To: AIDS Activists, Service Organizations, Community Constituency Groups, etc.

From: Karl Owens, David Rephun, ACT UP/NY

Date: February 27, 1991

Re: Hoffmann-La Roche's Obstruction of It's Own ddC "Expanded Access" Program!!

Dear Friend:

After nearly a year's worth of work, ACT UP, along with hundreds of other AIDS activists, AIDS researchers, community groups, physicians, etc. succeeded in getting Roche (albeit kicking and screaming all the way) to commit themselves to an expanded access program for its anti-HIV drug, ddC. Such commitment was made by Roche in September, 1990.

It has now become painfully clear that Roche has no (and probably never had any) intention of making ddC available through a true and real expanded access program. Instead, along with each promise of greater accessibility to ddC, Roche has created obstacles towards achieving that very end. And these obstacles have been fairly successful.

Consequently:

** physicians report that the local IRB requirement (which Roche insists on maintaining despite the FDA's willingness to provide a blanket IRB approval as was done with Bristol's ddl) causes approval delays of many months..

** the 1-800 information line provides wrong information and misdirection resulting in even longer delays..

** the amount of monitoring paperwork required by Roche is impossible for already overtaxed physicians to meet (and it's 6 times the amount required by Bristol)..

Therefore, ACT UP/NY on February 11, 1991 voted to initiate it's first boycott of a pharmaceutical company - Hoffmann-La Roche.

Though the boycott is only just beginning, we already have the support of AIDS physicians, AIDS researchers, community and professional organizations.
We NOW need your support in order to make this boycott a success. Here are some of the things you can do:

1. **Endorse the Boycott** - call David Rephun or Karl Owens at the numbers below or write to them at the ACT UP/NY workspace to sign on to the list of boycott endorsers
2. **Spread the Word** - Take the enclosed fact sheet, copy it and distribute it to your own constituency at your meetings, etc.
3. **Include Your Doctors** - Take the Physicians Outreach Packet and mail it out to all your local physicians, especially health care providers who work with people with HIV and/or AIDS.
4. **Involve the General Membership** - Ask your clients, members, staff, etc. to take the Patient Pack to their own physicians

Together we can end this crisis.

Any questions, suggestion can be addressed to:

David Rephun
212.254.3685 (phone)
212.929.4463 (fax)

Karl Owens
212.695.0755 (phone)
212.239.2761 (fax)
WHY WE MUST BOYCOTT ROCHE!

ROCHE IS BLOCKING ACCESS TO ddC

ddC is an anti-viral drug, manufactured by Hoffman-LaRoche (subsidiary of Roche, Ltd.), desperately needed by tens of thousands of individuals who have failed, or cannot tolerate, AZT.

After tremendous pressure Roche finally agreed in September 1990 to provide ddC on expanded access to those who need the drug. This was a sham!

ROCHE HAS SUCCESSFULLY BLOCKED ACCESS TO ddC BY:

IMPLEMENTING AN INDIVIDUAL IRB INSTEAD OF A NATIONAL IRB

It takes 4 to 7 months to receive ddC through Roche's expanded access program. It only takes 3 to 4 weeks to receive DDI.

To receive ddC, physicians must obtain an "individual" Institutional Review Board (IRB) approval from a local hospital for each patient. Bristol Myers, on the other hand, arranged a "national" IRB from the government for their expanded access program of DDI that covers requests from any physician, for any patient, anywhere in the country.

PRETENDING TO REQUEST A NATIONAL IRB—LIAR, LIAR, BUILDING ON FIRE!

Roche claims the government refuses to grant them a "national" IRB for ddC's expanded access program. We have learned the opposite to be true. The government would, in fact, support a national IRB for ddC.

REQUIRING UNNECESSARY PAPERWORK

The paperwork for each patient requesting ddC is the size of New York Telephone's yellow pages. Included in these tomes is the monitoring forms: 6 pages which must be filled out every 2 weeks. This is 6 times the reporting requirements for DDI!

The current paperwork for ddC would be more appropriate for a clinical trial rather than an expanded access program. For already overworked physicians this is a major deterrent; for some, an impossibility.

PATIENTS DIE WHILE DOCTORS FILL OUT FORMS

We have been trying to have Roche eliminate these roadblocks to ddC for the last five months. They have refused.

This major pharmaceutical company is making hundreds of millions of dollars from our community through the sale of a number of products and services. Yet, they will not spend a very minor amount of money to provide ddC to those in desperate need of the drug now: not 6 or 7 months from now.

NATION-WIDE BOYCOTT

Therefore, we are initiating a nation-wide BOYCOTT against Roche products and services until the following demands are met:

- Replace the requirement of a local IRB with a national IRB
- Reduce the monitoring paperwork to 2 pages per patient every 4 weeks
- Guarantee a maximum of 3 weeks from receipt of a completed application to delivery of drug to qualifying individuals
- Develop a formal procedure for reporting toxicities to physicians
- Participating in the expanded access program

ASK YOUR DOCTOR TO AVOID THESE ROCHE PRODUCTS.

All of these can be substituted by similar or identical products, and services.

<table>
<thead>
<tr>
<th>NO!</th>
<th>YES!</th>
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<tr>
<td>Valium</td>
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<td>Librium</td>
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<td>Intron A</td>
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For More Information Call Roche Boycott

212.564.2437 212 532.3812
February 20, 1991

Dear Physician:

Over this past year ACT/UP New York’s Treatment & Data Committee has been involved in negotiations with Roche Pharmaceuticals to ensure a reliable, safe and effective expanded access program for ddC. We had hoped that Roche would follow the very successful expanded access program of ddl sponsored by Bristol-Myers. Despite the clear success of the ddl program, Roche has continued to insist on very different protocols for ddC.

We have three principal areas of concern:

- The programs’ very small enrollment
- The requirement that physicians obtain individual and local IRB approval
- The unreasonable amount of paperwork involved for the individual physician

Roche has, in our opinion, made insufficient effort to address these concerns. As physicians, working day in and day out with the HIV infection, you have a unique kind of knowledge and power. We want you to use your power to boycott Roche.

1. Decline to see Roche Sales Reps
2. Prescribe equivalents to Roche drugs
3. Switch your business away from Roche to other lab and infusion/nursing services.
4. Call to add your name to the list of boycott endorsers. Or, register your dissatisfaction in a letter (see attached) to Roche executives.

We believe this boycott will accomplish three things: first, get Roche to greatly expand access to ddC, second, eliminate the need for local individual IRBs, by getting a national IRB approved and third, significantly cut the paperwork involved with access to ddC. We know this can be accomplished without compromising patient safety and your own ethical standards of treatment because it’s already been done quite safely with the Bristol-Myers ddl program.

Please work with us to give your patients more treatment options and hopefully make your job easier. Say “NO!” to Roche. Nothing speaks more eloquently to a pharmaceutical company than the message of an empty cash box. Roche stands in the way of you and your patients, by its stubborn refusal to enter the new era of doctor-patient collaborative experimental treatment.

Sincerely

Jim Serafini, Ph.D
Treatment & Data Committee
ACT UP/NY
212.877.3119
WHY WE MUST BOYCOTT ROCHE!

ROCHE IS BLOCKING ACCESS TO ddC

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ROCHE HAS SUCCESSFULLY BLOCKED ACCESS TO ddC BY:

IMPLEMENTING AN INDIVIDUAL IRB INSTEAD OF A NATIONAL IRB

It takes 4 to 7 months to receive ddC through Roche’s expanded access program. It only takes 3 to 4 weeks to receive DD1.

To receive ddC, physicians must obtain an “individual” Institutional Review Board (IRB) approval from a local hospital for each patient. Bristol Meyers, on the other hand, arranged a “national” IRB from the government for their expanded access program of DD1 that covers requests from any physician, for any patient, anywhere in the country.

PRETENDING TO REQUEST A NATIONAL IRB—LIAR, LIAR, BUILDING ON FIRE!

Roche claims the government refuses to grant them a “national” IRB for ddC’s expanded access program. We have learned the opposite to be true. The government would, in fact, support a national IRB for ddC.

REQUIRING UNNECESSARY PAPERWORK

The paperwork for each patient requesting ddC is the size of New York Telephone’s yellow pages. Included in these tomes is the monitoring forms: 6 pages which must be filled out every 2 weeks. This is 6 times the reporting requirements for DD1.

The current paperwork for ddC would be more appropriate for a clinical trial rather than an expanded access program. For already overworked physicians this is a major deterrent; for some, an impossibility.

PATIENTS DIE WHILE DOCTORS FILL OUT FORMS

We have been trying to have Roche eliminate these roadblocks to ddC for the last five months. They have refused.

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Therefore, we are initiating a nationwide BOYCOTT against Roche products and services until the following demands are met:

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For More Information Call Roche Boycott
212.564.2437  212 532.3812
February 1991

Mr. Irwin Lerner
President
Roche Laboratories
Division of Hoffmann-La Roche
340 Kingsland St.
Nutley, NJ 07110

Dear Mr. Lerner:

I am writing to register my dissatisfaction with Hoffmann-La Roche's program for expanded access to ddC. The design and administration of this program creates unacceptable barriers for patients who need this therapy.

One barrier is the requirement of a local IRB. Procuring an IRB is a lengthy process that can take many months. This barrier is easily removed by a national IRB which the government is willing to extend but Roche is unwilling to accept.

The administration of the program is sub-standard. Operators on 1-800-ddC-2144 are insufficiently trained, respond to inquiries with incorrect forms and information and are less than helpful. Enrolling patients for ddC takes six to eight weeks not two to three weeks like in the Bristol-Myers ddl program.

A third problem is the quantity of patient monitoring paperwork. The ddC weekly paperwork is six times that of ddl. Physicians, particularly, those with large AIDS case loads, find the paperwork load impractical and thus participation in the ddC program difficult.

A final problem is with the reporting of toxicity. Roche has provided a single report citing a few anecdotes of toxicities in program participants. This level of reporting is inadequate to insure the safety of patients enrolled in the program.

Rather than encouraging access, a lengthy IRB process, administrative bungling, burdensome paperwork, and inadequate safety controls discourage access. It is hard to imagine what objectives Hoffmann La Roche held for patient welfare in designing this program.

I support the boycott of Hoffmann-La Roche.

Sincerely,
Dear Dr.

As your patient I'd like to ask you to support a boycott of Roche drugs and labs. The purpose of this boycott is to pressure Roche into a genuine expanded access program for their drug ddC similar to the one for ddI that Bristol Myers has so successfully sponsored for over a year and a half. Roche is dragging its feet for solely monetary reasons not scientific ones. Please help me and other patients to have more treatment options.

At the recent FDA anti-viral advisory committee hearings in Rockville, Maryland Dr. David Ho of NYU/Diamond Clinic presented impressive data on the very serious extent of viral resistance to AZT even at 6 months of treatment. This fact alone would mandate access to ddC compatible to the access to ddI. We need ddC now. Please help us reach Roche by:

1. Boycotting Roche drugs and labs
2. Refusing to see Roche reps
3. Signing on to the boycott (call Jim Serafini, Ph.D 212.877.3119) Or, writing a letter to Roche executives (see attached)

We cannot be satisfied with the very limited and cumbersome program being sponsored by Roche. The sooner you act the sooner Roche will change its policy.

Thanks so much for your help in this important matter.

Sincerely,
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Sincerely,
CAF- Barry, 2 protocols,
TB (in the) 20 of the 180 slots,
PCP people, Resources questioned,
NAAI, a combo instead?
Not a consensus in community
would be great if consensus made study

- Minus -stat. cut
get tests - HRHC dollars I d.d.
HIVIG
Abbott not funding women, pregnant women, children.

CMV - anti-CMV IVIG - CMV ImmunoBlot
(+ a varicella one)

General Body
Abbott - some reimbursement
So Chicago, NY, SF - city w/FDA, school,
discuss, etc. To Chicago, NY, 1/22, 5/15

Breast Cancer lecture
Women's Health Forces, Sac., Mothers Day
G'Dale

State AIDS Conference - Brenda

Educational's - for general body
Outreach - Wed. 6 - go here.
Fourteen - Friday 3/3 Working group
Brenner, Thomas, Wray, Ravich, Dobson -
+rides
Mon 6 - go here
Compares A working group
IL2 - Cetus letter
AmFAR conference on community-based trials

Chicago
FDA workshop May 19th how to use esp access to get efficacy data

State A. Budget Task Force
UC-Seed $, good to attract Fed
25% (14%) funded in CA
As State finance cuts, study quickly
so know more when start Fed
Vase will ask for $, a write in that
UC must face community board
(ie wackers)

Vaccines for uninfected - maybe cut,
As so few applying for $ - visit
Medical, Copayments? Consent-free, as
costs move to bill Medical.

\[ B - 25\% \text{ of State budget}
\]
Hope taxes, so 11% cuts.

- ACT UP - long list, "office copy" - each Committee Has

Serena Markka Working Group - Brenda

State AIDS Activism Conference
Sat: LAST to committees (others?)

San: State issue focus,
Medical voicing + or pepsy AF label
Budget! Drug issues? Drugs, UC Research $
Condoleeza Rice, Merck, Hypercinc, Clax, Azie, etc.
Regulatory reform of drug approval process
New best case FDB (both days)
Insurance access if +
Lytic analysis for antibodies, blood CD4-
display, if < 800, many Asian women
- 100

Cause assess - Rick
Early intervention cuts (both days)
Insurance - Canadian model, Noto
with other health action groups,
DUT 7mg (into CAB area?)
Getting drug abuse study
(Trial past via bill of rights)
Dentists, doctors bill of rights
Politicians buddies
How access c. u.?, exp. access
Prisoners educational (esp. since dem in Mac)
Educ. on AIDS Drug Assist. Program,
outreach to ppl of color as AIDS activists
Regional, gap sizes, budgets, how to help each other
Pharmaceutical buddies (via in year access)
ACT UP contact list - 17 in title
Jackson's MASS protocol - will discuss after
CAB - Michelle G. Dali Huang who is
looking over specific disease
019 rollover - Jesse
Many ppl long on AZT
Kuba, Volb, Hess, 3-6. Decy study, AZT, ddC, ddi, B1-RG??
B1
Politics in ACTG
Want to do all comb at once, ddI, AZT
So need dose-varying on ddI
AIDS to enroll 12wks, then week
AZT + B1 should start now
If I or B1 done
Jesse will write by week end
Send letter + bring to review board
Ed next wk - BR M
Wth ? - Blood, mac 10s (see Mark & Nick)
CP KRA
190 patients
60 toxic
20 ddI/ddC control
20 TB
20 Fungal, cyanide
50 to PCR?
MAI people
MAI +
AZT + ddC
AZT in pregnant women
tested for carbs, people
052 Vaccines
085 Antivirals, resist, comb...
090 Intro

M. McKusick
CoD

147 Several epidemics, only downtown in SF ~1995
190 Lem - survival in SF
245 Medical timidity - "further research is needed"

Francis - 260

70 in Africa

Thailand - 5% of military recruits
US - 1.3/100 int/yr - 12x that for young blacks

307 HIV-2 constant in West Africa. Much less aggressive pathogenesis.

324 To early 20s - slow progression
380 Vaccines

Vollnoiding - 408
433 Toxo - int'l cooperation, USA France
Antiviral in Europe
8 highlights
A2T dose, 3x/day as good
Rash, slower at earlier
RICHMAN: -race after 3 yrs

468 Combini:
A2T + ddI
+ ddC
No concurrent A2T cox, dose.
Somewhat more successful at recovery, mortality
Exp. at lower CD4?
Prebi need full dose, current drug
OT-oral clearly better than AP
TB begg proposal worldwide - med. intervention

522 50-% adherent - about 75-
Weeks, exp. for treatment

Wotsy - 553

Several, <200 CD4, liberal to others
A2T decrease, exp. <200

514 OIs
Conant - for questions - 434

First therapy

3.6 A - Cofactor Lo
Francis - ote?
@ Not convinced by data on any
A - Immunomodulator
- Zagury - Hazel Time ?
Francis - pie in sky...

3.25 Zagury -

Volbs - Lymph nodes, spleen, etc. much
higher viras than in blood. (C04?)

268 Oral doseus, to sulfa?
Fishel da Te in press (Conant)

255 Sinusitis, new eye disease

223 Immigrants & travelers

194 Travel funding restrictions outside US
Int'l collaboration

180 Write letters

171 ddC, ddI, & AZT

150 Works...
& When add ddC? In her practice, ad
feasible to combine

Volbs. Now, maybe still a clear role.
For not adequate. Resistant not a big problem.
Breath add TBC, do - be careful, add C - 4
250 as when begin prep.
120 Concur. Should they sequence 3
Fever, other disease may press eg TB
Vold - Come, reject, is the rule
NSAID almost never needed. All can try
Note, not much trouble to add.

102 Q - Vomires due to constipation infrequent given
Vold; More, look text - not much need. All,
Note - vit C, zinc - Ha-pas
Concur: Receive 500 mg, 2 x day
vit C - moderate in most
Place for dose in not pub
Any convincing don't
Vold's: More interest in metabolic state - test
Acupuncture, etc. - not seen posters, may be there.

38 Pap
< 100, 2 / y
< 250, 1 / y
Q - Concur: proph < 50 CD4
AZT, add ddC and ddI if < 2500 CD4
if prog, earlier
< 250, continue a day
< 100, AP also
< 100, flu
< 50, talking or MAI. Study of vital.
If burn, < 50, consider clarith. for MAF
Tape 2

032 Count: Small gap who can resent cancer.

050 Salts?
Francis: renew record & killed while safety done - trying to squeeze all data.

078 Francis: needle + cellular.

092 Immune mod?
ALT21 - Ampligen -
CD8 expansion - may be most interesting.

112 Stress agent?
Count: definitely clin. impression.

150 CD8, nu-cnu-mod: immune mod.
- B12 or AZT, neuropathy
- cryptosporidiosis
- HPV + cervical.

Why not new drugs?

182 Francis: No magic bullet. Slow disease.

200 Acid-dissoc: p2U may come back.
220 Concur.
AZT + x-ifu combin. Some office.
Vdb. XHildeau, AZT + x-ifu
Still don't know dose
KS - a lot - tex
Combin may allow...

246 Francis
AZT, clear, Hep. C, toward normal
line.

McKensich
x-ifu to wash?

262 doAZT
Conard: Need fall of both 600, 75 or
Volk's 300 today an active dose.

281 Compound Q
accident. St Francis Hosp, ufe 200mg?
Videotape - to boshoua here.
SAVE THE DATE

CHANGING MANAGEMENT OF HIV DISEASE: UPDATE FROM THE VIIth INTERNATIONAL CONFERENCE ON AIDS

One of the objectives of the VIIth International Conference on AIDS in Florence was to present the latest scientific and clinical data on the management of HIV disease. Often the clinical implications of these data are unclear and require further clarification.

A panel of clinicians specializing in HIV disease will discuss these data and respond to your questions regarding the current management of HIV disease.

DATE: Monday, July 8, 1991
TIME: 7:00 PM - 9:00 PM
PLACE: San Francisco Marriott
       55 Fourth Street
       San Francisco, California
       Meeting Room: Yerba Buena Ballroom

FACULTY: Marcus Conant, MD, Moderator
         Donald Francis, MD
         Leon McKusick, PhD
         Robert Schooley, MD
         Paul Volberding, MD
         Constance Wofsy, MD

REGISTRATION: It is not necessary to register; however, if you would like to indicate your attendance at this workshop, please call 1-800-433-4584 between 9:00 AM and 5:00 PM Eastern Time and ask for the HIV Disease Update Coordinator.

This program is supported under an educational grant from Burroughs Wellcome Co.
Program Will Include Discussions of the Following Areas:

Antiviral Therapy for Early HIV Disease

Resistance to Antiviral Agents

Combination Therapy With Antiviral Agents

New Drugs/Vaccines

Opportunistic Infections — Prophylaxis/Therapy
Panel

Marcus Conant, MD
Moderator
Co-chair, California AIDS Leadership Committee
Physician in Private Practice
Clinical Professor of Dermatology
University of California, San Francisco
San Francisco, California

Donald Francis, MD
Centers for Disease Control Regional AIDS Consultant
Department of Health Services
Office of AIDS
Berkeley, California

Leon McKusick, PhD
Clinical Psychologist in Private Practice
Research Psychologist, Center for AIDS Prevention Studies
University of California, San Francisco
San Francisco, California

Paul Volberding, MD
Chief, AIDS Activities/Medical Oncology
San Francisco General Hospital
Professor of Medicine
University of California, San Francisco
San Francisco, California

Constance Wofsy, MD
Co-director, AIDS Activities
San Francisco General Hospital
Professor of Clinical Medicine
University of California, San Francisco
San Francisco, California
Course Evaluation Form

San Francisco, CA
July 8, 1991

INSTRUCTIONS: Complete information below. Please mark each item completely. Block in one response to each item. Complete subjective evaluations on back of form. Give this form to the Course Director before leaving.

RESPONSE CODE:

Mark SD  If you strongly disagree
Mark D   If you disagree
Mark N   If you neither agree nor disagree
Mark A   If you agree
Mark SA  If you strongly agree
# Changing Management of HIV Disease: Update from the VIIth International Conference on AIDS

## Program Structure and Format

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<td>Program met the stated objectives</td>
<td>SD</td>
<td>D</td>
<td>N</td>
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<td>2.</td>
<td>Content of program was current</td>
<td>SD</td>
<td>D</td>
<td>N</td>
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<td>3.</td>
<td>Program was too short</td>
<td>SD</td>
<td>D</td>
<td>N</td>
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<td>4.</td>
<td>Program was the right length</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
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<td>5.</td>
<td>Program was too long</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
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<td>6.</td>
<td>Date/time of the week were convenient</td>
<td>SD</td>
<td>D</td>
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## Speakers

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<td>7.</td>
<td>Instructors were well chosen</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>8.</td>
<td>Methods of presentation were skillful</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>9.</td>
<td>Level of presentation was appropriate to audience</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>10.</td>
<td>Discussion periods were adequate</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
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## Relevancy to Your Needs

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<tbody>
<tr>
<td>11.</td>
<td>Program met my personal needs</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>12.</td>
<td>Material presented in the program will be of direct value in my decision making</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>13.</td>
<td>Attendance at this course was well worth my time</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
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## Learning Aids

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<tr>
<td>14.</td>
<td>Physical facilities of meeting rooms were adequate</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>15.</td>
<td>Audiovisuals were useful and clear</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
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## Future Course Projections

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<tr>
<td>16.</td>
<td>I would recommend a repeat of this course to others</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
<tr>
<td>17.</td>
<td>I would seriously consider attending another program similar to this one</td>
<td>SD</td>
<td>D</td>
<td>N</td>
<td>A</td>
</tr>
</tbody>
</table>
## INDIVIDUAL COMMENTS

1. Have you been tested for HIV?  
   - [ ] Yes  
   - [ ] No  

   If you answered NO, do you anticipate getting tested in the near future?  
   - [ ] Yes  
   - [ ] No  

2. Are you currently on:  
   - [ ] AZT  
   - [ ] ddI  
   - [ ] ddC  

3. Do you anticipate changes in your life-style as a result of today's program?  
   - [ ] Yes  
   - [ ] No  

   If yes, what changes?  

4. Do you anticipate changes in your medical care as a result of today's program?  
   - [ ] Yes  
   - [ ] No  

   If yes, what changes?  
   - [ ] begin antiviral therapy  
   - [ ] continue on antiviral therapy  
   - [ ] change antiviral therapy  
     How?  
   - [ ] other  

5. What other medical materials and/or programs would be of value to you?  

6. The major strength of this program was:  

7. The major weakness of this program was:  

8. Comments on facilities and arrangements:  

9. Additional comments/suggestions:  

Participant Information Designation – Check Appropriate Response.

☐ HIV
  ☐ Uninfected
  ☐ Asymptomatic HIV(+)
  ☐ Early symptomatic HIV(+)
  ☐ PWARC (Person with ARC)
  ☐ PWAIDS (Person with AIDS)
  ☐ Unknown

☐ Health Care Worker
☐ Other

How did you learn about this program?

☐ Newspaper ad
☐ Flyers
  ☐ Clinic
  ☐ ASO
  ☐ Physician
☐ Word of mouth

What is your primary source of information for HIV disease and treatment?

☐ Physician
☐ ASO
☐ Media
☐ Clinical reprints
QUESTIONS?
Please use the space below to record any questions you wish to have addressed by the faculty during the question-and-answer period.

This question may be posed to:

__________________________________________
(Faculty Name)
Welcome!

a. Introduction of facilitators
b. Call for media/law enforcement
c. Statement of purpose
d. Explanation of our decision making process
e. Call for timekeeper and two vote counters
f. Agenda review and additions
g. Pass the bucket. Donations go towards paying for the meeting space
h. Welcome newcomers
i. Security reminder! Walk with a friend!!

1. General body introductions
2. Outreach/Newcomers
3. Secretary’s report
4. Treasurer’s report
5. General announcements/Pass sign-up sheets
   Outreach - Bill, Tabling - Bill, Treatment Issues Meeting
6. Educational
   a. Ryan White/CARE Funding
7. Proposal
   a. Letter endorsement - ASTRA Pharmaceuticals
   b. Letter endorsement - Competitiveness Committee
8. Report-backs
   a. D.S.S. meeting
   b. Agnos meeting
9. Discussion
   a. National HIV Coming Out Day
10. Miscellaneous
    a. Red Hot and Blue Committee
11. Committee Reports
12. Evaluations

Committees represented at last nights coordinating committee meeting were: General body/Treasurer, Treatment Issues, Fundraising/Outreach, Local Issues, Insurance and Women’s action. Absent from coordinating was: Secretary and one general body rep. Funds approved included $40 to attend Life Lobby meeting and $10 for Living with HIV book (A book which lists SF services for women and children with HIV)

**ACT UP/Golden Gate’s Statement of Purpose**

ACT UP/Golden Gate is a diverse, non-partisan group of individuals, united in anger and committed to direct action to end the AIDS crisis. We are engaged in a battle to reform the research and treatment of HIV and its associated opportunistic diseases, intensify HIV education and prevention efforts, and revolutionize the healthcare delivery system in this country. The HIV pandemic crosses all racial, age, sexual, cultural and class boundaries and we are committed to involving all affected communities in this fight. The fight against the HIV pandemic is our highest priority.

**ACT UP/Golden Gate’s Decision Making Process**

ACT UP/Golden Gate operates on a 2/3 majority vote process. Proposals are brought to the floor. After the proposal has been made, there is a call for clarifying questions and a time for discussion. When discussion has ended, the question is called and seconded. At this time a vote is taken. Facilitators will as for nays, abstentions and ayes. In order for the proposal to pass it must receive 2/3 majority vote.
Sari Staver
and
Andy Zysman, MD
Welcome You to
a Benefit for
ACT UP/Golden Gate's
Treatment Issues Committee

December 9, 1991
IVY's Restaurant
The Treatment Issues Committee of ACT UP/Golden Gate is comprised of volunteers involved in speeding the drug approval process, evaluating clinical trial design and expanding patient access to HIV treatments and therapies.

Among the issues which ACT UP/Golden Gate has been involved include the recent expansion of the AIDS Drug Program in California, the development of an expanded access protocol for Clarithromycin, the development of parallel track, and the expedited approval of ddI and soon to be approved ddC.

Tonights speakers are:

Jesse Dobson
Michael Wright
Michelle Roland
Brenda Lein
John James
Sari Staver
and
Andy Zysman, MD
Invite You To Support
AIDS Treatment Activists
At A
Cocktail Party Reception

Please Join Us At
Ivy's Restaurant
398 Hayes At Gough
On
Monday, December 9,
1991
6 p.m. to 8 p.m.

Open Bar
Hors d'oeuvres
The Treatment Issues Committee of ACT UP/Golden Gate is made up of volunteers involved in speeding the drug approval process, evaluating clinical trial design and expanding patient access to HIV treatments and therapies.

At this reception, you will have the opportunity to hear brief presentations by treatment activists about the latest medical and political developments.

Proceeds from this event will be used to defray travel expenses for committee members to attend medical conferences.

ACT UP T-Shirts, sweatshirts, and buttons will be on sale for your last minute holiday shopping!

Make Checks Payable to:
ACT UP/Golden Gate
Mail to
Andy Zysman, MD
418 45th Avenue, SF, CA 94121

To R.S.V.P. by phone (by December 4th, please) call Andy at 221-9733

Name: __________________________
Phone: __________________________

____ $100.00+ Patrons*
____ $100.00 Sponsor*
____ $ 50.00 Guest

____ Yes I will be attending
____ I am unable to attend, but please accept my donation to support the fight against AIDS. $ ____________

*Patrons and Sponsors will be acknowledged on the evening's program
Partial List of Event Sponsors:

The American Association of Physicians for Human Rights
Bay Area Physicians for Human Rights

Donald Abrams, MD
Keith Barton, MD
Peter Bradley, PhD
Lisa Capaldini, MD
Jim Dilley, MD
Milton Estes, MD
Jim Krajeski, MD
Wally Krampf, MD
Pierre Ludington
Bob Neger, MD
Jim O'Donnell, MD
David Ostrow, MD, PhD
Bill Owen, MD
Jane Petro, MD
Demetri Polites, MD
Mervyn Silverman, MD
Leonard Simpson, MD
Paul Volberding, MD
Edward Winger, MD
Rick Wolitz, MD
Stan Yantis, MD
Special Thanks to:

BAPHR, and Leonard Simpson, MD President
AAPHR, and Jane Petro, MD President, and Pierre Ludington, Executive Director

Andrew Foxwell of IVY's
Rutherford Hill Winery and Fallen Leaf Winery
Brenda Lein of ACT UP/Golden Gate for Graphics and Logistical Support

and Our Patrons and Sponsors

Patrons

Sari Staver
Jane Petro, MD
Ron Wilmot
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Bill Owen, MD
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Jerome Goldstein, MD

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Nanette Gartrell, MD
Rudy Isch DDS
Jim Krajewski, MD
Wally Krampf, MD

Pierre Ludington
Kenneth Mills, MD
Diane Mosbacher, MD PhD
Bob Neger, MD
David Ostrow, MD PhD
Demetri J. Polites, MD
Elliot River, MD
Mervyn Silverman, MD
Leonard Simpson, MD
Paul Volberding, MD
Jack Wilke, Md
Charles Williamson, MD
Edward Winger, MD
Ted Winn Jr, MD
Rick Wolitz, MD
Stan Yantis, MD
The AIDS Crisis
is not over, it is
just beginning.

ACT UP
GOLDEN GATE
Had enough?

In a recent study done by the Centers for Disease Control, it was found that 48% of women with HIV whose death certificates stated that the cause of death was HIV/AIDS, died from conditions which are not classified as AIDS. At the National Conference on Women and HIV Infection in 1990, one government official said, "Women have been overlooked in AIDS research, but I assure you it was unintentional."

Join ACT UP/Golden Gate's Women's Action Committee

Had enough?

Did you know that people are not dying of AIDS? In truth, people are dying of the many opportunistic infections (OIs) which attack their immune-suppressed systems. Most federally funded AIDS research has focused on antivirals: over 50% on AZT alone, with much of the balance of research being on similar compounds (ddI & ddC). Yes, antivirals are essential, but we have had to place constant pressure on pharmaceuticals and researchers to investigate therapies for the prevention and treatment of OIs. ACT UP/GG is there! Because of our pressure clinical trials are no longer created and conducted in a scientific vacuum. Because of our pressure the FDA drug approval process has been sped up. Because of our pressure unapproved drugs are being made available to those ineligible for narrowly designed clinical trials. We need your help to make sure that when drugs are approved they will be priced affordably.

Join ACT UP/Golden Gate's Treatment Issues Committee

Had enough?

There are 6 million Californians without health insurance—and thus without access to decent health care. People with HIV/AIDS have been hard hit by the nation's health care crisis. Even those with insurance are vulnerable to the whims of the insurance industry—sudden cancellations, premium increases and denial of claims. Meanwhile, the Dept. of Insurance does little to regulate insurers. 50,000 complaints were filed last year and not a single proceeding began against a major insurer.

Join ACT UP/Golden Gate's Insurance Committee

Had enough?

Is the San Francisco model for AIDS care falling apart? We think so! People with HIV/AIDS who depend on our public health department services are being forced to go through exhaustive delays in travel just to see a doctor. A 4 to 6 hour wait is not uncommon at San Francisco General hospital these days. The health care delivery system in San Francisco is falling apart. Does this bother you?

Join ACT UP/Golden Gate's City Hall Issues Committee

Had enough?

Due to current Immigration & Naturalization laws set by our government, all foreign born U.S. residents whom are HIV/AIDS infected can be prevented from re-entering the United States. These laws are unfounded and discriminating. Despite vast medical and social evidence that proves that infected foreigners are in no way a threat to national health or to the economy, the U.S. government still refuses to admit people with HIV/AIDS into this country!

Join ACT UP/Golden Gate's INS Working Group

Other committees and working groups include:

AIDS Drug Program/State Issues
Fundraising
HIV Testing Issues
Media Relations
Outreach
Prison Issues
And you can do something about this crisis.

We need your support. We want your support. We encourage you to attend our general meetings and join us in the fight against AIDS. In the last ten years there has been over 120,000 reported AIDS deaths in the United States. In the next year alone, another 50,000 are expected to die from AIDS.
Whatever your talent and whatever your interests, there is a place for you in ACT UP/Golden Gate. We rely on your support and we encourage you to participate with us in the fight against AIDS. Ending the AIDS epidemic is our ultimate goal and highest priority. ACT UP is about empowerment. You can make a difference. You can influence a change. You can do something about AIDS.

Thank you for your support and interest in the AIDS Coalition to Unleash Power, ACT UP/Golden Gate. We invite you our general meeting to meet us and hear about the work we are doing.

**General meetings are every Tuesday at 7 pm at 539 Hayes Street San Francisco CA 94102**

For additional information, call **415.252.9275.** Office hours are 11 am - 4 pm, Monday through Friday. Hotline: 415.252.9200 Fax: 415.252.9277

The AIDS crisis is not over.
ACT UP GOLDEN GATE
GENERAL MEETING AGENDA
1/14/92

!!WELCOME!! Especially Newcomers

a. Introduction of facilitators
b. Call for media/law enforcement
c. Statement of purpose (see below)
d. Explanation of our decision making process (see below)
e. Call for timekeeper & two vote counters
f. Agenda review and additions
g. Call for next weeks facilitators
h. Pass the bucket. This helps pay for the workspace.
i. Welcome Newcomers/Newcomers Outreach
j. Safety reminder.

1. GENERAL BODY INTRODUCTIONS
   - Nade
3. TREASURER'S REPORT
   - Adam
4. GENERAL ANNOUNCEMENTS/PASS SIGN-UP SHEETS
   - Jerry, Al
5. ZAPS & ACTIONS
   - HCFA
   - Pediatrics Presentation
   - HCFA
6. EDUCATIONALS
   - Diana Wara
7. PROPOSALS
   - Letter Endorsement
   - Request for Postage & Sticker funds
   - Virge
   - Virge
7. REPORTBACKS
   - Sandra Hernandez Meeting
   - Healthcare
   - Jerry
   - Vince
8. COMMITTEE REPORTS
9. EVALUATIONS

Committees represented at last night's Coordinating Committee were: Treatment Issues, General body rep., Treasury, Women's Action, Insurance.
Committees not represented were: City Hall Issues, Fundraising, Ks subcommittee. Funds approved were: $21.97 copy cost for Newcomers packets to Copy Central, $38.05 copy cost for treasury's Check Request Forms to Copy Central. Total: $60.02

ACT UP GOLDEN GATE'S STATEMENT OF PURPOSE
ACT UP/Golden Gate is a diverse, non-partisan group of individuals, united in anger and committed to direct action to end the AIDS crisis. We are engaged in a battle to reform the research and treatment of HIV and its associated opportunistic diseases, intensify HIV education and prevention efforts, and revolutionize the healthcare delivery system in this country. The HIV pandemic crosses all racial, age, sexual, cultural and class boundaries and we are committed to involving all affected communities in this fight. The fight against the HIV pandemic is our highest priority.

ACT UP GOLDEN GATE'S DECISION MAKING PROCESS
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ACT UP/GOLDEN GATE
COMMITTEE & WORKING GROUP SCHEDULES AND MEETING PLACES

ADP/STATE ISSUES WORKING GROUP
Time: Thursday, 7:00 p.m.
Place: To be announced
Contact: Todd Kooyers (861.6421)
         Brenda Lein (861.4827)

CITY HALL ISSUES COMMITTEE (CHIC)
Time: Thursday, 8:00 p.m.
Place: 32 Walter St., #14th St.
Contact: Ed Badard* (252.5773)
         Jerry Windley (861.5959)

HIV TESTING ISSUES WORKING GROUP
Time: To be announced
Place: To be announced
Contact: Andy Zysman (221.9733)

IMMIGRATION WORKING GROUP
Time: To be announced
Place: To be announced
Contact: Ney Fonseca (255.1251)
         Tomas Fabregas (510.451.9354)

PRISON ISSUES WORKING GROUP
Time: To be announced
Place: To be announced
Contact: Nadine (826.6958)
         Hank Wilson (864.0738)

TI KS SUBCOMMITTEE
Time: 1st & 3rd Thursday of the month, 6:00 p.m.
Place: Workspace, 539 Hayes St.
Contact: Linda Dolan (861.2066)
         Andy Zysman (221.9733)

HIV NATIONAL COMING OUT DAY WORKING GROUP
Time: Saturday, 7:00 p.m.
Place: 32 Walter St.
Contact: Ed Badard (252.5773)

COORDINATING COMMITTEE
Time: Monday, 7:30 p.m.
Place: Workspace, 539 Hayes St.
Contact: Any cc rep. designated below by *

FUND RAISING & OUTREACH COMMITTEE
Time: Wednesday, 7:30 p.m.
Place: To be announced
Contact: Andrea Ring* (337.0703)
         Bill Jessups (252.8560)

INSURANCE COMMITTEE
Time: Thursday, 5:00 p.m.
Place: Muddy Waters
Contact: Will McKey* (255.4785)
         David Lewis (285.7502)

TREATMENT ISSUES (TI)
Time: Thursday, 7:15 p.m.
Place: Workspace, 539 Hayes St.
Contact: Lynne Bloom* (621.6603)

WOMEN'S ACTION COMMITTEE (WAC)
Time: 1st Monday of each month, 6:30 p.m.
Place: Workspace, 539 Hayes St.
Contact: Judith Cohen* (431-9282)

GENERAL BODY REPRESENTATIVES
Adam Gerics - 931.2535
Al Ritter - 921.6506

SECRETARY
Nadine - 826.6958
Rick Forster - 296.6738

COORDINATING COMMITTEE MEMBERS
Adam Gerics (Treasurer/General Body Rep.) - 931.2535
Al Ritter (General Body Rep.) - 921.6506
Andrea Ring (Fund Raising) - 337.0703
Bill Jessups (Outreach) - 252.8560
Ed Badard (CHIC) - 252.5773
Judith Cohen (WAC) - 431-9282
Lynne Bloom (TI) - 621.6603
Will McKey (Insurance) - 255.4785

* COORDINATING COMMITTEE REPRESENTATIVE. WORKING GROUPS DO NOT HAVE COORDINATING COMMITTEE REPS.
Times and locations are subject to change. Please call the committee contact(s) or the hotline number (252.9200) to confirm times.

PLEASE NOTE: If you have any changes or additions/deletions from this list please contact Judith at 431-9282.

01.13.92
Mr. G'dali Braverman  
ACT UP/Golden Gate Treatment Issues  
241B Collingwood  
San Francisco, California 94114

Dear Mr. Braverman:

Your letter of February 6, 1992, to Commissioner David Kessler regarding ddC has been referred to my office for response.

In your letter you ask that the FDA expedite the review of ddC and include results from ACTG 155 in the evaluation of the ddC NDA.

FDA has made, and continues to make, a very serious commitment to the rapid review of all AIDS-related applications and the review of the NDA for ddC is no exception. However, just as every product is different, every application is also different with variations in the quality, quantity, and completeness of submitted data and the analytical challenges posed by the application. We have invested significant effort and resources to assessing the adequacy of the ddC application and in working with Hoffmann LaRoche to define troublesome issues and approaches to their resolution. We will take whatever steps are necessary to provide an optimal review of this application. We will not, however, jeopardize the ultimate ability to more clearly define safety parameters and proper use of ddC for patients and their physicians.

You also request that FDA hold a meeting of the Antiviral Drugs Advisory Committee during March. We regard a meeting of this committee to be an essential part of our consideration of the ddC NDA and will convene a meeting as soon as it is appropriate to do so. However, until a notice of an upcoming advisory committee meeting is published in the Federal Register, we may not publicly disclose the date, time, place, or agenda items of a meeting.

Regarding an expansion of the expanded access program for ddC, I am enclosing a copy of Hoffmann LaRoche's press release that addresses this issue.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research
Tagamet's trial? - Jay
Jim D

CC refers to me like G&D - quiet discussion.
Breast-implant chink - liability. Compelling/least
Op Ed today & WST, orphan - AIDS always
BM mtg. Planning & UF expanded access

Immun Ag
Nov 96 HIV - HVEU
Nov 96 HIV + 1600, told Swanz. Even 2 Europeans
in 2 wks - but prob. not till Fall.
CAF mtg today
Barriers to participation W G
ODB - They can dance in 24 hrs re enrolled
CC asked me FFR to call LST. Each is late, up to play, patient when to start, called single.
As early as you want.
Wasting syndrome protocol ideas: meal, cocoa,
Kaloracks, or Medrol, superbeta IV, + PE
Wasting - C. Dali - scheme to follow up this
NAC: Pepto, Bism. cocoa, low fat
Macio; Magacoc, OI - or empirical??

WACTO

CC: HIV - G Dali. Immune-based therapy
Driscoll: New Enforcement bill
Any Fed. judge can give injunction to stop a treatment

Brenda. Immune-based, vaccines, Adria, et al. World
ACT UP/Golden Gate's Treatment Issues Committee Report 5 March, 1992

The Treatment Issues Committee Meets Every Thursday Night At 7:30 P.M. at 539 Hayes Street in San Francisco.

Adria Pharmaceuticals and Rifabutin and MAI
ACT UP/Golden Gate attended a meeting with Adria pharmaceuticals to discuss their drug Rifabutin. Adria has completed two prophylaxis trials of rifabutin for Mycobacterium Avium Intracellulare (MAI) and they are in the process of getting an Investigational New Drug (IND) for a 5,000 person treatment trial. The treatment trial would be open to persons with less than 200 CD4 who have a prior AIDS diagnosis. ACT UP has demanded that Adria change the inclusion criteria so that persons with less than 200 CD4 with advanced ARC or who are severely symptomatic are eligible for the protocol. Additionally, ACT UP has asked that Adria review the data from their prophylaxis studies and do subset analysis to get some clues about drug interactions. Adria has currently got enough drug for the 5,000 person treatment trial, but has been reluctant to supply drug for a proposed CPCRA prophylaxis study, which would compare Abbot Labs' drug (500 b.i.d. twice daily) clarithromycin to Adria's (300) rifabutin. Throughout the course of the last week, Adria as conceded to supply drug for this trial.

Interesting development from Abbott labs, who has refused to compare two doses of clarithromycin in the CPCRA's MAI prophylaxis study. Abbott is starting its own MAI prophylaxis study, with 4 sites already on board, looking at 500 b.i.d. versus 500 b.i.d. twice daily. Abbott believes they have enough information available to go for a treatment IND.

(Note: Lowell Young still believes that MAI is not treatable with a single agent, it is very similar to Mtb in this way. A treatment trial using a variety of combinations should be conducted to determine the most effective combination of therapies to treat MAI.)

Gilliad Pharmaceuticals and HPMPC
ACT UP/Golden Gate attended at meeting with Gilliad, a pharmaceutical company developing a new anti-CMV drug called HPMPC. Pre-clinical and in-vitro (in the test tube) data suggest that HPMPC is active against Herpes Simplex Virus, Herpes Veracella and CMV. HPMPC is being looked at as a potential CMV prophylaxis. It is administered intravenously.

Gilliad is proposing a small phase I/II study for 20 patients who are CMV+, but who do not have active CMV. The sites may include Mount Zion Hospital in San Francisco and John Hopkins in Boston. The study, however, allows only for the use of AZT. ACT UP feels that Gilliad needs to allow for combination antiretroviral therapy on this trial. Gilliad conceded to allow for ddI use on this trial, but not ddC, saying they are concerned with nephrotoxicity (kidney function impairment). Further, ACT UP/Golden Gate pushed for a commitment from Gilliad to accrue women into this trial.

Immuno AG... Therapeutic Vaccines
ACT UP/golden Gate met with Martha Eibl and David Corkery of the Austrian based biotech company to discuss their candidate vaccine rgp160. Human testing of Immuno's rgp160 began in November of 1990 through the AIDS Vaccine Evaluation Group (AVEG) in the United States in a seronegative population. A phase I protocol for seropositive patients was announced at the November 1991 AVEG meeting in November of 1992. The trial is open to persons with greater than 600 CD4. Immuno is in the process of setting up two European studies, projected to be up and running by August of this year. Both studies will be short (1 year...6 month with 6 month
follow up) small studies accruing between 50 and 100 patients each. 1 trial will be for patients with high CD4, the other will be looking at persons with between 200-500 CD4.

ACT UP has asked that Immuno AG strongly consider expediting the process of researching their candidate vaccine in persons with less than 200 CD4 as soon as possible. Immuno has shown some sluggishness in looking at this vaccine in persons with less than 200 CD4 and is conservative in beginning a pediatric trial looking at the vaccines usefulness in reducing the risk of vertical transmission of HIV from mother to fetus in pregnant women. The pediatric committee of the AIDS Clinical Trials Group (ACTG) is very anxious to look at vaccine in perinatal trials.

3TC
Last week the treatment issues report announced that a trial of 3TC, an experiment nulceoside analogue, is still open and recruiting patients. 3TC is being developed by Glaxo pharmaceuticals and currently in clinical trials and those trials are still open. The trial is an NIH sponsored trial being conducted through the National Cancer Institute (NCI). The trial is being conducted in Washington D.C., Boston and British Columbia. For information on the trials, persons should contact either 1-800-TRIALS-A, or try the clinical trials hotline for the National Cancer Institute 1-800-Trials C.

The 3TC trial is a 24 week phase I/II study of the safety and pharmacokinetics, and preliminary activity of 3TC in HIV+ patients with AIDS or advanced ARC. It is an open label, non-comparative, dose escalating study. There will be no placebo arm and they will not be comparing 3TC to AZT, therefore everyone on the trial in Boston will be receiving Glaxo's drug. The trials are open to persons with less than 300 CD4 who have AIDS or advanced ARC. The trial is not open to persons prophylaxing for OIs other than PCP and candidiasis. Persons with pancreatitis or diabetes are excluded from the trial. Additionally, persons with neurologic abnormalities including HIV dementia or encephalopathy above grade II, active HIV-related peripheral neuropathy, history of peripheral neuropathy related to antiretroviral therapy or a history of seizures. Persons must stop all antiretroviral therapy for at least 21 days prior to their first baseline CD4 count. Persons must be at least 18 years old and cannot be pregnant. ACT UP/Golden Gate has an outline of the study design for persons seeking more information.

*Mycobacterium Tuberculosis* (Mtb)
Tuberculosis is highly contagious and at epidemic proportions in many major cites in the US. There has been a steady increase in the number of tuberculosis cases appearing in San Francisco over the past few years. Especially at risk are HIV+ persons. In New York there seems to be an outbreak of a multi-drug resistant (MDR) strain of TB. In San Francisco we have seen less of these multi-drug resistant strains. It is estimated that on the East Coast, 50% of the health care professionals who have developed MDR strains of TB have died from it. In New York there are currently 2,500 cases of diagnosed TB, in San Francisco there are currently 334 cases.

It is estimated that 30% of the staff at the Department of Social Services (DSS) at the main DSS building at 1440 Harrison, have tested TB+ by skin tests. While this number is critical, it is important to remember that not all of these persons are symptomatic with TB, and thus may not be contagious. Still, the number suggests there are problems at the DSS with proper building ventilation, which is clearly a concern for not only DSS staff but importantly, DSS clients, whose general health may be compromised because of poor access to health services, malnutrition and/or sub-standard living environments. TB is of especially important concern to HIV+ persons, who are at high risk of contracting tuberculosis. Some suggest that TB may become the next opportunistic infection. Extrapulmonary incidences of TB are currently in the definition of AIDS and occurrences of extrapulmonary TB in HIV+ persons constitute an AIDS diagnosis. It is expected that symptomatic pulmonary TB may also be opportunistic in persons with compromised immune function.

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**Treatment Issues Report for 5 March, 1992**

ACT UP/Golden Gate • 519 Castro MS-93 • SF, CA 94114 • (415)252-9200
The tuberculosis working group is waiting to hear about the next city services meeting and they are waiting on reports from both the Department of Public Health (DPH) and the Department of Social Services (DSS). The DPH will be presenting an update the status of the TB clinic and the status of isolation beds in San Francisco General Hospital. The DSS will be reporting on the prevalence of TB among DSS employees.

Dr. Schecter, director of the TB clinic in SF, says that funding is in place to deal with TB, but it is clear that she is accounting for neither the increasing rise of TB cases in San Francisco, nor the possibility of an outbreak of MDR TB. The next PI Perspective, the journal of Project Inform, will have a lengthy article outlining current therapies available for TB. Moreover, recently a group of AIDS activists from the East Coast met with the FDA to discuss the availability of TB drugs to treat MDR TB. There are currently two drugs, PAS and streptomycin, which are second line TB drugs, which could assist in treating MDR strains of TB, which are not available in this country. PAS is available in Canada and some well connected individuals are able to obtain the drug, additionally some buyers clubs are attempting to supply the drug. Streptomycin is not available in this country.

Some believe that the rise of MDR strains of TB are a product of non-compliance to treatment protocols. The standard treatment for TB is a six month regimen of a four drug combination, INH, rifampin, ethambutal and pyrazynamine. The therapy begins with all four drugs and after two months, ethambutal and pyrazynamine are dropped from the protocol. MDR strains arise when persons do not comply strictly to the protocol and the bacteria is allowed to mutate and another strain develops that is resistant to therapy. This MDR strain is then contagious as itself. TB is transmitted casually and proper ventilation is the only means of TB control. Overcrowding in homeless shelters with poor ventilation may be a major cause for increases in the incidence of TB. Homeless and poverty are probable relational factors which may account for non-compliance with TB treatment protocol that effect MDR strains.

Anyone who is HIV+ should be tested for tuberculosis. Tuberculosis should be of special concern to persons with less than 200 CD4. There are problems with the standard skin test for tuberculosis in persons with depressed immune function. Many persons with less than 200 CD4 will test positive for TB, regardless of whether or not they have been exposed. Conversely, persons with extremely depressed immune systems may be incapable of mounting an antigen response to the skin test and may falsely test negative. Sputom cultures and lung x-rays may be recommended. Additionally, treatment should begin for TB as soon as someone becomes symptomatic with TB. Symptoms include weight loss and night sweats. As these are common symptoms for other OIs, it is important that proper diagnosis is made. It is recommended generally, that HIV+ persons who test TB positive, but who are asymptomatic begin prophylaxis for TB. Controversy exists on the standard of care for persons who are and HIV+ who are TB+ and symptomatic. Some suggest that a six month treatment regimen is sufficient. The Center's for Disease Control (CDC) has issued guidelines recommending 9 month treatment regimens for HIV+ persons. Some activists believe a one year treatment regimen is the only sure way to eliminate TB from the system.

There will be an HIV/AIDS advisory meeting on March 18th, at 5:15 P.M. at 1440 Harrison in the 6th floor conference room to discuss this and other issues which concern the DSS. For more information on the TB Working Group call Matt Sharpe at (415)821-1096.

Pathogenesis Theories... (Pathogenesis n: the origination and development of disease) A report was given at Dr. Marcus Conants monthly meeting on a theory proposed by Dr. Michael Ascher that AIDS is an autoimmune disease. The study proceeds from the notion that HIV has been "unequivocally" established as the etiologic (causative) agent in AIDS.
The theory suggests that HIV produces something that locks onto CD4 or T4 cells and "turns them on" permanently. It is the permanent uncontrolled activation of these cells, by the body's own system, that leads to immune system decline. Ultimately, this activation disrupts generations of "memory cells" which lead to T cell loss, clonal deletion and eventually the development of AIDS.

There has been several theories which challenge the generally accepted HIV pathogenesis theory. These theories fall into four major categories:

- Immune decline is caused by the fusion of infected cells with uninfected cells (syncytia formation).
- "Autoimmune" reactions whereby healthy or uninfected cells somehow become the target for immune destruction.
- The generation of toxins which destroy or suppress "normal" cells.
- A mechanism by which normal immune function facilitates in cell-to-cell dissemination of viral infection and/or viral replication and cell death.

While it is clearly important to treat opportunistic infections and to develop drugs for these purposes, more basic science is imperative toward understanding and interrupting the mechanism by which HIV causes immunodeficiency. Based on this pathogenesis theory, therapeutic modalities should avoid immune stimulation and seek to block gp120 signals at CD4, as well as eliminate HIV-infected cells. The results of therapeutic vaccine studies may prove critical in developing a better understanding of this theory, which proposes that HIV induced immunodeficiency is "not the result of direct virus-mediated cell killing but rather the subversion of critical immunologic regulatory mechanism through the interaction of ...gp120 with the CD4 molecule on the T-lymphocytes." Moreover, this theory suggests that immunosuppression may be a possible treatment for HIV disease by reducing the effects of immune overactivation.

According to John James, if this theory were true, the drug cyclosporine should prove useful in managing HIV-disease. A trial of cyclosporine has concluded with an overall negative appraisal in spite of a pronounced but transient increase in CD4 T cells. For more information on this pathogenesis theory contact David Kilbridge (415)431-2865, who will be following up on developments.

Tagamet Warning
Dr. Bahari will presenting information on Tagamet in Amsterdam at the VIII International Conference on AIDS. The drug appears to be a real danger if it is combined with certain insecticides and persons using Tagamet should beware of insecticides.

CPCRA Community Advisory Forum Meeting
The Community Program for Clinical Research on AIDS (CPCRA) community advisory Forum meets the first Thursday of each month at 2 P.M. at the Community Consortium's office, on 18th and Folsom. The meetings are open to the public and interested parties are encouraged to attend. General topics of discussion included mechanisms to alleviate barriers to participation in clinical trials, including providing childcare and transportation and reimbursement of costs for trials. The local CPCRA has accrued 416 persons to their Observational Database (ODB) and expect to top out at 550, their is a commitment for the majority of additional persons accrued on the database to be women.

The Community Consortium, which is a site for the CPCRA, has sent a letter of intent to the American Foundation for AIDS Research (AmFAR) to apply for funds for a large simple trial. The trial would be determining the late versus early intervention with antiretroviral therapy.

Other topics of discussion included ideas for a trial for a wasting syndrome protocol and a proposed High dose IV vitamin C trail. Additionally, the consortium distributed abstracts which
have been submitted for the Amsterdam conference, including both CPCRA and Consortium (non-CPCRA) studies. For more information or written notes from this meeting, contact Brenda Lein (415)861-4827.

ACT UP on the Community Advisory Boards (CABs)...
For information on the ACTU pediatric CAB contact Vince Maloney at (415)922-5486. For information on UCSF's ACTU CAB contact Matt Chapel at (415)821-1722 or G'Dali Braverman at (415)252-5689. For information on the Community Consortium's (CPCRAs) CAB or Scientific Advisory Committee (SAC), contact Brenda Lein (415)861-4827. For information on the HIV/AIDS Advisory committee for the Department of Social Services contact Matt Sharpe (415)821-1096. For information on the Center for Positive Care's (CPC) CAB, contact Todd Kooyers (415)550-8599. For information on the East bay AIDS Center CAB contact Brenda Lein (415)861-4827.

AIDS Clinical Trials Group
ACT UP/Golden Gate is seeking funding to send 8 people to the upcoming ACTG conference in Washington DC this April. Additionally we will be seeking funds to send persons to Amsterdam for the International Conference on AIDS. To contribute to the treatment fund, please send contributions to the Treatment Issues Committee of ACT UP/Golden Gate at, 519 Castro Street, MS-93, SF, CA 94114 (please make checks payable to ACT UP/Golden Gate).

ACT UP!! FIGHT BACK!! FIGHT AIDS!! Support AIDS Treatment Activism!!

Clinical Trials and Treatment Information Telephone Numbers
For the AmFAR Treatment Directory, one of the best sources of info on experimental treatments call 1-800-336-4797. Clarithromycin compassionate use program 1-800-699-9118. The Community Consortium Directory for SF Clinical Trials 415-821-3144. National Trials Hotline 1-800-874-2572. ddC Hotline is 1-800-332-2144. BW566C80 Hotline 1-800-722-9292 (ask for Dr. Mike Rogers). Project Inform's Treatment & Drug Information Hotline 415-558-9051 or 1-800-334-7422 (CA) or 1-800-822-7422 (Outside of CA). Healing Alternative Foundation (Buyer's Club) 415-626-2316. AIDS Treatment News 1-800-TREAT-1-2. WORLD, a newsletter for, by and about women facing HIV disease (510)658-6930

This report was prepared and written by Brenda Lein of ACT UP/Golden Gate (415)861-4827.
TO: Jesse Dobson, Andrew Zysman  
FROM: Brenda and G'Dali  
DATE: 18 May, 1992  
RE: Fauci Meeting

Jesse and Andy, attached is a draft of some of the questions we are considering for the Fauci meeting. There will be a meeting tonight at AUGG office to develop a more extensive list, which will then be faxed to Fauci per his request. Please add/edit etc with your comments. Andy is putting together a list of KS questions, so we are not addressing them here (but feel free to fax them to G'Dali or Brenda if you can't make the meeting tonight). Tommorow is the deadline for getting this info to Tony! The following is a draft of questions to be asked at the Project Inform sponsored meeting with Anthony Fauci on 5/20/92.

- Why did you address Congress and vocalize the need for an increase in the NIH research budget and later address the appropriations committee and tell them that NIH funding was adequate? If funding is adequate than can we assume that there is enough money to increase research efforts into GLQ223 and NAC?

- What is the total DATRI budget? Please give us a brief overview on the research endeavors that are currently underway through DATRI. Please give us a brief overview of the intramural research projects. (Please provide us with a list of these projects at the Wednesday meeting, including the names of principal investigators on these projects. There is no need to go into an indepth presentation on DATRI and the intramural projects as long as we have references that we may use for future dialog).

- Given Michael Ashers' theory that AIDS is actually an autoimmune disease and given the recently published article demonstrating increases in infectious peripheral blood mononuclear cells post inoculation with vaccines and immunizations in chimps, what are your comments on the safety of therapeutic vaccines in HIV+ persons? If there is an abundance of gp120 in the circulating blood of late stage AIDS patients, why would adding more be beneficial? In vaccine therapy, how is it being determined whether neutralizing or enhancing antibodies production is being stimulated?

- Doctor Gallo has expressed interest in foscarnet's anti-HHV6 activity, as he believes that HHV6 may be a co-factor in disease progression. What is the status of this research?

- You are currently working on a pathogenesis study, analyzing biopsied lymphnodes from HIV+ persons. How long will this study be ongoing? What have you seen this far? Have you been able to gather further data to support the V-Beta/superantigen theory? Are you looking at trafficking of infected cells and if so, how are you doing this? Will you comment on this?

- It is the general feeling of the Hertzenbergs, the researchers in Stanford who have been studying NAC, that your study of NAC looked at the wrong markers to
demonstrate a rise in glutathione levels. Will you comment? What are your plans to conduct further research into NAC?

In IL-2 studies, how is it being determined if IL-2 is stimulating the production of new T4 cells versus simply pushing T4s out of the lymphnodes and into the peripheral blood? Could this actually be trafficking HIV, and how would this be determined? Is there a way to determine if a cell is a newly proliferated cell?

Who is coordinating research between the NCI TAT research (Gallo's TAT research) and the ACTG's?

What research is being planned to examine combination use of immune-based therapies? Moreover, what further research is being done into combination use of immune-based therapies to restore the immune system/function in persons with highly compromised immune systems (ie. less than 50 CD4)? Jonas Salk had recently mentioned that the immune function of someone with less than 50 T4 cells could be better than the immune function of persons with greater than 200 T4 cells. How is immune function being measured?

What support will you offer us in approaching the FDA in doing pilot studies using individual patients in wildly varying combination treatments (eg. how do we expedite novel research on a case by case basis, rather than phase I studies.. to the point, how do we translate innovative in-vitro studies into in-vivo studies more rapidly?)?

Could you supply us with a directory of primary contacts within Treatment Research Operations Program, Basic Research and Development Program and the Clinical Research Program for all of the branches coordinated under each of these divisions?

- NAC - long-term effects
- Ph III - pharma, not govt., ACT, ddC, ddC - par/can, to city
- TB plan funding
- FDA, vitamins, NIH study
- Neuro, to phys
- Neurology
- Autopsy, Pilot Studies
to: ACT UP/Golden Gate Treatment Issues
from: John James
date: 11/19/92
re: transition concerns, and proposed working group

The good news is that Clinton’s team seems to be handling its transition process well, and to be committed on AIDS. Nevertheless, signs suggest that we might face serious problems on research issues, especially saving those already infected, and redirecting a research/commercial AIDS industry with enormous inertia. Early indications are that Clinton may not receive appropriate input from our community on these issues.

- An op ed by Harvard’s William Haseltine in last Sunday’s New York Times is frightening. It essentially writes off people with HIV, offering the solution of condoms, prevention education, and testing (including a 10-minute home test for “a potential partner”), and ultimately a (clearly preventive not therapeutic) vaccine. It does advocate a quadrupling of each nation’s biomedical research budget, but in hopes of a “medical miracle” not seriously expected. There is no trace of acknowledgment that we already have dozens of attractive leads for potentially major treatment advances, which have not been rationally pursued because of commercial and political obstacles which could be fixed.

Since the op ed was heavily cut, it may not correctly represent the position of Haseltine the person. But its New York Times appearance makes it a significant indicator of the direction of national drift on this issue.

- Last week the AIDS Action Council and other organizations put together a meeting of about 50 people near Washington to further a process of articulating a consensus for input to the Clinton transition. We have heard that the meeting had great representation geographically and ethnically, but no gay physicians and no professional scientists (it did have treatment activists).

We have read the first draft of what is to be submitted to Clinton, and the research sections are next to worthless: a superficial wish list with no acknowledgment of the real problems, let alone analysis. There is nothing about the problem of the empty drug pipeline — the endless churning of approved drugs at taxpayer expense because commercial incentives dominated while government was ideologically opposed to asserting the public interest — the difference between commitment to saving lives vs. commitment to scientific empires and high-tech toys — the banal but effective and increasing blocks to research by university offices set up to harvest patent royalties, etc. In short, this “AIDS consensus” draft ignores the fact that a universe of commercial and professional turfs has evolved around incentives other than saving lives, that this universe has tremendous inertia and is unlikely to automatically redirect itself, or that the job of AIDS activism must include insisting on a national effort which actually hungers to save the lives of persons with AIDS or HIV.

Proposal: a transition working group to work with other organizations to build a treatment-activist force on research issues — both within and outside of other AIDS transition efforts.
to: ACT UP/Golden Gate Treatment Issues Transition Working Group
from: John S. James
date: 11/23/92

re: Proposed biomedical research recommendations

As San Francisco treatment activists with little Washington experience, we cannot design specific Federal programs, restructurings, or initiatives. But we do not need to be silent as this critical time, since we can recommend principles which should guide the management of Federal AIDS treatment research and development — together with specific problems which these principles are designed to correct, or other illustrative examples. And we can add our support to recommendations developed by others, including TAG and Project Inform.

We propose that the ACT UP/Golden Gate Transition Working Group develop a list of principles on which we agree. The list below is offered as a starting point for today's meeting. We can add to this list, or change or delete items on it, to build a consensus list of principles which can then be circulated to others. This process will bring clear analysis, based on the real-world experience of treatment activists, to the table when research decisions are made.

... . . . . . . . . . . . . . . . .

An effective national AIDS treatment research and development program must:

* Remember that the goal is to deliver results to people — especially major or substantial practical treatment improvements.

Problem: No amount of study of AZT, ddl, or ddC could possibly deliver a major treatment advance — yet that is where the largest share of Federal research effort is going. The usual excuse for this misdirection of resources is that there are no
other drugs to study. In fact, there are dozens or hundreds of promising leads which are never seriously evaluated or pursued — and there have been for years. The root problem is that usually only commercialized drugs can buy enough influence to navigate the immense obstacle course which blocks almost all potential treatments indefinitely.

Effective Federal management would recognize this systemic problem, listen to scientists who believe in a drug but need help to get it considered, and provide assistance as appropriate.

...Continually evaluate the present status of AIDS treatment research and development, project future scenarios all the way through treatment delivery, and take steps to fix glaring problems instead of ignoring or hiding them.

Problem: Today the drug development "pipeline" is empty; with the possible exception of d4T or compound Q, there is no potentially major antiretroviral drug in development except those in the earliest stages of human testing (such as protease inhibitors, tat inhibitors, and PMEA). This problem has been allowed to develop in full view for years, due to appalling delays even on drugs like tat inhibitors which leading mainstream AIDS scientists have long pleaded for. The current bleak treatment outlook is the totally predictable harvest of years of neglect, of high-level government indifference which did not give anyone the authority to address this problem effectively.

What is needed is a shepherding effort to facilitate the passage of promising new drugs, which usually do not yet have major commercial or academic constituencies, through the late preclinical and early clinical development. At that point, any potentially major advance would likely take off on its own. But without proactive efforts to correct systemic deficiencies in the early flow of new drugs, the same major advances will instead remain in the laboratory forever.

Conventional wisdom holds that the reason for lack of progress in AIDS treatments is the scientific difficulty in controlling HIV. But nobody could possibly know whether or not we would now have major treatment advances if different kinds of AIDS drugs (such as tat inhibitors or hypericin) had been properly
evaluated and tested years ago, when the information then existing clearly showed that they should have been. Scientific difficulty would be a legitimate excuse if the question were whether we could have been guaranteed better treatments already; of course there is no such guarantee. But the real question is whether we have properly managed the task of developing the treatment leads before us. And the answer is clearly that we have not.

- Reform the peer review process.

The current model of peer review has two hidden but central problems:

(1) Shortage of funds has greatly reduced the proportion of scientifically meritorious projects funded by the U.S. National Institutes of Health, to about 20 to 25 percent (need exact figures). Projects are rated for funding by averaging the ratings of individual judges on small peer-review committees. The practical mathematical consequence of this system is that, when the percentage of projects funded becomes low, every member of the committee has an effective blackball to kill any project they dislike; a single negative vote will cancel anything the other committee members may do. This consequence discourages originality, and encourages political horse trading and the development of narrow cliques based on funding of each others' proposals.

The problem could be ameliorated simply by changing the averaging formula to exclude one "outlier" — the single most unfavorable number — before averaging. Then anyone who wanted to blackball a particular grant would need to obtain the support of at least one other member of the committee in order to do so.

(2) The other problem is more fundamental, but could be addressed by borrowing from a different kind of peer review which has proven itself in a highly productive technology agency, DARPA (Defense Advanced Research Projects Agency).

In NIH peer review (and also in FDA advisory committees) the busy professionals who are asked to judge are given huge stacks of paper to read before the single meeting — on projects
they are usually unfamiliar with. In this situation it is humanly impossible to expect an in-depth review. Instead, the system forces superficial judgments, to the detriment of new and non-stereotyped ideas; it may also harm high-potential projects which would be threatening if successful.

In the DARPA model, experts are hired to act as internal entrepreneurs, but with no personal financial interest at stake. They can pick their projects and champion them over months or years, becoming world-class experts in the decisions they are called upon to make, intimately familiar with the subtleties which bear on ultimate success. DARPA has proven itself time and again, and is responsible for much of the U.S. success in high-tech military hardware. It favors the high-risk, high-reward development efforts which are so urgently needed for moving potential AIDS drugs from the laboratory through early clinical trials.

- Develop full partnership between government, industry, physicians, and patients.

Problem: The current "parallel track" program was apparently conceived without industry input; it is based largely on a picture of pharmaceutical companies as unlimited sources of money ready to be tapped. As a result, the program's success has been limited. Only the largest companies can easily use it, and usually they do so grudgingly. We have heard that the FDA has been repeatedly frustrated by the unwillingness of companies to make important drugs available. Parallel track may also be an important disincentive, keeping pharmaceutical companies away from early development of potentially important treatments, lest they come under great pressure to provide those treatments free. [The problems could be alleviated, however, by the FDA shifting the line between parallel track and accelerated approval, on the theory that if a drug is ready for release to thousands of patients through parallel track, it is also ready for release to the same patients through the market. Then the incentives would turn, with small and large companies alike propelled to bring their best drugs forward instead of keeping them out of public sight.]

But partnership also means that industry accept responsibility along with rewards. It cannot be acceptable to hold up
government for exorbitant payments or demands as the price for cooperation in trials. And it cannot price products to exclude most of the population from critical drugs and skim the cream from the rich and well insured.

Industry has an incentive to restrain price excess, in order to avoid price controls. And the president can help by setting a national tone. AIDS activists have had modest success in pushing prices down, with no help whatever from the White House. Such leadership could make public pressure more effective than it could ever have been in the past.

- Never write off those already infected when planning or managing treatment research.

This may seem obvious, but a November 15 1992 New York Times op ed by well-known AIDS researcher Dr. William Haseltine, chief of human retrovirology at Harvard University, clearly writes off persons with HIV, urging that AIDS be fought with condoms, testing (including a 10-minute home test for "a potential partner"), and "the greatest hope for a solution to the AIDS epidemic," a (preventive) vaccine. He does advocate a quadrupling of worldwide medical research budgets, but in hopes of "a medical miracle" which may or may not come some day, not as part of a serious plan to improve management of research. If people with these attitudes are put in control of Federal AIDS research, they will have to fight an ongoing war against a public not willing to settle for a "solution" which abandons a million Americans to death.

- Establish a medical research ombuds office, where anyone who learns about research snafus can report them, and expect to see action when appropriate.

Over the years we have seen important research delayed or stopped entirely by hundreds of different problems. (For example, one kind of snafu which is becoming increasingly important is obstruction by offices set up by universities to harvest patent rights and royalties; these offices block progress by forbidding university researchers from collaborating with outside groups, unless prohibitive negotiations and paperwork take place first. Other kinds of problems concern delays in journal publication; but the list goes on and on. Almost every
potential AIDS drug is its own unique horror story of missed opportunities.

The one common thread in most of the problems that have held up AIDS drugs is that in principle they could easily be solved — often with a couple phone calls if from the right place (such as from a research troubleshooting office operating with the support of the president). But individual scientists, physicians, patients, and activists seldom have the clout to get the problems seriously addressed.

• Begin a consensus process including government, industry, scientists, physicians, and patients, to examine what has worked and what has not in AIDS research so far, and develop plans to move forward.

(Martin Delaney has developed this proposal; we should ask him for details.)
to: SFAF Public Policy Roundtable

from: ACT UP/Golden Gate Treatment Issues
      contact G'Dali Braverman, 252-5689
AIDS Treatment News
      contact John S. James, 861-2432
Project Inform
      contact Tonisa Clardy, 558-8669

date: 11/24/92

re: AIDS Treatment Research and Development:
Points to Consider

AIDS treatment activists have learned much about what does or does not work in drug research and development — which must become more productive in order to save the lives of people with AIDS or HIV. No consensus of the AIDS community will be complete if this vital experience is disregarded.

As West Coast treatment activists with little Washington experience, we cannot design specific Federal programs, restructurings, or initiatives. And much evaluation is needed before new programs can be structured. But we do not need to be silent as this critical time, since we can recommend principles which should guide the management of Federal AIDS treatment research and development — together with specific problems which these principles are designed to correct, or other illustrative examples.

The draft below is intended as a consensus document in process. Other points can and will be added. Our aim is to show that, despite the complexity of research issues and the need for formal evaluation of what has and has not already been accomplished in treatment development, our community's experience in trying to speed treatment development can be helpful now as transition input to guide future improvements in treatment development.
An effective national AIDS treatment research and development program must:

• Remember that the goal is to deliver results to people — especially major or substantial practical treatment improvements.

Problem: No amount of study of AZT, ddl, or ddC could possibly deliver a major treatment advance — yet that is where the largest share of Federal research effort is going. The usual excuse for this misdirection of resources is that there are no other drugs to study. In fact, there are dozens or hundreds of promising leads which have been proposed by leading scientists but not seriously evaluated or pursued — and there have been for years. The root problem is that usually only commercialized drugs can buy enough influence to navigate the immense obstacle course which blocks almost all potential treatments indefinitely.

Also, far too little attention has been given to "alternative" treatments — those which do not have major pharmaceutical-company sponsorship but nevertheless develop a popular following.

Effective Federal management would recognize this systemic problem, listen to scientists who believe in a drug but need help to get it considered, and provide assistance as appropriate.

• Continually evaluate the present status of AIDS treatment research and development, project future scenarios all the way through treatment delivery to all groups that need access, and take steps to fix glaring problems instead of ignoring or hiding them.

Problem: Today the drug development "pipeline" is empty; with the possible exception of d4T or compound Q, there is no potentially major antiretroviral drug in development except those in the earliest stages of human testing (such as protease inhibitors, tat inhibitors, and PMEA). This problem has been allowed to develop in full view for years, due to appalling delays even on drugs like tat inhibitors which leading mainstream AIDS scientists have long pleaded for. The current bleak treatment outlook is the totally predictable harvest of years of neglect, of high-level government indifference which
did not give anyone the authority to address this problem effectively.

What is needed is a shepherding effort to facilitate the passage of promising new drugs, which usually do not yet have major commercial or academic constituencies, through the late preclinical and early clinical development. At that point, any potentially major advance would likely take off on its own. But without proactive efforts to correct systemic deficiencies in the *early* flow of new drugs, the same major advances will instead remain in the laboratory forever.

Conventional wisdom holds that the reason for lack of progress in AIDS treatments is the scientific difficulty in controlling HIV. But nobody could possibly know whether or not we would now have major treatment advances if different kinds of AIDS drugs (such as tat inhibitors or hypericin) had been properly evaluated and tested years ago, when the information then existing clearly showed that they should have been. Scientific difficulty would be a legitimate excuse if the question were whether we could have been guaranteed better treatments already; of course there is no such guarantee. But the real question is whether we have properly managed the task of developing the treatment leads before us. And the answer is clearly that we have not.

- Reform the peer review process.

In NIH peer review (and also in FDA advisory committees) the busy professionals who are asked to judge are given huge stacks of paper to read before the single meeting — on projects they are usually unfamiliar with. In this situation it is humanly impossible to expect an in-depth review. Instead, the system forces superficial judgments, to the detriment of new and non-stereotyped ideas; it may also harm high-potential projects which would be threatening if successful.

The problems could be ameliorated by borrowing methods that have been used in a very successful technology organization, the Defense Advanced Projects Research Agency (DARPA). In this model, experts are hired to act as internal entrepreneurs, but with no personal financial interest at stake. They can pick their projects and champion them over months or years,
becoming world-class experts in the decisions they are called upon to make, intimately familiar with the subtleties which bear on ultimate success. DARPA has proven itself time and again, and is responsible for much of the U.S. success in high-tech military hardware. It favors the high-risk, high-reward development efforts which are so urgently needed for moving potential AIDS drugs from the laboratory through early clinical trials.

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Another problem is the writing off of people with advanced disease from clinical trials. Persons with under T-helper counts under 50, or with certain infections such as CMV retinitis, are generally excluded from trials of AIDS treatments.

- Establish a medical research ombuds office, where anyone who learns about research snafu can report them, and expect to see action when appropriate.

Over the years we have seen important research delayed or stopped entirely by hundreds of different problems. (For example, one kind of snafu which is becoming increasingly important is obstruction by offices set up by universities to harvest patent rights and royalties; these offices block progress by forbidding university researchers from collaborating with outside groups, unless prohibitive negotiations and paperwork
take place first. Other kinds of problems concern delays in journal publication; but the list goes on and on. Almost every potential AIDS drug has its own unique horror story of missed opportunities.

The one common thread in most of the problems that have held up AIDS drugs is that in principle they could easily be solved — often with a couple phone calls if from the right place (such as from a research troubleshooting office operating with the support of the president). But individual scientists, physicians, patients, and activists do not always have the clout to get the problems seriously addressed.

- Address the lack of communication between researchers.

Researchers need more occasions to sit down together and talk about their work. This seldom happens at large conferences, except in hallway conversations or other incidental private meetings.

National leadership is needed to overcome the competitiveness, which often prompts researchers to keep their work...

- Begin a consensus process including government, industry, scientists, physicians, and patients, to evaluate what has worked and what has not in AIDS research so far, and develop plans to move forward.

Martin Delaney is developing specifics of a consensus evaluation process.

We need a full partnership between government, industry, physicians, patients, and patient advocates.
Esgos:
Deliver:

Liability
Place of someone's return in flight!
I breed small clumps
Strikes... in the center.

Hence $%

Tree AVM fight in all countries.

How canettle - price? pass,

"TIE only wanted... tests lobbying".

Respect for one another.

Let Apple get treated in Sweden & other places, too.

Society can't stand that - not lobbying. But capital.

Wuhan discovered by someone.

Akknowledge that Apple is fully into new products.

Necesitate support for deeper change.

Safe for women. EU thought women.

Active, open, nonviolent.

Clamor... to help in severe allegations.

Effective and intense music, come. Let Apple join.

Natural for women, highly desirable.

Akknowledge, discoutfractured better. Can, legs.


Complete, apple.

All are DEFENDABLE of great importance.

Reciprocal care, equal in an A circle... Caveman endurance.

Cay women, PESSO, not melon.

Conflict freedom.
Don't drive WMT
Racism. Sexism, homophobia - means - call out every
Race and vioence must be gone. 6 yr. - 1 yr. can change issues
WMT had 3, now 6 or 7. - Support greenery as they see fit.
Don't objectify defended. so defend a Fresh.
Use various: PISP, Women's Col's Lead, not just
Mathewson. A most forcefully
open minded. A comprehension/Not only a simple
help come need. Not even, but everyone in
Us, even. Not everyone, but everyone in the gift.
Confident. People's gift can make the gift.
Amply, knowledgeable, queer, sexy, dude, dynamic.

Liberty Green - The Clean Needle 4th need.
Sun 11-6 - Edison St Fair
FOSCAVIR AT $24,000+ A YEAR IS DRUG ABUSE!

A national boycott of Astra Pharmaceutical Products, Inc. has been launched by ACT UP/NY and the Treatment Action Group (TAG). This drastic measure is being taken to force Astra to reduce the wholesale price of Foscavir from $21,500 per year to $10,000 a year. Astra now concedes that $24,000+ a year wholesale is a more accurate figure. Research data, however, shows the actual wholesale price to be closer to $30,000 per year. Activists have been trying to negotiate with Astra to reduce the price, but Astra has been completely Intransigent.

The F.D.A. approved Foscavir as a therapy for cytomegalovirus (CMV) retinitis in people with AIDS (PWAs). Foscavir can delay the progression of blindness and prevent reinfection caused by CMV. Up to 46% of PWAs develop CMV retinitis. Cytovene (ganciclovir), the only other drug approved for CMV retinitis, is priced at $9,000 a year by Syntex. However, up to 40% of patients requiring therapy with ganciclovir cannot tolerate it or are not helped by the drug. Foscavir is their only alternative.

AT $24,000+ A YEAR, WHO CAN AFFORD NOT TO GO BLIND?

Astra claims that the price for Foscavir is a fair price based on the high cost of its development and the small size of its market. But Astra has been unwilling to offer any documentation that would support this claim. Foscavir, in fact, is neither difficult nor expensive to make. The chemical on which it is based was discovered in 1924 and the drug's anti-viral properties have been known since the 1970's. Foscavir was approved by the F.D.A. through an accelerated approval process which allowed Astra to market Foscavir years earlier than would have normally been possible.

Furthermore, Foscavir was developed with funding from the U.S. National Institutes of Health. The U.S. Government will, of course, not gain financially from the marketing of Foscavir. Rather, as a major purchaser of drugs, and with 40% of PWAs receiving Medicaid, the U.S. Government will be one of the victims of this ASTRAnomical greed.

AB Astra, the Swedish parent company, is one of the fastest growing drug companies in the world. In 1991, its pre-tax profits were up 36%; soaring to over $600 million. The company expects sales and profits to increase 20-25% in 1992. Activists recognize that drug companies need to make profits, but for Astra to place an exorbitant price on a life-saving drug, so that the company can meet its yearly growth projections is unconscionable.

With the absence of national health care in America, finding affordable health insurance is a pervasive problem. Usually, individuals fortunate enough to have private insurance are only reimbursed 80% of their medical costs. A drug that costs $24,000+ a year wholesale will cause patients to quickly reach their insurance caps. PWAs are being forced into already crumbling Medicaid programs by prof-

BOYCOTT XYLOCAINE!
(use lidocaine HCI)

Xylocaine, used by dentists and physicians worldwide, is one of Astra's biggest revenue-making products. Dentists and physicians are being asked to refrain from using Xylocaine in their practices until Astra reduces its wholesale price for FOSCAVIR to a still profitable $10,000 a year. Xylocaine is Astra's brand name for lidocaine HCI which is available from numerous companies.

FOR INFORMATION on how you, your dentist and your doctor can support the boycott, CONTACT ACT UP/NY or TAG through Jason Childers at 212-564-AIDS or Dave Rephun at 212-929-6143.

NO: XYLOCAINE
YES: Lidocaine HCI

Endorsed by:
AIDS ACTION BALTIMORE
AIDS ACTION COUNCIL
AIDS TRUST OF MARYLAND
GAY MEN'S HEALTH CRISIS
HARVEY MILK DEMOCRATIC CLUB
INTERNATIONAL STEERING COMMITTEE FOR PEOPLE WITH HIV/AIDS
LAMBDA LEGAL DEFENSE AND EDUCATION FUND
NEW YORK PHYSICIANS FOR HUMAN RIGHTS
OUTDOCS/GAY & LESBIAN DOCTORS PROJECT INFORM
STAND UP/HARLEM
(list in formation)

ACT UP TAG
FOSCAVIR A MAS DE $24,000 POR AÑO ES TRAFICO DE DROGAS

ACT UP/ NY Y EL GRUPO DE ACCION DE TRATAMIENTOS (TAG) ESTAN ORGANIZANDO UN BOYCOT NACIONAL CONTRA Astra Productos Farmaceuticos Inc. ESTA ACCION DRASTICA ES TOMADA PARA FORzar Astra a REDUCIR EL PRECIO, INCRECIBLEMENTE ALTO, DE LA MEDICINA FOSCAVIR, DE $24,000 A $10,000 POR AÑO. HACE MAS DE NUEVE MESES, ASTRA ANUNCIo QUE EL PRECIO ANUAL DE FOSCAVIR PODRIA SER $21,500 ANUALES. ASTRA RECONOCE AHORA QUE EL COSTO ANUAL MAS REALISTA ES $24,000 O MAS. LOS ESTUDIOS EFECTUADOS POR FUENTES INDEPENDIENTES INDICAN QUE EL PRECIO REAL POR AÑO SERA $30,000. DURANTE MESES LOS ACTIVISTAS HAN TRATADO DE NEGOCIAR UNA REDUCCION DEL PRECIO DE FOSCAVIR.

ASTRA HA SIDO TOTALMENTE INTRANSIGENTE LA OFICINA DE ALIMENTOS Y MEDICINAS DE LOS EEUU (FDA) AUTORIZO EL USO DE FOSCAVIR COMO TRATAMIENTO PARA INFECCION DE LA RETINA CON CYTOMEGALOVIRUS (CMV) EN PERSONAS CON SIDA (PWAS). FOSCAVIR PUEDE DEPORAR EL PROGRESO DE LA INFECCION ANTES QUE PRODUZCA CEGUERA Y PREVENIR LA REINFECCION CON CMV DE LA RETINA. EL 46% DE LAS PERSONAS CON SIDA DESARROLLA INFECCION DE CMV EN LA RETINA. CYTOVENE (GANCICLOVIR), PRODUCIDA POR EL LABORATORIO SYNTAX, LA OTRA MEDICINA APORBADA PARA TRATAMIENTO DE CMV, CUESTA $9,000 POR AÑO. SIN EMBARGO, CASI EL 40% DE LOS PACIENTOS NO PUEDEN TOLERAR O SON RESISTENTES AL GANCICLOVIR. PARA ELLOS FOSCAVIR ES EL UNICO TRATAMIENTO DISPONIBLE.

PERO... A $24,000 POR AÑO QUIEN PUEDE DARSE EL LUJO DE NO QUEDARSE CIEGO? ASTRA ASEGURO QUE EL PRECIO DE FOSCAVIR ES JUSTO, BASADO EN LOS ALTOS COSTOS ORIGINALES POR EL DESARROLLO DE LA MEDICINA Y EL REDUCIDO NUMERO DE PACIENTES QUE USARAN LA MEDICINA. PERO ASTRA SE NIEGA A MOSTRAR LA DOCUMENTACION QUE RESPALDA ESTE CRITERIO PARA DETERMINAR EL PRECIO DE FOSCAVIR. EN REALIDAD, FOSCAVIR FUE DESARROLLADA CON LA AYUDA FINANCIERA DE LOS INSTITUTOS NACIONALES DE SALUD (NIH) Y NO ES UNA MEDICINA DIFICIL O COSTOSA PARA PRODURCIR LA SUBSTANCIA QUIMICA EN QUE SE BASA FOSCAVIR FUE DESCUBIERTA EN 1924 Y LAS PROPIEDADES ANTIVIRALES DE LA DROGA SON CONOCIDAS DE LOS AÑOS '70. ASI DE APROBACION URGENTE DE MEDICINAS QUE PERMITIO A ASTRA PONER EN VENTA LA MEDICINA CON AÑOS ADELANTO AL PROCESO REGULAR DEL APROBACION.

EL GOBIERNO FEDERAL NO OBTERNA GANANCIAS POR EL DESARROLLO Y VENTA DE FOSCAVIR. POR EL CONTRARIO, SIENDO UN COMPRADOR MAYORISTA DE MEDICINAS Y CON EL 40% DE LAS PERSONAS CON SIDA EN MEDICAID, EL GOBIERNO FEDERAL SERA EN REALIDAD UNA DE LAS VICTIMAS DE LA CODICIA "ASTRONOMICAL" DE LA FARMACEUTICA.

ASTRA, LA COMPANIA SUECA DUENA DE ASTRA, ES UNA DE LAS COMPANIAS FARMACEUTICAS DE MAYOR CRECIMIENTO EN EL MUNDO. EN EL 1991 SUS INGRESOS, ANTES DE IMPUESTOS, CRECieron UN 36%, LLEGANDO A $600 MILLONES. LA COMPANIA ESPERA QUE LAS VENTAS Y GANANCIAS CREZCAN UN 20 A 25% EN 1992. LOS ACTIVISTAS RECONOZEN QUE LAS COMPANIAS FARMACEUTICAS NECESITAN OBTENER GANANCIAS, PERO ES MORALEMENTE INCEPTABLE QUE ASTRA PONGA PRECIOS EXORTANTES PARA UNA MEDICINA IMPRESCINDIBLE, SOLAMENTE PARA PODER CUMPLIR CON SUS GANANCIAS PROYECTADAS PARA EL AÑO.

DADA LA FALTA DE UN SISTEMA NACIONAL DE SALUD EN LOS ESTADOS UNIDOS, OBTENER TRATAMIENTO MEDICO O SEGURO MEDICO ACCESIBLE ES UN PROBLEMA CONSTANTE. GENERALMENTE, AQUELLOS INVIVUDOS A FORTUNADOS QUE DISPONEN DE SEGURO MEDICO PRIVADO SON REEMBOLSADOS SOLAMENTE EL 80% DE LOS GASTOS MEDICOS. UNA MEDICINA QUE CUESTA $24,000 POR AÑO A PRECIOS MAYORISTAS OBLIGARA A LOS PACIENTES A GASTA EL TOTAL MAXIMO ANUAL DISPONIBLE DE SUS SEGUROS MEDICOS. LAS PERSONAS CON SIDA ESTAN SIENDO FORZADAS A USAR MEDICAID POR COMPANIAS FARMACEUTICAS COMO ASTRA.

BOYCOTT XYLOCAINE (USE LDLOCAINE HCL)

LA MEDICINA "XYLOCAINE" USADO POR LOS DENTISTAS DE TODO EL MUNDO, ES UNO DE LOS PRODUCTOS ASTRA DE MAYOR VENTA. ESTAMOS PIDIENDO A LOS DENTISTAS Y MEDICOS QUE NO USEN XYLOCAINE, HASTA QUE ASTRA REDUZCA EL PRECIO DE FOSCAVIR A $10,000 POR AÑO UN PRECIO RAZONABLE. FUE PRODUIRA GANANCIAS SUFICIENTES PARA ASTRA. XYLOCAINE ES EL NOMBRE COMERCIAL DE ASTRA. LA MISMA MEDICINA PUEDE REEMPLAZARSE POR LDLOCAINE HCL, PRODUCIDA POR OTRAS COMPANIAS.

PARA INFORMACION SOBRE COMO AYUDAR EN EL BOYCOT, TONTU USTED COMO DENTISTA, POR FAVOR LLAMAR A: ACT UP/ NY O Y TAG, JASON CHILDERS (212) 564-AIDS (INGLES) O GUS VIANNA (212) 564-AIDS (ESPAÑOL/INGLES) O DAVID REPHUN (212) 929-6143.

BOYCOT ASTRA !!! BOYCOT "XYLOCAINE" !!!