

Ac
~~David~~

ACT UP

4/88

awakening. The faster it awakens, the more lives will be saved.

This article is appearing simultaneously in ACT UP Los Angeles newsletter, (213) 668-2357.

Official Statement issued by AIDS Action Committee of Boston 2 weeks ago affirmed support for Massachusetts General Hospital in response to a protest against the hospital by ACT UP Boston for turning away AIDS patients. Their beds were not full, but their "AIDS beds" were full. It is becoming increasingly evident, throughout the country, that the large, federally- and corporate-funded "AIDS service" organizations, in NY, Massachusetts, SF, LA and Minneapolis, are very sensitive to their funding sources, and less willing to take a stand. Many receive large grants from insurance companies, have a 2 million-dollar payroll, and a 2 mill + budget. They are easing us through the dying process.

- It is becoming increasingly useful to ~~stress~~ address the issue of AIDS research problems within the context of research for other diseases, and if the research is slow for all diseases (breast cancer, heart disease, etc.) than the fact that AIDS is an epidemic, and the projected numbers, must be stressed in that context.

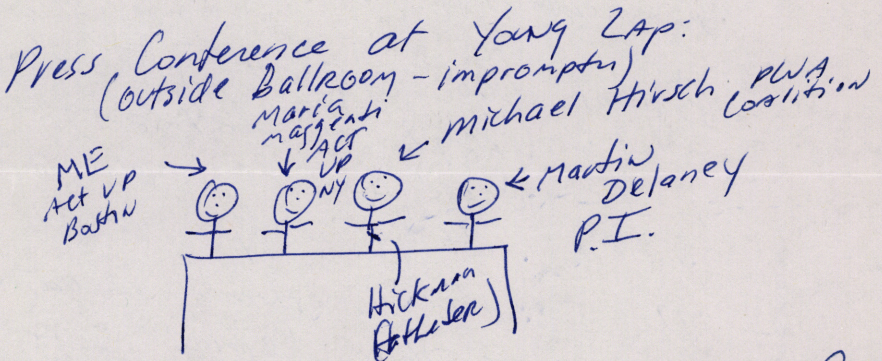
7/29/88

John -

Nemus sent the enclosed letter.

Boston Conference: wild:

- Zapped Burroghs - Wellcome guy during his speech.
- Massive protest of Frank Young. PWA's, PI, ACT UP, etc.
- Zapped Martin Hirsch + Jerry Groupman of Harvard Med school.



Your conference issue was well-received and we spread it around. (got more copies + planted them everywhere)

(over)
↓

- Dextran sulfate protocol has started accruing patients at UMASS Worcester. 45 mins from Boston.
- ACT UP/Boston will zap Lyphomed at its Bedford, MA facility (over 'proprietary information' bullshit and fight with competition taking precedence over saving lives, etc.) on August 4th.
- ACT UP/Boston offered seat on Dukakis Governor's task force on AIDS; took only a seat on treatment subcommittee; refused seat on board until proper gay, black, hispanic, female, PWA representation shown.
- Protocol 005 stopped - NO more accrual (except in Bethesda). Iris Long + I succeeded - it's over. Only a few patients left in study. (S.F.)
- The Institute for Human Sexuality had to remove their 'explicit' safe sex videos from their booth in the lobby - Hotel Mgmt. said 'families' were in residence. Big broo-ha-ha over acrylic penis rubber demo's as well. Most amusing; they ended up with a suite upstairs - place was packed.

ACT UP/Boston
492-2887 (49-ACTUP)
P.O. Box 483, Kendall Square Station, Cambridge, MA 02142

7/6/88

Mr. G. Steven Rose
20 Phillips St. Apt. A
Boston, MA 02114

John J. Jones
AIDS Treatment News

Dear John:

Hope Stockholm was useful and informative for you. More + More people within various systems here are reading ATN; my doctor doesn't though. Fenway Community Health in Boston is pushing for a new treatment center and released their year's research data + conclusions (plus some Stockholm news) at a presentation the other night; I was dismayed to hear that they had only studied anal sex and put across the notion that 'unsafe' sex of other varieties is OK. I am pretty sure that I didn't catch HIV getting sucked; just don't like it. Plus →
3



SILENCE=DEATH

By 1991 more people will have died of AIDS than in the entire Vietnam War.
Women, men, and children are all affected. . .
too many people are dying, too many people are silent.

The government's lack of action and silence on AIDS is a political scandal that must be investigated. Why is the government not treating this crisis as a national medical emergency? What is the government's real policy on AIDS?
Is this genocide?

it would seem to me that exchanging saliva, semen, etc. (urine?) spreads EBV/CMV like crazy, which are serious (especially CMV). Having owned a white bandanna for over a decade, I have great difficulty with people who continue to indulge in unprotected unsafe sex, but it's almost as if it's a last cause here in Roman Catholic Boston. The boys all feel 'guilty' about (using condoms) jacking off. (The Nuns in parochial school all said these were 'bad') So - they go out, get drunk, and get licked in the bushes. Oy Vey. ACT UP has been focusing on treatment issues - but maybe we need some *Prevention*. I will get to you with a copy of the 'Dementia' protocol soon, ⁽²⁰⁰³⁾ meanwhile, the ACT has (I'm off it now) done in my Hematocrit + I'm anemic (No transfusions yet.) + Bone-marrow Suppressed. I'm beginning to think the medical establishment is (en masse) 'demented'.

Steve Rose
ACT UP / Boston

*OR, some good safe sex clubs.
I'm going to NYC in desperation
1st thing tomorrow!!!

[1998]

ACT UP

John Hancock

**HOW MANY WILL DIE NEEDLESSLY THIS CHRISTMAS
FROM JOHN HANCOCK'S MURDEROUS POLICY ?**

WE DEMAND THIS POLICY BE CHANGED NOW !

Join ACT UP / Boston at the Hancock Tower Monday December 19 from 4:30 - 6:30

Help bring the message to Hancock policy holders that, unlike Blue Cross - Blue Shield, Harvard Community Health, Bay State and many other plans, **JOHN HANCOCK CONTINUES TO REFUSE TO COVER AEROSOLIZED PENTAMIDINE AS PRIMARY PROPHYLAXIS PRIOR TO THE FIRST BOUT OF PCP, THE #1 KILLER OF PWAs.**

Bring noise makers, whistles, bells, pots and pans and make the message heard.

Call (617) 492-2887 for C.D. training information

S I L E N C E = D E A T H

If you can't come, show your care by donating time, materials or money

\$5 _____, \$10 _____, \$20 _____, More _____

ACT UP/ Boston
PO Box 483
Kendall Square Station
Cambridge, MA 02142
(617) 49-ACTUP

Dear ACT UP, etc. organizations:

We are trying to change the ddI clinical trial protocols ACTG 116, 117, and 118 so that more people can enroll and have an opportunity to get ddI if they want it. For us in ACT UP/Boston this means communicating with people in the Harvard AIDS Clinical Trial Unit (ACTU) and probably demonstrating on Jan. 17 (would anyone care to make it national?) We have spent some time going over the protocols and wanted to share our conclusions with you, and hope that you can use these to raise the same or similar concerns at the ACTU nearest you.

Many researchers are blaming slow enrollment in the ddI trials on the existence of the new "parallel track" program. We maintain that these trials are proceeding no more slowly than the usual AIDS Clinical Trials Group (ACTG) trials. We cannot afford to have the parallel track program trashed, and changes in 116, 117, 118, and *most* ACTG trials are still desperately needed. Future trial design will be shaped by how we respond to trials *now*.

If there are no ACTUs near you, this underscores the need for the parallel track, and you can help by letting the ACTG researchers hear from you directly.

Enclosed you will find: 1) Proposed changes in ddI protocols, submitted to Harvard ACTU; 2) names and addresses of ACTUs around the country; 3) sample letter for those far away from ACTUs.

We urge you to review this information carefully, and act on it in whatever way you find appropriate as soon as possible. You can obtain more detailed info. about the ddI trials by calling 1-800-TRIALS-A.

Also enclosed:

1) *Foscarnet/ASTRA update and petition.* Activist groups around the country continue to demand the release of foscarnet for CMV retinitis. We've enclosed a chronology of our frustrating negotiations with ASTRA pharmaceuticals in Westboro, Mass., manufacturers of the drug.

2) *Sample Burroughs-Wellcome boycott materials.* The boycott is really happening! We've had a lot of success in persuading drugstores to display "shelf-talkers"-- signs urging customers to select generic alternatives to Burroughs-Wellcome products. Sticking the products works too (and often leads up to the shelf-talkers...)

Feel free to contact us for more information:

ddI contact: Ray Schmidt (617) 661-3115

foscarnet contact: Derek Link (617) ~~922-9972~~ 522-2427

B-W boycott contact: David Hamburger (617) 232-7970

Keep up the fight!



Ray Schmidt
ACTUP/Boston

November 21, 1989

ACT UP/Boston
P.O. Box 483
Kendall Square Station
Cambridge, MA 02142

To: Harvard ACTU

From: Mike Immel and Ray Schmidt for ACT UP/Boston

Attn: Dr. Martin Hirsch, Dr. Jerome Groopman, Dr. Robert Schooley, Dr. Davis Allen, and Dr. Deborah Cotton

Re: Recommendations for Changes to the ddi ACTU clinical trials 116, 117, 118, and the Treatment IND and Compassionate Use Protocol.

The current clinical trial designs for 116 and 117 fail to respond to the needs of patients seeking viable treatment options. We in the AIDS affected communities know that the *possibility of getting valuable treatment* is the motivation for patients to enter trials. To speak of the "public good" and the "honor of making history" as motivating benefits for trial entry is unrealistic because it denies the profound circumstances under which participants actually come to trials. For those doing well on AZT there is no good reason to enter these trials (because they may get randomized to ddi, or to much higher doses of AZT than they currently take); for those not doing well on AZT there is no good reason to enter these trials (because they may get randomized to AZT). To make the trials worthwhile to patients, the ACTU needs to adjust the dosage level of AZT to reflect current clinical use, implement a crossover design in trials 116 and 117, and to reduce the stringent entry criteria into trial 118 and the parallel track.

ACT UP/Boston has had several meetings with ACTU researchers and clinicians, carefully reviewed the referenced protocols, and debated at great length the design of these trials. We request that you review and formally respond by December 1, 1989 to the following recommendations.

1. AZT Dose Levels

a. The full dose AZT levels proposed in studies 116 and 117 are unacceptable in light of recent findings that half dose levels of AZT are equally if not more efficacious. The AZT levels should be changed to 600 mg/day or current patient dose.

2. Crossover in studies 116 and 117

a. Allows patients equal access to whichever drug works best. Crossover should be implemented after the first opportunistic infection or toxicity. Sufficient data can be gained for both clinical use and marketing needs with a crossover design. In the current design, patients enroll, are randomized to a study drug, and are forced to continue on that study drug through a series of opportunistic infections for 18 months, unless the patient *dies* first. The purpose of this design is to prove the value of ddi as extending life better than AZT. The current design allows patients to die to prove that ddi can be marketed as a life extending drug.

3. 118

- a. Current inclusion criteria call for a repeated drop in hematocrit level. No patient should be subjected to this condition more than once; *trial design must reflect the realities of clinical care*. The number of challenges required to prove AZT toxicity of any kind must be reduced to one.
- b. 118 should also be open to those who have not experienced AZT toxicity, but for whom AZT is no longer effective (based on onset of an OI, declining surrogate markers, and/or clinical status).
- c. Voluntary entry; enroll those who do not want AZT (*for whatever reason*) to take ddI in the trial setting of 118. To deny patients' motivations for bypassing the "standard" treatment of AZT in favor of an experimental drug prevents the rapid gathering of information on ddI, and coerces people into the use of AZT. Such voluntary entry would include thorough informed consent on the risks and the benefits of both AZT and ddI.
- d. With the above trial design revisions, 118 could be the largest sample group; currently trial 118 is the smallest sample group.

4. Treatment IND

- a. AZT toxicity requirements should be relaxed to match those of 118 as described above.

5. Compassionate Use Protocol

The requirement for 3 opportunistic infections within six months prior to enrollment is far too stringent.

AIDS Clinical Trials Group Centers

CALIFORNIA

***Southern California Pediatric Group**
Principal Investigator: Yvonne Bryson
Contact: To be announced

University of California at Los Angeles School of Medicine

Principal Investigator: David Golde
Contact: David Hardy 213 206 6414

Los Angeles County-University of Southern California Medical Center

Principal Investigators: Alexandra Levine
John Leedom
Contact: Yvonne Barranday or Jane Sullivan
213 226 5225 or 5226

University of California at San Diego Medical Center

Principal Investigator: Stephen Spector
Contact: Candice McIvor 619 543 6447

San Francisco General Hospital/University of California at San Francisco

Principal Investigator: John Mills
Contact: Marti Nash 415 821 5531

Stanford University School of Medicine

Principal Investigator: Thomas Merigan
Contact: Virginia Tallman 415 723 6231

***Northern California Pediatric Group**

Principal Investigator: Diane Wara
Contact: To be announced

DISTRICT OF COLUMBIA

George Washington University Medical Center

Principal Investigator: Richard Schulof
Contact: Jane Courtless 202 994 3027 or 2417

FLORIDA

University of Miami School of Medicine

Principal Investigators: Margaret Fischl
Gwendolyn Scott
Contact: Janie Reese 305 549 7323

ILLINOIS

Northwestern University Medical School

Principal Investigator: John Phair
Contact: Lisa Williams 312 908 4114

***Children's Memorial Hospital**

Principal Investigator: Ram Yogev
Contact: To be announced

INDIANA

Indiana University School of Medicine

Principal Investigator: Robert Jones
Contact: Bess Zwicky 317 274 8456

LOUISIANA

Tulane University Medical Center

Principal Investigator: Newton Hyslop, Jr.
Contact: Jennifer Istro 504 587 7316

MARYLAND

Johns Hopkins University Medical Center

Principal Investigator: John Bartlett
Contact: Carol Hendricksen/Ed Fuchs 301 955 2898

***Baltimore Pediatric Group**

Principal Investigator: John Modlin
Contact: To be announced

MASSACHUSETTS

Harvard Medical School

Principal Investigator: Martin Hirsch
Contact: Ellen Godfrey 617 726 5596

***Boston City Hospital**

Principal Investigator: Stephen Pelton
Contact: To be announced

***Boston Children's Hospital**

Principal Investigator: Kenneth McIntosh
Contact: Nancy Karthas/Kerrie Flynn 617 735 6832

University of Massachusetts Medical School

Principal Investigator: Neil Blacklow
Contact: Charla Andrews 617 856 3158

MINNESOTA**University of Minnesota Health Sciences Center**

Principal Investigator: Henry Balfour, Jr.
Contact: Sue Reaney 612 625 1462

MISSOURI**Washington University School of Medicine**

Principal Investigator: Lee Ratner
Contact: William Powderly 314 454 0058

NEW JERSEY**Robert Wood Johnson Medical School**

Principal Investigator: David Gocke
Contact: Doris Connolly 201 937 7710

***New Jersey Children's Hospital**

Principal Investigator: Edward Connor
Contact: 201 268 8452 or 8565

NEW YORK**University of Rochester Medical Center**

Principal Investigator: Raphael Dolin
Contact: Peggy Christy 716 275 5871

***Columbia University Medical Center**

Principal Investigator: Anne Gershon
Contact: To be announced

Albert Einstein College of Medicine of Yeshiva University

Principal Investigator: Ruy Soeiro
Contact: 212 430 3659 or 2371

State University of New York at Stony Brook

Principal Investigator: Roy Steigbigel
Contact: Ruth Ann Carpenter 516 444 1660

Cornell University Medical College

Principal Investigator: Henry Murray
Contact: Katherine Kelly 212 472 4769

Memorial Hospital/Memorial Sloan-Kettering Cancer Center

Principal Investigator: Donald Armstrong
Contact: Denise Bundow 212 794 7168 (KS)
Chris Cusumano 212 794 7168 (other protocols)

New York University Medical Center

Principal Investigators: Fred Valentine
William Borkowsky
Contact: Mary Ann Kiernan or Howard Ngai
212 340 6565

Mount Sinai School of Medicine

Principal Investigator: Henry Sacks
Contact: Pamela Weisen or John Schalhoub
212 241 8902

St. Luke's/Roosevelt Medical Center

Principal Investigator: Michael Greico
Contact: George McKinley 212 554 7192

NORTH CAROLINA**Duke University Medical Center**

Principal Investigator: Dani Bolognesi
Contact: John Bartlett 919 684 5260

The University of North Carolina at Chapel Hill School of Medicine

Principal Investigator: Stanley Lemon
Contact: Division of Infectious Diseases
919 966 2536

OHIO**The Ohio State University Medical Center**

Principal Investigator: Robert Fass
Contact: Jodi Malone 614 293 8732

Case Western Reserve University Medical Center

Principal Investigator: Michael Lederman
Contact: Carol Johnson 216 844 8175

University of Cincinnati College of Medicine

Principal Investigator: Peter Frame
Contact: Peggy Hall 513 872 6977

PENNSYLVANIA**University of Pittsburgh School of Medicine**

Principal Investigator: Monto Ho
Contact: Cynthia Zagieboylo

The Milton S. Hershey Medical Center

Principal Investigator: Elaine Eyster
Contact: Ann Hamory 717 531 8399

TEXAS***Baylor University College of Medicine**

Principal Investigator: William Shearer
Contact: To be announced

WASHINGTON**University of Washington School of Medicine**

Principal Investigator: Lawrence Corey
Contact: Ann Collier 206 223 4756

* Denotes Pediatric Group

recurs at the first reduced dose, withhold drug until hematologic values reach grade 2 and then resume at the second reduced dose level.
For grade 3 hyperuricemia toxicity (uric acid = 12.1 to 15 mg/dl): Withhold study medication until uric acid levels fall to = or < grade 1 toxicity levels and then resume dosing at the first reduced dose. If grade 3 toxicity recurs at the first reduced dose level, withhold study medication until uric acid levels fall to = or < grade 1 toxicity and then resume dosing at the second reduced level.
Toxicity grades according to NIAID Recommendations for Grading Acute and Subacute Toxic Effects (Adults).

Drug Company(ies):

Drug 1: Bristol-Myers
5 Research Parkway
Wallingford, CT 06492-7660
Contact Person: Unspecified

Phone: (203) 284-6000
Phone: 1-800-662-7999.

Drug 2: Burroughs-Wellcome
3030 Cornwallis Road
Research Triangle, NC 27709
Contact Person: Jacobs, Mary
Kirk, Ed.

Phone: (919) 248-3000

Participating Units:

UCLA:
UCLA School of Medicine
650 Circle Drive
Los Angeles, CA 90024
Contact Person: Hardy, David
St Denis, John
Walker-Chyle, Mary.

Phone: (213) 206-6414
Phone: (213) 206-6415

UCLA HARB:
Harbor General
1124 Carson Street
Torrance, CA 90509
Contact Person: Kruger, Sally

Phone: (213) 533-3848.

UCLA SPVA:
Sepulveda Veterans Medical Center
16111 Plummer Street
Sepulveda, CA 91343
Contact Person: Manchester, Betsy
Phone: (818) 364-3205
Phone: (818) 891-7711.

P/SCPG CDSI:
Cedars-Sinai Medical Center (Pediatrics)
8700 Beverly Boulevard
Los Angeles, CA 90048
Contact Person: Spring, Leslie
Phone: (213) 206-6369
Phone: (213) 855-4431.

P/SCPG CHLA:

Children's Hospital of Los Angeles (Pediatrics)
4650 Sunset Boulevard
Los Angeles, CA 90027
Contact Person: Spring, Leslie Phone: (213) 206-6369
Phone: (213) 669-2288.

P/SCPG LACM:
L A County Medical Center USC (Pediatrics)
1200 North State Street
Los Angeles, CA 90055
Contact Person: Unspecified Phone: (213) 226-3691.

P/SCPG LAPE:
UCLA Medical Center (Pediatrics)
10833 LeConte Avenue
Los Angeles, CA 90024
Contact Person: Spring, Leslie Phone: (213) 206-6369
Phone: (213) 825-5235.

USCA:
University of Southern California
1200 North State Street
Los Angeles, CA 90033
Contact Person: Barranday, Yvonne Phone: (213) 226-5225
Halley, Jane Phone: (213) 226-5226.

STAN:
Stanford University School of Medicine
300 Pasteur Drive
Stanford, CA 94503
Contact Person: Unspecified Phone: (415) 723-6231.

STAN KAIS:
Kaiser Permanente Medical Group
2200 O'Farrell Street
San Francisco, CA 94115-3394
Contact Person: Unspecified Phone: (415) 723-6231.

STAN PAVA:
Veterans Medical Center Palo Alto
3801 Miranda Avenue
Palo Alto, CA 94304
Contact Person: Unspecified Phone: (415) 723-6231.

UCSD:
University of California at San Diego
3821 4th Avenue
San Diego, CA 92103
SITE IS FULL
Contact Person: Jacobsen, Cindy Phone: (619) 298-7021.

UCSF:
San Francisco General Hospital
995 Potrero Street

San Francisco, CA 94110

Contact Person: Dionan, Barbara Phone: (415) 821-5089.

GWNH:

George Washington University Medical Center

2150 Pennsylvania Avenue NW

Washington, DC 20037

Contact Person: Courtless, Jane Phone: (202) 994-2497

Olson, Jamie Phone: (202) 994-2493.

HERS GWHP:

Hemophilia Treatment Center

2150 Pennsylvania Avenue NW

Washington, DC 20037

Contact Person: Russell, Stacy Phone: (202) 994-4608

Phone: (202) 994-7973.

MIAM:

University of Miami School of Medicine

1611 NW 12th Avenue

Miami, FL 33101

Contact Person: Morejon, Evelyn Phone: (305) 549-7538

Casuso, Juan Phone: (305) 549-7323.

NORT:

Northwestern University Hospital

303 E Superior Avenue

Chicago, IL 60611

Contact Person: Norman, Tamara Phone: (312) 908-9636

Phone: (312) 908-8388

Phone: (312) 908-1971.

NORT RUSH:

Rush Presbyterian/St Lukes Medical Center

1750 West Harrison

Chicago, IL 60612

Contact Person: Norman, Tamara Phone: (312) 908-9629

Phone: (312) 908-1971.

P/CHIG CHIG:

Chicago Children's Memorial Hospital (Pediatrics)

2300 Childrens Plaza Box 20

Chicago, IL 60614

Contact Person: Lovato, Gayle Phone: (312) 880-4757

Phone: (312) 880-4000.

INDI:

Indiana University Hospital

1100 West Michigan

Indianapolis, IN 46202-5250

Contact Person: Zwickle, Beth Phone: (317) 274-8456

Relue, Julie.

TULA:

Tulane University Medical Center
1430 Tulane Avenue
New Orleans, LA 70112-2899
Contact Person: Greenspan, Deborah Phone: (504) 584-3605
Gordon, Connie.

TULA HOTL:
Charity Hospital/Louisiana State University
1542 Tulane Avenue
New Orleans, LA 70112
Contact Person: Greenspan, Deborah Phone: (504) 584-3605
Phone: (504) 568-5030.

HARV BCHO:
Boston City Hospital
818 Harrison Avenue
Boston, MA 02118
Contact Person: Saunders, Carol Phone: (617) 424-5404.

HARV BIHO:
Beth Israel Hospital
330 Brookline Avenue
Boston, MA 02115
Contact Person: Hussey, Shelia Phone: (617) 735-4103
Phone: (617) 735-2000.

HARV MGHO:
Massachusetts General Hospital
Fruit Street Gray 440
Boston, MA 02114
Contact Person: Godfrey, Ellen Phone: (617) 726-5598
Phone: (617) 726-5596.

HARV NEDH:
New England Deaconess Hospital
185 Pilgrim Road
Boston, MA 01938
Contact Person: Fitch, Helen Phone: (617) 732-9729
Phone: (617) 732-5596.

MASS:
University of Massachusetts Medical Center
55 Lake Avenue North
Worcester, MA 01655
Contact Person: Andrews, Charla Phone: (508) 856-2456
Tolson, Karen Phone: (508) 856-3158.

MASS BSMC:
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199
Contact Person: Andrews, Charla Phone: (508) 856-2456
Tolson, Karen Phone: (413) 784-5376.

John Hopkins Hospital
600 North Wolfe Street
Baltimore, MD 21205
Contact Person: Hendrickson, Carol Phone: (301) 955-2898
Fuchs, Ed.

University of Minnesota Health Center
Box 437
Minneapolis, MN 55455
Contact Person: Reaney, Su Phone: (612) 625-1462
Reed, Nancy Phone: (612) 624-6119
Pollock, Susan.

Washington University of Medicine
660 South Euclid Street
St Louis, MO 63118
Contact Person: Klebert, Michael Phone: (314) 454-0538
Phone: (314) 454-0058.

University of North Carolina School of Medicine
547 Burnett Womack Building CSB 229 H
Chapel Hill, NC 27599-7030
Contact Person: Colclough, Ginga Phone: (919) 966-2536
Phone: (919) 966-6712
Phone: (919) 966-7198.

Duke University Medical Center
Box 3408
Durham, NC 27710
Contact Person: Reyle, Kelly Phone: (919) 684-5260.

University of New Jersey Robert Wood Johnson Medical School
1 Robert Wood Johnson
New Brunswick, NJ 08903
Contact Person: Connaly, Doris Phone: (201) 937-8930.

Jack Weiler Hospital
1300 Morris Park Avenue
Bronx, NY 10461
Contact Person: Vitaglieno, Laura Phone: (212) 430-3659.

Cornell University Medical Center
1300 York Avenue
New York, NY 10021
Contact Person: Weiss, Walter Phone: (212) 746-4177
Phone: (212) 554-7192.

MSKC:

Memorial Sloan-Kettering

1275 York Avenue

New York City, NY 10021

Contact Person: Popper, Bill

Phone: (212) 639-7168

Phone: (212) 794-8082.

NYUN:

Bellevue Hospital

27th and 1st Avenue

New York City, NY 10016

Contact Person: Kiernan, Mary Ann Phone: (212) 340-6565

Ngai, Howard

Phone: (212) 340-6401.

SLRO:

St Lukes/Roosevelt Hospital

428 West 59th Street

New York, NY 10019

Contact Person: Kolatch, Brenda Phone: (212) 523-6741

Phone: (212) 523-6722.

ROCH:

University of Rochester Medical Center

601 Elmwood Avenue

Rochester, NY 14642

Contact Person: Plank, Carol

Phone: (716) 275-5871.

ROCH BUFF:

State University of New York at Buffalo School of Medicine

462 Grider Street

Buffalo, NY 14215

Contact Person: Rothenberger, Sharon Phone: (716) 898-3848.

ROCH SYRA:

Suny Health Science Center

750 East Adams Street

Syracuse, NY 13210

Contact Person: Ricciardiello, Mary Phone: (315) 473-5533.

SUNY:

State University of New York at Stony Brook

T 15 080

Stony Brook, NY 11794-8153

Contact Person: Carpenter, RuthAnn Phone: (516) 444-1658

Roarke, Mary

Phone: (516) 444-1659

Phone: (516) 444-1660.

CINN:

University of Cincinnati Medical Center

Eden and Bethesda Avenues

Cincinnati, OH 45267-0405

Contact Person: Vigdorth, Ellen

Phone: (513) 558-6977.

OHIO:

Ohio State University Medical Center
410 West 19th Avenue
Columbus, OH 43210

Contact Person: Lowry, Donna

Phone: (614) 293-8112
Phone: (614) 293-8112.

HERS:

Hershey Medical Center
P O Box 850
Hershey, PA 17033

Contact Person: Mandia, Sharon

Phone: (717) 531-7488
Phone: (412) 621-3591.

PITT:

University of Pittsburgh School of Medicine
A 427 Crabtree Hall
Pittsburgh, PA 15261

Contact Person: Boggio, Kit
Groh, Chris

Phone: (412) 647-8125
Phone: (412) 647-8123
Phone: (412) 621-3591.

P/BYLR BYHH:

University of Texas Hermann Hospital
6411 Fannin Street
Houston, TX 77030

Contact Person: Griffiths, Marilyn
Phone: (713) 792-5334
Phone: (713) 792-4703.

P/BYLR BYTX:

Baylor Texas Children's Hospital (Pediatrics)
One Baylor Plaza
Houston, TX 77030

Contact Person: Hanson, Celine

Phone: (713) 798-1319.

WASH:

University of Washington School of Medicine
4800 Sand Point Way
Seattle, WA 98104

Contact Person: Thacker, Michi

Phone: (206) 223-3184.

Verification Date:

891017.

CWRH:

Case Western University Hospitals
2109 Adelbert Road
Cleveland, OH 44106

Contact Person: Bagby, Brenda

Phone: (216) 844-8175
Phone: (216) 844-7324.

STAN:

Stanford University School of Medicine
Division of Infectious Diseases S 156
Stanford, CA 94503

Contact Person: Unspecified

Phone: (415) 723-6231.

Dear _____,

You work at the nearest AIDS Clinical Trials Unit to me, and you are ____ miles away. Access to your clinical trials is an impossibility for [me, my friends, my lover, my sister, anyone in this town...]. This geographic limitation clearly illustrates the desperate need for parallel track access to all AIDS drugs in the FDA pipeline now and in the future.

Sincerely,

Innovative AIDS Drug Plan May Be Undermining Testing

By GINA KOLATA

The Federal Government's bold new plan to make promising but unproven AIDS drugs widely available at the same time that they are undergoing clinical trials appears to be foundering.

In the first test of the new system, at most 20 times as many people have flocked to free distributions of the new drug DDI than have signed up for the clinical trial, leaving researchers in despair over whether they will ever be able to complete the formal study.

Although Federal officials and a drug company spokesman said it was too soon to tell if the new method would work, the mood among many researchers is grim. At latest counts, only 75 patients had volunteered for the clinical trial, which requires 1,900 people, but 1,300 had applied to receive the drug outside the trial, and that number was increasing by 100 a day.

New Approach Is Announced

The new approach, called the parallel track, was announced in June by Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, as a significant new direction in drug testing. After numerous discussions with advocates for people with AIDS, Dr. Fauci said he favored the concept.

In the parallel track method, standard clinical trials would test a drug's safety and usefulness but, at the same time, the drug would be made available to patients who could not participate in

the trials. Dr. Fauci said he had decided it was not necessary to force patients with acquired immune deficiency syndrome to enter testing programs so they could receive a promising drug. He added that if the parallel track proved effective, it would be used in testing drugs for other diseases as well.

In September, after weeks of meetings with advocates for people with

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AIDS, the Bristol-Myers Company announced that it would put its promising new AIDS drug, DDI, on a parallel track. The drug is intended to slow the progress of the disease by interfering with reproduction of the AIDS virus. The human immunodeficiency virus that causes AIDS attacks the body's immune system and makes patients susceptible to a wide array of diseases, including cancers.

Objection of Patients

Some patients object to participating in clinical trials because they usually have just a 50 percent chance of receiving the new drug. For example, to test the Bristol-Myers drug, researchers would recruit about 1,900 patients for three trials. In two of them, half the 1,540 patients would receive AZT, the standard drug for AIDS, and the others would receive DDI. The third trial, whose recruitment goal is 360 patients, is for patients who cannot tolerate AZT.

As the trials progressed, the drug

that the clinical trials would soon start to attract many more patients. "I don't want to say that I am concerned and I don't want to say that I am not concerned," he said, and echoed Dr. Hoth's statement that it is too early to draw any conclusions. He noted that the expanded access to the new drug had begun before it was available for clinical trials, so "this was not, strictly speaking, parallel track."

Jerry Parrott, a Bristol-Myers spokesman, said the company was pleased with the enrollment so far in both clinical trials and the expanded access programs.

"A greater number of patients are receiving DDI in the open label protocols, but that's to be expected," he said.

Patients participate in the expanded access program if their doctors request the drug for them and assert that they fulfill the criteria. Mr. Parrott said that the company does not try to verify whether patients belong in expanded access rather than clinical trials. He said, though, that they would begin auditing patient enrollments in its programs, and this "should reveal problems if they exist."

But researchers who are trying to recruit patients for the clinical trials have a different perception. "A lot of us are very concerned," said Dr. Fred Valentine, who heads the DDI trials at New York University Medical Center. "There is a real issue here."

'A lot of us are very concerned. There is a real issue here.'

was also to be made available in an "expanded use" program to patients who did not qualify for the trials or who lived too far away from trial sites to participate.

While the National Institute of Allergy and Infectious Diseases, which runs the testing program, provided the figure of 75 patients enrolled in the trials, Bristol-Myers did not provide its own figures. But Dr. Douglas D. Richman of the University of California at San Diego, said the company disclosed at a private meeting with researchers two weeks ago that more than 1,300 patients had enrolled in the expanded access program and that the number was increasing by 100 a day.

Seriousness of Problem

Dr. Daniel Hoth, who administers the clinical trials program at the institute, which is part of the National Institutes of Health in Bethesda, Md., said "it is entirely too early to say" whether the experience so far with a parallel track method indicated a serious problem. "Of course we're worried, and we are looking at this very closely," he added.

Dr. Fauci said he was optimistic

Conflicting Issues

"People that have tried and tried to reassure the academic community that, yes, the parallel track will not dismantle our ability to do organized studies," he said. "But we have to face this head on. There really are conflicting issues here. If the philosophy is that anyone can decide at any point what drugs he or she wants to take, then you will not be able to do a clinical trial."

Dr. Richman said: "As it is designed, parallel track will not work. What was actually put in place is an invitation to disaster. It will prevent us from finding drugs that will help people."

DDI is a toxic drug, and the only way to know if its benefits outweigh its risks is to assess it in clinical trials with large numbers of people that compare it to the standard treatment, experts said.

"Without appropriate clinical trials, the only consensus that will be possible will relate to the drug's side effects," said Dr. Samuel Broder, director of the National Cancer Institute.



The New York Times/Marty Katz

Dr. Anthony Fauci of the National Institutes of Health defends parallel-track testing of AIDS drugs and says clinical tests could still succeed.

tute. In fact, he said that if the only data available on AZT were from programs like the expanded access ones, "AZT would have been completely dismissed as a drug that's too toxic." That is because AZT has so many negative effects that without the statistical comparisons that clinical trials provide, it would have been impossible to prove that taking the drug was better than not taking it.

Dr. Richman and others said that if the parallel track worked the way it was supposed to, patients could get the drug outside the trial groups only if they did not qualify for the tests. But Dr. Richman said, "It is not clear that the rules are being adhered to." He added that he knows of a number of patients who entered expanded access programs when they should

have been in clinical trials.

Dr. Groopman agreed. "Patients basically didn't want to enter a clinical trial comparing AZT with DDI," he said. "That is a major issue."

Defense of Program

Advocates for people with AIDS defend the expanded access concept. The real problem, they say, is with the clinical trials. Mark Harrington, a member of the AIDS Coalition to Unleash Power, said that because of bureaucratic problems the DDI trials started supplying the drug several weeks after it was available through expanded access programs.

"There was a big buildup on DDI all year long," Mr. Harrington said. "A lot of people want to take it and they don't want to wait five weeks for

the bureaucracy to churn out drugs."

He argued that if the drug had been available in trial groups at the same time as expanded access, "accrual would have been better." He predicted that the balance between test and expanded access groups would improve "in the coming weeks," and accused critics of "calling, foul prematurely."

Mr. Harrington acknowledged that many people with AIDS did not want to take a chance on receiving AZT

Many patients want more than a 50% chance of getting the drug.

rather than DDI in a trial because, he said, patients think the doses of AZT used in trials are much too high. "AZT is just as effective and less toxic in lower doses," he said.

Mr. Harrington added that no matter what academic researchers say, AIDS patients will never again accept clinical trials without a parallel track of expanded access. "There can be no turning back," he said. "We refuse to be coerced into trials." He said advocates had their own sources of DDI and if there had not been an expanded access program, "the underground market would have grown substantially."

Academic researchers say the idea that people will go into expanded access programs to get DDI a few weeks sooner indicates that patients are trying the drug in the hope that it will save them, not to help determine if it is worth taking.

This undercuts the argument of people who favor the parallel track that patients would enter a clinical trial to help test a drug.

But researchers say the idea of the parallel track was never logical. "These are political issues, not medical issues," Dr. Richman said. "Some of this may have developed because some people in scientific and regulatory positions are thinking more about the political aspects of testing drugs. But in the long run, patients may not be served best."

Dr. Donald Abrams, of San Francisco General Hospital, said: "Nobody ever said it was logical. It was a matter of acquiescing to political pressure. In our effort to get things to go a little faster, we can only hope that we are not slowed down."

ACT UP/ Boston and Astra Pharmaceuticals : a brief chronology

April 30, 1989:

First meeting of ACT UP/ Boston Astra Working Group.

May 15:

ACT UP/ Boston Astra Working Group meets with William Spickler and Cheryl Karol at Astra Headquarters in Westborough, Mass. ACT UP demands compassionate release of foscarnet in 2 situations: 1) when physician deems it is appropriate despite failure of patient to meet inclusion/exclusion criteria of formal trials; 2) for those whose geographic location makes trial participation impossible. Additional demand: make criteria for ACTG trials 092 and 093 less stringent. ACT UP/ Boston proposes chronology which, according to Spickler, seemed to allow ample time for Astra to add staff and ensure an adequate drug supply for implementation of an extended compassionate use program. ACT UP/ Boston agrees to meet with Astra Board of Directors to address likely objections.

May 26:

Wm. Spickler writes to ACT UP/ Boston; cites FDA restrictions and inadequate supplies of drug as stumbling blocks to increased access.

May 30:

ACT UP/ Boston writes to Astra in response; charges Astra with corporate greed as motive for failing to provide Foscarnet on wider basis.

May 31:

ACT UP/ Boston writes to Astra with enclosure of GCN article on Terry Sutton, a San Francisco activist who died while fighting for access to foscarnet; letter demands Astra "immediately and publicly release Foscarnet for compassionate use" to those who fit description in May 15 meeting (above).

June 15:

ACT UP demonstrates at Astra HQ. 15 are arrested. During demonstration, 2 ACT UP/ Boston members meet with Spickler and Bruce Manning. Manning's sole focus is on FDA approval. He refuses to address issue of "what about people who need this drug now?" Manning denies that production of adequate supply is geared toward "marketing" the drug. Astra reps propose CRIs as possible conduits for expanded release/testing of drug, and suggest supply situation will improve in "4-6 months."

June 16:

Massachusetts Commissioner of Public Health, Deborah Prothrow-Stith writes to Astra urging release of Foscarnet.

June 22:

ACT UP meets with Manning, Spickler at Astra HQ. Ca. 140 enrolled in trials to date. Astra expects to have "good data on safety/efficacy in the fall," cites "November/December" as likely targets for "full safety/efficacy data." Expect fast interim analysis ca. December 89/January 90; submission of data to FDA "before March 90, with full approval by June 90." Supply issue: Astra expects "stability samples" by the end of June 89. [No contract had yet been signed with a manufacturer.]

(more)

June 27:

Astra writes to Commissioner Prothrow-Stith; cites supply problems and lack of data re: safety or effectiveness as reasons for lack of widespread compassionate use.

July 26:

ACT UP/ Boston meets with Wm. Spickler. Spickler reports that FDA meeting with Astra had been cancelled. Supply: "Contractor making the situation impossible; asking for exclusivity, and unwilling to accept non-competing clause." Next meeting between FDA Commissioner and Astra scheduled for August 30. "Protocol 092 will probably be dropped." (092 was a clinical trial for patients with "non-immediately sight-threatening" CMV retinitis. No one enrolled.)

[Lack date of next meeting; early September. Spickler recommends ACT UP/ Boston request meeting with Astra's Foscarnet Steering Committee; indicates that Foscarnet is available case-by-case on a compassionate basis, but that this cannot be stated publicly.]

September 16:

ACT UP/ Boston writes to Astra Chief Executive Officer Lars Bildman, offering to meet with Astra's Foscarnet Steering Committee, and requesting information on: 1) status of FDA's projected requirements for approval of Foscarnet; 2) Astra's, and the FDA's, plans for treatment IND or other mechanism for the widespread distribution of Foscarnet at the earliest possible juncture; 3) supply problems; 4) pricing issues.

September 22:

Bildman writes to ACT UP/ Boston informing them of Spickler's departure from corporation. Informs ACT UP that Bruce Manning will maintain continued communications with group; that at August 30 FDA meeting, Astra laid out a clinical testing program that would permit them to submit a NDA in the spring of 1990. As of Sept. 22, Astra still had not received response from FDA to that proposal. FDA cited lack of safety data. Astra is "addressing aggressively our supply problems ... we are now in the final steps of entering into a contracting arrangement with another manufacturer to enable us to produce sufficient Foscarnet." Agrees to meet with ACT UP/ Boston after learning more from the FDA.

Astra's schedule is running smoothly, but thousands of PWAs with CMV right now still cannot get the drug.



Stephen Skuce
ACTUP/ Boston

Dear ACT UPs,

ACT UP/Boston continues to work for the release of foscarnet by the Astra Pharmaceuticals company. We conducted a highly visible CD at Astra headquarters near Boston last June. Over the summer, we had long meetings with different Astra departments. After these meetings, we discovered Astra was preventing us from meeting with the appropriate group, the Foscarnet Steering Committee. Astra has refused our demand to meet with this committee.

To increase pressure on the company, we have been at Astra CEO Lars Bildman's house in fabulous and fashionable Brookline, Mass. We have gone at early morning and late night hours to make sure Lars wasn't wasting time on sleep when he should be releasing foscarnet. We have had visually arresting signs. We distributed fliers to all of his neighbors warning them about Lars. We continue to increase the pressure. We know Lars is feeling the pressure because he hired 5 security guards with video cameras to protect his house!

Our newest idea is a petition demanding foscarnet's release. We hope to have many of Lars' neighbors' signatures. We also would like the members of your ACT UP chapters to have the opportunity to sign our petition. You will find a few copies enclosed. Please send them back to the address on the petition.

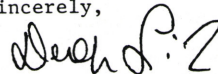
If any one of your members would like to join the protests against Lars, here is his address:

Lars Bildman
511 Chestnut Hill Ave.
Brookline, MA

Sending him letters, boxed packages, etc. are all great ideas.

Thanks for your help.

Sincerely,



Derek Link
Astra/Foscarnet Working Group
ACT UP/Boston
(617) 522-2427 (home)
(617) 522-AIDS (ACT UP line)

A Petition For Human Lives

WE, the undersigned, as People With AIDS and as those concerned about People With AIDS, demand that the Astra Pharmaceuticals Corporation release Foscarnet, a life- and sight-saving drug, immediately under a wide scale compassionate use program open to all People With AIDS:

To be sent to Astra Pharmaceuticals
50 Otis St.
Westborough, MA 01581

Name	Address



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Name	Address



In solidarity with People
With AIDS, we encourage
you to boycott

Sudafed

Selecting a generic or other
alternative will help to
lower the price of AZT.



Many experts claim that
Burroughs Wellcome is
profiteering off the AIDS
drug AZT. To encourage
Burroughs Wellcome to
lower the price, please
select a generic or other
alternative to:

Actifed



A national boycott has
been called against
Burroughs Wellcome for
their profiteering on the
AIDS drug AZT. Please
select a generic or other
alternative to:

Actifed



The AIDS drug AZT is
overpriced at \$6400/year.
To help lower the price,
please select a generic or
other alternative to:

Actifed

See the pharmacist for
details.



As part of a national boycott,
please select a generic or
other alternative to:

Actifed

to encourage Burroughs
Wellcome to lower the price
of the AIDS drug AZT from
\$6400/year.



To help lower the price of
the AIDS drug AZT, please
select a generic or other
alternative to:

Actifed

See the pharmacist for
details.



As part of a national boycott,
please select a generic or other
alternative to:

Actifed
Sudafed
Neosporin
Polysporin
Empirin

to encourage Burroughs
Wellcome to lower the price
of the AIDS drug AZT from
\$6400/year.



AIDS

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AU/B

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