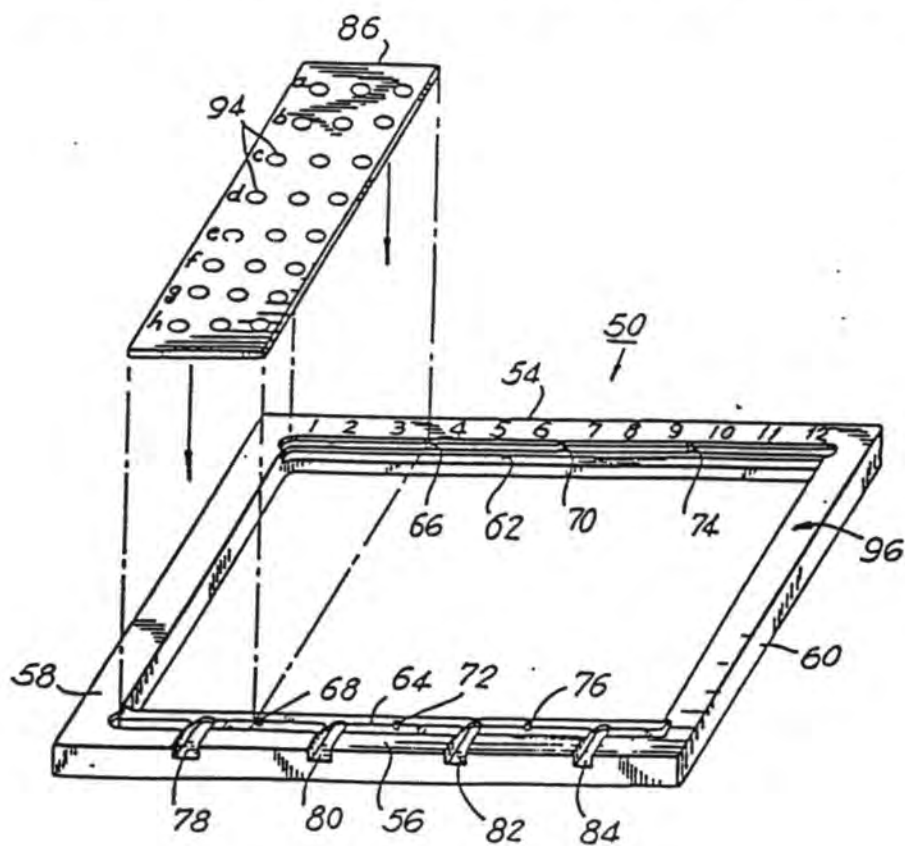
BIO-ANALITIC LABS, INC.
P.O. Box 388
Schoolhouse Road
Palm City, FL 34990

Tele: (407) 287-3340
Fax: (407) 287-3551
ATTN: DR. WILLIAM BARRY

TRADITIONAL MICROTITER PLATE



SLIDE IMMUNOASSAY (SIA) IN STANDARD MICROTITER FRAME



THE WHITE HOUSE

WASHINGTON

Steve -
202 -
2346728

January 12, 1994

Darlene A. Martin, R.N., Ph.D.
Associate Professor, Nursing Ethics & Policy
The University of Texas School of Nursing at Galveston
1100 Mechanic Avenue
Galveston, TX 77555-1029

Dear Ms. Martin:

This letter confirms the participation of Kristine M. Gebbie, National AIDS Policy Coordinator, at the "The Paradox of HIV/AIDS: Ethical, Legal, and Policy Issues in Caregiving," on March 3, 1994.

As we discussed, Ms. Gebbie plans to arrive at either late March 2 or early March 3 to deliver a keynote address on HIV/AIDS policy issues from a national perspective at 4:00 p.m. March 3, and to meet with the Galveston HIV/AIDS community. She will depart mid-morning Friday, March 4.

Please call me at (202) 632-1090 with any questions or for further clarification. I am enclosing a biographical sketch and curriculum vitae for your reference.

Sincerely,

W. Steve Lee, Executive Assistant
and Scheduler to the
National AIDS Policy Coordinator

Enclosures

The University of Texas Medical Branch at Galveston



School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals

November 2, 1993

Houston

Kristine M. Gebbie, RN, MN
Office of National AIDS Policy Coordinator
Executive Office of the President
750 17th St, NW, Suite 1060
Washington, DC 20503

Dear Ms. Gebbie:

We want to congratulate you on your recent appointment as the National AIDS Policy Coordinator and to tell you how pleased we are that you will be presenting the keynote address and the Kempner Lecture in Nursing Ethics at the national conference, **The Paradox of HIV/AIDS: Ethical, Legal, and Policy Issues in Caregiving**, March 3 and 4, 1994 at The University Texas Medical Branch, Galveston. Your presentation on HIV/AIDS policy issues is scheduled for March 3, 4:00 - 5:00 p.m. with a reception to follow. This letter is to confirm arrangements made between you and Dr. Phyllis Kritek your presentation. 5-7

We are very honored that you will be giving the main address. We expect the conference to be a substantive one that will foster thoughtful analysis and dialogue about paradigmatic issues. We are anticipating a diverse audience of approximately 250 persons including nurses, physicians, clergy, attorneys, AIDS Center staff, and Hospice workers. The conference is a special event sponsored by our new Center for Nursing Ethics and Policy.

We will be hosting a champagne reception on Thursday March 3 in your honor as the Kempner lecturer. Speakers, conference attendees, and community and state leaders will be our special guests. The reception will feature a display of art and photography by persons with HIV/AIDS as well as panels from the AIDS Quilt.

We appreciate your contribution of time and expertise to the conference. Travel, ground transportation and meal expenses during your stay will be reimbursed. We will arrange lodging for you and have the hotel direct bill us. Our CNE staff also will be pleased to assist you in making airline reservations. If made through our agent, we also can have airline tickets direct billed to us.

Please contact me at (409) 772-5029 (office) or (409) 744-4157 (home) or Phyllis Waters, Director of Continuing Nursing Education if we can be of any assistance. We will keep you and your staff updated as final conference plans are developed.

Again, thank you for finding time to include this event in your busy schedule. Everyone involved in the planning of this conference is very excited about your visit.

Sincerely,

Handwritten signature of Darlene A. Martin in blue ink.

Darlene A. Martin, R.N., Ph.D.
Associate Professor, Nursing Ethics & Policy
Conference Co-Chair

Handwritten signature of Phyllis J. Waters in blue ink.

Phyllis J. Waters, M.S., R.N.
Director, Nursing Joint Ventures/
Director, Continuing Nursing Education

The University of Texas Medical Branch at Galveston

School of Medicine
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals



*Fly into
Houston*

September 21, 1993

**Ms. Kristine Gebbie, National Aids Coordinator
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Room 738 G
Washington, D.C. 20503**

Dear Ms. Gebbie:

We are very pleased that you have consented to participate in our two day conference titled "The AIDS Experience: Ethical and Legal Dimensions". Based on a confirmation by your office, we have scheduled March 3 and 4, 1994 for this conference, and will be of course communicating with you concerning details. At this time I am writing to provide your office with written confirmation of this commitment to facilitate scheduling and planning.

We are very pleased that you are able to respond to this request. We anticipate attracting both a local and a more national audience for this conference, and believe it will be of great interest to many health care providers who can benefit from your expertise and from the focus on ethical and legal dimensions.

Thank you for your gracious responsiveness to our request.

Sincerely,

A handwritten signature in dark ink, appearing to read "Phyllis B. Kritek".

**Phyllis B. Kritek, RN, PhD, FAAN
Director, Doctor Program Development**

**cc: Mary Fenton, RN, Dr.PH,
Dean and Professor
Phyllis Waters, RN, MS,
Director, Nursing Joint Venture/CNE Assistant Professor
Darlene Martin, RN, PhD,
Director, Center for Nursing Ethics, Law & Policy**

THE WHITE HOUSE

WASHINGTON

January 12, 1994

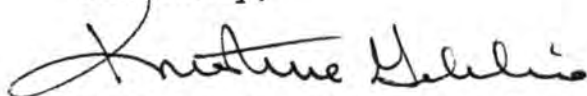
Sabine J. Beisler
Assistant Managing Editor
American Journal of Public Health
American Public Health Association
1015 15th Street, N.W.
Washington, D.C. 20002

Dear Ms. Beisler:

I am pleased to hear that you will publish my article in an upcoming issue of the American Journal of Public Health. The article, *Formulating Public Health Policy: The Case of AIDS* is an original paper and has not been previously published in whole or in part, and is not under publication consideration elsewhere. I am enclosing a signed copy of the federal employment statement.

If I can be of further assistance, please let me know.

Sincerely,



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

Enclosure

RECEIVED
JAN 5 1994

January 3, 1994



American Public Health Association

1015 Fifteenth Street, NW
Washington, DC 20005
202/789-5660

Mervyn Susser, MB, BCh,
FRCP(E), DPH
*Editor, American Journal
of Public Health*

Kristine M. Gebbie, RN, MN, FAAN
National AIDS Policy Coordinator
Office of National AIDS Policy
Executive Office of the President
750 Seventeenth Street, NW
Suite 1060
Washington, DC 20503

Re: #93/119E Formulating Public Health Policy: The Case of AIDS

Dear Ms. Gebbie:

I am glad to be able to tell you that the Editor has accepted your Editorial for an upcoming issue of the American Journal of Public Health.

You will soon receive a postcard with information on the approximate arrival date of your page proofs. We ask that you respond to the page proofs immediately.

Meanwhile, would you please sign and have all coauthors sign the enclosed copyright agreement form or, if appropriate, the federal employment statement.

We also need a short written statement signed by all authors indicating that the submitted paper or its essential substance has not been previously published and is not under publication consideration elsewhere.

Thank you for your help.

Sincerely,

Sabine J. Beisler
Assistant Managing Editor

cc: Dr. Susser

Enclosures

Notes to Authors:

Checking Your Tables, Figures, and References
for Publication in the
American Journal of Public Health

Journal space is at a premium; hence conciseness is valued highly and will increase your chances of acceptance.

Limit the use of tables and figures and format them correctly.

If your article includes tables and/or figures, please reexamine them and eliminate all that can be paraphrased in text or do not make a significant contribution to your paper. Those that must be included should be reviewed carefully for accuracy and conformance with formats presented in the *American Medical Association Manual of Style* (8th edition, 1989). Appendixes must be concise and should be included only when they provide essential information.

Prepare figures and photos for printing.

Figures should either be drawn professionally (and, ideally, made into photoprints, also called "glossies") or prepared on a computer and laser printed (dot matrix printouts are not acceptable because they lack definition). Photos should be in black and white and have a glossy finish. The recommended size is 5" by 7" or close to it.

Correct errors in citations.

Because many studies have found a high percentage of errors in reference lists, we ask that you check and verify your references. Please correct the following:

- Errors in the details of the citation (i.e., there are mistakes in the authors' last names or initials; the article title; the periodical volume, year, or page numbers).
- Errors in attribution (i.e., the reference fails to document the statement attributed to it).

Please check your references with the original source, not with another author's reference list, for these potential errors.

Additionally, please check conformance with the reference style presented in the *American Medical Association Manual of Style* (8th edition, 1989).

Thanks!



AMERICAN JOURNAL OF PUBLIC HEALTH

OFFICIAL JOURNAL OF THE

American Public Health Association

1015 Fifteenth Street, NW

Washington, D.C. 20005

(202) 789-5600

RE: MS# 03/119E FORMulating Public Health

Date: 11/3/94

Dear: Ms. Gebbie:

Please ask each author to read and sign one (1) of the statements below on copyright transfer or federal employment. If necessary, photocopy this document to distribute to co-authors for their signatures. Please return all copies promptly to the above address.

COPYRIGHT AGREEMENT

In compliance with the Copyright Revision Act of 1976, effective January 1, 1978, the American Public Health Association (APHA) in consideration of taking further action in reviewing and editing your submission, requests that each author sign a copy of this form before manuscript review can proceed. Such signatures shall evidence the mutual understanding between the APHA and the undersigned author (s) thereby transferring, assigning, or otherwise conveying all copyright to the APHA.

In consideration of the action of the APHA in reviewing and editing this submission, the authors undersigned hereby transfer, assign, or otherwise convey all copyright ownership to the APHA in the event that such work is published by the APHA.

Author(s) Signature(s)

Date Signed

US FEDERAL EMPLOYEES: If you prepared this manuscript as an employee of the US Federal Government, please so indicate by signing the following statement: I was an employee of the US Federal Government when this work was investigated and prepared for publication; therefore it is not protected by the Copyright Act and there is no copyright of which the ownership can be transferred.

Author(s) Signature(s)

Date Signed

Kristen M. Williams 1-5-94

JAN 12 1994

THE WHITE HOUSE

Dear Joan

Many thanks for the dinner, and the wonderful visit. I'm so enthused about what is happening at StLU & the possibilities for the future - Keep up the good work! Kristine

THE MILTON S. EISENHOWER FOUNDATION

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Mimi Silbert
Elizabeth Sturz
Roger W. Wilkins

January 15, 1994

Kristine H. Gebbie
7296 HHH
National AIDS Policy
Coordinator
Executive Office of the
President
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500



JAN 24 1994

Dear Ms. Gebbie:

The Honorable Henry G. Cisneros, U.S. Secretary of Housing and Urban Development, will be the Keynote Speaker for the Foundation's Benefit Dinner and Policy Forum on January 27 at the Mayflower Hotel in Washington, DC. The event will honor the twenty-fifth anniversaries of the Katzenbach Crime Commission, the Kerner Riot Commission and the Eisenhower Violence Commission, which were convened by President Lyndon B. Johnson.

We hope you can attend as our guest. Enclosed is an invitation. Please return the response card by January 24 if you would like to attend, so that we can reserve a complimentary ticket for you. Inquiries should be directed to Ms. Alfreda Edwards at (202) 789-3545.

The Mistress of Ceremonies will be Carole Simpson, Correspondent for *ABC News*, who has done excellent reporting on programs that work for children and youth.

The Co-Chairs of the Honorary Committee are Ms. Kerry Kennedy-Cuomo and Mr. James Rouse, Chairman of the Enterprise Foundation.

Other speakers and honorees include: Dr. Roger W. Wilkins, Congresswoman Maxine Waters, former Counselor to President Carter Lloyd N. Cutler (who was Executive Director of the Eisenhower Violence Commission), former U.S. Senator Fred R. Harris (who was a Member, and former Attorney General Nicholas deB. Katzenbach (who was Chair of the Crime Commission).

The Eisenhower Foundation is the private sector continuation of the National Commission on the Causes and Prevention of Violence and the National Advisory Commission on Civil Disorders. It is dedicated to implementing and replicating in American inner cities what Václav Havel calls "the butterfly effect," of comprehensive interdependence among child development, youth development, family strengthening, education, job training and placement, economic development and community policing. The Foundation publishes policy analyses, sponsors policy forums, evaluates replicated inner city programs and undertakes international exchanges.

TRUSTEES

THOMAS D. BARR
Partner
Cravath, Swaine & Moore
New York, NY

ROBERT E. DUKE
Director
Fund for the Metropolitan Museum of Art
New York, NY

YVONNE SCRUGGS
Director
Urban Policy Institute
Joint Center for Political and
Economic Studies
Washington, DC

GILBERT BONNEMAISON
President
European Forum of Local
Authorities for Urban Safety
Paris, France

M. ISOLINA FERRE
Founder
Centro Sister Isolina Ferre
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President
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San Francisco, CA

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Maurice Falk Professor
Yale Child Study Center
Yale University
New Haven, CT

FRED R. HARRIS
Professor
Department of Political Science
University of New Mexico
Albuquerque, NM

ELIZABETH STURZ
President
The Argus Community
Bronx, NY

ELLIOTT CURRIE
Professor
University of California, Berkeley
Berkeley, CA

BERNARD W. KINSEY
Chief Operating Officer, Rebuild L.A.
President, KBK Enterprises, Inc.
Los Angeles, CA

SOJI TERAMURA
Chief Executive Officer
Teramura International, Inc.
Washington, DC

LYNN A. CURTIS
President
The Eisenhower Foundation
Washington, DC

HARRY C. McPHERSON, JR.
Partner
Verner, Lipfert, Bernhard, McPherson &
Hand
Washington, DC

ROGER W. WILKINS
Clarence J. Robinson Professor
of History and American Culture
George Mason University
Fairfax, VA

JOY G. DRYFOOS
Independent Researcher & Author
Hastings on Hudson, NY

MARILYN MELKONIAN
President
TELESIS
Washington, DC

MARVIN E. WOLFGANG
Director
Sellin Center for Studies in
Criminology & Criminal Law
University of Pennsylvania
Philadelphia, PA

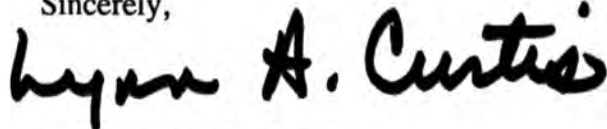
LULU MAE NIX
Executive Director
National Institute for Integrated Family
Services, Inc.
Camden, NJ

Page 2

In large part, the policy recommendations of these commissions are even more relevant today, especially in light of the President's recent speeches (in Los Angeles and Memphis) on crime and the First Lady's speeches concerning violence. The Forum's speakers will address the relevance of the commissions' recommendations to the policy of the Clinton Administration.

I hope you will join us for this celebration of hope.

Sincerely,

A handwritten signature in black ink that reads "Lynn A. Curtis". The signature is written in a cursive, flowing style.

Lynn A. Curtis, Ph.D.
President

Enclosure

THE WHITE HOUSE
WASHINGTON

January 13, 1994

A. Arthur Gottlieb, M.D.
President and Scientific Director
IMREG
Suite 1400
144 Elk Place
New Orleans, Louisiana 70112

Dear Dr. Gottlieb:

Thank you for sharing the additional information on your HIV therapeutic with me. It was also nice to see you at the Institute of Medicine Roundtable in December.

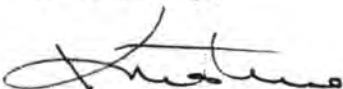
As National AIDS Policy Coordinator, I am devoted to the development and implementation of policies that will expedite the search for new HIV/AIDS therapies. I am working very closely with the Secretary of Health and Human Services, the Food and Drug Administration and the National Institutes of Health on the National Task Force on AIDS Drug Development, which I will not allow to become a mere bureaucratic space-filler.

I urge you to continue to work with the Food and Drug Administration on the issues you raised. It would be inappropriate for me to issue a statement such as the one you suggest.

I would also recommend you provide a written report to the National Task Force on AIDS Drug Development about the barriers or obstacles that you have identified in product development. While the Task Force cannot address product specific issues, it would help in our mission to remove these barriers.

Thanks again for writing.

Sincerely,



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

December 27, 1993

ACTION MEMORANDUM

TO: Alice Litwinowicz

FROM: W. Steve Lee

SUBJECT: Action items

DATE REQUIRED: January 5, 1994

The following items need your attention:

Letter from Arthur Gottlieb (December 20) on IMERG-1 FDA trial and approval. Needs a response drafted for KG's signature. Letter from 10/19 also attached.

Letter from Edward Kunuty (December 17, 1993) on HIV testing. Needs a response drafted for KG's signature.

IMREG



Suite 1400
144 Elk Place
New Orleans, LA 70112
(504) 523-2875
Telecopier: (504) 523-6201

DEC 22 1993

20 December 1993

pull prior correspondence
I think Alice drafted 1st reply
ask her to look at Alice's d. 1- ft
By Airborne

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
Executive Office of the President
200 Independence Avenue, SW, Room 738G
Washington, D.C. 20201

Dear Ms. Gebbie:

I am pleased that we had the opportunity to speak with you further, albeit briefly, at the Institute of Medicine Roundtable held in Washington on December 10, 1993. Indeed, I had intended to write to you in reply to your letter of October 19, 1993 which I found very disappointing.

It seems to me that perhaps I had not made clear what we were trying to achieve, and why an appropriate letter of support from a senior governmental official is critical to our survival and our ability to take our important therapeutic initiative in the area of immune-based therapeutics for HIV disease forward. From our discussion in Washington, I gather that you were not cognizant of the acute financial situation we face. I must say that the root of our difficulty goes back to the unconscionable actions in 1988-89 of some FDA and NIH staff who were responsible for creating a serious and undeserved credibility problem for us in the eyes of the investment community and potential strategic partners. This occurred despite the merits of our drug as documented by the FDA's Advisory Committee's judgement that IMREG®-1 may have an effect in HIV disease, the publication of the results of our clinical trial in the Annals of Internal Medicine (after critical peer review), and the judgment of an independent group of distinguished experts in the field whose names are appended to the Annals article.

What is very simply needed now is a statement from a senior governmental official that clears the air by: (1) Restating the Advisory Committee consensus that IMREG®-1 "may have an effect" in HIV disease (2) Indicating that this biologic deserves a fair and objective test in patients with HIV disease, pursuant to the clinical trial protocols that have been approved by FDA, and further indicating that (3) It is important, in light of the need to find new therapeutics that focus on the state of immune dysfunction in HIV/AIDS, that this testing get underway as soon as possible. I see nothing inappropriate about such a statement and am really perplexed by your view on this matter, particularly in light of the statements from Secretary Shalala and the President regarding the Administration's commitment to deal with the HIV/AIDS problem. Hopefully these statements and the appointment of the new Task Force on AIDS Drug Development are not merely symbolic, and the Administration ought to be able to see itself clear to making the aforementioned statement which will permit us to go forward and does not cost the government anything. We are a very good example of how governmental actions (or lack of action) can impair an important therapeutic initiative in HIV disease, and I submit this is a national AIDS policy issue which is appropriate to your charge.

I have enclosed two recent letters to FDA Commissioner David A. Kessler which I would urge you to review. If you feel unable to issue a statement from your office, then perhaps you might consider supporting the Commissioner in making a statement along the lines I have suggested in my letter to him of December 2, 1993.

I think it critical that all those in the federal government who are dealing with the problem of HIV/AIDS recognize the following:

- (1) Reestablishing control of the defective immune system in these patients is critical to control of this disease, irrespective of any antiviral approaches.
- (2) The antiviral drugs developed to date are very disappointing. Not only does the virus get the better of them, but they concomitantly depress the immune system which is exactly what one does not want to do.
- (3) I have known since my initial work on IMREG®-1 nearly 14 years ago that this biopharmaceutical had very potent effects on cell-mediated immunity. With my colleagues, I have repeatedly shown this, including a demonstration of this fact in a laborious structured, blinded, controlled validation study designed by FDA.
- (4) No other drug or biologic, in the class of immune-based therapeutics, has given the important results we reported in the Annals of Internal Medicine.
- (5) Since it is now recognized that it is essential that drugs affecting cell-mediated immunity be developed and tested, it is simple logic and compelling public policy that this drug be given a fair test without delay. It is five years since the Advisory Committee urged the FDA and the Company to work together to get this clinical trial underway "expeditiously".
- (6) We have not received one cent in federal money to date - compare that with the \$400 plus million spent by NIH on AIDS drug development which has yielded little of real value.
- (7) To be blunt, the federal government could readily justify a sole source contract of \$20 million to have IMREG®-1 tested in the clinical protocols which FDA has approved, based on what we have shown to date. Per your suggestion, I have written to Dr. Jack Killen at NIH on this point. I have received no reply.

Finally, as I told you in Washington, it will not be a good example of Administration policy in the areas of technology development, small business support and HIV/AIDS if we are forced to close the door because of the failure of

Kristine M. Gebbie, RN, MN
Executive Office of the President

20 December 1993
page 3

the government to issue a simple statement of support that will permit this important therapeutic initiative to go forward.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Arthur Gottlieb".

A. Arthur Gottlieb, M.D.
President and Scientific Director

Professor and Chairman
Department of Microbiology and Immunology
Tulane University School of Medicine

AAG/jn
enclosures

THE WHITE HOUSE
WASHINGTON

October 19, 1993

A. Arthur Gottlieb, M.D.
IMREG Inc.
Suite 1400
144 Elk Place
New Orleans, Louisiana 70112

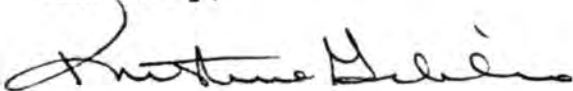
Dear Dr. Gottlieb:

Thank you for the update on your correspondence with the Food and Drug Administration (FDA). I am glad that you received the letter you were anticipating.

Because I was not a part of the earlier activity and am not a part of the regulatory structure, I do not find it appropriate to send a letter such as you suggest.

I do wish you well in your continuing research and development. Please let me know how things go in the future.

Sincerely,



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

Thank you for the update
on your correspondence
with the FDA. I'm glad that
~~things are proceeding~~
you received the letter you
were anticipating.

Because I was not a
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me know how things go in
the future. Sincerely

THE WHITE HOUSE

WASHINGTON

October 19, 1993

A. Arthur Gottlieb, M.D.
IMREG Inc.
Suite 1400
144 Elk Place
New Orleans, Louisiana 70112

Dear Dr. Gottlieb:

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Because I was not a part of the earlier activity and am not a part of the regulatory structure, I do not find it appropriate to send a letter such as you suggest.

I do wish you well in your continuing research and development. Please let me know how things go in the future.

Sincerely,

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

Prepared by: APO: KMGebbie: gw: 10/19/93: 632-1090: b:\gottlieb.019

THE WHITE HOUSE

SEP 20 1993

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	COPY	SURNAME	DATE

IMREG

Suite 1400
144 Elk Place
New Orleans, LA 70112
(504) 523-2875
Telecopier: (504) 523-6201

29 September 1993

Ms. Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
The White House
Washington, D.C. 20201

Dear Ms. Gebbie:

Thank you for your recent letter advising me that a letter from the FDA was being sent to us. I certainly appreciate your follow-up on this matter. We did, indeed, receive such a letter which I have enclosed. As you can see, it contains several positive statements restating prior FDA statements or conclusions.

Most importantly, thank you for such a warm and encouraging meeting when Mr. G. Wayne Smith and I came to your office. You not only have the background and experience to tackle these difficult problems, but you also have a keen awareness of the levels of frustration the AIDS scientific community faces in our ongoing relations with the U.S. Government. I was particularly appreciative of the opportunity to review some of the specific difficulties we had faced.

Without an improvement in the communication and the relationship with the key agencies overseeing AIDS research, advances in meeting the challenge of this disease will, of necessity, be impeded. During our meeting, you seem to have identified this as a more significant problem than you originally thought. This realization may result in one of the most significant contributions to AIDS success yet.

In short, we are very impressed with you and we stand ready to assist you in any way.

In the meantime, we are continuing to seek private capital which is essential to initiate the pivotal clinical trial of IMREG®-1 in HIV disease which was recommended by the FDA Advisory Committee.

During our discussion, I indicated that it would be very helpful if I could receive a letter from you restating the main message of the FDA letter and indicating the importance of our therapeutic initiative. Naturally, you need not be as specific as the FDA letter, since you were not involved in those procedures.

We are attaching a suggested draft letter for your consideration. We hope that we can work together with your office to achieve our mutual goal of moving forward toward the objective of obtaining effective therapeutics for HIV disease.

Ms. Kristine M. Gebbie, RN, MN
The White House

29 September 1993
page 2

Thank you for your dedication and devotion to this new important assignment
President Clinton has chosen to give to you.

Yours sincerely,

A handwritten signature in dark ink, appearing to read "Arthur Gottlieb", written in a cursive style.

A. Arthur Gottlieb, M.D.
President and Scientific Director

AAG/jn
enclosure

cc: Mr. G. Wayne Smith



Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

AUG 12 1993

Our Reference: BB-IND 1711

A. Arthur Gottlieb, M.D.
President
IMREG
Suite 1400
144 Elk Place
New Orleans, LA 70112



Dear Dr. Gottlieb:

The purpose of this letter is to summarize the status of the proposed clinical trials entitled "Effectiveness and Safety of IMREG-1 in the Treatment of Subjects Asymptomatic with Infection with the Human Immunodeficiency Virus," and "Effectiveness and Safety of IMREG-1 in the Treatment of Subjects Symptomatic with Infection with the Human Immunodeficiency Virus." These trials will follow up the recommendations of the FDA's Vaccines and Related Biological Products Advisory Committee, which, in April 1989, found that IMREG-1 may have an effect on the disease. The committee at that time recommended that a second controlled trial of IMREG-1 be carried out.

We have received protocols for the clinical trial which have been revised, in accordance with FDA/CBER's prior recommendations and comments. These revisions have resulted in acceptable clinical protocols without the need for further revision.

Accordingly, the Company may plan to proceed with the clinical trial of IMREG-1 pursuant to the aforementioned revised protocols. In accordance with applicable regulations, FDA/CBER must receive acceptable documentation of the following: (1) validation of the potency assay which CBER has approved for this purpose and which has been constructed by the Company and CBER on the basis of earlier studies of biological activity of this agent, and (2) the potency of the lots to be tested for efficacy in this clinical trial.

Sincerely yours,

Janet Woodcock, M.D.
Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Suggested Draft

I was pleased to have the opportunity to review the status of the biopharmaceutical IMREG®-1 with you, during our meeting on August 11, 1993. I understand that the FDA's Vaccines and Related Biological Products Advisory Committee has previously determined that IMREG®-1 may have an effect in HIV disease and that this Advisory Committee recommended that a second controlled trial of IMREG®-1 be carried out in patients with HIV disease.

It does seem to me that this is a very important therapeutic initiative in HIV disease/AIDS, particularly in light of the urgent need to find therapeutic agents that focus on treating the state of immune dysfunction which is seen in this disease. I understand that FDA has informed you that the protocols for this important clinical trial have been deemed acceptable by FDA. I think it is quite important that this major clinical trial of IMREG®-1 in a broad population of patients with HIV disease get underway in the near future.

Your Company is certainly to be commended for having brought this therapeutic initiative to this point. As you know, the Administration is committed to enabling small business and technology development. These policy objectives are particularly relevant in the instance of a small company, such as yours, where the technology addresses a disease of major public health concern.

I hope you will call on me, if I can further assist you in the achievement of your objectives.

Yours sincerely,

15 December 1993

David A. Kessler, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

BB-IND-1711

Dear Dr. Kessler:

I must ask for your urgent attention to the following: On December 2, 1993 I wrote to you concerning our status. A copy of that letter is enclosed. Having not heard from you, and in view of recent developments and our critical situation, I am compelled to follow-up in the hope that you will take the appropriate action I suggested in my December 2 letter. I regret the necessity to be blunt, but our situation has important public policy as well as regulatory implications, and we are not in a position to temporize.

Since beginning to work with Ms. Amanda Pedersen in September 1991, I have tried to convey the serious problem we have regarding the continuing impression in the public mind, as reflected by many parties, that the FDA "has it in for the Company" and while the Agency will appear to treat us in a professional manner, it has no intention of permitting the IMREG®-1 therapeutic initiative to go forward, and will continue to put obstacles in its way. I recognize, of course, that neither you nor I are responsible for these impressions and I trust that you would not agree with them. Nevertheless, we must in fact deal with the reality of the perceptions that are out there. For this reason, I have tried to get a clear statement from your office as suggested in my December 2 letter, to correct these damaging perceptions. Although, I had been led to believe, as a result of my discussions with FDA staff, that the Agency does not endorse or otherwise comment on investigational drugs, such an asserted policy is not consistent with the following recent actions of the Agency which have come to my attention:

- Item - At the Institute of Medicine Roundtable for the Development of Drugs and Vaccines against AIDS, held in Washington, last Friday, December 10, 1993, Dr. Kathryn Zoon, the Director of CBER, in her presentation entitled, Regulatory Perspective on Development and Evaluation of Immune-Based Therapies, referred to the investigational cytokine Interleukin-12 and stated that "we (the FDA) will look with enthusiasm as to what IL-12 may offer" and further that "we will follow IL-12 with enthusiasm". I attended this meeting and personally heard these remarks.
- Item - The September 1, 1993 issue of the Journal of Immunology contains an article on IL-12 entitled, "Effects of IL-12 on the Generation of Cytotoxic Activity in Human CD8+ T Lymphocytes." The authors of this article are all members of CBER and are so identified. The abstract of this article (enclosed) states ".....that IL-12 may play an important immunoregulatory role on CTL development in vivo and may be a useful tool for manipulating this process in vivo for investigational and immunotherapeutic purposes".

We view these statements as positive statements made by FDA staff about another investigational biologic. We are unable to understand why statements of this kind are being made by the Agency about IL-12 which, as far as we know, has not been put into a single patient or test subject. In contrast, the Agency appears unwilling to issue a constructive statement of this type on our behalf, notwithstanding that: (1) We have tested the IMREG®-1 biopharmaceutical in some 300 patients for periods of six months to 4 1/2 years, (2) Your own Advisory Committee reached a consensus that IMREG®-1 may have an effect in HIV disease, (3) Important indications of clinical benefit were seen in our initial controlled trial, the results of which were published in the Annals of Internal Medicine (July 1991). No toxicity was observed. (4) Protocols for a second controlled clinical trial in a broad population of HIV infected patients have been approved by CBER, (5) The professional reputations of the principals of our Company were severely damaged by FDA and NIH staff in 1988. It would almost seem as if certain drugs or biologics have "Most Favored Drug" (MFD) status, while others do not. It would appear that such status was conferred on AZT and it appears that IL-12 is another agent in this category.

It seems to me that the Agency should not assume the cloak of impartial objectivity, asserting that it can not make statements on behalf of a particular agent, while having FDA staff make public statements of "enthusiasm" for another biologic.

I must reiterate that our difficulties began in 1988-89, at which time this Company was the subject of a variety of malicious rumors and leaks arising from within FDA and NIH, alleging improprieties and irregularities in the conduct of the initial controlled trial of IMREG®-1 in HIV disease, and in the resultant database from the clinical trial. These allegations were without any foundation. Additionally, after the FDA Advisory Committee on Vaccines and Related Biologics had thoroughly reviewed that clinical trial and allegations thereto, the Committee reached a clear consensus, on the public record, that the drug (IMREG®-1) may have an effect in HIV disease. Notwithstanding that clear consensus, the Wall Street Journal reported (on the basis of a statement by an FDA spokesperson) that the Advisory Committee had concluded that the drug had no effect. The impression gleaned from that report, and the antecedent scenario, have created a climate of suspicion in the sophisticated biotechnology investment community and the pharmaceutical industry, about the Company's relationship with the FDA, and has severely limited the Company's access to the capital markets and strategic corporate partners.

It is essential that you be aware of the damage that we have sustained, as a result of the events of 1988-89. We continue to this day to be plagued by these misimpressions. The only way that I now see to salvage this situation is for your office to make a statement along the lines I suggested in my December 2 letter. Indeed, although I had also suggested in that letter that we might make a statement along those lines, and that we did not see a basis for the Agency to object to that course of action, I must say that in light of Dr. Zoon's public statement on IL-12 (above), any statement by us would now do little good since the endorsement of IL-12 by Dr. Zoon has created another credibility problem for us.

Finally, I noted, in your recent appearance on the ABC program "Day One" that you made or concurred with two important points: (1) that the original clinical trial of AZT was flawed, and (2) that the Agency "must take some risks"

if drugs for HIV (AIDS) are to be developed. You are correct on both of these points. Since no toxicity has been observed with the IMREG®-1 biopharmaceutical, there is little (if any) risk in permitting the CBER approved clinical trial of this agent to go forward and to make a statement to the public along the lines of that outlined in my letter of December 2nd. If there is risk, it is in not enabling IMREG®-1 to receive the fair and objective test it deserves, based on the consensus of your own Advisory Committee. I note that you have spoken of flexibility in FDA's approach to the development of HIV/AIDS therapeutics. Certainly, one element of good public policy in this area would be to ensure that Agency policy or practice does not make it impossible for an initiative in HIV/AIDS such as ours to proceed.

Yours sincerely,



A. Arthur Gottlieb, M.D.
President and Scientific Director

Professor and Chairman
Department of Microbiology & Immunology
Professor of Medicine
Tulane University School of Medicine

AAG/jn
enclosure

cc: Amanda Pedersen, Esq.

2 December 1993

David A. Kessler, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

It is over two years plus since my last direct communication to you regarding our investigational biopharmaceutical, IMREG®-1. My last letter of 9 July 1991 summarized a number of concerns and I am pleased that with the help of Ms. Amanda Pedersen of your office, a number of issues have indeed been resolved. Bearing in mind the finding and recommendation of the FDA's Vaccines and Related Biological Products Advisory Committee, given nearly five years ago, that IMREG®-1 may have an effect in HIV disease and that a second controlled clinical trial should be carried out expeditiously, we and FDA staff have worked interactively to achieve this objective.

As noted in my letter of 9 November 1993 to Dr. Woodcock (copy enclosed), we have met the requirements stipulated in CBER's letter of November 28, 1991 with regard to what we had to do in order to conduct the clinical trial recommended by the Advisory Committee. In particular, the protocols for this clinical trial have been approved by CBER, and data from the potency validation study indicates that this biopharmaceutical enhances delayed type hypersensitivity which is, of course, a direct manifestation of human cell-mediated immunity. I had withheld further direct contact with you until data from the validation study had been obtained and it had been shown that biological activity could be clearly demonstrated against placebo. We recognize, of course, the importance of having the potency validation data which we have submitted prior to proceeding with the aforementioned clinical trial. As well, we understand that there are several product matters which will need to be addressed prior to filing a Product License Application. However, given the absence of toxicity of this biopharmaceutical we think the clinical trial deserves to go forward expeditiously, subject to applicable regulations which pertain to lot release and which apply to all Sponsors.

As you are well aware, there has been a major change in recent months in the thinking within the medical-scientific community about HIV/AIDS therapeutics. In particular:

- (1) It is recognized that the major thrust on antivirals has given disappointing results.
- (2) Cell mediated immunity is clearly disordered in HIV disease. This is reflected in the progressive loss of DTH responsiveness to recall antigens. In turn, the absence of DTH is predictive of progression to AIDS (Annals of Internal Medicine, August 1993).

- (3) In light of (1) and (2), it is now recognized that there must be a major effort to develop drugs or biologics that impact on the state of immune dysregulation in this disease. This is, in fact, a theme that I have sounded for several years.

We think it important to note that the results obtained in our initial placebo controlled trial of IMREG®-1 in patients with AIDS Related Complex, as described in the Annals of Internal Medicine 115:84 (1991), are certainly consistent with, and would be expected from, the observation that IMREG®-1 enhances delayed type hypersensitivity, a direct indication of the action of this agent on the cell-mediated immune system.

I have been impressed by your commitment, as reported in the media, to cut regulatory red tape and speed approval of promising HIV/AIDS drugs. As is evident, we are a very small Company with very limited resources. In order to fulfill the recommendation of the Advisory Committee that a second controlled clinical trial be carried out, we must obtain the necessary resources to support the trial. Our particular situation is very tenuous and in order that this important therapeutic initiative be taken forward, there is a need for a statement from your office which indicates that this clinical trial deserves to go forward and clarifies any misunderstanding that may exist in the public mind (including the sophisticated biotechnological investment community) regarding the attitude of the FDA to this Company and the IMREG®-1 investigational biopharmaceutical. I hope you will agree that it would be highly desirable to eliminate the us (Company) vs. them (FDA) perception which had unfortunately been generated by past events, and that we can convey the message to the public that the Company and the Agency are working together to give the IMREG®-1 biopharmaceutical the fair and objective test it deserves. While we have received a letter from Dr. Janet Woodcock dated August 12, 1993 which is helpful, and we certainly appreciate her help as well as that of Ms. Amanda Pedersen, we now feel that a statement from your office is appropriate and necessary in order to ensure that the Advisory Committee's recommendation for a second clinical trial is carried out. The following are the components of what we believe is an appropriate statement, under the circumstances:

- (1) Pursuant to the Advisory Committee finding that IMREG®-1 may have an effect in HIV disease, and its recommendation that a second controlled clinical trial of this biopharmaceutical should be carried out to confirm efficacy, protocols for such a clinical trial in a broad population of patients with HIV have been constructed by the Company and approved by FDA.
- (2) The Company may now proceed with the clinical trial, pursuant to applicable regulations. The Agency believes it important that this second controlled clinical trial be carried out as soon as possible, within the context of the critical need to find and test drugs that impact on the immune dysfunction that is seen in this disease.

David A. Kessler, M.D.
U.S. Food and Drug Administration

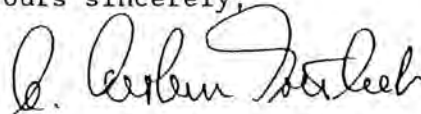
2 December 1993
page 3

- (3) FDA would be willing to consider an application for a Treatment Protocol (Expanded Use, Parallel Track), once the clinical trial is underway and adequate enrollment has occurred. This course of action had been previously suggested by former Commissioner Frank E. Young, M.D.
- (4) A clear statement which indicates that the Company will receive fair, objective and timely review of matters pertaining to the clinical trial and the resultant data, and negates allegations to the contrary from whatever source. The Agency will continue to assist the Company in meeting all Agency regulations along the accelerated approval pathway for HIV/AIDS therapeutics.

Our thinking is that such a conservative statement is appropriate and clearly warranted under the circumstances. Should you feel that the Agency can not make a statement of this kind, it is our intention to issue a comparable statement on our behalf - in that scenario, we would see no basis for the Agency to object and we would ask for your concurrence on this point.

I am, of course, available to meet or speak with you at any time.

Yours sincerely,



A. Arthur Gottlieb, M.D.
President and Scientific Director

AAG/jn
enclosure

*Ltr to Woodcock
dated 11/9/93*

THE WHITE HOUSE
WASHINGTON

January 13, 1994

MEMORANDUM TO ROBERT RUBIN, Assistant to the President for
Economic Policy, National Economic Council

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

SUBJECT: Business response to the effects of AIDS on the economy

Ms. Bluma Appel, Chairperson of the Canadian Foundation For AIDS Research has met with me regarding her proposal for a joint U.S./Canadian meeting of representatives of business and industry on the economic effects of AIDS, not only to the loss of worker productivity but also regarding effects on consumer buying.

Ms. Appel has had discussions with Wilbur Hawkins, Deputy Assistant Secretary for Economic Development at Commerce and the Assistant Secretary-Designate William Ginsberg. She is also working with their counterparts in Canada to make this a joint cooperative effort.

At some point, we will need to work with your staff to ascertain some of the information necessary to help pull this meeting together and make it worthwhile and productive. Could you please let me know who on your staff should be our liaison for this and other issues that may arise in this area? Our contact person here is Andrew E. Barrer, Ph.D. (telephone: 632-1090).

Thank you for your cooperation and assistance.

THE WHITE HOUSE
WASHINGTON

January 13, 1994

MEMORANDUM TO LAURA TYSON, Chairperson
Council of Economic Advisors

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

SUBJECT: Business response to the effects of AIDS on the economy

Ms. Bluma Appel, Chairperson of the Canadian Foundation For AIDS Research has met with me regarding her proposal for a joint U.S./Canadian meeting of representatives of business and industry on the economic effects of AIDS, not only to the loss of worker productivity but also regarding effects on consumer buying.

Ms. Appel has had discussions with Wilbur Hawkins, Deputy Assistant Secretary for Economic Development at Commerce and the Assistant Secretary-Designate William Ginsberg. She is also working with their counterparts in Canada to make this a joint cooperative effort.

At some point, we will need to work with your staff to ascertain some of the information necessary to help pull this meeting together and make it worthwhile and productive. Could you please let me know who on your staff should be our liaison for this and other issues that may arise in this area? Our contact person here is Andrew E. Barrer, Ph.D. (telephone: 632-1090).

Thank you for your cooperation and assistance.

THE WHITE HOUSE
WASHINGTON

January 13, 1994

MEMORANDUM

TO: Rosalyn Kelly, Executive Assistant to Assistant to the President for Domestic Policy

FROM: Kristine M. Gebbie, R.N., M.N. *N. Steve Lee for*
National AIDS Policy Coordinator

SUBJECT: Meeting with Direct Access Diagnostics

I received the copy of the November 24 letter from Bruce Fried on the Wexler Group requesting a meeting with Carol and their client, Direct Access Diagnostics, to discuss their home testing and counseling service. The product they wish to discuss is pending FDA approval. I received a similar letter (as did Dr. David Satcher at CDC) and plan to meet with them January 13. It is not my intention to offer any commitments or comments on the product, but simply to gather information. I also understand that there is a meeting scheduled with Dr. Satcher later this month.

Because there are several potential problems with home HIV testing, I recommend that Carol not schedule the meeting and defer to this office for information gathering and the FDA for approval. Let me know if you have any questions.

Enclosures

THE WHITE HOUSE

WASHINGTON

January 13, 1994

Ben Merrill, Esquire
1020 S.W. Taylor Street
Suite 330
Portland, OR 97205-2588

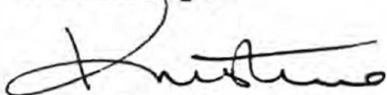
Dear Ben:

You are now back in Portland, resuming life as an attorney, and the National AIDS Policy Office is ending its first "Week without Ben" in over four months. I want to take this opportunity to thank you formally for your contributions and your efforts.

As I have said several times, not many would take the leap you did, to join this office in a loosely-defined role, assisting in the process of making the new approach to national AIDS policy a reality. Your energy and enthusiasm for the process carried us through many a day! I am particularly appreciative of the work you did to put me and others in the office in contact with a number of people in Washington and elsewhere who are interested in our mission and with whom we need to be in regular contact. As you know, some of those contacts have resulted in resources and people to further the cause.

Whatever our formal relationships in months and years to come, I know that our paths will cross as we continue to pursue our common goal of stopping the HIV epidemic and responding compassionately to all of those infected by the virus or affected by its presence in their families and communities. I wish you the very best in all that you do.

Sincerely,



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

THE WHITE HOUSE

WASHINGTON

January 13, 1994

Ben Merrill, Esquire
1020 S.W. Taylor Street
Suite 330
Portland, OR 97205-2588

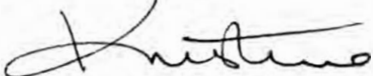
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Sincerely,



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

JAN 15 1994

JAN 14 1994

THE WHITE HOUSE

Dear Martha -

It was a real pleasure
meeting you and being able
to spend some time with you.

I hope you continue in your
successful efforts... you've
already made a great contribution
in chairing the Wisconsin AIDS
fund. All the best - Kristine Golech

THE WHITE HOUSE
WASHINGTON

Ms. Martha P. Thermansen
5320 NorthLake Drive
Milwaukee, Wisconsin 53217

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Still Caring After Five Years

Wisconsin AIDS Fund
Annual Meeting

9pgs

**Still Caring
After Five Years**

**Wisconsin AIDS Fund
ANNUAL MEETING**

**January 12, 1994
Pfister Hotel
Grand Ballroom**

January 17, 1994

Mr. Anthony Lake
Assistant to the President for
National Security Affairs
The White House
Washington, D.C. 20500

Dear Mr. Lake:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

The President has instructed me to ensure that all White House and EOP senior staff receive HIV/AIDS education and prevention training. The White House and EOP personnel office are implementing plans for training sessions of 2-3 hours. Because your time is valuable, I will personally conduct two shorter make-up briefings in room 180 of the OEOP at 9:00 a.m. on January 26 and February 8. The briefings will focus on national and international HIV/AIDS issues and the Administration response to this crisis.

Those of you unable to attend a make-up briefing will be assigned to one of the training sessions scheduled for all other staff. You will be able to reschedule the assigned date on a space available basis. Please make every effort to attend some session. My final report to the President on White House and EOP HIV/AIDS training will include an attendance report. It is important that this Administration set an example for the rest of the nation by dealing with HIV/AIDS issues in a progressive fashion.

I appreciate your time and look forward to seeing you at the briefing. If you have any questions please call me at 632-1090 or Lance Alworth at 690-5560.

Sincerely,


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

January 17, 1994

Mr. Thomas (Mack) F. McLarty
Assistant to the President and
Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. McLarty:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Roy M. Neel
Assistant to the President and
Deputy Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Neel:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Bernard W. Nussabaum
Assistant to the President and Counsel
The White House
Washington, D.C. 20500

Dear Mr. Nussabaum:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Howard G. Paster
Assistant to the President and
Director of Legislative Affairs
The White House
Washington, D.C. 20500

Dear Mr. Paster:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. John D. Podesta
Assistant to the President and
Staff Secretary
The White House
Washington, D.C. 20500

Dear Mr. Podesta:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. John M. Quinn
Assistant to the President and Chief of Staff
and Counselor to the Vice President
The White House
Washington, D.C. 20500

Dear Mr. Quinn:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Robert E. Rubin
Assistant to the President for
Economic Policy
The White House
Washington, D.C. 20500

Dear Mr. Rubin:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Eli J. Segal
Assistant to the President and
Director of the Office of National Service
The White House
Washington, D.C. 20500

Dear Mr. Segal:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. Ricki Seidman
Assistant to the President and
Counselor to the Chief of Staff
The White House
Washington, D.C. 20500

Dear Mr. Seidman:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. George R. Stephanopoulos
Assistant to the President for
Policy and Strategy
The White House
Washington, D.C. 20500

Dear Mr. Stephanopoulos:

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Sincerely,

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

January 17, 1994

Mr. Samuel (Sandy) R. Berger
Deputy Assistant to the President
for National Security Affairs
The White House
Washington, D.C. 20500

Dear Mr. Berger:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. W. Bowman Cutter
Deputy Assistant to the President for
Economic Policy
The White House
Washington, D.C. 20500

Dear Mr. Cutter:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. David E. Dreyer
Deputy Assistant to the President and
Director of Planning
The White House
Washington, D.C. 20500

Dear Mr. Dreyer:

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Sincerely,

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

January 17, 1994

Mr. Jeffery L. Eller
Deputy Assistant to the President and
Director of Media Affairs
The White House
Washington, D.C. 20500

Dear Mr. Eller:

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Sincerely,

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

January 17, 1994

Mr. John B. Emerson
Deputy Assistant to the President and
Deputy Director of the Office of Presidential
Personnel
The White House
Washington, D.C. 20500

Dear Mr. Emerson:

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I appreciate your time and look forward to seeing you at the briefing. If you have any questions please call me at 632-1090 or Lance Alworth at 690-5560.

Sincerely,

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

National AIDS Policy Coordinator

January 17, 1994

Mr. John A. Gaughan
Deputy Assistant to the President and
Director of the White House Military Office
The White House
Washington, D.C. 20500

Dear Mr. Gaughan:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. John P. Hart
Deputy Assistant to the President for
Intergovernmental Affairs
The White House
Washington, D.C. 20500

Dear Mr. Hart:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Steven M. Hilton
Deputy Assistant to the President and
Deputy Director of Public Liaison
The White House
Washington, D.C. 20500

Dear Mr. Hilton:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Keith Mason
Deputy Assistant to the President and
Deputy Director of Intergovernmental Affairs
The White House
Washington, D.C. 20500

Dear Mr. Mason:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Bruce N. Reed
Deputy Assistant to the President
for Domestic Policy
The White House
Washington, D.C. 20500

Dear Mr. Reed:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Steven J. Ricchetti
Deputy Assistant to the President for
Legislative Affairs (Senate)
The White House
Washington, D.C. 20500

Dear Mr. Ricchetti:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Jeffrey H. Watson
Deputy Assistant to the President and
Deputy Director of Intergovernmental Affairs
The White House
Washington, D.C. 20500

Dear Mr. Watson:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Robert O. Boorstin
Special Assistant to the President
for Policy Coordination
The White House
Washington, D.C. 20500

Dear Mr. Boorstin:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Keith O. Boykin
Special Assistant to the President
and Director of News Analysis
The White House
Washington, D.C. 20500

Dear Mr. Boykin:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. R. Nicholas Burns
Special Assistant to the President and
Director, Russian, Ukranian and
Eurasian Affairs
The White House
Washington, D.C. 20500

Dear Mr. Burns:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. Paul Carey
Special Assistant to the President for
Legislative Affairs
The White House
Washington, D.C. 20500

Dear Mr. Carey:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. Richard A. Clarke
Special Assistant to the President
and Senior Director for Global Issues
and Multilateral Affairs
The White House
Washington, D.C. 20500

Dear Mr. Clarke:

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

January 17, 1994

Mr. Paul R. Dimond
Special Assistant to the President
for Economic Policy and Director
to the National Economic Council
The White House
Washington, D.C. 20500

Dear Mr. Dimond:

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

January 17, 1994

Mr. Thomas S. Epstein
Special Assistant to the President
for Political Affairs
The White House
Washington, D.C. 20500

Dear Mr. Epstein:

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Sincerely,

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

January 17, 1994

Mr. Robert Fauver
Special Assistant to the President
for National Security Affairs and
Economic Policy
The White House
Washington, D.C. 20500

Dear Mr. Fauver:

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

January 17, 1994

Mr. Richard E. Feinberg
Special Assistant to the President
for National Security Affairs
The White House
Washington, D.C. 20500

Dear Mr. Feinberg:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Jody Greenstone
Special Assistant to the President and
Assistant to the Counselor to the President
The White House
Washington, D.C. 20500

Dear Mr. Greenstone:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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

January 17, 1994

Mr. Elwood J. Holstein
Special Assistant to the President for
Economic Policy
The White House
Washington, D.C. 20500

Dear Mr. Holstein:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Martin S. Indyk
Special Assistant to the President
for National Security Affairs
The White House
Washington, D.C. 20500

Dear Mr. Indyk:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

The President has instructed me to ensure that all White House and EOP senior staff receive HIV/AIDS education and prevention training. The White House and EOP personnel office are implementing plans for training sessions of 2-3 hours. Because your time is valuable, I will personally conduct two shorter make-up briefings in room 180 of the OEOB at 9:00 a.m. on January 26 and February 8. The briefings will focus on national and international HIV/AIDS issues and the Administration response to this crisis.

Those of you unable to attend a make-up briefing will be assigned to one of the training sessions scheduled for all other staff. You will be able to reschedule the assigned date on a space available basis. Please make every effort to attend some session. My final report to the President on White House and EOP HIV/AIDS training will include an attendance report. It is important that this Administration set an example for the rest of the nation by dealing with HIV/AIDS issues in a progressive fashion.

I appreciate your time and look forward to seeing you at the briefing. If you have any questions please call me at 632-1090 or Lance Alworth at 690-5560.

Sincerely,

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

January 17, 1994

Mr. William H. Itoh
Special Assistant to the President
for National Security Affairs
The White House
Washington, D.C. 20500

Dear Mr. Itoh:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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Sincerely,

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

January 17, 1994

Mr. Timothy J. Keating
Special Assistant to the President
for Legislative Affairs
The White House
Washington, D.C. 20500

Dear Mr. Keating:

On September 30, 1993 the President directed that the entire federal workforce participate in HIV/AIDS education and prevention training prior to World AIDS Day, December 1, 1994. To set an example, he asked that White House and Executive Office of the President (EOP) staff receive training first. Senior staff briefings for White House and EOP personnel were held in November. My records indicate you did not attend.

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