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RESTRICTION CODES

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THE NATIONAL NATIVE AMERICAN AIDS PREVENTION CENTER

2100 Lake Shore Avenue, Suite A
Oakland, California 94606

Phone: (510) 444-2051
Fax: (510) 444-1593

August 2, 1996

Honorable William J. Clinton
President, United States of America
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

We understand that your office has reversed the decision by the Centers for Disease Control and Prevention (CDC) to allow open competition for the contract to operate the CDC/National Center for HIV, STD, and TB Prevention Information Services. We understand that you have directed CDC to restrict competition to small businesses.

We strongly urge you to reconsider this decision.

This new contract is for the continuation and expansion of the services of the CDC National AIDS Clearinghouse, a project that has been providing prevention information and technical assistance to the AIDS community for the past nine years. Because the only known way to stop the spread of HIV infection is through prevention education, the HIV/AIDS and allied communities that we serve, need, and are entitled to the best AIDS information services obtainable. While the spread of the epidemic has slowed in some communities, others are just beginning to appreciate the devastation that HIV and AIDS can cause their homes and communities. CDC statistics indicate what many of us have already witnessed: in this second decade of the AIDS epidemic, populations that have historically struggled against poverty, alcohol & drugs and substandard health care are the same ones experiencing a dramatic increase in HIV infection.

These groups, along with all other Americans, deserve to have desperately-needed AIDS information services continue uninterrupted and with the highest quality of efficient obtainable service. We understand that CDC determined in an extensive market survey, that no small businesses were qualified to operate the new information service. Yet, HHS overruled CDC, directing the agency to restrict competition for this project to small businesses only. Why should our community have to settle for an unqualified contractor? Competition will allow the government to choose the best contractor at the best price, regardless of the size of the business.. Our constituency needs and deserves nothing less.

Thank you for giving this important matter your consideration.

Sincerely,

Miguel Martinez

Miguel Martinez
Media Program Coordinator

kinko's
Your branch office

fax cover sheet

FILE COPY

Kinko's Hyde Park • Telephone (773) 643-2424 • Fax (773) 643-4291

Date 01-07-97 Number of pages 1 (including cover page)

to: Name Peggy Fleming from: Name Captain Johnnie
DIR. Office of Nat. AIDS Policy
Company White House Company Temple of Christ
2042 E. 79th St #138 Chgo IL 60649

(FAX) Telephone (202) 632-1096 Telephone 773-918-2662

Comments Please send copy of letter sent to churches asking them to commemorate World AIDS Day!

J.H.B.

Mailed 1/8/97

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NUTRITION FOR LIFE

Volume 2, Number 1 — Copy and apply as needed — January 1997

Produced and Distributed by the Department of Family Medicine and Community Health, Tufts University School of Medicine, Boston, MA

More News from the Vancouver AIDS Conference

What constitutes aggressive nutrition support in HIV care needs to be better defined. The *Nutrition for Life* newsletter has repeatedly emphasized protein adequacy in diets, based on extrapolation of nutrient requirements in other infectious diseases and clinical findings from our own cohort. Here are three protein-related abstracts:

Measurements of nutritional status in 162 HIV-positive subjects included 3-day food records, bioelectric impedance for body composition, lab measures for serum albumin and transferrin, and resting energy expenditure. Results: There was a positive association between protein intake and lean body mass (LBM). Conclusions: Total protein intake was associated with LBM (a measure of wasting). This suggests that AIDS wasting syndrome is more severe in individuals who are consuming inadequate levels of protein.

Abstract We.B.3265 **(updated),** "Nutritional Correlates With CD4 Counts in HIV-Infected Individuals," by Di Franco MG, et al. Tufts University School of Medicine and Harvard School of Public Health, Boston, MA.

Quite simply, the effect of a hypercaloric, hyperproteic diet (40 kcal/kg usual weight and 2 g pro-

continued on page 3

Attention to Magnesium Levels

Low magnesium levels in HIV-positive asymptomatic people have been reported in 30% of subjects tested. A recent study [Skurnick JH, et al. JAIDS & Hum Retrov 1996; 12(1):75-83] raised that finding to 50%.

Even a normal blood test for magnesium can hide the fact that tissue levels might be low. Magnesium is a cofactor for many-functions in the body, most importantly helping energy production—especially in muscle cells—and helping protein synthesis.

The US population consumes a slightly deficient amount of magnesium each day. This has no observable consequence until metabolic stress occurs and marginal stores of magnesium are depleted. HIV infection qualifies as a significant stress. Bactrim, a common anti-PCP drug, also interferes with magnesium metabolism. Diarrhea can increase losses. Fat malabsorption also reduces magnesium absorption from the intestines, as does a high calcium and vitamin D intake. (Think about the quantity of milk-based liquid supplements people are consuming.) Periods of poor eating contribute to low intake of magnesium as well.

Deficiency symptoms are muscle weakness, depression, and vertigo/dizziness. Low magnesium levels appear to contribute to low calcium levels (commonly seen in AIDS patients) when no other identifiable cause exists. Anecdotal reports by Mary Romeyn, MD and Lark Lands, PhD say that 400 mg per day of magnesium restores calcium levels to normal in people with HIV who have low blood calcium levels.

High magnesium foods are whole grains, legumes (kidney beans, black beans, chick peas,

continued on page 5

Coping with nausea

Even when you're nauseated, not eating contributes to wasting and more nausea. Eat anyway! Here are some quick ideas to try:

- Munch some crackers or dry toast to absorb stomach acid.
- Stick to solid foods at meals; drink fluids between meals.
- Eat well-cooked, easy-to-digest foods, not raw, spicy, or fried. Try boiled chicken, boiled potato, simple rice, or canned carrots.
- Sniff a slice of fresh lemon for 2 minutes to settle the stomach.
- Try ginger tea or ginger ale, grate fresh ginger, or sprinkle powdered ginger in drinks and food.
- Peppermint tea settles the stomach and relieves gas and bloating.

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January 1997

HIV Prevention NEWS

A publication of the National PTA's HIV Prevention and Education Project

What's New at the PTA

New PTA Resources

Two new publications— the *Building a Healthy Child* health activities kit and the *National PTA Leader's Guide To Environmental Issues*—will be available from the National PTA in January 1997. *Building a Healthy Child*, an interactive health activities kit for children in grades K-6, will be available this month. Based on topics identified by a nationwide survey of PTA members, the kit contains 10 easy-to-use, low-cost activities to be used as independent learning events or in a larger health fair format. Activities include *Ask First: The Look-Alike Game* (poison prevention), *Endurance Challenge* (physical fitness), *Mirror, Mirror On The Wall* (self-esteem), *Pin the Foods on the Pyramid* (nutrition), *Safety Challenge* (bike safety), and *Where Do They Go?* (disease prevention). The kit also includes planning information for leaders, topic resources, reproducible tip sheets for parents, and ideas for additional activities. Check the January/ February issue of *Our Children* magazine for information on how to obtain a copy for your PTA.

The *National PTA Leader's Guide To Environmental Issues*—an easy-to-read, reproducible booklet—explores ways that PTAs and their members can address environmental concerns at home, at school, and in the community. Issues such as air pollution, emergency planning, environmental tobacco smoke, drinking water quality, indoor air quality, lead poisoning, pesticides, radon, and recycling are highlighted along with a step-by-step guide on how your PTA can mount a successful environmental issues campaign. This month, local unit presidents will receive a postage-paid reply card from the National PTA to request the leader's guide and additional information on environmental issues.

TV Ratings System Debated

The National PTA joined with several other organizations in registering their concerns over the age-based ratings system announced by the Television Ratings Implementation Group in December 1996. Under this system, programs will receive ratings based on the overall content rather than specific components such as violence or adult language giving parents limited information to determine viewing options for their children. In November 1996, the National PTA, Dr. Joanne Cantor of the University of Wisconsin at Madison, and the Institute for Mental Health Initiatives released the results of a joint study on television rating systems. The study found 80

See What's New *on page 3*

News from the Field

In December 1996, President Clinton unveiled his administration's plan for addressing the AIDS epidemic. Developed under the supervision of the President's National AIDS Policy Supervisor Patricia Fleming, the National AIDS Strategy identifies six primary goals for efforts in this area:

- Developing a cure and vaccine.
- Reducing the number of new infections of HIV to zero.
- Guaranteeing access to affordable services for people with HIV and AIDS.
- Fighting AIDS-related discrimination.
- Maintaining a leadership role in dealing with the international epidemic.
- Translating advances in research into prevention and treatment efforts.

The Office of National AIDS Policy, the Interdepartmental Task Force on HIV and AIDS, and other federal agencies are charged with creating a plan of action to achieve these goals. In 1997, the administration hopes to see progress in the development of a vaccine for HIV, to create treatment guidelines for physicians, to address AIDS discrimination in nursing homes, and to further reduce perinatal HIV transmission. The administration has chosen to remain neutral on the issue of funding needle-exchange programs as a means of reducing transmission rates among drug users.

The document won the endorsement of the President's Advisory Council on AIDS—members believe the document will be a solid foundation for the government's response to the epidemic. Many AIDS service providers are encouraged by the report and are anxious to see the recommendations implemented.

SidAlerte Internationale
Association humanitaire

Patricia S. FLEMING
Interim National AIDS Policy Coordinator
The White House

WASHINGTON DC
USA

Dear Sir, Madam

First of all, please allow me to wish you, along with the rest of the SidAlerte team, my best wishes for the new year. I hope that 1997 will be the year you succeed in all your personal and professional projects.

Your professional situation has naturally led us to send you our magazine, free of charge.

By subscribing today :

- You will be participating in the **humanitarian action** that SidAlerte is responsible for in Africa : To bring support to the medical professionals, to provide assistance to AIDS orphans and widows, to train medical and care staff...

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Please return today the enclosed subscription form today along with your payment.

Thank you for your trust

Yours faithfully

Garance UPHAM
President of SidAlerte Internationale

Thanks to your subscription, the SidAlerte journal will be able to be distributed, free of charge and more widely, in the countries most affected by HIV. Thank you for your help and solidarity.

SidAlerte Internationale
7, rue du Lac - 69003 LYON - FRANCE
Tel : +33 4 78 60 65 65 / Fax : +33 4 78 60 67 67 / e-mail : sidalerte@babel.asi.fr

JANUARY 1, 1997

Copy To Ms. Fleming

file copy

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

I DO NOT WISH TO CAUSE ANY UNDUE EMBARRASSMENT TO MS. FLEMING, BUT IF A RESPONSE IS NOT FORTHCOMING FROM HER, WHETHER IT BE POSITIVE OR NEGATIVE, IN REPLY TO MY LETTER TO HER DATED SEPTEMBER 1, 1996 (ATTACHED), I SHALL HAVE TO INCLUDE THESE PARAGRAPHS IN THE NEXT LETTER WHICH I WILL BE MAILING OUT TO VARIOUS PARTIES THROUGHOUT THE UNITED STATES AND THE WORLD WHO I THINK MIGHT BE INTERESTED IN THE PROBLEM OF HIV/AIDS:

> "ON MAY 26, 1993, ACTING ON MY BEHALF, CONGRESSMAN PETER J. VISCLOSKY FORWARDED MY HIV/AIDS RESEARCH TO BERNADINE HEALY, M.D., WHO WAS THEN DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH."
>
> "ON JUNE 18, 1993, ALTHOUGH SHE DID NOT AGREE WITH ITS CONCLUSION, DR. HEALY ISSUED A RESPONSE TO MY RESEARCH TO CONGRESSMAN VISCLOSKY."
>
> "UNFORTUNATELY, A SIMILAR RESPONSE HAS NOT BEEN FORTHCOMING FROM MS. PATRICIA S. FLEMING, PRESIDENT CLINTON'S DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY, "THE AIDS CZAR", TO CONGRESSMAN VISCLOSKY'S DECEMBER 10, 1996 LETTER (ATTACHED)."

I AM MYSTIFIED AS TO WHY MS. FLEMING HAS CHOSEN NOT TO ISSUE A RESPONSE TO MY SEPTEMBER LETTER WHICH REFLECTS THE CULMINATION OF THREE ADDITIONAL YEARS OF MY RESEARCH SINCE 1993.

TO REITERATE - THE ONLY THING I WANT IS AN ANSWER TO EITHER ONE OF THE TWO QUESTIONS WITH WHICH I CONCLUDED THAT SEPTEMBER 1, 1996 LETTER; THEY WERE:

> "IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?"
>
> "IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?"

AT THE VERY LATEST, MY NEXT LETTER WILL BE MAILED OUT TO "VARIOUS PARTIES" BY FEBRUARY 3, 1997.

COPIES TO:

MS. FLEMING, THE WHITE HOUSE
CARMENA PARRIS, AIDE TO MS. FLEMING
RICHARD SORIAN, AIDE TO MS. FLEMING
DWAYNE LAWLER,
WASHINGTON OFFICE OF CONGRESSMAN VISCLOSKY
DAVID ROZMANICH,
GARY OFFICE OF CONGRESSMAN VISCLOSKY

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEE ON APPROPRIATIONS
CONGRESSIONAL STEEL CAUCUS
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CONGRESSIONAL COALITION
- MIDWEST VICE-CHAIR
WHIP-AT-LARGE

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Washington, DC 20515–1401

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VALPARAISO, IN 46383
(219) 464–0315

December 10, 1996

Ms. Patricia S. Fleming
Director, Office of National Aids Policy
750 17th Street, NW
Suite 600
Washington, D.C. 20503

Dear Ms. Fleming:

I am writing on behalf of my constituent, Mr. John Roberts. Enclosed please find literature submitted to me concerning the HIV virus and the AIDS disease. Mr. Roberts believes he is putting forth a viable measure to halt the dreaded disease. In fact, Mr. Roberts feels that his proposition contains the "magic bullet" that can "cripple" HIV.

On September 1, 1996, Mr. Roberts had written you with his concerns and has yet to have received a response. I ask that you please review the enclosed material and issue a reply to both Mr. Roberts and myself.

If you have any questions concerning this matter, I urge you to contact me or my District Director, David Rozmanich, at 219-884-1177. Thank you for your time and kind attention to this matter.

Sincerely,

Peter J. Visclosky
Member of Congress

PJV:dsr

SEPTEMBER 1, 1996

AN OPEN LETTER TO:

PATRICIA S. FLEMING
DIRECTOR
OFFICE OF NATIONAL AIDS POLICY
THE WHITE HOUSE
WASHINGTON

COPY WITH ENCLOSURES TO: _____

DEAR MS. FLEMING,

JUST TO BE SURE THAT YOU RECEIVE IT, I HAVE SENT DUPLICATE PACKETS OF MY RESEARCH TO YOU. ONE I HAVE SENT BY REGULAR MAIL AND THE OTHER ONE BY CERTIFIED MAIL. BOTH PACKETS WERE DIRECTED TO YOUR ADDRESS AT 750 17th St. N.W., SUITE 600, WASHINGTON, D.C. (202-632-1090). ZIP - 20503.

AS YOU CAN SEE, THE PACKET CONTAINS THIS LETTER TO YOU, MY JULY 22, 1996 LETTER TO DR. STANDISH AND MY 35 PAGE "FILE" DATED JANUARY 1, 1996.

AFTER READING THESE DOCUMENTS YOU WILL SEE WHY I AM CONVINCED THAT I HAVE DISCOVERED A "MAGIC BULLET" TO "CRIPPLE" HIV, THE VIRUS WHICH IS THE ROOT CAUSE OF AIDS. THE MAGIC BULLET IS THE CHEMICAL COMPOUND KNOWN AS "ACETALDEHYDE".

IF I HAD HIV/AIDS AND WAS TOLD THAT I MIGHT BE HELPED IMMEASURABLY BY OBTAINING A CERTAIN NUTRIENT FROM MY LOCAL HEALTH FOOD STORE, BY HAVING MY PHYSICIAN PRESCRIBE FOR ME A CERTAIN CHEMICAL AND BY HAVING THAT SAME PHYSICIAN ADMINISTER A PARTICULAR PROCEDURE TO ME ONCE A WEEK IN HIS OFFICE, I WOULD NOT LET 24 HOURS LAPSE BEFORE AT LEAST TRYING TO FIND OUT ALL OF THE DETAILS.

THE CORE OF THE HEALING PROCESS IS SIMPLY THIS -

1. N-ACETYL CYSTEINE ("NAC") WOULD HELP RESTORE APOPTOSIS BACK TO NORMAL LEVELS.

2. NAC WILL AFFORD THE BODY 100% PROTECTION AGAINST THE TOXIC EFFECTS OF UNMETABOLIZED ACETALDEHYDE.

3. UNMETABOLIZED ACETALDEHYDE WILL POISON HIV, THEREBY "INACTIVATING" IT.

MS. FLEMING, IN YOUR LETTER (SEE PAGE 13 OF MY FILE) YOU STATE:

"IT IS IMPORTANT TO ASSESS ANY POTENTIAL AVENUE OF RESEARCH..... SHOULD ANY NEW INFORMATION DEVELOP, I ENCOURAGE YOU TO SHARE IT WITH THE NIH."

MS. FLEMING, I AM SENDING THIS PACKET TO NUMEROUS PEOPLE INCLUDING -

1. WILLIAM E. PAUL, M.D., DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

2. JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

HOWEVER, MS. FLEMING, I FEEL THAT THE ULTIMATE DECISION ABOUT THIS MATTER RESTS IN YOUR HANDS.

PRESIDENT HARRY S. TRUMAN KEPT A SIGN ON HIS WHITE HOUSE DESK WHICH STATED:

"THE BUCK STOPS HERE."

MS. FLEMING, IN MY OPINION, "THE BUCK" HAS LANDED UPON YOUR DESK.

IF YOU THINK THAT MY IDEAS HAVE POTENTIAL VALIDITY, ARE YOU PREPARED TO DIRECT DR. PAUL TO IMPLEMENT IMMEDIATELY (STARTING TOMORROW, FOR INSTANCE) A CLINICAL TRIAL OF THE PROCEDURE WHICH I DESCRIBE IN MY "HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS" (STARTING ON PAGE 7 OF MY JULY 22 LETTER)? IT IS MY HOPE THAT AFTER 18 WEEKS OF SUCH A TRIAL, THE PATIENTS WOULD SHOW AN INCREASE IN THEIR T-CELL COUNT.

IF YOU DO NOT FEEL THAT SUCH A COMMAND FALLS WITHIN THE SCOPE OF YOUR AUTHORITY, THEN THE CONCEPT OF AN "AIDS CZAR" IS JUST A FICTION, IS IT NOT?

IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?

IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

P.S. IF THE TRIAL IS UNDERTAKEN -

1. THE PATIENTS SHOULD AVOID FOODS CONTAINING NITRITES. CERTAIN PREPARED MEATS SUCH AS HOT DOGS AND BACON CONTAIN NITRITES. THE PHYSICIANS' DESK REFERENCE, PAGE 2642, 49th EDITION, 1995 STATES:

   "IN RATS, SIMULTANEOUS INGESTION OF DISULFIRAM AND NITRITE IN THE DIET FOR 78 WEEKS HAS BEEN REPORTED TO CAUSE TUMORS, AND IT HAS BEEN SUGGESTED THAT DISULFIRAM MAY REACT WITH NITRITES IN THE RAT STOMACH TO FORM A NITROSAMINE, WHICH IS TUMORIGENIC. DISULFIRAM ALONE IN THE RATS' DIET DID NOT LEAD TO SUCH TUMORS. THE RELEVANCE OF THIS FINDING TO HUMANS IS NOT KNOWN AT THIS TIME."
   (IT IS MY HUNCH THAT HUMANS WOULD BE AFFECTED IN A SIMILAR MANNER - j.s.r.)

2. THE PATIENTS SHOULD NOT DRINK CITY WATER.
   SUPER-NUTRITION, PAGE 115 STATES: "CHLORINE IS AN OXIDANT, TOO; MOST OF US DRINK CHLORINATED WATER WHICH CONSUMES VITAMIN E IN OUR BODY."
   "GOOD HOUSEKEEPING", PAGE 84, AUGUST, 1996 STATES: "VITAMIN E's BENEFITS APPEAR TO BE LARGELY RELATED TO ITS ANTIOXIDANT PROPERTIES."

P.P.S. I HOPE TO HAVE MS. FLEMING'S RESPONSE AT SOME TIME WITHIN THE NEXT FEW WEEKS. IF YOU WOULD LIKE TO SEE IT, JUST LET ME KNOW, AND I WILL MAIL A COPY OF IT TO YOU.

NOVEMBER 18, 1996

2nd REQUEST

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

AGAIN, I WRITE TO YOU.

LAST MONTH I PERSONALLY DELIVERED MY LETTER TO YOUR GARY OFFICE TO THE ATTENTION OF YOUR CONGRESSIONAL AIDE, MARA CANDELARIA. I THOUGHT THAT THIS WOULD SUFFICE; I DID NOT MAIL A COPY OF IT TO YOUR WASHINGTON OFFICE.

AS YOU CAN SEE FROM THAT LETTER, I ALSO MAILED A COPY OF IT TO MS. PATRICIA S. FLEMING, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY, THE WHITE HOUSE.

THIS TIME, JUST TO BE SURE THAT I COVER ALL OF THE BASES, I AM SENDING THIS LETTER TO -

1. YOUR WASHINGTON, D.C. OFFICE
2. YOUR GARY OFFICE (ATTENTION MARA CANDELARIA)
3. MS. FLEMING, THE WHITE HOUSE

THIS LETTER HAS THE FOLLOWING ATTACHMENTS -

1. MY OCTOBER 15, 1996 LETTER TO YOU
2. MY SEPTEMBER 1, 1996 LETTER TO MS. FLEMING
3. MY JULY 22, 1996 LETTER TO LEANNA J. STANDISH, ND, PhD
4. MY 35 PAGE FILE DATED JANUARY 1, 1996

CONGRESSMAN VISCLOSKY, IN MY OPINION, MS. FLEMING IS DUTY BOUND TO ISSUE A RESPONSE TO EITHER YOU OR ME.

CONGRESSMAN VISCLOSKY, AS MY REPRESENTATIVE TO THE CONGRESS OF THE UNITED STATES OF AMERICA, I HEREBY RESPECTFULLY EXPECT OF YOU TO EFFECT THIS END.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPY WITH ENCLOSURE TO:

PATRICIA S. FLEMING, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY
THE WHITE HOUSE, WASHINGTON, D.C.
MARA CANDELARIA, CONGRESSIONAL AIDE
GARY, INDIANA

OCTOBER 15, 1996

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

AS YOU CAN SEE FROM THE CERTIFIED MAIL DOMESTIC RETURN RECEIPT (ATTACHED) THAT THE OFFICE OF PATRICIA S. FLEMING RECEIVED MY PACKET OF RESEARCH RELATIVE TO HIV/AIDS.

IT CONSISTED OF -

1. MY SEPTEMBER 1, 1996 LETTER TO HER (ATTACHED)
2. MY JULY 22, 1996 LETTER TO LEANNA J. STANDISH, ND, PhD (ATTACHED)
3. MY 35 PAGE FILE DATED JANUARY 1, 1996 (ATTACHED)

WOULD YOU PLEASE REQUEST OF MS. FLEMING THAT SHE REPLY TO ME.
TO QUOTE FROM MY LETTER TO HER:

" IF YOU THINK THAT MY IDEAS HAVE POTENTIAL VALIDITY, ARE YOU PREPARED TO DIRECT DR. PAUL TO IMPLEMENT IMMEDIATELY (STARTING TOMORROW, FOR INSTANCE) A CLINICAL TRIAL OF THE PROCEDURE WHICH I DESCRIBE IN MY "HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS" (STARTING ON PAGE 7 OF MY JULY LETTER)? IT IS MY HOPE THAT AFTER 18 WEEKS OF SUCH A TRIAL, THE PATIENTS WOULD SHOW AN INCREASE IN THEIR T-CELL COUNT.

IF YOU DO NOT FEEL THAT SUCH A COMMAND FALLS WITHIN THE SCOPE OF YOUR AUTHORITY, THEN THE CONCEPT OF AN "AIDS CZAR" IS JUST A FICTION, IS IT NOT?

IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?

IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?"

CONGRESSMAN VISCLOSKY, THANK YOU FOR YOUR HELP IN THIS MATTER.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
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COPY WITH ENCLOSURES TO MS. PATRICIA S. FLEMING, THE WHITE HOUSE

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PATRICIA S. Fleming, Director
OFFICE of NATIONAL Aids Policy
750 17TH St. N.W.
Suite 600
WASHINGTON, D.C. 20503

4a. Article Number
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X Arthur C. Altwater

PS Form **3811**, December 1994 Domestic Return Receipt

Thank you for using Return Receipt Service.

JANUARY 1, 1997

COPY TO CARMENA PARRIS

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

I DO NOT WISH TO CAUSE ANY UNDUE EMBARRASSMENT TO MS. FLEMING, BUT IF A RESPONSE IS NOT FORTHCOMING FROM HER, WHETHER IT BE POSITIVE OR NEGATIVE, IN REPLY TO MY LETTER TO HER DATED SEPTEMBER 1, 1996 (ATTACHED), I SHALL HAVE TO INCLUDE THESE PARAGRAPHS IN THE NEXT LETTER WHICH I WILL BE MAILING OUT TO VARIOUS PARTIES THROUGHOUT THE UNITED STATES AND THE WORLD WHO I THINK MIGHT BE INTERESTED IN THE PROBLEM OF HIV/AIDS:

> "ON MAY 26, 1993, ACTING ON MY BEHALF, CONGRESSMAN PETER J. VISCLOSKY FORWARDED MY HIV/AIDS RESEARCH TO BERNADINE HEALY, M.D., WHO WAS THEN DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH."
>
> "ON JUNE 18, 1993, ALTHOUGH SHE DID NOT AGREE WITH ITS CONCLUSION, DR. HEALY ISSUED A RESPONSE TO MY RESEARCH TO CONGRESSMAN VISCLOSKY."
>
> "UNFORTUNATELY, A SIMILAR RESPONSE HAS NOT BEEN FORTHCOMING FROM MS. PATRICIA S. FLEMING, PRESIDENT CLINTON'S DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY, "THE AIDS CZAR", TO CONGRESSMAN VISCLOSKY'S DECEMBER 10, 1996 LETTER (ATTACHED)."

I AM MYSTIFIED AS TO WHY MS. FLEMING HAS CHOSEN NOT TO ISSUE A RESPONSE TO MY SEPTEMBER LETTER WHICH REFLECTS THE CULMINATION OF THREE ADDITIONAL YEARS OF MY RESEARCH SINCE 1993.

TO REITERATE - THE ONLY THING I WANT IS AN ANSWER TO EITHER ONE OF THE TWO QUESTIONS WITH WHICH I CONCLUDED THAT SEPTEMBER 1, 1996 LETTER; THEY WERE:

> "IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?"
>
> "IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?"

AT THE VERY LATEST, MY NEXT LETTER WILL BE MAILED OUT TO "VARIOUS PARTIES" BY FEBRUARY 3, 1997.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPIES TO:

MS. FLEMING, THE WHITE HOUSE
CARMENA PARRIS, AIDE TO MS. FLEMING
RICHARD SORIAN, AIDE TO MS. FLEMING
DWAYNE LAWLER,
WASHINGTON OFFICE OF CONGRESSMAN VISCLOSKY
DAVID ROZMANICH,
GARY OFFICE OF CONGRESSMAN VISCLOSKY

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEE ON APPROPRIATIONS
CONGRESSIONAL STEEL CAUCUS
EXECUTIVE COMMITTEE CHAIRMAN
NORTHEAST-MIDWEST
CONGRESSIONAL COALITION
MIDWEST VICE-CHAIR
WHIP AT-LARGE

Congress of the United States
House of Representatives
Washington, DC 20515–1401

2464 RAYBURN BUILDING
WASHINGTON, DC 20515–1401
(202) 225–2461

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GARY, IN 46408
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6070 CENTRAL AVENUE
PORTAGE, IN 46368
(219) 763–2904

VALPARAISO CITY HALL
166 LINCOLNWAY
VALPARAISO, IN 46383
(219) 464–0315

December 10, 1996

Ms. Patricia S. Fleming
Director, Office of National Aids Policy
750 17th Street, NW
Suite 600
Washington, D.C. 20503

Dear Ms. Fleming:

I am writing on behalf of my constituent, Mr. John Roberts. Enclosed please find literature submitted to me concerning the HIV virus and the AIDS disease. Mr. Roberts believes he is putting forth a viable measure to halt the dreaded disease. In fact, Mr. Roberts feels that his proposition contains the "magic bullet" that can "cripple" HIV.

On September 1, 1996, Mr. Roberts had written you with his concerns and has yet to have received a response. I ask that you please review the enclosed material and issue a reply to both Mr. Roberts and myself.

If you have any questions concerning this matter, I urge you to contact me or my District Director, David Rozmanich, at 219-884-1177. Thank you for your time and kind attention to this matter.

Sincerely,

Peter J. Visclosky
Member of Congress

PJV:dsr

SEPTEMBER 1, 1996

AN OPEN LETTER TO:

PATRICIA S. FLEMING
DIRECTOR
OFFICE OF NATIONAL AIDS POLICY
THE WHITE HOUSE
WASHINGTON

COPY WITH ENCLOSURES TO: _____

DEAR MS. FLEMING,

JUST TO BE SURE THAT YOU RECEIVE IT, I HAVE SENT DUPLICATE PACKETS OF MY RESEARCH TO YOU. ONE I HAVE SENT BY REGULAR MAIL AND THE OTHER ONE BY CERTIFIED MAIL. BOTH PACKETS WERE DIRECTED TO YOUR ADDRESS AT 750 17th St. N.W., SUITE 600, WASHINGTON, D.C. (202-632-1090). ZIP - 20503.

AS YOU CAN SEE, THE PACKET CONTAINS THIS LETTER TO YOU, MY JULY 22, 1996 LETTER TO DR. STANDISH AND MY 35 PAGE "FILE" DATED JANUARY 1, 1996.

AFTER READING THESE DOCUMENTS YOU WILL SEE WHY I AM CONVINCED THAT I HAVE DISCOVERED A "MAGIC BULLET" TO "CRIPPLE" HIV, THE VIRUS WHICH IS THE ROOT CAUSE OF AIDS. THE MAGIC BULLET IS THE CHEMICAL COMPOUND KNOWN AS "ACETALDEHYDE".

IF I HAD HIV/AIDS AND WAS TOLD THAT I MIGHT BE HELPED IMMEASURABLY BY OBTAINING A CERTAIN NUTRIENT FROM MY LOCAL HEALTH FOOD STORE, BY HAVING MY PHYSICIAN PRESCRIBE FOR ME A CERTAIN CHEMICAL AND BY HAVING THAT SAME PHYSICIAN ADMINISTER A PARTICULAR PROCEDURE TO ME ONCE A WEEK IN HIS OFFICE, I WOULD NOT LET 24 HOURS LAPSE BEFORE AT LEAST TRYING TO FIND OUT ALL OF THE DETAILS.

THE CORE OF THE HEALING PROCESS IS SIMPLY THIS -

1. N-ACETYL CYSTEINE ("NAC") WOULD HELP RESTORE APOPTOSIS BACK TO NORMAL LEVELS.

2. NAC WILL AFFORD THE BODY 100% PROTECTION AGAINST THE TOXIC EFFECTS OF UNMETABOLIZED ACETALDEHYDE.

3. UNMETABOLIZED ACETALDEHYDE WILL POISON HIV, THEREBY "INACTIVATING" IT.

MS. FLEMING, IN YOUR LETTER (SEE PAGE 13 OF MY FILE) YOU STATE:

"IT IS IMPORTANT TO ASSESS ANY POTENTIAL AVENUE OF RESEARCH..... SHOULD ANY NEW INFORMATION DEVELOP, I ENCOURAGE YOU TO SHARE IT WITH THE NIH."

MS. FLEMING, I AM SENDING THIS PACKET TO NUMEROUS PEOPLE INCLUDING -

1. WILLIAM E. PAUL, M.D., DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

2. JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

HOWEVER, MS. FLEMING, I FEEL THAT THE ULTIMATE DECISION ABOUT THIS MATTER RESTS IN YOUR HANDS.

PRESIDENT HARRY S. TRUMAN KEPT A SIGN ON HIS WHITE HOUSE DESK WHICH STATED:

"THE BUCK STOPS HERE."

MS. FLEMING, IN MY OPINION, "THE BUCK" HAS LANDED UPON YOUR DESK.

IF YOU THINK THAT MY IDEAS HAVE POTENTIAL VALIDITY, ARE YOU PREPARED TO DIRECT DR. PAUL TO IMPLEMENT IMMEDIATELY (STARTING TOMORROW, FOR INSTANCE) A CLINICAL TRIAL OF THE PROCEDURE WHICH I DESCRIBE IN MY "HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS" (STARTING ON PAGE 7 OF MY JULY 22 LETTER)? IT IS MY HOPE THAT AFTER 18 WEEKS OF SUCH A TRIAL, THE PATIENTS WOULD SHOW AN INCREASE IN THEIR T-CELL COUNT.

IF YOU DO NOT FEEL THAT SUCH A COMMAND FALLS WITHIN THE SCOPE OF YOUR AUTHORITY, THEN THE CONCEPT OF AN "AIDS CZAR" IS JUST A FICTION, IS IT NOT?

IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?

IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

P.S. IF THE TRIAL IS UNDERTAKEN -

1. THE PATIENTS SHOULD AVOID FOODS CONTAINING NITRITES. CERTAIN PREPARED MEATS SUCH AS HOT DOGS AND BACON CONTAIN NITRITES. THE PHYSICIANS' DESK REFERENCE, PAGE 2642, 49th EDITION, 1995 STATES:

   "IN RATS, SIMULTANEOUS INGESTION OF DISULFIRAM AND NITRITE IN THE DIET FOR 78 WEEKS HAS BEEN REPORTED TO CAUSE TUMORS, AND IT HAS BEEN SUGGESTED THAT DISULFIRAM MAY REACT WITH NITRITES IN THE RAT STOMACH TO FORM A NITROSAMINE, WHICH IS TUMORIGENIC. DISULFIRAM ALONE IN THE RATS' DIET DID NOT LEAD TO SUCH TUMORS. THE RELEVANCE OF THIS FINDING TO HUMANS IS NOT KNOWN AT THIS TIME."
   (IT IS MY HUNCH THAT HUMANS WOULD BE AFFECTED IN A SIMILAR MANNER - j.s.r.)

2. THE PATIENTS SHOULD NOT DRINK CITY WATER.
   SUPER-NUTRITION, PAGE 115 STATES: "CHLORINE IS AN OXIDANT, TOO; MOST OF US DRINK CHLORINATED WATER WHICH CONSUMES VITAMIN E IN OUR BODY."
   "GOOD HOUSEKEEPING", PAGE 84, AUGUST, 1996 STATES: "VITAMIN E's BENEFITS APPEAR TO BE LARGELY RELATED TO ITS ANTIOXIDANT PROPERTIES."

P.P.S. I HOPE TO HAVE MS. FLEMING'S RESPONSE AT SOME TIME WITHIN THE NEXT FEW WEEKS. IF YOU WOULD LIKE TO SEE IT, JUST LET ME KNOW, AND I WILL MAIL A COPY OF IT TO YOU.

NOVEMBER 18, 1996

2nd REQUEST

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

AGAIN, I WRITE TO YOU.

LAST MONTH I PERSONALLY DELIVERED MY LETTER TO YOUR GARY OFFICE TO THE ATTENTION OF YOUR CONGRESSIONAL AIDE, MARA CANDELARIA. I THOUGHT THAT THIS WOULD SUFFICE; I DID NOT MAIL A COPY OF IT TO YOUR WASHINGTON OFFICE.

AS YOU CAN SEE FROM THAT LETTER, I ALSO MAILED A COPY OF IT TO MS. PATRICIA S. FLEMING, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY, THE WHITE HOUSE.

THIS TIME, JUST TO BE SURE THAT I COVER ALL OF THE BASES, I AM SENDING THIS LETTER TO -

1. YOUR WASHINGTON, D.C. OFFICE
2. YOUR GARY OFFICE (ATTENTION MARA CANDELARIA)
3. MS. FLEMING, THE WHITE HOUSE

THIS LETTER HAS THE FOLLOWING ATTACHMENTS -

1. MY OCTOBER 15, 1996 LETTER TO YOU
2. MY SEPTEMBER 1, 1996 LETTER TO MS. FLEMING
3. MY JULY 22, 1996 LETTER TO LEANNA J. STANDISH, ND, PhD
4. MY 35 PAGE FILE DATED JANUARY 1, 1996

CONGRESSMAN VISCLOSKY, IN MY OPINION, MS. FLEMING IS DUTY BOUND TO ISSUE A RESPONSE TO EITHER YOU OR ME.

CONGRESSMAN VISCLOSKY, AS MY REPRESENTATIVE TO THE CONGRESS OF THE UNITED STATES OF AMERICA, I HEREBY RESPECTFULLY EXPECT OF YOU TO EFFECT THIS END.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPY WITH ENCLOSURE TO:

PATRICIA S. FLEMING, DIRECTOR, OFFICE OF NATIONAL AIDS POLICY
THE WHITE HOUSE, WASHINGTON, D.C.
MARA CANDELARIA, CONGRESSIONAL AIDE
GARY, INDIANA

OCTOBER 15, 1996

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

AS YOU CAN SEE FROM THE CERTIFIED MAIL DOMESTIC RETURN RECEIPT (ATTACHED) THAT THE OFFICE OF PATRICIA S. FLEMING RECEIVED MY PACKET OF RESEARCH RELATIVE TO HIV/AIDS.

IT CONSISTED OF -

1. MY SEPTEMBER 1, 1996 LETTER TO HER (ATTACHED)
2. MY JULY 22, 1996 LETTER TO LEANNA J. STANDISH, ND, PhD (ATTACHED)
3. MY 35 PAGE FILE DATED JANUARY 1, 1996 (ATTACHED)

WOULD YOU PLEASE REQUEST OF MS. FLEMING THAT SHE REPLY TO ME.
TO QUOTE FROM MY LETTER TO HER:

" IF YOU THINK THAT MY IDEAS HAVE POTENTIAL VALIDITY, ARE YOU PREPARED TO DIRECT DR. PAUL TO IMPLEMENT IMMEDIATELY (STARTING TOMORROW, FOR INSTANCE) A CLINICAL TRIAL OF THE PROCEDURE WHICH I DESCRIBE IN MY "HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS" (STARTING ON PAGE 7 OF MY JULY LETTER)? IT IS MY HOPE THAT AFTER 18 WEEKS OF SUCH A TRIAL, THE PATIENTS WOULD SHOW AN INCREASE IN THEIR T-CELL COUNT.

IF YOU DO NOT FEEL THAT SUCH A COMMAND FALLS WITHIN THE SCOPE OF YOUR AUTHORITY, THEN THE CONCEPT OF AN "AIDS CZAR" IS JUST A FICTION, IS IT NOT?

IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?

IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?"

CONGRESSMAN VISCLOSKY, THANK YOU FOR YOUR HELP IN THIS MATTER.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPY WITH ENCLOSURES TO MS. PATRICIA S. FLEMING, THE WHITE HOUSE

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PS Form 3800, April 1995

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750 17th St. N.W.
Suite 600
WASHINGTON, D.C. 20503

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6. Signature: *(Addressee or Agent)*
X Kathleen C Atwater

PS Form **3811**, December 1994 Domestic Return Receipt

Thank you for using Return Receipt Service.

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: Patsy

Draft response for POTUS and forward to CHR by: —

Draft response for CHR by: _____

Please reply directly to the writer (copy to CHR) by: Carmela

Please advise by: - Please have it be

Let's discuss: PF:/

For your information: CHR: The original was sent to the President by messenger per Jeffery Crowley 2/13/96

Reply using form code: _____

File: _____

Send copy to (original to CHR): Carmela

Schedule ? : ☐ Accept ☐ Pending ☑ Regret

Designee to attend: _____

Remarks: See if this is the copy for POTUS or a cc.

Warm up corr. or response

2/14

PF -
Diane in Jim Dorskind's office is drafting a response

C

CP /

2/14 Julie w/call

C

Good!
Please tell
Julie Domeo.
~~Ask her~~ 6-5392

+ Call Jim Dorskind 7610 6-5460
and ask if he's going
~~to~~ to draft an answer.
(I hope he is.)

Diane is drafting

Thanks! P

URGENT

Facsimile Transmittal Sheet

FEB 7 1996

NAPWA

DATE: February 7, 1996
TO: The Honorable Carol Rasco
FAX#: 202.456.2878
FROM: Jeffery S. Crowley
RE:
 # OF PAGES INCLUDING COVER: 3
MEMO:

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CONTACT US IMMEDIATELY

1413 K Street, NW, 7th Floor
Washington, DC 20005-3405
(202) 898-0414 (Voice)
(202) 898-0435 (Fax)

February 7, 1996

The President
The White House
Washington, DC 20500

Dear Mr. President:

We are writing to express our extreme concern regarding the National Governors Association (NGA) Medicaid reform proposal. We are appalled at the implication from your recent comments that you may support this plan.

Over the past few months, we have written to you on numerous occasions regarding the need for a strong federal commitment to protecting the guarantee to high quality health care for low-income Medicaid beneficiaries--and we have frequently recognized your strong leadership in advocating for this program. The NGA plan would be devastating to people with AIDS and other Medicaid beneficiaries. The governors' plan repeals Title XIX--the backbone of a meaningful guarantee to health coverage for eligible beneficiaries--and it does not meet any of the criteria you have established for acceptable Medicaid reform. The NGA proposal is nothing more than a block grant, which you have opposed, dressed up in language meant to provide assurances and guarantees that are, in fact, meaningless. If you were to support this plan, it would betray the commitments you have made to people with AIDS at your December summit and on several other occasions.

We believe that there are three critical questions you must ask yourself in assessing any reform plan:

Who is covered?
The governors' plan fails the beneficiary because it would allow states to define disability for purposes of Medicaid eligibility. The NGA plan contains assurances that the disabled would receive coverage. By removing the existing federal disability definition, however, current disabled beneficiaries are vulnerable to becoming ineligible. Indeed, before we had the current federal disability definition there were great inequities in access to Medicaid among the disabled. It is easy to imagine that some states would seek to define disability in a way that intentionally excludes some or all people with HIV/AIDS.

What services are covered?
The governors' plan fails the beneficiary because it would repeal current law provisions related to statewideness, comparability and amount, duration and scope. It is not enough simply to state that a specific benefit will be provided. Benefits and services must be provided equally in all parts of a state, benefits must be provided equally to all categories of beneficiaries, and they must be provided in amounts determined by a health care provider to be effective and medically necessary. States should not be free to arbitrarily limit access to services.

How are individuals ensured of receiving the coverage for which they qualify?
The governors' plan fails the beneficiary because it takes away an individual's private right of action. This provision of the law is absolutely necessary to ensure that individuals have recourse if a state does not provide them with a service for which they qualify. A guarantee to coverage or benefits is relatively meaningless unless there is a means to enforce it. People with AIDS have used a private right of action to fight discrimination and to gain the same access to prescription drugs and other services as other Medicaid beneficiaries within their states. If these provisions are lost, people with AIDS could find that, on paper, they are guaranteed access to a medication or a service, but in reality it is denied to them.

It is essential that any reform plan be able to provide satisfactory answers to all of these questions. Failing even one, then the proposal should be rejected. Medicaid payments represent the federal government's largest form of financial support to the states, totaling nearly $100 billion per year. We believe that you and the Congress owe it to the American people to insist that states are held accountable for the federal money they receive.

We urge you to stand firm, as you have done to date, in opposing the current NGA Medicaid proposal and any other plan that could threaten health care for millions of vulnerable low-income Americans.

Sincerely,

AIDS Action Council

AIDS Policy Center for Children, Youth and Families

Cities Advocating for Emergency AIDS Relief

Gay Men's Health Crisis

Housing Works

Human Rights Campaign

National Association of People with AIDS

National Minority AIDS Council

Project Inform

San Francisco AIDS Foundation

Texas AIDS Network

FILE COPY

OCTOBER 15, 1996

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

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IT CONSISTED OF -

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CONGRESSMAN VISCLOSKY, THANK YOU FOR YOUR HELP IN THIS MATTER.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPY WITH ENCLOSURES TO MS. PATRICIA S. FLEMING, THE WHITE HOUSE

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PS Form **3800**, April 1995

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X Arthur C. Atwater

PS Form **3811**, December 1994 Domestic Return Receipt

Thank you for using Return Receipt Service.

SEPTEMBER 1, 1996

AN OPEN LETTER TO:

PATRICIA S. FLEMING
DIRECTOR
OFFICE OF NATIONAL AIDS POLICY
THE WHITE HOUSE
WASHINGTON

COPY WITH ENCLOSURES TO: _____

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AS YOU CAN SEE, THE PACKET CONTAINS THIS LETTER TO YOU, MY JULY 22, 1996 LETTER TO DR. STANDISH AND MY 35 PAGE "FILE" DATED JANUARY 1, 1996.

AFTER READING THESE DOCUMENTS YOU WILL SEE WHY I AM CONVINCED THAT I HAVE DISCOVERED A "MAGIC BULLET" TO "CRIPPLE" HIV, THE VIRUS WHICH IS THE ROOT CAUSE OF AI THE MAGIC BULLET IS THE CHEMICAL COMPOUND KNOWN AS "ACETALDEHYDE".

IF I HAD HIV/AIDS AND WAS TOLD THAT I MIGHT BE HELPED IMMEASURABLY BY OBTAINING A CERTAIN NUTRIENT FROM MY LOCAL HEALTH FOOD STORE, BY HAVING MY PHYSICIAN PRESCRIBE FOR ME A CERTAIN CHEMICAL AND BY HAVING THAT SAME PHYSICIAN ADMINISTER A PARTICULAR PROCEDURE TO ME ONCE A WEEK IN HIS OFFICE, I WOULD NOT LET 24 HOURS LAPSE BEFORE AT LEAST TRYING TO FIND OUT ALL OF THE DETAILS.

THE CORE OF THE HEALING PROCESS IS SIMPLY THIS -

1. N-ACETYL CYSTEINE ("NAC") WOULD HELP RESTORE APOPTOSIS BACK TO NORMAL LEVELS.

2. NAC WILL AFFORD THE BODY 100% PROTECTION AGAINST THE TOXIC EFFECTS OF UNMETABOLIZED ACETALDEHYDE.

3. UNMETABOLIZED ACETALDEHYDE WILL POISON HIV, THEREBY "INACTIVATING" IT.

MS. FLEMING, IN YOUR LETTER (SEE PAGE 13 OF MY FILE) YOU STATE:

"IT IS IMPORTANT TO ASSESS ANY POTENTIAL AVENUE OF RESEARCH..... SHOULD ANY NEW INFORMATION DEVELOP, I ENCOURAGE YOU TO SHARE IT WITH THE NIH."

MS. FLEMING, I AM SENDING THIS PACKET TO NUMEROUS PEOPLE INCLUDING -

1. WILLIAM E. PAUL, M.D., DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

2. JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

HOWEVER, MS. FLEMING, I FEEL THAT THE ULTIMATE DECISION ABOUT THIS MATTER RESTS IN YOUR HANDS.

PRESIDENT HARRY S. TRUMAN KEPT A SIGN ON HIS WHITE HOUSE DESK WHICH STATED:

"THE BUCK STOPS HERE."

MS. FLEMING, IN MY OPINION, "THE BUCK" HAS LANDED UPON YOUR DESK.

IF YOU THINK THAT MY IDEAS HAVE POTENTIAL VALIDITY, ARE YOU PREPARED TO DIRECT DR. PAUL TO IMPLEMENT IMMEDIATELY (STARTING TOMORROW, FOR INSTANCE) A CLINICAL TRIAL OF THE PROCEDURE WHICH I DESCRIBE IN MY "HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS" (STARTING ON PAGE 7 OF MY JULY 22 LETTER)? IT IS MY HOPE THAT AFTER 18 WEEKS OF SUCH A TRIAL, THE PATIENTS WOULD SHOW AN INCREASE IN THEIR T-CELL COUNT.

IF YOU DO NOT FEEL THAT SUCH A COMMAND FALLS WITHIN THE SCOPE OF YOUR AUTHORITY, THEN THE CONCEPT OF AN "AIDS CZAR" IS JUST A FICTION, IS IT NOT?

IN CONCLUSION, MS. FLEMING, DO YOU THINK THAT MY IDEAS HAVE PRACTICAL MERIT? IF SO, HOW SOON ARE YOU PREPARED TO INITIATE A CLINICAL TRIAL? TOMORROW?

IF YOU DO NOT THINK THAT MY IDEAS HAVE PRACTICAL MERIT, MS. FLEMING, COULD I KNOW OF THE SCIENTIFIC REASONING UNDERLYING YOUR JUDGEMENT?

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

P.S. IF THE TRIAL IS UNDERTAKEN -

1. THE PATIENTS SHOULD AVOID FOODS CONTAINING NITRITES. CERTAIN PREPARED MEATS SUCH AS HOT DOGS AND BACON CONTAIN NITRITES. THE PHYSICIANS' DESK REFERENCE, PAGE 2642, 49th EDITION, 1995 STATES:

   "IN RATS, SIMULTANEOUS INGESTION OF DISULFIRAM AND NITRITE IN THE DIET FOR 78 WEEKS HAS BEEN REPORTED TO CAUSE TUMORS, AND IT HAS BEEN SUGGESTED THAT DISULFIRAM MAY REACT WITH NITRITES IN THE RAT STOMACH TO FORM A NITROSAMINE, WHICH IS TUMORIGENIC. DISULFIRAM ALONE IN THE RATS' DIET DID NOT LEAD TO SUCH TUMORS. THE RELEVANCE OF THIS FINDING TO HUMANS IS NOT KNOWN AT THIS TIME."
   (IT IS MY HUNCH THAT HUMANS WOULD BE AFFECTED IN A SIMILAR MANNER - j.s.r

2. THE PATIENTS SHOULD NOT DRINK CITY WATER.
   SUPER-NUTRITION, PAGE 115 STATES: "CHLORINE IS AN OXIDANT, TOO; MOST OF US DRINK CHLORINATED WATER WHICH CONSUMES VITAMIN E IN OUR BODY."
   "GOOD HOUSEKEEPING", PAGE 84, AUGUST, 1996 STATES: "VITAMIN E's BENEFITS APPEAR TO BE LARGELY RELATED TO ITS ANTIOXIDANT PROPERTIES."

P.P.S. I HOPE TO HAVE MS. FLEMING'S RESPONSE AT SOME TIME WITHIN THE NEXT FEW WEEKS. IF YOU WOULD LIKE TO SEE IT, JUST LET ME KNOW, AND I WILL MAIL A COPY OF IT TO YO

JULY 22, 1996

LEANNA J. STANDISH, ND, PhD
DIRECTOR
BASTYR UNIVERSITY AIDS RESEARCH CENTER
144 N.E. 54th STREET
SEATTLE, WASHINGTON 98105-9916

DEAR DR. STANDISH,

THANK YOU FOR YOUR RECENT LETTER, DATED JUNE 27, 1996 (ATTACHED).

ALSO ATTACHED ARE CONGRESSMAN VISCLOSKY'S LETTER TO YOU, DATED JULY 10, 1996; MY LETTER TO CONGRESSMAN VISCLOSKY, DATED JUNE 23, 1996; MY LETTER TO YOU, DATED MAY 11, 1996; AND PROFESSOR MANKES' LETTER TO ME DATED 16 APRIL, 1993.

I HAVE ALSO INCLUDED IN THIS ENVELOPE THE DOCUMENT WHICH I HAVE REFERRED TO AS MY "FILE". IN MY LETTER TO CONGRESSMAN VISCLOSKY IT IS ITEM NUMBER 8.

AS YOU CAN SEE, IT IS DATED JANUARY 1, 1996 AND IS 35 PAGES LONG.

DR. WHITESCARVER'S COMPLETE LETTER, DATED AUGUST 9, 1995, TO CONGRESSMAN VISCLOSKY COMPRISES PAGES 32 and 33 OF MY FILE.

DR. STANDISH, I WOULD LIKE TO AFFORD YOU A LITTLE BIT OF HISTORY -

BECAUSE OF MY EFFORTS, THE NATIONAL INSTITUTES OF HEALTH, ONE OF THE MOST RENOWNED MEDICAL RESEARCH FACILITIES IN THE WORLD REVISED ITS EVALUATION OF A CERTAIN CHEMICAL.

FOR THE PAST 28 YEARS I HAVE BEEN A LIBRARIAN AT THE LAKE RIDGE SCHOOL SYSTEM OF GARY, INDIANA. IN OCTOBER I WILL BE 60.

THROUGHOUT MY COLLEGE YEARS I NEVER TOOK A COURSE IN BIOLOGY OR ANY OF THE MEDICAL SCIENCES. THE ONLY CHEMISTRY COURSE WHICH I DID TAKE I ALMOST FLUNKED.

I BARELY KNOW THE DIFFERENCE BETWEEN A T-CELL AND A T-BAG.

NEVERTHELESS, BECAUSE OF MY EFFORTS, THE NATIONAL INSTITUTES OF HEALTH REVISED ITS EVALUATION OF THE CHEMICAL COMPOUND, "ACETALDEHYDE".

THE FOLLOWING PASSAGE COMES FROM 100 QUESTIONS AND ANSWERS ABOUT AIDS - A GUIDE FOR YOUNG PEOPLE BY MICHAEL THOMAS FORD, MACMILLAN PUBLISHING, NEW YORK, 1992, PAGE 5:

> "IN EARLY 1981, FIVE PREVIOUSLY HEALTHY YOUNG GAY MEN WERE SEEN AT A CLINIC IN LOS ANGELES. EACH HAD SYMPTOMS THAT APPEARED TO BE THE RESULT OF DAMAGED IMMUNE SYSTEMS. THIS WAS UNUSUAL BECAUSE NONE OF THE MEN HAD ANYTHING IN THEIR MEDICAL HISTORIES TO EXPLAIN THEIR CONDITIONS. SHORTLY AFTER THESE CASES WERE REPORTED, IN JUNE OF THAT YEAR, OTHER PHYSICIANS AROUND THE COUNTRY BEGAN TO REALIZE THAT THEY, TOO, WERE SEEING SIMILAR CASES IN YOUNG MEN."

SINCE THE BEGINNING OF THE AIDS PANDEMIC, SCIENTIFIC RESEARCHERS HAVE BEEN FRANTICALLY SEARCHING FOR A SUBSTANCE WHICH MIGHT HALT THE DEADLY MULTIPLICATION (REPLICATION) OF THE AIDS VIRUS - HIV.

THE PROBLEM IS BEST EXPRESSED BY PETER S. ARNO, Ph.D. AND KARYN L. FEIDEN IN THEIR BOOK, AGAINST THE ODDS; THE STORY OF AIDS DRUG DEVELOPMENT, POLITICS & PROFITS, PAGE 17:

> "BETWEEN 1987 AND 1991 THE NATIONAL CANCER INSTITUTE TESTED 40,000 CHEMICAL COMPOUNDS AT FACILITIES IN FREDERICK, MARYLAND AND BIRMINGHAM, ALABAMA, TO SEE IF ANY COULD DISABLE THE AIDS VIRUS. DESPITE TO ODDS AGAINST FINDING A BREAKTHROUGH DRUG, RESEARCHERS CONTINUE TO SCREEN FOR COMPOUNDS THAT CAN INHIBIT HIV AT EACH STEP IN THE INFECTION PROCESS: WHEN IT BINDS TO THE CD4 MOLECULE; WHEN IT PENETRATES THE HELPER T CELL; WHEN IT TRANSCRIBES ITS GENETIC CODE INSIDE; AND WHEN IT REPLICATES. A MORE PROMISING DIRECTION FOR FUTURE RESEARCH IS TARGETED DRUG DEVELOPMENT - THAT IS, DESIGNING AN EFFECTIVE DRUG ON THE KNOWN BIOLOGICAL STRUCTURE OF HIV."

ON JANUARY 1, 1993 I READ A SHORT ARTICLE IN THE GARY POST TRIBUNE ABOUT THE RESEARCH OF PROFESSOR RUSSELL F. MANKES OF THE ALBANY MEDICAL COLLEGE, NEW YORK.

THE RESEARCH CONCERNED THE CAUSE OF A "HANGOVER"; PROFESSOR MANKES CONCLUDED:

> "THE HEADACHE, UPSET STOMACH AND BAD AFTERTASTE THAT ACCOMPANY A HANGOVER COME FROM THE TOXIC BY-PRODUCT OF ALCOHOL, A CHEMICAL CALLED ACETALDEHYDE....."

AFTER READING THIS ARTICLE, IT OCCURRED TO ME THAT ACETALDEHYDE MIGHT BE EFFECTIVE IN DESTROYING THE AIDS VIRUS (I HAVE SINCE LEARNED THAT THE CORRECT BIOLOGICAL TERM TO USE IS "INACTIVATE" AND NOT "DESTROY" WHEN REFERRING TO A VIRUS).

THROUGHOUT 1993 I CONTINUALLY SUGGESTED TO THE NATIONAL INSTITUTES OF HEALTH THAT ACETALDEHYDE MIGHT BE EFFECTIVE IN "DESTROYING" HIV, THE AIDS VIRUS.

THROUGHOUT 1993 THE NATIONAL INSTITUTES OF HEALTH DID NOT AGREE WITH ME. THIS IS WHAT THEY HAD TO SAY ABOUT ACETALDEHYDE:

> "THE MOLECULES YOU SUGGEST ARE NORMAL METABOLITES FORMED DURING NORMAL BODY FUNCTIONING, AND WOULD HAVE NO EFFECT ON HIV OR AIDS."
> NATIONAL INSTITUTES OF HEALTH (NIH) LETTER TO ME DATED JANUARY 26, 1993

> "HOWEVER, ACETALDEHYDE IS A NORMAL METABOLITE OF THE HUMAN BODY AND WILL HAVE NO EFFECT ON HIV INFECTION."
> NIH LETTER TO ME DATED MARCH 24, 1993

> "ACETALDEHYDE, HOWEVER, ONLY HAS BEEN ASSOCIATED WITH SOME OF THE SIDE EFFECTS OF DTC, e.g., FATIGUE AND NAUSEA.
> AS THERE IS CURRENTLY NO SCIENTIFIC BASIS TO BELIEVE THAT ACETALDEHYDE HAS ANY ANTI-HIV ACTIVITY, THE NIH IS NOT PURSUING THE DEVELOPMENT OR PRECLINICAL EVALUATION OF THIS AGENT."
> NIH LETTER TO CONGRESSMAN VISCLOSKY DATED JUNE 18, 1993

> "ACETALDEHYDE IS A NORMAL METABOLITE OF THE HUMAN BODY THAT WOULD NOT SIGNIFICANTLY HINDER HIV INFECTION."
> NIH LETTER TO ME DATED SEPTEMBER 22, 1993

"TO DATE, THE NIH HAS NOT IDENTIFIED ANY COMPELLING DATA OR A CONVINCING RATIONALE TO PURSUE ACETALDEHYDE AS AN ANTI-HIV AGENT."
NIH LETTER TO ME DATED NOVEMBER 1, 1993

THESE PASSAGES COME FROM THE LETTERS OF FOUR DIFFERENT SCIENTISTS EMPLOYED AT THE TIME BY THE NATIONAL INSTITUTES OF HEALTH.

NEVERTHELESS, AFTER 1993 I CONTINUED TO MAIL UPDATES OF MY RESEARCH TO BOTH THE NATIONAL INSTITUTES OF HEALTH AND MISCELLANEOUS PRIVATE CITIZENS, SCIENTISTS, GOVERNMENT OFFICIALS AND ORGANIZATIONS WHO I THOUGHT MIGHT BE CONCERNED ABOUT THE PROBLEM OF HIV/AIDS; AS OF MARCH 21, 1996 THE FIGURE TOTALLED 70.

ON DECEMBER 13, 1994 THE NATIONAL INSTITUTES OF HEALTH SENT TO ME A LETTER IN WHICH THIS STATEMENT WAS MADE:

"THE KNOWN TOXICITY OF ACETALDEHYDE WOULD HAVE LIKELY PREVENTED EVALUATION EVEN IF THE AGENT HAD SHOWN ANTI-HIV ACTIVITY IN THE DRUG SCREEN PROGRAM SPONSORED BY THE NATIONAL CANCER INSTITUTE."

ON FEBRUARY 1, 1995 THE CENTERS FOR DISEASE CONTROL WROTE TO ME A LETTER IN WHICH THEY ANSWERED MY QUESTION, "DOES ACETALDEHYDE DESTROY HIV IN THE TEST TUBE?" THUSLY:

"ALL THE ALDEHYDES ARE CAPABLE OF INACTIVATING HIV; HOWEVER, THEIR ACTUAL EFFECTIVENESS DEPENDS ON THE CONCENTRATION USED."

AND IN HIS AUGUST 9, 1995 LETTER TO CONGRESSMAN VISCLOSKY (SEE PAGE 32 OF MY FILE) DR. WHITESCARVER STATED:

"THE FACT THAT ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS....."

AT THIS POINT IN TIME I AM GOING TO ASSUME THAT ACETALDEHYDE NOT ONLY "INACTIVATES" HIV IN THE TEST TUBE BUT ALSO IN THE HUMAN BODY.

THERE IS ONLY ONE PROBLEM WITH ACETALDEHYDE - IT IS HIGHLY TOXIC; REFER TO PROFESSOR MANKES' LETTER.

DR. STANDISH, IN YOUR LETTER YOU ASK:

"I THOUGHT DR. WHITESCARVER'S RESPONSE TO YOUR LETTER WAS PROBABLY ON THE MARK. HOW DO YOU REPLY TO HIS CRITICISMS?"

ON PAGES 25 AND 26 OF MY FILE I RESPONDED TO SOME OF THE CRITICISMS MADE BY DR. WHITESCARVER, BUT, CORRECT ME IF I AM WRONG DR. STANDISH, I THINK THAT THE SPECIFIC CRITICISMS YOU HAVE IN MIND AT THE PRESENT TIME ARE THOSE WHICH I DELINEATED IN MY MAY 11, 1996 LETTER TO YOU. FOR CLARITY SAKE, LET ME REPEAT THEM AGAIN:

"THE FACT THAT ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS DOES NOT NECESSARILY MAKE IT A GOOD CANDIDATE FOR ANTI-HIV THERAPY IN HUMANS."

"THE HIGH TOXICITY OF ACETALDEHYDE MAKES IT A SIGNIFICANTLY LESS DESIRABLE CANDIDATE FOR USE IN INDIVIDUALS WHO SUFFER FROM SEVERELY WEAKENED IMMUNE SYSTEMS AND WHO ARE PRONE TO CONTRACTING NUMEROUS OPPORTUNISTIC INFECTIONS AND MALIGNANCIES."

IN HIS LETTER (PAGE 32 OF MY FILE) DR. WHITESCARVER ALSO STATES:

"MR. ROBERTS, HOWEVER, INSISTS THAT THE TOXICITY COULD BE AMELIORATED BY THE ADMINISTRATION OF SULFUR AMINO ACIDS AND VITAMIN C. HE CITES RESEARCH CONDUCTED TWENTY YEARS AGO IN NORMAL, UNINFECTED MICE. THIS RESEARCH, HOWEVER, IS NOT APPLICABLE TO HUMANS INFECTED WITH HIV."

DR. STANDISH, WHEN ANY SCIENTIFIC STUDY OBTAINS A 100% RESULT, ISN'T THIS AN INDICATION THAT SOMETHING OF SINGULAR IMPORTANCE MAY HAVE OCCURRED?

REFER TO PAGE 34 OF MY FILE; SPECIFICALLY LOOK AT COMBINATION CB3 OF TABLE 2 - ALL OF THE RATS, 30 OUT OF 30, 100%, WERE PROTECTED AGAINST A LETHAL DOSE OF ACETALDEHYDE.

IT IS MY ASSUMPTION THAT RATS AND MONKEYS ARE USED IN BIOLOGICAL EXPERIMENTS BECAUSE IF CERTAIN RESULTS ARE ACHIEVED WITH THEM, THESE SAME RESULTS MAY OCCUR IN HUMAN BEINGS.

AS A MATTER OF FACT, JUST RECENTLY - JULY 17, I SAW A BRIEF REPORT ON THE TELEVISION NEWS OF A SCIENTIFIC STUDY WHICH UTILIZED RATS TO DEMONSTRATE THAT NICOTINE WAS JUST AS ADDICTIVE AS HEROIN AND COCAINE. I MIGHT BE WRONG, BUT I THINK THAT THE SUBSTANCE RELEASED IN THE RATS' BRAINS WAS "DOPAMINE". THE CLEAR INDICATION OF THE STUDY WAS THAT HUMAN BEINGS WERE ADDICTED IN A SIMILAR MANNER.

I'LL NEVER FORGET A TELEVISION INTERVIEW WITH ONE OF THE MOST POPULAR SINGERS OF OUR TIME - RAY CHARLES. HE SAID IT WAS EASIER FOR HIM TO KICK THE HEROIN HABIT THAN TO GIVE UP SMOKING.

I AM ABOUT TO LIST THREE STUDIES. THE AUTHOR CONCLUDES ONE OF THEM ("COMPARISON OF PROTECTION.....") WITH THESE WORDS:

"FINALLY, IT SHOULD BE NOTED THAT OUR EXPERIMENTS WERE CARRIED OUT ONLY IN ANIMALS (RATS). FURTHER ANIMAL EXPERIMENTATION IS NECESSARY BEFORE ANY EXTRAPOLATION OF THESE FINDINGS FOR HUMAN USE CAN BE CONSIDERED."

I AM GOING TO ASSUME THAT HUMAN BEINGS WOULD BE PROTECTED AS EASILY AND AS FULLY AGAINST THE HARMFUL EFFECTS OF ACETALDEHYDE POISONING AS WERE THE RATS IN THESE STUDIES PROVIDING OF COURSE THAT THEY (THE HUMANS) INGEST THE PARTICULAR SUBSTANCES WHICH THE AUTHOR MENTIONS.

THE PARTICULAR AUTHOR, OR SHOULD I SAY SCIENTIFIC RESEARCHER, TO WHOM I AM REFERRING IS HERBERT SPRINCE, OR SHOULD I SAY HERBERT SPRINCE AND ASSOCIATES.

IN MY OPINION, THE RESEARCH THAT "THEY" HAVE DONE IS SOME OF THE MOST OVERLOOKED OF THE 20th CENTURY. IT COULD BE OF VITAL IMPORTANCE TO MILLIONS OF PEOPLE THROUGHOUT THE WORLD.

IN MY OPINION, ANY PERSON WHO IS ADDICTED TO SMOKING AND/OR DRINKING WILL MOST LIKELY NOT GIVE UP THEIR HABIT SIMPLY BECAUSE THEY KNOW THAT IT IS BAD FOR HIS OR HER HEALTH.

P.S. DR. SPRINCE'S ASSOCIATES WERE CLARENCE M. PARKER, GEORGE G. SMITH AND LEON J. GONZALES. THE WORLD OF SMOKERS AND DRINKERS OWES THEM AN IMMENSE DEBT OF GRATITUDE.

HOWEVER, WOULDN'T IT BE BENEFICIAL FOR THAT PERSON TO KNOW THAT HE OR SHE COULD SLOW DOWN THE RATE AT WHICH THEY ARE CAUSING THEIR BODY TO DETERIORATE, BECAUSE OF THEIR BAD HABITS, BY SIMPLY SUPPLEMENTING THEIR DIET WITH NATURAL FOODS SUCH AS VITAMIN C, CYSTEINE AND THIAMINE (VITAMIN B1).

I'LL BET THAT VERY, VERY FEW PROBLEM SMOKERS AND DRINKERS ARE AWARE OF THIS FACT.

HERE ARE THREE OF THE MAJOR SPRINCE STUDIES. I HAVE INCLUDED THE COMPLETE ABSTRACT OF THE FIRST ONE IN MY FILE (SEE PAGE 23). EVERY SMOKER AND DRINKER SHOULD MEMORIZE THE FIRST TWO SENTENCES OF THAT ABSTRACT -

> "ACETALDEHYDE IS A TOXIC SUBSTANCE COMMON TO HEAVY DRINKING OF ALCOHOL AND HEAVY SMOKING OF CIGARETTES. IT HAS BEEN IMPLICATED THEREBY IN DISEASES OF THE CARDIOVASCULAR, RESPIRATORY, AND CENTRAL NERVOUS SYSTEMS." P.S.

THE SPRINCE STUDIES -

> 'PROTECTIVE ACTION OF ASCORBIC ACID AND SULFUR COMPOUNDS AGAINST ACETALDEHYDE TOXICITY: IMPLICATIONS IN ALCOHOLISM AND SMOKING', "AGENTS AND ACTIONS", VOL. 5/2 (1975)
>
> 'COMPARISON OF PROTECTION BY L-ASCORBIC ACID, L-CYSTEINE, AND ADRENERGIC-BLOCKING AGENTS AGAINST ACETALDEHYDE, ACROLEIN, AND FORMALDEHYDE TOXICITY: IMPLICATIONS IN SMOKING', "AGENTS AND ACTIONS", VOL. 9/4 (1979)
>
> 'PROTECTIVE ACTION OF SULFUR COMPOUNDS AGAINST ALDEHYDE TOXICANTS IN CIGARETTE SMOKE', "EUROPEAN JOURNAL OF RESPIRATORY DISEASES", (1985) 66. SUPPL. 139. 102-112

AGAIN, IT IS MY ASSUMPTION THAT THE HUMAN BODY COULD BE PROTECTED AGAINST THE TOXICITY OF ACETALDEHYDE BY INGESTING THE FOLLOWING NATURAL NUTRIENTS IN THE AMOUNTS SPECIFIED:

	mM/kg
L-ASCORBIC ACID (VITAMIN C)	2.0
L-CYSTEINE FB (A FREE FORM AMINO ACID)	1.0
THIAMIN.HCL (VITAMIN B1)	.3

I LIKE TO REFER TO THIS AS "THE SPRINCE RATIO".

THIS MORNING I WENT TO MY LOCAL HEALTH FOOD STORE AND CHECKED OUT THE PRICES. HERE THEY ARE:

> L-ASCORBIC ACID, 250 CAPSULES, $16.63 (EACH CAPSULE CONTAINS 500mg)
> L-CYSTEINE FB, 60 CAPSULES, $13.95 (EACH CAPSULE CONTAINS 500mg)
> 60 CAPSULES OF THE GENERIC BRAND COST $6.95
> THIAMIN.HCL, 200 TABLETS, $7.15 (EACH TABLET CONTAINS 100mg)

AS I WAS DRIVING HOME FROM THE HEALTH FOOD STORE I REMEMBERED THAT THERE WAS ANOTHER SUBSTANCE IN THE SPRINCE STUDY ('PROTECTIVE ACTION OF ASCORBIC ACID.....') WHICH GENERATED A 100% RESULT. IN FACT, WHEN I LOOKED AT THE STUDY AGAIN I SAW THAT THERE WAS TWO NOT ONE : N-ACETYL-L-CYSTEINE AND L-CYSTEIC ACID.H_2O. FOR CLARITY SAKE, I HAVE ATTACHED TABLE 1 OF THIS STUDY. I HAVE LABELLED THE TWO "100%".

P.S. THE LAST SENTENCE, TOO, SHOULD BE MEMORIZED - "OUR FINDINGS COULD POINT THE WAY TO A POSSIBLE BUILD-UP OF NATURAL PROTECTION AGAINST THE CHRONI BODY INSULT OF ACETALDEHYDE ARISING FROM HEAVY DRINKING OF ALCOHOL AND HEAVY SMOKING OF CIGARETTES."

nds against
Smoking[1])

. GONZALES
ments of Psychiatry
niversity, Philadelphia.

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elevated by *both* heavy
heavy cigarette smok-
relationship of acetal-
cts of *both* alcohol and
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al. [4], and is strength-
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play a role in the devel-
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smoking, acetaldehyde
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ed to be related to the
e tracheobronchial tree
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with the 'free lung cell
[8]. This response is
umbers of macrophages
by cigarette smoke and
significant exposure re-
lopment of pulmonary
RYLANDER [8]). From

the foregoing, it is evident that acetaldehyde is a toxic substance common to heavy alcohol drinking and heavy cigarette smoking and implicated in cardiovascular and pulmonary disease [4]. Therefore it becomes important to search for in vivo protectants against its adverse effects. Such protectants (particularly, naturally-occurring ones) could be of potential therapeutic value as preventives for tissues chronically exposed to elevated acetaldehyde levels.

In the previous publications from this laboratory [1–3], details were presented of the protective action in rats of L-cysteine free base (FB), thiamin · HCl, and L-2-methylthiazolidine-4-carboxylic acid against acetaldehyde toxicity and lethality at a carefully standardized LD 90 dose level. This study presents our findings on the protective action of related sulfur compounds and ascorbic acid against acetaldehyde toxicity in rats at the same standardized LD 90 dose level.

Materials and methods

The following is a brief outline of the methodology used; details are set forth in our previous publication [1]. Carworth Farms (CFE) strain male albino rats 90 ± 5 days old and weighing 365 ± 20 grams were deprived of food, but not water, overnight. Next morning, they were reweighed just prior to test for calculation of dosages of the test compounds. Compounds tested and the doses used are listed in Tables 1 and 2 under 'results'. Test compounds were freshly prepared as solutions or fine suspensions in physiological (0.9%) saline purged with nitrogen gas to protect against undesirable oxidation. Dilutions were made to concentrations convenient for oral intubation of the desired dose at convenient volumes (1–2.5 ml). Acetaldehyde was always freshly distilled just before use.

For initial screening, 30 rats per day were generally tested in equal groups (5 rats/group). Such tests were made in duplicate on two consecutive days to give a *minimum* of 10 rats/group tested. When a given test compound showed definite protection, these tests were replicated with more rats to the total number indicated in Table 1. Test compounds or combinations thereof were intubated orally 30–45 minutes prior to oral intubation of

Table 1
Protective action of L-ascorbic acid and sulfur compounds against anesthetic and lethal effects of acetaldehyde in the rat. (Toxic oral dose of acetaldehyde used was LD 90 = 18 m*M*/kg.)

Compounds tested (oral dose)	Dose (m*M*/kg)	% anesthetized after 3–10 minutes	% dead after 3 hours	24 hours	72 hours
Control (saline)	–	96 (48/50)	54 (27/50)	90 (45/50)	90 (45/50)
Reduced forms					
L-Ascorbic acid	2.0	53 (8/15)	27 (4/15)	27 (4/15)	27 (4/15)
L-Cysteine (FB)	2.0	20 (5/25)	8 (2/25)	20 (5/25)	20 (5/25)
DL-Homocysteine (FB)	2.0	60 (6/10)	50 (5/10)	60 (6/10)	60 (6/10)
L-Glutathione (Rd.)	2.0	47 (7/15)	0 (0/15)	33 (5/15)	33 (5/15)
N-Acetyl-L-cysteine	2.0	10 (2/20)	0 (0/20)	0 (0/20)	0 (0/20)
Oxidized forms					
L-Dehydroascorbic acid	2.0	80 (8/10)	20 (2/10)	70 (7/10)	70 (7/105)
L-Cystine	2.0	87 (13/15)	47 (7/15)	93 (14/15)	93 (14/10)
DL-Homocystine	2.0	90 (9/10)	30 (3/10)	90 (9/10)	100 (10/1)
L-Glutathione (Ox.)	2.0	80 (8/10)	10 (1/10)	80 (8/10)	80 (8/10)
DL-Thioctic acid	2.0	60 (6/10)	60 (6/10)	70 (7/10)	70 (7/10)
Other sulfur compounds					
Thiamin · HCl	2.0	10 (2/20)	0 (0/20)	10 (2/20)	10 (2/20)
L-MTCA	2.0	25 (5/20)	5 (1/20)	25 (5/20)	25 (5/20)
Taurine	2.0	45 (9/20)	15 (3/20)	45 (9/20)	45 (9/20)
Cysteamine · HCl	2.0	53 (8/15)	33 (5/15)	67 (10/15)	67 (10/15)
Sodium metabisulfite	2.0	5 (1/20)	0 (0/20)	5 (1/20)	5 (1/20)
L-Cysteic acid · H_2O	2.0	13 (2/16)	0 (0/16)	0 (0/16)	0 (0/16)

Compounds tested were intubated orally 30–45 minutes prior to oral intubation of 18 m*M*/kg of acetaldehyde (LD 90 dose). Doses are expressed in m*M*/kg. After intubation, rats were observed over a 24–72 hour period for anesthetic effects (loss of elevation and righting reflexes) and lethal response (deaths). Figures in parentheses = No. of rats anesthetized or dead/No. of rats tested. Anesthesia (loss of righting reflexes) with acetaldehyde generally occurred within 3–10 minutes and lasted for 5–15 minutes. Deaths were recorded at 3, 24, and 72 hours.

ONLY EXPERIENCE COULD TELL WHICH OF THE THREE ("THE SPRINCE RATIO", N-ACETYL-L-CYSTEINE, L-CYSTEIC ACID.H_2O) WOULD BE THE MOST EFFECTIVE IN TREATING HUMAN BEINGS. HOWEVER, AT THIS TIME I WANT TO FOCUS UPON N-ACETYL-L-CYSTEINE.

REFER TO PAGE 10 OF MY FILE WHEREIN I HAVE INCLUDED PASSAGES OF AN INTERVIEW WHICH DR. RICHARD A. PASSWATER HAD WITH DR. LUC MONTAGNIER. AFTER YOU READ THIS PAGE, AND AFTER YOU HAVE CONSIDERED WHAT I HAVE WRITTEN THUS FAR, I ASK YOU THIS - COULD THIS BE THE SCENARIO? -

> N-ACETYL-L-CYSTEINE WOULD SERVE A TWO FOLD FUNCTION: NOT ONLY WOULD IT RESTORE APOPTOSIS BACK TO NORMAL LEVELS, BUT IT WOULD ALSO PROTECT THE BODY AGAINST THE HARMFUL EFFECTS OF ACETALDEHYDE POISONING.

ONLY EXPERIENCE WOULD TELL, AND THAT IT WHY IT IS SO VITAL TO HAVE A CLINICAL TRIAL.

BY THE WAY, DR. PASSWATER DEFINES 'APOPTOSIS' THUSLY:

> "DEVELOPMENTAL OR PROGRAMMED CELL DEATH CHARACTERIZED BY MEMBRANE BLEBS, EXTENSIVE CHROMATIN CONDENSATION, AND DNA FRAGMENTATION. PLAYS A ROLE IN NEGATIVE SELECTION OF DEVELOPING T CELLS AND THE KILLING OF TARGETS BY CYTOTOXIC T LYMPHOCYTES."

HIS COMPLETE INTERVIEW WITH DR. MONTAGNIER CAN BE FOUND ON PAGES 50-65 OF "WHOLE FOODS", SEPTEMBER, 1995.

IN YOUR LETTER YOU QUESTIONED:

> "WE ADVERTISED EXTENSIVELY THROUGHOUT THE U.S. IN BOTH THE CONVENTIONAL AND ALTERNATIVE MEDICAL/SCIENTIFIC/AIDS ACTIVIST COMMUNITIES KNOW THAT WE WERE LOOKING FOR EXCELLENT RESEARCH PROJECTS IN ALTERNATIVE MEDICINE AND AIDS. WHY DIDN'T YOU APPLY?"

DR. STANDISH, IT WAS NOT UNTIL I RECEIVED THE LETTER DATED JANUARY 25, 1996 FROM THE CDC NATIONAL AIDS CLEARINGHOUSE (SEE ATTACHMENT TO MY FEBRUARY 11, 1996 LETTER) THAT I BECAME AWARE OF THE EXISTENCE OF THE OFFICE OF ALTERNATIVE MEDICINE.

IN YOUR LETTER YOU STATE:

> "I MUST SAY THAT THE WAY YOU PRESENT YOUR IDEAS MAKES IT DIFFICULT TO EVALUATE THEM OBJECTIVELY."

TO FACILITATE MATTERS, I HAVE COMPOSED A HYPOTHETICAL CONVERSATION WHICH I WOULD HAVE WITH MY PHYSICIAN IF I HAD HIV/AIDS.

I KNOW IN MY MAY 11, 1996 LETTER TO YOU I ASKED THAT YOU GIVE CONSIDERATION TO ONLY "A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV"; HOWEVER, MY HYPOTHETICAL CONVERSATION WILL EMPLOY ELEMENTS OF BOTH THE "MILD" AND "INTENSIVE" APPLICATION.

THE NUMBER IN PARENTHESIS WILL INDICATE THE PAGE OF MY FILE ON WHICH THE DATA TO WHICH I REFER OCCURS.

GOOD MORNING DOCTOR. I WOULD LIKE TO PRESENT YOU WITH SOME RESEARCH I HAVE DONE RELATIVE TO HIV/AIDS. I CALL IT MY 35 PAGE FILE.

I WOULD LIKE FOR YOU TO CONTINUE ON IN YOUR ADMINISTRATION OF MEDICINES TO ME TO HELP ME FIGHT OFF THE INROADS WHICH OPPORTUNISTIC INFECTIONS MIGHT BE MAKING UPON MY BODY.

HOWEVER, I WOULD LIKE FOR YOU TO PRESCRIBE ANTABUSE FOR ME SO THAT I CAN START TAKING IT ON A DAILY BASIS.

AS I SAID IN MY FILE (8) IT IS MY ASSUMPTION THAT ANTABUSE WOULD NOT PROVE TO BE A DETRIMENT -

> "THE PRESENCE OF ANTABUSE IN THE LIVER WOULD NOT HINDER THE EFFECT WHICH MEDICINES MIGHT HAVE IN WARDING OFF THE OPPORTUNISTIC INFECTIONS ENGENDERED BY HIV/AIDS."

DOCTOR, WITH ANTABUSE IN MY LIVER I THINK WE CAN BEGIN THE ATTACK ON THE VIRUS WHICH IS THE CAUSE OF ALL MY PROBLEMS - HIV.

DOCTOR, I HAVE BECOME AWARE OF A CHEMICAL WHICH CAN INACTIVATE HIV; IT IS CALLED ACETALDEHYDE.

BOTH THE NATIONAL INSTITUTES OF HEALTH AND CENTERS FOR DISEASE CONTROL HAVE ACKNOWLEDGED THAT ACETALDEHYDE WILL INACTIVE HIV IN THE TEST TUBE (21).

DOCTOR, I AM GOING TO MAKE THE ASSUMPTION THAT ACETALDEHYDE WILL INACTIVATE HIV IN THE HUMAN BODY.

BASICALLY, DOCTOR, MY CONVERSATION WITH YOU TODAY WILL PRETTY MUCH DUPLICATE WHAT I HAVE WRITTEN IN MY FILE. HOWEVER, THERE WILL BE ONE MAJOR VARIANCE - TWO WEEKS FROM NOW I DO NOT WANT TO START OFF WITH THE 100 PROOF LIQUOR AS I ORIGINALLY STATED (24); INSTEAD, I WANT TO START OFF WITH A LIGHT WINE (12% ALCOHOL).

ALSO, I WANT THE TRIAL TO LAST 18 WEEKS, NOT 16 WEEKS AS I ORIGINALLY SUGGESTED (23).

FOR THE FIRST TWO WEEKS, BY TAKING A DAILY DOSAGE OF ANTABUSE, NOT TO EXCEED 500 mg (24), I ASSUME I WILL SUFFICIENTLY "PLUG UP" MY LIVER. FOR THE REMAINDER OF THE TRIAL PERIOD - 16 WEEKS - I WILL TAKE A DAILY ANTABUSE DOSAGE OF 250mg (24).

DURING THIS INITIAL TWO WEEK "PLUG UP" PERIOD I WILL BE CAREFUL NOT TO DRINK ALCOHOL OF ANY KIND WHATSOEVER. I UNDERSTAND THAT BY SO DOING I COULD MAKE MYSELF DEATHLY ILL. IN ADDITION, I WILL BE CAREFUL TO AVOID "HIDDEN ALCOHOLS" SUCH AS THAT FOUND IN AFTERSHAVE LOTIONS, CERTAIN SAUCES, FERMENTED VINEGAR, MARINADES, DESSERTS AND OTHER FOODS PREPARED WITH ANY ALCOHOL (26).

HOWEVER, I WILL IMMEDIATELY BEGIN TO INCLUDE IN MY DIET SUCH FOODS AS APPLES AND ORANGES (9) AND WILL DO SO FOR THE ENTIRE 18 WEEK PERIOD OF THE TRIAL. I UNDERSTAND THAT THIS COULD MAKE ME A LITTLE BIT NAUSEOUS, BUT IT SHOULDN'T BE TOO BAD; THE NAUSEA, OF COURSE, WOULD WELL UP BECAUSE OF THE SLIGHT, INCREASED (26) AMOUNT OF UNMETABOLIZED ACETALDEHYDE FLOWING IN MY BLOODSTREAM. DOCTOR, THIS CONSTITUTES THE BASIS OF "A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

IN TWO WEEKS, DOCTOR, I WANT TO COME BACK TO YOUR OFFICE AND HAVE YOU BEGIN THE TREATMENT WHICH I CALL "AN INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

THE PROCEDURE WILL RESULT IN THE RELEASE OF A CONSIDERABLE AMOUNT OF POISONOUS ACETALDEHYDE INTO MY BLOODSTREAM.

YOU MIGHT BE RELUCTANT TO DO IT, BUT DOCTOR, I HAVE COME ACROSS SOME RESEARCH WHICH, I THINK, WILL AFFORD ME PROTECTION AGAINST THE TOXICITY OF ACETALDEHYDE.

THE RESEARCH TO WHICH I REFER HAS BEEN DONE BY HERBERT SPRINCE AND HIS ASSOCIATES (22-23).

SPRINCE HAS DISCOVERED AN AMAZING FACT OF NATURE (22); I WISH TO QUOTE IT AGAIN AT THIS TIME BECAUSE IT IS SO INTRIGUING:

> "TO THE BEST OF OUR KNOWLEDGE, OUR FINDINGS DEMONSTRATE FOR THE FIRST TIME THAT DIRECT (SPRINCE'S EMPHASIS) PROTECTIVE ACTION AGAINST ACETALDEHYDE TOXICITY AND LETHALITY CAN BE OBTAINED WITH CERTAIN NATURALLY-OCCURRING METABOLITES, NAMELY L-ASCORBIC ACID, L-CYSTEINE, AND THIAMIN, PREFERABLY IN COMBINATION AT REDUCED DOSE LEVELS."

I CALL THIS "THE SPRINCE RATIO":

L-ASCORBIC ACID (VITAMIN C)	2.0
L-CYSTEINE FB (A SULFUR COMPOUND)	1.0
THIAMINE.HCL (A SULFUR COMPOUND)	.3

AND PLANNED ON USING THESE NUTRIENTS IN MY TRIAL (24).

HOWEVER, ON JULY 22 A FACT OCCURRED TO ME THAT CAUSED ME TO CHANGE MY MIND - I REMEMBERED THAT ANOTHER NUTRIENT IN THE SPRINCE STUDY ALSO AFFORDED 100% PROTECTION AGAINST THE LETHALITY OF ACETALDEHYDE POISONING; THAT NUTRIENT IS

N-ACETYL-L-CYSTEINE.

FOR CONVENIENCE SAKE, IT IS CALLED "NAC".

ON PAGE 7 OF MY FILE I DEFINED IT; HERE IS THE FIRST SENTENCE OF THAT DEFINITION:

> "N-ACETYL CYSTEINE IS A MORE STABLE FORM OF THE SULFUR AMINO ACID L-CYSTEINE, AND IS A POWERFUL ANTIOXIDANT."

DR. LUC MONTAGNIER WHOSE LABORATORY DISCOVERED HIV IS GIVING IT SERIOUS CONSIDERATION (10).

THEREFORE, BY USING THIS NUTRIENT AND EMPLOYING ACETALDEHYDE COULDN'T WE POSSIBLY LAND A ONE/TWO KNOCKOUT PUNCH AGAINST THE DEADLINESS OF HIV; TO SUMMARIZE:

1. NAC WOULD HELP TO RESTORE APOPTOSIS BACK TO NORMAL LEVELS (10).

2. NAC WILL AFFORD 100% PROTECTION AGAINST THE TOXIC EFFECTS OF UNMETABOLIZED ACETALDEHYDE (SEE SPRINCE TABLE 1 ATTACHED TO MY JULY 22 LETTER TO DR. STANDISH).

3. UNMETABOLIZED ACETALDEHYDE WILL INACTIVATE HIV (21).

IF THIS INDEED WOULD OCCUR, I WOULD LIKE TO REPEAT THE TWO PARAGRAPHS AT THE BOTTOM OF PAGE 10 OF MY FILE; I HAVE MADE ONE SLIGHT REVISION TO THE SECOND PARAGRAPH:

> "I WOULD LIKE TO CONCLUDE MY RESEARCH BY SUGGESTING THAT ANTIOXIDANTS AND UNMETABOLIZED ACETALDEHYDE MIGHT BE OF SOME CONSIDERABLE BENEFIT TOWARD RESTORING HIV/AIDS PATIENTS TO A MODICUM OF GOOD HEALTH.
>
> "THERE IS NO DOUBT IN MY MIND, WHATSOEVER, THAT ACETALDEHYDE, IN COMBINATION WITH N-ACETYL-L-CYSTEINE (NAC), WILL EVENTUALLY BE SHOWN TO BE THE MOST USEFUL POISON EVER DEVISED BY NATURE FOR THE BENEFIT OF MANKIND."

THE CURRENT PRICE FOR NAC AT THE HEALTH FOOD STORE IS $3.90 FOR 30 CAPSULES. EACH CAPSULE CONTAINS 600 mg.

BY THE WAY, DOCTOR, AS A MATTER OF GOOD HEALTH I WILL START TAKING NAC ON A DAILY BASIS. DR. MONTAGNIER, WITH HIS APPLICATION OF IT, DID NOT START TO SEE GOOD RESULTS UNTIL AFTER SIX MONTHS (10).

OF COURSE, AS YOU ARE ABOUT TO SEE, DOCTOR, WHEN I COME TO YOUR OFFICE ONCE A WEEK YOU WILL PROBABLY HAVE ME TAKE DOUBLE, TRIPLE OR QUADRUPLE MY NORMAL DAILY AMOUNT OF NAC.

HERE THEN, DOCTOR, IS THE "INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV" WHICH I WANT YOU TO ADMINISTER TO ME -

THE PROCEDURE WILL PROBABLY TAKE ALL MORNING OR ALL AFTERNOON (ABOUT 4 HOURS) (24) THE FIRST THING YOU WOULD DO, DOCTOR, IS TO HAVE ME SWALLOW MY INCREASED "DOSAGE" OF NAC - AND HERE I WILL LEAVE IT TO YOUR EXPERTISE TO DETERMINE THE AMOUNT. IN THE SPRINCE STUDY, 2.0 mM/kg (MILLIMOLES/KILOGRAM) OF NAC WAS ADMINISTERED TO THE RATS. EACH OF THE NAC CAPSULES CONTAINS 600 mg. I DO NOT KNOW HOW TO EQUATE GRAMS WITH MOLES.

30 TO 45 MINUTES LATER (24), DOCTOR, I WANT YOU TO GIVE TO ME 15 mL (½ oz) OF UNFORTIFIED WINE TO DRINK. I THINK THE ALCOHOL CONTENT WILL BE ABOUT 12%.

IF MY LIVER WERE NOT "PLUGGED UP" WITH ANTABUSE IT WOULD QUICKLY METABOLIZE ALL OF THE ACETALDEHYDE THAT WOULD HAVE BEEN GENERATED BY DRINKING THIS WINE; I THINK THAT 18.6 MINUTES WOULD BE THE MAXIMUM TIME INVOLVED (35).

HOWEVER, SINCE MY LIVER IS PLUGGED UP, LET'S ASSUME THAT 4 HOURS IS NEEDED TO DO THE JOB; IN OTHER WORDS, POISONOUS, TOXIC, LETHAL UNMETABOLIZED ACETALDEHYDE WILL BE FLOWING THROUGHOUT MY BODY FOR AN UNUSUALLY LONG PERIOD OF TIME.

HOWEVER, DOCTOR, I WILL NOT BE WORRIED ABOUT THIS BECAUSE THE RESEARCH OF HERBERT SPRINCE AND HIS ASSOCIATES HAS SHOWN THAT N-ACETYL-L-CYSTEINE AFFORDS 100% PROTECTION AGAINST ACETALDEHYDE POISONING.

THIS THEN WOULD BE THE SCENARIO - FOR THE FOUR HOUR PERIOD MY BODY WOULD BE PROTECTED AGAINST THE TOXICITY OF ACETALDEHYDE WHILE AT THE SAME TIME THIS TOXICITY WOULD BE "INACTIVATING" MILLIONS OF AIDS VIRUSES - HIV. THE WORST THING THAT MIGHT HAPPEN TO ME DURING THE FOUR HOUR PERIOD IS THAT I MIGHT BECOME A LITTLE BIT SLEEPY.

THE IMPORTANT THING WE HAVE TO TAKE INTO CONSIDERATION, DOCTOR, IS HOW QUICKLY IS NAC METABOLIZED? IF IT IS METABOLIZED WITHIN ½ HOUR, MY "PROTECTIVE CUSHION" AGAINST THE TOXICITY OF ACETALDEHYDE WILL EVAPORATE. IF FOUR HOURS IS NEEDED TO METABOLIZE IT, I HAVE NOTHING TO WORRY ABOUT.

THIS THEN MIGHT BE THE "BUSY SCENARIO" - EVERY ½ HOUR, OR EVERY HOUR, OR EVERY 1½ HOUR, OR EVERY TWO HOURS I WOULD HAVE TO REPLENISH MY BODY WITH A "DOSE" OF NAC. I MIGHT HAVE TO BE AWAKENED TO DO SO. THAT IS WHY IT WILL BE NECESSARY FOR YOU TO KEEP YOUR EYE ON ME, DOCTOR, DURING THE ENTIRE FOUR HOUR PERIOD.

DURING MY NEXT THREE VISITS, DOCTOR, I WOULD LIKE FOR YOU TO REPEAT THIS PROCEDURE. IF I SUFFER NO ILL EFFECTS FROM THIS PROCEDURE, I WANT YOU TO CHANGE IT THUSLY:

WEEKS 5,6,7,8: ALCOHOL AMOUNT - 1 oz. OF UNFORTIFIED WINE (12% ALCOHOL)
WEEKS 9,10,11,12: ALCOHOL AMOUNT - ½ oz. OF FORTIFIED WINE (18% ALCOHOL)
WEEKS 13,14,15,16: ALCOHOL AMOUNT - 1 oz. OF FORTIFIED WINE (18% ALCOHOL)

IF AFTER 16 WEEKS OF THIS TREATMENT, AND IF I AM AMENABLE TO IT, IT WOULD BE MY EVENTUAL GOAL, DOCTOR, TO COME TO YOUR OFFICE ONCE A WEEK,AND YOU WOULD ADMINISTER TO ME 1 oz. OF 100 PROOF LIQUOR (50% ALCOHOL); HOPEFULLY, NO ILL EFFECTS WOULD OCCUR, AND MILLIONS UPON MILLIONS OF AIDS VIRUSES WOULD BE "INACTIVATED".

WHAT GOOD RESULTS MIGHT OCCUR? DOCTOR, IT IS MY CONJECTURE THAT ACETALDEHYDE WAS THE OPERATIVE FORCE IN A FRENCH HIV STUDY WHICH WAS DETAILED IN "THE LANCET", SEPTEMBER 24, 1988, PAGES 702-706.

HERE ARE THE RESULTS OF THAT STUDY RELATIVE TO SOME OF THE PATIENTS WHO HAD DITIOCARB (RELATED TO ANTABUSE) IN THEIR LIVERS:

1. CD 4+ (T-CELL) COUNT INCREASED
2. ENLARGED SPLEEN AND LYMPH NODES SHRANK
3. DIARRHEA DISAPPEARED
4. WEIGHT RESUMPTION OCCURRED
5. PERSISTENT FEVERS DISAPPEARED
6. IMPROVEMENT IN CLINICAL STATUS IN 42% OF THE PATIENTS

WELL, THAT'S ABOUT IT, DOCTOR; JUST A FEW THINGS BEFORE I GO -

I'LL CONTINUE TO EAT ALOT OF FRUIT (9).
I'LL SUPPLY MY BODY WITH ZINC (27).

DOCTOR, COULD A DIETARY DEFICIENCY OF ZINC CONTRIBUTE TO THE DEVELOPMENT OF ALCOHOLISM? (27)

DOCTOR, IN THE INTERVIEW HE HAD WITH DR. PASSWATER, DR. MONTAGNIER ALSO MENTIONED ZINC ALONG WITH THESE NUTRIENTS - SELENIUM, BETA CAROTENE, VITAMINS A, C AND E, ENZYMES SUPEROXIDE DISMUTASE (SOD) AND CATALASE, AND PROTEINS SUCH AS METALLOTHIONINE. (10) DOCTOR, I AM GOING TO INCLUDE THESE NUTRIENTS INTO MY DIET. I AM NOT A SMOKER, BUT IF I WERE,I WOULD BE SURE TO INCLUDE AN ABUNDANT AMOUNT OF VITAMIN C BECAUSE:

"..... EACH CIGARETTE SMOKED DESTROYS AN ESTIMATED 25 mg OF VITAMIN C; THIS MAY BE AS MUCH AS MANY PEOPLE OBTAIN IN THEIR DIET. THE RDA IS ONLY 50 mg." (27)

DOCTOR, I READ AN INFORMATIVE BOOK ABOUT VITAMIN C; IT IS:

THE HEALING FACTOR - VITAMIN C AGAINST DISEASE BY IRWIN STONE
GROSSET & DUNLAP, NEW YORK, 1972

OH, BY THE WAY DOCTOR, DO YOU KNOW THE MEANING OF THE TERM - "ZINC FINGERS"? COULD A DIETARY DEFICIENCY OF ZINC EXACERBATE HIV/AIDS? (9)

DOCTOR, ON PAGE 3 OF MY FILE I BET $148.00 THAT THE WORD, "ACETALDEHYDE", IS NEVER MENTIONED ON ANY OF THE 452 PAGES OF THE BOOK -

DISULFIRAM AND ITS METABOLITE ..... (3)

DOCTOR, I STILL HAVE MY $148.00.

DOCTOR, WAS I CORRECT ABOUT MY UNDERSTANDING OF THE RESEARCH OF THE THREE JAPANESE RESEARCHERS? (3,4,5)

THEIR ACETALDEHYDE CONTAINING COMPOUND INHIBITED MORE THAN 90% OF THE N-MYRISTOYLATION OF P17 GAG PROTEIN PRODUCED IN THE HIV-1-INFECTED MT-4 CELLS. (4)

IF THEY HAD USED "PURE" ACETALDEHYDE - CH_3CHO - WOULD A 100% RESULT HAVE BEEN ACHIEVED? IF SO, WHY DIDN'T THEY USE "PURE" ACETALDEHYDE?

IN ANY EVENT, WAS I RIGHT WHEN I MADE THIS STATEMENT:

> "IN OTHER WORDS, HIV, WHICH IS THE VIRUS WHICH IS THE ROOT CAUSE OF AIDS, CANNOT BEGIN TO MULTIPLY AS LONG AS A CERTAIN COMPOUND CONTAINING ACETALDEHYDE IS PRESENT." (5)

AND FINALLY, DOCTOR, WHAT DO YOU THINK ABOUT THE COMMENTS I MADE ON PAGE 27? -

1. AVOID SUGAR
2. INCLUDE MOLASSES (RICH IN IRON)
3. AVOID FOOD ADDITIVES SUCH AS MSG
4. INCLUDE VINEGAR
5. INCLUDE GARLIC

I WOULD LIKE TO MENTION AGAIN THE BOOKS I LISTED ON PAGE 27 -

SUPER-NUTRITION BY DR. PASSWATER
SUGAR BLUES BY WILLIAM DUFTY

DOCTOR, IN CONCLUSION I WOULD LIKE TO REPEAT A STATEMENT WHICH DR. MONTAGNIER MADE TO DR. PASSWATER:

> "I AM CONVINCED THAT OXIDATIVE STRESS IS INDEED INVOLVED IN THE PROGRESSION FROM HIV INFECTION TO THE AIDS STAGE. I BELIEVE, THEREFORE, THAT ANTIOXIDANTS ARE NECESSARY IN THE TREATMENT. BUT ANTIOXIDANTS ARE NOT SUFFICIENT BY THEMSELVES." (10)

I WISH TO SUGGEST THAT THE ADDITIONAL FACTOR THAT DR. MONTAGNIER IS LOOKING FOR IS UNMETABOLIZED ACETALDEHYDE.

DOCTOR, THANK YOU AGAIN FOR YOUR HELP AND COOPERATION. I'LL SEE YOU AGAIN NEXT WEEK.

WELL, THAT'S ABOUT IT, DR. STANDISH.

THANKS FOR YOUR TIP ABOUT THE DIVISION OF RESEARCH GRANTS AT THE NIH, A LEAD WHICH I WILL PURSUE.

IN ADDITION, I WILL CONTINUE IN MY EFFORT TO MAKE THE PUBLIC AWARE OF MY RESEARCH BY MAILING THIS LETTER TO MISCELLANEOUS PRIVATE CITIZENS, SCIENTISTS, GOVERNMENT OFFICIALS AND ORGANIZATIONS.

IF YOU, DR. WHITESCARVER, CONGRESSMAN VISCLOSKY OR PROFESSOR MANKES HAVE ANY COMMENTS OR CRITICISMS, PLEASE MAIL THEM TO ME WITHIN THE NEXT FEW WEEKS, AND I WILL ATTACH THEM TO THIS LETTER.

AT THE VERY LATEST, SEPTEMBER 1, I WISH TO MAIL COPIES OF THIS LETTER TO THE "70" WHICH I HAVE ALREADY MENTIONED, AND OTHERS IN OUR SOCIETY WHO I THINK MIGHT BE CONCERNED ABOUT THE PROBLEM OF HIV/AIDS.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPIES TO:

CONGRESSMAN PETER J. VISCLOSKY, WASHINGTON, D.C. AND GARY, INDIANA
JACK WHITESCARVER, Ph.D., NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND
PROFESSOR RUSSELL F. MANKES, Ph.D., THE ALBANY MEDICAL COLLEGE, ALBANY, NEW YORK

BASTYR
UNIVERSITY

Research Department
144 N.E. 54th Street
Seattle, Washington 98105-9916
FAX (206) 517-3599

John S. Roberts
P.O. Box H.
Hogart, IN 46342
June 27, 1996

Dear Mr. Roberts,

Thank you for your persistent energy in trying to get the AIDS research community to take seriously your ideas about acetaldehyde and Antabuse. I cannot fully assess the validity of your ideas since I do not have in my possession a document from you that you refer to as your "file". I must say that the way you present your ideas makes it difficult to evaluate them objectively. Nevertheless, I am not one to dismiss even crazy sounding ideas without carefully going over the facts. I thought Dr. Whitescarver's response to your letter was probably on the mark. How do you reply to his criticisms?

The NIH funded Bastyr University AIDS Research Center recently distributed $105,000 for two small AIDS studies in alternative medicine. That $105,000 was the total allocation in our budget for funding extramural research. We advertised extensively throughout the U.S. in both the conventional and alternative medical/scientific/AIDS activist communities know that we were looking for excellent research projects in alternative medicine and AIDS. Why didn't you apply?

If our AIDS Research Center is refunded by the NIH in 1997, we will have funding for more extramural research studies. In which case, I urge you to write a sound scientific proposal, have it fairly evaluated by scientific review. If your idea is worthy of pursuit and you can construct a sound experimental design to test your hypothesis, then the Center may be able to fund the kind of study you feel is so urgently needed. I recommend that you contact the Division of Research Grants at the NIH (phone 301- 435- 0714) and ask them for a grant proposal form called the PHS-398 that you will need to complete in order to obtain any NIH funding. I think that the rigor required to complete a reasonable NIH style grant proposal will help you clarify your ideas and make them more accessible, and therefore more powerful to other scientists and physicians.

I hope this helps.

Leanna J. Standish, ND, PhD
Director
Bastyr University AIDS Research Center

cc: U.S. Representative Peter J. Viscloski
Jack Whitescarver, PhD Deputy director OAR, NIAID

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

COMMITTEE ON APPROPRIATIONS
CONGRESSIONAL STEEL CAUCUS
EXECUTIVE COMMITTEE CHAIRMAN
NORTHEAST-MIDWEST
CONGRESSIONAL COALITION
MIDWEST VICE-CHAIR
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July 10, 1996

Dr. Leanna Standish
Bastyr University
144 NE 54th Street
Seattle, Washington 98105

Dear Dr. Standish:

Enclosed please find correspondence submitted to my office by my constituent, John S. Roberts.

Mr. Roberts has done research and has described two procedures through which HIV might be "inactivated" by acetaldehyde. He has sent material to you outlining his findings. Mr. Roberts is asking my office to request a response to his claim. Any information which you could provide John Roberts would be greatly appreciated.

Should you have any questions, please feel free to contact my District Director, David Rozmanich, at (219) 884-1177.

Sincerely,

Peter J. Visclosky
Member of Congress

PJV:dsr

JUNE 23, 1996

THE HONORABLE PETER J. VISCLOSKY
UNITED STATES HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

AS YOU CAN SEE, I HAVE SENT THIS LETTER TO YOU BY CERTIFIED MAIL; I HAVE ALSO PERSONALLY DELIVERED A COPY OF IT TO YOUR GARY, INDIANA OFFICE.

I HAVE ALSO SENT A COPY OF IT BY CERTIFIED MAIL TO BOTH DR. LEANNA STANDISH, CENTER FOR ALTERNATIVE MEDICINE RESEARCH IN HIV/AIDS, NATIONAL INSTITUTES OF HEALTH AND JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH.

CONGRESSMAN VISCLOSKY, I NEED YOUR HELP.

WOULD YOU PLEASE REQUEST OF DR. STANDISH THAT SHE RESPOND TO MY LETTER OF MAY 11, 1996 (ATTACHED).

IF SHE THINKS THAT MY "MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV" MIGHT BE VIABLE, COULD SHE MAIL TO ME THE NAMES OF RESEARCHERS WHOM I MIGHT CONTACT TO ASK TO APPLY FOR A $30,000 GRANT FROM HER OFFICE; OF COURSE, I WOULD NOT BE THE RECIPIENT OF ANY FUNDING WHATSOEVER.

IF SHE DOES NOT THINK THAT MY "MILD PROCEDURE" IS VIABLE, COULD SHE AFFORD ME THE RATIONALE BEHIND HER CONCLUSION.

TO RECAPITULATE, ON MAY 11 OR MAY 12 I MAILED TO DR. STANDISH AND DR. WHITESCARVER A PACKET CONTAINING THE FOLLOWING (I PERSONALLY DELIVERED SAID PACKET TO YOUR GARY OFFICE):

1. THE MAY 11 LETTER TO DR. STANDISH.
2. A FOUR PAGE ADVERTISEMENT WHICH I PLACED ON "THE INTERNET" DATED APRIL 9, 1996.
3. A 3 PAGE LETTER CONTAINING THE NAMES AND ADDRESSES OF MISCELLANEOUS PRIVATE CITIZENS, SCIENTISTS, GOVERNMENT OFFICIALS AND ORGANIZATIONS WHO I THOUGHT MIGHT BE INTERESTED IN MY HIV/AIDS RESEARCH; THE TOTAL FIGURE TO DATE IS 70. LETTER DATED 3/21/96.
4. A THREE PAGE LETTER TO "CURRENT HEALTH 2" DATED FEBRUARY 29, 1996.
5. A FIVE PAGE LETTER TO THE LAKE COUNTY AIDS TASK FORCE, DATED FEBRUARY 25,1996.
6. AN EIGHT PAGE LETTER TO BOTH THE DIRECTORS OF THE NATIONAL INSTITUTES OF HEALTH AND THE OFFICE OF ALTERNATIVE MEDICINE (NIH), DATED FEBRUARY 11, 1996.
7. A FOUR PAGE LETTER TO WYETH-AYERST LABORATORIES (THE COMPANY WHICH OWNS THE PATENT AND MANUFACTURING RIGHTS TO "ANTABUSE"), DATED JANUARY 27, 1996.
8. A THIRTY FIVE PAGE FILE OF MY RESEARCH RELATIVE TO HIV/AIDS, DATED JANUARY 1, 1996.

IF, BY HAPPENSTANCE, THIS PACKET DID NOT COME TO THE ATTENTION OF ANY OF YOU, JUST LET ME KNOW (219-763-1933), AND I WILL MAIL IT TO YOU IMMEDIATELY.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342

MAY 11, 1996

DR. LEANNA STANDISH
CENTER FOR ALTERNATIVE MEDICINE RESEARCH IN HIV/AIDS
NATIONAL INSTITUTES OF HEALTH
BASTYR UNIVERSITY
144 NE 54th STREET
SEATTLE, WASHINGTON 98105

DEAR DR. STANDISH,

TODAY IT OCCURRED TO ME THAT I SHOULD WRITE THIS LETTER TO YOU.

THROUGHOUT 1993 THE NATIONAL INSTITUTES OF HEALTH TOLD BOTH ME AND CONGRESSMAN PETER J. VISCLOSKY OF INDIANA THAT ACETALDEHYDE WOULD HAVE NO EFFECT UPON THE AIDS VIRUS - HIV.

IN DECEMBER, 1994 AND AUGUST, 1995 THE NATIONAL INSTITUTES OF HEALTH (NIH) CHANGED ITS POSITION (SEE PAGE 28 OF MY FILE).

TO BE MORE SPECIFIC - IN HIS LETTER TO CONGRESSMAN VISCLOSKY (SEE PAGES 32 AND 33 OF MY FILE) JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR OF THE OFFICE OF AIDS RESEARCH, NIH, STATED:

> "THE FACT THAT ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS DOES NOT NECESSARILY MAKE IT A GOOD CANDIDATE FOR ANTI-HIV THERAPY IN HUMANS."
>
> "THE HIGH TOXICITY OF ACETALDEHYDE MAKES IT A SIGNIFICANTLY LESS DESIRABLE CANDIDATE FOR USE IN INDIVIDUALS WHO SUFFER FROM SEVERELY WEAKENED IMMUNE SYSTEMS AND WHO ARE PRONE TO CONTRACTING NUMEROUS OPPORTUNISTIC INFECTIONS AND MALIGNANCIES."

IN MY RESEARCH I DESCRIBE TWO PROCEDURES BY WHICH HIV MIGHT BE "INACTIVATED" BY ACETALDEHYDE.

AT THIS TIME I AM NOT SUGGESTING THAT YOU GIVE CONSIDERATION TO THE "INTENSIVE APPLICATION" OF UNMETABOLIZED ACETALDEHYDE; HOWEVER, I WOULD APPRECIATE IT IF YOU WOULD GIVE CONSIDERATION TO

> "A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

IF YOU THINK THAT A CLINICAL TRIAL IS FEASIBLE, COULD YOU FORWARD TO ME THE NAMES, ADDRESSES AND TELEPHONE NUMBERS OF ANY "AIDS ACTIVISTS" WHO MIGHT HAVE THE INTEREST AND WHEREWITHAL TO INITIATE SUCH A TRIAL; A LICENSED PHYSICIAN WOULD BE NECESSARY IN ORDER TO PRESCRIBE ANTABUSE.

IF YOU DON'T THINK THAT SUCH A TRIAL IS FEASIBLE, I WOULD APPRECIATE RECEIVING FROM YOU THE RATIONALE BEHIND YOUR CONCLUSION.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPIES WITH ENCLOSURES TO:

CONGRESSMAN PETER J. VISCLOSKY, INDIANA
JACK WHITESCARVER, Ph.D., DEPUTY DIRECTOR, OFFICE OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH

AND _____

The Albany Medical College
Albany New York 12208

DEPARTMENT OF PHARMACOLOGY & TOXICOLOGY
THE NEIL HELLMAN MEDICAL RESEARCH BUILDING, A-136
(518) 445-5303
FAX (518) 445-5799

Mr. John S. Roberts
POB H
Hobart , IN 46342

16 April, 1993

Dear Mr. Roberts,

I received a package of correspondence from and to you relative to acetaldehyde and HIV today. I am really not sure why it was sent to me as I am not an AIDS researcher, my area of expertise lies in Toxicology, specifically alcohol. From your correspondence it appears that you have developed the hypothesis that acetaldehyde may be a useful adjunct to therapy for HIV infected individuals. It appears that this hypothesis has generally been dismissed by the NIH, specifically by Dr. John Bader..

From my perspective I would like to add a degree of caution to your continued efforts. Acetaldehyde, a highly toxic intermediate of alcohol metabolism, could in fact cause damage to viruses, However, the danger lies in the specificity of the toxicity. The therapeutic drugs which are being developed (such as AZT, DDC, etc.) rely on the principal of selective (or specific) toxicity, they cause death or damage to the infectious agent or diseased cell at doses which do not significantly affect normal function. A chemical that kills the patient while it kills the virus or cancer is not a useful drug. In the case of acetaldehyde, as you so rightly pointed out, it is toxic (and severely so) to a wide variety of human organ systems at exceedingly low dose levels. We believe it may also target the T-cells of the immune system and produce a lessening of their function, something which would be very dangerous in an HIV infected human. I do not dismiss your hypothesis, only add a note of caution to your quest.

It is important to remember that the more we learn about the basic biology of a disease process, the more likely we are to find a cure. I would urge you to continue your efforts, particularly with members of congress, to increase funding for medical research generally since, as amply illustrated by your letters, we cannot determine from where the next advance will come (perhaps the cure for AIDS will be found by research on the genetics of the fruit fly!!).

If I may be of any assistance to you please do not hesitate to write.

Sincerely,

Russell F. Mankes, Ph.D.
Associate Professor

JANUARY 1, 1996

AIDS - CAN DEATH BE DELAYED? - PERHAPS

BY
JOHN S. ROBERTS

*ADVERTISEMENT REVISION, 1/11/96:

TO: _____

_____

_____

AIDS
THE AIDS VIRUS, HIV,
CAN BE CRIPPLED BY THE
CHEMICAL, ACETALDEHYDE.
IS A LONGER LIFE POSSIBLE?
CAN DEATH BE DELAYED?
- PERHAPS -

I AM GOING TO ASSUME THAT WHOEVER READS THIS FILE IS CONCERNED ABOUT THE PROBLEM OF AIDS.

IT IS MY HOPE THAT THE MEDIA WILL PROMOTE THE FOLLOWING ADVERTISEMENT FREE OF CHARGE AS A PUBLIC SERVICE FOR AN INDETERMINATE PERIOD OF TIME:

~~AIDS - CAN DEATH BE DELAYED?~~
~~- PERHAPS -~~
MAIL $5.00 TO ROBERTS, P.O. BOX H,
HOBART, IN 46342 TO OBTAIN 35 PAGES
OF MEDICAL RESEARCH

P.S. ~~ANY PROFIT WOULD BE DONATED TO CRIA (COMMUNITY RESEARCH INITIATIVE ON AIDS) OF NEW YORK CITY.~~

ON PAGE 17 OF THEIR BOOK, AGAINST THE ODDS; THE STORY OF AIDS DRUG DEVELOPMENT, POLITICS & PROFITS, THE AUTHORS PETER S. ARNO, Ph.D., AND KARYN L. FEIDEN MAKE THIS STATEMENT:

> "BETWEEN 1987 AND 1991 THE NATIONAL CANCER INSTITUTE TESTED 40,000 CHEMICAL COMPOUNDS AT FACILITIES IN FREDERICK, MARYLAND, AND BIRMINGHAM, ALABAMA, TO SEE IF ANY COULD DISABLE THE AIDS VIRUS. DESPITE THE ODDS AGAINST FINDING A BREAKTHROUGH DRUG, RESEARCHERS CONTINUE TO SCREEN FOR COMPOUNDS THAT CAN INHIBIT HIV AT EACH STEP IN THE INFECTION PROCESS: WHEN IT BINDS TO THE CD4 MOLECULE; WHEN IT PENETRATES THE HELPER T CELL; WHEN IT TRANSCRIBES ITS GENETIC CODE INSIDE; AND WHEN IT REPLICATES. A MORE PROMISING DIRECTION FOR FUTURE RESEARCH IS TARGETED DRUG DEVELOPMENT - THAT IS, DESIGNING AN EFFECTIVE DRUG ON THE KNOWN BIOLOGICAL STRUCTURE OF HIV."

ON JANUARY 1, 1993 I BECAME AWARE OF THE TOXIC CHEMICAL COMPOUND KNOWN AS

"ACETALDEHYDE".

P.S. On 9/11/96 CRIA Requested this deletion.

PAGE 2

ON JANUARY 11, 1993 I WROTE A LETTER IN WHICH I ASKED THIS QUESTION OF DR. LUC MONTAGNIER, THE DISCOVERER OF THE VIRUS WHICH CAUSES AIDS - HIV:

> "HAS ANY RESEARCH EVER BEEN CONDUCTED TO SEE WHETHER ACETALDEHYDE MIGHT BE EFFECTIVE IN DESTROYING THE AIDS VIRUS?"

I MAILED A COPY OF THIS LETTER TO DR. JOHN P. BADER OF THE NATIONAL INSTITUTES OF HEALTH AND RANDY SHILTS (RECENTLY DECEASED, A VICTIM OF AIDS) OF THE SAN FRANCISCO CHRONICLE AND THE AUTHOR OF AND THE BAND PLAYED ON, A BOOK ABOUT THE DEVELOPMENT OF THE AIDS EPIDEMIC.

ON JANUARY 19, 1993 I WROTE A LETTER TO CONGRESSMAN PETER J. VISCLOSKY OF INDIANA IN WHICH I MADE THESE UNDER-LINED STATEMENTS:

> "THE HUMAN BODY CAN BE POISONED WITH A HIGHLY TOXIC SUBSTANCE AND STILL SURVIVE AND THE NAME OF THAT SUBSTANCE IS ACETALDEHYDE."
>
> "IT IS MY HYPOTHESIS THAT WHILE ACETALDEHYDE IS POISONING THE BODY, IT WILL AT THE SAME TIME DESTROY THE AIDS VIRUS."

I MAILED COPIES OF THIS LETTER TO DR. MONTAGNIER, DR. BADER AND RANDY SHILTS. ON JANUARY 26, 1993 DR. BADER WROTE TO ME A LETTER IN WHICH HE STATED:

> "THE MOLECULES YOU SUGGEST ARE NORMAL METABOLITES FORMED DURING NORMAL BODY FUNCTIONING, AND WOULD HAVE NO EFFECT ON HIV OR AIDS."

THROUGHOUT 1993 OTHER SCIENTISTS AT THE NATIONAL INSTITUTES OF HEALTH MAINTAINED THIS POSITION.

ON DECEMBER 13, 1994 DON LUCKETT, A PROGRAM ANALYST WITH THE NATIONAL INSTITUTES OF HEALTH, WROTE TO ME A LETTER IN WHICH HE STATED:

> "THE KNOWN TOXICITY OF ACETALDEHYDE WOULD HAVE LIKELY PREVENTED EVALUATION EVEN IF THE AGENT HAD SHOWN ANTI-HIV ACTIVITY IN THE DRUG SCREEN PROGRAM SPONSORED BY THE NATIONAL CANCER INSTITUTE."

ON FEBRUARY 1, 1995 AN "INFORMATION SPECIALIST" OF THE CENTERS FOR DISEASE CONTROL WROTE TO ME A LETTER IN WHICH THIS STATEMENT IS MADE; THE PARENTHESIS IS MINE:

> "ALL THE ALDEHYDES ARE CAPABLE OF INACTIVATING HIV (IN THE TEST TUBE); HOWEVER, THEIR ACTUAL EFFECTIVENESS DEPENDS ON THE CONCENTRATION USED."

ON AUGUST 9, 1995 DR. JACK WHITESCARVER WROTE A LETTER TO CONGRESSMAN VISCLOSKY IN WHICH HE STATED THE LATEST POSITION OF THE NATIONAL INSTITUTES OF HEALTH RELATIVE TO ACETALDEHYDE:

> "THE FACT THAT ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS DOES NOT NECESSARILY MAKE IT A GOOD CANDIDATE FOR ANTI-HIV THERAPY IN HUMANS."

DR. WHITESCARVER'S COMPLETE LETTER IS INCLUDED IN THIS FILE.

MY KNOWLEDGE OF BIOLOGY IS MINIMAL; I BARELY KNOW THE DIFFERENCE BETWEEN A GENE AND A CHROMOSOME; HOWEVER, I AM GOING TO ASSUME THAT THE WORDS "DESTROY" AND "INACTIVATE" ARE ALMOST SYNONYMOUS.

OTHER THAN THE DIFFERENCE OF OPINION I HAD WITH THE NATIONAL INSTITUTES OF HEALTH IN 1993 REGARDING THE NATURE OF ACETALDEHYDE, NO ONE TO WHOM I HAVE MAILED MY RESEARCH (SEE PAGE30) HAS WRITTEN OR CALLED TO TELL ME THAT I HAVE MADE ANY MIS-STATEMENTS OF SCIENTIFIC OR MEDICAL FACT.

ON DECEMBER 21, 1995 I WENT TO THE LIBRARY AT THE INDIANA UNIVERSITY SCHOOL OF MEDICINE, NORTHWEST CAMPUS, GARY. I WANTED TO SEE WHAT REFERENCES MIGHT BE PULLED UP ON THE COMPUTER RELATIVE TO "DISULFIRAM" AND HIV OR AIDS. THE "AIDSLINE DATA BASE" OF THE NATIONAL LIBRARY OF MEDICINE WAS UTILIZED; THE LIBRARIAN KINDLY HELPED ME OUT.

THE PRINTER WHIPPED OUT A FEW ABSTRACTS; UNFORTUNATELY, THE WORDS, "KEYSTONE CONFERENCE" WERE NOT MENTIONED IN ANY OF THEM; HOWEVER, THE PRINT-OUT DID REVEAL THAT A BOOK ENTITLED:

> DISULFIRAM AND ITS METABOLITE DIETHYLDITHIOCARBAMATE: PHARMACOLOGY AND STATUS IN THE TREATMENT OF ALCOHOLISM, HIV INFECTIONS, AIDS AND HEAVY METAL TOXICITY. 1st ed.
> BY P.K. GESSNER AND T. GESSNER, CHAPMAN & HALL PUBLISHERS, 1992
> LONDON AND NEW YORK, 452 PAGES

HAS BEEN WRITTEN.

AS I LEFT THE LIBRARY AND STARTED TO DRIVE HOME, SOMEWHAT DISAPPOINTED, I THOUGHT OF SOMETHING ELSE WHICH I WANTED TO FIND OUT FROM THE COMPUTER. I DROVE AROUND THE BLOCK, PARKED THE CAR AND WENT BACK INTO THE LIBRARY. THE LIBRARIAN WAS ABOUT TO LEAVE FOR THE DAY, BUT AGAIN SHE KINDLY HELPED ME OUT.

THIS TIME I REQUESTED THAT SHE ENTER THE WORDS "ACETALDEHYDE" AND HIV OR AIDS.

AGAIN, THE PRINTER WHIPPED OUT THE ABSTRACTS.

ON THE FOLLOWING PAGE I HAVE INCLUDED TWO OF THEM. I DID NOT REALIZE THEIR SIGNIFICANCE UNTIL I RE-READ THEM A FEW TIMES; THE UNDER-LINING IS MINE. I AM INDEBTED TO THESE JAPANESE RESEARCHERS - A. TASHIRO, S. SHOJI AND Y. KUBOTA.

ACETOALDEHYDE IS THE SAME THING AS ACETALDEHYDE.

AFTER YOU READ THESE ABSTRACTS YOU MUST WONDER - HAS ANY CHEMICAL YET BEEN DISCOVERED THAT CAN INACTIVATE HIV AS EFFECTIVELY AS ACETALDEHYDE?

USE WHATEVER WORD YOU WANT - "DESTROY" OR "INACTIVATE" - ACETALDEHYDE WILL DO IT TO THE VIRUS WHICH CAUSES AIDS - HIV.

MIGHT I BE MORE CORRECT AND ACCURATE IF I WERE TO SAY, "HIV CANNOT REPLICATE WHEN ACETALDEHYDE IS PRESENT".

AS I HAVE MENTIONED, THE BOOK, DISULFIRAM AND ITS METABOLITE DIETHYLDITHIOCARBAMATE HAS BEEN WRITTEN AND IS CURRENTLY AVAILABLE. I CALLED A LOCAL BOOKSTORE AND FOUND OUT THAT THE TOTAL PRICE IS $148.00; I WILL TRY TO OBTAIN A COPY OF THIS BOOK THROUGH INTER-LIBRARY LOAN.

I DISLIKE GAMBLING, BUT, I WOULD BE WILLING TO BET THAT THE WORD, "ACETALDEHYDE", IS NEVER MENTIONED ON ANY ONE OF THE 452 PAGES OF THIS BOOK. HOW MUCH TO BET? LET'S SAY $148.00; IF I AM RIGHT, I WILL KEEP THE MONEY; IF I AM WRONG, I WILL DONATE THE $148.00 TO CRIA.

y
PROG:

3
SI - MED/90121218
AU - Tashiro A
AU - Shoji S
AU - Kubota Y
TI - Antimyristoylation of the gag proteins in the human immunodeficiency virus-infected cells with N-myristoyl glycinal diethylacetal resulted in inhibition of virus production.
AB - The gag proteins of human retroviruses such as human immunodeficiency virus (HIV-1) are specifically myristoylated in their amino termini (1, 2, 3). N-myristoyl glycinal diethylacetal (N-Myr-GOA) and other N-Myr-compounds (N-Myr-Gly-GOA, N-Myr-Gly-Gly-GOA and N-Myr-Gly-Gly-Gly-GOA) were newly synthesized and investigated for activity of antimyristoylation of these gag proteins and for influence on viral replication. Of the N-Myr-compounds tested, N-Myr-GOA most severely inhibited the protein myristoylation; N-Myr-Gly-GOA also inhibited it, but moderately. Furthermore, it was observed that N-Myr-GOA at 20 microM caused noticeable inhibition (about 80%) of the production of mature HIV in the HIV-1-infected MT-4 cells. In this system, N-Myr-GOA substantially inhibited more than 90% of the N-myristoylation of p17 gag protein produced in the HIV-1-infected MT-4 cells. These results suggest that the N-myristoylation of p17 gag protein of HIV-1 may be essential in its structural assembly or maturation.
SO - Biochem Biophys Res Commun. 1989 Dec 29;165(3):1145-54.

4
SI - MED/89033966
AU - Shoji S
AU - Tashiro A
AU - Kubota Y
TI - Antimyristoylation of gag proteins in human T-cell leukemia and human immunodeficiency viruses with N-myristoyl glycinal diethylacetal.
AB - N-Myristoyl (N-Myr-) glycinal (aminoacetoaldehyde, GO) diethylacetal (A), which is abbreviated as N-Myr-GOA, and other N-Myr-compounds (N-Myr-Gly-GOA, N-Myr-Gly-Gly-GOA, and N-Myr-Gly-Gly-Gly-GOA) were newly synthesized and then employed for NH2-terminal antimyristoylation of structure proteins in the human T-cell leukemia virus (HTLV-I) and the human immunodeficiency virus (HIV). The protein myristoylation of structure proteins p19gag, of HTLV-I, and p17gag, of HIV, was determined separately, using radiolabeled myristic acid, in vitro. The radiolabeled proteins, after immunoprecipitation with an antiserum to adult T-cell leukemia (ATL) or the anti-p17gag monoclonal antibody of HIV, were identified as p19gag of HTLV-I and p17gag of HIV by fluorography after SDS-polyacrylamide gel electrophoresis (SDS-PAGE). The protein myristoylation was resistant to NH2OH-treatment. Of the N-Myr-compounds tested, N-Myr-GOA remarkably prevented the myristoylation of p19gag and p17gag, but N-Myr-Gly-Gly-GOA and N-Myr-Gly-Gly-Gly-GOA did not.
SO - J Biochem (Tokyo). 1988 May;103(5):747-9.

SS 2 /C?
USER:
stop y
TIME 0:01:44 NLM TIME 16:30:10
. . .

THE ABSTRACTS OF THE RESEARCH OF THESE JAPANESE SCIENTISTS CONTAIN A WORD WHICH I HAVE NEVER HEARD OF BEFORE - MYRISTOYLATION. I HAVE CONSULTED SEVERAL DICTIONARIES BUT HAVE COME UP EMPTY HANDED.

I AM GOING TO MAKE A SURMISE AS TO WHAT THIS WORD MEANS BY EXAMINING ITS DERIVATION.

THE WORLD BOOK DICTIONARY STATES THAT "MYRISTIC" IS "OF OR DERIVED FROM THE NUTMEG." THIS IS TRACED BACK TO MEDIEVAL LATIN IN WHICH "MYRISTICA" MEANS NUTMEG TREE.

A PHOTOGRAPH OF NUTMEGS APPEARS ON THE FOLLOWING PAGE.

ON THE FOLLOWING PAGE IS ALSO A PHOTOGRAPH OF CELL DIVISION. DOESN'T STAGE 3, THE METAPHASE, LOOK LIKE A NUTMEG? I AM GOING TO SURMISE THAT MYRISTOYLATION DESCRIBES THE APPEARANCE OF THE CELL AT THIS STAGE - IT LOOKS LIKE A NUTMEG, AND IT IS READY TO DIVIDE.

AM I RIGHT OR WRONG? IF I AM RIGHT, COULD WE SAY THAT THE SAME DESCRIPTION WOULD APPLY TO A VIRAL BODY WHEN IT IS AT THIS STAGE? THEN, ANYTHING THAT HAD THE POWER OF "ANTIMYRISTOYLATION" WOULD PREVENT A UNIT OF LIFE FROM REACHING THAT STAGE OF DEVELOPMENT WHEREIN IT DIVIDED (REPLICATED) ITSELF.

THEN AGAIN, I COULD BE ENTIRELY WRONG ABOUT THIS. ANOTHER ABSTRACT I READ SAID THAT MYRISTOYLATION HAS TO DO WITH "LIPID MODIFICATION".

IN ANY EVENT, THESE JAPANESE ABSTRACTS TELL US THAT ACETALDEHYDE IS PART OF A COMPOUND, ABBREVIATED (N-MYR-GOA), THAT "REMARKABLY PREVENTED" MYRISTOYLATION WITH THE RESULT THAT "VIRAL REPLICATION" WAS "SEVERELY INHIBITED".

IN OTHER WORDS, HIV, WHICH IS THE VIRUS WHICH IS THE ROOT CAUSE OF AIDS, CANNOT BEGIN TO MULTIPLY AS LONG AS A CERTAIN COMPOUND CONTAINING ACETALDEHYDE IS PRESENT.

THERE IS ONLY ONE PROBLEM WITH ACETALDEHYDE - IT IS A POISON CAPABLE OF CAUSING DEATH.

AS DR. WHITESCARVER STATED IN HIS LETTER:

> "THE HIGH TOXICITY OF ACETALDEHYDE MAKES IT A SIGNIFICANTLY LESS DESIRABLE CANDIDATE FOR USE IN INDIVIDUALS WHO SUFFER FROM SEVERELY WEAKENED IMMUNE SYSTEMS AND WHO ARE PRONE TO CONTRACTING NUMEROUS OPPORTUNISTIC INFECTIONS AND MALIGNANCIES."

WHAT IF THE DEADLY NATURE OF ACETALDEHYDE COULD SOMEHOW BE NULLIFIED? I THINK THE MEANS IS AT HAND - I HAVE LABELLED IT "THE SPRINCE RATIO". PLEASE REFER TO PAGE 34.

I WISH TO ASK A SIMPLE QUESTION - WHY DIDN'T ALL OF THOSE 30 RATS DIE AFTER BEING POISONED WITH A LETHAL DOSE OF ACETALDEHYDE? (I AM SPECIFICALLY REFERRING TO "TABLE 2", COMBINATION GROUP "CB3") OR PERHAPS THE BETTER QUESTION TO ASK IS - HOW WERE ALL THOSE 30 RATS ABLE TO LIVE AFTER BEING POISONED WITH A LETHAL DOSE OF ACETALDEHYDE?

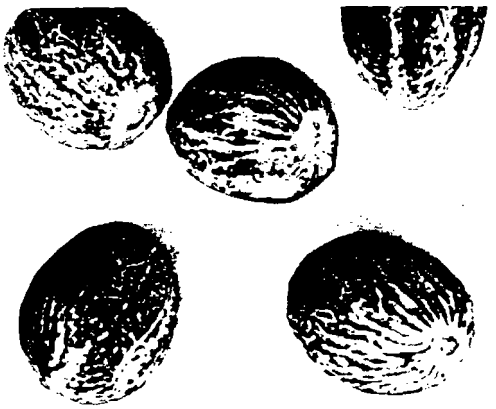
I THINK THE ANSWER SOMEHOW INVOLVES ASCORBIC ACID (VITAMIN C), CYSTEINE AND THIAMIN; I THINK THE ANSWER ALSO INVOLVES "ACETYL COENZYME A" - SEE PAGE 7.

SPRINCE'S RESEARCH, "PROTECTIVE ACTION OF ASCORBIC ACID (VITAMIN C - j.s.r.) AND SULFUR COMPOUNDS AGAINST ACETALDEHYDE TOXICITY: IMPLICATIONS IN ALCOHOLISM AND SMOKING", STATES:

A. "CURRENTLY, THE PHYSICIANS' DESK REFERENCE OF 1974 RECOMMENDS A HIGH DOSE OF ASCORBIC ACID (1g) FOR MANAGEMENT OF THE SEVERE EFFECTS OF THE DISULFIRAM-ETHANOL REACTION." p.168
   (THIS REACTION IS CAUSED BY UNMETABOLIZED ACETALDEHYDE; IN 1995 THE RECOMMENDATION IS STILL 1g - j.s.r.)

PAGE 6

NUTMEG is the kernel of a tropical fruit, which is widely used as a spice. When the fruit is ripe it looks like a golden-yellow pear hanging among shiny, gray-green leaves. The tree grows to be as much as 70 feet high and is an evergreen. The trees originally grew in the Molucca (Spice) Islands, but they have been successfully raised in all of the East Indies, the West Indies,



J. R. Watkins Co.

Kernels of Nutmeg provide the spice used in cooking. A membrane covering the kernel provides mace, another spice.

Brazil, Ceylon, and India. Nutmeg trees have long, pointed leaves with well-marked veins. The pale-yellow flowers droop in clusters, and look like lilies of the valley.

As the fruit ripens, the fleshy part becomes rather hard, somewhat like candied fruit. It finally splits open at the top, showing a bright-scarlet membrane, which partly covers the nut. The spice called *mace* comes from this membrane. The kernels are the familiar household nutmegs.

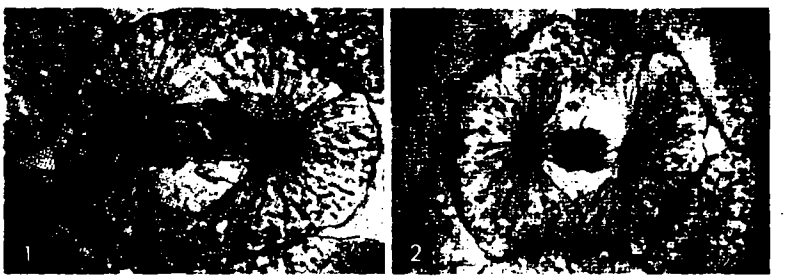
Nutmeg trees do not begin bearing until they are about nine years old. Each tree produces from 1,500 to 2,000 nuts yearly. The fleshy part of the fruit is often preserved and eaten like candy. A clear oil, called *oil of mace*, is made from the kernel.

Scientific Classification. Nutmeg trees belong to the nutmeg family, *Myristicaceae*. They are genus *Myristica*, species *M. fragrans*.

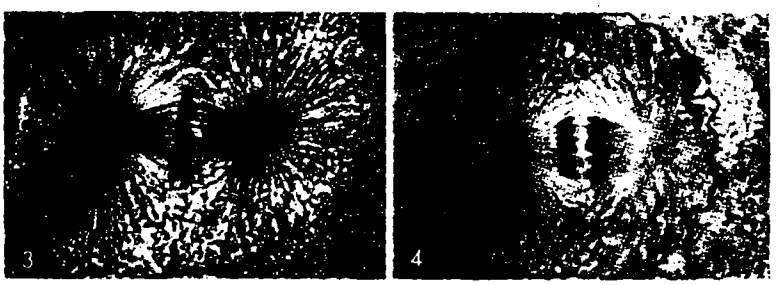
HAROLD NORMAN MOLDENKE

See also MACE.

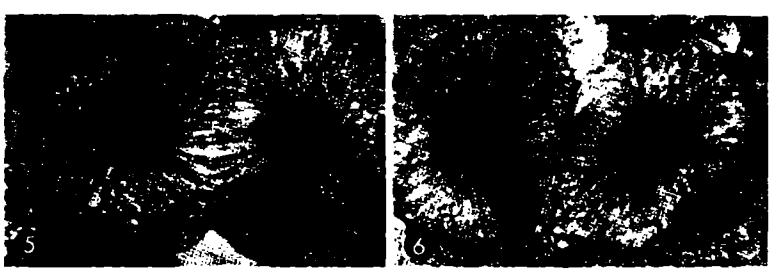
TRAIT TRANSMISSION IN THE DIVISION OF BODY CELLS



First, strands of deoxyribonucleic acid (DNA), which carry genetic "messages" and appear as granular chromatin, thicken, shorten, and duplicate themselves. Centrioles and asters take up positions at opposite ends of the cell, or poles. 1. As the beginning stage, or prophase, continues, the DNA strands and associated nucleoproteins form visible chromosomes. 2. At the end of the prophase, the chromosomes are linked to the poles by a football-shaped series of fibers called the spindle.



These micrographs show the first steps in cell division. 3. In the metaphase, the chromosomes form a flat plate, here seen edgewise. It lies at the middle of the spindle, whose fibers now are clearly visible. The original chromosomes and their duplicates lie along the plane. 4. In the anaphase, the two sets of chromosomes are pulled apart by the spindle fibers, allowing one set of chromosomes to go into each cell.

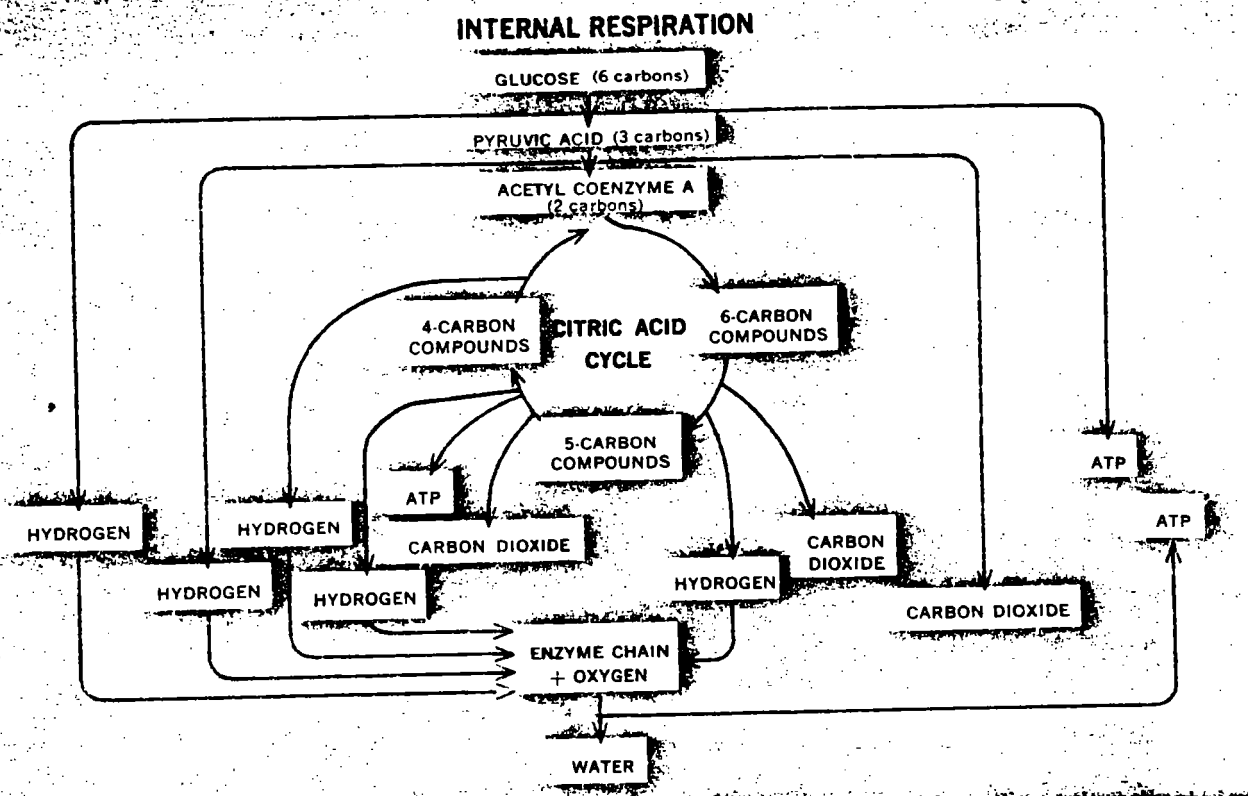


Cell division is completed in the telophase. 5. The two sets of chromosomes are drawn to their respective poles, and the spindle begins to disappear. The cell membrane pinches at mid-cell. 6. The membrane has pinched so far that the cell will soon be divided, and the chromosomes are starting to spread and thin.

THE WORLD BOOK ENCYCLOPEDIA
VOLUME 14, PAGE 465
1973 EDITION

COMPTON'S ENCYCLOPEDIA
VOLUME 11, PAGE 43d
1975 EDITION

THIS DIAGRAM WAS TAKEN FROM THE MERIT STUDENTS ENGYCLOPEDIA,
VOLUME 15, PAGE 592, 1990 EDITION



"AN ADULT MAN, FOR EXAMPLE, IS COMPOSED OF MORE THAN 100 TRILLION DIFFERENT CELLS."
MERIT STUDENTS ENCYCLOPEDIA, VOLUME 4, PAGE 278, 1990 EDITION

"INTERNAL RESPIRATION OCCURS INSIDE EVERY LIVING CELL. IT CONSISTS OF A SERIES OF CHEMICAL REACTIONS IN WHICH THE ENERGY IN FOOD MOLECULES IS RELEASED A STEP AT A TIME."
MERIT STUDENTS ENCYCLOPEDIA, VOLUME 15, PAGE 592, 1990 EDITION

THE FORMULA FOR ACETALDEHYDE IS CH_3CHO. IT CONTAINS TWO CARBON ATOMS.

"ACETYL COENZYME A (Co A), ACETYL DERIVATIVE OF COENZYME A, A SULFUR-CONTAINING NUCLEOTIDE, THAT IS A PRECURSOR IN THE METABOLISM OF FATTY ACIDS, CARBOHYDRATES, AND PROTEINS, BEING AN IMPORTANT INTERMEDIATE IN THE KREBS' CYCLE. COENZYME A FUNCTIONS AS A CARRIER OF THE 2-CARBON ACETYL GROUP, WHICH IS ATTACHED TO THE SULFUR GROUP."
THE RANDOM HOUSE ENCYCLOPEDIA, PAGE 1880, 1977

N-ACETYL CYSTEINE IS A MORE STABLE FORM OF THE SULFUR AMINO ACID L-CYSTEINE, AND IS A POWERFUL ANTIOXIDANT. IT IS AN EXCELLENT PRECURSOR OF GLUTATHIONE, ANOTHER MAJOR ANTIOXIDANT. GLUTATHIONE IS ALSO THE PRECURSOR, WITH SELENIUM, OF GLUTATHIONE PEROXIDASE, ONE OF THE MOST IMPORTANT ANTIOXIDANT ENZYMES IN THE BODY.

PAGE 8

B. "BIOCHEMICALLY, IT HAS ALREADY BEEN SUGGESTED THAT CYSTEINE CAN PROTECT COENZYME A AGAINST ACETALDEHYDE INHIBITION BY COMPLEXING PREFERENTIALLY WITH ACETALDEHYDE. PRESUMABLY, REDUCED GLUTATHIONE, HOMOCYSTEINE, AND N-ACETYL-CYSTEINE COULD ALSO COMPLEX WITH ACETALDEHYDE BY VIRTUE OF THEIR FREE (-SH) GROUPS." p.168

C. "THIAMIN COULD ALSO SERVE AS A PROTECTANT AGAINST ACETALDEHYDE FOR SOME VERY GOOD REASONS. THUS, AS COCARBOXYLASE (PYROPHOSPHATE) IT IS BELIEVED TO COMPLEX NORMALLY WITH ACETALDEHYDE TO EVENTUALLY FORM ACETYL COENZYME A BY WAY OF THE LIPOIC (THIOCTIC) ACID PATHWAY." p.16

D. "THIS POSSIBILITY IS SUPPORTED BY REPORTS THAT ASCORBIC ACID HAS A THIAMIN-SPARING ACTION IN VIVO WHICH MAY DUE TO THIAMIN DISULFIDE ACTIVATION IN TISSUES BY CYSTEINE." p.169

E. "FINALLY, IT IS IMPORTANT, TOO, TO REMEMBER THAT CYSTEINE BY COMPLEXING WITH ACETALDEHYDE MAY PROTECT THE (-SH) GROUPS OF COENZYME A AND REDUCED LIPOIC ACID, BOTH OF WHICH ARE ASSOCIATED WITH THIAMIN PYROPHOSPHATE ACTIVITY. THUS, COMBINATIONS OF ASCORBIC ACID, CYSTEINE, AND THIAMIN IN CERTAIN RATIOS COULD FUNCTION MORE EFFECTIVELY THAN ANY OF THESE COMPOUNDS ALONE AS PROTECTANTS AGAINST ACETALDEHYDE."P16

AM I CORRECT ABOUT THIS? - THERE SEEMS TO BE SOME SORT OF AN INTRINSIC AND UNIQUE BIOCHEMICAL RELATIONSHIP THAT COULD BE SAID TO EXIST BETWEEN ACETYL-COENZYME A AND ACETALDEHYDE.

ACETALDEHYDE IN COMBINATION WITH ASCORBIC ACID, CYSTEINE AND THIAMIN MIGHT EVENTUALLY BE RECOGNIZED AS THE MOST FELICITOUS, UNIQUE AND USEFUL POISON KNOWN TO MAN.

WHEN YOU READ THIS FILE YOU WILL NOTE THAT I HAVE DESCRIBED TWO PROCEDURES:

"A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV."

"AN INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV."

THREE YEARS AGO I HAD A HUNCH ABOUT ACETALDEHYDE. IT IS MY PRESENT HUNCH THAT THE "INTENSIVE APPLICATION" COULD BE ADMINISTERED SAFELY; THE ONLY SIDE EFFECT MIGHT BE THAT THE PATIENT OR PATIENTS WOULD BECOME A LITTLE BIT SLEEPY.

HOWEVER, IN CASE THE MEDICAL COMMUNITY WOULD STILL CONSIDER THE "INTENSIVE APPLICATION" TOO RISKY TO IMPLEMENT, I WISH THEN TO CONCLUDE BY FOCUSING UPON THE "MILD APPLICATION". ALTHOUGH THEY WOULD NOT BE AS DRAMATIC AS THOSE (WHICH I THINK WOULD BE) ENGENDERED BY THE "INTENSIVE APPLICATION", THERE SHOULD, NEVERTHELESS, BE SOME POSITIVE RESULTS.

FIRST, I AM GOING TO MAKE THREE ASSUMPTIONS -

1. IN AND OF ITSELF, ALONG AS ALCOHOL IS NOT DRUNK, THERE IS NO HARM IN "PLUGGING UP" THE LIVER WITH ANTABUSE.

2. THE PRESENCE OF ANTABUSE IN THE LIVER WOULD NOT HINDER THE EFFECT WHICH MEDICINES MIGHT HAVE IN WARDING OFF THE OPPORTUNISTIC INFECTIONS ENGENDERED BY HIV/AIDS.

3. THERE IS ENOUGH ACETALDEHYDE IN THE FOODS LISTED BY THE "JOURNAL OF APPLIED TOXICOLOGY", OCTOBER, 1991, PAGE 374 TO DO SOME GOOD. TO QUOTE THIS JOURNAL AGAIN:

> 'ACETALDEHYDE HAS BEEN IDENTIFIED IN OAK LEAVES, TOBACCO, APPLES, BROCCOLI, COFFEE, GRAPES, GRAPEFRUIT, ORANGES, LEMONS, ONIONS, PEACHES, PEARS, PINEAPPLES, RASPBERRIES, STRAWBERRIES ANY MANY SPICES. EUROPEAN BEERS HAVE BEEN FOUND TO CONTAIN AS MUCH AS 13.5 mgl(-1). THE ACCEPTABLE DAILY INTAKE RECOMMENDED BY FAO/WHO IS 0.0-2.5 mg kg(-1) BODY WEIGHT.'

THE PATIENT WILL TRY TO INCLUDE AS MANY OF THESE FOODS AS IS PRACTICAL INTO HIS OR HER DIET; THE PATIENT MIGHT BECOME NAUSEOUS FROM TIME TO TIME, BUT THIS IS TO BE EXPECTED. THE UNMETABOIZED ACETALDEHYDE FLOWING IN THE BLOODSTREAM WOULD BE THE CAUSE OF THIS NAUSEA.

WHAT THEN DOES THE "MILD APPLICATION" INVOLVE? THE ANSWER IS SIMPLY THIS - GOOD HEALTH AND NUTRITIONAL HABITS.

IN MY FILE I MENTION THAT CIGARETTE SMOKING SHOULD BE AVOIDED BECAUSE IT DEPLETES THE BODY OF VITAMIN C. I NOW THINK THAT IT IS IMPRACTICAL TO ASK A PERSON TO STOP SMOKING; INSTEAD, I WOULD RECOMMEND THAT HE OR SHE SUPPLEMENT THEIR DIET WITH VITAMIN C TABLETS. HOWEVER, A SMOKER MIGHT HAVE TO BE VERY CAREFUL; REMEMBER THAT THE "JOURNAL OF APPLIED TOXICOLOGY" LISTED TOBACCO AS CONTAINING ACETALDEHYDE, AND TOO MUCH SMOKING, WITH ANTABUSE IN THE LIVER, MIGHT HAVE A SERIOUS SIDE EFFECT UNLESS THE BODY WAS BEING REPLENISHED WITH ASCORBIC ACID (VITAMIN C), CYSTEINE AND THIAMINE.

ORANGE JUICE, OF COURSE, CONTAINS AN ABUNDANT SUPPLY OF VITAMIN C. CYSTEINE AND THIAMINE CAN BE OBTAINED, WITHOUT PRESCRIPTION, FROM ANY HEALTH FOOD STORE.

WITH THE "MILD APPLICATION" THE PATIENT WILL EASILY ACQUIRE VITAMIN C, AND, UPON REFLECTION, I THINK IT WOULD DO NO HARM TO INCLUDE ALSO CYSTEINE AND THIAMINE IN THE DIET; THESE INGREDIENTS ARE, OF COURSE, ABSOLUTELY ESSENTIAL IN THE "INTENSIVE APPLICATION".

IN MY FILE I RECOMMEND THAT ZINC TABLETS BE TAKEN. I HAVE SINCE DISCOVERED THAT CASHEWS ARE RICH IN ZINC.

I THINK A DIETARY DEFICIENCY IN ZINC MIGHT PREDISPOSE A DRINKER TO BECOME AN ALCOHOLIC; SEE PAGE27 OF MY FILE.

HERE ARE TITLES OF THREE ABSTRACTS RELATIVE TO ZINC WHICH I FOUND IN THE "JOURNAL OF CELLULAR BIOCHEMISTRY", SUPPLEMENT 21B, 1995, APRIL 2-23,1995 OF THE KEYSTONE SYMPOSIA ON MOLECULAR & CELLULAR BIOLOGY:

> 'A NOVEL ZINC FINGER PROTEIN LOCALIZED IN DISCRETE NUCLEAR DOMAINS IN DEVELOPING OLIGODENDROCYTES' p.139
>
> 'RETROVIRAL NUCLEOCAPSID PROTEINS WITH CCCC OR CCHH TYPE Zn++FINGERS FUNCTION IN RNA PACKAGING BUT RENDER VIRUS PARTICLES NON-INFECTIOUS' p.190
>
> 'A NEW CLASS OF ANTI-VIRAL DRUGS ATTACK HIGHLY CONSERVED ZINC FINGERS IN RETROVIRAL NUCLEOCAPSID PROTEINS' p.191

IT IS MY HUNCH THAT A DIETARY DEFICIENCY OF ZINC WILL EXACERBATE HIV/AIDS.

PAGE 10

WHEN INTERVIEWED BY DR. PASSWATER ("WHOLE FOODS"/SEPTEMBER, 1995, pp. 50-65) DR. MONTAGNIER, THE DISCOVERER OF HIV, MENTIONED THE FOLLOWING NUTRIENTS ON PAGE 56 - SELENIUM, ZINC, BETA CAROTENE, VITAMINS A, C AND E, ENZYMES SUPEROXIDE DISMUTASE (SOD) AND CATALASE, AND PROTEINS SUCH AS METALLOTHIONINE.

ON PAGE 56 DR. PASSWATER ALSO ASKED THIS QUESTION OF DR. MONTAGNIER:

"WHAT SORTS OF INVESTIGATIONS HAVE BEEN MADE WITH NAC (N-ACETYL CYSTEINE j.s.r. OR OTHER ANTIOXIDANTS SUCH AS LIPOIC ACID AND CURCUMIN AS POSSIBLE MEDIATORS OF THE PROGRESSION TO AIDS?"

TO WHICH DR. MONTAGNIER REPLIED:

"WE STARTED SOME OPEN TRIALS WITH NAC FOLLOWING THE WORK OF THE HERZENBERGS AT STANFORD AND THAT OF DROGE IN GERMANY. IN HIV INFECTED PATIENTS, THE GLUTATHIONE SYSTEM IS DEPRESSED EVEN AT EARLY STAGES. THE RATIONALE IS TO RESTORE THE OXIDATIVE PROTECTION SYSTEM BACK TO NORMAL.

"WHEN WE TREAT PATIENTS FOR LESS THAN SIX MONTHS WITH NAC, WE DON'T SEE MUCH CHANGE. HOWEVER, WHEN THE NAC TREATMENT IS LONGER THAN SIX MONTHS, NAC WILL RESTORE APOPTOSIS (DEVELOPMENTAL OR PROGRAMMED CELL DEATH - j.s.r.) BACK TO NORMAL LEVELS. THIS IS A PRELIMINARY RESULT, AND WE WILL REPEAT THE STUDY IN OUR NEW APPLIED RESEARCH LABORATORY. WE PLAN TO OPEN A NEW RESEARCH CENTER AT THE END OF THIS YEAR FOR HIV ASYMPTOMATIC PATIENTS; THERE WE WILL FOLLOW A BATTERY OF LABORATORY MARKERS AND TREAT PATIENTS ACCORDINGLY.

"I AM CONVINCED THAT OXIDATIVE STRESS IS INDEED INVOLVED IN THE PROGRESSION FROM HIV INFECTION TO THE AIDS STAGE. I BELIEVE, THEREFORE, THAT ANTIOXIDANTS ARE NECESSARY IN THE TREATMENT. BUT ANTIOXIDANTS ARE NOT SUFFICIENT BY THEMSELVES."

I WOULD LIKE TO CONCLUDE MY RESEARCH BY SUGGESTING THAT ANTIOXIDANTS AND UNMETABOLIZED ACETALDEHYDE MIGHT BE OF SOME CONSIDERABLE BENEFIT TOWARD RESTORING HIV/AIDS PATIENTS TO A MODICUM OF GOOD HEALTH.

THERE IS NO DOUBT IN MY MIND, WHATSOEVER, THAT ACETALDEHYE, IN COMBINATION WITH ASCORBIC ACID, CYSTEINE AND THIAMINE WILL EVENTUALLY BE SHOWN TO BE THE MOST USEFUL POISON EVER DEVISED BY NATURE FOR THE BENEFIT OF MANKIND.

John S. Roberts

NOVEMBER 18, 1995

MR. RICK LOFTUS, RESEARCH ASSOCIATE
CRIA
COMMUNITY RESEARCH INITIATIVE ON AIDS
275 SEVENTH AVENUE
NEW YORK, NY 10001-6708

DEAR MR. LOFTUS,

RECENTLY I HAD ACCESS TO "THE INTERNET". I CAN'T QUITE REMEMBER WHAT I EXACTLY TYPED IN, BUT I THINK IT WAS A COMBINATION OF "KEYSTONE", "AIDS" AND/OR "HIV". EVENTUALLY I BECAME AWARE OF THE NAME, "ANNE DE GROOT".

I CALLED HER, AND SHE GAVE ME THE NAME OF "L.E. HENDERSON" OF FREDERICK, MARYLAND; SHE SPECIFICALLY MENTIONED ABSTRACT D4-127 OF THE "JOURNAL OF CELLULAR BIOCHEMISTRY", SUPPLEMENT 21B, 1995.

SHE ALSO GAVE ME THE ADDRESS AND TELEPHONE NUMBER OF THE KEYSTONE SYMPOSIA IN SILVERTHORNE, COLORADO.

I CALLED DR. LOUIS E. HENDERSON AND DR. JIM BENNETT, DIRECTOR OF THE KEYSTONE SYMPOSIA, AND NEITHER ONE OF THEM IS AWARE OF DISULFIRAM (ANTABUSE) BEING USED IN THE TREATMENT OF HIV/AIDS.

DR. HENDERSON'S ABSTRACT, PAGE 191 IS ENTITLED:

> "A NEW CLASS OF ANTI-VIRAL DRUGS ATTACK HIGHLY CONSERVED ZINC FINGERS IN RETROVIRAL NUCLEOCAPSID PROTEINS".

I DON'T KNOW WHETHER THIS HAS ANY RELEVANCE, BUT IN MY OWN RESEARCH I POINTED OUT THE FACT THAT ZINC WAS AN ESSENTIAL COMPONENT IN THE DIET OF ANYONE WHO DRANK ALCOHOL -

> "AS ABSORBED ALCOHOL IS PASSED THROUGH THE LIVER BY THE CIRCULATING BLOOD, IT IS ACTED UPON BY ADH (ALCOHOL DEHYDROGENASE), A ZINC-CONTAINING ENZYME FOUND CHIEFLY IN THE LIVER CELLS....."
>
> ENCYCLOPAEDIA BRITANNICA, MACROPAEDIA, VOLUME 1, PAGE 438, 1974 EDITION

COULD A DIETARY DEFICIENCY OF ZINC EXACERBATE HIV/AIDS?

MR. LOFTUS, AT THIS POINT IN TIME I AM INTRIGUED AS TO THE SOURCE OF YOUR INFORMATION -

> ".....PRESENTATIONS ON DISULFIRAM ATTRACTED MUCH ATTENTION....."

SOON, I AM GOING TO FORWARD TO MS. PATRICIA S. FLEMING AND OTHERS AN UPDATE TO MY RESEARCH. IF I HAD SPECIFIC DATA FROM YOU IT WOULD BE MOST HELPFUL.

UNLESS I HEAR DIFFERENTLY FROM YOU I AM GOING TO ASSUME THAT THE "PRESENTATIONS ON DISULFIRAM" DELINEATED POSITIVE RESULTS SIMILAR TO THOSE

FOUND IN THE LANG STUDY ("THE LANCET", SEPTEMBER 24, 1988, PAGES 702-706); IN THIS CLINICAL TRIAL, LANG EMPLOYED A CHEMICAL "COUSIN" OF DISULFIRAM (ANTABUSE) - DITIOCARB; TO SUMMARIZE LANG'S FINDINGS:

1. 42% OF THE DITIOCARB RECIPIENTS SHOWED IMPROVEMENT IN THEIR CLINICAL STATUS AS COMPARED TO 5% IN THE PLACEBO GROUP.
2. THE CD4+ CELL COUNT INCREASED IN SOME OF THE PATIENTS.
3. ENLARGED SPLEEN AND LYMPH NODES SHRANK IN SOME OF THE PATIENTS.
4. DIARRHEA DISAPPEARED IN SOME OF THE PATIENTS.
5. SOME OF THE PATIENTS REGAINED WEIGHT.
6. PERSISTENT FEVERS DISAPPEARED IN SOME OF THE PATIENTS.

IF I AM CORRECT ABOUT MY ASSUMPTION THAT THE "PRESENTATIONS ON DISULFIRAM" DID INDEED LIST POSITIVE RESULTS, THIS THEN JUST MIGHT BE A TANGENTIAL CORROBORATION OF A HYPOTHESIS WHICH I PROPOSED TO CONGRESSMAN PETER J. VISCLOSKY OF INDIANA IN A LETTER DATED JANUARY 19, 1993; IN THAT LETTER I STATED:

"THE HUMAN BODY CAN BE POISONED WITH A HIGHLY TOXIC SUBSTANCE AND STILL SURVIVE AND THE NAME OF THAT SUBSTANCE IS ACETALDEHYDE."

"IT IS MY HYPOTHESIS THAT WHILE ACETALDEHYDE IS POISONING THE BODY, IT WILL AT THE SAME TIME DESTROY THE AIDS VIRUS."

SINCE 1993 I HAVE BECOME AWARE THAT THE CORRECT BIOLOGICAL TERM IS "INACTIVATE" NOT "DESTROY" WHEN REFERRING TO A VIRUS.

BOTH THE NATIONAL INSTITUTES OF HEALTH AND THE CENTERS FOR DISEASE CONTROL HAVE ACKNOWLEDGED TO ME THAT ACETALDEHYDE CAN INACTIVATE HIV.

IN MY RESEARCH I DESCRIBED TWO PROCEDURES ("INTENSIVE" AND "MILD") WHEREIN I THOUGHT ACETALDEHYDE MIGHT BE SAFELY EMPLOYED TO INACTIVATE HIV.

MY PRESENT GOAL IS TO TRY TO CONVINCE SOMEONE/SOMEWHERE WITH MEDICAL EXPERTISE AND/OR AUTHORITY TO CONDUCT A 16 WEEK CLINICAL TRIAL OF THE "MILD" PROCEDURE; TO RECAPITULATE IT BRIEFLY - IN THIS PROCEDURE THE PATIENT WOULD TAKE ANTABUSE TABLET ONCE A DAY, WOULD REFRAIN FROM DRINKING ALCOHOL, WOULD REFRAIN FROM EATING ANYTHING WITH SUGAR IN IT, WOULD REFRAIN FROM SMOKING CIGARETTES (SMOKING DEPLETES THE BODY OF VITAMIN C), WOULD REFRAIN FROM EATING FOODS WITH FOOD ADDITIVES SUCH AS MSG (MONOSODIUM GLUTAMATE), WOULD TAKE ZINC SUPPLEMENTS AND WOULD MAKE THESE FOODS PART OF HIS OR HER DIET - APPLES, BROCCOLI, GRAPES, GRAPEFRUIT, ORANGES, LEMONS, ONIONS, PEACHES, PEARS, PINEAPPLES, RASPBERRIES AND STRAWBERRIES.

IF MY HYPOTHESIS IS CORRECT, AND SINCE THESE FOODS NATURALLY CONTAIN ACETALDEHYDE, THERE SHOULD BE SOME SLIGHT IMPROVEMENT IN THE PATIENT'S HEALTH AFTER 16 WEEKS OF THIS REGIMEN.

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

COPIES TO:
MS. PATRICIA S. FLEMING, THE WHITE HOUSE
CONGRESSMAN PETER J. VISCLOSKY
PROFESSOR ANNE DE GROOT, M.D., BROWN UNIVERSITY
LOUIS E. HENDERSON, Ph.D., FREDERICK CANCER RESEARCH DEVELOPMENT CENTER
JAMES BENNETT, Ph.D., DIRECTOR, KEYSTONE SYMPOSIA

THE WHITE HOUSE

WASHINGTON

OCT 18 1995

Mr. John S. Roberts
Post Office Box H
Hobart, IN 46342

Dear Mr. Roberts:

Thank you for your letter of September 18. I appreciate your interest in finding a cure for AIDS. This is a goal we all share most strongly.

It is important to assess any potential avenue of research. In their correspondence with you, the Office of AIDS Research at the National Institutes of Health has expressed its views regarding the potential of your proposed approach. Should any new information develop, I encourage you to share it with the NIH.

Thanks again for your interest.

Sincerely,

Patricia S. Fleming
Director
Office of National AIDS Policy

n:g1926

OCTOBER 1, 1995

MR. RICK LOFTUS, RESEARCH ASSOCIATE
CRIA
COMMUNITY RESEARCH INITIATIVE ON AIDS
275 SEVENTH AVENUE
NEW YORK, NY 10001-6708

DEAR MR. LOFTUS,

THANK YOU FOR YOUR LETTER OF SEPT. 21, 1995 (COPY ATTACHED).

IN MY LETTER WHICH I WRITE TO YOU TODAY I SHALL BE REFERRING TO A SEPTEMBER 4, 1995 LETTER WHICH I MAILED TO CONGRESSMAN PETER J. VISCLOSKY OF INDIANA AND VARIOUS OTHER SCIENTISTS, GOVERNMENT OFFICIALS AND ORGANIZATIONS; IT CONSISTS OF 17 PAGES.

IF PERCHANCE ANY OF THOSE TO WHOM I MAIL A COPY OF THIS LETTER (OCTOBER 1) DID NOT RECEIVE THAT SEPTEMBER 4 LETTER, JUST LET ME KNOW, AND I WILL MAIL TO THEM A COPY OF IT.

IN YOUR LETTER YOU STATE:

> "YOU ARE PROBABLY AWARE THAT PRESENTATIONS ON DISULFIRAM ATTRACTED MUCH ATTENTION DURING THE MOST RECENT KEYSTONE CONFERENCE ON AIDS PATHOGENESIS, THIS PAST SPRING."

I AM NOT AWARE OF THE "KEYSTONE CONFERENCE" AND ITS FINDINGS RELATIVE TO DISULFIRAM (ANTABUSE). WAS THE WORD "ACETALDEHYDE" EVER MENTIONED DURING THIS CONFERENCE? ON PAGE 7 OF MY SEPTEMBER 4 LETTER I STATED:

> "THUS FAR, I HAVE FAILED TO TURN UP ONE INSTANCE IN ANY OF THE PUBLISHED LITERATURE WHEREIN 'ACETALDEHYDE' IS MENTIONED IN THE SAME CONTEXT WITH 'HIV' AND/OR 'AIDS' AND/OR 'DITIOCARB'; ....."

WERE THE PRESENTATIONS AT THE KEYSTONE CONFERENCE PUBLISHED? IF SO, I WOULD BE MOST INTERESTED IN KNOWING THE SOURCE. MR. LOFTUS, ANY HELP WHICH YOU COULD AFFORD ME WOULD BE MUCH APPRECIATED.

IT IS MY PRESENT GOAL TO INTEREST SOMEONE/SOMEWHERE WITH MEDICAL EXPERTISE AND/OR AUTHORITY IN LAKE AND PORTER COUNTY, INDIANA AND COOK COUNTY, ILLINOIS TO INITIATE A CLINICAL TRIAL OF THE PROCEDURE WHICH I CALL ON PAGE 7 OF MY SEPTEMBER 4 LETTER -

> "A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

MY ULTIMATE GOAL, OF COURSE, IS TO HAVE INITIATED A CLINICAL TRIAL OF THE PROCEDURE WHICH I CALL ON PAGE 4 OF MY SEPTEMBER 4 LETTER -

> "AN INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

IF SUCH A TRIAL EVER WOULD PROVE TO BE SUCCESSFUL, I SHALL BE INDEBTED TO PROFESSOR RUSSELL F. MANKES OF THE ALBANY MEDICAL COLLEGE AND RICHARD A. PASSWATER, Ph.D. OF THE SOLGAR NUTRITIONAL RESEARCH CENTER.

A JANUARY 1, 1993 NEWSPAPER ARTICLE, WHICH QUOTED PROFESSOR MANKES, MADE ME AWARE OF ACETALDEHYDE. AND, AS I STATED ON PAGE 4 OF MY SEPTEMBER 4 LETTER:

"AS RICHARD A. PASSWATER, Ph.D., STATED ON PAGE 128 OF HIS BOOK, SUPER-NUTRITION (DIAL PRESS, 1975; POCKET BOOK, 1976):

'A COMBINATION OF CERTAIN SULFUR AMINO ACIDS AND VITAMIN C GAVE 100 PERCENT PROTECTION AGAINST A STANDARD LETHAL DOSE OF ACETALDEHYDE IN LABORATORY RATS.' "

RECENTLY, DR. PASSWATER WAS KIND ENOUGH TO MAIL TO ME A COPY OF AN INTERVIEW HE HAD ON MAY 3, 1995 WITH DR. LUC MONTAGNIER, THE DISCOVERER OF HIV. I HAVE ATTACHED A COPY OF THE FIRST PAGE, AND THE COMPLETE ARTICLE CAN BE FOUND ON PAGES 50-65, "WHOLE FOODS", SEPTEMBER, 1995.

MR. LOFTUS, IN YOUR LETTER YOU STATE:

".....THE USE OF SULFHYDRYL-CONTAINING COMPOUNDS TO INHIBIT HIV IS AN APPROACH THAT IS BEING TAKEN SERIOUSLY BY A NUMBER OF INVESTIGATORS NATIONWIDE."

THIS IS JUST A TANGENTIAL REFERENCE; HOWEVER, I WOULD LIKE TO POINT OUT THAT "THE SPRINCE RATIO", WHICH I MENTION ON PAGE 4 OF MY SEPTEMBER 4 LETTER, INCLUDES TWO SULFUR CONTAINING COMPOUNDS. AGAIN, "THE SPRINCE RATIO":

L-ASCORBIC ACID (VITAMIN C)	2.0
L-CYSTEINE FB (A SULFUR COMPOUND)	1.0
THIAMINE.HCL (A SULFUR COMPOUND)	.3

COULD ALL OF THIS HAVE SOMETHING TO DO WITH THE "INTERNAL RESPIRATION" OF EACH CELL WHICH INVOLVES THE "CITRIC ACID CYCLE" AND "ACETYL COENZYME A"?

"ACETYL COENZYME A (Co A), ACETYL DERIVATIVE OF COENZYME A, A SULFUR-CONTAINING NUCLEOTIDE, THAT IS A PRECURSOR IN THE METABOLISM OF FATTY ACIDS, CARBOHYDRATES, AND PROTEINS, BEING AN IMPORTANT INTERMEDIATE IN THE KREBS' CYCLE. COENZYME A FUNCTIONS AS A CARRIER OF THE 2-CARBON ACETYL GROUP, WHICH IS ATTACHED TO THE SULFUR GROUP." (UNDERLINING MINE)

THE RANDOM HOUSE ENCYCLOPEDIA, PAGE 1880, 1977 EDITION

MR. LOFTUS, THANKS AGAIN FOR YOUR LETTER, AND, NEEDLESS TO SAY, I AM MOST CURIOUS TO KNOW THE FINDINGS OF THE KEYSTONE CONFERENCE REGARDING DISULFIRAM (ANTABUSE).

P.S. PROFESSOR MANKES' REFERENCE TO ACETALDEHYDE HAD TO DO WITH A "HANGOVER". "THE HEADACHE, UPSET STOMACH AND BAD AFTERTASTE THAT ACCOMPANY A HANGOVER COME FROM THE TOXIC BY-PRODUCT OF ALCOHOL, A CHEMICAL CALLED ACETALDEHYDE, SAID RUSSELL MANKES, ASSOCIATE PROFESSOR OF TOXICOLOGY AND PHARMACOLOGY AT THE ALBANY MEDICAL COLLEGE". DR. PASSWATER'S REFERENCE TO ACETALDEHYDE WAS IN THE CONTEXT OF A PARAGRAPH ENTITLED "VITAMIN C DETOXIFIES POISONS".

PAGE 16

YOURS TRULY,

John S. Roberts

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COPIES TO:

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MS. JEANNE WHITE, PRESIDENT, RYAN WHITE MEMORIAL FOUNDATION, NOBLESVILLE, INDIANA
AmFAR, NEW YORK CITY, ATTENTION: JEFFREY LAURENCE, M.D., AND ELIZABETH TAYLOR
PEDIATRIC AIDS FOUNDATION, SANTA MONICA, CALIFORNIA
BERNADINE HEALY, M.D., CLEVELAND CLINIC FOUNDATION
MS. BRENDA LEIN, PROJECT INFORM, SAN FRANCISCO
JOHN S. JAMES, AIDS TREATMENT NEWS, SAN FRANCISCO
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PROFESSOR STEVEN M. WOLINSKY, M.D., DIVISION OF INFECTIOUS DISEASES,
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MRS. JANE SCHROEDER, MERRILLVILLE
MS. JEAN LUBECKIS, LANSING, ILLINOIS
F. RITCHEY EIBEL AND JOHN H. BETJEMANN, THE METHODISTS HOSPITALS, NORTHWEST INDIANA
MRS. JOYCE MORRIS, ACWORTH, GEORGIA
ROBERT ERB, LAKE COUNTY AIDS TASK FORCE, INDIANA
DR. LUC MONTAGNIER, INSTITUT PASTEUR, PARIS

AND _____

Sept. 21, 1995

Mr. John S. Roberts
POB H
Hobart IN 46342

Dear Mr. Roberts,

Thank you for your information regarding disulfiram and acetaldehydes for HIV infection.

As you may know, CRIA is involved in a number of independent clinical trials of potential AIDS treatments for all people with HIV. We are studying salicylic acid derivatives as anti-HIV agents, as well as cyclophosphamide to inhibit HIV-associated B-cell hyperactivity. While ongoing work prevents us from initiating any new trials at the moment, we are always on the lookout for new ideas.

You are probably aware that presentations on disulfiram attracted much attention during the most recent Keystone conference on AIDS pathogenesis, this past spring. While I am not aware of any human trials having sprung from this research--at least not yet-- the use of sulfhydryl-containing compounds to inhibit HIV is an approach that is being taken seriously by a number of investigators nationwide.

Sincerely,

Rick Loftus

Rick Loftus, research associate

Community Research Initiative on AIDS
275 Seventh Avenue, New York, NY 10001-6708 Phone: 212/924-3934 Fax: 212/924-3936

PAGE 18

Antioxidant Nutrients and AIDS: Exploring the Possibilities

An interview with Dr. Luc Montagnier, the discoverer of HIV.

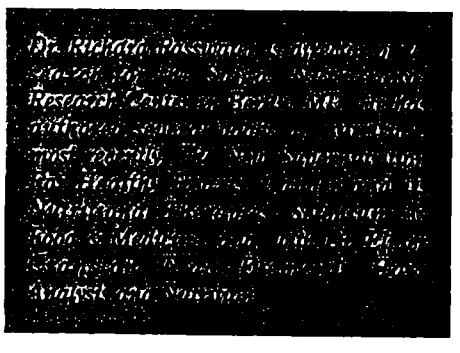
BY RICHARD A. PASSWATER, PH.D.

It doesn't seem like too many years ago that we learned of a dreadful new and mysterious disease that threatened to wipe out mankind. Little was known about this new disease, except that it was spreading rapidly. Some projected that it would be killing us by the millions within a few years and bankrupting our health care system along the way.

Fortunately, this hasn't happened, and a large part of the reason why it has not is due to Dr. Luc Montagnier of the Pasteur Institute in Paris. He and his colleagues discovered the cause of the disease we now call Acquired Immune Deficiency Syndrome (AIDS) and determined how it's transmitted.

AIDS was formally recognized as a new disease on June 5, 1981 when the Centers for Disease Control (CDC) reported that five Los Angeles men had developed an unexplained immune deficiency. It is characterized as the breakdown of the body's immune system due to the decrease of selected cells in the immune system. This decrease results in defects in immune function which then allows "opportunistic" infections that cannot infect people with healthy immune systems to readily infect and soon kill AIDS patients.

During 1980, there were a few reports of certain diseases such as rare cancers and infections leading to quick "wasting" of the patient and rapid death.[1,2] There particularly was an increase in cases of Pneumocystis carinii pneumonia and herpes simplex. This was followed by an increase in the incidence of Kaposi's sarcoma.



The CDC established a task force led by Dr. James Curran to look for other cases, present and past, and to learn what they could about these alarming new reports. At that time, the earliest confirmed case they could find occurred in 1978. As the number of similar reports increased, they were recognized as a common disorder of the immune system in 1981. It was found that these patients had a depletion of certain white blood cells that play a critical role in defending the body against invading organisms. These cells were formerly called T4-helper lymphocytes, but now by international convention are called CD4 lymphocytes. (CD stands for cluster of differentiation markers.) Because immunology knowledge is rapidly expanding and terminology is perplexing and changing, a glossary for the relevant terms used in this discussion is provided on Page 63.

Later investigation has identified several other immune changes, but the depletion of CD4 lymphocytes has been related to AIDS ever since its first description. With the dramatic reduction in the number of CD4 lymphocytes, the ratio of CD4 to CD8 cells changes; this is often used as a marker of the disease progress.

Thanks to the research of Dr. Montagnier and his colleagues, the cause of this mysterious disease which behaved differently from normal viral or bacterial infections, was uncovered relatively quickly in 1983.[3] As a result, most of us don't have to worry about this disease and we don't give much thought to Dr. Montagnier's discovery. As an example, you can receive a blood transfusion today and not have to worry about Human Immune Deficiency Virus (HIV) which is the virus that causes AIDS, being transmitted to you in the blood you receive. The fact that a test had been developed to detect HIV in blood was a comforting thought to me when I needed blood a few years ago.

'I estimate that Dr. Montagnier's discovery has saved more than two million lives worldwide and about 400,000 in America.'

Even those who are at high risk owe a huge "thank you" to Dr. Montagnier because his discovery of both HIV-1 and HIV-2 strains of the virus has led to protective preventive measures.

HIV is an unusual virus. It is a retrovirus which means that it reverses the normal pattern of replication. Its genetic material contains only RNA instead of DNA. Retroviruses depend on an enzyme called reverse transcriptase to use the genetic material in the white blood cells that they infect to make the proteins needed for the virus to survive. In essence, the HIV turns the

DATE: _____

TO: _____

_____

_____

ATTENTION: ANYONE WHO MIGHT BE CONCERNED ABOUT AIDS

I WANT TO MAKE YOU AWARE OF MY RESEARCH PERTAINING TO HIV/AIDS (SEE ATTACHED).

MY CURRENT GOAL IS TO CONVINCE SOMEONE/SOMEWHERE WITH MEDICAL EXPERTISE AND/OR AUTHORITY TO INITIATE A CLINICAL TRIAL THAT WOULD USE THE CHEMICAL KNOWN AS "ANTABUSE".

THE PURPOSE OF SUCH A TRIAL WOULD BE TO SEE IF THE SUFFERING OF CHILDREN AFFLICTED WITH AIDS COULD BE ALLEVIATED BY UTILIZING A PROCEDURE THAT I CALL:

"A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

MY KNOWLEDGE OF BIOLOGY AND DISEASES IS MINIMAL; HOWEVER, I AM GOING TO ASSUME THAT THE SYMPTOMS OF HIV/AIDS INFECTION WHICH APPEAR IN CHILDREN WOULD BE SIMILAR TO THOSE APPEARING IN ADULTS.

THE SYMPTOMS OF WHICH I SPEAK ARE:

1. ENLARGED SPLEEN AND LYMPH NODES
2. DIARRHEA
3. WEIGHT LOSS
4. PERSISTENT FEVER

IF MY THINKING IS CORRECT, A SLIGHT DIMINUTION OF THESE SYMPTOMS SHOULD APPEAR DURING THE COURSE OF THE TRIAL (16 WEEKS).

IN ADDITION, THERE MIGHT BE A SLIGHT INCREASE IN THE CD4-POSITIVE LYMPHOCYTES (T-HELPER CELLS).

JOHN S. ROBERTS
POST OFFICE BOX H
HOBART, INDIANA 46342
219-763-1933

SEPTEMBER 4, 1995

THE HONORABLE PETER J. VISCLOSKY
HOUSE OF REPRESENTATIVES
2464 RAYBURN BUILDING
WASHINGTON, D.C. 20515-1401

DEAR CONGRESSMAN VISCLOSKY,

ATTACHED IS A COPY OF YOUR LETTER TO ME DATED AUGUST 22, 1995.

I AM NOT ASKING YOU TO PROCEED ANY FURTHER ON MY BEHALF.

I WANT TO THANK YOU FOR THE HELP YOU HAVE AFFORDED ME OVER THE PAST 3½ YEARS.

I WRITE THIS LETTER SOLELY FOR THE PURPOSE OF ESTABLISHING IT AS THE MEANS BY WHICH I HOPE TO INFLUENCE SOMEONE/SOMEWHERE WITH MEDICAL EXPERTISE AND/OR AUTHORITY TO INITIATE A CLINICAL TRIAL WHICH WOULD UTILIZE THE CHEMICAL COMMONLY KNOWN AS "ANTABUSE". THE OBJECTIVE OF SUCH A TRIAL WOULD BE TO SEE IF THE INCREASED AMOUNT OF UNMETABOLIZED ACETALDEHYDE IN THE BLOODSTREAM, DUE TO THE PRESENCE OF ANTABUSE IN THE LIVER, WOULD HAVE ANY EFFECT ON INACTIVATING THE VIRUS WHICH CAUSES AIDS - HIV.

BEFORE I PROCEED FURTHER, I AM GOING TO ASSUME THAT SOMEONE MIGHT READ THIS LETTER AND NOT KNOW WHAT ANTABUSE IS AND WHAT IT DOES. I WISH TO OFFER A BRIEF EXPLANATION.

IN ORDER TO QUENCH THE ALCOHOLIC'S CRAVING FOR A DRINK, PHYSICIANS PRESCRIBE ANTABUSE.

IT IS HOPED THAT IF THE ALCOHOLIC KNOWS, IN THE BACK OF HIS MIND, WHAT TERRIBLE CONSEQUENCES WILL ENSUE IF HE TAKES A DRINK, WHILE ANTABUSE IS IN HIS SYSTEM, HE WILL REFRAIN FROM DRINKING - HENCE THE TERM, "AVOIDANCE THERAPY".

HERE IS WHAT COULD HAPPEN IF YOU COMBINE ALCOHOL AND ANTABUSE -

> "DISULFIRAM (ANTABUSE) IS A DRUG TO TREAT ALCOHOLISM. WHEN ALCOHOL IN THE BLOODSTREAM INTERACTS WITH DISULFIRAM, IT CAUSES A FLUSHED FACE, SEVERE HEADACHE, CHEST PAINS, SHORTNESS OF BREATH, NAUSEA, VOMITING, SWEATING AND WEAKNESS. SEVERE REACTIONS MAY CAUSE DEATH....."
>
> PAGE 976, COMPLETE GUIDE TO PRESCRIPTION & NON-PRESCRIPTION DRUGS, H. WINTER GRIFFITH, M.D., THE PUTNAM PUBLISHING GROUP, NEW YORK, 1993

LET'S SUPPOSE THE ALCOHOLIC HAS BEEN TAKING ANTABUSE ON A DAILY BASIS BUT ONE DAY DECIDES -

> "AH, TO HELL WITH IT. I'M GOING TO TAKE A DRINK. I DON'T GIVE A DAMN WHAT ANYONE SAYS OR THINKS."

HE COULD STOP TAKING ANTABUSE, BUT HE WOULD HAVE TO WAIT ABOUT A WEEK BEFORE HE COULD START DRINKING AND NOT BE IN DANGER OF EXPERIENCING "THE ANTABUSE REACTION". IT TAKES THE BODY ABOUT A WEEK'S TIME TO "FLUSH OUT" COMPLETELY ALL OF THE ANTABUSE THAT HAS BEEN SWALLOWED.

SCIENTIFICALLY, I COULD SAY THAT WHEN A PATIENT SWALLOWS ANTABUSE "RAPID INTRACELLULAR PENETRATION" TAKES PLACE IN THE LIVER; IN ADDITION, ANTABUSE HAS A SLOW RATE OF METABOLISM - UP TO SEVEN DAYS.

I AM NOT GOING TO SAY THIS. FROM NOW ON I WILL SAY - WHEN A PERSON SWALLOWS ANTABUSE HE "PLUGS UP" HIS LIVER WITH ANTABUSE. AS I WRITE THIS LETTER I AM NOT AWARE OF ANY ILL EFFECTS WHICH WOULD BE CAUSED BY PLUGGING UP THE LIVER WITH ANTABUSE, OTHER THAN THE FACT THAT ALCOHOL SHOULD BE AVOIDED.

WHAT OCCURS IN THE BODY WHEN ANTABUSE IS IN THE LIVER AND A DRINK IS DRUNK? WHAT CAUSES THE SEVERE REACTION TO ALCOHOL?

ALCOHOL IS BROKEN DOWN (METABOLIZED) IN THE FOLLOWING WAY:

> "AS ABSORBED ALCOHOL IS PASSED THROUGH THE LIVER BY THE CIRCULATING BLOOD, IT IS ACTED UPON BY ADH (ALCOHOL DEHYDROGENASE), A ZINC-CONTAINING ENZYME FOUND CHIEFLY IN THE LIVER CELLS. THE ALCOHOL MOLECULE IS CONVERTED BY THIS ACTION TO ACETALDEHYDE, ITSELF A HIGHLY TOXIC SUBSTANCE, BUT THIS IS IMMEDIATELY ACTED UPON BY ANOTHER ENZYME, ALDEHYDE DEHYDROGENASE, AND CONVERTED TO ACETATE, MOST OF WHICH ENTERS THE BLOODSTREAM AND IS ULTIMATELY OXIDIZED TO CARBON DIOXIDE AND WATER."
>
> PAGE 438, ENCYCLOPAEDIA BRITANNICA, MACROPAEDIA, VOLUME 1, 1974 EDITION

THE "JOURNAL OF APPLIED TOXICOLOGY", OCTOBER, 1991, PAGE 374 STATES THAT "THE HALF-LIFE OF ACETALDEHYDE IN THE BLOOD WAS ESTIMATED AS 3.1 MIN."; THIS FIGURE WAS DERIVED FROM EXPERIMENTS UPON RATS, BUT I AM ASSUMING THAT IT IS NEARLY THE SAME FOR HUMAN BEINGS.

I AM NOT GOING INTO SCIENTIFIC DETAIL, BUT I WILL SAY THAT BY UTILIZING THIS HALF-LIFE FIGURE THE CONCLUSION IS THAT ACETALDEHYDE "A HIGHLY TOXIC SUBSTANCE" IS QUICKLY CHANGED (METABOLIZED) IN THE HUMAN BODY INTO SOMETHING HARMLESS WITHIN ¼ HOUR'S TIME.

WHEN THE LIVER IS PLUGGED UP WITH ANTABUSE, THIS CANNOT HAPPEN. ACETALDEHYDE CANNOT BE QUICKLY CHANGED INTO SOMETHING HARMLESS. IT REMAINS "UNMETABOLIZED" AND FLOWS THROUGH THE BLOODSTREAM AS A TOXIC POISON FOR A PERIOD OF HOURS.

THIS IS WHAT CAUSES THE SEVERE REACTION TO ALCOHOL WHEN ANTABUSE IS PLUGGING UP THE LIVER - A TOXIC POISON, ACETALDEHYDE, IS FLOWING IN THE BLOOD, AND THE BODY IS TRYING TO COPE WITH IT AS BEST AS IT CAN. SOMETIMES FAILURE RESULTS AND DEATH ENSUES.

ATTACHED IS A COPY OF THE AUGUST 9, 1995 LETTER WHICH JACK WHITESCARVER, Ph.D. SENT TO YOU, CONGRESSMAN VISCLOSKY.

BOTH THE CENTERS FOR DISEASE CONTROL AND NATIONAL INSTITUTES OF HEALTH HAVE ACKNOWLEDGED THAT HIV, THE VIRUS WHICH CAUSES AIDS, CAN BE INACTIVATED IN THE TEST TUBE BY ACETALDEHYDE -

> "ALL THE ALDEHYDES ARE CAPABLE OF INACTIVATING HIV; HOWEVER, THEIR ACTUAL EFFECTIVENESS DEPENDS ON THE CONCENTRATION USED."
> CENTERS FOR DISEASE CONTROL LETTER TO ME, DATED FEBRUARY 1,1995
>
> "THE FACT THAT ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS DOES NOT NECESSARILY MAKE IT A GOOD CANDIDATE FOR ANTI-HIV THERAPY IN HUMANS."
> DR. WHITESCARVER'S LETTER

PAGE 22

I AM GOING TO ASSUME THAT THE WORDS "INACTIVATE" AND "DESTROY" ARE ALMOST SYNONYMOUS.

THE KEY QUESTION, OF COURSE, IS:

CAN ACETALDEHYDE "INACTIVATE" HIV IN A LIVING HUMAN BEING?

THE NATIONAL INSTITUTES OF HEALTH IS THE ONLY GOVERNMENTAL AGENCY WHICH CAN INITIATE AND CONDUCT A CLINICAL TRIAL; UNDERSTANDABLY, IT IS UNWILLING TO EXPERIMENT WITH ACETALDEHYDE BECAUSE, AS DR. WHITESCARVER STATES:

> "THE HIGH TOXICITY OF ACETALDEHYDE MAKES IT A SIGNIFICANTLY LESS DESIRABLE CANDIDATE FOR USE IN INDIVIDUALS WHO SUFFER FROM SEVERELY WEAKENED IMMUNE SYSTEMS AND WHO ARE PRONE TO CONTRACTING NUMEROUS OPPORTUNISTIC INFECTIONS AND MALIGNANCIES."

LET US SUPPOSE, FOR ARGUMENT'S SAKE, THAT ACETALDEHYDE CAN INACTIVATE HIV IN THE LIVING HUMAN BEING.

THE KEY QUESTION, OF COURSE, IS:

HOW COULD ACETALDEHYDE'S TOXICITY BE AMELIORATED OR NEGATED?

IN LATE JUNE OF THIS YEAR I LOCATED AND READ A SCIENTIFIC STUDY WHICH WAS CONDUCTED 20 YEARS AGO; THE STUDY DEALT WITH EXPERIMENTAL RESEARCH UPON RATS; THE PURPOSE OF THIS RESEARCH WAS TO DETERMINE THE EFFECTIVENESS WHICH CERTAIN SUBSTANCES MIGHT HAVE IN PROTECTING THESE RATS AGAINST THE TOXICITY OF ACETALDEHYDE POISONING; THE NAME OF THE STUDY IS:

> "PROTECTIVE ACTION OF ASCORBIC ACID AND SULFUR COMPOUNDS AGAINST ACETALDEHYDE TOXICITY: IMPLICATIONS IN ALCOHOLISM AND SMOKING"

AND IT IS BY HERBERT SPRINCE AND HIS ASSOCIATES, AND IT IS FOUND IN "AGENTS AND ACTIONS" 5(2) 164-73, MAY 75.

MY KNOWLEDGE OF BIOLOGY IS MINIMAL; HOWEVER, IT IS MY IMPRESSION THAT IF A CERTAIN RESULT CAN BE OBTAINED FROM AN EXPERIMENT UPON RATS, THIS SAME RESULT JUST POSSIBLY MIGHT BE ACHIEVED IF HUMAN BEINGS WERE THE OBJECT OF THE EXPERIMENT.

I AM GOING TO ASSUME THAT THE SPRINCE STUDY HAS APPLICABILITY TO THE HUMAN CONDITION. I THINK THAT HIS CONCLUSION AND "RATIO" SHOULD BE GIVEN SERIOUS CONSIDERATION.

THE SPRINCE CONCLUSION:

> "TO THE BEST OF OUR KNOWLEDGE, OUR FINDINGS DEMONSTRATE FOR THE FIRST TIME THAT DIRECT (SPRINCE'S EMPHASIS) PROTECTIVE ACTION AGAINST ACETALDEHYDE TOXICITY AND LETHALITY CAN BE OBTAINED WITH CERTAIN NATURALLY-OCCURRING METABOLITES, NAMELY L-ASCORBIC ACID, L-CYSTEINE, AND THIAMIN, PREFERABLY IN COMBINATION AT REDUCED DOSE LEVELS."

"THE SPRINCE RATIO":

L-ASCORBIC ACID (VITAMIN C)	2.0
L-CYSTEINE FB (A SULFUR COMPOUND)	1.0
THIAMINE.HCL (A SULFUR COMPOUND)	.3

I WISH TO QUOTE SPRINCE'S ABSTRACT IN FULL:

> "ACETALDEHYDE IS A TOXIC SUBSTANCE COMMON TO HEAVY DRINKING OF ALCOHOL AND HEAVY SMOKING OF CIGARETTES. IT HAS BEEN IMPLICATED THEREBY IN DISEASES OF THE CARDIOVASCULAR, REPIRATORY, AND CENTRAL NERVOUS SYSTEMS. PROTECTION AGAINST ACETALDEHYDE TOXICITY (i.e. ANESTHESIA AND LETHALITY) WAS STUDIED IN RATS BY ORAL INTUBATION OF TEST COMPOUNDS 30-45 MINUTES PRIOR TO ORAL INTUBATION OF A STANDARDIZED ORAL LD 90 DOSE (18 MILLIMOLES/KILOGRAM) OF ACETALDEHYDE. ANIMALS WERE MONITORED FOR ANESTHESIA (LOSS OF RIGHTING REFLEXES) AND LETHALITY FOR 72 HOURS. A TOTAL OF 18 COMPOUNDS WAS TESTED. L-ASCORBIC ACID AT 2 MILLIMOLES/KILOGRAM (mM/kg) SHOWED MODERATE PROTECTION AGAINST ANESTHESIA AND MARKED PROTECTION AGAINST LETHALITY. GREATEST PROTECTION AGAINST ANESTHESIA AND LETHALITY WAS OBTAINED AT 2mM/kg WITH EACH OF THE FOLLOWING: L-CYSTEINE, N-ACETYL-L-CYSTEINE, THIAMINE.HCL, SODIUM METABISULFITE, AND L-CYSTEIC ACID. A COMBINATION OF L-ASCORBIC ACID WITH L-CYSTEINE, AND THIAMIN.HCL AT REDUCED DOSE LEVELS (2.0, 1.0 AND 0.3 mM/kg, RESPECTIVELY) GAVE VIRTUALLY COMPLETE PROTECTION. A DETAILED LITERATURE REVIEW IS PRESENTED OF THE RATIONALE AND SIGNIFICANCE OF THESE FINDINGS. OUR FINDINGS COULD POINT THE WAY TO A POSSIBLE BUILD-UP OF NATURAL PROTECTION AGAINST THE CHRONIC BODY INSULT OF ACETALDEHYDE ARISING FROM HEAVY DRINKING OF ALCOHOL AND HEAVY SMOKING OF CIGARETTES."

IN ADDITION, I HAVE ATTACHED A COPY OF PAGE 166 OF THE SPRINCE STUDY. LOOK AT COMBINATION "CB3". NONE OF THESE RATS WERE DEAD AFTER 72 HOURS. IN FACT, THE WORST THING THAT OCCURRED TO THEM WAS THAT OUT OF 30 ONLY 3 RATS BECAME ANESTHETIZED AFTER 3-10 MINUTES.

AS RICHARD A. PASSWATER, Ph.D., STATED ON PAGE 128 OF HIS BOOK, SUPER-NUTRITION (DIAL PRESS, 1975; POCKET BOOK, 1976):

> "A COMBINATION OF CERTAIN SULFUR AMINO ACIDS AND VITAMIN C GAVE 100 PERCENT PROTECTION AGAINST A STANDARD LETHAL DOSE OF ACETALDEHYDE IN LABORATORY RATS."

AT THIS TIME I WOULD LIKE TO PROPOSE A CLINICAL TRIAL OF A PROCEDURE WHICH I LABEL "AN INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV".

1. CONDUCT THE CLINICAL TRIAL FOR SIXTEEN WEEKS.

2. FIRST, HAVE THE PATIENT PLUG UP HIS LIVER WITH ANTABUSE; FOLLOW THE REGIMEN RECOMMENDED BY THE PHYSICIANS' DESK REFERENCE, PAGE 2642, 1995 EDITION FOR THE TREATMENT OF ALCOHOLISM:

PAGE 24

A. THE TABLET SHOULD BE "PREFERABLY CRUSHED AND WELL MIXED WITH LIQUID".

B. "INITIAL DOSAGE SCHEDULE - IN THE FIRST PHASE OF TREATMENT, A MAXIMUM OF 500 mg DAILY IS GIVEN IN A SINGLE DOSE (SWALLOWED) FOR ONE TO TWO WEEKS." (TO BE SURE THE LIVER IS TOTALLY PLUGGED UP, UTILIZE TWO WEEKS; ALSO BE SURE TO TELL THE PATIENT TO AVOID ALCOHOL DURING THIS TIME).

C. "MAINTENANCE REGIMEN - THE AVERAGE MAINTENANCE DOSE IS 250mg DAILY (RANGE, 125 TO 500mg); IT SHOULD NOT EXCEED 500mg DAILY." (THIS SHOULD BE DONE EVERYDAY THROUGHOUT THE FOURTEEN REMAINING WEEKS OF THE TRIAL).

(OF COURSE, ALL QUANTITIES AND TIME PERIODS WHICH I MENTION IN THIS LETTER ARE ARBITRARY AND SUBJECT TO CHANGE; MEDICAL EXPERTISE WOULD DICTATE WHAT IS BEST; HOWEVER, THERE IS ONE CONSTANT WHICH WILL REMAIN INVARIABLE - THE SPRINCE RATIO.)

(I AM GOING TO ASSUME THAT IT TAKES 4 HOURS FOR A PLUGGED UP LIVER TO METABOLIZE (CHANGE INTO SOMETHING HARMLESS) THE ACETALDEHYDE THAT IS ENGENDERED IN THE HUMAN BODY AFTER 1 Oz. (A SHOT) of 100 PROOF ALCOHOL IS DRUNK.)

3. THE TRIAL WILL TAKE PLACE AT A PHYSICIAN'S OFFICE OR CLINIC; FOR FOURTEEN WEEKS THE PATIENT WILL REPORT TWICE A WEEK, LET'S SAY MONDAY AND THURSDAY; THE PATIENT WILL BE TOLD THAT TREATMENT WILL LAST ALL MORNING OR ALL AFTERNOON.

4. BEGIN THE TRIAL THUSLY - HAVE THE PATIENT INGEST L-ASCORBIC ACID (VITAMIN C), L-CYSTEINE FB AND THIAMINE.HCL; MEDICAL EXPERTISE WOULD DETERMINE THE AMOUNT; HOWEVER, THE SPRINCE RATIO WOULD BE ADHERED TO.

5. 30 TO 45 MINUTES LATER, ADMINISTER ALCOHOL IN THE MANNER DESCRIBED BY THE PHYSICIANS' DESK REFERENCE, PAGE 2642:

"....A DRINK OF 15 mL (½ oz) OF 100 PROOF WHISKEY, OR EQUIVALENT, IS TAKEN SLOWLY. THIS TEST DOSE OF ALCOHOLIC BEVERAGE MAY BE REPEATED ONCE ONLY, SO THAT THE TOTAL DOSE DOES NOT EXCEED 30 mL (1 oz) OF WHISKEY. ONCE A REACTION DEVELOPS, NO MORE ALCOHOL SHOULD BE CONSUMED. SUCH TESTS SHOULD BE CARRIED OUT ONLY WHEN THE PATIENT IS HOSPITALIZED, OR COMPARABLE SUPERVISION AND FACILITIES, INCLUDING OXYGEN, ARE AVAILABLE."

6. LET US SUPPOSE THAT IT TAKES AN HOUR FOR L-ASCORBIC ACID, L-CYSTEINE FB AND THIAMINE.HCL TO BE METABOLIZED COMPLETELY. WOULDN'T IT BE A GOOD IDEA THEN TO ADMINISTER A "BOOSTER" OF THIS COMBINATION EVERY ½ HOUR DURING THE 4 HOUR PERIOD? - SO THAT THE PROTECTIVE "CUSHION" AFFORDED BY THESE SUBSTANCES AGAINST POISONOUS, UNMETABOLIZED ACETALDEHYDE WOULD NOT BE DISSIPATED. IN THE MEANWHILE, DURING THIS 4 HOUR PERIOD, MILLIONS OF AIDS VIRUSES ARE BEING INACTIVATED BY THIS SAME, POISONOUS, UNMETABOLIZED ACETALDEHYDE.

7. CHECK THE RESULTING "T-HELPER CELL" COUNT AS THE TREATMENT PROGRESSES.

DR. WHITESCARVER STATES:

"MR. ROBERTS CONTENDS THAT THE LANG STUDY PRODUCED POSITIVE RESULTS BECAUSE PATIENTS WHO PARTICIPATED IN THE STUDY MAY HAVE DISREGARDED PROTOCOL PROHIBITIONS ON ALCOHOL CONSUMPTION, WHICH WOULD RAISE LEVELS OF ACETALDEHYDE TO TOXIC LEVELS. DR. LANG, HOWEVER, NEVER SUGGESTED THAT A SIGNIFICANT NUMBER OF HIS PATIENTS DEVIATED FROM THE PROTOCOL REGIMEN."

ON SEVERAL OCCASIONS I MAILED TO JEAN-MARIE LANG, HÔPITAL HAUTEPIERRE, STRASBOURG, FRANCE, COPIES OF MY RESEARCH. I NEVER ELICITED A RESPONSE FROM HIM.

IF DR. WHITESCARVER IS PRIVY TO ADDITIONAL INSIGHTS OF DR. LANG OTHER THAN THOSE PUBLISHED IN HIS ARTICLE, I WOULD APPRECIATE KNOWING ABOUT IT.

AN EXAMINATION OF THE LANG ARTICLE REVEALS THAT THE WORDS "WINE", "ALCOHOL" AND "ACETALDEHYDE" NEVER APPEAR.

AN EXAMINATION OF THE LANG ARTICLE REVEALS THAT A SENTENCE LIKE THIS NEVER APPEARS:

"SINCE DITIOCARB IS SIMILAR TO ANTABUSE, WE WARNED OUR PATIENTS TO REFRAIN FROM DRINKING WINE; WE TOLD THEM THAT IF THEY DID DRINK WINE THEY COULD BECOME VERY SICK."

THE LANG STUDY IS A COMPILATION OF RESEARCH WHICH OCCURRED AT SIX DIFFERENT LOCALES IN FRANCE.

WHEN THE SCIENTISTS COMBINED THEIR DATA, THIS IS ONE OF THE FACTS THAT APPEARED - 19% OF THE PATIENTS WHO RECEIVED DITIOCARB EXPERIENCED NAUSEA COMPARED TO 3% WHO RECEIVED PLACEBO.

IN ALL OF THE DESCRIPTIONS WHICH I HAVE READ ABOUT "THE ANTABUSE REACTION" THERE IS ONE WORD THAT INVARIABLY APPEARS - "NAUSEA".

WHEN I NOTICED THIS 19% FIGURE I GOT THE HUNCH THAT SOME OF THESE FRENCH PATIENTS MIGHT HAVE EXPERIENCED THE ANTABUSE REACTION.

THE DRINKING OF WINE SO PERMEATES THE CULTURE OF FRANCE THAT I THINK THE RESEARCHERS SIMPLY FORGOT TO TAKE IT INTO ACCOUNT AS A FACTOR.

DR. WHITESCARVER STATES:

"THERE COULD BE MANY EXPLANATIONS FOR THE PRELIMINARY FINDINGS THAT HAVE LITTLE OR NOTHING TO DO WITH THE PHARMACOLOGICAL ACTIVITY OF DITIOCARB OR ACETALDEHYDE. THERE IS NO EVIDENCE TO DATE TO SUSPECT THAT INCREASED LEVELS OF ACETALDEHYDE WERE RESPONSIBLE FOR THE OBSERVED RESULT."

PAGE 26

AFTER THE LANG STUDY, THREE OTHER MAJOR "DOUBLE-BLIND", "PLACEBO-CONTROLLED" STUDIES WERE CONDUCTED RELATIVE TO HIV/AIDS. THE WORD "ACETALDEHYDE" IS NEVER MENTIONED IN ANY OF THESE STUDIES. THUS FAR, I HAVE FAILED TO TURN UP ONE INSTANCE IN ANY OF THE PUBLISHED LITERATURE WHEREIN "ACETALDEHYDE" IS MENTIONED IN THE SAME CONTEXT WITH "HIV" AND/OR "AIDS" AND/OR "DITIOCARB"; IF DR. WHITESCARVER IS AWARE OF SOME UNPUBLISHED STUDIES WHICH EXIST, I WOULD APPRECIATE KNOWING ABOUT THEM.

OF COURSE, IT IS MY HOPE THAT SOMEONE/SOMEWHERE WITH MEDICAL EXPERTISE AND/OR AUTHORITY WILL DECIDE TO CONDUCT A SIXTEEN WEEK CLINICAL TRIAL OF THE AFOREMENTIONED PROCEDURE WHICH I CALL "AN INTENSIVE APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV" WITH A WILLING VOLUNTEER OR VOLUNTEERS.

IF THOSE IN THE MEDICAL COMMUNITY ARE STILL RELUCTANT TO INITIATE THIS TRIAL BECAUSE OF ACETALDEHYDE'S TOXICITY, I HAVE AN ALTERNATIVE PROCEDURE TO SUGGEST. I CALL THIS ONE "A MILD APPLICATION OF UNMETABOLIZED ACETALDEHYDE TO INACTIVATE HIV". THE RESULTS MIGHT NOT BE DRAMATIC, BUT, NEVERTHELESS, THERE SHOULD BE SOME SLIGHT IMPROVEMENT IN THE PATIENT'S HEALTH.

THE SAME "JOURNAL OF APPLIED TOXICOLOGY" WHICH I HAVE CITED STATES:

> "ACETALDEHYDE HAS BEEN IDENTIFIED IN OAK LEAVES, TOBACCO, APPLES, BROCCOLI, COFFEE, GRAPES, GRAPEFRUIT, ORANGES, LEMONS, ONIONS, PEACHES, PEARS, PINEAPPLES, RASPBERRIES, STRAWBERRIES AND MANY SPICES."

WHY NOT DO THIS? - PLUG UP THE PATIENT'S LIVER WITH ANTABUSE AND RECOMMEND A DIET RICH IN ORANGE JUICE AND THE FRUITS LISTED BY THIS JOURNAL.

THE IMPORTANT THING TO KEEP IN MIND ABOUT THIS PROCEDURE IS THAT ALCOHOL IS TO BE AVOIDED <u>COMPLETELY</u>. OF COURSE, ALCOHOL CANNOT BE DRUNK AND "HIDDEN ALCOHOLS" ARE TO BE AVOIDED -

1. THE FUMES OF AFTER-SHAVE LOTIONS HAVE BEEN KNOWN TO SET OFF THE ANTABUSE REACTION.

2. WATCH OUT FOR SAUCES, FERMENTED VINEGAR, MARINADES, DESSERTS OR OTHER FOODS PREPARED WITH ANY ALCOHOL.

PROBABLY NO INHERENT DANGER WOULD BE IMPLICIT IN THIS PROCEDURE OTHER THAN THE FACT THAT THE PATIENT MIGHT FEEL NAUSEOUS FROM TIME TO TIME BECAUSE OF THE SLIGHT INCREASED AMOUNT OF UNMETABOLIZED ACETALDEHYDE FLOWING IN HIS BLOODSTREAM BECAUSE OF DRINKING ORANGE JUICE OR EATING FRUIT.

CONDUCT THIS TRIAL FOR SIXTEEN WEEKS. THE PATIENT COULD IMMEDIATELY START DRINKING ORANGE JUICE AND EATING FRUIT; HE WOULD NOT HAVE TO WAIT TWO WEEKS UNTIL HIS LIVER GOT TOTALLY PLUGGED UP.

THE PATIENT WOULD NOT HAVE TO REPORT TWICE A WEEK TO THE PHYSICIAN'S OFFICE OR CLINIC.

IT WOULD BE THE PATIENT'S RESPONSIBILITY TO INCLUDE ORANGE JUICE AND FRUIT IN HIS DIET.

IT WOULD BE THE PATIENT'S RESPONSIBILITY TO SWALLOW HIS ANTABUSE TABLET EVERYDAY.

ONCE A MONTH THE PATIENT COULD REPORT TO HAVE HIS "T-HELPER CELL" COUNT MEASURED.

AGAIN, THIS PROCEDURE MIGHT NOT YIELD MUCH OF A RESULT; NEVERTHELESS, THERE SHOULD BE SOME SLIGHT IMPROVEMENT IN THE PATIENT'S HEALTH.

IN BOTH THE "INTENSIVE" AND "MILD" APPLICATIONS, CIGARETTE SMOKING SHOULD BE AVOIDED; SUPER-NUTRITION, PAGE 47, STATES:

> ".....EACH CIGARETTE SMOKED DESTROYS AN ESTIMATED 25mg OF VITAMIN C; THIS MAY BE AS MUCH AS MANY PEOPLE OBTAIN IN THEIR DIET. THE RDA IS ONLY 50mg."

IN BOTH THE "INTENSIVE" AND "MILD" APPLICATIONS, THE PATIENT SHOULD AVOID GOING INTO A ROOM IN WHICH AIR WICK IS PRESENT; THE "JOURNAL OF APPLIED TOXICOLOGY", TO WHICH I HAVE REFERRED, STATES:

> "ACETALDEHYDE IS A PRIMARY COMPONENT IN AIR WICK, A COMMERCIAL ROOM DEORDORANT." ACETALDEHYDE IS ALSO EMITTED BY WOOD BURNING, OAK LEAF BURNING, COFFEE ROASTING AND MOTOR VEHICLE EXHAUSTS.

IN THE "INTENSIVE" APPLICATION THE PATIENT SHOULD TAKE ZINC SUPPLEMENTS OR EAT FOODS RICH IN ZINC, NAMELY - BEEF, PORK, LAMB CHOPS, OYSTERS, PEANUTS, BEEF LIVER, BREWER'S YEAST OR WHEAT GERM; BECAUSE AS THE ENCYCLOPAEDIA BRITANNICA STATED:

> "AS ABSORBED ALCOHOL IS PASSED THROUGH THE LIVER BY THE CIRCULATING BLOOD, IT IS ACTED UPON BY ADH (ALCOHOL DEHYDROGENASE), A ZINC-CONTAINING ENZYME FOUND CHIEFLY IN THE LIVER CELLS."
>
> (THIS IS JUST A SIDE THOUGHT - COULD A DIETARY DEFICIENCY OF ZINC CONTRIBUTE TO THE DEVELOPMENT OF ALCOHOLISM?)

A FEW DAYS AGO I GOT THIS HUNCH - PATIENTS IN BOTH THE "INTENSIVE" AND "MILD" APPLICATIONS SHOULD AVOID FOODS OR BEVERAGES WHICH CONTAIN SUGAR. ELIMINATE SODA POP, CANDY, PASTRIES AND PACKAGED BREAKFAST CEREALS FROM THE DIET. CHECK THE LABELS OF EVERYTHING THAT IS BOUGHT. IF IT CONTAINS SUGAR OR CORN SYRUP, DON'T BUY IT.

ALL OF THIS MIGHT NOT DO ANY GOOD, BUT THEN AGAIN, IT WON'T DO ANY HARM. FOR THE DELETERIOUS EFFECTS WHICH SUGAR HAS UPON THE HUMAN BODY, REFER TO THE BOOK, SUGAR BLUES, BY WILLIAM DUFTY; PUBLISHER, WARNER BOOKS, 1976.

IT IS ALSO MY HUNCH THAT FOOD ADDITIVES SUCH AS MONOSODIUM GLUTAMATE (MSG) SHOULD BE AVOIDED.

I THINK THAT "INTENSIVE" AND "MILD" PATIENTS WOULD ALSO BENEFIT BY INCLUDING IN THEIR DIET BLACKSTRAP MOLASSES AND APPLE CIDER VINEGAR, THE RAW-UNFILTERED-ORGANIC KIND MADE FROM FRESH WHOLE APPLES; HEALTH FOOD STORES CARRY THIS ITEM.

BLACKSTRAP MOLASSES IS RICH IN IRON. I DON'T HAVE ANY FACTS ABOUT VINEGAR YET; IT'S JUST A HUNCH; BUT I THINK IT COULD BE BENEFICIAL. GARLIC SHOULD BE CONSIDERED TOO.

WELL, I GUESS I BETTER NOT GO OFF ON TOO MUCH OF A TANGENT DISCUSSING DIET. I AM REALLY NOT THAT KNOWLEDGEABLE ABOUT IT. I REPEAT, GOOD BOOKS TO REFER TO ARE SUPER-NUTRITION AND SUGAR BLUES.

I CONSIDER THIS LETTER TO BE THE CONCLUSION TO MY RESEARCH ON HIV/AIDS. IN ALL CANDOR I MUST SAY THAT I AM SOMEWHAT BEMUSED BY THE REPLIES WHICH HAVE COME FROM THE OFFICES OF THE NATIONAL INSTITUTES OF HEALTH (NIH) RELATIVE TO THE CHEMICAL KNOWN AS "ACETALDEHYDE".

THROUGHOUT 1993 NIH STATED:

"ACETALDEHYDE IS A NORMAL METABOLITE OF THE HUMAN BODY"
"FORMED DURING NORMAL BODY FUNCTIONING"
"AND WILL HAVE NO EFFECT ON HIV INFECTION"

IN LATE 1994 NIH STATED:

"THE KNOWN TOXICITY OF ACETALDEHYDE WOULD HAVE LIKELY PREVENTED EVALUATION EVEN IF THE AGENT HAD SHOWN ANTI-HIV ACTIVITY IN THE DRUG SCREEN PROGRAM SPONSORED BY THE NATIONAL CANCER INSTITUTE."

THE NIH NOW STATES, IN 1995:

".....ACETALDEHYDE INACTIVATES THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN TEST TUBE EXPERIMENTS....."

I WISH NOW TO DELINEATE SOME OF THE RESULTS OF THE LANG STUDY; THE FULL REFERENCE TO THE ARTICLE IS:

JEAN-MARIE LANG, CHRISTIAN TREPO, MYRIAM KIRSTETTER, ET AL: 'RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF DITIOCARB SODIUM ('IMUTHIOL') IN HUMAN IMMUNODEFICIENCY VIRUS INFECTION', "THE LANCET", SEPTEMBER 24, 1988, PAGES 702-706.

THE SUMMARY (ABSTRACT) OF THE ARTICLE READS:

"83 PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION (CDC GROUPS II, III, OR IV-A WERE RANDOMISED IN A CROSSOVER TRIAL OF SODIUM-DIETHYLDITHIOCARBAMATE (DITIOCARB SODIUM, 'IMUTHIOL') (10 mg/kg BODY WEIGHT GIVEN ORALLY ONCE A WEEK) AGAINST PLACEBO. EACH ARM OF THE TRIAL LASTED 16 WEEKS. THE DISEASE DID NOT PROGRESS TO CDC-DEFINED ACQUIRED IMMUNODEFICIENCY SYNDROME IN THE DITIOCARB GROUP BUT DID SO IN 4 PATIENTS IN THE PLACEBO GROUP (3 BETWEEN WEEK 0 AND 16, 1 BETWEEN WEEK 17 AND 32). DITIOCARB WAS ALSO ASSOCIATED TO A SIGNIFICANTLY GREATER EXTENT THAN PLACEBO WITH RELIEF OF CONSTITUTIONAL SYMPTOMS, IMPROVEMENT IN CLINICAL STATUS (INCLUDING SHRINKAGE OF ENLARGED SPLEEN AND LYMPH NODES), AND IMPROVEMENT IN IMMUNE FUNCTION (AS MEASURED BY CD4+ CELL COUNT AND SKIN TEST REACTIVITY). WHEN PLACEBO WAS REPLACED BY DITIOCARB, SIMILAR IMPROVEMENTS WERE OBSERVED, WHEREAS SYMPTOMS SLOWLY REAPPEARED AND CD4+ CELL LEVELS PROGRESSIVELY DECLINED WHEN DITIOCARB TREATMENT WAS REPLACED BY PLACEBO."

IN THE ARTICLE LANG STATES (BY THE WAY, NONE OF THE PATIENTS WERE TAKING AZT (ZIDOVUDINE) BECAUSE IT WAS NOT AVAILABLE IN FRANCE AT THE TIME):

"ALL THE 9 PATIENTS IN THE DITIOCARB GROUP WITH A HISTORY OF WEIGHT LOSS AT ENTRY REGAINED NORMAL WEIGHT AFTER 16 WEEKS' TREATMENT. THE SPLEEN BECAME IMPALPABLE IN 4 OF THE 7 DITIOCARB RECIPIENTS, BUT IN NONE OF 8 PLACEBO RECIPIENTS, WITH SPLENOMEGALY AT ENTRY."

"WHEN CHANGE IN CLINICAL STATUS WAS SCORED AS IMPROVED, STABLE, OR WORSE BY THE PHYSICIANS AFTER 16 WEEKS, 42% OF THE DITIOCARB RECIPIENTS HAD IMPROVED COMPARED WITH ONLY 5% IN THE PLACEBO GROUP ($p<0.01$)."

LANG TABLE II (ATTACHED) HIGHLIGHTS THE "DISAPPEARANCE OF CONSTITUTIONAL SYMPTOMS" AND THEY ARE 'PERSISTENT DIARRHOEA, WEIGHT LOSS, PERSISTENT FEVER'. ALSO NOTE "DISAPPEARANCE OF SPLENOMEGALY".

AND TO TOP IT OFF, THE LANG STUDY SHOWED AN INCREASE IN THE CD4-POSITIVE LYMPHOCYTES (T-HELPER CELLS):

"THE PRESENT FINDINGS, AND THOSE ACCOMPANYING LONG-TERM ADMINISTRATION OF DITIOCARB (3 YEARS), CLEARLY SHOW THAT THE CD4+CELL-DEFECT IS NOT AGGRAVATED. IN FACT, THE REVERSE OCCURRED, WITH DITIOCARB PRODUCING AN INCREASE IN CD4+CELLS AND IMPROVEMENT IN CONSTITUTIONAL SYMPTOMS OF AIDS-RELATED COMPLEX. FURTHERMORE, PRELIMINARY DATA IN A SMALL NUMBER OF PATIENTS INDICATE THAT DITIOCARB DOES NOT ENHANCE HIV REPLICATION IN VITRO OR IN VIVO."

ALSO SEE LANG TABLE III (ATTACHED).

TO SUMMARIZE THE IMPROVEMENTS NOTED BY LANG IN THOSE PATIENTS WHO WERE SWALLOWING DITIOCARB (RELATED TO ANTABUSE):

1. CD4+CELL COUNT INCREASED
2. ENLARGED SPLEEN AND LYMPH NODES SHRANK
3. DIARRHEA DISAPPEARED
4. WEIGHT RESUMPTION OCCURRED
5. PERSISTENT FEVERS DISAPPEARED
6. IMPROVEMENT IN CLINICAL STATUS IN 42% OF THE PATIENTS

IF UNMETABOLIZED ACETALDEHYDE WAS NOT THE CAUSE, WHAT, INDEED, WAS THE CAUSE OF THESE POSITIVE RESULTS?

YOURS TRULY,

John S. Roberts

JOHN S. ROBERTS
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219-763-1933

COPIES TO:

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JACK WHITESCARVER, Ph.D., NATIONAL INSTITUTES OF HEALTH, OFFICE OF AIDS RESEARCH
MS. PATRICIA S. FLEMING, NATIONAL AIDS POLICY COORDINATOR, THE WHITE HOUSE

CONTINUED ON THE NEXT PAGE

PAGE 30

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AND (updated 1/1/96 - j.s.r.) - "MAGIC"JOHNSON, DR. VARMUS, DR. PAUL, DR. BADER, EMBASSY OF JAPAN-WASHINGTON, D.C., DR. GALLANT, PROFESSOR DIETRICH, DR. HERSH, PROFESSOR HASELTINE, CHICAGO TRIBUNE, CHICAGO SUN-TIMES, DR. NULL, TONY BROWN PRODUCTIONS, BONAVENTURE HOUSE, DR. COHAN PAM ZEKMAN, "PLUS VOICE", "POZ", ROBERT ERB, NEW YORK TIMES, NEW YORKER, (MARK TAYLOR, JIM GORDON, SCOTT BOSLEY-POST-TRIBUNE), DR. CUTLER, DR. FEUERS, HIV TALK RADIO, WYETH-AYERST LABORATORIES, DR. HIRSCH, "OUT/LOOK", DR. BAGASRA, DR. HENDERSON, DR. BENNETT, PROFESSOR ANNE DE GROOT

PETER J. VISCLOSKY
1ST DISTRICT, INDIANA

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August 22, 1995

Mr. John S. Roberts
Post Office Box H
Hobart, Indiana 46342

Dear John:

I write to apprise you of a reply I have received from the National Institutes of Health (NIH) in response to your proposal for a cure for AIDS.

Enclosed, please find a copy of the letter I received from the NIH's Deputy Director of the Office of AIDS Research, Jack Whitescarver, Ph. D. I regret that this response is not more encouraging, but I believe it clearly addresses your concerns.

Be assured that I will continue to monitor all research efforts in the fight against AIDS with your views in mind. Do not hesitate to let me know if you have any other questions or concerns.

Sincerely,

Peter J. Visclosky
Member of Congress

PJV:clm
Enclosure

NATIONAL INSTITUTES OF HEALTH
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AUG - 9 1995

The Honorable Peter J. Visclosky
House of Representatives
2464 Rayburn Building
Washington, D.C. 20515-1401

Dear Mr. Visclosky:

The Office of AIDS Research (OAR) has been asked to reply to correspondence you have forwarded to Dr. Harold Varmus, Director of the National Institutes of Health (NIH), from one of your constituents, Mr. John S. Roberts. Mr. Roberts has written numerous letters to various scientists, government officials, and organizations advocating the use of acetaldehyde for the treatment of HIV infection and AIDS. You may recall that the NIH addressed this issue, at your request, in response to a similar letter from Mr. Roberts in June 1993. A copy of this correspondence is enclosed for your convenience.

The fact that acetaldehyde inactivates the human immunodeficiency virus (HIV) in test tube experiments does not necessarily make it a good candidate for anti-HIV therapy in humans. There are many agents known to be active against HIV. Researchers at the National Cancer Institute have identified over 3,000 compounds that are active against HIV, and the NIH currently is developing and evaluating the most promising ones.

The high toxicity of acetaldehyde makes it a significantly less desirable candidate for use in individuals who suffer from severely weakened immune systems and who are prone to contracting numerous opportunistic infections and malignancies. Mr. Roberts, however, insists that the toxicity could be ameliorated by the administration of sulfur amino acids and vitamin C. He cites research conducted twenty years ago in normal, uninfected mice. This research, however, is not applicable to humans infected with HIV.

In an attempt to substantiate his contention, Mr. Roberts repeatedly cites a study conducted in France by Dr. J.M. Lang that produced preliminary data suggesting that the drug Ditiocarb may have activity against HIV infection. This result, however, was not reproduced in later studies. Mr. Roberts contends that the Lang study produced positive results because patients who participated in the study may have disregarded protocol prohibitions on alcohol consumption, which would raise patient levels of acetaldehyde to toxic levels. Dr. Lang, however, never suggested that

a significant number of his patients deviated from the protocol regimen.

There could be many explanations for the preliminary findings that have little or nothing to do with the pharmacological activity of Ditiocarb or acetaldehyde. There is no evidence to date to suspect that increased levels of acetaldehyde were responsible for the observed result. Consequently, there is little justification for committing limited resources to investigating this possibility at this time. In any case, furture support for research in this area would require the submission of a grant application by a competent research scientist. Funding then would be contingent on it passing a dual level of peer review.

The NIH currently is supporting more promising scientific approaches to the development of anti-HIV and AIDS therapies. For instance, a nucleoside analogue known as 3TC has shown promise in combination with other anti-HIV compounds in initial clinical trials. Several HIV protease inhibitors also have shown promise as well as an immune system modulator, interleukin-2. Currently, NIH-sponsored researchers are evaluating over 65 different agents in AIDS clinical trials.

I hope this information will prove useful in addressing the concerns of your constituent. Please contact us again if we can provide any additional assistance.

Sincerely,

Jack Whitescarver

Jack Whitescarver, Ph.D.
Deputy Director

Enclosure

PAGE 34

Table 2
Protective action of combinations of L-ascorbic acid and certain sulfur compounds against anesthetic and lethal effects of acetaldehyde in the rat. (Toxic oral dose of acetaldehyde used was LD 90 = 18 m*M*/kg.)

Combinations (CB) tested (oral dose)	Dose (m*M*/kg)	% anesthetized after 3–10 minutes	% dead after 3 hours	24 hours	72 hours
CB1: L-Cysteine FB	1.0				
Thiamin · HCl	0.3	60 (6/10)	10 (1/10)	60 (6/10)	60 (6/10)
CB2: L-Cysteine FB	2.0				
Thiamin · HCl	0.3	13 (2/15)	0 (0/15)	13 (2/15)	13 (2/15)
CB3: L-Ascorbic acid	2.0				
L-Cysteine FB	1.0	10 (3/30)	0 (0/30)	0 (0/30)	0 (0/30)
Thiamin · HCl	0.3				
CB4: L-Ascorbic acid	2.0				
N-Acetyl-L-cysteine	1.0	15 (3/20)	5 (1/20)	5 (1/20)	5 (1/20)
Thiamin · HCl	0.3				
Intraperitoneal (i.p.) dose					
CB3 (i.p.): Composition same as CB3		33 (5/15)	13 (2/15)	20 (3/15)	20 (3/15)

Combinations of test compounds were prepared as single solutions in saline. Procedural details of intubation and observations made are the same as described in Table 1 footnote, except for Combination CB3 (i.p.). Combination CB3 (i.p.) was administered intraperitoneally once a day for four days prior to dosing with acetaldehyde. On the fourth day, acetaldehyde (18 m*M*/kg) was intubated orally 30–45 minutes after the last intraperitoneal injection of Combination CB3 (i.p.).

acetaldehyde at the LD 90 dose level carefully standarized for rats of the above strain, sex, age, weight, and overnight treatment and found to be 18 m*M*/kg as previously reported [1]. Doses were expressed in m*M*/kg. Rats were observed after intubation over a 72-hour period for anesthetic effects (loss of righting reflexes) and lethal response (deaths). Further details of the test procedure and data obtained are presented in Tables 1 and 2.

The effect of using different routes of drug administration on protectant activity against acetaldehyde was also tested with a combination of ascorbic acid, cysteine, and thiamin (i.e., combination CB3 in Table 2). In this case, the protectant combination CB3 was administered intraperitoneally and the acetaldehyde orally. For details of procedure, see Table 2.

All test compounds listed in Tables 1 and 2 were obtained from the NBC Division of ICN Pharmaceuticals, Inc., with the exceptions listed as follows: DL-thioctic acid (Aldrich), taurine (Schwarz-Mann), cysteamine · HCl (Eastman), sodium metabisulfite (Fisher), and L-MTCA (see Reference 1 for its preparation). Compounds not listed in Table 1 were from the following sources: BAL (Aldrich), DTT (NBC), and DTE (NBC). Acetaldehyde was obtained from the Eastman Kodak Company.

Results

Results are self-evident from Table 1 and Table 2.

From Table 1, it is obvious that the reduced forms of L-ascorbic acid, L-cysteine FB, L-glutathione, and *N*-acetyl-L-cysteine gave marked protection in rats against the anesthetic and lethal effects of acetaldehyde. Thus, 72 hours after treatment, lethal values were only 27% for L-ascorbic acid, 20% for L-cysteine FB, and 33% for reduced glutathione compared to 90% for saline controls. Complete protection (zero % lethality) was obtained with *N*-acetyl-L-cysteine, but only meager protection with DL-homocysteine (60% lethality). Protection against transitory anesthetic effects was best obtained with L-cysteine and its *N*-acetyl derivative (20% and 10% anesthetized, respectively) in comparison with the saline control (96% anesthetized). The oxidized forms of these compounds showed very little protectant activity against either anesthetic or lethal effects of acetaldehyde. Other sulfur compounds which gave virtually complete protection against anesthetic and lethal effects were sodium metabisulfite ($Na_2S_2O_5$) which resulted in only 5% lethality and L-cysteic acid in zero % lethality. On the other hand, the amines taurine and cysteamine · HCl showed much less protection than their corresponding acids (L-cysteic acid and L-cysteine, respectively). Preliminary screening tests with compounds not listed in Table 1 gave the following results: BAL (2,3-dimercapto-1-propanol) was found to be non-protective at 0.5 m*M*/kg, a dose not too far removed from its lethal dose level of 1.0 m*M*/kg. On the other hand, DTT (diothiothreitol) and DTE (diothioerythreitol) at

LANG

TABLE II—CLINICAL OUTCOME OF HIV INFECTION IN FIRST ARM OF TRIAL

—	Active	Placebo	p†
Progression to AIDS	0/38	3/39 (PCP, *Mycobact avium*, and Kaposi sarcoma)	..
Disappearance of constitutional symptoms* (IV-A patients)	8/11	0/5	<0·001
Lymphadenopathy score	−0·43‡ (SD 1·94)	+0·43‡ (SD 1·26)	<0·05
Disappearance of splenomegaly	4/7	0/8§	<0·05

*Persistent diarrhoea, weight loss, persistent fever.
†Fisher's exact test.
‡Change from baseline.
§No spleen became impalpable; two additional spleen enlargements were noted.

LANG

TABLE III—CD4 CELL COUNT DURING THE FIRST ARM OF TRIAL

—	Active		Placebo		
	Patients tested	Median (mean, SD) count	Patients tested	Median (mean, SD) count	p*
Baseline	42	415 (405, 111)	41	380 (389, 132)	NS
Week 8	36	479 (517, 172)	39	420 (461, 226)	NS
Week 16	36	522 (542, 215)	38	420 (447, 181)	<0·05

*Student's *t* test.

LANG

TABLE IV—SIDE-EFFECTS

Adverse reaction	Percentage of patients with adverse reactions	
	Active (n = 83)	Placebo (n = 79)
Unpleasant taste	41 (32)	4 (3)
Abdominal discomfort	33 (26)	8 (6)
Nausea	19 (15)	3 (2)
Sensation of malaise	10 (8)	1 (1)
Anorexia	9 (7)	1 (1)
Excitement	6 (5)	3 (2)
Somnolence	5 (4)	1 (1)
Vomiting	2 (2)	1 (1)
Rash	0 (0)	0 (0)

Number of patients in parentheses. No patient in either group had >25% drop in haemoglobulin concentrations, red or white cell count, or platelet count.

REISINGER

TABLE II—T-HELPER CELL COUNTS PER µl BLOOD IN PATIENTS WITH INITIAL COUNT BELOW 814/µl

Route	Time (mo)	Placebo	DTC
Oral	0	467 (193)	493 (204)
	6	442 (327)	428 (167)
	% loss	5·9 (53·5)	5·4 (37·7)
Intravenous	0	422 (283)	388 (225)
	6	250 (263)	352 (345)
	% loss	51·4 (35·6)	20·8 (30·4)

HALF-LIFE OF ACETALDEHYD

10

3.1 min → 5

6 × 3.1 = 18.6 MINU

3.1 min → 2.5

3.1 min → 1.25

98.43
1.57
100.00

3.1 min → .625

(6) 3.1 min → .313

98.43% METABOLIZED AT THIS POINT

3.1 min → .157

3.1 min → .079

3.1 min → .040

3.1 min → .020

3.1 min → .010

3.1 min → .005

3.1 min → .0025

3.1 min → .0013

DRAFT

DRAFT LETTER FROM PATSY TO CONFERENCE ATTENDEES

Dear:

I want to join in thanking you for having participated in the history-making White House Conference on HIV and AIDS. In the years ahead, I think we will look back and see this as a major event in refocusing the Nation's attention to this epidemic.

The fight against AIDS is a truly national effort -- marshalling the forces of individuals such as yourself, community organizations, the private sector, and government agencies. President Clinton, as he made clear during his remarks at the Conference, is deeply committed to doing whatever it takes to put an end to the epidemic. At the Conference, he affirmed our Nation's goal of finding a cure and a vaccine for HIV and his continued support for prevention, care, and services programs, including Medicaid, which provides support to nearly 50 percent of people with AIDS.

Thank you again for participating in the Conference. I look forward to working with you in fulfilling the promise of the Conference.

Sincerely,

Patricia S. Fleming
Director, Office of National AIDS Policy

Enclosure: Transcript of President Clinton's remarks at the White House Conference on HIV and AIDS, December 6, 1995.

n:conf.tu

OK

N.A Tks conf. Letter aid2_66.wp5 (2:st) 266

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C:\Val.Doc

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PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

REPORT ONE
INITIAL STEPS FOR PRESIDENTIAL ACTION
JULY 28, 1995

OUR MISSION

Our mission is to provide information and recommendations to the President regarding programs and policies to promote effective prevention of HIV disease, advance research on HIV and AIDS, and promote quality services to persons living with HIV disease and AIDS.

PREAMBLE

With over 250,000 Americans having died of AIDS, an estimated 1 million more currently infected, and over 40,000 new infections each year, it is critical that the President of the United States commit to use his personal leadership to raise the level of public education, compassion and concern.

He must make the battle against AIDS one of the most visible and continuing priorities of his Presidency. The cost to our country, in life, in lost productivity, in financial terms, in anguish and in grief, is incalculably large.

The Council will work intensively with the President over the coming months to issue more recommendations. Because we do not have the luxury of time, we are issuing a few initial recommendations for the President that require immediate attention. We believe that visible and courageous leadership on the part of the President can and must provide the spark that ignites the American people and brings them together in unprecedented partnerships between people with HIV, health care providers, researchers, foundations, business, spiritual leaders, community activists, political leaders of both parties, and Americans of all races and sexual orientations.

The majority of our recommendations will be presented in the coming months. After these first two days of meetings we feel compelled to advocate the following goals and actions:

A. LEADERSHIP

Much of America has lapsed into a complacency about AIDS even while the epidemic continues to expand its path of devastation. The President must commit to use his personal leadership to raise the level of public education, compassion, and concern by pledging to make the battle against AIDS one of the most visible and continuing priorities of his Presidency. He should courageously ask the American public to confront the difficult issues of sexuality, drug use, and social and racial prejudice that profoundly damage our ability to combat the disease. More important than a single media event, however, is an ongoing commitment and strategy from the President to seek out opportunities to **frequently** confront the AIDS crisis wherever appropriate. Therefore we recommend that:

1. **The President himself must engage the American public through a National Summit which encompasses the scientific, medical, social and political aspects of the AIDS epidemic. This Summit, which should be held by the end of this year, should consider the impact of race, culture, poverty, disability, region, gender, sexual orientation, and age on our ability to develop an effective national AIDS strategy.**

   The December 6th White House Conference on HIV and AIDS represents a rapid response to this important recommendation. This is a truly historic event.

2. **The President should then proceed with an address declaring the battle against HIV a national health priority and laying out his vision for the end of this epidemic.**

   In the context of the Conference, the President will address the American people about the high priority the fight against AIDS has for this Administration. The President plans to remain engaged in his government's response to the epidemic. Discussions are already under way about additional steps that need to be taken to assure that the full force of the Presidency is used in tackling the many aspects of AIDS.

B. PREVENTION

The President's investment priorities -- including biomedical research and the Ryan White CARE Act -- have consistently received significant funding increases. HIV prevention programs, such as specific population based targeted programs, demand a similar level of commitment.

1. **The President makes HIV Prevention an investment priority during budgetary decision making**

   The President's commitment to prevention remains strong. The current focus of attention is, needless to say, on the discussions related to the FY 1996 budget. While preliminary conversations have occurred with regard to FY 1997, until a budget agreement is in place it will not be possible to respond authoritatively to this recommendation.

C. SERVICES

1. **The President should continue his support of the Ryan White CARE act and should endeavor to prevent the Congress from attaching unnecessary funding restrictions. He should also continue to vigorously support funding levels for the Ryan White CARE Act that are responsive to the rising caseloads and costs of delivering comprehensive services to people with HIV/AIDS and make it a budget priority.**

   The President's support for the CARE Act has been consistent and clearly articulated to the public and Congress. The President spoke out several times against the divisive tactics and amendments offered by Jessie Helms. Administration officials at all levels made clear to Congress our position opposing all negative and extraneous amendments. It is unfortunate that the Republicans' distraction with the fight over Medicaid and the budget has delayed completion of action on Ryan White reauthorization, a measure for which there is such strong bipartisan support.

   It should also be noted that while a Labor-HHS appropriations bill is not likely to be enacted in the immediate future, in all the Administration's communications with the Congress on this subject we have expressed our opposition to the cuts (or elimination, in the House bill) of the AIDS Education and Training Centers and our belief that the increases provided for Ryan White Care Act programs are insufficient to meet the increased demand.

C. SERVICES (CONT.)

2. **The President must maintain a strong commitment to the entitlement status of the Medicaid program, including a willingness to veto any legislation which inadequately funds or transforms Medicaid into a block grant.**

   The President's leadership on this issue has been and continues to be strong and clear. The importance of protecting the essential elements of Medicaid and assuring adequate funding for it have been consistent themes. The President has stated that he will veto the original Republican proposals to gut Medicaid and has stated that he will continue to do so until they agree to protect the fundamentals of the current Medicaid program. The support of the AIDS community has been important in the fight with Congress and all who work on this Administration are appreciative of the community's strong efforts.

3. **The President must continue to demonstrate his strong support for the Housing Opportunities for People with AIDS (HOPWA) and other federal housing programs that serve people living with AIDS. The President should make housing for People with AIDS an FY 97 priority.**

   The President has demonstrated his support for housing programs in the FY 1996 budget cycle -- still far from completion. He has made clear that he opposes some of the cuts in housing programs (though HOPWA is protected) in the pending VA-HUD appropriations bill. The concerns around AIDS housing -- both AIDS-specific housing programs and those that serve the needy generally, including people with AIDS -- will be among those carefully watched through the rest of the FY 1996 cycle and in the development of the FY 1997 budget. Understandably, the exact parameters of that budget agreement for the current discussion will not be known until an overall fiscal year is reached.

D. RESEARCH

1. **The President should continue to show strong support for a coordinated federal approach to HIV/AIDS research, including continued support for the Office of AIDS Research (OAR).**

   The President's commitment to finding a cure and a vaccine are strong. The entire Administration was behind the efforts to maintain the single appropriation for AIDS research at NIH; that effort is ongoing in the context of the Labor-HHS appropriations for FY 1996.

E. COMBATING DISCRIMINATION / SOCIAL PREJUDICE

1. **In talking publicly about HIV, the President should vigorously speak out against HIV-related discrimination and condemn prejudice based on race/ethnicity and sexual orientation which damage our efforts to combat AIDS. The President should strongly and visibly oppose any amendments to HIV-related legislation which are designed to divide the American people along lines of sexual orientation, substance use history, race/ethnicity, or other factors.**

   The President has done that throughout his term. He was eloquent in his response to Senator Jesse Helms' divisive tactics during the Ryan White CARE Act debate. As you probably know, the President has most recently endorsed passage of the Employment Non-Discrimination Act, which would ban discrimination based on sexual orientation. All enforcement arms of the Administration have been working effectively and collaboratively in challenging HIV-related discrimination.

INTERIM ACTIONS AUGUST - NOVEMBER

1. Resolution on Mandatory HIV testing August 1995

"We urge the Administration to ask the House-Senate Conference Committee to oppose Mandatory Testing and to support the Kassebaum Amendment to the Reauthorization of the Ryan White CARE Act (Senate version) over the Coburn Amendment (House version)."

2. Letter the President on Medicaid cuts November 1995

As members of your Advisory Council on AIDS, many of whom are living with HIV, and as people personally dedicated to the national fight against AIDS, we are writing to remind you of the vital importance of the Medicaid program to the health care of Americans living with AIDS. The Medicaid program provides health care for nearly half of all adults living with AIDS, and 90 percent of all children with AIDS depend on the Medicaid program for health care services which are essential to their quality and duration of life.

As you know, measures passed by the Republican House and Senate leadership would block grant the Medicaid program to reduce federal funding by $170 billion over the next seven years. The House and Senate bills would repeal Title XIX of the Social Security Act and with it the myriad of federal requirements and regulations guaranteeing that low-income women and children, disabled individuals and senior citizens receive a range of health care services at nominal or no cost and with a meaningful choice of providers. Under the Budget Reconciliation bills, no class of current or future beneficiaries, including people living with HIV/AIDS who qualify for services as disabled persons, will be assured eligibility, a set of comprehensive services, qualified health care providers, or minimal costs. In human terms, this uncertainty could easily translate into dramatic increases in morbidity and premature mortality for people with HIV/AIDS.

If the House and Senate pass their respective Reconciliation measures as expected, it is only through your leadership that the Medicaid program can be preserved as a fundamental health safety net for 34 million Americans. We implore you to veto the Budget Reconciliation bill when it reaches your desk, and to work vigorously for a budget agreement with the Congress which preserves the entitlement status of the Medicaid program with enough federal funding to maintain vital health care services to the millions of vulnerable Americans who depend upon it. There is no more important action you can take as our national leader to ensure that PWA's have access to care.

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FACSIMILE COVER SHEET

TO: Debra

FAX NUMBER: 690-7560

FROM: Carmena Parris

DATE: 2-29-96

PAGES INCLUDING COVER SHEET: 7

COMMENTS:

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PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

REPORT TWO
CONTINUED STEPS FOR PRESIDENTIAL ACTION
DECEMBER 8, 1995

PREAMBLE

The Council is pleased to present to the President a second set of action steps needed in the war against AIDS. We appreciate the prompt action taken by the administration to convene a historic White House conference on HIV/AIDS as proposed by the Council in July. We are also grateful to the scores of leaders from across the United States who gathered at the White House on December 6 to contribute their hard work, expertise, and suggestions. Many of their proposals are incorporated into the action items that follow. Others, including those in issue areas not yet addressed by this Council, will be further reviewed by the Council and incorporated into action items that we will propose over the coming months.

A. LEADERSHIP

1. **During his State of the Union Address, the President should renew his commitment to ending the AIDS epidemic and to committing our nation's resources to preventing new infection, caring for people now living with HIV/AIDS, and finding a cure, vaccine, and effective treatments for HIV. The President should, during this address, announce the immediate release of his updated National Plan on AIDS.**
2. **To further accomplish the goals President Clinton outlined at the White House Conference on HIV/AIDS, the Clinton/Gore Administration should ensure that key Cabinet Secretaries initiate and maintain regular, face-to-face meetings with HIV service providers, people living with HIV/AIDS and their advocates to ensure consistent and ongoing communication and partnership with community members on the front-lines of the AIDS epidemic.**

B. SERVICES

Consistent with the Council's July 28, 1995 recommendation and its subsequent letter to the President regarding the Medicaid and Medicare programs, the President should:

1. **Continue to support and defend the entitlement status and funding for Medicaid and Medicare; and continue to oppose any efforts to restrict eligibility and services for people living with HIV/AIDS.**
2. **Direct that any waivers granted to States under the Medicaid program ensure access to a comprehensive continuum of care for people living with HIV/AIDS. To implement this policy, the President should direct the Health Care Financing Administration (HCFA) to establish national criteria by which to assess State waiver applications and to ensure that these criteria be consistent with current health care knowledge. These criteria also should be consistent with the provisions of the Americans with Disabilities Act (ADA), and State plans should be reviewed for this purpose by the Department of Health and Human Services (DHHS) Office of Civil Rights.**
3. **Direct HCFA to ensure that State Medicaid programs cover HIV testing and counseling.**
4. **Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA)-approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.**

B. SERVICES (CONT.)

The Nation's health care system is moving at an accelerated rate toward managed care. Managed care services must be available and responsive to persons living with HIV/AIDS. It is essential that comprehensive HIV health care systems (e.g., those currently supported by the Ryan White CARE Act), continue to be available to persons with HIV/AIDS in the new environment. To accomplish this:

1. **The Administration should direct those Federal Agencies that either finance or administer health care services (including but not necessarily limited to HCFA, the Department of Veterans Affairs, the Department of Defense and the Bureau of Prisons), to develop oversight guidelines for HIV managed care programs. This will also require effective regulatory enforcement mechanisms.**
2. **The Administration should direct the Health Resources and Services Administration (HRSA) to develop a coordinated Agency-wide approach which provides effective education, training, and technical assistance to HIV/AIDS providers and AIDS service organizations on health care management issues. Such an approach should include active participation by the private sector.**
3. **Because complementary therapies are widely used, the President should direct all appropriate agencies to support the investigation of the efficacy of complementary treatment therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.**

Because care and treatment are continually evolving, ongoing education and training for all health care providers is critical. To ensure the highest quality of care and to maintain a knowledgeable, stable HIV/AIDS health care work-force:

1. **The President should continue to support full funding to a national network of AIDS Education and Training Centers (AETC's), and direct HRSA to ensure that the work of AETCs is coordinated with community providers and planning groups.**
2. **The Administration should direct HRSA to review and report to the Council at its next meeting the effectiveness of the Bureau of Health Professions' education activities specific to HIV/AIDS.**

C. PREVENTION

We are delighted that the President had committed to set a goal of reducing the number of new infections every year until there are no more new infections. We have made some recommendations in the prevention area to assist in accomplishing this goal.

The HIV/AIDS pandemic is a series of epidemics. These epidemics have affected specific populations in very different ways. Our country has experienced success in curbing the spread of some of these epidemics and yet in others there is continued and dramatic growth. The CDC, under this recommendation will annually issue a report to the President and the country on populations, both geographic and demographic in nature, where we continue to experience a disproportionate increase in new HIV infection. This will give the Public Health Service, the business community, and countless volunteer organizations, the ability to focus on the most severely impacted HIV/AIDS populations.

1. **The President should direct the CDC to produce an annual estimate of HIV incidence based on seroprevalence studies and work to ensure that there is a reasonable relationship between epidemiological trends and CDC prevention funding. This report should specifically examine the demographic characteristics and geographic distribution of populations that experience disproportionate increases in new infections.**
   a) **The CDC should issue an annual estimate of HIV incidence based on seroprevalence studies to the President that provides a geographic and demographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections.**
   b) **Direct the Secretary of Health and Human Services to ensure that resources are allocated to accomplish this task.**
   c) **Ensure that funding is adequate and responsive to the epidemiological trends, needs and prevention infrastructure of affected communities.**
2. **The President should direct the Centers for Disease Control and Prevention (CDC) to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk taking behavior.**
   a) **Direct the CDC to join with the National Institutes of Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk taking behaviors in populations that show a continuing disproportionate increase in AIDS cases.**
   b) **Direct the Secretary of Health and Human Services to coordinate the planning of an early warning system and ensure its ongoing use.**

C. PREVENTION (CONT.)

Injection drug use is the largest factor contributing to the continuing spread of HIV in this country. The Centers for Disease Control and Prevention estimates that 40,000 - 60,000 new HIV infections occurring annually, 50% are occurring among injection drug users. Additional infections occur through sexual contact with injection drug users. Injection drug use is directly or indirectly responsible for the overwhelming majority of HIV infections among women and infants. We will only by able to end this epidemic by responding rapidly and effectively.

1. **The Administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use which accounts for at least 50% of new HIV infections. In addition, high risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug paraphernalia, as well as the high risk sexual behavior associated with drug and/or alcohol use.**

   a) **Increase the access to effective substance abuse prevention and treatment research programs by:**

   - **Opposing Congressional efforts to cut SAMHSA and other federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations.**
   - **Restoring budget requests for SAMHSA and other federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.**
   - **Supporting the continuation of specific funding for NIDA's AIDS demonstration projects.**

   b) **Revise the Department of Justice Model Drug Paraphernalia Act which serves as a model for state drug paraphernalia laws to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among injection drug users.**

   c) **The President should direct the Secretary of Health and Human Services to provide a recommendation (within 90 days) regarding the impact of needle exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies and data on needle exchange programs, and should include specific recommendations for programs and demonstration projects to implement needle exchange. The Secretary shall develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded.**

C. PREVENTION (CONT.)

The Administration has begun to plan for the combining of HIV/STD and TB funding. The current proposal does not adequately safeguard the community planning process. This proposal does not take into consideration the need for measures that are relevant to communities of color, gay and bisexual men, substance users, youth, women, and/ or other communities and groups that have not been captured by existing data.

1. **The President should reaffirm his support for community based planning for prevention activities.**
   a) **Direct the CDC to maintain HIV prevention programs independent of any consolidated grants programs including the currently proposed Performance Partnerships Grants.**
   b) **Direct the CDC to continue direct funding to community-based organizations.**
   c) **Direct the CDC with the assistance of existing national minority organizations and other appropriate partners to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing continued disproportionate increase in new infections.**

HIV/AIDS is established and growing throughout Indian Country, and threatening a population already reduced to 1.4 million from war, disease and poverty. Since the Indian Health Service (IHS) is the only health service provider for Native Americans on Reservations, there is a need for prevention services specifically directed to Native Americans. We recommend that the President:

1. **Direct the Director of the IHS to develop a comprehensive AIDS prevention and care plan for Indian Country within 90 days with the input of consumers of services.**

D. RESEARCH

A vaccine to prevent AIDS and an anti-HIV topical microbicide to prevent infection are feasible technologies which can be developed. Such technologies represent the most promising ultimate solutions for control of the global pandemic.

These technologies will require the cooperation and collaboration of government, community representatives, private industry, and academia, in the U.S. and other nations, to overcome ~~current obstacles~~ and to develop these products as rapidly as possible.

1. **The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicides, and to "reinvent" the government's involvement in development of these products.**

Women infected heterosexually by HIV represent the fastest-growing group diagnosed with AIDS in the United States, and account for half of all cases in Africa and an increasing proportion of cases in Asia. Since women may not be able to demand the use of condoms by their partners, female-controlled methods such as anti-HIV topical microbicides to prevent sexual transmission of HIV are urgently needed.

1. **The priority for funding by the OAR for microbicide research and development, as well as funding within CDC, must be increased substantially, with a concomitant increase of FTE's allocated for this priority.**
2. **The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.**

Advances in HIV/AIDS therapies, vaccines, and microbicides require the dissemination, acceptance, and use of these products by the populations which can benefit by them. Such applications of biomedical discoveries require the expertise of the social and behavioral sciences.

1. **In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.**
2. **HHS should develop ongoing mechanisms to assure the rapid translation of breakthrough research findings into clinical practice.**

D. RESEARCH (CONT.)

While the results of ongoing microbicide research are awaited, it is urgent to promulgate public health recommendations for preventing sexual transmission of HIV by using existing, licensed pharmaceutical products, for "off label" indications, based on the best available information currently available.

1. **A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicides (e.g., nonoxynol-9) and other licensed products (e.g., chlorhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.**

Women of all ages, including those of childbearing potential, have been excluded from many clinical trials of drugs for treatment of HIV/AIDS.

1. **We ask the FDA to comment by January 31, 1996 upon the proposed FDA regulations which require "inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives which allow the inclusion of women should be provided."**
2. **The FDA must require a sponsor to file gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the Federal Register, Vol. 60, No. 174 at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects between genders.**
3. **The Secretary of HHS should publish for public comment by March 1, 1996 the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain a written consent from the father of the fetus should not disqualify her from participation in a federally-funded clinical trial. This fact should be so stated in the protocol consent form.**

E. COMBATING DISCRIMINATION / SOCIAL PREJUDICE

Because HIV-related discrimination and mandatory testing negatively impacts the public health by deterring people from voluntary counseling and treatment, the President should:

1. **Rescind mandatory testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department and the military, where there is no compelling public health justification.**
2. **Instruct the U.S. Centers for Disease Control and Prevention (CDC) to review it's guidelines that arbitrarily restrict HIV infected health care workers and that lead to discrimination against them, and to ensure that these guidelines are consistent with prevailing scientific and public health knowledge on the issue.**
3. **Oppose any Congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message we recommend that the President state that the veto is, in part, due to the inclusion of this provision.**
4. **Direct the CDC, Immigration and Naturalization Service, and Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.**

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

REPORT TWO
CONTINUED STEPS FOR PRESIDENTIAL ACTION
DECEMBER 8, 1995

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4. **Direct HCFA to report to the Council, at its next meeting, possible strategies to address the need to ensure that all Food and Drug Administration (FDA)-approved drugs are covered under State Medicaid plans, even when prescribed for "off-label" indications. These strategies should address both policies and vigorous enforcement mechanisms.**

B. SERVICES (CONT.)

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3. **Because complementary therapies are widely used, the President should direct all appropriate agencies to support the investigation of the efficacy of complementary treatment therapies and provide increased financial support for this effort. Therapies shown to have benefit should be reimbursed under Medicaid.**

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   a) **The CDC should issue an annual estimate of HIV incidence based on seroprevalence studies to the President that provides a geographic and demographic analysis of the populations where there is a continuing disproportionate increase in new HIV infections.**
   b) **Direct the Secretary of Health and Human Services to ensure that resources are allocated to accomplish this task.**
   c) **Ensure that funding is adequate and responsive to the epidemiological trends, needs and prevention infrastructure of affected communities.**
2. **The President should direct the Centers for Disease Control and Prevention (CDC) to develop a behavioral surveillance mechanism that will provide an analysis of patterns in risk taking behavior.**
   a) **Direct the CDC to join with the National Institutes of Drug Abuse (NIDA) and other relevant agencies to institute surveillance methods for detecting patterns of risk taking behaviors in populations that show a continuing disproportionate increase in AIDS cases.**
   b) **Direct the Secretary of Health and Human Services to coordinate the planning of an early warning system and ensure its ongoing use.**

C. PREVENTION (CONT.)

Injection drug use is the largest factor contributing to the continuing spread of HIV in this country. The Centers for Disease Control and Prevention estimates that 40,000 - 60,000 new HIV infections occurring annually, 50% are occurring among injection drug users. Additional infections occur through sexual contact with injection drug users. Injection drug use is directly or indirectly responsible for the overwhelming majority of HIV infections among women and infants. We will only by able to end this epidemic by responding rapidly and effectively.

1. **The Administration should pursue a comprehensive strategy to decrease HIV transmission related to injection drug use which accounts for at least 50% of new HIV infections. In addition, high risk sexual behavior while under the influence of drugs and/or alcohol accounts for another significant percentage of new cases of HIV disease. Strategies must explicitly address the sharing of injection drug paraphernalia, as well as the high risk sexual behavior associated with drug and/or alcohol use.**

   a) **Increase the access to effective substance abuse prevention and treatment research programs by:**

   - **Opposing Congressional efforts to cut SAMHSA and other federal funding for drug abuse treatment and prevention programs in FY 1996 appropriations.**
   - **Restoring budget requests for SAMHSA and other federal funding for drug abuse treatment and prevention programs to at least the FY 1995 levels.**
   - **Supporting the continuation of specific funding for NIDA's AIDS demonstration projects.**

   b) **Revise the Department of Justice Model Drug Paraphernalia Act which serves as a model for state drug paraphernalia laws to make it consistent with current reports, studies, and data relating to the access to sterile syringes as an effective intervention to counter HIV transmission among injection drug users.**

   c) **The President should direct the Secretary of Health and Human Services to provide a recommendation (within 90 days) regarding the impact of needle exchange programs on HIV infection and substance abuse. The recommendation should be based upon current reports, studies and data on needle exchange programs, and should include specific recommendations for programs and demonstration projects to implement needle exchange. The Secretary shall develop and execute a plan to carry out the recommendations and indicate what programs and demonstration projects will be started or expanded.**

C. PREVENTION (CONT.)

The Administration has begun to plan for the combining of HIV/STD and TB funding. The current proposal does not adequately safeguard the community planning process. This proposal does not take into consideration the need for measures that are relevant to communities of color, gay and bisexual men, substance users, youth, women, and/ or other communities and groups that have not been captured by existing data.

1. **The President should reaffirm his support for community based planning for prevention activities.**
   a) **Direct the CDC to maintain HIV prevention programs independent of any consolidated grants programs including the currently proposed Performance Partnerships Grants.**
   b) **Direct the CDC to continue direct funding to community-based organizations.**
   c) **Direct the CDC with the assistance of existing national minority organizations and other appropriate partners to structure its technical assistance programs to address the prevention program development and infrastructure needs of populations that are currently experiencing continued disproportionate increase in new infections.**

HIV/AIDS is established and growing throughout Indian Country, and threatening a population already reduced to 1.4 million from war, disease and poverty. Since the Indian Health Service (IHS) is the only health service provider for Native Americans on Reservations, there is a need for prevention services specifically directed to Native Americans. We recommend that the President:

1. **Direct the Director of the IHS to develop a comprehensive AIDS prevention and care plan for Indian Country within 90 days with the input of consumers of services.**

D. RESEARCH

A vaccine to prevent AIDS and an anti-HIV topical microbicide to prevent infection are feasible technologies which can be developed. Such technologies represent the most promising ultimate solutions for control of the global pandemic.

These technologies will require the cooperation and collaboration of government, community representatives, private industry, and academia, in the U.S. and other nations, to overcome current obstacles and to develop these products as rapidly as possible.

1. **The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicides, and to "reinvent" the government's involvement in development of these products.**

Women infected heterosexually by HIV represent the fastest-growing group diagnosed with AIDS in the United States, and account for half of all cases in Africa and an increasing proportion of cases in Asia. Since women may not be able to demand the use of condoms by their partners, female-controlled methods such as anti-HIV topical microbicides to prevent sexual transmission of HIV are urgently needed.

1. **The priority for funding by the OAR for microbicide research and development, as well as funding within CDC, must be increased substantially, with a concomitant increase of FTE's allocated for this priority.**
2. **The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.**

Advances in HIV/AIDS therapies, vaccines, and microbicides require the dissemination, acceptance, and use of these products by the populations which can benefit by them. Such applications of biomedical discoveries require the expertise of the social and behavioral sciences.

1. **In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.**
2. **HHS should develop ongoing mechanisms to assure the rapid translation of breakthrough research findings into clinical practice.**

D. RESEARCH (CONT.)

While the results of ongoing microbicide research are awaited, it is urgent to promulgate public health recommendations for preventing sexual transmission of HIV by using existing, licensed pharmaceutical products, for "off label" indications, based on the best available information currently available.

1. **A public health policy consensus panel should be convened by the Public Health Service by the end of April 1996 to assess the possible efficacy of available spermicides (e.g., nonoxynol-9) and other licensed products (e.g., chlorhexidine, benzalkonium chloride, diaphragms) to be used in "harm reduction" algorithms to decrease sexual transmission of HIV. The panel should include senior public health policy officials (CDC, FDA, HHS Secretary's Office), research agencies (NIH), community groups (women's health research advocates, commercial sex workers, interested foundations), academia, and industry. The meeting should also feature a review of the entire status of anti-HIV microbicide research.**

Women of all ages, including those of childbearing potential, have been excluded from many clinical trials of drugs for treatment of HIV/AIDS.

1. **We ask the FDA to comment by January 31, 1996 upon the proposed FDA regulations which require "inclusion of women in all clinical trials of drugs for treatment of HIV/AIDS in which there is no known evidence of reproductive toxicity. When such toxicity has been documented, alternatives which allow the inclusion of women should be provided."**
2. **The FDA must require a sponsor to file gender accrual analysis in the annual Investigational New Drug (IND) report, as stated in the final version of the proposed regulations published in the Federal Register, Vol. 60, No. 174 at 46794. In addition, for the New Drug Application (NDA) and the product licensing application (PLA), the regulations must require sponsors to analyze clinical data by gender and assess potential differences, including reporting on side effects between genders.**
3. **The Secretary of HHS should publish for public comment by March 1, 1996 the proposed regulations regarding participation of pregnant women in clinical trials, with the following revision: A pregnant woman's inability to obtain a written consent from the father of the fetus should not disqualify her from participation in a federally-funded clinical trial. This fact should be so stated in the protocol consent form.**

E. COMBATING DISCRIMINATION / SOCIAL PREJUDICE

Because HIV-related discrimination and mandatory testing negatively impacts the public health by deterring people from voluntary counseling and treatment, the President should:

1. **Rescind mandatory testing and/or discriminatory policies currently in place in the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department and the military, where there is no compelling public health justification.**
2. **Instruct the U.S. Centers for Disease Control and Prevention (CDC) to review it's guidelines that arbitrarily restrict HIV infected health care workers and that lead to discrimination against them, and to ensure that these guidelines are consistent with prevailing scientific and public health knowledge on the issue.**
3. **Oppose any Congressional efforts to require that otherwise qualified military service personnel who test positive for HIV be discharged, including a veto of the Department of Defense Reauthorization Act if such a provision is included. In his veto message we recommend that the President state that the veto is, in part, due to the inclusion of this provision.**
4. **Direct the CDC, Immigration and Naturalization Service, and Department of State to monitor and coordinate the HIV testing of immigrants to ensure informed consent, pre- and post-test counseling, and appropriate legal and health referrals and to ensure that waivers of the HIV exclusion are granted on a priority basis when permitted by statute. Also, when permitted by statute, the INS and the Executive Office of Immigration Review (EOIR) should grant stays of deportation, suspension of deportations, extended voluntary departure, deferred action, and asylum based on the social group category of HIV-positive individuals.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Bldg: SOLAR
Room: 3A24
Tel: (301) 402-0443
Fax: (301) 402-1456

July 29, 1996

Ms. Patsy Fleming
Office of National AIDS Policy
Suite 600
750 17th Street NW
Washington, DC 20503

Dear Ms. Fleming: Patsy

On behalf of the National Institute of Allergy and Infectious Diseases and the UNAIDS Program, thank you for participating in the satellite symposium on topical microbicides. Your presentation was an inspiration and set the stage for a successful symposium. The hour, the venue and the absence of Dr. Novick, notwithstanding, we have gotten a lot of positive feedback on the meeting.

Overall, topical microbicides received quite a bit of attention at the conference, hopefully this will help us in establishing the critical mass of scientists and resources necessary to deliver safe, effective topical microbicides in a timely fashion.

We are moving ahead with plans to submit the papers for publication; this will be done in August. As we mentioned in the letter of invitation, we would be very interested in publishing your remarks as a preface to the supplement. In order to submit this with the manuscripts we have to receive the statement no later than August 7, 1996. As soon as we finish our negotiations with the publisher, I will get back to you to confirm the journal and the anticipated publication date.

Again, thank you for the outstanding job that you did in Vancouver. We look forward to working with you in the future on the research and development of topical microbicides.

Sincerely,

Penelope J. Hitchcock, D.V.M., M.S.
Chief, Sexually Transmitted Diseases Branch
Division of Microbiology and Immunology

Zeda Rosenberg, D. Sc.
Senior Scientist for Adult Prevention Research
Efficacy Trials Branch
Division of Acquire Immunodeficiency Syndrome

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bldg: SOLAR
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Tel: (301) 402-0443
Fax: (301) 402-1456

July 29, 1996

Ms. Patsy Fleming
Office of National AIDS Policy
Suite 600
750 17th Street NW
Washington, DC 20503

Dear Ms. Fleming: Patsy

On behalf of the National Institute of Allergy and Infectious Diseases, thank you for participating in the satellite symposium on STD Treatment to Prevent HIV Infection. Your presentation was excellent and was an integral part of the success of the symposium. The hour, the venue notwithstanding, we have gotten a lot of positive feedback on the meeting.

Overall, STD prevention and control received quite a bit of attention at the conference, hopefully this will help us in establishing the critical mass of scientists and resources necessary to deliver this safe, effective intervention in a timely fashion. thanks!

Again, thank you for your words of inspiration and support. We look forward to working with you in the future on the prevention and control of STDs as a safe, cost-effective approach to prevent the spread of human immunodeficiency virus infection.

Sincerely,

Penelope J. Hitchcock, D.V.M., M.S.
Chief, Sexually Transmitted Diseases Branch
Division of Microbiology and Immunology

Zeda Rosenberg, D. Sc.
Senior Scientist for Adult Prevention Research,
Efficacy Trials Branch
Division of Acquire Immunodeficiency Syndrome

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MEMORANDUM

TO: Working Group (See Distribution below)
Preventing Substance Abuse and HIV: A National Leadership Forum

FROM: C. Godfrey Jacobs, Project Director

SUBJECT: Meeting of September 26, 1996

DATE: September 24, 1996

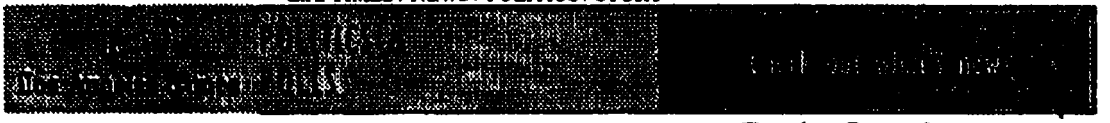
This is to confirm the meeting of the Working Group on September 26, 1996 starting at 8:30 a.m. The anticipated adjournment of the meeting is 4:00 p.m. The meeting will be held at the Residence Inn Pentagon City, 550 Army Navy Drive, Arlington, Virginia. The telephone number at the hotel is: (703) 413-6630.

Attached with this memorandum, please find the proposed agenda for the meeting. Also attached are all manner of directions for reaching the hotel and a map of the area.

Should you have any questions or additions to the agenda, please call me at (703) 998-0287, ext. 273. I look forward to seeing you on Thursday. Thank you!

Distribution:

Bill Bukoski
Bob Denniston
Melanie Duckworth
Helen Fox Fields
Russ Gerber, M.D.
Steven Gust, Ph.D.
Mel Haas, M.D.
Warren Hewitt
Dennis Jarvis
Noble Jones
Stephen Jones, M.D.
Ann Mahony
Adolfo Mata
Pam McDonnell
Stephanie McGencey
John Miles
Lucy Perez, M.D.
Cynthia Prather, Ph.D.
Barbara Roberts, Ph.D.
LaHoma Romocki
Julie Scofield
Jack Stein



Tuesday, September 24, 1996

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FRONT PAGE
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ORANGE COUNTY
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VENTURA COUNTY

COLUMN ONE

An AIDS Fighter on a Tightrope

As head of the president's advisory panel, L.A. doctor R. Scott Hitt maneuvers between an administration that's done more than any other to battle the disease and a gay community that wants a cure.

By FAYE FIORE, Times Staff Writer

WASHINGTON--The door opens to a narrow row house in the southeast section of town and Dr. R. Scott Hitt steps in out of the heat. The room is smoky and cluttered with papers. A neglected cigarette burns in an ashtray.

Gray suit buttoned and white collar crisp, he has just descended into one of the bunkers where the political war on AIDS is fought, this one the home of an activist working to bring down the cost of dreadfully expensive new drugs for people who will die without them.

A leading Los Angeles AIDS doctor, Hitt is here as chairman of President Clinton's Advisory Council on HIV/AIDS. He listens attentively to a financial wish list. His physician self tells him it is perfectly justifiable, but his political self knows it is patently impossible.

"If you could ask for one thing, what would it be? We can't be asking for 20 things," Hitt says bluntly. "We are not going to get 20 things."

It is his willingness to accept this political fact of life and move on that has most disturbed critics in the 15 months since Hitt was made one of Clinton's chief advisors on AIDS. He maneuvers between two often hostile camps: an administration that has done more than any other about AIDS and a gay community that will be satisfied with nothing less than a cure.

Under Hitt's direction, the advisory council that was roundly dismissed as irrelevant before it even met appears to be getting through to an administration many believe got off to a slow start on AIDS.

Within the first six weeks, Hitt and his panel churned out eight recommendations on what the White House should do immediately about AIDS. Clinton promptly followed all eight, most notably assembling in record time a White House conference on the disease President Reagan wouldn't even mention.

Hitt was pretty proud of that. But a lot of people in the AIDS community dismissed it as no big deal.

Some activists wonder whether this handsome 37-year-old doctor with a million-dollar house in the Hollywood Hills, a silver Mercedes and one of the most lucrative AIDS practices in the country has what it takes to squeeze money out of a tight-fisted Congress or advise Clinton on needle exchanges and miracle drugs most AIDS patients

cannot afford to buy.

"He's not tough enough on Clinton and he will have to take a long hard look at his role in this community after Clinton's presidency is over," fumed Steve Michael, a Washington AIDS activist. "We can make Clinton a better president on AIDS, but Scott Hitt has got to help us. He can't be standing there covering the president's flanks."

Even some council members were wary at first of his unimposing style, but quickly came to respect him. "Scott is a directed cannon, not a loose cannon. He isn't stupid; he does not embarrass the president," said council member Benjamin Schatz, who is executive director of the Gay and Lesbian Medical Assn. in San Francisco.

"He's blond and good-looking and likes to have fun, so some people mistook him for a lightweight," Schatz said. "Why aren't heterosexual women with large breasts taken seriously? Well, he's the gay male equivalent of that."

The legacy of other gay activists who have managed to enter Clinton's inner circles--only to be booted for remarks considered impolitic-- taught Hitt something about the workings of Washington: When one has the ear of the president of the United States, it is wiser to whisper than to scream.

Indeed, Hitt gets high marks at the White House. "He usually does it with a quiet voice, but he provides the right kind of leadership around there," said White House Chief of Staff Leon Panetta. "He is very respected among the people concerned about AIDS."

In Los Angeles' gay power circles, Hitt has long been known as an activist who spends his days fighting the virus with medicine, his nights and weekends fighting it with politics. His friends call him the "Ever-Ready Doctor." Countless evenings at home are devoted to phoning and faxing, as he juggles a busy, not to mention emotionally grueling, practice.

He has distinguished himself in his field, having treated more than 1,000 HIV patients at Pacific Oaks Medical Group in Beverly Hills, the nation's largest HIV private practice. He is a founding director of the Victory Fund, which raises thousands of dollars for gay political candidates, and a founder of Access Now for Gay and Lesbian Equality, a civil rights group.

It was in front of the stone fireplace in the living room of Hitt's contemporary bungalow that Bill and Hillary Clinton won the early trust of gay leaders out of 1992's crowded field of Democrats vying for the presidential nomination. His endorsement subsequently helped deliver the gay vote for Clinton in droves.

Three years passed before Clinton rewarded Hitt's loyalty, enough time for the president to fall from grace among gays and lesbians for his retreat on homosexuals in the military, his slowness in naming an AIDS commission, and his failure--in the view of many activists--to come out swinging against the epidemic.

Even when the council was finally named, friends warned Hitt that running the advisory commission would be a thankless job. This would be the largest and most diverse such panel ever assembled: 40% of its 30 members are HIV-positive; half are homosexual or bisexual; a third are people of color; all have been personally affected by the epidemic and are strongly opinionated about AIDS.

Hitt would be the first openly gay person selected to lead a presidential advisory council--the third focused on AIDS under Presidents Bush and Clinton. Its mandate would be to guide the president on national AIDS policy with a $240,000 annual budget and no support staff. Even before its first meeting, the council would be dismissed as irrelevant by many in the AIDS community. Nothing it accomplished would ever be enough.

"I told him he was opening himself up to a disappointment, that

this was another in a long line of commissions about AIDS," said David Mixner, a former Clinton advisor on gay issues whose recent book, "Stranger Among Friends," details his disappointment in the president. "But he has built an astounding record in a very short time, and it has a lot to do with Scott's unique ability to push, push, push. He goes 18 hours a day."

*

The capital has that rumpled look it gets in late summer. Backs of dress shirts are stained dark with sweat and hairdos are beginning to frizz. Hitt's black loafers click against the marble floor in the Hart Senate Office Building. He has just paid homage to Nevada Sen. Harry Reid, a moderate Democrat and member of the powerful Appropriations Committee that is vital to deciding how much federal money is spent on AIDS.

A wall of pay phones beckons, and Hitt stops to check on a patient. The subject matter switches from politics to medicine. Sentences pour from his mouth as he inquires about pathology reports and prognoses. It is as if he has been speaking a foreign language all morning and has just lapsed comfortably into the effortless fluency of his native tongue.

"Who thought that, the pathologist?" Hitt demands, sounding utterly self-assured for the first time today. "Well, the surgeon doesn't know. Get a second opinion on what we need to do for this guy. He's been in pain for four weeks."

It was clear from the start that this Washington stuff would not be easy, even for a whiz kid from Tucson who graduated from high school at 16, started medical school at 20, established himself as a cutting-edge AIDS physician by 30 and was called to serve by the president at 36.

On the day Hitt was at the White House being told by Vice President Al Gore that he would chair the council, 50 gay elected officials from around the country happened to be down the hall preparing for a historic meeting with the administration's senior advisors. The officials watched in shock as four Secret Service agents put on rubber surgical gloves before touching the bags and briefcases they had set out for routine inspection.

The agents said later the gloves were "for protection." Clinton was furious. And Hitt learned the lesson that within the walls of the White House, no gesture is insignificant.

"This was an historic day with so many gay and lesbian leaders invited to the White House, and it was overshadowed by a mistake some guards made. That's frustrating," Hitt said.

It would not occur to him until later that this concept of the bad eclipsing the good was no mishap; it was the culture of politics. For all of his efforts to laud this president for his achievements in the war on AIDS, it seemed to him that the news media emphasized the president's failings while activists dismissed most praise as pandering.

The council's last report in July lauded Clinton for his "strong commitment" to increased funding for the Ryan White CARE Act that funds community-based care for AIDS patients, his opposition to dismantling Medicaid, and a 43% increase in discretionary AIDS funding when other federal budget increases averaged 3%. It also chastised Clinton for "lack of action" in AIDS prevention and discrimination, calling for "greater courage and leadership" on the president's part.

Some grumbled the report was too soft.

"How do you judge the president?" Hitt responds from the backseat of his third taxicab of the day as he lurches through Washington on one of his monthly visits. "One way is to say the

epidemic is still going on, people are still dying and damn it, we're upset. The other way is to say this president has done more than every other combined, and that's just as wrong. Who couldn't do more than the other presidents combined? The answer is somewhere in between."

Not that he's reticent about criticizing the president. Hitt concedes he has lost the enthusiasm he had for candidate Clinton four years ago and rates his performance on gay civil rights as "underwhelming." But on AIDS, he says, Clinton has been "good to very good" in many areas.

Still, there are miles to go in the fight against AIDS, the No. 1 killer of Americans between 25 and 44. Yet whatever the council has achieved under Hitt's leadership can perhaps best be measured in inches: The president's mention of the disease in this year's State of the Union address and his nomination acceptance speech last month; the panel's insistence that Clinton stand firm against cuts in Medicaid, upon which half of AIDS patients rely; its influence in repealing part of a defense bill that would have forcibly discharged HIV-positive members of the military; its public reproval of Clinton for failing to show more courage in AIDS prevention.

"We could spend a trillion dollars on AIDS," Hitt says. "Our recommendation could be to fund everything. But our job is to help the president prioritize and then follow up on what he does. Discretionary spending on AIDS went up 43%. Maybe it should have been 80%, but 43% is something to be happy about." In all, Hitt said, the federal government spends more than $3 billion a year on AIDS research, treatment and care.

He mentions that because of improvements in care, Sherman Oaks Medical Center has recently closed its AIDS unit. Similarly, the AIDS Healthcare Foundation recently announced it is closing its oldest hospice, in Elysian Park, in part because of similar successes in treating AIDS.

It's nearly 5 o'clock. Hitt will spend the night at a friend's home and head back to Los Angeles in the morning to see patients. His practice has been bringing in less money lately, partly because his patients are responding to new drug therapies.

"He has nothing to gain from this. He's not trading up for a better job," one Los Angeles AIDS activist said. "This Congress is not going to approve a gay man in a high government position. Maybe this guy really is all about making advances on AIDS."

Hitt's thoughts turn to one of his oldest patients, a man who is not responding to those new drugs that seem to be working miracles for so many. He wonders aloud what to try next. Whatever he does in Southern California might buy a few more months. Much of what he does in Washington might not be felt for years. But at least the president is listening. And for Hitt, that's something.

* * *

Profile: Russell Scott Hitt

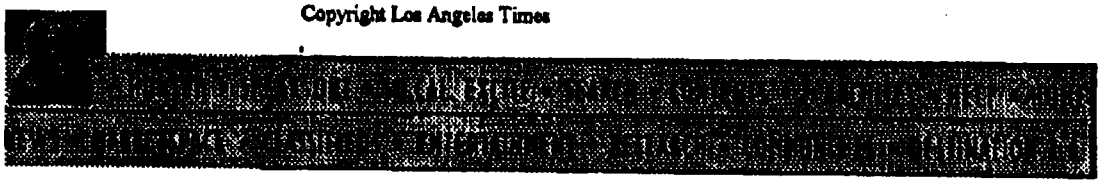
Physician and chairman of the Presidential Advisory Council on

Physician and chairman of the Presidential Advisory Council on HIV/AIDS.

* Born: Sept. 28, 1958
* Residence: Hollywood Hills
* Education: University of Arizona, University of Arizona School of Medicine.
* Career highlights: Partner at Pacific Oaks Medical Group, the nation's largest private-practice provider of HIV/AIDS health care.

Member of board of directors of AIDS Project Los Angeles.

* Personal: Partner Alex Koleszar, a computer consultant and artist.



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001. memo	Linet Harley to Patricia Fleming (1 page)	07/29/1996	b(6)

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Clinton Presidential Records
National AIDS Policy Office
Patsy Fleming (National AIDS Strategy)
OA/Box Number: 10183

FOLDER TITLE:
[Miscellaneous Correspondence] [1]

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rs3215

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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RR. Document will be reviewed upon request.

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b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE BLACK LEADERSHIP COMMISSION
BLCA
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New York, NY 10010
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212-614-0057 - Fax

Just The Fax

Page(s) including cover: 2

Date: July 29 1996

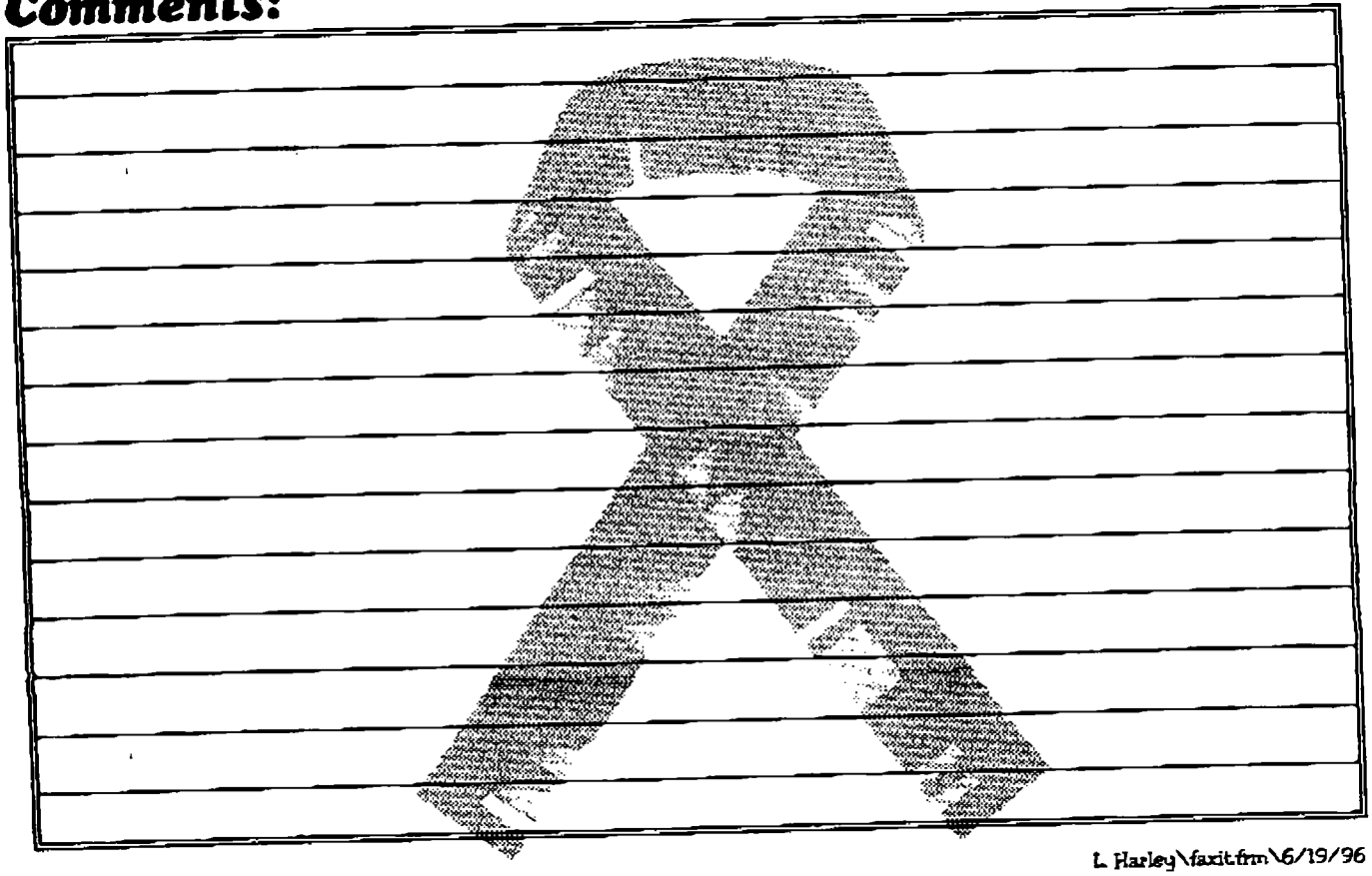
Name: Ms. Patricia Fleming

Company: White House

Fax #: 202 632-1096 Phone #:

From: Linet Harley

Comments:



L. Harley\faxit.frm\6/19/96

Yankelovich Partners

julie

101 Merritt 7 Corporate Park, Norwalk, CT 06851-9794 USA

Fax Transmittal

To:	Patsy Fleming
Company:	National Aids Program Office
Phone:	(202) 632-1090
Fax:	(202) 632-1096
From:	Chris Harris
Company:	Yankelovich Partners Inc.
Phone:	1-800-326-6784
Fax:	(203) 845-8200
Date:	August 7, 1996
Number of Pages:	2 (including cover page)

Comments:

The following is a letter describing Yankelovich Partners and the study we are conducting regarding the health care industry. Your participation on this important study would be greatly appreciated. If you have any additional questions, please do not hesitate to call. Thank you.

Yankelovich Partners Inc.
101 Merritt 7 Corporate Park
Norwalk, CT 06851
(203) 846-0100
(203) 845-8200 Fax

Yankelovich Partners

August 7, 1996

Ms. Patsy Fleming
Aids Coordinator
National Aids Program Office
Department of Health and Human Services
200 Independence Ave. S.W.
Washington, DC 20201

Dear Ms. Fleming:

Recently you spoke to one of my associates, Joe Boldt, regarding a nationwide research study we are conducting among people like yourself about the health care industry. The purpose of this study is to understand perceptions of certain companies in the industry and the services they provide.

Yankelovich Partners Inc. is a national market research firm and you have my assurance that this is solely a research project and that absolutely no selling is involved. Your comments will be combined with responses from other participants so that your individual responses remain completely confidential. Your name and your organization's name will not be identified in any way.

The interview lasts approximately 20 minutes and your participation would be greatly appreciated. If you have any further questions, please do not hesitate to call Mr. Boldt at 1-800-326-6784.

Sincerely,

Chris Harris
Research Manager

Dup.

Yankelovich Partners

101 Merritt 7 Corporate Park, Norwalk, CT 06851-9794 USA

Fax Transmittal

To:	Anthia
Organization:	National AIDS Program Office
Phone:	(202) 632-1090
Fax:	(202) 632-1096
From:	Chris Harris
Company:	Yankelovich Partners Inc.
Phone:	1-800-326-6784
Fax:	(203) 845-8200
Date:	August 14, 1996
Number of Pages:	2 (including cover page)

Comments:

The following is a letter describing Yankelovich Partners and the study we are conducting regarding the health care industry. Your participation on this important study would be greatly appreciated. If you have any additional questions, please do not hesitate to call. Thank you.

Yankelovich Partners Inc.
101 Merritt 7 Corporate Park
Norwalk, CT 06851
(203) 846-0100
(203) 845-8200 Fax

Yankelovich Partners

August 14, 1996

Ms. Patsy Fleming
AIDS Coordinator
National AIDS Program Office
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Ms. Fleming:

Recently you spoke to one of my associates, Joseph Boldt, regarding a nationwide research study we are conducting among people like yourself about the health care industry. The purpose of this study is to understand perceptions of certain companies in the industry and the services they provide.

Yankelovich Partners Inc. is a national market research firm and you have my assurance that this is solely a research project and that absolutely no selling is involved. Your comments will be combined with responses from other participants so that your individual responses remain completely confidential. Your name and your organization's name will not be identified in any way.

The interview lasts approximately 20 minutes and your participation would be greatly appreciated. If you have any further questions, please do not hesitate to call Mr. Boldt at 1-800-326-6784.

Sincerely,

Chris Harris
Research Manager

561-655-1023 C What's the last name? Labre. Lalce, Labie ?? P

10/14/96

Deare Ms. Fleming;

Thank-you for your efforts on behalf of persons w/ HIV in our country. In particular, we appreciate your help in procuring funding increases for Ryan White II & III which benefit approximately 2,500 people a year in our community.

Shawna Dunn
West Palm Beach, FL

Glenn P. Hyden PLWA
Lake Worth, FL

FILE COPY

THE WHITE HOUSE

10/27/96

Dear Shawna, Glenn & LaDee,

Thanks for your note. It means so much to me to know you recognize what we are trying to do in the Clinton Administration.

We'll keep fighting!

Sincerely,
Patsy Fleming

9702916

United States Department of State

Washington, D.C. 20520

February 20, 1997

SENSITIVE BUT UNCLASSIFIED

MEMORANDUM TO ALL DEPARTMENT AND AGENCY
EXECUTIVE SECRETARIES

Subject: Meeting of the Interagency Working Group on the Freely Associated States

Deputy Assistant Secretary of State for East Asian and Pacific Affairs, Aurelia E. Brazeal, will chair a meeting of the Interagency Working Group on the Freely Associated States (FAS) on **Wednesday, April 2, 1997, at 2:00 p.m. in Room 6210 at the Department of State.**

The purpose of the meeting is to: (1) improve coordination of U.S. programs under the Compact of Free Association with the FAS, former U.S.trust territories which are now independent countries; (2) formally begin the process of assessing the benefits/costs of domestic programs carried out in the FAS, in preparation for negotiations with the Marshall Islands and Federated States of Micronesia beginning in 1999 on arrangements to follow expiration of many provisions of the Compact in 2001; and (3) plan for economic consultations this spring with the FAS as called for by the Compacts.

Given our long history in administering these areas as trust territories, a broad range of U.S. domestic programs continue to operate now that the countries are independent, some specified in the Compact and others under separate authorities. Discussion at the IWG meeting will be based in part on summary tables which outline U.S. programs carried out in Freely Associated States. Draft tables are attached, with funding levels for FY 1995. We request that each agency provide additions or corrections to the tables by **March 12**, with approximately FY96 funding levels and FY97 estimates, so that we may provide as complete information as possible to the IWG.

We invite participants to come prepared to discuss their plans to begin agency reviews of federal programs and services available to the FAS, in light of the upcoming negotiations as well as the USG objective of promoting self-sufficiency in the FAS.

SENSITIVE BUT UNCLASSIFIED

The IWG meeting will be held in room 6210 at the Department of State. Principals at the Deputy Assistant Secretary level are invited to represent agencies with significant program responsibilities in the FAS; other agencies are invited to determine the appropriate level of representation. Please provide the name, phone and fax of the person responsible for coordination in this effort within your agency by **March 1.** Please provide your agency's comments on the program tables by **March 12.** And finally, please provide the name, date of birth and social security number of participants to the IWG by **March 31** to Ms. Gladys Williams, Office of Pacific Island Affairs, Department of State. She can be contacted at 202-647-3546, fax: 202-647-0118.

William J. Burns
Executive Secretary

Attachments:

1. Background Paper.
2. Marshall Islands Program Summary.
3. FSM Program Summary.
4. Palau Program Summary.
5. Executive Order 12569.
6. 1993 Review.
7. List of Addressees.

BACKGROUND

The United States ended its trust territory relationship and entered into Compacts of Free Association with the Marshall Islands (RMI) and Federated States of Micronesia (FSM) in October and November 1986, respectively, and with Palau in October 1994. Under the Compact, a number of U.S. federal programs and services were extended to the Freely Associated States (FAS) with the goal of promoting "economic advancement and self-sufficiency."

The Compacts will remain in effect for 15 years (except for security and defense provisions which are of longer duration). Negotiations are scheduled to open no later than October 1999 with the RMI and FSM on post-Compact arrangements. Prior to the start of the negotiations, the USG will need to conduct an overall review of its political, security and economic interests in the FAS. As part of that review, agencies will need to evaluate interests served by continuing programs to the RMI and FSM as well as make post-Compact program recommendations. Moreover, agencies will need to assess the effectiveness of current programs in terms of promoting self-sufficiency in the FAS and make program recommendations for the RMI, FSM and Palau for the years that remain up to the expiration of the Compacts.

Executive Order 12569 of October 16, 1986, established the Interagency Group on Freely Associated State Affairs "for the purpose of providing guidance and oversight with respect to the establishment and implementation of policy concerning the Compact and United States relations with the Freely Associated States." The Interagency Group is chaired by a designee of the Department of State and consists of representatives of the Departments of Interior, Defense, Commerce, Energy, and Justice, the Joint Chiefs of Staff, the Office of Management and Budget, the National Security Council, and such other departments and agencies as may from time to time be appropriate.

In order to carry out most effectively current USG responsibilities and to lay the groundwork for our future relations with the FAS, the Department of State considers that it is timely to: (1) identify all domestic USG programs currently carried out in the FAS; (2) initiate an assessment of the effectiveness of these programs, in light of our interests and obligations to move the FAS towards self-sufficiency; and (3) develop program recommendations for the RMI, FSM and Palau for the remaining years of the Compacts; and (4) develop post-Compact program recommendations for the RMI and FSM.

As a channel of discussion on economic development and self-sufficiency, the Compacts call for annual economic consultations. Economic consultations have been held twice - once with the RMI and FSM in 1994 in Washington, D.C., and subsequently in-country with the RMI, FSM and Palau in 1995. The State Department, in conjunction with the Department of Interior, plans to organize economic consultations for the RMI, FSM and Palau during the first half of this year in D.C. It is expected that federal agencies implementing programs and services in the FAS will participate in these meetings, and discussions should be used to assess the effectiveness of federal programs. It is anticipated that 2-day consultations will be held for each country with specific hours scheduled for each agency to discuss its relevant programs and services.

Summary tables of USG programs in the RMI, FSM and Palau are being prepared to facilitate IAG discussions and economic consultations.

2/1/97 TAB 2
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MARSHALL ISLANDS MATRIX
for FISCAL YEAR 1995

I. **COMPACT FINANCIAL ASSISTANCE** - Direct Payments (Authorized by the Compact Act and appropriated through the Office of Insular Affairs)

Section Number	Purpose	Fiscal Year 1995
103(h)(2)	Enewetak Operations (food assistance)	$1,089,000
103(i)	Rongelap Resettlement	6,979,000
103(k)	Enjebi	nil
103(l)	Bikini Resettlement	nil
111	Tax and Trade Compensation	1,996,000
177	Nuclear Claims	nil
211	Current	8,125,000
211	Capital	13,975,000
213	Kwajalien Impact	1,900,000
214	Energy Production	2,000,000
215	Communications Operations and Maintenance	300,000
215	Communications Hardware	nil
216	Maritime Surveillance	371,400
216	Medical Programs	531,600
216	Scholarships	797,000
217	Inflation	11,224,000
221(b)	Health and Education Block Grant	3,000,000
224	Ebeye Causeway	499,000
Sub-total		$52,787,000

II. **DIRECT PROGRAM ASSISTANCE** - Grant Expenditures (Authorized under the Compact Act, sections 105(h), 111 and 226, but paid through individual agencies)

Agency or Department		Fiscal Year 1995
Agriculture		43,696
Commerce		nil
Education (primary & secondary)		1,257,854
Environmental Protection Agency		90,570
Federal Emergency Management Agency		211,786
Health and Human Services		2,897,649
Interior		952,351
Director Grants (Technical Assistance)	768,000	
Operations and Maintenance Improvement Program	10,960	
Water Projects	148,268	
Anti-Substance Abuse Education and Public Service Announcements	8,705	
Youth Activities Programs	7,894	
Law Enforcement Training	4,340	
PIRAAP Review Meetings (anti-drugs)	3,534	
Historic Preservation Fund from fiscal year 1990	650	
Justice		nil
Labor		432
Sub-total		$5,454,338

III. **INDIRECT PROGRAM ASSISTANCE** (Estimated value; benefits accrue to the Marshall Islands, but no payments made to the Marshall Islands Government)

Agency or Department		**Fiscal Year 1995**
Interior		$545,000
Asian Development Bank	333,000	
Pacific Islands Training Initiative	75,000	
Close-Up Foundation	50,000	
Sea Grant	50,000	
Statistical Analysis	75,000	
Pacific Islands Health Officers Association	50,000	
University of Hawaii Pacific Business Center	12,000	
Energy (medical program)		6,800,000
Public Health Service		300,000
Sub-total		7,645,000

IV. **GUARANTEED FEDERAL SERVICES** (No payments to the Marshall Islands Government; the Office of Insular Affairs reimburses other Federal agencies)

Section Number	**Purpose**	**Fiscal Year 1995**
122	Foreign Service Institute training	90,000
221(a)	Weather Service	750,000
221(a)	Audits	321,380
221(a)	Postal Service	250,000
221(a)	Federal Aviation Administration	275,000
Sub-total		1,886,380

TOTAL COMPACT FINANCIAL AND PROGRAM ASSISTANCE 67,772,718

FEDERATED STATES OF MICRONESIA MATRIX for Fiscal Year 1995

I. **COMPACT FINANCIAL ASSISTANCE** - Direct Payments (*Authorized by the Compact Act and appropriated through the Office of Insular Affairs*)

Section Number	Purpose	Fiscal Year 1995
211(a)(2)	Current Account	$30,600,000
211(a)(2)	Capital Account	20,400,000
212	U.S. Military Civic Action Teams	1,000,000
214(b)	Energy Production	3,000,000
215(a)(2)	Communications Operations and Maintenance	600,000
216(a)	Maritime Surveillance/Medical Referrals/Scholarships	3,668,000
217	Inflation Account	25,576,000
221(b)	Health and Education Block Grant	7,000,000
	Other Construction	1,497,000
Sub-total		$93,341,000

II. **DIRECT PROGRAM ASSISTANCE** - Grant Expenditures (*Authorized under the Compact Act, sections 105(h), 111 and 226, but paid through individual agencies*)

Agency or Department		Fiscal Year 1995
Agriculture		$100,639
Commerce		663,104
Education (primary and secondary)		3,766,708
Environmental Protection Agency		592,606
Federal Emergency Management Agency		507,937
Health and Human Services		2,168,051
Historic Preservation, Advisory Council on (Interior)		211,837
Housing and Urban Development		38,306
Insular Affairs, Office of (Interior)		4,371,100
Capital Improvement	3,332,151	
Technical Assistance	1,038,949	
Labor		1,544,112
Transportation		4,637
Sub-total		$13,969,037

III. **INDIRECT PROGRAM ASSISTANCE** (*Estimated value; benefits accrue to the Federated States of Micronesia, but no payments made to the Government of the Federated States of Micronesia*)

Agency or Department		Fiscal Year 1995
Insular Affairs, Office of (Interior)		
Pacific Islands Training Initiative	75,000	
Close-Up Foundation	50,000	
Sea Grant	50,000	
Statistical Analysis	75,000	
Pacific Islands Health Officers Association	50,000	
University of Hawaii Pacific Business Center	12,000	
Sub-total		$312,000

IV. **GUARANTEED FEDERAL SERVICES** (*Unless asterisked, no payments to the Government of the Federated States of Micronesia; the Office of Insular Affairs reimburses other Federal agencies*)

Section Number	Purpose	Fiscal Year 1995
122	Foreign Service Institute training	$90,000
221(a)	Weather Service	750,000
221(a)	* Audits	630,000
221(a)	Postal Service	250,000
221(a)	Federal Aviation Administration	275,000
Sub-total		$1,995,000

TOTAL COMPACT FINANCIAL AND PROGRAM ASSISTANCE $109,617,037

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PALAU MATRIX
for Fiscal Year 1995

I. **COMPACT FINANCIAL ASSISTANCE** - Direct Payments (*Authorized by the Compact Act and appropriated through the Office of Insular Affairs*)

Section Number	Purpose	Fiscal Year 1995
211	Government Operations	$108,947,000
212(a)	Road Construction	53,000,000
212(b)	Capital Improvement	36,000,000
213	Military Rights Compensation	5,500,000
214	Energy Production	2,000,000
215	Inflation Adjustment	34,167,000
Sub-total		$239,614,000

II. **DIRECT PROGRAM ASSISTANCE** - Grant Expenditures (*Authorized under the Compact Act, sections 105(h), 111 and 226, but paid through individual agencies*)

Agency or Department		Fiscal Year 1995
Agriculture		$1,117,562
Commerce		19,987
Education (primary and secondary)		5,233,531
Energy		147,565
Environmental Protection Agency		1,446,245
Federal Emergency Management Agency		62,334
Health and Human Services		2,191,459
Housing and Urban Development		491,925
Insular Affairs, Office of (Interior)		4,833,857
Capital Improvement	4,520,989	
Land Survey Program	30,528	
President's Legal Counsel	7,473	
Statistical Training Workshop	102	
Compact Transition Assistance	20,219	
Economic Planning Advisor	48,756	
Junior Statesman Program	1,305	
Pharmaceutical Supplies Workshop	90	

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Hospital Electrical Engineer	5,000	
Engineers' Conference	2,028	
Hyperbaric Medical Technicians' Training	8,712	
National Sealant Conference and Workshop	2,100	
Marine Law Enforcement Program	2,999	
Pacific Islands Regional Anti-Substance Abuse Program (PIRAAP) Review Meetings	1,673	
PIRAAP Conference	20	
PIRAAP Army Ranger Training	2,244	
PIRAAP Youth Action Program II	21,780	
DARE Training	220	
Palau Agriculture Census	16,351	
Babeldaob Road Project	20,351	
Statistical Program Travel and *Per Diem*	20,514	
Project DARE Training	30	
Reg. Law Enforcement Anti-drug Training	3,906	
Reg. Law Enforcement Anti-drug Equipment	560	
Operations and Maintenance Coordinator	43,646	
Water System Operations and Maintenance	46,997	
Aimeliik Power Plant OH	20,250	
Justice		63,066
Labor		329,211
Transportation		443,942
Sub-total		$16,380,684

III. **INDIRECT PROGRAM ASSISTANCE** (*Estimated value; benefits accrue to Palau, but no payments made to the Government of Palau*)

Agency or Department		**Fiscal Year 1995**
Insular Affairs, Office of (Interior)		
Pacific Islands Training Initiative	75,000	
Close-Up Foundation	50,000	
Sea Grant	50,000	
Statistical Analysis	75,000	
Pacific Islands Health Officers Association	50,000	
University of Hawaii Pacific Business Center	12,000	
Sub-total		$312,000

Federal Register
Vol. 51, No. 202
Monday, October 20, 1986

Presidential Documents

Title 3—

The President

Executive Order 12569 of October 16, 1986

Management of the Compact of Free Association With the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau

By the authority vested in me as President by the Constitution and laws of the United States, including the Compact of Free Association (the Compact) and Public Law 99–239, (the Act), it is ordered as follows:

Section 1. *Responsibility of the Secretary of State.* The Secretary of State shall conduct the government-to-government relations of the United States with the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau (the "Freely Associated States"), including any subdivisions, officials or persons thereof, and may delegate or allocate such of his authority under this Order to such other United States officials as he may from time to time deem desirable. The authority of the Secretary of State shall include, consistent with Article V of Title One of the Compact and section 105(b)(1) of the Act, the establishment and maintenance of representative offices in the Freely Associated States and supervision of the United States representatives and their staff. The Secretary also shall provide, in accordance with applicable law, for appropriate privileges, immunities, and assistance to representatives to the United States designated by the Governments of the Freely Associated States, together with their officers and staff. In accordance with applicable law and the provisions of this Order, the Secretary also shall have the authority and responsibility to take such other actions as may be necessary and appropriate to ensure that the authorities and obligations of the United States set forth in the Compact and its related agreements and in the laws of the United States as they relate to the conduct of government-to-government relations with the Freely Associated States are carried out. The Secretary shall provide from appropriations made to the Department of State such funds as may be necessary to carry out the provisions of this Order in relation to the activities of the Department of State.

Sec. 2. *Responsibility of the Secretary of the Interior.* The Secretary of the Interior shall be responsible for seeking the appropriation of funds for and, in accordance with the laws of the United States, shall make available to the Freely Associated States the United States economic and financial assistance appropriated pursuant to Article I of Title Two of the Compact; the grant, service, and program assistance appropriated pursuant to Article II of Title Two of the Compact; and all other United States assistance appropriated pursuant to the Compact and its related agreements. The Secretary shall coordinate and monitor any program or any activity by any department or agency of the United States provided to the Freely Associated States and shall coordinate and monitor related economic development planning. This Section shall not apply to services provided by the Department of Defense to the Freely Associated States or to activities pursuant to Section 1 of this Order, including activities under the Peace Corps Act.

Sec. 3. *Interagency Group on Freely Associated State Affairs and the Office of Freely Associated State Affairs.*

(a) There is established an Interagency Group on Freely Associated State Affairs for the purpose of providing guidance and oversight with respect to the establishment and implementation of policy concerning the Compact and United States relations with the Freely Associated States.

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IV. **GUARANTEED FEDERAL SERVICES** (*No payments to the Government of Palau; the Office of Insular Affairs reimburses other Federal agencies*)

Section Number	Purpose	Fiscal Year 1995
122	Foreign Service Institute training	$90,000
221(a)	Weather Service	750,000
221(a)	Audits	321,380
221(a)	Postal Service	250,000
221(a)	Federal Aviation Administration	275,000
Sub-total		$1,886,380

TOTAL COMPACT FINANCIAL AND PROGRAM ASSISTANCE $258,193,064

(b) The Interagency Group shall consist of the Secretary of State or his designee, who shall chair the Group, and of the principal officers or their designees from the Departments of the Interior, Defense, Commerce, Energy, and Justice, the Organization of the Joint Chiefs of Staff, the Office of Management and Budget, the National Security Council, and such other departments and agencies as may from time to time be appropriate.

(c) The Interagency Group shall make such recommendations as it shall deem appropriate to the President, through the Assistant to the President for National Security Affairs, concerning United States relations with the Freely Associated States. The Interagency Group also shall provide such guidance as it deems appropriate to departments and agencies delegated authority by this Order concerning administration of laws with respect to the Freely Associated States.

(d) If any department or agency charged by this Order with implementation of the Compact or other laws of the United States with respect to the Freely Associated States concludes that noncompliance sanctions pursuant to section 105(g) of the Act are appropriate, it shall make appropriate recommendations to the Interagency Group. The Interagency Group shall consider these recommendations and report its findings to the President for his review in making that determination.

(e)(1) There shall be in the Department of State an Office of Freely Associated State Affairs to conduct United States relations with the Freely Associated States and carry out related matters, as the Secretary of State shall direct or delegate, and provide appropriate support to the Interagency Group.

(2) The Office shall be headed by a Director designated by the Secretary of State, to whom the Secretaries of State, Defense, and the Interior may, to the extent permitted by law, delegate any or all of their respective authorities and responsibilities as described in this Order, including the authority to supervise the United States representatives referred to in Section 4 of this Order. The Director shall serve as Executive Secretary of the Interagency Group.

(3) Personnel additional to that provided by the Secretary of State may be detailed to the Office by the Executive departments and agencies that are members of the Interagency Group, and by other agencies as appropriate. Executive departments and agencies shall, to the extent permitted by law, provide such information, advice, and administrative services and facilities as may be necessary for the fulfillment of the functions of the Office.

Sec. 4. *United States Representatives to the Freely Associated States.* The United States Representative assigned to a Freely Associated State in accordance with Article V of Title One of the Compact shall represent the Government of the United States in an official capacity in that Freely Associated State, and shall supervise the actions of any Executive department or agency personnel assigned permanently or temporarily to that Freely Associated State.

Sec. 5. *Cooperation among Executive Departments and Agencies.* All Executive departments and agencies shall cooperate in the effectuation of the provisions of this Order. The Interagency Group and Office of Freely Associated State Affairs shall facilitate such cooperative measures. Nothing in this Order shall be construed to impair the authority and responsibility of the Secretary of Defense for security and defense matters in or relating to the Freely Associated States.

Sec. 6. *Delegation to the Secretary of the Interior.* The following authorities are delegated to the Secretary of the Interior:

(a) Reporting to the Congress on economic development plans prepared by the Government of the Federated States of Micronesia and the Government of the Marshall Islands, pursuant to sections 102(b) and 103(b) of the Act;

(b) The determination required by section 103(e) of the Act concerning the qualifications of the investment management firm selected by the Government of the Marshall Islands;

(c) Reporting to the Congress with respect to the impact of the Compact of Free Association on the United States territories and commonwealths and on the State of Hawaii, pursuant to section 104(e)(2) of the Act; and

(d) Causing an annual audit to be conducted of the annual financial statements of the Government of the Federated States of Micronesia and the Government of the Marshall Islands, pursuant to section 110(b) of the Act.

Sec. 7. *Delegation to the Secretary of State.* The following authorities are delegated to the Secretary of State:

(a) Reporting to the Congress on crimes in the Federated States of Micronesia and the Marshall Islands which have an impact upon United States jurisdictions, pursuant to sections 102(a)(4) and 103(a)(4) of the Act;

(b) Submitting the certification and report to the Congress for purposes of section 5 of the Fishermen's Protective Act of 1967, pursuant to section 104(f)(3) of the Act; and

(c) Reporting, with the concurrence of the Secretary of Defense, to the Congress on determinations made regarding security and defense, pursuant to section 105(q) of the Act.

Sec. 8. *Supersession and Saving Provisions.*

(a) Subject to the provisions of Section 9 of this Order, prior Executive orders concerning the former Trust Territory of the Pacific Islands are hereby superseded and rendered inapplicable, except that the authority of the Secretary of the Interior as provided in applicable provisions of Executive Order No. 11021, as amended, shall remain in effect, in a manner consistent with this Order and pursuant to section 105(c)(2) of the Act, to terminate the trust territory government and discharge its responsibilities, at which time the entirety of Executive Order No. 11021 shall be superseded.

(b) Nothing in this Order shall be construed as modifying the rights or obligations of the United States under the provisions of the Compact or as affecting or modifying the responsibility of the Secretary of State and the Attorney General to interpret the rights and obligations of the United States arising out of or concerning the Compact.

Sec. 9. *Effective Date.* This Order shall become effective with respect to a Freely Associated State simultaneously with the entry into force of the Compact for that State.

Ronald Reagan

THE WHITE HOUSE,
October 16, 1986.

[FR Doc. 86-23810
Filed 10-17-86; 10:26 am]
Billing code 3195-01-M

UNCLASSIFIED

1993

FEDERAL SERVICES IN THE FREELY ASSOCIATED STATES

SUMMARY AND INTRODUCTION

In November 1992, the Interagency Group on the Freely Associated States (FAS) began to review federal programs and services provided to the Federated States of Micronesia (FSM) and the Republic of the Marshall Islands (RMI). This review, mandated by the National Security Council, was undertaken because we had no reliable estimate of total U.S. costs of programs and services provided the FAS, and there appeared to be inadequate oversight of the programs. As an initial step of this review, a complete inventory was compiled for the first time of the 253 programs of more than 40 U.S. departments and agencies operating in the FAS and their costs.

We learned that total federal expenditures for the RMI in FY 92 were about $102.5 million, or over $2000 per capita for a population somewhat over 48,000. In the FSM total expenditures were about $228 million, or over $1100 per capita for a population somewhat over 114,000. On a per capita basis, the FAS are the largest receipients of U.S. aid. On an absolute basis, they would fall around fifth, after Turkey and Russia.

As a second step, the IAG used the inventory to examine federal programs from a policy point of view. This paper summarizes the results of the review thus far, makes policy recommendations on federal programs in the FAS, and is designed to form part of a subsequent overall review of U.S. relations with the FAS at the mid-point of the period of U.S. funding of the Compact of Free Association.

The impact of federal programs in the FAS is distinctly mixed, and the goal of self-sufficency set in the Compact of Free Association is not in sight. Some programs where we have considerable control, such as telecommunications and housing finance, have made a significant contribution to development. Other important sectors, particularly education and health, are woefully inadequate by the standard of self sufficiency.

In spite of the long period of U.S. trusteeship, the FAS in many ways is comparable to the poorer third world countries. Over 70 per cent of the GDP in the FAS consists of U.S. grants, a substantial portion of aid is devoted to public sector wages and salaries, and 80 per cent of household income is spent on imported goods. A recent ADB study estimates that when Compact funds decline or end, the FSM (the RMI's situation is comparable) will face "unmanageable structural adjustment problems as real monetary income per capita could decline from $1050 in 1990 to $350 in 2002".

If we are to emphasize the achievement of as much self-sufficiency as possible during the second half of the Compact, we should:

1. Aggressively implement the economic development procedures as set forth in the Compact of Free Association Act (P.L. 99-239) in order to better focus the considerable resources we provide;

2. Improve U.S. agency staffing and coordination of the development strategy;

3. Seek the cooperation of the Freely Associated States and the Congress in adjusting programs and funding to more effectively promote self-sufficiency and development in critical economic sectors.

ASSISTANCE TO THE FREELY ASSOCIATED STATES

At the risk of some oversimplification, there are basically two ways in which the FAS are assisted by the U.S. The first of these is direct funding specified in the Compact of Free Association or accompanying legislation. "Direct funding" means programs for which a dollar amount is established by legislation. Examples are the sums specified in the Compact to mitigate nuclear test effects on certain atolls in the RMI, and the annual full faith and credit cash grants scheduled over 15 years to the operations and capital accounts of the RMI and the FSM. Using FY 92 to create a snapshot of federal funding, direct funding under the Compact was about $61 million for the RMI; for the FSM it was about $86.8 million.

This funding is distinct from the second general source of funds and services -- the operation of federal domestic programs in the FAS. These are generally mandated by the Compact or by accompanying or subsequent legislation, often without a specific dollar figure attached: "the programs and services of the following agencies shall be made available"; or "shall make available...at levels equivalent to those available to the Trust Territory of the Pacific Islands during the year prior to the effective date of this Compact, the services and related programs of...". Parenthetically, it should be noted that this type of wording creates some important questions which need consideration, e.g., does "programs and services" mean all the programs of an agency, including those not hitherto operating in the FAS? Are they to be provided indefinitely since the Compact is of indefinite duration? Agency views on this differ.

The inventory of these programs and services attempted to describe and establish a cost to the U.S. Government for every program active in the FAS in any of the last

three fiscal years (FY90-92). At present count, a total of 253 federal programs operate in the FAS, fairly evenly divided between the FSM and the RMI. Most of these operate as extensions of their domestic equivalents. They are wide ranging and include payment for transport of FAS mail, $4.5 million for Head Start, and subsidies that the FAS governments probably could not assume, e.g., loans for housing at one percent interest, loans for telecommunications development at below-market rates, infrastructure grants, small business loans at four percent interest, etc.

Again using FY 92 for a snapshot of funding, in the RMI we identified about $41.5 million of expenditures for federal programs and services; in the FSM, there was approximately $41.3 million. A significant part of the total (about $23.1 million), was spent by the Federal Emergency Management Agency (FEMA), which is obligated under the Compact to provide emergency assistance to these typhoon subject states. There are also large programs for health ($6.3 million for the Public Health Service), education ($7.5 million) and $11.4 million for eight agencies of the Agriculture Department.

Adding the two types of assistance, total federal expenditures for the RMI in FY 92 were about $102.5 million, or over $2000 per capita for a population somewhat over 48,000.

In the FSM, total expenditures were about $128.1 million, or over $1100 per capital for a population somewhat over 114,000.

This makes a grand total of about $230.6 million for U.S. expenditures for the FAS in FY 92. By way of comparison, on a per capita basis Israel receives about $666 of appropriated funds (this is not an entirely a balanced comparison since Israel has off-budget sources of assistance). Even on an absolute basis, the FAS are among the largest recipients of U.S. funding, falling just after Israel, Egypt, Turkey, and Russia.

COORDINATION OF U.S. PROGRAMS

The survey of programs and expenditures also led to some conclusions, confirmed by the subsequent policy review:

1. Lack of Oversight. While undeniably carrying out Congressional mandates, the economic development strategy was muddled by last minute amendments, and was undermined by inadequate implementation of the review and monitoring procedures. One of the primary goals of the Compact is promoting "economic advancement and self-sufficiency"; this is surely an attribute of the "full measure of

self-government" which the Compact seeks to provide. Yet there does not appear to be a specific connection between economic self-sufficiency and the agencies and types of programs mandated to operate in the islands.

It is important to recall that such a broad range of Federal programs was not originally intended. Instead, economic development was to be driven by a package of tax and trade incentives which were deleted from the Compact during final Congressional consideration. Many of the Federal programs were added in a last minute effort to compensate for the loss of essential elements of the economic development package. Unfortunately, this alternative approach appears to be less effective in promoting economic development and self-sufficiency.

Moreover, interagency discussions made clear that there is no well-coordinated U.S. strategy to follow up on efforts to promote economic self-sufficiency. The bases for a joint U.S.-FAS strategy are provided in provisions of the Compact which call for economic development plans, annual reports on the use of funds by the FAS states, and annual consultations on economic development. However, the Compact was brought into force by a waiver of the requirement for economic plans (which were subsequently developed), the FAS governments have not always submitted annual reports on a timely basis, and as of mid 1993 only one preliminaty consultation was held, with the FSM. The FAS states have in their economic plans development strategies, but there is little linkage or complementarity with U.S. agency activities. Indeed, there apparently is little, if any, contact between most U.S. agencies and FAS economic planners.

One of the reasons for this sitation is that the U.S. approached the RMI and FSM during the time they were trust territories in a similar manner to other insular possessions (such as Guam and Puerto Rico) rather than as foreign countries. In a foreign country with comparable programs, we would have a fully-staffed AID mission to coordinate the flow of funding and measure implementation. However, aid to U.S. possessions assumes effective self-governance and, therefore, no aid mission is perceived to be needed. Now that they have become independent countries, this dicotomy has blurred and raised a question about the need for better coordination of U.S. assistance.

Under the Compact Act, Section 105(b)), the Secretary of the Interior is responsible for monitoring any program or activity provided to the FAS and related economic development planning. Section 224 requires government-to-government agreements for programs that are not stipulated in the Compact. These agreements normally would require the involvement of the Department of State via the

Embassy. In essence, this means that programs and services may be provided to the FAS only after consultation with Interior and State. Until recently there was little attempt at complying with this oversight of federal programs.

2. Little Priority to Self-Sufficiency. Related to the lack of oversight is the fact that although it may promote some economic advancement, much of the assistance we are providing the FAS governments is not designed to result in self-sufficiency. For example, funding the transport of the FAS' mail is undoubtedly a useful service to the FAS (and what Congress intended), but without provisions for phase out/take over has little relation to self-sufficiency. Similarly, direct health care provided by PHS personnel does not seem to be related to any strategy for the development of an adequate health infrastructure.

Most agency programs have some elements which could encourage self-sufficiency, but agency representatives noted a tendency to take federal programs for granted. Indeed, some in the interagency group felt that the nature and extent of their programs, in fact perpetuated dependency.

3. Lack of Criteria. A special and unique relationship is of course created by the Compact. One of its facets is that many of our programs in the FAS do not meet the normal humanitarian or nation building criteria we use in providing assistance to other sovereign states.

4. Lack of USG Interagency Coordination. Perhaps because they are generally mandated by legislation, often as extensions of domestic programs, there is little interagency consideration or communication on U.S. programs in the FAS. While the Interior and State Departments are generally informed, the fact that funds come from so many different parts of the budget with different congressional oversight tends to limit discussion of programs to those immediately concerned and inhibits coordination and the formulation of an overall U.S. strategy.

Thus, State and Interior co-chaired the first-ever review of all programs beginning last November. This ongoing coordination process provides the best mechanism available to assess and monitor FAS programs.

THE PROGRAM REVIEW

In its policy review, the Interagency Group sought to determine what each agency's program accomplished during the first half of the Compact, what remains to be done, the contribution of programs to self-sufficiency, and the lessons learned (detailed questions we sought to answer are at attachment one). For convenience, discussion was

divided into infrastructure, the environment, social and education issues, and disaster assistance.

1. Infrastructure: Some Development Successes

There were some satisfactory results in the development of infrastructure. Perhaps the most successful and a model to be emulated wherever possible is telecommunications program administered by the Rural Electrification Agency. The REA believes that both the FSM and the RMI will have state of the art telecommunications systems when U.S. loan-financed projects are completed. The national telecommunications authorities are politically fenced off from other programs and the possibility of transferring funds; thus, the REA by its loan conditions can guarantee a pool of revenues earmarked for system use.

REA telecommunications loans to the RMI have totaled $22.7 million and to the FSM $41 million. The national telecommunications authorities in each nation have used the funds to expand service to additional subscribers, to obtain state-of-the-art equipment, and to install typhoon-proof underground lines.

In the FSM four new central buildings were completed and 480 miles of cable installed. Eventually, 7,000 subscribers will be served; 1,300 now have service. In the RMI three central office buildings have been completed and 125 miles of cable installed. The RMI system now serves 1,300; eventually it will serve 3,600. Both nations have made extensive and effective efforts to hire and train local workers, but providing adequate training courses in the islands has been a problem.

FAA assistance has been used to build and maintain navigation systems, to develop and publish approach and departure procedures, and, in the RMI, to upgrade the civil aviation establishment and aircraft to meet U.S. certification standards. The FAA also sponsors intensive training for FAS aviation personnel. It is establishing a fixed telecommunications network in the FSM, a project reimbursed by the FSM government.

The FAA noted that if airport revenues could be earmarked for aviation uses, (in the same manner that telecommunications revenues are for telecommunications uses), there would be adequate resources to support civil aviation development.

The Farmers Home Administration estimates that its program accounts for over 70 percent of operational and capital improvement financing for housing in the FAS - a level which might be beyond the ideal. The FmHA, which is protected from defaults by an escrow arrangement with the

FAS governments, has been forcing the development of housing standards and institutional structures involved with housing. However, the FmHA program could not be assumed by the FAS governments without U.S. financial support. Furthermore, FmHA's continued management and supervison may increase dependency rather than encourage the formation of effective indigenous institutions.

Some Lessons Learned from Infrastructure Aid

-- NOAA and others noted success in small development projects with FAS government involvement and a contribution of FAS funds.

-- Some agencies also noted better project results when U.S. and FAS agencies work together on projects.

-- In general, it appears that the more successful infrastructure projects are those that emphasize development of professional local managers, require funds generated to remain in the program to fund upkeep and maintenance, and which are supported by local contributions in the payment for services or through taxes.

-- Although FAS decision makers may wish to retain the possibility of transferring funds to other parts of the budget, we may want to require that port, utility and other autonomous authorities develop services that are maintained from segregated revenues, as is the case with REA and the Department of the Interior's Operations and Maintenance Improvement Program.

-- Nearly all agency representatives noted the problems of maintainance of equipment and infrastructure, which appear to affect nearly all U.S. programs. Interior has set up an effective O&M program with the islands, but it is not clear how we can encourage maintainance where we do not have specific leverage.

-- Compact funds are financing foreign, especially Japanese, contractors. The Compact does not contain a "buy American" requirement. U.S. firms allege this is because they cannot compete against foreign entities that do not have to follow U.S. requirements for minimum wage and safety standards. There is an authorization to offset the higher cost of hiring U.S. firms, but it has never been funded.

2. Environmental Assistance

In discussion of the environment, increasing FAS awareness was noted, exemplified in the formulation of national environment strategies by both the FSM and the RMI. In spite of $18 million of EPA grants over the last few years, drinking water and waste disposal remain

significant problems. There are still schemes in the RMI, thus far thwarted, to import U.S. or other waste for disposal.

On the other hand, some agency representatives cited continuous improvement in FSM natural resource agencies. In particular there were reports of success in small projects in which U.S. agencies cooperated and coordinated. It was noted that in many of the islands forest preservation is essential to water, soils, and agriculture and thus to any economic development. While progress in protecting the environment seemed slow, the situation did not yet seem critical; there had not to date been significant confrontations of development and environmental interests.

Given AID's environmental initiative in Asia (for which the FAS is eligible) and the environmental expertise which has been built up in the U.S., the environment might be a candidate for additional funding, perhaps by redirection of effort. Resources devoted to the environment in the FAS have, with the exception of EPA grants, been small. Preservation of the environment is basic to tourism, one of prime areas for development.

3. Disaster Assistance

Disaster assistance is a very significant part of U.S. funding for the FAS. In addition to a total of $23.1 million of assistance in FY 92 from the FEMA, there was $31.5 million to the FSM in FY 91 from that agency, and a total of $4.5 million in emergency food assistance from Agriculture's Food and Nutrition Service in FY 92.

Dealing in the same manner with the FAS as it does with American states, FEMA is a major source of funds for construction (or re-construction) of public facilities, as well as a source of support for temporary housing for individuals, and for construction to mitigate potential hazards.

FEMA and the Interior Department are trying to encourage a relationship between disaster planning and planning for public infrastructure and development. There are in addition problems of maintainance failures by the FAS which increase the damage caused by typhoons or are represented as hazard damage. The contribution of disaster relief programs to self-sufficiency is problematic - the FAS often use Compact funds to meet their matching funds requirements, the participation of the FAS governments in the programs is not great, and feeding programs tend to last several years (vs. 30 days in the U.S.).

4. Education and Social Assistance

In discussing social and health issues, there appeared an interagency consensus that these two critical areas for development are woefully inadequate. Strongly affected by the FAS's geographic separation and weak economies, the health situation is much like that of the poorer third world countries, characterized by a large percentage of young people, high birthrates, high infant mortality rates, malnutrition, and an increase in mental problems possibly due to the conflict between traditional and Western values.

It is obviously difficult to explain malnutrition, especially among children, in a country receiving $2000 per capita of U.S. funding. Since this appears largely to be a result of poor diet, not lack of food, it should be within the power of the FAS governments to do something about it. At the same time, we should assure that the U.S. programs involved in health education are doing all they can.

While the PHS sees some improvement in the health situation over the past five years, there is not an appropriate health infrastructure, and without PHS presence the health situation would stabilize at its low level or deteriorate. As noted above, about $6.3 million total was spent by the PHS in the FAS in FY 92. This included a PHS-sponsored medical training program that graduated its first trainees, but who are below the standard of physicians' assistants in the U.S.

The PHS supports community health centers, training of nurses, and inter alia provides block grants for child health, immunization and preventive health measures. It is not clear that the large number of individual grants provided to the FAS is the most effective use of our resources. We may wish to ask the Congress for authority to "bundle" grants in connection with a sectoral strategy for health.

In education, where at least half of the population is under 16, the resources allocated appear to be wholly inadequate to the numbers requiring education and the lack of basic materials and infrastructure. The lack of text books, particularly in the local languages, lack of trained teachers, primitive school facilities, some with real sanitation problems, and lack of teaching materials are all aggravated by the islands spread over long distances.

It was noted that when the Compact was signed, the FAS agreed to a phaseout of education funding in return for some of the funds granted in the Compact. The FAS later asked Congress to restore their elegibility for some

programs, such as Pell Grants, which has been done. Nevertheless, a quarter of those finishing elementary school do no not have places available to them in middle school. Peace Corps programs, also operating in the education area, seemed to be making a real contribution in the FSM, but not to be well utilized by the RMI. We may wish to examine the programs of some third world states that have done well with comparable, or fewer, resources.

In conclusion, the situation of the FAS at mid-point of the Compact in terms of the contributions of federal programs is spotty. If our goal is to achieve the greatest amount of economic advancement and self-sufficiency possible during the period of Compact funding, the results are thus far disappointing - over 70 per cent of the GDP in both states consists of U.S. grants, a substantial portion of aid is devoted to public sector wages and salaries, and, in turn, 80 per cent of household income is spent on imported goods. A recent ADB study estimates that when Compact funds decline or end, the FSM (the RMI's situation is comparable) will face "unmanageable structural adjustment problems as real monetary income per capita could decline from $1050 in 1990 to $350 in 2002".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Bethesda MD 20814

FEB 20 1997

Dear Colleague:

Enclosed is the third issue of *HIV FOCUS*, an information bulletin containing articles relevant to programs funded by Title III of the Ryan White C.A.R.E. Act. Please feel free to reproduce the bulletin and distribute it widely. If you need additional copies or further information about the bulletin, contact Diane Cairns of my staff at (301)594-4432.

Sincerely,

Deborah Parham

Deborah Parham, Ph.D., R.N.
Chief, HIV Primary Care Programs Branch
Bureau of Primary Health Care

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

Dear Colleague:

You may have seen recent media coverage on a number of issues relevant to perinatal HIV prevention. To update you on the latest research findings, the Centers for Disease Control and Prevention (CDC) has created the enclosed "Perinatal HIV Prevention Update."

The update discusses evidence of progress to date, the ongoing research to improve perinatal HIV prevention, and the importance of providing women and their physicians with the best possible information.

We hope you find this update useful.

Sincerely,

Melissa B Shepherd

Melissa Shepherd
Acting Associate Director
for Communications

Enclosure

CDC UPDATE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NCHSTP National Center for HIV, STD & TB PREVENTION

February 1997

Perinatal HIV Prevention Update

Evidence of Progress and Challenges for the Future

Over the past two years, researchers throughout the nation have documented dramatic declines in mother-to-infant (perinatal) transmission of HIV, indicating the success of recent perinatal prevention efforts. In 1994, clinical trials conducted by the National Institutes of Health (NIH) showed that HIV-infected women could reduce the risk of transmitting the virus to their babies by as much as two-thirds through administration of zidovudine (ZDV or AZT) during pregnancy, labor, and delivery, and by giving their babies AZT for the first 6 weeks after birth. In 1994, the Public Health Service (PHS) issued guidelines for using AZT during pregnancy, and in 1995, published guidelines for routinely counseling all pregnant women about HIV and offering them an HIV test.

As health care providers across the country have incorporated these guidelines into clinical practice, perinatal HIV transmission has dropped dramatically. On a national level, the number of children reported to CDC with perinatally acquired AIDS declined 27% between 1992 and 1995, with the most dramatic drop in cases occurring in 1994 and 1995. Additionally, research from numerous states has documented a declining rate of perinatal HIV transmission.

- Among women in CDC's Perinatal AIDS Collaborative Transmission Study (PACTS), AZT use increased following the publication of CDC guidelines, and the rate of perinatal transmission dropped from 21% to 11%. The PACTS study includes women from 4 cities, New York City, Newark, Atlanta, and Baltimore.

- Another multi-site study, the Women and Infants Transmission Study (WITS), tracks perinatal transmission in several groups of women from New York, Massachusetts, Illinois, Texas, and Puerto Rico. In the WITS study, the rate of perinatal transmission dropped to 8% in 1994, declining from a rate of 19% prior to the AZT guidelines.

- In North Carolina, perinatal HIV transmission dropped from 21% in 1993 to 6.2% in the first half of 1996.

Ongoing Research to Improve Perinatal HIV Prevention

Despite these encouraging findings, challenges remain for perinatal prevention. Perhaps greatest among these is the need to ensure pregnant women have access to quality prenatal care early in pregnancy and can sustain care throughout pregnancy and beyond. In order for HIV-infected women to benefit from treatment advances for themselves and their children, they must be reached early in pregnancy with the opportunity to learn their HIV status and to consider treatment for their health and for preventing transmission to their children. When women are provided appropriate information and counseling, studies show that acceptance of HIV testing and AZT treatment is extremely high.

Yet, some children are infected despite AZT use by their mothers. AZT is not 100% effective in preventing transmission, and a great deal remains unknown about the mechanisms by which AZT reduces transmission, as well as the potential for long-term side-effects for the exposed women and children. Moreover, new combination therapies offer promise for improved treatment for HIV-infected women. Researchers must

explore the possibility that AZT treatment during pregnancy may reduce the effectiveness of these therapies for women later in life. CDC, NIH, and other researchers continue to study these questions to determine if there are more effective, simpler, or safer preventive therapies or practices available. Research is ongoing in a number of areas:

- PACTS and WITS are evaluating the impact of other factors on perinatal transmission, such as the mother's stage of HIV disease, and the time from rupture of membranes (water breaking) to delivery. These studies have found that when a mother's membranes have ruptured more than 4 hours before delivery, the risk of transmission is increased. These findings suggest that changes in obstetric practice may also help reduce HIV transmission. If physicians can reduce the duration of ruptured membranes, the chances of transmission can likely be reduced.

- If a shorter course of AZT during pregnancy were shown to be as effective as the treatment regimen now recommended, both the costs and potential risks from AZT use could be reduced. In developing countries where over 90% of new HIV infections occur, the extensive AZT course now recommended in the U.S. is generally not feasible. CDC and other researchers are now working with researchers in developing countries to determine if administering AZT or other antiretrovirals for a shorter time period during pregnancy and/or during delivery will be as effective in reducing perinatal HIV transmission.

- New combination therapies using protease inhibitors in combination with existing antiretroviral drugs such as AZT and 3TC have recently been shown to reduce the amount of HIV particles circulating in the blood of some infected individuals to non-detectable levels. While no one yet knows how long this effect will last or impact the disease progression, these results are promising for the quality of life of HIV-infected individuals. To determine if these or other therapies may be as, or even more, effective than AZT alone in preventing perinatal transmission, NIH is beginning to study both the safety and efficacy of other options for perinatal prevention.

Efforts to Further Explore Potential Long-Term Side Effects

Neither the mothers nor the children studied have reported serious side effects immediately following the AZT regimen currently recommend. Effects have been limited largely to mild, reversible anemia in the infants. Researchers do not know if the mothers or the infants exposed to AZT will experience any side effects over time. Current recommendations stress that a woman should make a personal decision about taking AZT only after she discusses the benefits and potential risks for herself and her child with her health care provider. Researchers have long been aware that AZT could potentially cause rare long-term side effects, even though none have been reported to date in any of the exposed children. Since the discovery of AZT's effectiveness in perinatal HIV prevention occurred recently, the oldest children exposed to this regimen are now 5 years old. The guidelines recommend that they be followed until age 21 to ensure that any side effects are detected.

To further explore any theoretical or potential risks of long-term side effects of AZT, two laboratory studies have recently examined the question of whether AZT may cause cancer in the offspring of pregnant mice exposed to various doses of the drug. The relevance of these studies for human beings is not known, and the studies arrived at different conclusions. The first study was designed to determine if AZT, when given in extremely high doses to pregnant mice, could result in cancer in their offspring. Researchers found that when AZT is given in these high doses to pregnant mice, it can cause tumors in the liver, lung, and genital tract of their infants. The second study was designed to examine the long-term outcomes in the offspring of mice given much lower doses of AZT (designed to replicate the level of AZT in the blood of pregnant women following current treatment guidelines). This study found no increase in tumors.

The relationship between the doses of AZT used in these studies and those used in clinical practice in humans

is not well understood. Since very few drugs have been studied in mice, scientists do not know if these studies can be used to reliably predict long-term effects in humans. Moreover, mice metabolize AZT very differently than humans. For example, AZT collects in high concentrations in the urine of mice, but does not do so in humans. Tumors seen in the vaginal tract of mice could be related to the direct contact with urine. But researchers do not know the mechanisms by which AZT caused the tumors in mice. Researchers are therefore uncertain if the outcomes of either of these mouse studies have any relevance to human beings. At this point, the long-term risks to humans remain theoretical. NIH and CDC, along with a "blue ribbon" panel of scientific experts, have concluded that the dramatic benefits of AZT in preventing perinatal transmission far outweigh the hypothetical concerns raised by these mouse studies, and that the current treatment guidelines should not be changed. However, both agencies continue to support additional research and the practice of informing women of any potential risks of AZT use.

Providing Women and Their Physicians the Best Possible Information

As the science continues to evolve in all of these areas, it continues to be critical that women and their health care providers have the information they need to make the best decisions for their health and the health of their babies. Community leaders and organizations should play a key role in reaching women at risk with complete information in terms they can understand. The agencies of the PHS regularly review research findings, and when necessary, the PHS perinatal task force reviews all relevant guidelines. The perinatal task force will soon be convened to review recent data on other risk factors, alternate therapies for HIV-infected individuals, and potential toxicity of AIDS drugs. The task force will outline areas requiring further study and ensure that current guidance reflects knowledge to date.

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