

San Francisco General Hospital
Medical CenterSAN FRANCISCO GENERAL HOSPITAL
995 Potrero Avenue, Ward 84
San Francisco, Calif. 94110
(415) 821-5531MEMORANDUM

DATE: January 28, 1987

TO: AIDS Attending Staff

FROM: Donald I. Abrams, M.D.

RE: AIDS Consult Service Attending

We are currently in the process of seriously attempting to organize an official AIDS elective for house staff and medical students. The focus of the elective experience would be spending time on the inpatient AIDS consult services with some outpatient clinic time to complement the Ward experience. Certainly, it would be unreasonable to expect Michael Clement to be entirely responsible for the inpatient attending on this service twelve months of each year.

With the commitment involved for two months of medical attending, plus additional time attending on each of our subspecialty services it is also difficult to imagine making time to have another month of attending added to our annual teaching duties. To this end, Merle Sande has agreed, in theory, to allow staff willing to serve as AIDS inpatient attending to have only one month each year of general medical attending duties. The purpose of this communication is to poll the AIDS attending staff regarding interest and availability for serving as AIDS inpatient attending for at least one month each year.

Please indicate below your preferences and return this to my box as soon as possible.

Name: Constance Wotsy

I would be interested in being the AIDS consult service inpatient attending: Yes X No

If yes . . .

In addition to two months of medical attending: ☐

In exchange for one less month of general medical attending: ☒

For more than one month each year: ☐

A:cac
(0128da2)

*With some reservations - do hate to give up
Cpu medicine
but couldn't do both
Gave to give it a try!*

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

August 14, 1987

Martha Bert, M.D.
Urban Institute
2100 M Street NW
Washington, D.C. 20037

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Dr. Bert:

I am writing to express my interest in being a consultant to the planned NICHD research grant DBS-87-13 on social and behavioral aspects of health and fertility related behavior.

I have a particular interest in this area since I am the principal investigator of a research project called Project AWARE (Association for Women's AIDS Research and Education), which over the last two years has enrolled 700 sexually active women in a point prevalence study for HIV in San Francisco. From our experience in testing and counseling and my wider clinical experience with all AIDS risk populations, it is clear that merely making barrier protection available and instructing people in the need for AIDS prevention does not change behavior and thus prevent deaths. All aspects of behavior, expectation, societal mores, etc. must be investigated so that we can truly change behavior to adopt safer sex practices and avoid HIV and a wide variety of other sexually transmitted diseases for populations at risk.

Of particular interest is the opportunity to conduct prospective planning of the best means in which to integrate all aspects of knowledge and behavior that might lead to better health. We have been putting out fires in sexual protection area for some time, particularly with the AIDS epidemic. Good planning is needed.

I have attached a recent editorial that conveys some of my thoughts in the area of women who are infected with HIV.

I look forward to possible collaboration in this research endeavor.

Sincerely,

A handwritten signature in cursive script, reading "Con B Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Principal Investigator, Project AWARE
San Francisco General Hospital

CBW:m

encl

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Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

January 25, 1987

Claire D. Brindis, Dr.PH
Institute for Health Policy Studies
1326 Third Avenue
University of California, San Francisco
San Francisco, CA. 94143-0936

Dear Claire:

What a superb piece of work. You really should feel extraordinarily proud and it must feel like an albatross has been lifted from your shoulders, even if the mama albatross has been replaced perhaps by some albatross offspring. The HIV portion looks perfectly reasonably and I like the fact that it is not the main feature but rather just one of the multiplicity of issues that adolescents encounter.

Great Job!

Connie

Connie Wofsy

CW:sb

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

August 14, 1987

Nathan Clumeck, M.D.
Associate Professor and
Chief, Division of Infectious Diseases
Director, AIDS Activities
St. Pierre Hospital
Rue Haute, 322
B-100 Brussels
BELGIUM

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Nathan:

It caused my considerable anguish to relay the information to you in our telephone call today. Your grant proposal is splendid. Judith and I were very impressed at the thoroughness and quality of the proposal, especially since you had not previously made an application in NIH format.

I genuinely had no idea that you had not received a copy of the guidelines for the grant application indicating the three-part requirement. I had genuinely not realized at the initiation of our collaboration that this was a program project grant rather than the smaller RFA that would be a single well thought out project, such as the one you have drawn up in collaboration with our similar studies. To get a program project involves at least three areas, usually of different investigative topics. In order to be funded, all three projects must receive scores which merit funding. This would usually mean an epidemiology piece, for instance a virology piece, and a treatment piece. Likewise, the intent of the application is to have investigators in the United States go to the foreign country and spend considerable time in the foreign country. Obviously, we are not in a position to do that, nor is it required, since you, your colleagues, and laboratory collaborators have the full capabilities to carry out the research in a first-class way. The basis of our collaboration is obviously one of having similar projects which would allow superb comparison of similar populations and behaviors in two very different countries.

I feel chagrined that I did not anticipate these issues and contact you directly. We ourselves were in the midst of a very very large grant application procedure for an unrelated project, and I confess that it's easy to let other issues which seem to be less urgent take a backseat.

In my conversation with Dr. Miller, it was clear that there have been a number of letters of intent from a variety of institutions, many of whom are likely to more broadly fill the criteria of the

Nathan Clumeck, M.D.
August 14, 1987

Page 2

RFP. I am afraid that to try to expand to three full projects at this time is virtually impossible. Three full projects are not

In my conversation with Dr. Miller, it was clear that there have been a number of letters of intent from a variety of institutions, many of whom are likely to more broadly fill the criteria of the RFP. I am afraid that to try to expand to three full projects at this time is virtually impossible. Three full projects are not suggested by the study design, and it would require many additional collaborators, as each project must have its own subprincipal investigator.

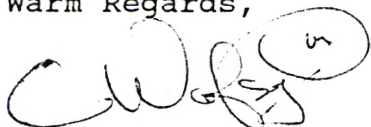
I hope the research project will proceed and look forward to collaborating regardless of NIH association. Upon return from my vacation at the end of August, I will explore the possibility further of an RO-1 grant application, though that too sounds like it is targeted very much at United States investigators setting up research projects in another country, rather than the funding going directly to foreign investigators. This is unfortunate, as the collaborative arrangement would be a very, very nice one.

I deeply regret my role in failing to recognize the scope of the project, and failing to realize that the NIH had sent me materials which were not available to you. Any neglect on my part was absolutely unintentional.

Since I looked at the application carefully, I thought I would attach some comments which you might find of use as you proceed with these projects. Really, there was very little that could be found that merited significant suggestion.

I will be in continued communication. My best wishes to Stephen DeWit. He has obviously put alot of effort into this, and it shows.

Warm Regards,

A handwritten signature in dark ink, appearing to read 'C. Wofsy', with a small circle around the 'y'.

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

cc: Judith Cohen

encls

COMMENTS - Grant Application: Heterosexual Studies in Belgium

Section II, Page 8, Aims, Item 5: Under the issue of cofactors, it would seem very valuable to look at the role of genital ulcers in the population at large if examination facilities are available. Later in the application, the intent to do pelvic examinations if clinically indicated is stated. One of the striking differences between the United States and Africa is the role of genital ulcers in both acquisition and transmission. It would be very fascinating to see if the presence of ulcerative lesions parallels cultural differences.

Page 10, last paragraph: A sentence such as "Belgium is unique in having a large African population residing in a Western European country, and thus offers an excellent opportunity to examine cultural, social, and economic factors that may contribute to spread" might be added somewhere and highlight the value of Belgium specifically for studying heterosexual transmission.

Page 11: In the typing, I think there are some addition errors in the numbers stated. 215 heterosexuals with 94 Caucasians and 118 Black, and then the numbers in parenthesis don't match. The list under the Caucasian group adds up to 149, which differs from the numbers listed up above.

Page 17, Four sexually active women: You have defined sexually active women as a woman with more than one regular male partner. Just for information, in our studies we have defined sexually active as five or more partners in the last three years. We decided it would be best to exclude the lowest risk individuals, that is, those with two, three or four partners.

Page 20, Questionnaire: In our questionnaire we have information about travel to other countries, etc, which would be interesting for comparison with Europe. I am sure that you have that included in your questionnaire, but I didn't see it mentioned.

Page 22: The NIH requires antibody results to be given to the individual. If this proposal is actually submitted at any time, it will be necessary to find some way to actively find the subject to give antibody results.

Since I have read the proposal carefully, I thought I would send these comments along to you for whatever usefulness they provide.

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Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

September 11, 1987

Barbara Coyle
Director of Education
Southern Tier AIDS Program Incorporated
65 Broad Street
Johnson City, New York 13790

Dear Ms. Coyle,

I am most appreciative of your invitation to speak to the Southern Tier AIDS program at their regional conference in April of 1988. Unfortunately, I must decline the invitation as I have a number of commitments in April which will involve travel away from San Francisco. It is rewarding to see the number of programs that are springing up all over the country, and I offer my sincerest support for your efforts and hope that you will be able to find a suitable speaker for the program. Since there have been so many cases there are now an increasing number of individuals with considerable experience in dealing with the patient care, political, and social issues surrounding AIDS.

Best wishes!

A handwritten signature in cursive script, appearing to read "C. Wofsy", is written over the typed name.

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:ms

SOUTHERN TIER AIDS PROGRAM INC.



September 3, 1987

Dr. Constance Wofsky
AIDS Unit
San Francisco General Hospital
1001 Potrero Ave.
San Francisco, CA 94110

65 BROAD STREET
JOHNSON CITY, NEW YORK 13790
OFFICE: 607-798-1706
HOTLINE: 607-723-6520

ADMINISTRATIVE:
EXECUTIVE DIRECTOR
CHARLENE LEE
DIRECTOR OF EDUCATION
BARBARA COYLE
DIRECTOR OF SUPPORT SERVICES
WILLIAM VAUGHAN

Dear Dr. Wofsky:

The Southern Tier AIDS Program has been providing services to people with AIDS and their families since 1984. Additionally, we provide education, training and prevention information to and eight county region in upstate New York.

We are beginning to organize a regional conference to be held in April of 1988. We would like to invite you to address the participants as the keynote speaker. Would you be kind enough to let me know if you are available, the most convenient dates for you, and the fees involved?

I hope I make look forward to working with you.

Sincerely,

Barbara Coyle
Barbara Coyle
Director of Education

BC/ra

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 23, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Ray Daniels
Senior Product Manager
Diagnostics Division
Abbott Laboratories
Abbott Park, IL 60064

Dear Ray:

The opportunistic infection section bibliography is enclosed. All references will ultimately have to be renumbered. Let me know if you need more information from. me.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

encl

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City and County of San Francisco

Department of
Public Health

San Francisco General Hospital
Medical Center



May 5, 1987

TO: Bonnie Dattel, M.D.

FROM: Connie Wofsy, M.D. *Connie Wofsy*

RE: Inservice--Vaginitis and Common GYN Problems

This is a confirmation of our previous discussion. We look forward to seeing you on Tuesday, May 19 at 8:00 AM in the Ward 86 Conference Room.

We are seeing more women and need updating on the approach to very common GYN problems: vaginitis, yeast, trichomonas, nonspecific vaginitis (+ herpes), and a mention of cervicitis, especially chlamydia and general evaluation. This conference is informal with MD's NP's and RN's in attendance. The pharmacist, Dr. Robbie Wong and staff have been developing a handout for routine treatment. A copy is attached for your review.

CW:m

enc

cc: L. Kaplan
R. Wong

MEDICATIONS TO TREAT VAGINAL
INFECTIONS

Bonnie - This is draft
with a few of my
concerns

I. Candida Albicans- yeast infections

- * Drugs of choice: Monistat Vaginal Cream or Suppositories or
- * Clotrimazole Vaginal Cream or Suppositories- Use one applicatorful or one suppository vaginally at bedtime for seven nights

Other drugs:

- * Nilstat Vaginal tablets- Insert one tablet daily for 2 weeks
- Mycelex G 100mg Vaginal tablets- Insert one tablet at bedtime for 7 nights
- Mycelex G 500mg Vaginal tablets- Insert one tablet at bedtime one time

II. Gardnerella (Hemophilis vaginalis)

- * Sultrin Triple Sulfa Cream and Vaginal tablets- Insert one applicatorful twice daily for 4-6 days or one tablet at bedtime and in the morning for 10 days
- AVC Cream or Suppositories (when H. vaginalis, C. albicans, or trichomonas vaginalis isolation is not possible)- Insert one applicatorful or one suppository daily or twice daily for one menstrual period

metronidazole 500mg po b.i.d x 7 days.

III. Trichomonas vaginalis

- * Drug of choice: Metronidazole 2 grams orally one time or 250mg three times daily for 7 days
- Vagisec Plus Suppository or douche- douche and insert vaginally one suppository each morning and at bedtime for 14 days

MEDICATIONS TO TREAT URINARY
INFECTIONS

I.A. Treatment of acute cystitis

for simple, uncomplicated, non-pregnant females, non-recurrent infection with duration less than 6 days

- * Septra DS 3 tablets X 1 or
- * Ampicillin 3 grams X 1 or
- Amoxicillin 3 grams X 1

B. Treatment of acute cystitis

for infections of duration longer than 6 days or recurrent infection

- * Ampicillin 250mg every 8 hours for 10-14 days
- Amoxicillin 250mg every 8 hours for 10-14 days
- * Septra DS one tablet twice daily for 10-14 days
- * Tetracycline 250mg every 6 hours for 10-14 days
- * Doxycycline 100mg one tablet twice daily for 10-14 days
- * Nitrofurantoin 500mg-1g every 6 hours for 10-14 days

- * For relief of dysuria- ^{pyridium} phenazopyridine 200mg three times daily (warning this drug colors urine orange, red or brown)

*I love it
Freud loves it! (Sigmund)*

II. Treatment of urethral syndrome
for patients with (sins) and symptoms of UTI but have less
than 10^7 bacteria under the microscope

- *Tetracycline 500mg four times daily for 7 days
- *Erythromycin 500mg four times daily for 7 days

III. Prophylactic treatment

for patients who have had greater than 3 UTI's in one year

- *Septra DS 1/2 tablet at bedtime or three times per week for 6 mos
- *Nitrofurantoin 50-100mg at bedtime for 6 months
- Methamine mandelate 500mg four times daily with 500mg vitamin C
- Trimethoprim 100mg at bedtime for 6 months

* indicates that the satellite pharmacy in building 90 stocks
this drug

T. White 4/87

R. Wong

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

September 4, 1987

Richard H. Davis, Ph.D.
City College of San Francisco
50 Phelan Avenue
San Francisco, California 94112

Dear Dr. Davis:

In anticipating the program for the City College students on November 5th covering the issue of "Clinical Manifestations of AIDS" I realize that I need to have a more specific understanding of what topics they will have heard. It is actually unusual to present the topic of clinical manifestations, per se, to a non-medical group. It will take a little bit of creativity on my part to present what is largely a medical topic to this non-medical audience. When I lecture to lay groups, including very educated and intelligent lay groups as your audience will be, I usually only briefly touch on clinical manifestations. What would help me is 1) a list of the times and topics and presentors that the students will be exposed to during the program so that I can know what they have had before me and what will come; 2) a brief paragraph describing your perception of what the students will be interested in that will come under the topic of "clinical manifestations".

Although it is tedious sometimes to do things by letter, I also realize that the game of telephone tag becomes so extensive for both of us that it is probably faster to slip something in the mail.

Best wishes.

Sincerely,

A handwritten signature in cursive script, reading "Constance B. Wofsy".

Constance B. Wofsy, MD
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CW/mc

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 28, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Richard Davis, Ph.D.
Department of Biology
City College of San Francisco
50 Phelan Avenue
San Francisco, CA 94112

Dear Dick:

More in our ongoing communication about the City College course. I have reviewed the topic headings that you have suggested might be included in the "Clinical Aspects of AIDS". To me, it reflects your extremely broad base of personal information and asks questions that are at the very cutting edge. It seems a little technical to me, but I'll do what I can. I think probably the best thing is for me just to come, to talk about AIDS from the perspective of a physician involved for six years and see where the thing goes. The ironic thing is that even for a "AIDS expert", it is no longer possible to know the cutting edge of all the questions there are.

We will see how it goes.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 13, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Joan S. Dorfamann, M.D., Ph.D.
Director, Maternal & Child Health
San Mateo County
225 W. 37th Avenue
San Mateo, CA 94403

Dear Dr. Dorfamann:

I have received your letter and questionnaire regarding perinatal and pediatric AIDS. I am astonished at the percent of children who are positive, 14 out of 28 is extraordinary. I am not completing the questionnaire, as it really isn't germane to what I do. I see no pediatric AIDS, and our exposure to pregnant women is only through research avenues. I presume that you have sent the questionnaire to the departments of pediatrics and obstetrics and gynecology at San Francisco General Hospital. They would be in a much better position to respond to the mechanisms that take place at this institution.

Best wishes.

Sincerely,

A handwritten signature in cursive script, reading "Con B Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 28, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Irene Gilbert Gibson
[REDACTED]
[REDACTED]

Dear Ms. Gibson:

I am delighted to hear that the AIDS/ARC Update was of value to you, and that there is representation from Stanislaus County and the many other parts of California at in-depth discussions of AIDS. In reference to the six tests you recall listed which included HIV and guaiac, I must say that I have no recollection and am not able to provide you with the information you are seeking. I never write my talks down, and the slides become dispersed very quickly into other talks in different formats. So, I unfortunately, have no way of going back and determining what my comments were at the time. I suspect that I may have said something along the line of how important routine tests are, such as checking blood pressure, doing a stool guaiac, doing a pap smear, etc, in general preventative medicine. And, that I hope a time will come when HIV carries no greater stigma than these tests, so that we can incorporate it into the general medical workup. Unfortunately, routine incorporation to the medical workup at this time is not feasible.

Best wishes in your work in Stanislaus County.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

IRENE GILBERT GIBSON

[REDACTED]

September 17, 1987

Dear Dr Wofsy,

In July, I attended the AIDS Update Conference in San Francisco, along with a small contingent from Stanislaus County. It was a wonderful opportunity to exchange ideas and information and renew our spirit and energies to do what we can to stem the advance of AIDS.

Something you said, and had on a visual, repeats itself in my head. I have misplaced my notes, and am not sure that I captured the entire thing. Therefore, I have

telephoned Angie Lewis today
to learn how to contact you.

Now I am writing to ask if
you would be so kind as
to tell me what you said about
a dream you hold for the
future when HIV will be one of
the routine tests included in
anyone's workup or regular physical
examination. As I recall, the
visual listed about six tests,
but I can remember only HIV
and quiac.

for your convenience I am
enclosing a self-addressed-stamped-
envelop (ala Sierra Club SASE).

I want to let you know that I
thought the whole conference was
excellent and your presentation particularly
inspiring. Thank you.
Very truly yours, Irene Wilson

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

November 25, 1987

Laura Grandin, Ph.D.
Chairperson
Mayor's Advisory Council on
Children, Youth and Families
City and County of San Francisco
City Hall
San Francisco, CA. 94102

Dear Dr. Grandin:

Thank you for your kind invitation to participate in the San Francisco Youth AIDS Education Round Table on December 18, 1987. I am honored to be asked; unfortunately, I must be excused from attending inasmuch as there is an unavoidable conflict with a previously scheduled meeting.

Best wishes for the success of this worthwhile conference.

Sincerely,

A handwritten signature in cursive script, reading "Constance B. Wofsy".

Constance B. Wofsy, M.D.
Co-Director
AIDS Activities Division
Assistant Chief
Infectious Diseases
San Francisco General Hospital

CW:sb

Laura Grandin, Ph.D.

November 18, 1987

Dear Colleague:

The Center For Disease Control in Atlanta, Georgia recently received a significant budget augmentation for use in educating children and youth about AIDS, on a nationwide basis. Ms Laurie Sherman, the Director of the National AIDS Information Campaign for CDC, and her staff, have extensive, current information about AIDS and a thorough knowledge of AIDS education campaigns for adults, but they aren't as well informed about how to reach young people.

I agreed to convene a Round Table of key San Francisco policy-makers, service providers, and youth educators to meet with Ms Sherman, to help shape the national youth AIDS education campaign. Ms Sherman will show videotapes of current CDC AIDS education efforts, and educate us about the CDC's "America Responds To AIDS" campaign, of which the youth education project is a part.

I am inviting you to participate in the San Francisco Youth AIDS Education Round Table. While the purpose of the Round Table is to provide guidance to the Center For Disease Control, in the development of its children and youth AIDS education campaign, we will also use this opportunity to talk among ourselves and to review the goals, objectives and status of San Francisco's own youth AIDS education efforts.

This will not be an opportunity to solicit funds from CDC, but an information sharing and advisory session. Please come prepared to share your thoughts on some of the following kinds of questions:

1. What should be the chronological parameters for youth AIDS education?
2. Which are the high-risk youth target populations?
3. What do kids need to know about AIDS? What are the most important messages an effective AIDS education campaign would convey?
4. What is the best way to teach kids what they need to know about AIDS? scare tactics? low key teaching? referrals to local AIDS education resources?
5. What is the best vehicle for teaching kids what they need to know about AIDS? T.V. commercials? radio commercials? billboards? transit signs? personal information packets? classroom curriculum?

6. To whom do kids listen? sports heroes? rock stars? other kids? physicians? young adults?
7. What is the best way to deal with the denial of mortality so characteristic of young people?

Ms Sherman will fly out from Atlanta to consult with us on Friday December 18, 1987. We will convene promptly at 9:00 am and we will finish by noon. The meeting will be held in the library at the Hall of Flowers, in Golden Gate Park. (As you enter the park from the Sunset side, on 9th Avenue at Lincoln, the Hall of Flowers is the building to your immediate left.)

Due to the nature of our task and the size of the meeting room I am limiting the group to twenty-two invitees who provide a broadly representative range of information about youth and AIDS. Ms Sherman and I will be preparing information packets for each of you, so please confirm your attendance by calling me at 681-4745. If I don't hear from you by November 30, 1987 I will not plan on your attendance on December 18th.

Thank you for taking the time to participate in this important effort.

Sincerely,

Laura Grandin, Ph.D.

Laura Grandin, Ph.D., Chairperson
Mayor's Advisory Council
On Children, Youth and Families

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 29, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Marlene E. Haffner, M.D.
Director, Office of Orphan
Products Development
Food and Drug Administration
Rockville, MD 20857

Dear Dr. Haffner:

We all very much enjoyed the opportunity to meet you and Mr. Sturniolo during your visit on July 15. We take great pride in our study and were gratified in your interest. I hope everything proved satisfactory. I also hope that all went well with the hearings that really brought you to San Francisco in the first place.

I am enclosing the acknowledgment of invitation to act as a field reviewer and have checked the "I regret that I am unable to accept your invitation" box. I truly wish that I were able to do all of the important tasks that need to be done. As one of the epicenters of the AIDS epidemic, so much AIDS related material comes our way that it would be best for me not to commit to an additional activity on any kind of regular basis. As you know, I recently reviewed a grant for the FDA and would consider episodically doing so again in a similar situation. I would, however, rather not be on the list to regularly review grants, particularly as many of the applications lie outside the area of AIDS related activities.

Best wishes. I look forward to seeing you again.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

encl

ACKNOWLEDGMENT OF INVITATION

Food and Drug Administration
Office of Orphan Products Development (HF-35)
5600 Fishers Lane, Room 12A40
Rockville, Maryland 20857

☐ I am pleased to accept your invitation as a consultant Field Reader and await further correspondence regarding the agenda and schedule. (Please include a copy of your current curriculum vitae with this form.)

☒ I regret that I am unable to accept your invitation.

Constance B. Wofsy
(Signature)
7/25/87
(Date)

Medical Speciality: (Please indicate area for assignment of reviews.)

Mailing Address: (In order to use express mail service it is necessary to have additional information such as name of building, room number, etc. Please make additions and corrections if needed.)

Constance B. Wofsy, M.D.
San Francisco General Hospital
995 Potrero Avenue, Ward 84
San Francisco, CA 94110

Telephone: (Please include area code.)

415-821-5531



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 8 1987

Constance B. Wofsy, M.D.
San Francisco General Hospital
995 Potrero Avenue, Ward 84
San Francisco, CA 94110

Dear Dr. Wofsy:

On behalf of the Commissioner of the Food and Drug Administration (FDA), it is a pleasure to invite you to become a consultant Field Reader for the Office of Orphan Products Development. Field Readers will have primary responsibility for evaluating research grant applications to support clinical research on the safety and effectiveness of orphan products.

In recent years there has been an increasing interest in the plight of patients with rare diseases who are being deprived of demonstrated or potentially useful drugs, medical devices, and foods for special medical purposes because there are inadequate resources to support research in this area. In addition, certain products are considered potentially useful in patients with common diseases but they lack commercial sponsorship for one of several reasons such as their patentability status. Of further concern are marketed products that appear to be beneficial for serious conditions with no established therapy or to have a therapeutic advantage over other available agents but are not labeled for use in those conditions because additional confirmatory studies are required.

Although the pharmaceutical industry has made a significant number of drugs available for the treatment of uncommon diseases over the years and the federal government, private foundations, and disease-oriented organizations have supported research, it was generally agreed that additional efforts were needed. A number of programs including the Orphan Drug Act were, therefore, implemented during the past several years.

One of these was the establishment by FDA of an Office of Orphan Products Development to identify and facilitate the availability of promising orphan products. Part of this program involves the support of research by means of grants to researchers from FDA's budget as appropriated yearly. A request for applications (RFA) is issued when funds are made available, and grant applications are received.

Such proposals, by government regulation, are open both to academic researchers and for-profit firms.

A list of the applications funded as a result of our previous RFA is appended.

When grant applications are submitted to FDA they undergo initial review by Field Readers (extramural consultants with expertise in the specific areas encompassed by the application). This consists of an in-depth review of the scientific merit of each application. A second level review of all grant proposals is conducted by a National Advisory Council which prioritizes the proposals on the basis of the comments from the Initial Review Group and on adherence to the goals of the Orphan Products Development Program. Proposals chosen for grant support are monitored by FDA scientists to assure that the study designs are appropriate to meet our objectives of securing data useful in consideration of marketing approval.

As a participant in this process, you will evaluate the proposal and prepare a written report on its merits. No travel will be involved.

This Office depends on the peer review process and on experts like you to evaluate the quality, originality, significance, need, and probable contribution of each application seeking support from this office.

I hope you will find it possible to accept this invitation and give us the benefit of your valued counsel. You may indicate your acceptance or declination by signing and returning the enclosed Acknowledgment of Invitation.

If you have any questions about the work of the Orphan Products Development Field Readers, please feel free to contact Ms. Carol Wetmore at telephone [REDACTED].

I appreciate the many demands on your time, but hope that you will be able to accept this important appointment.

Sincerely yours,

Carol A. Wetmore

for Marlene E. Haffner, M.D.
Director, Office of Orphan
Products Development

Enclosures

GRANT AWARDS

Office of Orphan Products Development
Food and Drug Administration
September 1986

MOUNT SINAI SCHOOL OF MEDICINE, New York, New York
Louis M. Aledort, M.D.
Immunoadsorption for Inhibitors to Factors VIII and IX

NEW YORK MEDICAL COLLEGE, Valhalla, New York
Karl E. Anderson, M.D.
LHRH Analogue for Prevention of Porphyria Attacks

UNIVERSITY OF MICHIGAN, Ann Arbor, Michigan
George J. Brewer, M.D.
Maintenance Therapy of Wilson's Disease with Zinc

CASE WESTERN RESERVE UNIVERSITY SCHOOL OF MEDICINE, Cleveland, Ohio
Gary M. Brittenham, M.D.
Chelation Therapy of Iron Overload with Oral PIH

THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, Baltimore, Maryland
Saul W. Brusilow, M.D.
Urea Cycle Enzymopathies; Phase III Studies of Phenylbutyric Acid

REGENTS OF THE UNIVERSITY OF CALIFORNIA, Irvine, California
M. Arthur Charles, M.D., Ph.D.
Use of Programmable Implantable Insulin Pump in Unstable Diabetes

UNIVERSITY OF ARIZONA, Tucson, Arizona
Paul F. Consroe, Ph.D.
Clinical Trial of Cannabidiol in Huntington's Disease

BIONEXUS, INC., Raleigh, North Carolina
Mr. Charles DeSmet
Treatment of AV Malformations with n-Butyl Cyanoacrylate

BIONEXUS, INC., Raleigh, North Carolina
Mr. Charles DeSmet
Treatment of Corneal Perforations with Butyl Cyanoacrylate

WAKE FOREST UNIVERSITY, Winston-Salem, North Carolina
James C. Eisenach, M.D.
Epidural Clonidine for Postoperative Pain Control

HEALTH SCIENCES, COLUMBIA UNIVERSITY, New York, New York
Stanley Fahn, M.D.
Botulinum Toxin Injection for Spasmodic Torticollis

GRANT AWARDS (Continued)

Office of Orphan Products Development
Food and Drug Administration
September 1986

BAYLOR COLLEGE OF MEDICINE, Houston, Texas
George D. Ferry, M.D.
Olsalazine Treatment of Childhood Ulcerative Colitis

UNIVERSITY OF IOWA, Iowa City, Iowa
Gail A. McGuinness, M.D.
Dexamethasone to Prevent Bronchopulmonary Dysplasia

KENNEDY INSTITUTE, Baltimore, Maryland
Hugo W. Moser, M.D.
Glycerol Trioleate Therapy for Adrenoleukodystrophy

RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER, Chicago, Illinois
Richard D. Penn, M.D.
Intrathecal Baclofen for Severe Spasticity

DUKE UNIVERSITY, Durham, North Carolina
Charles R. Roe, M.D.
Carnitine and Acetylcarnitine in the Organic Acidurias

STANFORD UNIVERSITY, Stanford, California
Ron G. Rosenfeld, M.D.
Growth Hormone Therapy in Hypophosphatemic Rickets

UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER, Denver, Colorado
Barry H. Rumack, M.D.
Hydroxocobalamin/Thiosulfate as a Cyanide Antidote

DANA-FARBER CANCER INSTITUTE, Boston, Massachusetts
Stephen E. Sallan, M.D.
Studies on Asparaginase in Childhood Acute Lymphoblastic Leukemia

REGENTS OF THE UNIVERSITY OF CALIFORNIA, La Jolla, California
Deborah Shure, M.D.
Clinical Trial of Pulmonary Angioscopy

CHILDREN'S HOSPITAL CORPORATION, Boston, Massachusetts
S. T. Treves, M.D.
Radionuclide Angiocardiography with Iridium-191m

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86N-04161]

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the anticipated availability of funds for Fiscal Year 1987 for awarding grants to support clinical trials on safety and effectiveness of orphan products. FDA expects to award up to 30 grants ranging from \$20,000 to \$70,000 in direct costs per annum for up to 3 years. Applications exceeding these limits will be considered nonresponsive.

DATES: Applications must be received by March 6, 1987. The earliest beginning date for awards is September 1, 1987.

ADDRESSES: Requests for application forms should be submitted to, and application kits are available from, Olia M. Hopkins, address below.

FOR FURTHER INFORMATION REGARDING THE PROGRAMMATIC ASPECTS OF THIS NOTICE CONTACT:

Benjamin P. Lewis, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rm. 12A-40, Rockville, MD 20857, 301-443-4903.

FOR FURTHER INFORMATION REGARDING THE FINANCIAL ASPECTS OF THIS NOTICE CONTACT:

Olia M. Hopkins, State Contracts and Assistance Agreements Branch (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rm. 15A-17, Rockville, MD 20857, 301-443-6170.

SUPPLEMENTARY INFORMATION: FDA will support the clinical studies covered by

this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 13.103.

I. Background

FDA has established the Office of Orphan Products Development to identify and facilitate the availability of orphan products. Orphan products are drugs, biologics, medical devices (including in vitro diagnostics), foods for medical purposes, and veterinary products that may be useful in an uncommon or common disease but that lack committed commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products for which there is evidence suggesting usefulness in an uncommon serious disease but which are not labeled for that disease because substantial evidence of safety and effectiveness for that use is lacking.

One way to make orphan products more easily available is to support research to determine whether the products are safe and effective. FDA has allocated funds to support such research since Fiscal Year 1983. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

II. Research Goals and Objectives

A. Clinical Studies

As a rule, FDA will only consider awarding grants to support clinical studies for determining whether the products are safe and effective for premarket approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or under section 351 of the Public Health Service Act (42 U.S.C. 262). These clinical studies may be designed to assist in the approval of unapproved products or of unapproved new uses to already marketed products.

Ordinarily, at least some preliminary clinical research suggesting effectiveness and relative safety should already be available. However, FDA will also consider applications concerning products for which persuasive pharmacologic evidence is available that a product has a reasonable possibility of being effective even though no clinical trials have yet been performed.

Applications should be for one discrete clinical trial. The applicant must provide supporting evidence that the product to be investigated is available to the applicant in the form needed for the clinical trial.

Because funds are limited, FDA cannot consider large research projects involving many subjects (human or animal, in the case of a veterinary drug) and long-term followup. The typical study that FDA will consider for support may involve up to several dozen subjects, will be well-controlled, and will be designed to provide substantial evidence of the product's safety and effectiveness.

The agency will also consider funding pharmacokinetic studies if such studies are necessary to determine safe and effective doses in subjects with serious organ disease that might affect drug disposition. However, FDA will only consider pharmacokinetic studies if they are part of studies for determining effectiveness of a product or a proposed to obtain information about products about which there is already a significant amount of evidence showing effectiveness. FDA's standards for adequate and well-controlled studies should be followed. In designing a well-controlled study, the investigator should especially keep in mind that historical controls or use of the subject as his or her own control are generally less desirable and reliable than a active control or, when ethical, placebo controls. The applicant's proposal should provide a rationale for use of the control method chosen to satisfy considerations of scientific quality and ethical realities.

In the case of veterinary products, research studies should be designed to show the safety and efficacy of a product for which there is some evidence that treatment of animals with it could lead to the prevention or mitigation of a serious zoonotic disease in humans.

B. Significance

Each investigator submitting a grant application for a proposed human or veterinary orphan use in response to this request for applications should include a short statement explaining why preliminary evidence suggests that the product meets the objectives of the orphan products development program and why the product to be studied is an orphan product as described in the "Background" section of this notice. This statement should appear in the application under section 2—"Significance."

C. Statistical Support

Statistical expertise is helpful in the planning, design, execution, and analysis of clinical investigations and clinical pharmacology to ensure the validity of estimates of safety and

efficacy obtained from human studies. Applicants are expected to provide a statistical justification for the number of patients chosen for the trial based on the proposed outcome measures. Applicants should also document the appropriateness of the statistical procedures to be used in the analysis of the results.

D. Journal References

Published reports are necessary and often critical for the review process and can help to support the investigator's research intent. Applicants should include six copies of reprints of all relevant references for FDA review. This includes favorable and unfavorable reports.

III. Human Subject Protection and Informed Consent

A. Research Involving Human Subjects

If the research involves human subjects and is not exempt from human subject review, the applicant must include a completed signed HHS 596 form, without which the application will not be reviewed. Applicants should carefully review the section on human subjects on pages 3 and 4 of the instructions in the application kit. In addition, applicants must provide information about six items described in section 2-E of the instructions in the application kit. These six items include: the characteristics of the subjects, the sources of research materials, recruitment plans and consent procedures, any potential risks, procedures for protecting against or minimizing potential risks, and potential benefits to the subjects. Failure to include this information may result in deferral of the application. The goal should be to include enough information in a sufficiently clear fashion so that reviewers will not have to delay action on the application while obtaining more information.

B. Informed Consent

Consent and/or assent forms and any additional information to be given to a subject must accompany the grant application (Form PHS 398). Failure to include this information may result in deferral of the application. Information that is given to the subject or the subject's representative shall be in language that the subject or his or her representative can understand. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or by which the subject or representative releases or

appears to release the investigator, the sponsor, or the institution or its agents from liability.

If a study involves both adults and children, separate consent forms should be provided for the adults and for the parents or guardians of the children.

C. Elements of Informed Consent

The elements of informed consent are as stated in the regulations at 45 CFR 46.116 and 21 CFR 50.25; they are as follows:

1. Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject:

(a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(b) A description of any reasonably foreseeable risks or discomforts to the subject.

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(e) A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that FDA may inspect the record.

(f) For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject.

(h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently foreseeable.

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(c) Any additional cost to the subject that may result from participation in the research.

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(f) The approximate number of subjects involved in the study. The informed consent requirements are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

Nothing in this notice is intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable Federal, State, or local law.

IV. Reporting Requirements

A financial status report must be submitted no later than 90 days after the close of each budget period. Annual progress reports must be submitted with all noncompeting continuation applications. A final progress report and invention statement must be submitted by 90 days after the expiration date of the approved project period.

V. Mechanism of Support

A. Award Instrument

Support will be in the form of grant awards which will be subject to all policies and requirements that govern the research grant programs of the Public Health Service, including the provisions of 42 CFR Part 52 and 45 CFR Part 74. The regulations promulgated under Executive Order 12372 do not apply to this program.

All grant awards are subject to the requirements for clinical investigations imposed by sections 505, 507, 512, and 515 of the Federal Food, Drug, and Cosmetic Act; section 351 of the Public Health Service Act; and regulations

promulgated under any of these sections.

B. Eligibility

These grants are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity.

C. Length of Support

The length of the study will depend upon the nature of the study. FDA anticipates that a majority of the studies can be completed in 1 year. As to those studies the expected duration of which is more than 1 year, continuation of support beyond the first year will depend on (1) performance during the preceding year and (2) the availability of funds.

D. Funding Plan

The number of studies funded will depend on the quality of the applications, the probable importance of the product, and the availability of funds.

VI. Review Procedure and Criteria

A. Review Method

All applications responding to this request for applications will be reviewed for scientific and technical merit by experts in the field of the subject of such specific application. The experts will review and evaluate each application based on its scientific merit. The applications will also be subject to a second review to evaluate them in light of the aims of the Orphan Products Development Program. Applications will also be reviewed before issuance of an FDA grant award to ensure to the extent practicable that proposed studies are consistent with requirements for investigations and marketing approval under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

B. Review Criteria

Applications must be responsive to this request for applications. Applications that are judged to be nonresponsive will be referred to the National Institutes of Health (NIH) for consideration as unsolicited applications if both the applicant and NIH concur. Absent concurrence by either the applicant or NIH, the application will be returned to the applicant. Applications will be reviewed according to the following criteria:

1. Responsiveness to this request for applications with specific emphasis on:

- (a) Whether the product is an orphan product.
- (b) Whether the proposal contains one discrete clinical trial.

(c) Whether there is supporting evidence that the product is available to the applicant in the form needed for the investigation.

(d) Whether the product is subject to premarket approval by FDA.

(e) Whether the proposed study can be completed within the budget and time limitations as stated in this request for applications.

2. The soundness of the rationale for the proposed study.

3. The appropriateness and quality of the study design.

4. The adequacy of the evidence that the proposed number of subjects can be recruited and the study completed during the proposed project period.

5. The adequacy of plans for complying with regulations for protection of human and animal subjects.

6. The qualifications of the investigator and support staff and resources available to them.

VII. Submission Requirements

The original and six copies of the completed application should be delivered to, and application kits are available from, Otia M. Hopkins, address above.

Note.—The application should not be mailed to NIH.

The outside of the mailing package and the top of the application face page should be labeled "Response to RFA-FDA-OP-87-1."

Applications must be received by 5 p.m. on March 6, 1987. A package carrying a legible proof-of-mailing date assigned by the carrier, which date must be no later than 1 week prior to the date of receipt, is also acceptable. The date of receipt will be waived only in extenuating circumstances. To request such a waiver, the applicant should include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of an application. Unless a waiver is granted, applications received after the deadline will be returned to the applicant.

Completed Form PHS 398, "Application for Public Health Service Grant." Part of section 2—"Significance"—should include a short statement of why the product is appropriate to the objectives of the Orphan Products Grants Program.

If human subjects are involved, completed Form HHS 596, "Protection of Human Subjects," Assurance/Certification/Declaration (part of Form PHS 398) and Human Subject Consent Forms and/or Assent Form(s) should be submitted.

Six copies of all reprints critical to the review process should accompany the Form PHS 398 grant application.

Note.—The forms and reprints described above are to be mailed to FDA as stated in the address section of this notice. The NIH mailing label at the end of application kit should not be used.

VIII. Method of Application

A. Format for Application

Applications must be submitted on Form PHS 398, Public Health Service Grant Application. The face page of the application must reflect the request for applications number, RFA-FDA-OP-87-1. Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

The collection of information requested on Form PHS 398 and the instructions have been submitted by the Public Health Service to the Office of Management and Budget (OMB), and were approved and assigned OMB control number 0925-0001.

B. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: December 1, 1986.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-24 Filed 1-2-87; 8:45 am]

BILLING CODE 4160-01-M

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

January 20, 1987

David F. Hale
President and CEO
Gensia Pharmaceuticals, Inc.
11180 Roselle Street, Suite A
San Diego, CA. 92121-1207

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Mr. Hale:

Enclosed, please find a curriculum vitae, an editorial authored by Constance B. Wofsy, M.D., which appeared in the Journal of the American Medical Association, and a recent picture for your use relative to the Young President's Organization meeting in San Diego on February 23, 1988. If any further material is required, please do not hesitate to contact me.

Dr. Wofsy will be arriving in San Diego at approximately 2:17 p.m. on the afternoon of February 23rd and departing after the meeting ends at approximately 9:00 p.m. This letter will also confirm that the \$500.00 honorarium will be made payable to the general Foundation for Medicine.

If you have any questions or require further information, please do not hesitate to contact me at [REDACTED].

Sincerely,

Samuel L. Broyles

Samuel L. Broyles
Administrative Assistant
AIDS Activities Division
University of California, San Francisco
San Francisco General Hospital

SB:sb

Enclosures

March 10

ann Meredith
March 24

C.V. / titles / Brosieth
460 40th St
Oakland 94609
655-7289

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SCHOOL OF MEDICINE

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

DATE: August 7, 1987
SUBJECT: JEFF HANSON
AIDS Education Programs Coordinator
TO: Paul Volberding
FROM: Constance Wofsy *CW*

As you know, Jeff Hanson has been accepted in a M.P.H./Ph.D. program at UC/Berkeley School of Public Health to start on approximately September 1, 1987. He has recently been hired as the coordinator of the AIDS Education Programs and comes highly qualified and has shown excellent potential in that position in his first few weeks of taking on his job responsibilities here. He proposes to maintain his current position at 25 hours per week and conduct master's studies at UC/Berkeley. This is far from ideal, as a full-time project coordinator is most desirable. However, the opportunity for graduate work for Jeff, Jeff's dedication to the education project, and the short timespan in getting the project off the ground argue for making a special consideration in this instance.

We have agreed:

- 1.) As of September 1, Jeff will work 25 hours per week maintaining the current job description.
- 2.) Part-time secretarial help will be needed so that the phones and other general issues can be handled during all work hours. Jeff will work with Barbara Woodruff in defining whether this can be best managed by contributing part of a secretarial salary or hiring somebody on a part-time, temporary basis.
- 3.) At the end of the second course program, the feasibility of long-term management under this arrangement will be evaluated to confirm its advisability on Jeff's part and feasibility for the education program with AIDS Activities.

I hope this will prove satisfactory. It seems workable to me and to the others on the Executive Education Planning Committee.

cc: B. Woodruff
J. Hanson
D. Abrams
T. Hall

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 13, 1987

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Holly Hartz, Director
Corporate Communications
KQED
500 8th Street
San Francisco, CA 94103

Dear Holly:

I enjoyed very much speaking with the KQED employee's group. They were certainly very attentive and laughed at all the right places. I hope they found the information useful and indeed hope they all decide to have a very frank discussion with our hypothetical 15 year old sons, daughters, neices, nephews, brothers, and sisters.

As reimbursement, a check should be made out to me, Constance B. Wofsy, M.D., and sent to the address above. My social security number is [REDACTED] as this is usually required for your records.

Again, thank you and keep up the very good work at KQED.

Sincerely,

A handwritten signature in cursive script, reading "Constance B. Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 4, 1987

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

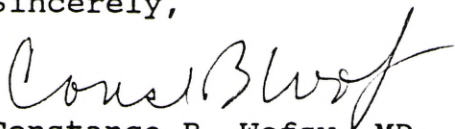
Ese Havez, MD
Program Director
AIDS Awareness Congress
Reproductive Health Center
78 Serfsong Road
Kiawa Island, SC 29455

Dear Dr. Havez:

Thank you for your kind invitation to participate in the AIDS Awareness Congress to be held November 7-9, 1987. Unfortunately, other obligations will prevent me from attending. I must likewise decline your kind invitation to join the editorial board of the international journal "Archives of AIDS Research" as my existing obligations will not allow me to take on an additional obligation at this time.

I am most appreciative of both invitations as I am sure the projects will be most successful and make significant contributions.

Sincerely,


Constance B. Wofsy, MD
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CW/mc

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SCHOOL OF MEDICINE

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

August 12, 1987

Anne Helton, RN, MS, ACCE
Co-Chair, Women and AIDS Subcommittee
AIDS Foundation Houston, Inc.
3927 Essex Lane
Houston, TX 77027

Dear Ms. Helton:

A most gracious thank you for the invitation to be a keynote speaker at the "AIDS and Women" conference to be held March 26, 1988 in Houston. Unfortunately, that coincides with the Spring vacation from the schools, and I have a family committment at that time. I'm delighted to see that you are addressing this very important topic, and wish you the very best with your conference.

Sincerely,

A handwritten signature in cursive script, reading "Constance B. Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m



AIDS FOUNDATION HOUSTON, INC.

3927 Essex Lane
Houston, Texas 77027
(713) 623-6796

July 30, 1987

Constance Wofsey, MD
San Francisco General Hospital
Department of Oncology
1001 Potrero Ave,
San Francisco, California 94110

Dear Dr. Wofsey,

This is to invite you to be the keynote speaker at a one-day "Aids and Women" conference to be held March 26, 1987 in Houston, Texas. It is sponsored by the AFH. An overview of the day is listed below:

MORNING

Plenary Session (1 hour, 15 min. approx.) - "AIDS 101" (working title only) this would be an overview of the problem, including intro to the virus, transmissions, risks, etc. (Since the focus is on women and AIDS we want to include something on pregnancy, childbearing and sexual assault survivors fears as well). This is the keynote we would like you to provide.

BREAK

PANEL

(1 hour, 15 min approx.) We would like your participation on this panel which will discuss political, civil rights, legal and ethical issues. Our plan is to include an attorney and politician.

LUNCH

AFTERNOON WORKSHOPS (attendees will choose one)

Psychosocial Aspects; Childbearing Issues; Lesbian Health and IV Drug Use.

SPECIAL GENERAL SESSION-PERSONAL REFLECTIONS

POST CONFERENCE NETWORKING

The above gives you an idea of our plans for the day. The target audience will be "the community" and we expect to draw many health care workers (nurses, counselors, etc) as well. We hope you will be able to keynote this important conference. Your expenses and an honorarium would be included. Please feel free to contact me [REDACTED] if you have any questions or write me with your response. Thank you for considering this request.

Sincerely,

Anne Helton

Anne Helton, Co-Chair, Women and AIDS Subcommittee

c/c Bets Anderson, Co-Chair, Women and AIDS Subcommittee

ANNE HELTON, RN, MS, ACCE

Consultant

**Health Education
Program Planning**

Expertise:

**Prevention of Violence
Media Development
Patient Advocacy**

**11 Boulevard Green
Bellaire, Texas 77401**



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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 17, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Melissa Hunt, Producer
Michael Trikilis Productions, Inc.
8730 Sunset Blvd
Los Angeles, CA 90069

Dear Melissa:

It was a pleasure to participate in your program in Denver devoted to issues surrounding AIDS in the 80's. I enjoyed very much watching the whole production, and hope I will have the opportunity to see the final piece. I realize it will not be broadcast until late August, but since I don't get the Playboy channel if it's possible to forward a VHS copy to me, I would love to have a look at it. I realize of course that it's copyrighted and can not be disseminated and would honor that.

I have forwarded your letter to the AWARE staff to send some materials. We are actually a research organization and don't have a formal brochure per se, but do get many inquiries for safe sex information, etc., and will pass that on to you.

Again, thank you for the opportunity to work with you and best wishes for future productions.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. B. Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

Michael Trikilis Productions, Inc.

July 9, 1987

Dr. Connie Wofsy

██████████
San Francisco, CA 93127

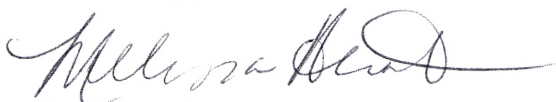
Dear Dr. Wofsy:

On behalf of the staff and hosts of "Women On Sex", I would like to thank you for joining us as a guest in Denver. Your expertise and presence helped make the topic 'Sexual Survival in the 80's' a high quality presentation that we are quite proud of.

By the way, we would all like more information about A.W.A.R.E. Could you send any brochures you might have?

I hope your flight back to San Francisco was safe and uneventful. Again, thank you.

Sincerely,



Melissa Hunt
Producer

*AWAKE
I've sent a letter
Can you forward
materials.
Thanks*

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SANTA BARBARA • SANTA CRUZ

August 17, 1987

SCHOOL OF MEDICINE

David Jacobus,
Jacobus Pharmaceuticals
P.O. Box 5290
Princeton, NJ 08540

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear David:

I hope you had a profitable visit here. A lot certainly seemed to have gotten accomplished. Ileana has been busy getting another grant out, and I've been in a flurry getting ready for my vacation and tying up all the loose ends. I am enclosing for you the institutional review board documents that you requested, and I have contacted the laboratory and they have agreed that they will be able to provide at minimum a printout of the individual patients and their lab results. Unfortunately, this particular computer program didn't go into effect until August of 1986. Consequently, the continuity will be broken for those patients who began enrolling earlier than August of 1986, and some patchwork of computer printout and chart duplication will be required.

I had hoped to finalize all of this with Mr. Ed Wong in the Clinical Laboratories at San Francisco General Hospital, and with the final approval of Dr. Gene Gottfried, the Director of the Clinical Laboratory, before I left on vacation, however, it has simply not proved possible to get all the details completed. I must therefore prevail upon you to wait until my return to finalize the issue including the possibility of getting direct tapes to you. The information is on microfiche with an ASKI printer which is not coded. This is all a little bit of greek to me, and I've not been able to explore it further, but there are options open.

Dr. Medina will be here in my absence and you can communicate with her about the other issues that were still held pending.

I hope you have a relatively relaxed end of summer. I will be in communication upon my return.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. Wofsy", is written over a circular stamp.

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

cc: Ileana Medina, M.D.

encls

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

September 13, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

David P. Jacobus, M.D.
Jacobus Pharmaceutical Company, Inc.
37 Cleveland Lane, P.O. Box 5290
Princeton, NJ 08540

Dear David:

You have not been forgotten. I have discovered that Kjeld Molvig (pronounced Kel Molvig), who does all the computer management for the Department of Medicine, has a program that will do, I think, pretty much what you have in mind. He is beginning to work on it, and I have given him your number so that you can talk computer-speak to be sure that the information can be transferred appropriately. Ileana has been gathering together the other pieces that you need, and I think things are moving in a reasonable manner. The head of the FDA came out to pay a visit and gave us a very good understanding of just why the kind of meticulousness that you are requiring is to the mutual advantage of investigator, FDA, and patient. I understand that the FDA is making the dapsone issue quite a high priority, which is very rewarding. On our end, we are starting a new physician education program, and it is a very busy month, so please be understanding, as we try to get everything done simultaneously and with some degree of alacrity.

Best wishes.

Sincerely,

A handwritten signature in cursive script, reading "Constance W.", is written in dark ink.

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

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SCHOOL OF MEDICINE

Please address reply to
AIDS ACTIVITIES D
San Francisco General
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94

September 4, 1987

Cedric Jones
Product Manager
Lyphomed Inc.
10401 W. Touhy Ave.
Rosemont, IL 60018

Dear Mr. Jones:

This letter will follow our telephone conversation of September 4th requesting sponsorship to attend the recently planned symposium updating the use of aerosol pentamidine for pneumocystis pneumonia to be held on Sunday, October 4th in New York City. As you know, I was one of the key participants in the first Lyphomed symposium and shared the data from our prospective study comparing pentamidine to trimethoprim sulfa and first episode pneumocystis patients. I have since remained actively involved in pneumocystis research studies and chair our Pneumocystis Studies Group at San Francisco General Hospital. The major thrust of the research at this time, of course, is on aerosol pentamidine, conducted by Drs. Montgomery, Hopewell and others.

I would like to attend the aerosol pentamidine symposium and am requesting that Lyphomed sponsor transportation to New York City and would appreciate a contribution toward hotel expenses. As you are aware, I was invited to be part of the Lyphomed Advisory Board but because of personal reasons was unable to attend the initial meeting. I of course remain actively interested and do a great deal of lecturing on the subject and feel that sponsorship would be entirely appropriate.

I congratulate you for putting together this symposium. I am sure it will be very, very worthwhile and well received. I hope you will look favorably on my request. I look forward to hearing from you.

Sincerely,

Constance B. Wofsy
Constance B. Wofsy, MD
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CW/mc

*I think an earlier
copy has gotten
waylaid in the
mail.
Thanks.*

*Federal
Expressed
9/16*

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

September 4, 1987

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Product Manager
Lyphomed Inc.
10401 W. Touhy Ave.
Rosemont, IL 60018

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Sincerely,

Constance B. Wofsy
Constance B. Wofsy, MD
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CW/mc

*I think an earlier
copy has gotten
waylaid in the
mail.
Thanks.*

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SCHOOL OF MEDICINE

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AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

September 4, 1987

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Product Manager
Lyphomed Inc.
10401 W. Touhy Ave.
Rosemont, IL 60018

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Sincerely,

Constance B. Wofsy, MD
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CW/mc

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 29, 1987

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Patrick Joseph, M.D.
3100 Summit, 3rd Floor, South Bldg
Oakland, CA 94609

Dear Pat:

My condom file was woefully incomplete for lack of the federal specifications for condom manufacture and testing. I so hate loose ends. I am glad that I can round out my file as appropriate. I particularly like section 3.10, workmanship. It states that "the workmanship shall be first class throughout." The federal government seems particularly concerned that the condoms shall be free from defects that might detract from their appearance or might impair their serviceability. It is so good to know that the government is on top of these things and that shoddy workmanship will not be tolerated.

As always, it is good to have such a fine collegial relationship that we can periodically exchange the latest scientific information.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities Division
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

FROM THE DESK OF

PATRICK JOSEPH, M.D.

Infectious Diseases

Telephone (415) 834-2800

7/20/87

Connie:

I thought you might be interested
in these "Gov't Specs".



INTERIM FEDERAL SPECIFICATION

CONDOM, RUBBER CONTRACEPTIVE

This Interim Federal Specification was developed by the General Services Administration, Federal Supply Service, Standardization Division, Washington, D. C. 20406, based upon currently available technical information. It is recommended that Federal agencies use it in procurement and forward recommendations for changes to the preparing activity at the address shown above.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers the requirements for rubber contraceptive condoms.

1.2 Classification. Condoms covered by this specification shall be of the following types, as specified (see 6.1):

- Type I - Round end.
- Type II - Reservoir end.
- Type III - Reservoir end, lubricated.

2. APPLICABLE DOCUMENTS

2.1 The following documents of the issue in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein.

Federal Standards:

Fed. Std. No. 123 - Marking for Domestic Shipments (Civilian Agencies).

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20402.

(Single copies of this specification and other Federal specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, D. C., Atlanta, Chicago, Kansas City, Mo., Fort Worth, Denver, San Francisco, Los Angeles, and Seattle, Wash.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

Military Standards:

- MIL-STD-105 - Sampling Procedures and Tables for Inspection by Attributes.
- MIL-STD-129 - Marking for Shipment and Storage.

(Copies of Military Specifications and Standards required by contractors in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

3. REQUIREMENTS

3.1 Material. Condoms shall be manufactured from natural rubber latex. The rubber latex shall be free from embedded grit or discoloration, and shall be transparent or translucent.

3.2 Dimensions. The condoms shall meet the dimensional requirements as specified in table I (see 4.4.2).

FSC 6515

87

TABLE I. Dimensional requirements

Wall thickness Millimeters (mm.)	Length (mm.)	Width (flat) (mm.)
0.04 to 0.07 mm.*	200 mm. $\pm$ 20 mm.	50 mm. $\pm$ 5 mm. - 2 mm.

*No reading shall exceed 0.09 mm.

3.3 Construction. Condoms shall consist of cylindrical latex rubber sheaths with one end open having a thin ring of several layers of latex contiguous with sheath. Types II and III shall have a visible shoulder with a reservoir end.

3.4 Weight. The maximum weight of each condom shall be 1.7 grams (see 4.4.3).

3.5 Bursting strength. The condoms shall break at a minimum of 1.0 cubic foot volume when air inflated to burst before and after accelerated aging (see 4.4.4).

3.6 Pinholes. The condoms shall show no evidence of pinholes when tested by an electronic testing machine in accordance with the manufacturer's method of conducting this examination (dry or wet). Each condom in the lot shall be subjected to this test, and the condoms that fail shall be discarded (see 4.4.5).

3.7 Water leakage. After the pinhole examination and prior to shipment the durability of the condoms shall be verified on sampling basis (see tables II and III), by a water leakage test (see 4.4.6).

3.8 Lubricant. The lubricant used with the type III condoms shall be in conformance with the manufacturer's current commercial practice. Any material applied to the condoms (type III) as a lubricant or dusting powder shall not have a deleterious effect on the condoms, or have a harmful or irritating effect upon the body.

3.9 Identification marking. Each individual condom shall have the manufacturer's name or symbol and date of manufacture.

3.10 Workmanship. The workmanship shall be first class throughout. The condoms shall be free from defects which effect their durability, detract from their appearance, or which may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory acceptable to the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.1.1 Inspection. Inspection is defined as both examination (such as visual, auditory, etc., investigation without the use of special laboratory appliances or procedures) and testing (determination by technical means of physical and chemical properties). Inspection records of the examinations and tests shall be kept complete and available to the Government.

4.1.2 Inspection of components. In accordance with 4.1, the supplier is responsible for insuring that materials and components are manufactured, tested, and inspected to ensure conformance with the requirements of applicable specifications.

4.2 Objective evidence. The supplier shall provide objective evidence acceptable to the contracting officer that the requirements of 3.1 and 3.8 for which specific inspection has not been provided, have been satisfied.

4.3 Sampling. Sampling plans in tables II and III for the water leakage test are matched to certain plans in MIL-STD-105. The normal, tightened, and reduced inspection provisions of MIL-STD-105 may be used, as applicable as sampling plans in this specification.

4.4 Examination and tests.

4.4.1 Visual examination. Examination for visual defects shall be performed on sample condoms selected for the water leakage test. Sample sizes and acceptance/rejection numbers, expressed in percent defective, shall be the same as specified in table II of the water leakage test. One or more imperfections in material and workmanship on the same condom shall constitute a defective condom. Results of visual examination shall be recorded separately from test results.

4.4.2 Dimensions. Measure the thickness of the condoms at three spots, 1 centimeter (cm.) from the open end, 3 cm. from the shoulder end, and at the mid-distance between these two points. Compute the average of the readings. Measurements on types II and III condoms shall not include the reservoir end. Five condoms selected at random from each lot shall be measured (see 3.2). The acceptance number shall be zero.

4.4.3 Weight. Twenty individual condoms selected at random from each lot shall be weighed on an analytical balance (see 3.4). The acceptance number shall be zero.

4.4.4 Bursting strength test. Eight individual condoms selected at random from each lot shall be inflated to burst and checked at break for minimum inflation. Before accelerated aging, the volume of air used to inflate the condoms to burst shall be not less than 1.0 cubic foot (cu. ft.). After accelerated aging, by suspending the condoms in an air oven at 70° C. for 7 days, the volume of air used to inflate condoms to burst shall be not less than 1.0 cu. ft. (see 3.5). The acceptance number shall be zero.

4.4.5 Pinhole examination. The test for pinholes shall be performed on 100 percent basis (no sampling). The electronic testing shall be performed by utilizing an electronically charged liquid bath (wet method), or a gammeter test (dry method) which examines the goods dry. Condoms failing to pass this test shall be removed (see 3.6).

4.4.6 Water leakage test. Place condoms in a funnel rack approximately 12 inches above the base support and fill each with 300 millimeters of water. Close the open end by squeezing it together at the beaded portions. Lay the filled condom on a piece of dry white filter paper, roll the condom from side to side and observe for leakage. After the 100 percent pinhole examination, (see 3.7), and prior to shipment, the condoms shall be tested for water leakage in accordance with tables II and III.

TABLE II. Sampling plans for water leakage test and visual examination

(Pinholes in area from closed end to 6 inches above it. The acceptance (ac.) and rejection (re.) numbers represent defectives.)							
Lot size 35,000 and less				Lot size 35,001 - 150,000			
Type of sampling plan	Cumulative sample size	Ac	Re	Type of sampling plan	Cumulative sample size	Ac	Re
Single	500	2	3	Single	800	5	6
Double	315	0	3	Double	500	2	5
	630	3	4		1000	6	7
Multiple	125	#	2	Multiple	200	#	4
	250	0	3		400	1	5
	375	0	3		600	2	6
	500	1	4		800	3	7
	625	2	4		1000	5	8
	750	3	5		1200	7	9
	875	4	5		1400	9	10
Lot size 150,001 - 500,000				Lot size 500,000 and over			
Single	1250	7	8	Single	2000	14	15
Double	800	3	7	Double	1250	7	11
	1600	8	9		2500	18	19
Multiple	315	0	4	Multiple	500	1	7
	630	1	6		1000	4	10
	945	3	8		1500	8	13
	1260	5	10		2000	12	17
	1575	7	11		2500	17	20
	1890	10	12		3000	21	23
	2205	13	14		3500	25	26

#Acceptance not permitted at this sample size.

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

November 18, 1987

Jay Katz
Resource Applications
720 Light Avenue
Baltimore, MD. 21230-3895

Please address reply to undersigned at
AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Jay:

I have received your request to speak at your excellent yearly conference for April 14, 15, and 16, 1988. I have thoroughly enjoyed my participation in the last couple of years and have received some outstanding feedback as well as just a nice sense of conviviality and enthusiasm in the course direction. Unfortunately, I have overbooked myself for the month of April and just can't fit in another East Coast trip.

I am genuinely sorry to decline; please keep me in mind for next year. I am sure this year's program will go just as well as the last two have. You have a very successful thing going.

Best wishes,

Constance B. Wofsy

Constance B. Wofsy, M.D.
Co-Director
AIDS Activities Division
Assistant Chief
Infectious Diseases
San Francisco General Hospital

*I really am sorry
I can't do it.*

CW:sb

11/17/87
11:50 AM

REQUEST TO SPEAK

DATE 4/14, 15, 16/88 DAY THU/FRI/SAT TIME OF DAY _____

LOCATION NEW YORK CITY

SPONSOR RESOURCE APPLICATIONS

TOPIC WANTS TO CONFER W/ YOU-POSSIBLES: WOMEN & AIDS
ADOLESCENTS & AIDS

AUDIENCE 500 PRIMARY CARE PHYSICIANS AND NURSES

HONORARIUM \$600.00

EXPENSES MOTEL/AIRFARE (THEY WILL MAKE ARRANGEMENTS) INCIDENTALS

CONTACT JAY KATZ

PHONE 301-962-0250

COMMENTS KATZ AVAILABLE FRI, 11/20; M, T, W OF NEXT WEEK

DATE CALLED _____

PHONE CALL

FOR CW or Sam DATE 11-17 TIME 11:30 A.M.
P.M.

M

OF

PHONE

AREA CODE

NUMBER

EXTENSION

MESSAGE

☒ TELEPHONED

☐ RETURNED
YOUR CALL

☒ PLEASE CALL

☐ WILL CALL AGAIN

☐ CAME
TO SEE YOU

☐ WANTS
TO SEE YOU

SIGNED

TOPS  FORM 4003

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 23, 1987

Nandini Kuehn
Center for Health Training
2229 Lombard Street
San Francisco, CA 94123

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Ms. Kuehn:

This letter is in regard to Lauren Poole, nurse practitioner, who works at San Francisco General Hospital in two capacities-- one as a research nurse practitioner for Project AWARE, Association for Women's AIDS Research and Education, and as a patient care provider for male and female patients on Ward 86, the AIDS Clinic at San Francisco General Hospital. I have worked with Lauren for the last three years and at all times and in all capacities, she has done a superb job and is able to adapt herself to the varied situations that she faces professionally. Lauren has a background in women's health care issues and has had direct experience evaluating, advising, and medically caring for several dozen women who have been infected with HIV or who are at high risk. She has found a way to "get into their space", so that she can make some reasonable assessment of what the individual is facing from that person's point of view. The women we see in our research study and in our clinic come from many different walks of life and are as varied as educated health professionals to women of various races and cultures who have not had the benefit of significant education or who have used IV drugs for a long period of time and present some rather difficult management problems. All of these are handled with considerable aplomb and diplomacy.

Lauren has done considerable speaking on topics of women and AIDS to a variety of professional and lay groups and has very good insights on how to incorporate HIV related issues into issues relating to women's care, self-esteem, and other health care issues relating directly to women's health. In this capacity she has been a significant resource person for others in the AIDS unit and those in other departments at San Francisco General Hospital.

Most of all, Lauren is a very warm and sincere woman with a very good general balance in facing emotionally charged issues. She is someone people feel comfortable listening to. I recommend her to you without reservation.

Sincerely,

A handwritten signature in cursive script, reading "Constance B. Wofsy".

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

TO: C. Wofsy, J. Cohen, R. Fahrner
FROM: L. Poole
RE: Letters of reference
DATE: 7/22/87

I have accepted an offer to participate in a program sponsored by the Center for Health Training which will train women's health clinicians about AIDS risk assessment and screening in women's health care settings. I need three BRIEF letters of reference that are required for their grant.

Please write a brief letter from your particular perspective addressing my:

- previous experience as a Women's Health Nurse Practitioner
- current experience as a provider of health care and counseling to women at risk and women with ARC/AIDS
- experience doing public speaking, consulting and teaching for a variety of agencies and institutions grappling with how to incorporate AIDS issues into women's health care settings
- position at SFGH as resource person for issues concerning women and AIDS
- anything else good you can think of! !

This can truly be brief. I have the job already so it is essentially a formality, but I might be able to use such letters in the future for similar opportunities.

You can either give the letter to me or mail it directly to:

Nandini Kuehn
Center for Health Training
2229 Lombard Street
SF, CA 94123

THANKS THANKS THANKS

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

July 23, 1987

Nandini Kuehn
Center for Health Training
2229 Lombard Street
San Francisco, CA 94123

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Ms. Kuehn:

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Most of all, Lauren is a very warm and sincere woman with a very good general balance in facing emotionally charged issues. She is someone people feel comfortable listening to. I recommend her to you without reservation.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director, AIDS Activities
Assistant Chief, Infectious Diseases
San Francisco General Hospital

CBW:m

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

January 25, 1987

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Gifford S. Leoung, M.D.
San Francisco General Hospital
Bdlg. 80, Ward 84
995 Potrero Avenue
San Francisco, CA. 94110

Dear Gifford:

The proposal to more closely evaluate seroprevalence in the Asian community is an important one that seriously needs investigation. In our research studies of women through Project A.W.A.R.E., we realize that it has been difficult to attract subjects from the Asian community and feel that this collaborative effort from within the community will maximize a good response. We will be glad to review with you our process of establishing community outreach so that you can incorporate similar training and orientation within your project.

This is an important endeavor which has my support.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director
AIDS Activities Division
Assistant Chief
Infectious Diseases
San Francisco General Hospital

CW:sb

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

January 21, 1988

Please address reply to the undersigned at:

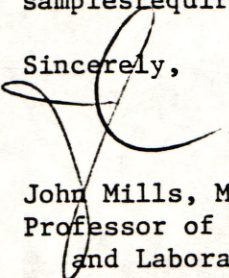
DIVISION OF INFECTIOUS DISEASES
Building 80, Ward 84
San Francisco General Hospital
995 Potrero Avenue
San Francisco, CA 94110

Gifford S. Leoung, MD
San Francisco General Hospital
Bldg. 80, Ward 84

Dear Gifford:

I have reviewed the proposal by David Ja and you entitled "HIV Epidemiology in Asian Homosexual and Bisexual Males". This is an important project which I am prepared to support. My laboratory will be able to process and store the serum samples required without difficulty.

Sincerely,


John Mills, MD
Professor of Medicine, Microbiology
and Laboratory Medicine, University of
California, San Francisco;
Chief, Division of Infectious Diseases,
San Francisco General Hospital

JM/cc

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SANTA BARBARA • SANTA CRUZ

SCHOOL OF MEDICINE

January 25, 1987

Pat Lilly
North Shore Health Department
Administrative Offices
253 East 14th Street
North Vancouver
British Colombia, Canada
V7L 2N5

Please address reply to undersigned at

AIDS ACTIVITIES DIVISION
San Francisco General Hospital
Building 80, Ward 84
1001 Potrero Avenue
San Francisco, CA 94110

Dear Mrs. Lilly:

I have received your cordial letter asking about the possibility of slide duplication and must regretfully say that I am unable to provide slide duplicates. I lecture very frequently and many people have requested copies of various and sundry slides. It became clear to me early on that I would have to make a general policy that applied across the board. Many others like you have particular interest in what I call my "collectible" slides.

I am delighted that my talk got some important points across and am appreciative of your positive feedback. I regret that I am not able to comply with your request and hope that you will understand and not feel that there is anything at all personal implied in my response.

Very best wishes in your ongoing good works.

Sincerely,

Constance B. Wofsy, M.D.
Co-Director
AIDS Activities Division
Assistant Chief
Infectious Diseases
San Francisco General Hospital

CW:sb

NORTH SHORE HEALTH DEPARTMENT

MEMBER OF METROPOLITAN HEALTH SERVICE OF GREATER VANCOUVER

WEST VANCOUVER OFFICE:
265 - 20TH ST.
WEST VANCOUVER, B.C. V7V 3Y3
TELEPHONE: 922-9136

ADMINISTRATIVE OFFICES:
253 EAST 14TH ST.
NORTH VANCOUVER, B.C. V7L 2N5
TELEPHONE: 988-5231

Dr. C.B. Wofsy
Co-director of Aids Activities and Principal Investigator,
Project Aware,
San Francisco General Hospital
San Francisco, Calif.

Wants slide
duplicates

Dear Dr. Wofsy;

On November 3, 1987, I heard you speak in Vancouver. Your presentation was excellent and I was fascinated to see the slides you used. Is there any chance that you would consider having some of them duplicated and sent to me? I am a Community Health Nurse giving many AIDS workshops. Although I can certainly have slides made that are pertinent to B.C. and Canada, many of the ones you used - those of headlines, posters, pictures, cartoons, are ones that I could never put together up here (I haven't seen a good banana cartoon here!)

If you would do this, I would be very grateful, would gladly reimburse you for costs and would promise to use the slides wisely and well.

Yours truly, (Mrs) Pat Lilly