FOIA Number: 2018-0756-F

FOIA MARKER

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Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Kristine Gebbie

Subseries:

OA/ID Number: 3766

FolderID:

Folder Title:
August Chron Files 1993 [5]

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	3	2

MAIN
03009

NAPO Document Control Slip

NAPO Number : 7159 PHS Number : OS Number : Document Type : White House Letter

Document Date: 8/17/93 Refer'd Date : 8/17/93 Int Due Date : 8/17/93 Ext Due Date : 8/17/93
NAPO Xref : PHS Xref : OS Xref : Keyer ID : SHenson
Purge Date : 8/17/95 Disposition : DESTROY Final Date : 8/17/93 Document Loc : MAIN-03D09

********** Correspondent Information **********

From : GEBBIE Title : DIRECTOR Organization : ONAPC
Address : City : WASHINGTON State : DC Zip : 20500
On Behalf Of : To : JULIUS BEDDINGFIELD

********** Subject or Title **********

5205 FIORE TERRACE B103 - SAN DIEGO, CA 92122

********** Keywords **********

GEBBIE

********** Special Instructions **********

********** Assignment/Action History **********

Process Type : Kristine Gebbie Correspondence

Assignee	Initials	Action	Status	Due Date	Completed	Comments TO assignee
Kristine M. Gebbie	_____	DIRS	CLOS	8/17/93	8/17/93	

****

Related WordPerfect Filenames: _____ _____ _____

Comments FROM assignees:

THE WHITE HOUSE

WASHINGTON

August 12, 1993

Mr. Julius Beddingfield
5205 Fiore Terrace B103
San Diego, California 92122

Dear Mr. Beddingfield:

Thank you for writing, and for your interest in more effective methods of preventing transmission of HIV.

Three agencies in the Public Health Service deal with the various aspects of a product related to stopping the spread of HIV in medical facilities. Both the Centers for Disease Control and Prevention and National Institutes of Health are involved in research. The process of approving any new product is the responsibility of the Food and Drug Administration. You may wish to contact these agencies directly at the following addresses:

Office of AIDS Coordination
Centers for Disease Control and Prevention
Executive Park Building
1600 Clifton Road, N.E.
Mail Stop - D21
Atlanta, GA 30333

Executive Secretariat
National Institutes of Health
Building 1, B-156
9000 Rockville Pike
Bethesda, MD 20892

Executive Secretariat (HF -40)
Food and Drug Administration
Parklawn Building, Room 16-70
5600 Fishers Lane
Rockville, MD 20857

Your interest in contributing to our efforts to stop this epidemic is appreciated. Best wishes to you in your continuing efforts.

Sincerely,

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

THE WHITE HOUSE

WASHINGTON

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Food and Drug Administration
Parklawn Building, Room 16-70
5600 Fishers Lane
Rockville, MD 20857

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Sincerely,

Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
Prepared by: APO: ALitwinowicz: gw: 8/12/93: 690-5471: b:\bedding.fld

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

August 9, 1993

Mr. Julius Beddingfield
5205 Fiore Terrace B103
San Diego, California 92122

Dear Mr. Beddingfield:

Thank you for writing, and for your interest in more effective methods of preventing transmission of HIV.

Three ~~Agencies~~ of the Public Health Service deal with ~~the~~ various aspects of a product related to stopping the spread of HIV in medical facilities. Both the Centers for Disease Control and Prevention and National Institutes of Health are involved in research. The process of approving any new product is the responsibility of the Food and Drug Administration. You may wish to contact these Agencies directly. — HHS' address, fax #'s?

Your interest in contributing to our efforts to stop this epidemic is appreciated. Best wishes to you in your continuing efforts.

Sincerely,

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

needs thanks for writing & referral to approp. agencies

Dear MRS Kristine C

I Julius Beddingfield have t
very hard to help very much to help stop
the spread of aids in medical facilities. This
product presently being used except for the
working part of this item, that helps stop
the spread of the diease. This product will
raise awareness in these facilities as well.
Prevention is our only defence until there is a cure.
Being the new commissioner this item can show
that you are doing something about this killer.
There are also more to this for disposal and
containers for medical waste. Please contact
my self Julius at (619) 558 3652. Also this
product will help to generate U.S. dollars
being that it will be a U.S. product. I would
welcome your help and aduise on eventualy having
this product manditory in usage in Federal
medical facilities. Please respond

7.28.93

Thank you.
Julius Beddingfield

We are presently introducing a new product to the health field to help stop the spread of AIDS and hepatitis.There is a similar product being used in all medical facilities, except for the working part of the product, that helps to stop the spread of AIDS.This product is ahead of its time in the prevention area.

Prevention is the only defense we have to fight AIDS, until there is a cure.

This product is major in the prevention of the spread of the disease.

All contacts must be address to;

JULIUS BEDDINGFIELD
5205 FIORE TERRACE B103
SAN DIEGO, CA 92122
Phone (619) 558-3652

Julie Beddingfield
5705 Fiore Terrace B203
SD, Ca. 92122

Fold at line over top of envelope to the right of the return address

CERTIFIED

P 152 654 531

MAIL

UNITED STATES POSTAL SERVICE

0000

92075

U.S. POSTAGE PAID SAN DIEGO, CA 92192 JUL 29 '93 AMOUNT

$2.00

0001673/-05

29 Lilac USA

RETURN RECEIPT REQUESTED

Kristine Gibbie
NATIONAL AIDS Policy Cordinator
729 H. 200 Independence AVE.
South West Washington, D.C. 20201

MESSENGER RECEIPT CARD

CERTIFIED

Date AUG - 4 1993

Descriptio P 152 654 531

From SAN DIEGO, CA

Addressed to KRISTINE GIBBIE

Building HHH Room No. 729-H

Time Received 7:30 Messenger

Time Delivered Received by

☆U.S. GPO: 1989-624-674/10191

MAIN
03D09

NAPO Document Control Slip

NAPO Number : 7175 PHS Number : OS Number : Document Type : White House Letter

Document Date: 8/18/93 Refer'd Date : 8/18/93 Int Due Date : 8/18/93 Ext Due Date : 8/18/93
NAPO Xref : PHS Xref : OS Xref : Keyer ID : KWilliam
Purge Date : 8/18/95 Disposition : DESTROY Final Date : 8/18/93 Document Loc : MAIN-03D09

********** Correspondent Information **********

From : GEBBIE Title : DIRECTOR Organization : ONAPC
Address : City : WASHINGTON State : DC Zip : 20500
On Behalf Of : To : FRANS PEETOOM

********** Subject or Title **********

AMERICAN RED CROSS - PACIFIC NORTHWEST - REGIONAL BLOOD SERVICE - 3131 N. VANCOUVER AVENUE - PO BOX 3200 - PORTLAND, OR 97208

********** Keywords **********

GEBBIE

********** Special Instructions **********

********** Assignment/Action History **********

Process Type : Kristine Gebbie Correspondence

Assignee	Initials	Action	Status	Due Date	Completed	Comments TO assignee
Kristine M. Gebbie	_____	DIRS	CLOS	8/18/93	8/18/93	

Related WordPerfect Filenames: _____ _____ _____

Comments FROM assignees:

THE WHITE HOUSE

Dear Frans -

Thank you for writing - and for the good wishes - I need them all!

I'm just starting to work on staffing the office, & will send Ms DeRosa relevant job announcements - I appreciate your recommendation -

Cordially

American Red Cross

Pacific Northwest
Regional Blood Services
3131 N. Vancouver Ave.
P.O. Box 3200
Portland, Oregon 97208
(503) 284-1234
FAX: 503-284-9899

July 16, 1993

Kristine Gebbie
National AIDS Policy Coordinator
200 Independence Avenue SW
6HH Building, Room 738
Washington DC 20201

Dear Kristine:

Since your name has been mentioned many times by many people in Oregon over the last several weeks, I thought it appropriate to extend my warm congratulations on your new appointment. You are indeed courageous in assuming this politically difficult role. All of us here who know and respect you, wish you well in dealing with the challenging issues you face.

Another factor in writing this letter is that I would like to bring someone to your attention in case you are looking for an excellent staff addition. This person is Mary B. De Rosa, an attorney with Arnold & Porter (Washington, DC office) with whom I have worked extensively in a few post-transfusion AIDS cases that Red Cross has been involved in locally. In one of our recent conversations your name came up, and she expressed interest in working for you. Knowing how well educated she is in the many facets of AIDS issues, and how much she demonstrates the right level of thoughtfulness and sensitivity on these issues, I thought she might be a real asset to your team, if you are looking for this type of person. I believe she would be genuinely excited to work for you. Mary De Rosa can be reached at Arnold & Porter in Washington, DC, telephone # 872-6700. If this suggestion is of no use whatsoever, please ignore it. Just accept my expression of support for your new leadership role.

Best Personal Regards,

Frans Peetoom

Frans Peetoom, MD,PhD
Director, Blood Services

FP/sg/gebbie

Keep this name/# on hand (De Rosa) for Job Announcements in the future —

American Red Cross

Pacific Northwest
Regional Blood Services
3131 N. Vancouver Ave.
P.O. Box 3200
Portland, Oregon 97208

701

PRESORTED FIRST CLASS

PORTLAND OREG. JUL 16'93

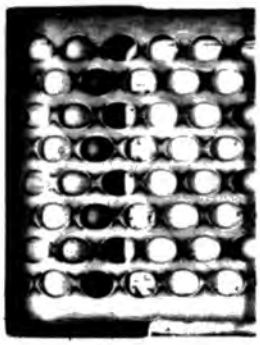
P.B. METER 6126810

POSTAGE 0.24 8

Kristine Gebbie
National AIDS Policy Coordinator
200 Independence Avenue SW
6HH Building, Room 738
Washington, DC 20201

Aug 14

THE WHITE HOUSE

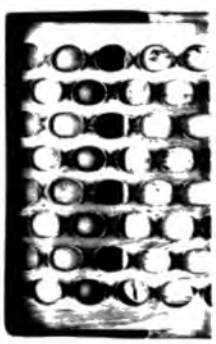


Dear Sue & colleagues —

Thank you! for the lovely flowers - They bring a note of Northwestern cheer into a muggy Washington DC day. I very much appreciate the support & encouragement from my fellow nurses —

Cristina

THE WHITE HOUSE
WASHINGTON



Sue Hegewary, Ph.D.
Dean
Washington School of Nursing
Seattle, WA

Aug 14

THE WHITE HOUSE

Dear Ruth —

Thank you so much for writing — and for the good wishes! I learned so much in my St Louis years — and I'm certainly having to draw on all of it these days! Please give my best to all of my SLU colleagues — I look forward to seeing you one day before too long —

Best wishes

MEDICAL COLLEGE OF PENNSYLVANIA

Office of Development and Alumnae/i Relations

A Member of Allegheny Health, Education and Research Foundation

3300 Henry Avenue
Philadelphia, PA 19129
Telephone (215) 842-7100
Fax (215) 843-6862

Confirmed

August 11, 1993

Ms. Kristine Gebbie
AIDS Policy Coordinator
Department of Health and Human Services
Room 728H
Hubert Humphrey Building
299 Independence Avenue
Washington, DC 20201

Dear Ms. Gebbie:

Per your discussion with Tom Vernon, I would like to confirm that you have agreed to speak to the National Board of the Medical College of Pennsylvania at our November meeting at the Ritz Carlton, Pentagon City.

We were hoping you would be able to address the National Board and other MCP alumnae/i from the Washington, D.C. area on Monday evening, November 1, 1993 as our dinner speaker.

We would be honored to have you address our Board. We are particularly interested in hearing about women and AIDS, if that is possible.

I have enclosed our Board brochure for you to review.

Please respond to our request via Ms. Lorey Schwartz, Assistant Director for Volunteer Programs, Medical College of Pennsylvania. She is also available to answer any questions you might have.

Sincerely,

Ruth Dubois

Ruth Dubois
Program Committee
National Board

MEDICAL COLLEGE OF PENNSYLVANIA

HISTORY

1850
- Founded as the Female Medical College of Pennsylvania, the first and longest surviving medical school devoted to the education of female physicians

1867
- Name changed to the Woman's Medical College of Pennsylvania

1969
- Institution became coeducational

1970
- Name is changed to the Medical College of Pennsylvania

1988
- Became a member of Allegheny Health Services, now Allegheny Health, Education and Research Foundation (AHERF)

1991
- Became academic anchor of Allegheny Health, Education and Research Foundation, an academic-based, integrated health care delivery system

1992
- Opened in August, a new education and research center at 2900 Queen Lane

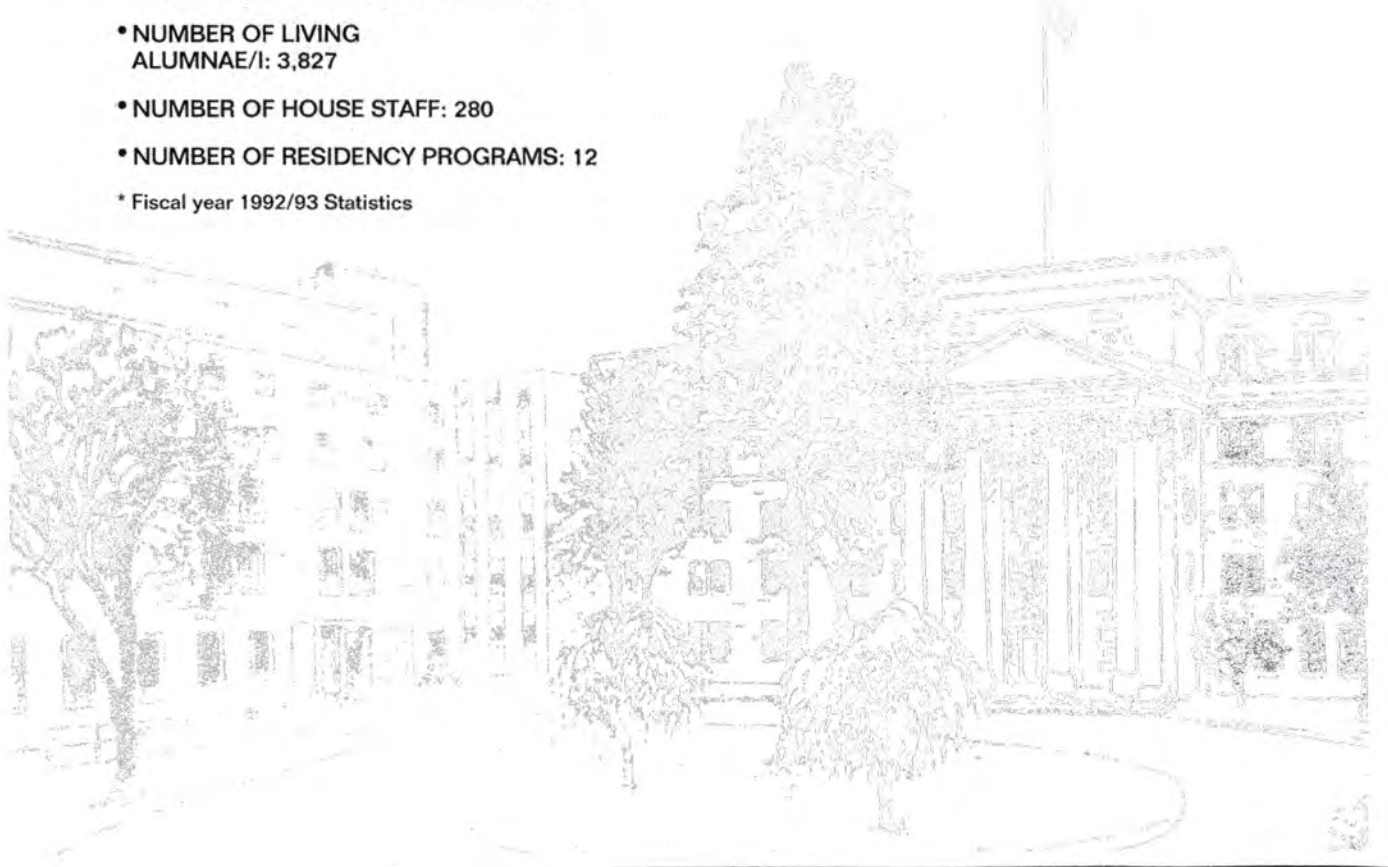
CURRENT STATUS*

- ADMINISTRATION:
  D. Walter Cohen, D.D.S.
  President and CEO

  Leonard L. Ross, Ph.D.
  Executive Vice President, Chief Academic Officer and Annenberg Dean
- ENDOWMENT: $26 million
- NUMBER OF FACULTY: 1,282
  (includes 280 at Allegheny Campus)
- NUMBER OF MEDICAL STUDENTS: 495
- NUMBER OF STUDENTS IN GRADUATE DEGREE PROGRAMS: 121
- NUMBER OF LIVING ALUMNAE/I: 3,827
- NUMBER OF HOUSE STAFF: 280
- NUMBER OF RESIDENCY PROGRAMS: 12

* Fiscal year 1992/93 Statistics

The National Board of the Medical College of Pennsylvania



FOUNDED: 1953

MISSION STATEMENT:

The National Board of the Medical College of Pennsylvania, comprised of prominent women leaders throughout the United States, Canada and Mexico, dedicates itself to the promotion of the Medical College of Pennsylvania by working to further the advancement of women in medical education and science, and, in so doing, contributing to the knowledge and practice of medicine that improves the quality of life. To that end, the National Board members serve as ambassadors for the Medical College of Pennsylvania, acquaint the finest potential students with the College, raise funds for the College, and support special designated projects which are associated with the goals of the National Board.

MEMBERSHIP:

The membership of the National Board is comprised of women from all walks of life. The Board includes approximately 120 women who represent more than 30 states, Canada and Mexico.

The membership obligation of an active member is:

- A minimum $250 contribution annually to the Fund for MCP
- Attendance at one meeting per year or excused by the President
- Participation on one of the committees

MEMBERSHIP REWARDS:

Members are presented with the opportunity to keep abreast of issues facing medical education, research and care. Meetings provide the arena for members to learn about health care issues that may affect them or their families.

Membership affords women who have an interest in health care issues and/or issues affecting women in medicine the opportunity to "network" with women from all walks of life throughout the United States, Mexico and Canada.

PROGRAMS:

The Marion Spencer Fay National Board Award is presented annually to an outstanding woman physician or scientist as a reflection of the College's support for women in medicine.

The National Board Award is endowed for $250,000 by members and friends of the National Board. Allegheny Health, Education and Research Foundation has matched that amount to ensure that the Award will be given in perpetuity.

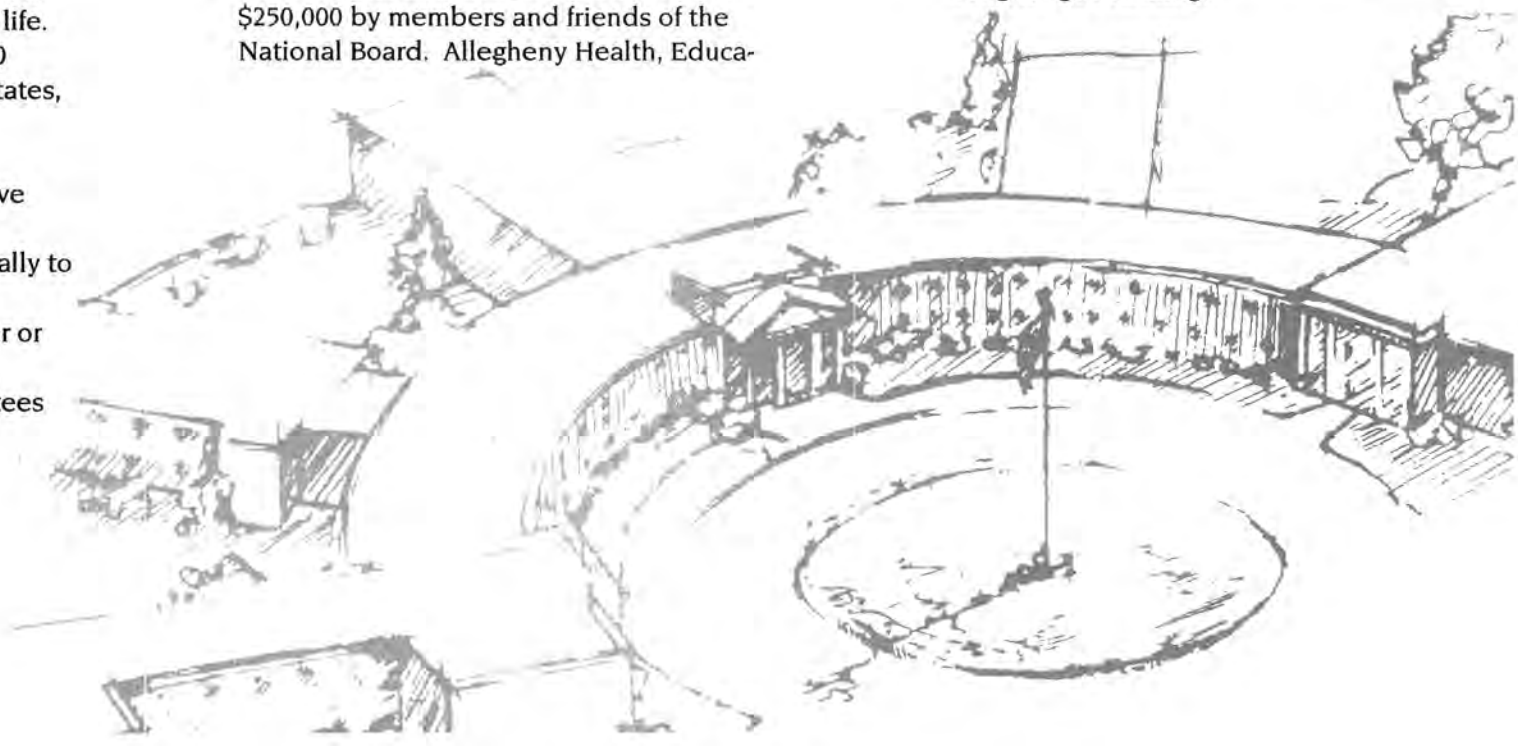
MEETINGS:

The National Board meets twice annually. The Fall Meeting is generally held in Washington, D.C., and the Spring Meeting is held in Philadelphia. Regional meetings may be scheduled in Florida, the Southwest, California or other locations as determined by the College and the Executive Council of the Board.

COMMITTEES:

STANDING:
Awards, Development, Membership, Nominations.

SPECIAL:
Archives, Bylaws, Communications, Program, Past Presidents, Protocol, Long-range Planning.



MEDICAL COLLEGE OF PENNSYLVANIA

Office of Development and Alumnae/i Relations

A Member of Allegheny Health, Education and Research Foundation

3300 Henry Avenue
Philadelphia, PA 19129
Telephone (215) 842-7100
Fax (215) 843-6862

October 18, 1993

Ms. Kristine M. Gebbie, RN, MN
National AIDS Policy Coordinator
Department of Health and Human Services
Room 728H
Hubert Humphrey Building
299 Independence Avenue
Washington, DC 20201

Dear Ms. Gebbie:

On behalf of the National Board of the Medical College of Pennsylvania, we are so pleased to have you join us as our dinner speaker on Monday evening, November 1, 1993 at the Ritz-Carlton, Pentagon City.

Cocktails begin at 7:00 pm and dinner begins at 7:30 pm. The room location is the Mezzanine Level Plaza C and D. The Ritz-Carlton Pentagón City is located at 1250 S. Hayes Street Arlington, Virginia, (703)415-5000. Valet parking is available.

We appreciate your taking time out of your busy schedule to address our Board and alumnae/i. In recognition of your support of our program, we would be glad to make a charitable contribution to an organization of your choice, if you would like. Please let me know.

Please feel free to call me directly at (215)842-7106 if I can answer any questions for you about the program. Also, please let me know if you have any audio-visual needs. I would be glad to arrange this for you.

Sincerely,

Lorey Schwartz

Lorey J. Schwartz
Assistant Director for Alumnae/i and Volunteer Programs

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Veronica F. Rempusheski, PhD, RN
Nurse Researcher
Beth Israel Hospital
330 Brookline Avenue
Boston, Massachusetts 02215

Dear Dr. Rempusheski:

I am honored that you invited me to join you at the Nursing Conference in Beijing. Unfortunately, I will be unable to attend.

I am truly sorry to miss this opportunity to meet with nursing professionals from all over the world.

Sincerely,

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

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Mr. Tim Themy-Kotronakis
T & T Medical Products U.S.A.
P.O. Box 27488
Salt Lake City, Utah 84127

Dear Mr. Themy-Kotronakis:

Thank you for your words of congratulations on my appointment as the National AIDS Policy Coordinator. My apologies for the delay in response, things have been rather hectic around here these past few weeks.

I have forwarded your letter to the Office of Device Evaluation at the Food and Drug Administration. They have an application process for reviewing and analyzing devices or inventions such as yours.

Best of luck with your invention.

Sincerely,

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

CC: Food and Drug Administration,
Executive Secretariat

THE WHITE HOUSE

WASHINGTON

August 16, 1993

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T & T Medical Products U.S.A.
P.O. Box 27488
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Sincerely,

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National AIDS Policy Coordinator

CC: Food and Drug Administration,
Executive Secretariat

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Mr. J. T. Simoniello
55 Peters Place 2C
Red Bank, New Jersey 07701-1720-555

Dear Mr. Simoniello:

Thank you for sending me the August 1993 issue of AIDS Clinical Care. My duties as the National AIDS Policy Coordinator include integrating all available scientific data in a comprehensive plan to combat HIV and AIDS. Input from all Americans is important as we move forward in our fight against this epidemic.

Sincerely,

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

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Alan E. Gambrell
Washington D.C. Representative
SEICUS D.C. Office
2700 Connecticut Avenue NW
Suite 302A
Washington, D.C. 20008

Dear Mr. Gambrell:

Thank you for your kind words of congratulations and for sending me the information on SEICUS.

I look forward to working with SEICUS as I get fully involved in my responsibilities as the National AIDS Policy Coordinator. We clearly share many priorities and interests.

Sincerely,

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

8/16/93

cc. incoming to Jim Cannon

THE WHITE HOUSE

Dear Bill & Deborah

Thank you for your kind letter - and the information on your local program - you're tackling some of the toughest issues head on! I look forward to seeing you before long.

Warmest

7205

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Mr. J. T. Simoniello
55 Peters Place 2C
Red Bank, New Jersey 07701-1720-555

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Sincerely,

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

Prepared by: APO: JLehman: gw: ~~7/28/~~9/14/93: 690-5471: b:\simonie2.816

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

August 16, 1993

Mr. J. T. Simoniello
55 Peters Place 2C
Red Bank, New Jersey 07701-1720-555

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Sincerely,

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

first letter - already sent

July 30, 1993

Mr. J. T. Simoniello
55 Peters Place 2C
Red Bank, New Jersey 07701-1720-555

Dear Mr. Simoniello:

Thank you for writing. A wide range of products are under review for possible use in combatting HIV infection. The challenge of fully understanding the human immune system is a great one.

Sincerely,

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

Prepared by: APO: KMGebbie: gw: 7/28/93: 690-5471: b:\simoniel.100

J.T. SIMONIELLO
55 PETERS PL-2C
RED BANK NJ. 07701-1720-555
1-908-530-1655

MS. KRISTINA M. GERRIBIE RN MN
1600 PENNSYLVANIA AVE.
WASINGTON D.C. 20001

DEAR MS. GERRIBBIE RN MN.

HERE IS AN ARTICLE FROM MASS. MEDICAL SOCIENTY - AIDS CLINICAL CARE, WALTHAM MASS. 02154-1649 ON AIDS VACCINES FOR HIV.

THANK YOU FOR YOUR RECENT LTR.

VTY.
JT.S.
RB. NJ.

Need 2 2
thanks for
further info
note

IMMUNOMODULATION - ADJUSTMENT OF THE IMMUNE RESPONSE TO A DESIRED LEVEL, AS IN IMMUNOPOTENTIATION, IMMUNOSUPPRESSION, OR INDUCTION OF IMMUNOLOGIC TOLERANCE.

CD4 & CD8+ CELLS - IMMUNE RESPONSES TO THE VIRUS.

TRIALS ARE NOW UNDER WAY EVALUATING THE EFFECTS OF THERAPEUTIC VACCINATION IN PERSONS WITH VARYING LEVELS OF CD4 CELLS.

ACTG-209 - LATE STAGE INFECTION

AIDS CLINICAL CARE

IN THIS ISSUE

August 1993
Volume 6 Number 8

THE PUBLISHING DIVISION
of the Massachusetts Medical Society

PUBLICATIONS
AIDS Clinical Care; Journal of the American Board of Family Practice; Journal Watch; Morbidity and Mortality Weekly Report; The New England Journal of Medicine

CLINICAL TOPIC

NIAID Issues Preliminary Guidelines on Use of Antiretrovirals

64

RESEARCH NOTES

HIV Leading Cause of Death in Young Adults

Viral Causes of Diarrhea in HIV

Occupational Exposure to HIV

Predicting Perinatal HIV Transmission

Liposomal Amphotericin B for Cryptococcosis

66

CASE WATCH

from the Centers for Disease Control and the World Health Organization

WORLD AIDS CASES	**2,500,000***
U.S. AIDS CASES	**289,320**
U.S. AIDS DEATHS	**182,275**

Total U.S. cases and deaths reported through 3/93
*Estimated

FEATURE TOPIC

Therapeutic Vaccines for HIV

Therapeutic vaccination as an intervention to control or eradicate infection is a novel concept which, except possibly in the case of rabies, had not been pursued prior to the AIDS era. As the HIV epidemic continues and the limited efficacy of currently available therapeutic options becomes increasingly clear, an alternate strategy such as vaccination is welcomed.

The concept of attacking HIV through immunomodulation, specifically via administration of an HIV vaccine, is intriguing. The potential advantages of this approach, compared with antiretroviral therapy, are severalfold, including anticipated diminished toxicity. However, numerous questions about vaccine therapy remain. As a result, at the present time, this intervention is only available to patients through participation in investigational trials. A number of trials employing vaccine candidates are now under way in an attempt to answer these questions and thus help determine whether or not FDA approval should be granted to one or more of these products.

The goal of therapeutic vaccination is to maintain high level HIV immune surveillance.

Rather than detailing every HIV vaccine now being tested, the purpose of this discussion is to identify the essential issues surrounding vaccine therapy, including scientific rationale; strategies that one might employ; safety concerns; determinants of efficacy; demonstrated efficacy to date; and potential usage. Accompanying tables highlight trials currently under way which have been designed to begin addressing these issues.

Rationale for vaccine therapy

The ultimate goal of vaccine therapy is to induce the immune system of the infected individual to better recognize and more effectively fight HIV than it does in response to natural infection.

Infection by HIV in most cases elicits a brisk immune response to the virus, including both HIV-specific neutralizing antibodies and CD8+ cytotoxic T cells. These "primed" host effectors function to attack, respectively, cell-free virus and virally infected cells. Studies to date in seroconverting individuals have correlated the appearance of these host responses with an impressive decline in the rate of HIV replication. However, while viral replication is significantly lessened — particularly in the periphery where high titers of HIV-specific neutralizing antibodies and high numbers of CD8 cytotoxic effectors prevail — it is generally never completely inhibited. Instead, viral replication continues, particularly in lymph nodes and other sequestered sites. The result is a steady increase in total body burden of HIV over time and the eventual onset of HIV disease manifestations.

Much remains to be learned about the immunopathogenesis of HIV infection. However, what is known perhaps helps us understand why HIV disease progresses despite such impressive HIV-specific immune responses early in the course of infection. HIV possesses the unique ability to infect and interact with an essential immune effector, the T helper cell. High-frequency contact between HIV and T helper cells occurs in germinal centers of lymph nodes where T helper cells reside in high numbers and circulating virus is efficiently trapped. Thus, within lymph nodes, T helper

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Founded in cooperation with
American Foundation for AIDS Research

Table 1 Strategies for therapeutic HIV vaccine development

Vaccine strategy	Historical prototype	Primary advantage	Drawbacks	Candidates in human trial
Live, attenuated virus	Measles	Immunogenicity — most closely simulates natural infection; therefore, most likely of all approaches to boost the array of responses primed by natural infection	Safety concerns — potential for reversion to wild-type virus	None (SIV and HIV2 in macaques)
Whole, inactivated virus	Polio	Safety, as compared to live virus approach	Immunogenicity — not likely to induce either Tc* (e.g., nonreplicating vaccine immunogen) or NAb† (e.g., if devoid of outer envelope proteins) responses as efficiently as a live virus approach	gp 120-depleted inactivated HIV
Viral "particles"	None	Safety, as compared to live virus approach	Immunogenicity — may not induce Tc response as efficiently as a live virus approach	p 24 VLP
Recombinant proteins	Hepatitis B	Safety, as compared to live virus approach	Immunogenicity — presentation of viral epitopes may differ from natural infection; therefore certain responses (e.g., Tc) may be inefficiently boosted	rgp 160 rgp 120 rp 24
Synthetic peptides	None	Safety Immunogenicity — theoretically allows design of a construct preferentially composed of highly immunogenic T and B cell epitopes (gp 120, p 24 regions) and devoid of potentially immunosuppressive epitopes (gp 41 regions)	Immunogenicity — potentially decreased secondary to HLA restrictions of peptide(s) employed	gp 120 epitopes (V3 loop) gag epitopes (p 17 peptides)
Anti-idiotypes	None	Potential to block viral entry into host cells (e.g., soluble CD4 equivalent)	Safety — potential for induction of autoimmune or other aberrant host responses	

* CD8+ cytotoxic T cells
† neutralizing antibody

cells are readily infected, and, as a result of virus as well as host immune mediated mechanisms, become dysfunctional and are ultimately destroyed.

Eventually, germinal centers dissolve and the host consequently loses the capability of regenerating T helper cells. As a result of the loss of T helper cell support, as well as other events, circulating HIV-specific CD8 cytotoxic cell and antibody responses wane over time. Thus, when total lymph node dissolution occurs and high titer viremia ensues, the host is incapable of effectively responding.

To date, antiretrovirals have been the primary therapeutic modality employed in an attempt to slow the HIV disease course. The goal of this form of intervention is to suppress HIV replication for prolonged periods. If effective at containing infection within lymph nodes, antiretrovirals have the potential to halt the HIV disease course through preservation of numbers and function of T helper cells as well as their regenerative capability.

A goal of vaccine therapy is to achieve these same ends by alternate means. A major assumption is that the immune system of infected individuals is suboptimally stimulated to recognize HIV over time, thus limiting its efficacy at combating virus during periods of enhanced replication or spread. Serial vaccination ("boosting") with immunogens (particles, proteins and/or peptides) which resemble HIV may be able to compensate for this. The aim of vaccination is to boost HIV-specific memory T helper cells which, via enhanced interleukin 2 release and/or other means, will secondarily stimulate HIV-specific CD8 cytotoxic cell and antibody responses. Depending on the type of HIV immunogen employed, therapeutic vaccination may also function to boost cytotoxic cell and antibody responses directly. The ultimate goal of this form of intervention is to maintain high level HIV immune surveillance to effectively counteract virus during periods of enhanced replication and spread.

Potential vaccine strategies

A number of candidate HIV vaccines are now undergoing evaluation as ther-

apeutics. The majority of these products are under concurrent study for prophylactic use. Whether a strategy that is ultimately shown to be efficacious for prevention of infection will also prove beneficial as a therapeutic, or vice versa, remains unknown. However, certain issues related to vaccine design are likely shared. These include the type of immunogen to use (e.g., infectious vs. noninfectious HIV antigen); the spectrum of viral epitopes to include (e.g., whole virus vs. one or more proteins or peptides); and which strain or strains of virus to employ. At least one of the therapeutic vaccine trials now under way (e.g., ACTG 214, which compares a variety of the recombinant HIV envelope products) was specifically designed to begin looking at these issues.

Table 1 outlines various strategies for therapeutic HIV vaccine development and the potential advantages and drawbacks of each. Table 2 summarizes the candidates now under most active evaluation as therapeutics in the U.S. and elsewhere. To date, the recombinant HIV envelope products have undergone the most study, as this approach is thought to be safe and the envelope proteins contain a number of epitopes which have been shown to be immunogenic for both T and B cells.

Safety of HIV vaccine for seropositives

The safety of administering an HIV vaccine to a person infected with HIV requires taking into account both the safety of a particular vaccine and the safety of vaccination as an intervention. Since the beginning of the HIV epidemic, the safety of administering vaccines to persons infected with HIV has been questioned. The use of live, attenuated vaccines, such as polio or BCG, has understandably generated concern, given the potential for vaccine vector-induced disease. However, the safety of administering any vaccine, live or attenuated, has been at issue, given the theoretical possibility of enhancing HIV replication as a result of vaccine-induced activation of virally infected T helper cells and monocytes/macrophages.

From numerous studies evaluating the immunogenicity of various commercial vaccines in seropositive individuals, it appears that vaccination is safe. However, only limited data have been collected that convincingly support the postulate that vaccination does not enhance HIV replication. Thus, it seems prudent for all future trials of vaccines in seropositives to include the appropriate virologic and immunologic studies needed to verify that this is the case. The various phase I therapeutic HIV vaccine trials now under way (through the AIDS Clinical Trials Group and AIDS Vaccine Evaluation Group) are monitoring for vaccine-induced enhancement of HIV replication through a variety of virologic assays. At least one study (ACTG 137) suggests that enhanced viral replication does not occur (Table 3). However, the utility of these analyses is clearly dependent on the population of patients chosen for study. If the study population has early stage infection, given there is minimal viral replication occurring in the periphery, this question may be difficult to answer through studies limited to whole blood or plasma. Instead, serial analyses of viral activity within infected lymph nodes may be required.

As to the safety of the specific HIV vaccine candidates, studies conducted to date (Table 4), have for the most part been small and phase I in design and limited in study population to asymptomatic seropositive individuals. Minimal adverse effects, occurring primarily at the vaccine injection site, have been observed. However, some of the newer adjuvants, such as MDP-PE/F59, which is administered with the Chiron env 2-3 vaccine, have been associated with systemic complaints such as fever and chills. As larger scale studies are conducted and evaluations extended to other study populations, such as those with late stage infection and seropositive children and pregnant women, the toxicity profile of the various vaccine candidates and their adjuvants will be more completely defined. From data gathered thus far, however, it is anticipated that the toxicity rate

Table 2 Candidate therapeutic HIV vaccines in clinical trial

Product	Preparation	HIV Strains	Adjuvant	Manufacturers
Recombinant proteins				
1. HIV envelope				
rgp 160 (Vax/Syn)	Baculovirus-derived	IIIB, MN	Alum	MicroGeneSys [MGS] (CT)
rgp 160	Vaccinia-derived	IIIB	Alum	ImmunoAG [IA] (Austria)
rgp 120	CHO-cell derived	IIIB, MN	Alum	Genentech [GEN] (CA)
rgp 120, env 2-3	Yeast-derived	SF2	MTP-PE/MF59	Chiron [CHI] (CA)
rgp 120	CHO-cell derived	SF2	MTP-PE/MF59	Chiron (CA)
2. HIV core				
rp 24	Baculovirus-derived	IIIB	Alum	MicroGeneSys (CT)
p 24VLP	Yeast-derived	IIIB	Alum	British Biotechnology [BBT] (UK)
Whole inactive virus				
gp 120-depleted HIV	Formaldehyde-inactivated	African	Incomplete Freund's (IFA)	Immune Response Corps (IRC) (CA)
Peptides				
T1 SPIOA (V3 Loop peptides)	Synthetic-derived	Mixture	Incomplete Freund's	Duke University
HGP-30 coupled to KLH (e.g., p 17 peptides)	Synthetic-derived	SF2	Alum	Alpha 1 Biomedicals (DC)

and profile will remain low and favorable compared with antiretrovirals.

Efficacy and determinants of efficacy

The goal of HIV vaccine therapy is to eradicate or control replicating virus through immunomodulation and, as a result, prevent further disease progression. While the mechanism of effect clearly differs, this is also the aim of antiretroviral therapy. Hence, when therapeutic vaccine trials are designed, it is logical to construct endpoints which parallel those of antiretroviral trials. Thus, for phase I vaccine trials, primary concerns should include safety and determination of optimum dose and dosing schedule. In addition, however, efforts should be made to characterize the vaccine's immunogenicity through assessment of effects on the host humoral (antibody) and cellular (CD4 and CD8 cell) immune responses to virus. For phase II and III studies, the emphasis would then shift to determination of vaccine efficacy, as measured by effect on clinical outcome, viral burden, and host immune status.

However, HIV vaccines represent a novel therapeutic approach, and it is quite possible that the seropositive population likely to benefit most from this strategy is one which has undergone limited study in therapeutic trials to date, e.g., those living at the very early stages of infection. While it remains to be shown, it is anticipated that vaccine intervention will be most helpful to those in a relatively early stage of infection. Trials are now under way evaluating this (e.g., ACTG 209, which evaluates the effects of therapeutic vaccination in persons with varying levels of CD4 cells). Since patients with early stage infection have preserved not only CD4 number but also function and ability to regenerate these cells, they are more likely than later stage patients to respond immunologically to vaccination. If this proves to be the case, then the clinical, virologic, and immunologic parameters for determining therapeutic efficacy in phase I vaccine trials may need to differ from the measures that have generally been used in antiretroviral trials.

Meanwhile, if the results of ACTG 209 suggest that HIV vaccines may also benefit later stage patients, phase III vaccine trial outcome measures for this population may not need to differ greatly from those employed in antiretroviral trials.

Little is known about the potential therapeutic efficacy of HIV vaccines at this time, as the majority of trials conducted to date (Table 3) have been phase I. Thus, assessments have necessarily been limited to vaccine safety and immunogenicity. What we have learned, however, is that the majority of the vaccines appear to be safe and that, based on results from the Walter Reed and ACTG 137 trials, this therapeutic approach appears to be safe. In addition, again from these two trials, which employed the same vaccine and studied a similar patient population, it has been demonstrated that therapeutic vaccination can boost both humoral and cellular immune responses to virus, and that it may also stabilize and, in some cases, boost CD4 numbers as well. However, what these changes mean for long term effects on virus, HIV disease course, and patient survival remains to be determined. These questions can only be answered through carefully designed large scale efficacy trials. It is anticipated that such trials will begin within the next several months. Meanwhile, trials are also under way to evaluate the potential therapeutic role of HIV vaccines in other settings, such as late stage infection (ACTG 209);

Table 3 Selected therapeutic HIV vaccine trials conducted to date

Trial	Design	Study population (number)	Primary endpoints and results
Salk vaccine (IRC Product)	Phase II, placebo (adjuvant)-controlled; dose ranging, single schedule	Asymptomatic, CD4 >600/mm^3(48)	Safety — local reactions only Immunogenicity — development of skin test (DTH)* response to the immunogen; increase in serum p 24 Ab
Walter Reed (MGS rgp 160 III B)	Phase I, open label; dose ranging, 2 schedules	WR stage 1/2 (30)	Safety — local reactions only (87%) No adverse effect on host cellular immunity (CMI)† Immunogenicity — development of new and/or increased Ab and in vitro CMI responses to HIV envelope (63%). Subjects with higher CD4 counts (>600/mm^3) at entry and/or who received monthly injections of vaccine demonstrated a greater response rate.
ACTG 137, "Active Immunization of Asymptomatic, HIV-infected Individuals with Recombinant HIV gp 160 Antigen: A Phase I/II Study of Immunogenicity and Toxicity." (MGS rgp 160 IIIB)	Phase I, placebo (hepatitis B vaccine) — controlled; dose-ranging, single schedule	Asymptomatic, CD4 >400/mm^3 (65)	Safety — local reactions only. No increase in HIV burden by DNA PCR. Immunogenicity — similar to Walter Reed Trial. Additionally, an increase in CD4 and CD8 Tc response to HIV was observed in 2/2 subjects evaluated.

* Delayed type hypersensitivity

† As measured by serial CD4 enumerations and in vivo (DTH) and in vitro lymphoproliferative (LP) responses to recall antigens (candida, mumps, tetanus)

Table 4 Selected therapeutic HIV Vaccine trials under way

Asymptomatic seropositive trials	Pregnant women and infant trials
ACTG 209, "A Phase I/II Trial of Vaccine Therapy of HIV-1 Infected Individuals with 50-500 CD4 Cells/mm^3." (Gen rgp 120 MN)	ACTG 234, "Active Immunization of Asymptomatic HIV-infected Pregnant Women: A Phase I Study of Safety and Immunogenicity of Vaxsyn Recombinant gp160."* (MGS rgp 160 IIIB)
ACTG 214, "A Comparative Study of Several HIV-1 Derived Immunogens in Infected Individuals with >500 CD4 Cells/mm^3." (MGS, Gen and Chi envelope products)	ACTG 235, "Active Immunization of Asymptomatic HIV-Infected Women: A Phase I Study of Safety and Immunogenicity of MN rgp 120/HIV-1 Vaccine."† (Gen rgp 120 MN)
	ACTG 218, "A Placebo Controlled, Phase I Trial to Evaluate the Safety and Immunogenicity of Recombinant Envelope Proteins of HIV-1 gp 160 and gp 120 in Children ≥1 Month Old with Asymptomatic HIV Infection." (MGS, Gen and Chi envelope products)

* also AVEG 102
† also AVEG 104

during pregnancy, to prevent transmission of HIV from an infected mother to her fetus (ACTG 234, 235); and during the first months of life in infants born to seropositive mothers (ACTG 218).

Data from these various trials may help clarify the therapeutic potential of HIV vaccines. In addition, if a beneficial effect is observed, it is anticipated that the investigative efforts of virologists and immunologists who are involved in the trials will help identify the mechanism of that effect. Understanding the mechanism would likely enhance our understanding of not only the pathogenesis of HIV infection but also the correlates of protective immunity, both of which are clearly essential for the development of more effective therapies for those already infected, as well as a truly efficacious preventive vaccine. ■

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Further Reading

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9. *Redfield R; et al. HIV vaccine therapy: Phase I safety and immunogenicity using rpg 160.* VIII International Conference on AIDS/III STD World Congress, Amsterdam 1992; 1:16.45,139.
10. *Recommendations of the advisory committee on immunization practices (ACIP): Use of vaccines and immune globulins in persons with altered immunocompetence.* MMWR 1993; 42:1-18.

Emphasizing Hope for Those Living with HIV

Pessimism in the AIDS community following June's 9th International Conference on AIDS in Berlin creates the misimpression that there is little to offer those living with HIV disease. Preliminary results from the Concorde study suggested AZT may be less helpful when started in early stages of infection, and the benefits less durable, than previously thought. However, these results have not yet been published, and a number of questions about the study design and interpretation of results have been raised. Furthermore, the benefits of AZT in advanced stages of disease have been well established, and newer antiretroviral agents administered sequentially or in combination may prolong the initial transient benefit of AZT.

Antiretroviral drugs such as AZT and developments in the prevention and treatment of opportunistic infections have helped people with HIV live longer and in better states of health. Sadly, we realize, and knew before the Berlin meetings, that current therapies are limited and ultimately inadequate. Greater effort needs to be directed toward the development of new therapies and toward prevention, which remains the single most potent weapon against the HIV epidemic.

It is unkind and untrue, however, to suggest that we can do nothing to help people with HIV disease. We can provide care, prevent and treat complications, and in many cases prolong life. It is hope and not despair that we should emphasize.

The preceding is adapted from a letter to the editor of The New York Times *from Drs. Michael Rigsby and Gerald Friedland; it was published June 28, 1993. Dr. Rigsby is Director of HIV/AIDS, Veterans Administration Hospital, West Haven, and Assistant Professor of Medicine, Yale Medical School. Dr. Friedland is Co-Editor of* AIDS Clinical Care.

NIAID Issues Preliminary Recommendations on Antiretrovirals

An independent panel of experts convened by the National Institute of Allergy and Infectious Diseases (NIAID) released preliminary recommendations on the use of antiretroviral drugs in the care of adults infected with HIV. Final recommendations are being peer-reviewed for publication, and NIAID spokespersons emphasized that the results published here are preliminary in nature.

The panel's recommendations, issued June 25, are not federal or NIAID policy, but serve as guidelines for providers treating adults with early, intermediate, and late stage HIV disease in using the antiretroviral agents AZT, ddI, and ddC. These preliminary recommendations are notable for their flexibility, not because current antiretroviral agents are ineffective against HIV, but because data available at this time cannot be viewed as definitive. Trials in progress and new trials may provide further clarification in the future.

During the two-day conference, held June 23-24, 18 panel members — including physicians, investigators, statisticians, and people living with HIV infection — heard presentations and discussions from more than 30 investigators and clinicians involved in HIV research worldwide, as well as members of the HIV-infected community and the public.

Merle Sande, MD, chair of the panel and Chief of Medical Services at San Francisco General Hospital, said "we recognize that no 'average' patient exists. Some patients will do better and others, worse, than clinical studies would predict. Doctors and patients should work as a team to design treatment strategies that are clinically sound and appropriate for each individual patient's needs, priorities and circumstances of daily life."

The panel recognized that the choice to accept or decline antiretroviral therapy ultimately rests with the patient. Moreover, the panel noted that early intervention doesn't mean just giving drugs to stable, asymptomatic HIV-infected patients. Instead, early intervention involves managing the patient's overall health status, and providing emotional and psychological support.

The panel's preliminary recommendations were presented by the NIAID in the following narrative format. These same recommendations are depicted on the facing page in a table format prepared by ACC editors.

EXPERT PANEL'S PRELIMINARY RECOMMENDATIONS

For patients who have never before received antiretroviral therapy:

- For patients without symptoms whose CD4+ T cell counts are above or equal to 500/mm^3, the panel recommends continued observation and clinical and immunological monitoring (measurement of CD4 counts) every 6 months.
- For patients without symptoms whose CD4 counts are between 200 and 500 and who are stable over time, the panel recommends consideration of the following two options:
  1) initiation of antiretroviral therapy
  2) continued observation and monitoring for clinical or laboratory evidence of deterioration, at which point antiretroviral therapy should be initiated.
- For patients with CD4 counts between 200 and 500 who present with symptoms related to HIV disease, the panel recommends starting antiretroviral therapy.

When choosing an initial antiretroviral therapy:

- Use AZT as first-line therapy in patients who have received no prior antiretroviral therapy. The recommended dose is 600 mg/day in divided doses.
- The recommendation to initiate therapy with AZT applies to patients with or without symptoms, with CD4 counts between 200 and 500 or below 200, or to patients with severe AIDS-

Related Complex or AIDS regardless of their CD4 counts.

■ Combination therapy with AZT and ddI or AZT and ddC may be considered, although clinical trials have not conclusively demonstrated clinical benefit to date.

On changing initial therapy in patients who are tolerating an initial antiretroviral therapy:

■ In patients tolerating initial therapy, the panel recommends continuing AZT for patients who appear to be stable with CD4 counts above 300.

■ For patients who have CD4 counts below 300, the panel recommends consideration of two options:

1) continuing AZT, or

2) changing to ddI.

The panel notes that the strongest data supporting a change in therapy to ddI were seen in patients who had been on AZT for 4 months or longer (median duration of 13 months' prior AZT).

For patients who are intolerant of AZT, or who experience progression of disease despite AZT therapy:

■ In patients with CD4 counts between 200 and 500 and 50 to 200 who are intolerant of AZT, the panel recommends switching to ddI monotherapy. For AZT intolerant patients with CD4 counts of less than 50, the panel recommends switching to ddI or ddC monotherapy. Another option includes discontinuing antiretroviral therapy.

■ For patients with CD4 counts between 200 and 500 and 50 to 200 who show signs of clinical progression, the panel recommends initiating an alternative antiretroviral regimen. Options include monotherapy, for example with ddI, or initiation of combination therapy by adding a second agent, either ddI or ddC.

■ For patients with CD4 counts below 50 and who have evidence of disease progression, the panel recommends switching to an alternative monotherapy, either ddI or ddC.

Other options include combination therapy.

■ For patients with CD4 counts above 500 who are taking AZT but experience intolerance, the panel recommends discontinuation of therapy. ■

NIAID Preliminary Recommendations on Antiretrovirals
Issued June 25, 1993

Table 1 Preliminary recommendations on initiating therapy for patients who have never before received antiretroviral therapy

Patient condition	Preliminary recommendations	Agent/s
Asymptomatic; CD4 cell count ≥500/mm^3	Observe, monitor clinical status and CD4 counts every 6 mo.	No antiretroviral therapy
Asymptomatic; CD4 200-500; stable over time	Either 1. Initiate therapy or 2. Observe*, monitor; initiate therapy if clinical or laboratory evidence of deterioration	AZT divided doses equal to 600 mg/day; may consider AZT and ddI or AZT and ddC combination.†
Symptomatic; CD4 200-500	Start antiretroviral therapy	
Symptomatic or asymptomatic; CD4 ≤500	Start antiretroviral therapy*	
AIDS or severe ARC with any CD4 count	Start antiretroviral therapy	

* Apparent inconsistencies are noted; finalized guidelines on antiretroviral treatment are expected to be published later in a peer-reviewed journal.

† Clinical benefit of combination therapy has not yet been demonstrated.

Table 2 Preliminary recommendations on change of therapy in patients tolerating an initial therapy

Patient condition	Preliminary recommendation
CD4>300, stable	Continue AZT
CD4<300	Either: 1. Continue AZT, or 2. Change to ddI (especially if AZT therapy duration is > 4 mo.)

Table 3 Preliminary recommendations for patients intolerant of AZT

Patient condition	Preliminary recommendation	Alternative regimen
CD4≥500; AZT intolerant	Discontinue antiretroviral therapy	No antiretroviral agent
CD4 50-500; AZT intolerant	Switch antiretroviral agents	ddI
CD4<50; AZT intolerant	Switch antiretroviral agents or discontinue antiretroviral therapy	ddI or ddC or no antiretroviral

Table 4 Preliminary recommendations for patients who experience disease progression despite AZT therapy

Patient condition	Preliminary recommendation	Alternative regimen
CD4 50-500; disease progresssion	Change antiretroviral regimen	ddI monotherapy or AZT and ddI or AZT and ddC
CD4<50; disease progression	Switch to alternative monotherapy or may consider using combination therapy	ddI; ddC; AZT and ddI; or AZT and ddC

Tables prepared by AIDS Clinical Care

HIV Infection as a Leading Cause of Death in Young Adults

Death from HIV infection continues to mount at an alarming rate. To evaluate the extent to which HIV infection is a leading cause of death, researchers from the CDC examined causes of adult death (25 to 44 years old) in large U.S. cities.

Based on 1990 data from the National Center for Health Statistics, HIV was the leading cause of death among young men in New York, New Jersey, California, Florida, and Massachusetts and in 64 of 172 cities with a population of 100,000 or more (37%); the proportion of deaths ranged from 16% in Bridgeport, CT, to 61% in San Francisco and included, in addition to the large coastal urban cities, interior metropolitan areas such as Minneapolis; Kansas City; Portland, OR; Macon, GA; and San Antonio. Among women, HIV was the leading cause of death in 9 of 172 cities (5%); the proportion of deaths ranged from 15% in Baltimore to 43% in Newark.

The authors note that these data may underestimate the true impact of HIV infection because HIV is underreported on death certificates. However, the study does demonstrate the widespread impact of HIV infection in large cities in all regions of the country.

Selik RM; et al. HIV infection as leading cause of death among young adults in US cities and states. JAMA 1993 Jun 16; 269:2991-4.

Viral Causes of Diarrhea in HIV

Diarrhea is a frequent complication of HIV infection that can be difficult to manage. Some studies have identified bacterial and parasitic causes of diarrhea. However, less is known about enteric viruses. In this prospective study, Grohmann et al. used recently developed techniques (PCR, an enzyme immunoassay, and stool concentrates for polyacrylamide-gel electrophoresis to detect viral antigens) to evaluate the association between diarrhea and a group of novel enteric viruses (astroviruses, picobirnaviruses, and caliciviruses).

They compared rates of viral detection in stool specimens from 110 adult patients with advanced HIV disease both with and without diarrhea. Overall, patients with diarrhea showed more evidence of enteric viruses than patients without diarrhea (35% vs. 12%). Astrovirus (12% vs. 2%) and adenovirus (9% vs. 3%) were identified significantly more often in patients with diarrhea than in those without diarrhea. Picobirnavirus was identified in 6 of 65 patients with diarrhea and was associated with prolonged viral shedding and chronic diarrhea. The authors were unable to identify an immune response to any virus, possibly due to the advanced stage of HIV infection in these patients.

While astrovirus and adenovirus are known human pathogens, this is the first report of an association between picobirnavirus and diarrhea in humans. As more sensitive techniques are used to diagnose diarrheal disease in HIV-infected patients, it is likely that new pathogens will be identified. It is to be hoped that new therapies will then follow.

Grohmann GS; et al. Enteric viruses and diarrhea in HIV-infected patients. N Engl J Med 1993 Jul 1; 329:14-20.

Predicting Perinatal HIV Transmission

The identification of factors that affect perinatal HIV transmission is important for developing prevention strategies and for counseling pregnant HIV-infected women. St. Louis and colleagues evaluated several maternal and obstetric factors in a cohort of 324 HIV-infected pregnant women from Zaire to identify risk factors for perinatal transmission.

Of the 323 live-born infants, HIV infection status was indeterminate for 62 infants (19%). Definitive perinatal HIV status could be determined for 261 infants; 69 (26%) were infected. Of the 14 women who were p24 antigen positive, 71% transmitted HIV to their children (RR, 3.0). Depressed CD4 lymphocyte count was not significantly associated with HIV transmission; however, an elevated CD8 lymphocyte count (above 1800/mm^3) did correlate with HIV transmission (transmission rate, 50%; RR, 2.2). In a multivariate analysis, a CD8 count greater than 1800 cells/mm^3, p24 antigenemia, placental membrane inflammation, and prolonged fever were all significantly associated with an increased risk for HIV transmission. Breastfeeding and mode of delivery were not evaluated because almost all subjects had vaginal deliveries and breastfed.

The results of this study suggest that the risk of perinatal HIV transmission varies considerably among subgroups of women and that clinical and laboratory findings can identify women at highest risk of perinatal HIV transmission. More large studies in other female populations are needed to confirm these findings.

St. Louis ME; et al. Risk for perinatal HIV-1 transmission according to maternal immunologic, virologic, and placental factors. JAMA 1993 Jun 9; 269:2853-9.

Occupational Exposure to HIV

Despite the lack of data on efficacy, prophylactic AZT is often used by health care workers after occupational exposure to HIV. This study represents the results of a continuing surveillance program by the CDC of health care worker exposures to HIV-infected blood occurring in over 300 institutions since 1983.

Of the 1245 exposed workers, 89% (1103) involved percutaneous exposure (e.g., via needlestick) and 11% involved contact with mucous membranes (75) or non-intact skin (67). Four workers, all with percutaneous exposure, seroconverted (0.36% of percutaneous exposures).

The use of postexposure prophylactic AZT increased during the study period, from 5% between October and December of 1988 to 43% between January and June of 1992. One of the health care workers who had taken AZT seroconverted, adding one case to seven previously reported cases of AZT prophylaxis failure in HIV-exposed health care workers. Seventy-five percent of those taking AZT reported adverse drug reactions, mostly nausea, myalgias, and headache.

This study confirms previous reports of low HIV transmission rates after occupational exposure. The size and design of the study did not permit an evaluation of the efficacy of postexposure prophylactic AZT. The authors encourage continued participation by health care workers in the surveillance project in the hope that a better understanding of the risks of occupational exposure to HIV and the role of postexposure prophylaxis can be achieved.

Tokars JI; et al. Surveillance of HIV infection and zidovudine use among health care workers after occupational exposure to HIV-infected

blood. Ann Intern Med 1993 Jun 15; 118:913-9.

Liposomal Amphotericin B for Cryptococcosis

For most cases of cryptococcal disease, amphotericin B is the drug of choice for initial therapy; however, toxicity limits its use. An intravenous liposomal formulation of amphotericin B has been developed that delivers the drug within a phospholipid membrane, hence reducing its toxicity. Coker et al. report the results of a phase II noncomparative European study that evaluated the efficacy and safety of liposomal amphotericin B (AmBisome) in HIV-infected patients.

Of the 18 patients without any previous therapy, 14 were cured, 2 improved, and 2 failed treatment. Of the 19 patients with meningitis, 3 died (2 died within the first 2 weeks). Sterilization of cerebrospinal fluid was achieved in 67% of evaluable cultures. Toxicity was generally mild; 24% of patients had serum creatinine elevations, 44% had ALT elevations, and only 1 patient had fever and chills.

The results of this study suggest that high doses of liposomal amphotericin B can be given safely with efficacy rates similar to those reported for amphotericin B. Randomized trials comparing liposomal amphotericin B with amphotericin B are now needed to establish the role of each in the treatment of cryptococcal infections.

Coker RJ; et al. Treatment of cryptococcosis with liposomal amphotericin B (AmBisome) in 23 patients with AIDS. AIDS 1993 Jun; 7:829-35.

Skin Diseases and Drug Reactions in HIV Infection

Clinicians recognize that HIV-infected patients have frequent skin problems and drug reactions, but the relation between the course of skin disease and stage of HIV infection has not been quantified. Coopman and colleagues reviewed data from a large HMO in Boston and compared the frequency of dermatologic diagnoses in HIV-positive patients with the rate for HIV-negative patients (aged 20 to 29 years).

Seventy-nine percent of the 684 HIV-infected patients (618 men and 66 women) received dermatologic diagnoses. The average number of new skin disease diagnoses (excluding drug reactions) rose with advancement in disease stage (from 1.0 per person per year before documentation of HIV to 1.9 after the diagnosis of AIDS). Visit rates for men with AIDS as compared with HIV-negative men were more than 10 times higher for nummular dermatitis, herpes simplex, herpes zoster, bacterial folliculitis, impetigo, cutaneous candidiasis, and pruritus.

Cutaneous drug reactions were identified in 125 of 666 HIV-infected patients; 70% had one reaction, 21% had two, 10% had three, 6% had four, and one patient had five. The most common type of drug reaction was morbilliform rash (88%). The highest rate of drug reactions occurred with sulfa drugs (149 to 200 reactions per 1000 courses), followed by trimethoprim with or without dapsone (156 per 1000 courses), and the aminopenicillins (93 per 1000 courses).

The results of this study demonstrate the significant morbidity associated with skin disease in HIV infection and suggest that skin problems may increase as immune function deteriorates. More information is needed on the determinants of skin disease in HIV infection.

Coopman SA; et al. Cutaneous disease and drug reactions in HIV infection. N Engl J Med 1993 Jun 10; 328:1670-4.

HIV Seroreversion Is Exceedingly Rare

Do HIV-infected individuals ever lose HIV antibody? U.S. Army investigators addressed this question in a retrospective review of all HIV test results from patients with one or more seroreactive samples that were followed by one or more unreactive blood samples.

A true seroreversion required a positive ELISA, Western blot, and EIA confirmed by retesting, followed by a negative test at a later date. Between 1985 and 1992, only 6 of 4911 seroreactive individuals were potential seroreverters. True seroreversion had occurred in none; 5 patients had samples from uninfected patients that had been incorrectly attributed to them, and one patient was found to be seroreactive when retested. Testing errors were identified for an additional 23 of 26 patients who had a single positive sample prior to the negative test; 3 patients had suspected testing errors that could not be confirmed.

Using data from over 2.5 million HIV-tested patients, the authors calculated a cumulative testing error rate of 12.4 per 1 million patients. The authors conclude that true seroreversion is exceedingly rare, if it occurs at all, and that most cases of suspected seroreversion are probably the result of testing errors.

Roy MJ; et al. Absence of true seroreversion of HIV-1 antibody in seroreactive individuals. JAMA 1993 Jun 9; 269:2876-9.

Detection of HIV in Cervical and Vaginal Secretions

The identification of factors that increase the risk of heterosexual HIV transmission can help in the development of effective preventive strategies. To evaluate factors that may influence infectivity, a group of investigators working in Nairobi tried to characterize the frequency and correlates of HIV detection in endocervical and vaginal specimens.

They prospectively collected cervical and vaginal samples for HIV DNA testing from 97 HIV-seropositive women who attended a sexually transmitted disease clinic. HIV DNA was detected in 28 (33%) of 84 cervical samples and 13 (17%) of 77 vaginal samples using the polymerase chain reaction (PCR). In a multivariate model, detection of cervical HIV DNA was independently associated with use of oral contraceptives (RR, 11.6), pregnancy (RR, 4.5), and cervical ectopy (RR, 5.0), and there was a trend toward increased HIV detection among women with cervical mucopus. The presence of vaginal HIV DNA did not correlate with any of the factors studied. Unfortunately, CD4 counts were not available. Sexually transmitted disease did not correlate with detection of HIV DNA from either vaginal or cervical secretions, but, data on *Treponema pallidum*, genital herpes, and chlamydia were not available.

Future larger studies are needed that include data on CD4 counts and all sexually transmitted diseases to put these results in perspective. Meanwhile, reducing unprotected sexual activity remains the cornerstone of prevention.

Clemetson DBA; et al. Detection of HIV DNA in cervical and vaginal secretions. JAMA 1993 Jun 9; 269:2860-4.

JUDITH CURRIER, MD, MSc

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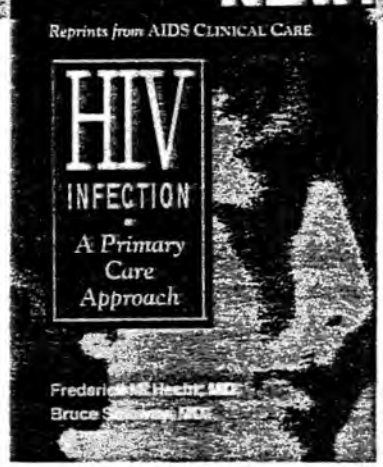

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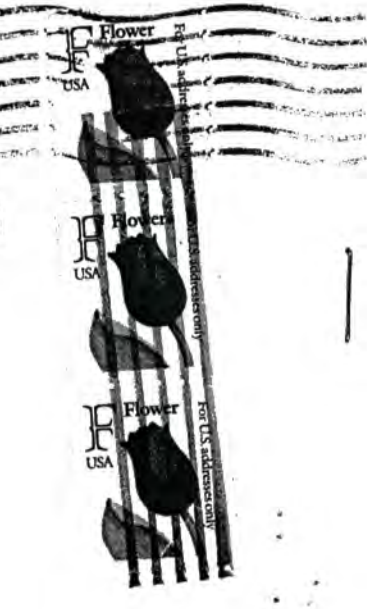

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MS. KRINSTINA M. GERMABBIE RN. MN
THE WHITE HOUSE
1600 PENNSYLVANVIA AVE.
WASHINGTON D.C. 20001

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On Behalf Of : To : VERONICA F REMPUSHESKI

********** Subject or Title **********

NURSE RESEARCHER BETH ISRAEL HOSPITAL 330 BROOKLINE AVENUE BOSTON MASSACHUSETTS 02215

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THE WHITE HOUSE

WASHINGTON

August 16, 1993

Veronica F. Rempusheski, PhD, RN
Nurse Researcher
Beth Israel Hospital
330 Brookline Avenue
Boston, Massachusetts 02215

Dear Dr. Rempusheski:

I am honored that you invited me to join you at the Nursing Conference in Beijing. Unfortunately, I will be unable to attend.

I am truly sorry to miss this opportunity to meet with nursing professionals from all over the world.

Sincerely,

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

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National AIDS Policy Coordinator

Prepared by: APO: JLehman: gw: ~~7/28/93~~ 8/14/93 (KMG): 690-5471: b:\rempushe.816

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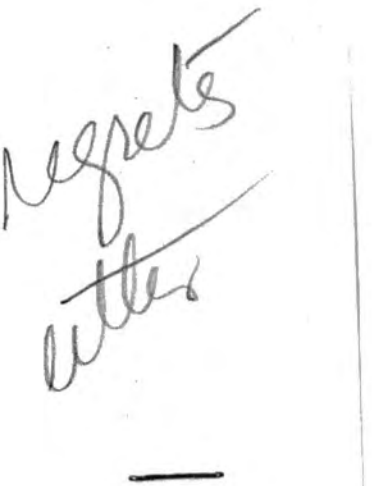

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Veronica F. Rempusheski, RN, PhD
Nurse Researcher

(617) 735-2128
FAX (617) 278-7477

July 29, 1993

Ms. Christine M. Gebbie
Department of Health
1112 Quince Street, Southeast
Olympia, WA 98501

Dear Ms. Gebbie:

At the invitation of the Chinese Nursing Association, the Citizen Ambassador Program will be administering the international side of a joint Nursing Conference in Beijing, China, in March 1994. The Conference theme, "Global Nursing Values 2000: Nursing on the Threshold of a New Century," will reflect current and future nursing challenges, focusing on: Nursing Education, Case Management, Elder Care, and Nursing Research. I was honored to be selected to serve as faculty to head the Nursing Research contingent to the Conference, and I invite you to join me.

Chinese nurses, along with nurse professionals from throughout the world, face new challenges in nursing research as we approach the next millenium. The Conference sections will be structured through poster sessions and informal workshops. Topics I feel will be relevant to Conference discussions are the following:

--Integrating research in clinical practice: Bridging the research-practice gap

--Linguistic and conceptualization issues in nursing research

--Subject consent and other ethical consideration in conducting nursing research with human subjects

--Integrative reviews and meta analysis of nursing research

--Triangulation of research methods and analysis

Please read through the enclosed schedule of events and activities that will comprise the Conference week. The Conference format will encourage one-to-one interaction between North American and Chinese delegates, as well as provide an opportunity for the leaders in nursing research from each region to discuss their views as we near the 21st century.

Our nursing contingent to the Conference will assemble in San Francisco on March 4, 1994. The delegation will then travel to Beijing, returning to San Francisco on March 11. Special fares for Canadian departure points will be arranged from Vancouver and Toronto to San Francisco. The estimated cost per Conference delegate is U.S. $2975, or per guest, U.S. $2875 (departing from and returning to San Francisco or Vancouver). For those coming from Toronto, the estimated cost is an additional U.S. $175. This includes transportation, all Conference meetings and activities, accommodations, most meals, and substantially all other costs.

There will also be a supplemental program of cultural activities, and a separate schedule will be arranged for spouses and accompanying guests who do not wish to attend the professional sessions. In addition, a post-Conference cultural program will be offered, at an additional cost. If you will be joining the Conference in Beijing on March 5, the international air will be credited to your account.

For U.S. citizens, expenses associated with this project may be deductible as an ordinary and necessary business expense under Sections 162 and 274 of the Internal Revenue Code of 1986, if participation is closely related to one's business or occupation. (We suggest that you consult with a tax advisor to determine whether tax deductibility is applicable.) Following the delegation's return, a journal of the professional activities will be provided to each participant.

The enclosed registration form for participation in the Conference should be completed and returned to the Citizen Ambassador Program as soon as possible. Once your membership is confirmed, their staff will contact you with additional information.

Due to the exceptional interest this exchange opportunity is sure to generate, and the extensive planning and communication involved, I strongly urge you to contact Mr. Jerry Smith, Director of Nursing Programs, or Ms. Stacey Merrill, Project Coordinator, as soon as possible if you intend to accept the invitation. They can be reached at (509) 534-0430 in the Pacific time zone or by fax at (509) 534-5245.

I look forward to working and learning with you in China, a fascinating and complex country. We will come away with new friendships and long-term professional relationships, vivid memories of an ancient culture, and a new perspective on our profession.

Sincerely,

Veronica F. Rempusheski

Veronica F. Rempusheski, PhD, RN
Nurse Researcher

VFM/je

Enclosures

cc: Jerry Smith
Director, Nursing Programs
People to People Citizen Ambassador Program
Dwight D. Eisenhower Building
Spokane, Washington 99202

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International Nursing Conference
Beijing, People's Republic of China

GLOBAL NURSING VALUES

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nursing on the threshold of a new century

March 5–11, 1994

WORKING SESSIONS PROGRAM TOPICS

CASE MANAGEMENT—
the nurse's role in patient education and case monitoring

ELDER CARE—
the challenge of our aging populations

NURSING EDUCATION—
development of nurse professionals in their expanding role

NURSING RESEARCH—
the value of comparative studies and clinical research

TRADITIONAL NURSING CARE—
Cross-cultural evaluation and comparison of nursing practices in the People's Republic of China

The Chinese Nursing Association is providing a forum for the exchange of ideas as nursing prepares for the healthcare challenges of the 21st century. This dialogue between East and West will provide opportunities to share with our Chinese colleagues and gain new insights into traditional Chinese approaches to patient care.

▲ A visiting medical education team gives advice to rural mothers.

▲ Traditional Chinese medicines use about 2,000 kinds of medicinal herbs.

NURSING CONFERENCE REGISTRATION FORM

*PLEASE **PRINT** OR TYPE; PHOTOCOPY, FILL OUT, AND SUBMIT THIS FORM FOR ANY ACCOMPANYING GUEST WHO WILL PARTICIPATE AS A PROFESSIONAL DELEGATE*

1. **CONFERENCE SECTION OF INTEREST:** Case Management ☐ Research ☐ Eldercare ☐ Education ☐ Traditional Nursing Practice ☐

2. **DELEGATE INFORMATION** *(Circle preferred title and use full legal name as it appears on your passport.)*

Mr., Mrs., Ms., Dr., Prof. _____ *(first)* _____ *(middle)* _____ *(last)*

MALE ☐ FEMALE ☐ PREFERRED FIRST NAME *(if different from legal name)*: _____

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EMERGENCY CONTACT: _____ *(name)* _____ *(day phone)* _____ *(evening phone)*

NOTE: Following our receipt of your registration form, you will be sent a professional delegate profile form to fill out (this will facilitate professional arrangements).

3. **ACCOMPANYING GUEST** *(Circle preferred title and use full legal name; if professional delegate, complete a separate form.)*

Mr., Mrs., Ms., Dr., Prof. _____ *(first)* _____ *(middle)* _____ *(last)* _____ *(preferred first name)*

ADDRESS: _____

OCCUPATION: _____ PHONE: _____

4. **PASSPORT AND VISA INFORMATION** *(Passport not necessary for registration, although you should apply for one as soon as possible.)*

Delegate

Birthdate _____ Birthplace _____

Citizenship _____ Passport No. _____ Exp.Date _____

Guest

Birthdate _____ Birthplace _____

Citizenship _____ Passport No. _____ Exp.Date _____

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☐ Please assign a roommate (*additional charge if none is available*) Smoker ☐ Non-smoker ☐ Either ☐

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6. **DEPOSIT**

☐ Enclosed is my check in the amount of $_____ (minimum U.S. $500 per delegate or guest) as a deposit toward membership in this delegation. I understand this registration is subject to the Terms and Conditions of Participation on reverse side. (All checks are to be made payable to the Citizen Ambassador Program; mail to Dwight D. Eisenhower Building, S. 110 Ferrall Street, Spokane, Washington, 99202.)

☐ I authorize $_____ (minimum U.S. $500 per delegate or guest) deposit to be charged to my credit card. Bill me for the balance.

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I have read and agree to the Terms and Conditions of Participation on reverse. _____

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CITIZEN AMBASSADOR PROGRAM ®

TERMS AND CONDITIONS OF PARTICIPATION

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Project costs and air fares and rules/regulations used in determining the Project Cost are those in effect approximately six months prior to project departure; therefore, the actual Project Cost is subject to change—upward or downward—should land costs and/or air fares change prior to your departure date.

INCLUDED IN PROJECT COST

Transportation. Roundtrip airline transportation from the origination city listed in the Invitational Letter based on the lowest applicable group or excursion air fare, economy class jet service or tourist or economy propeller service, whichever is available, unless otherwise stipulated. Unless otherwise stipulated, the delegation must travel together on the same flight(s) for the entire itinerary. Transportation between your hometown and departure city, as well as deviations from the group air schedule, may be subject to additional charges.

Accommodations, Meals, Excursions. First-class hotel accommodations, based on two persons sharing twin-bed room with private bath/toilet facilities, where available. Single room accommodations may be impossible or difficult to obtain; single room will be requested, if desired, and supplemental charges will be made. Supplement will also apply if single room is assigned by necessity. Two meals per day [continental breakfast (except in some countries where full breakfast is customary and would therefore be provided) and table d'hote luncheon or dinner]. In some cases three meals per day may be provided. All necessary transfers, airport to hotel and vice versa, including luggage porterage of two pieces per person, and interpreter courier assistance. All special meetings, interviews and visitations, including interpreter/guide assistance where necessary. Entrance fees. Hotel servant gratuities and taxes as levied by the hotels, and all tips to porters, guides and drivers for group services.

NOT INCLUDED IN PROJECT COST

Passport and Visa. Each person must apply in person for his own passport to his Passport Office or Clerk of the District, State or Federal Court. Visas will be applied for by People to People Citizen Ambassador Program, but each participant will be responsible for visa fees.

Airport Taxes Charged at Airports. Cost for these will be approximately $10, and will be paid upon departure from appropriate airports.

CANCELLATIONS

Upon receipt of written notification, full refund is made on cancellations 60 days or more before departure date less a $50 per person administration fee and less any out-of-pocket costs incurred, such as visa fees. For cancellations after that date, administration fees will be charged according to the following schedule: less than 60 days before departure—$250 per person; less than 30 days—$500 per person; less than 15 days—$750 per person. This fee is in addition to out-of-pocket expenses, cable fees necessary to effect cancellation of overseas arrangements, forfeitures to hotels, airlines and overseas agents, and any other unrecoverable costs. These unrecoverable amounts are often substantial and it may take up to 90 days to determine the exact amount and the refund due, if any. If a member must cancel after trip has begun and/or does not use a portion of the services already prepaid, refunds will be whatever recoverable monies are obtained from hotels/contractors and airlines. No refunds are made for unused excursions and special program activities, except in special cases where delegates purchase trip cancellation insurance through a reputable insurance firm to offset cancellation cost in case of a medical emergency.

RESPONSIBILITY

The People to People Citizen Ambassador Program is a division of International Ambassador Programs, Incorporated, a Washington corporation based in Spokane, Washington. An individual's membership in this delegation is accepted by the People to People Citizen Ambassador Program only in accordance with the following statement of conditions and responsibilities:

The sponsors reserve the right to decline to accept or retain any person as a project participant. Should any person's health or physical infirmity or general deportment, in the judgment of the delegation leader, impede the operation of the project or the rights or welfare or enjoyment of other participants, the leader has the right to terminate that person's participation, and a refund of unused services, where such refund can be obtained from land operators, is the limit of the sponsor's responsibility should such person be required to depart the project.

In arranging for transportation or conveyance, hotel accommodations or other services and in carrying out the project, neither the sponsors nor their agents shall be responsible or liable for any loss, cost, damage, injury, delay, irregularity, or expense of any kind whatsoever, arising from the use of any conveyance, accommodations, or services, or thefts, pilferage, government restrictions or regulations and any loss or expense resulting from the above contingencies shall be borne by the project member. Nor shall the sponsors nor their agents be responsible nor liable in respect to any faults or defaults, acts or omissions of any transportation carrier, hotel or other services, and services are subject to the laws of the respective countries visited.

The sponsors shall not be responsible in any way for loss or damage to project members' baggage or personal effects. (Luggage, personal effects, and accident insurance is recommended.) This Agreement, including its interpretation and its performance, and all proceedings hereunder shall be construed in accordance with the laws of the State of Washington. In any action or other proceeding that may be brought arising out of, in connection with, or by reason of this Agreement, the laws of the State of Washington shall be applicable and controlling. The parties shall litigate all such claims and matters in connection with this Agreement in the Courts of the County of Spokane, State of Washington.

If the project must be cancelled, the liability of the People to People Citizen Ambassador Program or its agents is limited to refund of monies received by People to People Citizen Ambassador Program or its agents. The sponsors reserve the right, in their sole discretion, to withdraw the project (in which case refund will be made) or to make such alterations in the schedule as they may deem necessary or desirable. In particular, where special visits and/or meetings are scheduled to be arranged, the sponsors cannot be held responsible for changes, substitutions or alternate arrangements which may be necessary, should for any reason the appointment for such special visits and/or meetings be changed or cancelled by the principals involved. Alternate arrangements or substitute programs will be arranged where possible in such instances.

No refund will be made for services not taken in case of sickness, accident or emergency resulting in omission of service for less than three consecutive days. Refund will be made on the basis of such amount, if any, as is actually recovered on unused accommodations and services, less all expense and charges incidental to effecting cancellation. Refund for unused transportation tickets will be made in accordance with the respective carrier's regulations.

Each Citizen Ambassador Program project is specifically approved by People to People International. All delegates become full members of People to People International for that calendar year through their participation in the Citizen Ambassador Program.

7209

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Alan E. Gambrell
Washington D.C. Representative
SEICUS D.C. Office
2700 Connecticut Avenue NW
Suite 302A
Washington, D.C. 20008

Dear Mr. Gambrell:

Thank you for your kind words of congratulations and for sending me the information on SEICUS.

I look forward to working with SEICUS as I get fully involved in my responsibilities as the National AIDS Policy Coordinator. We clearly share many priorities and interests.

Sincerely,

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

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Prepared by: APO: KMGebbie: gw: 8/14/93: 690-5471: b:\gambrell.816

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National AIDS Policy Coordinator

Thanks for sending the material. I look forward to working with SEICUS as I get more fully into my responsibilities. We clearly share many priorities & interests.
—Susan

SIECUS

Sex Information and Education Council of the United States
130 West 42nd St.
Suite 2500
New York, NY 10036
212-819-9770

SIECUS

Sex Information and Education Council of the U.S.

Alan E. Gambrell
Washington, D.C. Representative

SIECUS D.C. Office:
2700 Connecticut Avenue N.W. • Suite 302A • Washington, D.C. 20008
Phone/Fax: (202) 265-2405

July 29, 1993

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

Dear Ms. Gebbie:

On behalf of SIECUS, the Sex Information and Education Council of the U.S., congratulations on your appointment as National AIDS Policy Coordinator.

We were pleased to hear a core perspective, shared by SIECUS, that you voiced in a recent McNeil-Lehrer interview about the complexity of HIV/AIDS prevention efforts. You stated, in part, that prevention involved "helping people sustain behavior change over a life time, behavior change around sex, around what they do for pleasure, about addicting substances, and that's very difficult." These were indeed reassuring words.

As you settle into your new responsibilities, I wanted to provide you with background information about SIECUS and an outline of our priorities specific to HIV/AIDS and their relevance to your office. Two key areas are highlighted below that SIECUS feels are relevant to the mission of your office. (NOTE: We appreciated the opportunity to share these ideas with your office in the recent brain-storming session with Buck Buckingham of your staff.)

SIECUS Priorities on HIV/AIDS Prevention.

1. **Improving HIV/AIDS prevention efforts targeting: school-age youth and gay/bisexual men.** Earlier this year, SIECUS completed a study on state HIV/AIDS education activities. The key finding is that, although all states have developed the infrastructure to support HIV/AIDS education programs, youth are not being provided with information they need to reduce the risk of becoming infected with HIV. This includes: a balance of information between abstinence and safer sex, discussion of sexuality in a positive framework, condom information, discussion of issues about sexual orientation, instruction about sexual responsibility and decision-making, among others.

In addition, efforts targeting out-of-school and disproportionate youth are severely-underfunded. This includes efforts targeting gay/bisexual youth, runaway/homeless youth, and youth with high rates of STDs.

Needs/Priorities.

- CDC programs that promote continued and improved HIV/AIDS education programs, particularly on providing more straightforward information on sexuality, safer sex, condoms, and responsibility and decision-making skills development. An integral component of these reform efforts is improved targeting of disproportionate risk populations (e.g., redesign of RFPs, technical assistance to communities and states, and funding of appropriate HIV/AIDS prevention programs).

- Coordination between CDC and the Department of Education on: (1) school-based HIV/AIDS prevention and (2) promoting an expanded focus at the Department of Education on HIV/AIDS prevention within the context of comprehensive health education. Of particular concern is the omission of health education as a priority subject in Goals 2000 and its omission in pending federal legislation authorizing educational reform activities. The National AIDS Policy Coordinator seems well-suited to play a role in facilitating communication between Secretary Shalala and Secretary Riley on these issues.

2. **Sexual behavior research out of NIH.** Recent Congressional opposition to the conduct of sexual behavior research, including efforts specific to HIV/AIDS prevention, have resulted in a disruption of long-delayed sexual behavior research efforts. As you have stated, we need to know more about human sexuality in order to design prevention programs that will have an impact on HIV/AIDS, as well as STDs and teenage pregnancy. With the recent passage of the NIH Revitalization Act, and the formation of the new NIH Office of Behavioral and Social Science Research, there is an opportunity to promote new efforts on HIV/AIDS prevention and sexual behavior research, particularly through coordinated agreement among federal agencies on the importance of such efforts and education of Congress about the critical need for research in combatting AIDS.

Priorities/Needs.

- Coordination between key officials at NIH and HHS in educating Congress on the role of sexual behavior research in HIV/AIDS prevention efforts.

- Interaction between CDC and NIH (i.e., the Office of Behavioral and Social Science Research as well as the new AIDS office at NIH) on prevention priorities.

Background on SIECUS.

SIECUS is committed to the basic principle that sexuality is a natural and healthy part of living and that each individual must have the right and the ability to make responsible sexual choices. SIECUS is a national nonprofit organization with over 2,500 members, including sexuality educators, university educators, family planning providers, psychologists, social workers, and other professionals focused on sexuality education and sexual rights issues. Founded in 1964, SIECUS provides technical assistance and information clearinghouse services on a range of sexuality issues.

SIECUS Public Policy Priorities. There are five priority areas guiding the advocacy efforts of SIECUS. They are outlined below. In addition, enclosed is a position paper outlining our priorities.

* support for comprehensive sexuality education;

* implementation of straightforward and explicit HIV/AIDS prevention education;

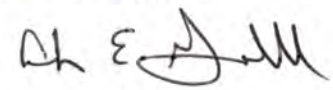
* support for reproductive rights;

* elimination of bias based upon sexual orientation; and

* opposition to censorship of art and sexually-explicit materials (elimination of restrictive regulations on funding through the National Endowment for the Arts).

Once again, congratulations on your appointment. Please feel free to call upon SIECUS in your efforts to bring about improved coordination and mobilization of the federal government's resources in the fight against AIDS. I can be reached at (202) 265-2405 (phone/Fax) and look forward to working with your office.

Sincerely,



Alan E. Gambrell

SIECUS DC Policy Office
2700 Connecticut Ave., NW, Suite 302A
Washington, DC 20008

enclosures

Clinton Presidential Records
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Siecus: Sex Information and Education Council of the United States
Annual Report 1991-1992

16pgs

SIECUS

Sex Information and Education Council of the United States

ANNUAL REPORT
1991-1992

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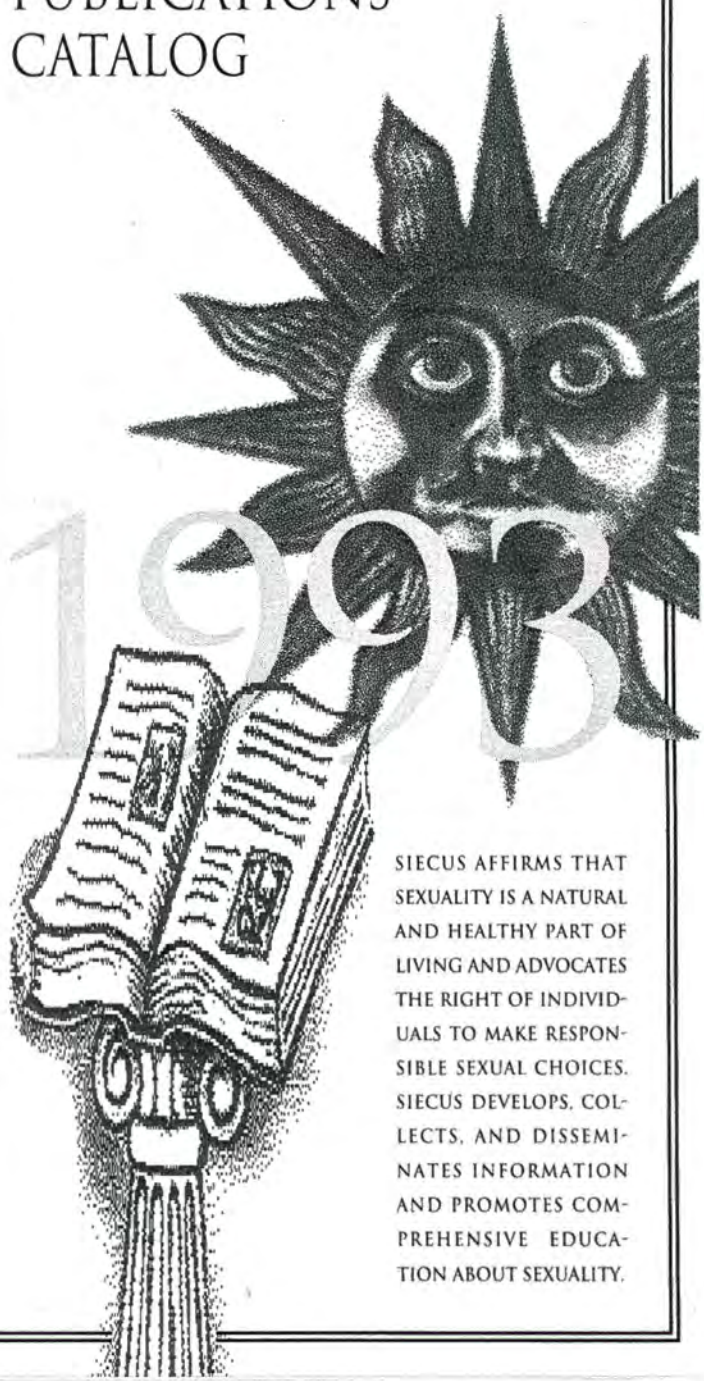
Siecus Publications Catalog

12 pgs

SIECUS

PUBLICATIONS CATALOG



1998

SIECUS AFFIRMS THAT SEXUALITY IS A NATURAL AND HEALTHY PART OF LIVING AND ADVOCATES THE RIGHT OF INDIVIDUALS TO MAKE RESPONSIBLE SEXUAL CHOICES. SIECUS DEVELOPS, COLLECTS, AND DISSEMINATES INFORMATION AND PROMOTES COMPREHENSIVE EDUCATION ABOUT SEXUALITY.

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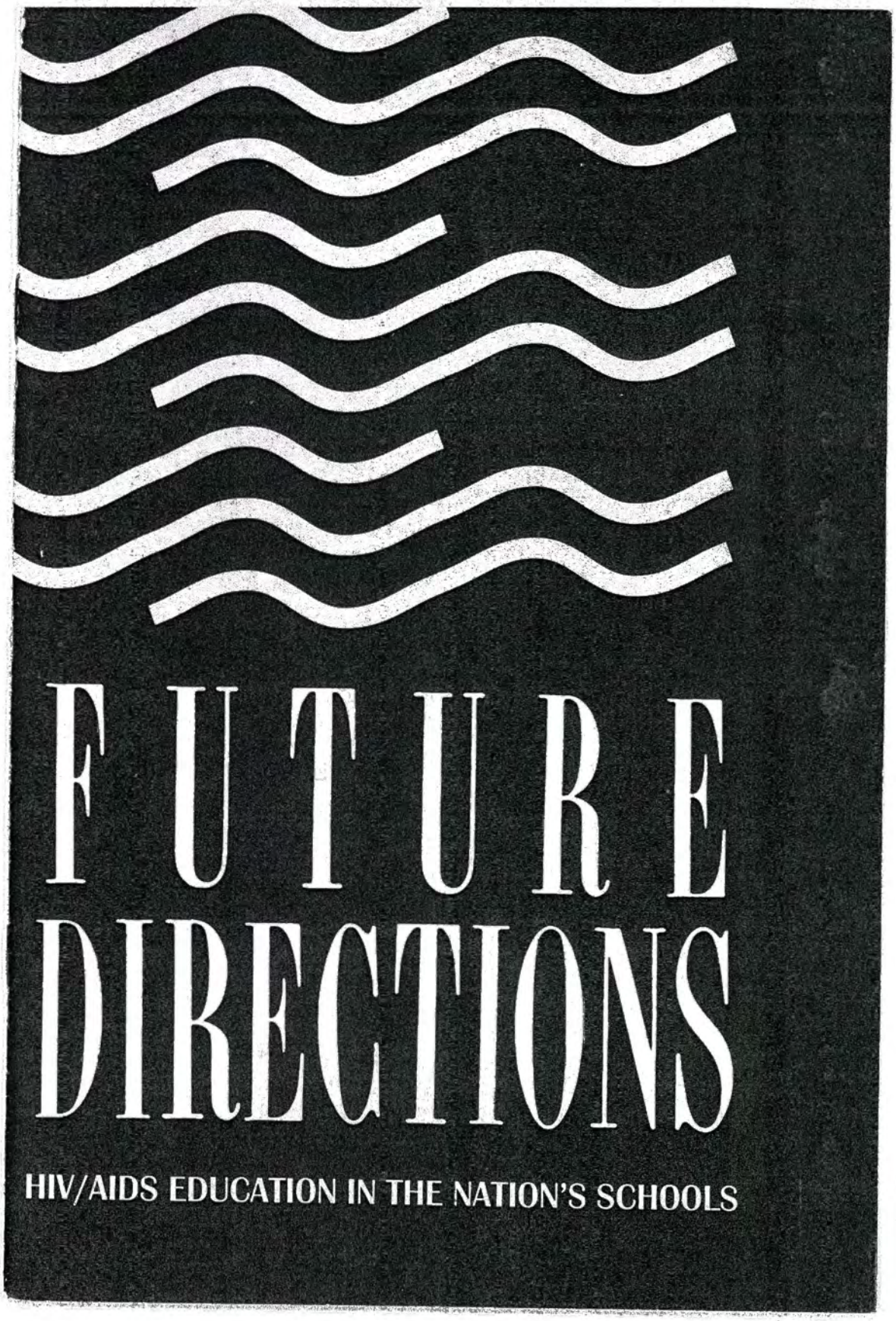
Future Directions:
HIV/AIDS Education in the Nations Schools

36 pgs


FUTURE
DIRECTIONS
HIV/AIDS EDUCATION IN THE NATION'S SCHOOLS

NAPO Document Control Slip

NAPO Number : 7209 PHS Number : OS Number : Document Type : White House Letter

Document Date: 9/09/93 Refer'd Date : 9/09/93 Int Due Date : 9/09/93 Ext Due Date : 9/09/93
NAPO Xref : PHS Xref : OS Xref : Keyer ID : SBURROUG
Purge Date : 9/09/95 Disposition : DESTROY Final Date : Document Loc : -03D10

********** Correspondent Information **********

From : GEBBIE Title : DIRECTOR Organization : NAPO
Address : City : WASHINGTON State : DC Zip : 20503
On Behalf Of : To : ALAN E GAMBRELL

********** Subject or Title **********

SIECUS SEX INFORMATION AND EDUCATION COUNCIL OF THE U.S. WASHINGTON D C REPRESENTATIVE 2700 CONNECTICUT AVENUE N.W. SUITE 302A WASHINGTON D C 20008

********** Keywords **********

********** Special Instructions **********

********** Assignment/Action History **********

Process Type : Kristine Gebbie Correspondence

Assignee	Initials	Action	Status	Due Date	Completed	Comments TO assignee
Kristine M. Gebbie	_____	DIRS	ASGN	9/09/93		

****

Related WordPerfect Filenames: _____ _____ _____

Comments FROM assignees:

7226

THE WHITE HOUSE

WASHINGTON

August 16, 1993

Mr. Tim Themy-Kotronakis
T & T Medical Products U.S.A.
P.O. Box 27488
Salt Lake City, Utah 84127

Dear Mr. Themy-Kotronakis:

Thank you for your words of congratulations on my appointment as the National AIDS Policy Coordinator. My apologies for the delay in response, things have been rather hectic around here these past few weeks.

I have forwarded your letter to the Office of Device Evaluation at the Food and Drug Administration. They have an application process for reviewing and analyzing devices or inventions such as yours.

Best of luck with your invention.

Sincerely,

Kristine Gebbie

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

CC: Food and Drug Administration,
Executive Secretariat

Kristine,

In the past, we have referred these types of letters/suggestions to:

Office of Device Evaluation
FDA

They have an application process, etc. for reviewing device suggestions.

Bert —

yes - he should get a thanks & I've sent your letter on to Office of

K —

THE WHITE HOUSE

WASHINGTON

August 16, 1993

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Sincerely,

Kristine Gebbie

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

CC: Food and Drug Administration,
Executive Secretariat

P.S.

See NIH response enclosed.

Also see circled paragraph in letter. It suddens me this man may be giving false hopes for a price.

— Bert

THE WHITE HOUSE

WASHINGTON

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National AIDS Policy Coordinator

CC: Food and Drug Administration,
Executive Secretariat

Prepared by: APO: JLehman : gw: 8/18/93: 690-5471: b:\t-kontro.kis

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

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

CC: Food and Drug Administration,
Executive Secretariat

T & T
Medical Products U.S.A.

Factory & Offices:
2109 West 2300 South
Salt Lake City, Utah 84119 U.S.A.

Mailing Address:
P.O. Box 27488
Salt Lake City, Utah 84127 U.S.A.

Telephone: 801-973-6400 • Fax: 801-973-6463 • Telex: 910-240-4492

6 August, 1993

Ms. Kristine M. Gebbi
CZAR ON AIDS PROGRAM
The White House, U.S. Government
1600 Pennsylvania Avenue
Washington D.C. 20005

Via Federal Express

Dear Ms. Bebbi:

This is my third communication to you the past 30 days without an answer. I wish you well - I know you are busy.

Enclosed find ample material describing my HIV-AIDS treating invention "THE AIDS TREATING MACHINE".

The full page ads I placed in several national and international magazines causes my phones to ring-off the hook. Calls are from AIDS R & D facilities, Hospitals, and two Foreign Goverments seeking possible answer to their very high HIV-AIDS problems...

Ms. Gebbi, you as my Government in charge of AIDS, have a responsibility to look into my invention and guide me, help me help the world.
I am NOT looking for glory or money, guidance only!

Enclosed what I sent President Clinton yesterday.

The next couple of weeks the whole world will know about my machine due to my extensive advertisements.

Try to communicate with me Ms. Gebbi!

Thank You

Tim Themy-Kotronakis
President and Inventor
"THE AIDS TREATING MACHINE"

T & T MEDICAL PRODUCTS U.S.A.

P.S...F.Y.I. Over 20 people phoned me to warn me that you will have the "sharks", regulators with their guns here to haul me away and empty my facility, TRUE?

****

T&T
Medical Products U.S.A.

Factory & Offices:
2109 West 2300 South
Salt Lake City, Utah 84119 U.S.A.

Mailing Address:
P.O. Box 27488
Salt Lake City, Utah 84127 U.S.A.

Telephone: 801-973-6400 • Fax: 801-973-6463 • Telex: 910-240-4492

4 August, 1993

President of the United States of America
Mr. Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20005

By Federal Express

Dear Mr. President:

Enclosed find material concerning my invention on treating the millions of peoples worldwide that are infected with the HIV-AIDS disease.

As you and everybody knows, no real treatment is available despite of the fact that the U.S. Government is spending 80 billion dollars a year.
Ask anyone, they will tell you "...it is more profitable to treat HIV-AIDS that to cure it".

Mr. President, my invention has been tested and tested and tested on humans & animals for many years, recently, on humans with the HIV-AIDS - excellent results.
The treatments were free!
Mr. President, I have sent my brochures to everyone in your Government and so far I received NO reply from anyone.
I am asking for help, NOT financial, to make my machine available, free, to as many as I can treat, to prove its efficacy.

My full page ads in several magazines causes my phone to ring off its hook, from all over the world. I need your help to start the free treatments. Give me that help Mr. President.

CAUTION...if some regulators causes me trouble, there will be a "bloody mess".

Respectfully Yours,

Tim Themy-Kotronakis
President and Inventor
"THE AIDS TREATING MACHINE"

T & T MEDICAL PRODUCTS U.S.A.

Elly T Katabira
Department of Medicine
Mulago Hospital
P.O.Box 8933,
Kampala,
UGANDA.

September 16, 1990

Mr Tim Themy-Kotronakis
President
STER-O-LIZER, INC.
2109 West 2300 South
Salt Lake City, Utah 84119
U.S.A.

Dear Mr Themy-Kotronakis

Thank you very much for your letter dated August 15, 1990. It arrived while I was still in San Francisco from where I returned a week ago. I was impressed by your discovery for a near cure for AIDS and certainly I would like to give it a try with some of my patients. However, I would like to get some more

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

December 17, 1992

Mr. Tim Themy-Kotronakis
Brinecell, Inc.
2109 West 2300 South
Salt Lake City (WVC), Utah 84119

Dear Mr. Themy-Kotronakis,

Thank you for your fax to Dr. Hoth regarding your experimental treatment for HIV infection. Dr. Hoth forwarded your fax to me for review by the scientific staff within the Division of AIDS.

Based on the information you provided, the Division of AIDS scientific staff has recommended that at this time the Division not pursue your experimental treatment. It was felt that there was insufficient pre-clinical efficacy data to warrant further consideration for use in human clinical trials.

We thank you for your submission and wish you luck in your endeavors.

Sincerely,

Frank E. Cefali, R.N., M.P.H.
Special Assistant to the
Associate Director
Clinical Research Program, NIAID, NIH

WEBER STATE UNIVERSITY

CHEMISTRY DEPARTMENT
FAX (801)-626-7445

Facsimile Transmittal Sheet

DATE 28 July 93

TO **Name** Tim

Company Brinecall

FAX Number 973-6463

FROM **Name** Lynn Moyes

Department Great Basin

NUMBER OF PAGES (including this cover page) 4

Rough Draft Only.
Final copy by 15 August

Jim

Table 1. Bactericidal Effect of the AIDS Treating Machine*

E. Coli		S. aureus	
Time (sec)	CFU/ml	Time (sec)	CFU/ml
0	73,000,000	0	86,000,00
10	< 100	10	4,100
20	< 10	20	20
30	< 10	30	0
60	0	60	0

*AC Amps = 3
DC Amps = 6
DC Volts = 26

30 sec warmup
1 ml inoculum
2 ml brine solution

Table 3. Sporocidal Effect of the AIDS Treating Machine at 15 g NaCl/Liter.*

Time (sec)	CFU/ml
0	1,970
15	730
30	7
60	0
120	0

*DC Amps = 10
AC Amps = 3.4
DC Voltage = 26

30 sec warmup
6 ml blood
1 ml spores 10^{-3}
6 ml brine solution

REGISTRATION NO.: 1718874
FOR: 1993

OWNER/OPERATOR NO.: 9917006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF MEDICAL DEVICE ESTABLISHMENT

NOTE: This form is authorized by Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2)(21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

REGISTERED ESTABLISHMENT

BRINECELL, INC.
2109 WEST 2300 SOUTH
SALT LAKE CITY, UT
84119 UNITED STATES

OWNER/OPERATOR

BRINECELL, INC.
2109 WEST 2300 SOUTH
SALT LAKE CITY,, UT
84119 UNITED STATES

OFFICIAL CORRESPONDENT

TIM THEMY-KOTRONAKIS
BRINECELL, INC.
2109 WEST 2300 SOUTH
SALT LAKE CITY, UT
84119

ESTABLISHMENT TYPE

(M) MANUFACTURER

Detach Part 1 and Keep as Proof of Registration.
Complete and Return Part 2.
Detach and Refer to Part 3 for Specific Instructions.

Form FDA 2891a (2/91) — Part 1 - Keep for Your Records — Form Approved OMB No. 0910-0060; Expiration Date 12-31-92

1718874

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF MEDICAL DEVICE ESTABLISHMENT

A Type of Submission (mark one (X) only): ☐ No Change ☐ No Longer Device Establishment ☐ Correction ☐ Out of Business

REGISTERED ESTABLISHMENT INFORMATION 1718874

BRINECELL, INC.
2109 WEST 2300 SOUTH

SALT LAKE CITY, UT
84119 UNITED STATES

B CORRECTIONS TO REGISTERED ESTABLISHMENT INFORMATION

Business Name
Address
Address
City State
Zip Country

ESTABLISHMENT TYPES (If information below is inaccurate, correct in column to right)

☐ Initial Distributor ☐ Contract Sterilizer ☐ Rebuilder/Refurbisher ☐ Repkgr/Relabeler
☒ Manufacturer ☐ Specification Dev. ☐ Contract Mfr.

C CORRECTIONS TO ESTABLISHMENT TYPE (To correct, mark (X) all which currently apply)

☐ Initial Distributor ☐ Contract Sterilizer ☐ Rebuilder/Refurbisher ☐ Repkgr/Relabeler
☐ Manufacturer ☐ Specification Dev. ☐ Contract Mfr.

OWNER/OPERATOR INFORMATION 9917006

BRINECELL, INC.
2109 WEST 2300 SOUTH

SALT LAKE CITY,, UT
84119 UNITED STATES

D CORRECTIONS TO OWNER/OPERATOR INFORMATION

Business Name
Address
Address
City State
Zip Country
Phone No. ( ) Ext.

Symbolizing the head-wreath of Cotinus–branches of wild olive transplanted by Heracles from the Hyperboreans to treeless Olympia and established in 884 B. C. by the Greek King Iphitus as the sacred and eminent honor of the Olympic athlete–The Athlon Prize embodies the wild olive's hardy resistance to the heat and drought which inflicted Olympia and the Greek athlete's doctrine of 'ponos' . . . knowing the physical and mental euphoria accorded exclusively to those who experienced the deprivation, exhaustion and discomfort ascribed by Pindar to be the essence of athletics: Kalos Kagathos . . . Physical Distinction–Nobility of Mind.

THE ATHLON PRIZE OF SOUTHERN CALIFORNIA

Tim Themy Cotronakis // INVENTOR

Swimming Pool Water Purification // 1970

Conferred in recognition of dedication to or exceptional achievement in Southern California interscholastic swimming, diving and water polo as a collaboration of Educator, Athlete and Water in confronting the potential of youth with the disciplines of aquatics athletics and their unique contributions to the psychological, social, physiological and moral maturity of young people as self-identified individuals.

J. Kenneth Fagans
Commissioner, California Interscholastic Federation, Southern Section

Thomas C. Haines
President, Southern California Swimming Coaches Association

Chairman, Kalos Kagathos Foundation

CALIF. INTERSCHOLASTIC FED. SO. SECTION

P. O. BOX 488
11011 ARTESIA BLVD.
ARTESIA, CALIFORNIA 90701
PHONE (213) 860-2414

JUNE 3, 1970

TIM THEMY COTRONAKIS , INVENTOR

FOR THOSE WHO KNOW AND ENJOY SWIMMING, THERE HAS ALWAYS BEEN THE ANNOYING RESIGNATION TO THE SPOILER OF IT ALL. PARTICULARLY TO THE AQUATICS ATHLETE WHO MUST ENDURE A SEEMINGLY INTERMINABLE DAILY MILEAGE OF EYE, EAR, AND NOSE INFLAMMATION DUE TO CHLORINE DISINFECTION OF SWIMMING POOL WATER. TIM THEMY HAS CHANGED ALL THAT AND THE SWIMMING FRATERNITY IS INDEBTED TO HIS RESEARCH AND DEVELOPMENT OF VERITABLE, IRRITATION-FREE, SWIMMING POOL WATER PURIFICATION.

SINCERELY,

J. Kenneth Fagans

J. KENNETH FAGANS
COMMISSIONER OF ATHLETICS
CHAIRMAN, ATHLON PRIZE COMMITTEE

State of California — Department of Public Health

To: All Local Health Officers — Date: December 30, 1965

From: Bureau of Sanitary Engineering — Subject: Approval of Chloro-Guard Chlorine Generator, Aquamatic Products, Inc., for Swimming Pool Disinfection

Morse Laboratories of Sacramento, California, have submitted a report evaluating the performance of the Chloro-Guard Chlorine Generator in accordance with procedures established by the State Department of Public Health for "Approval of Equipment to be Used in Public Swimming Pools".

The Chloro-Guard Generator was submitted to three independent tests, summaries of which follow:

1. Capacity

A Model 9A generator was installed on a 40,000-gallon private pool, and data was obtained for chlorine production and integrity of the electrodes after 316 hours of continuous use. It was found that the generator had the capacity required by the Swimming Pool Regulations (Section 7806), and examination of the electrodes after the test showed them to be in excellent condition. The success of this experience led to a field study.

2. Field Demonstration

A Model C150 was installed at the 150,000-gallon outdoor pool of the Alhambra Union High School in Martinez, California, for a 30-day test period. The pool is heated, and water temperature during the study was maintained at 81°F. An amperometric chlorine residual recorder with a 24-hour chart was connected to the pool return line just ahead of the D.E. filter. Chloride content of the pool at the start was 1,300 ppm, and salt was added until the second week, during which the chloride was 1,734 ppm. No further salt was added during the test period. The pool was used by 9,360 people at an average of 522 per day. Natural light intensity usually exceeded 5,000 foot-candles, the capacity of the light meter. Periodic checks of the pool were made by personnel from the Contra Costa County Health Department and the Bureau of Sanitary Engineering. Adequate chlorine residuals were continuously maintained throughout the test period, and all samples collected for bacteriological analyses met coliform and plate count limits. No chlorine stabilizers were used. pH values remained nearly constant, although minor adjustment made by the addition of HCl was necessary.

3. Electrode Life

In order to make a rational estimate of the probable service life of electrodes, a set designed for use at 7 volts and 12 amps was operated at 100 volts and approximately 26 amps for a total of 100 hours. There was no evidence of failure.

Summary

On the basis of the laboratory and field test data submitted by Morse Laboratories and obtained from independent inspections made by Bureau and Contra Costa County Health Department personnel, the Bureau of Sanitary Engineering approves the Chloro-Guard Chlorine Generators for use in public swimming pools.

Although we expect that the generators will give satisfactory performance, we request that we be notified if you find any malfunctioning or improperly installed units. A record of inadequate performances would require revocation of this approval.

H. B. Foster, Jr., Chief
Bureau of Sanitary Engineering

HBF
PCW:EO

NOTE BY BRINECELL, INC. MAY 1992, SALT LAKE CITY, UTAH

THIS DOCUMENT SHOWS THAT THE STATE OF CALIFORNIA APPROVED OUR THEN "CHLORO-GUARD" CHLORINE GENERATOR FOR USE IN PUBLIC SWIMMING POOLS.

TIM THEMY-KOTRONAKIS
FOUNDER AND PRESIDENT OF THE THEN
"CHLORO-GUARD ELECTRONICS, INC"
SACRAMENTO, CALIFORNIA
AND NOW PRESIDENT OF
BRINECELL, INC.

****

T&T
Medical Products U.S.A.

Factory & Offices:
2109 West 2300 South
Salt Lake City, Utah 84119 U.S.A.

Mailing Address:
P.O. Box 27488
Salt Lake City, Utah 84127 U.S.A.

Telephone: 801-973-6400 • Fax: 801-973-6463 • Telex: 910-240-4492

Finally! "THE AIDS TREATING MACHINE" Is it the Answer?

It is natural, understandable, and acceptable that the medical community will reject our machine, at first. However, a thorough investigation will erase all doubts.

The claims we make are not only realistic, they are ultra-conservative based on our 30 years R&D and tests on animals and humans without negative effects.

It may interest you to know that my son, Constantinos Themy-Kotronakis, and I, Tim Themy-Kotronakis, are the inventors and manufacturers, with only a high school education. What we know, that cannot be matched, is anodes and cathodes, which are the heart and soul of **"THE AIDS TREATING MACHINE."**

We started in Sacramento, California in 1960 making the CHLORO-GUARD, a swimming pool chlorine generator. In 1973 we moved to Salt Lake City, Utah to manufacture the STER-O-LIZER, a surgical instrument sterilizer. In 1980 we began manufacturing BRINECELL oxidant generators to oxidize organics in industrial effluents now in service by many industries in many countries.

After concentrating on HIV-AIDS, we feel we have perfected **"THE AIDS TREATING MACHINE"** and are now announcing it to the world. Is it the answer?

This letter and brochure are being sent to U.S. Government officials, HIV-AIDS Foundations world-wide, the World Health Organization, the national and international media, and of course, the medical communities.

Use of **"THE AIDS TREATING MACHINE"** to help those infected with the HIV-AIDS virus will depend upon the action the recipients of this letter take.

Your communication and constructive criticism is welcome.

Sincerely,
T&T Medical Products U.S.A.

Tim Themy-Kotronakis, President

Enclosure
July 1993

Dr. phil., I. J. Wilk
P.O. BOX 5006
STANFORD, CALIFORNIA 94309
TELEPHONE (415) 325-0281 • FAX (415) 325-3138

For many years Brinecell, Inc. has manufactured electrolysis systems using a special anode. Not only is this anode, and the corresponding cathode, very stable, operating even at relatively high voltages, the mixture generated at the anode is an extremely powerful oxidant when using saline solutions as electrolyte.

Among the oxidants isolated have been ozone, oxygen, chlorine, and free radicals. It would be wrong to consider the solution merely as one containing chlorine. An idea of the potency as an antimicrobial agent can be shown when comparing the effectiveness of chlorine-hypochlorite and the electrolyzed solution in destroying Legionella pneumophila, the cause of Legionnaires Disease.

This microorganism is not easy to kill. Using about equal concentrations of oxidant (the oxidant in the mixture is reported as chlorine), it was found that the electrolyzed solution is about 410 times more powerful in destroying this organism than chlorine-hypochlorite. Even spores of B. Subtilis were eliminated in a few minutes with an oxidant concentration (reported as chlorine) of 0.2 - 0.8 mg/L.

July 1993

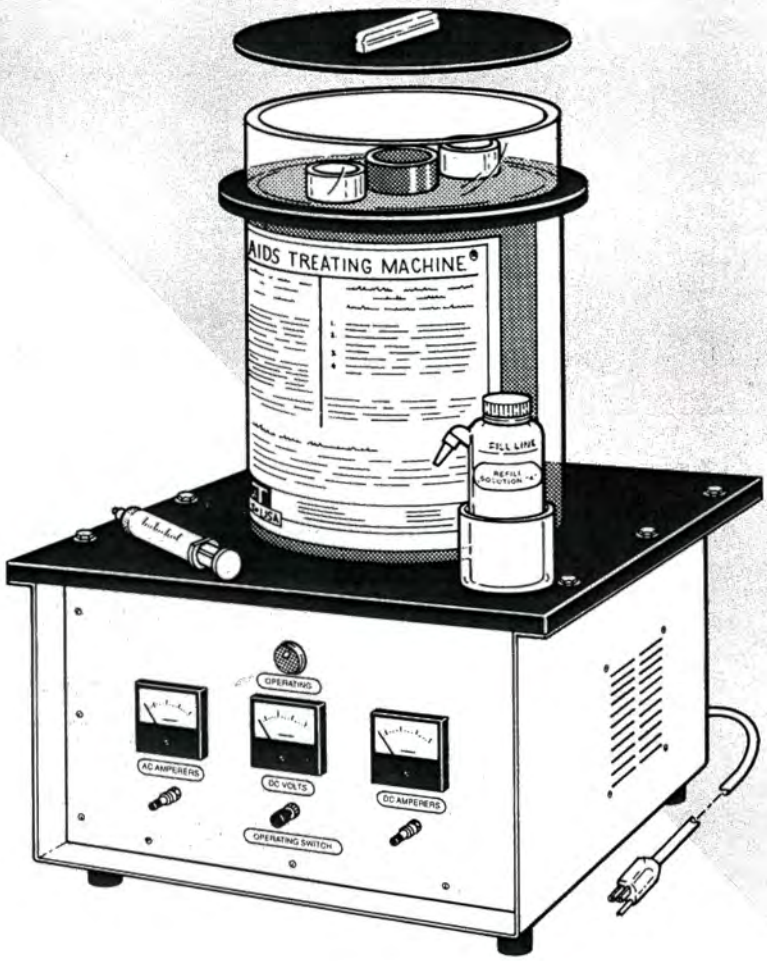
THE AIDS TREATING MACHINE

THE AIDS TREATING MACHINE de-activates pathogens, viruses and the most resistive spore, Bacillus subtilis, within 60 seconds by electrolyzing H_20 and NaCl (SOLUTION "A") provided, using proprietary electrolytic chamber and patented anodes.

Laboratory data available upon written request only.

SOLUTION "A" may be administered intravenously, intermuscularly, orally, via enema, or a combination. The quantity, method and frequency of application depends upon the patient's condition as determined by a qualified physician.

After completing the 7-day efficacy test as follows, compare blood analysis "before" and "after" treatment.



HERE IS THE 7-DAY EFFICACY TEST:

Analyze blood, paying special attention to the CD-4 count.

AM: Administer at least twenty cc's and drink eight cc's of treated SOLUTION "A".

PM: Administer at least twenty cc's and drink eight cc's of treated SOLUTION "A".

DIET DURING 7-DAY EFFICACY TEST:

Avoid all illegal drugs, liquor and tobacco.

Avoid raw or cooked vegetables and fruits, and above all -- soft drinks.

Eat three meals each day consisting of meat, beans, pasta, dairy products, and drink plenty of water.

Manufacturing electrochemical equipment under US Patent Nos. 4236992, 4201651 and 4316787 since 1960. We serve many industries throughout the world.

T&T Medical Products USA

Factory & Offices:
2109 West 2300 South
Salt Lake City, Utah 84119 USA

Mailing Address:
P.O. Box 27488
Salt Lake City, Utah 84127 USA

Phone: 801-973-6400 Fax: 801-973-6463 Telex: 910-240-4492

Since 1993 *Litho: July 1993*

Below is a copy of the AIDS TREATING MACHINE decal.

THE AIDS TREATING MACHINE ®

GENERATING SPORICIDAL AND VIRUCIDAL AGENTS TO TREAT HIV-AIDS

The sole purpose of this machine is to generate virucidal and sporicidal agents via electrolysis of H_2O and NaCl (SOLUTION "A") provided, using proprietary electrolytic chamber and multipatented anodes.

The sole purpose of the treated SOLUTION "A" is to be administered by qualified physicians to humans infected exclusively with the HIV-AIDS virus.

Whether SOLUTION "A" is treated or untreated, it must not be used for any other purpose!

HERE ARE INSTRUCTIONS ON HOW TO OPERATE THE AIDS TREATING MACHINE

1. Plug into any 120/240 VAC 50/60 Hz outlet. The plug on this machine determines the voltage to be used.
2. Fill its chamber with SOLUTION "A" provided, about 10 liters/quarts. Replenish as needed.
3. Press-in Operating Switch. The red light will come "on" indicating operation.
4. Immediately after the red light goes "off", draw the treated SOLUTION "A" with a syringe. Administer within 60 seconds.

CAUTION: Constant use of this machine will cause the SOLUTION "A" to overheat. If temperature reaches 150 F / 65 C, drain and replace with fresh SOLUTION "A". Drained SOLUTION "A" may be preserved for future use.

IMPORTANT: Solution "A" must not be substituted under any conditions!

Treated SOLUTION "A" may be administered intravenously, intermuscularly, orally, via enema, or a combination. The treated SOLUTION "A", method of application, frequency and quantity of use depends upon the patient's condition as determined by a qualified physician. The pH of the treated SOLUTION "A" may be over 7.

THE AIDS TREATING MACHINE is manufactured entirely in Salt Lake City, Utah U.S.A., under the following three U.S. patents: Nos. 4316787, 4236992 and 4201651.

Manufacturing electrochemical equipment under US Patent Nos. 4236992, 4201651 and 4316787 since 1960. We serve many industries throughout the world.

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INFORMATION ON . . .

"THE AIDS TREATING MACHINE"