CONFERENCE SUMMARY

A Summary of the Second AIDS Treatment Activist Conference, Washington, DC, September 27-29, 1991

This summary is a compilation of materials submitted by presenters or painstakingly transcribed and prepared by Charlie Cox of ACT UP/DC. During several of the strategy sessions, the activists divided into smaller working groups. The discussions of those sessions are also summarized ("Strategy Working Sessions"). You will find several of the summaries to be very informative and others just a little more than a tease. Therefore, with each event summary, we have attempted to provide the names of activists to contact for additional information. Garence Franke-Ruta's presentation for the strategy session on pharmaceutical companies is worth a thorough read. The summary of the Universal Health Care Workshop does not, admittedly, capture the complexity of that issue. We recommend you contact one of the three organizations listed at the end of it for additional information. Several supporting documents gathered after ATAC2 are attached (read Derek Hodel's testimony to the National Commission on AIDS).

From the feedback we've received, ATAC offers a much needed opportunity for activists to meet, talk and plan - both in and away from the formal sessions. Linking the conference to the two national actions proved cost-effective and time-efficient for those involved. Originally, ATAC2 was scheduled to coincide with the AIDS Clinical Trials Group (ACTG) meeting in July 1991, but was moved to September to be a part of the 30 Days of Actions campaign. The first ATAC was held in conjunction with an ACTG meeting in November 1990. As many of you probably already know, the next two meetings of the ACTG will be held in Washington, DC. If there is to be an ATAC3, perhaps it should be linked to the November meeting. Of course, whether to organize an ATAC3 is your call. Frederick Nunley of ACT UP/DC (202.328.AIDS) has agreed to be the contact for coordinating this discussion.

ATAC2 was supported by donations from ACT UP, ACT UP/DC, ACT UP/Network, AIDS Action Council, Gay Men's Health Crisis, Human Rights Campaign Fund, and the National Gay & Lesbian Task Force. *Finally, should you have any comments or questions about this summary, please call me at 202.544.0139, or write to me at 619 Seventh Street NE, Washington, DC 20002.*

Jason Heffner
DC ATAC2 Committee

27 September 1991 -
Opening Session:

The intent of this session was to introduce the participants to the components and purpose of ATAC2 and to explain the two demonstrations scheduled for Monday, 30 September at the White House and Tuesday, 1 October at Capitol Hill.

The conference consisted of four strategy sessions that focused on: Congress; the drug development and approval process; third party payment - the health insurance industry and government entitlements; and the pharmaceutical companies. The conference also included a workshop on universal health care, in order to broaden the focus of the conference and educate ATAC2 participants in the reasons for the Capitol Hill action. It served, too, as a chance for participants to discuss the crisis in the health care industry and examine, as a group, what AIDS activists want in a universal health care program.

The reasons and structure of the two actions scheduled for Monday and Tuesday were explained. The White House demonstration was intended to close the 30 days of Actions directed at George Bush which had begun with the Kennebunkport action on 1 September. The purpose of the White House demonstration was to call attention to Bush's lack of leadership during the AIDS crisis and to call on him

to appoint a cabinet-level AIDS czar.

The second action addressed the issue of health care and the need for a universal health care program and called on Congress to enact legislation that would ensure that all people would have access to medical treatment regardless of their HIV status.

The genesis of ATAC and how we came to ATAC2 were discussed. The first ATAC was comprised of over twenty-four workshops on specific treatment issues. ATAC2 kept this as a component, but added the goal of mapping out some long-term goals and strategies for AIDS activists.

28 September 1991 -
Strategy Session 1: Targeting Congress

Facilitators: Robert Warnock and Jason Heffner
Presenters: Tim Westmoreland, Staff Council to House of Representatives Sub-committee on Health and the Environment; and Steve Smith, Legislative Affairs Director, Human Rights Campaign Fund

AIDS activists have had a significant impact on how AIDS is perceived by politicians and AIDS policy is developed. Activists' meetings with various companies and organizations have been successful. Sometimes, it has taken an action to bring about meetings, but the end result has usually been positive change on the part of companies. We are now at a point where it is no longer just activists that are requesting meetings. Rather, members of Congress and their staffs are requesting meetings with activists and opening lines of communication. In order to capitalize on this, we need to know how Congress works and the tools that will help us accomplish our goals.

Tim: In Congress everything is accomplished by committee. There are three types: authorization, appropriations, and budget. The legislation is introduced and then sent to the appropriate committee and sub-committee. It is in the subcommittee that the legislation is marked-up and amended. One needs to find the subcommittee that is considering the targeted legislation and identify the key person(s) to talk to. After the legislation is considered by the subcommittee, it is sent to the whole committee where it is once more amended and debated. After this, the legislation is reported out of committee and sent to the whole House, where once more it is amended and debated, and finally voted on. A similar situation exists in the Senate. Once the legislation is passed by both chambers it is then sent to a conference committee which is comprised of members from both houses, where the differences surrounding the legislation are resolved. The legislation is then reported back to both chambers where it is voted on once more; if accepted by both chambers, the legislation is sent to the President for his signature or veto.

The next step in the process is to send the legislation to the Appropriations Committee where funding for the previously passed legislation is determined. It is not enough just to get the legislation passed, it is just also essential to follow-up with the Appropriations Committee and ensure that proper funding is established for the previously passed legislation. The same process is followed in the appropriations process as in the authorization process (subcommittee, committee, House and Senate vote, conference committee, compromise legislation, final House and Senate vote, presidential signature or veto).

Next in the process is the Budget Committee. It is in this committee that overall spending is determined; it is, therefore, important to let the appropriate committee/subcommittee staffer know just how much money will be needed so that appropriate levels of funding can be appropriated for health care, etc.

It is appropriate to contact your Members of Congress who are on the subcommittees.

It is very important to understand that when you make an appointment to see a Representative or a Senator, you are not going to meet with them, but with a member of his or her staff. Do not feel insulted or slighted, this is the person who can be the most helpful in presenting your case to the Representative or Senator. You should work not just with the Washington staff, but with the home staff as well. The district office staff can have a significant impact on the Washington staff since the district staff is in constant contact with constituents.

It is also important to remember that staff members are under a great deal of pressure; their time is very limited. So when dealing with the staff be quick and to the point. Give them a one-page fact sheet; anything more and they will not read it since they do not have the time. Emphasize how it will affect people at home, not just the nation. Always emphasize that you are willing to come back in to discuss the issues. Also, after the meeting, write a thank you note to the Representative or Senator for their staffer's time, this makes an impression on the Representative or Senator, and may help the staffer get your point across to the Representative or Senator. It also helps the staffer to recall you and the matter discussed.

Also, when working with Congress remember that there are three groups you need to be concerned about: those who are very disposed to positive AIDS legislation; those who are opposed to AIDS legislation; and those who have no opinion. This last group is the one that you need to focus on; when dealing with them make it personal, bring in members of the family, lovers, co-workers, etc., so that the staffer can see that not just the activist is concerned about this issue, but that all "main stream"

groups are concerned about this issue.

Steve: As an actual lobbyist I would recommend that even before you meet with the Representative's or Senator's district or Washington staff, review their record and know what their stance is on your issue. Call their office and ask for a copy of their voting record on AIDS issues and any statements that they may have issued. Find out what you can do to inform them about your issue or even possibly change their vote.

Also, do not be afraid to cultivate the staff person so that they can turn into an advocate for your position; that staff person may be able to educate, influence or change the mind of the Representative or Senator. Build relationships with the members of the staff. Do not underestimate the influence or power of a Congressional staffer. Also, remember that there is a high turnover rate among Congressional staffers and that you may have to start all over again and cultivate the new staff person responsible for your issue.

Keep track of the pending legislation that is going to affect your issue. Let the staffer know what is happening; they will appreciate this and it will go a long way in helping advance your cause.

One of the other areas which will aid you in your attempt to educate the Representative or Senator is to be cognizant of their background. Are they lawyers, educators, business people, economists, etc.? Try to hone in on their area of interest, or bring in an ally from another interest group who they have worked with before.

Again, write a thank you letter, and in that letter reiterate your position so that the staffer will recall the meeting and be prompted to more action.

One of the other issues you also need to be cognizant of is how sensitive members of Congress are to the press and the role they play in the legislative process. The media also serves as an educational tool and can influence, not just the general public, but members of Congress as well.

Ed. Note: Since ATAC2, the Human Rights Campaign Fund has inaugurated a newsletter, "AIDS Treatment Politics." Call Terry Beswick at 202.628.4160 to get a copy.

For more information:

Tim Westmoreland, Office of Rep. Henry Waxman, 2418 Rayburn Building, Washington, DC 20515, 202.255.3976

Steve Smith, Human Rights Campaign Fund, 1012 14th Street, Washington, DC 20005, 202.628.4160

Strategy Working Session: "Why do you support a bigot like Jesse Helms?"

Summary by Maxine Wolfe

This strategy group evolved out of the session on "Targeting Congress." It was directed toward developing a strategy for lessening the hold that Jesse Helms has over the Senate (and the hold other conservatives have over the House of Representatives). In other words, how can we prevent the fact that those people who are supposed to be our supporters suddenly (and in droves) vote with Helms anytime he suggests that to do otherwise would be to "promote homosexuality." This agenda crystallized with the de-funding of educational material (remember him waving around GMHC comic books) -- a vote on which most senators supported him, including the backers of the National Gay Rights Bill -- and has continued down to the current criminal penalties for HIV+ doctors. The point is that no matter what bills we might get introduced into Congress (and the Senate specifically) and no matter how much we pre-educate people, as long as Helms can continue to get people to vote with him and not challenge or even publicly acknowledge his bigotry, we will never get what we want and may lose what we have.

In trying to figure out what we can do to be sure that people who are supposed to be our supporters vote with us and against him, we decided to target these very people in the '92 election campaigns. In order to accomplish this, various strategies were discussed:

1. Meeting with congressional staffers and cultivating those relationships, providing information and so on -- the approach of the traditional lobbyists. Staff people brief the Representative and can give us information about proposed or pending legislation. The group did not dismiss this as one possible strategy but, in fact, this has been done and still people we "have informed" have voted with Helms.
2. A second strategy discussed was "terrorizing" staff people. Most agreed this was not an appropriate tactic--it was better to confront the actual senator or representative on this level, if necessary.
3. Getting a meeting with the senator or representative. Traditional lobbyists told us "You will never get to meet with the senator or representative because they are too busy." This was their rationale for cultivating relationships with staff people. However, senators and representatives <u>are</u> meeting with someone and we want that to be us. ACT UP/Maine talked about sitting in at their senator's office and getting a meeting with him as a result. He has not met with any of the other progressive groups in the state. However, this strategy, while useful in some circumstances, does not inform constituents. The senator or representative can tell you anything they want, but it does not mean they will vote correctly.
4. "Since," as Tim Westmoreland informed us, "every representative thinks they have an inalienable

right to be reelected," making them answer in front of their constituents would place the most pressure on them in an election year. This was the strategy we talked about using for the campaign--"Why do you support a bigot like Jesse Helms?" It has the advantage of allowing us to give our information to a senator's or representative's constituents along with their voting record--something few constituents are aware of.

Our goal in this campaign is to focus on those candidates who are thought, by their constituents, to be progressive or moderate and who would be expected, by their constituents, to vote for things which they have voted against (or vice versa). We would focus on HIV/AIDS issues, but would also have information regarding other related issues. We would produce fact sheets about HIV/AIDS issues and the senators' or representatives' voting records. We would follow the candidates to their campaign appearances in local areas and distribute the fact sheets. These fact sheets might include questions addressed to the candidate, and the last question could be "Why do you support a bigot like Jesse Helms?" Our goal would not be to disrupt these appearances, but to get the constituents to ask the kinds of questions that will put pressure on the candidate, and make the candidate feel that they have more to lose by supporting Helms than homosexuals.

We talked about having an action at the Democratic Convention in NYC next summer which would raise the same issues.

We also agreed that we need to give people information, not ideology. Robert Bray of the National Gay and Lesbian Task Force (202.332.6483) agreed to provide us with the voting records of our "supposed supporters" as well as Helms' and other conservative senator's or representative's voting records. We also developed a list of organizations which rate candidates voting records on a range of issues and are going to get that information in order to link the issues in constituents minds and inform ourselves.

In the discussion that followed, when this was presented at the summary session, it was suggested that we have to be careful with this type of strategy because we may be giving Helms, et. al. ammunition by showing the voting records of their "opponents." We could unintentionally support constituent views that their senator or representative voted correctly. However, we are doing this campaign only with people who are supposed to have supported us so the situation is different than in North Carolina. However, it is also illustrates why we must have facts about our issues beyond just showing voting records. For example, we should explain why mandatory HIV testing of medical professionals is not appropriate, and who else said this besides us, as well as the candidates' voting records on this issue.

For more information:

Maxine Wolfe, 222A 14th Street, Brooklyn, NY 11215, 718.499.8270

Strategy Working Session: Communications

During the presentation on "Targeting Congress" it was clear that a major problem facing AIDS activists was the lack of timely information flow about AIDS-related issues before Congress, the FDA, HCFA, etc. There was a common belief, among those attending, that those Congressional lobbyists currently in place for HIV/AIDS and gay/lesbian concerns felt their first allegiance to be AIDS service organizations, and that there was little or no communication with AIDS activists/advocacy groups.

An additional concern was time--speed is crucial. We need to anticipate (rather than react to) legislative issues, treatment bills, etc., in enough time to organize zaps, letter writing, demos or trips to legislative offices. Many times the word gets out too late to really do anything but a token effort. However, it was noted that what many of us did not need was one more publication to read. We decided to organize a bi-weekly newsletter that would be 1-2 pages in length, with each entry very sparse--who, what, where, when, and how, a paragraph at most, sacrificing rhetoric in the interests of information alone. The model for the entries would be the "Action Alerts" sent out by unions or by GLAAD. In addition, the newsletter would be accessible by a computer bulletin board service.

How this newsletter would be different: There was a lot of legitimate concern about re-inventing the wheel. Couldn't this work be done by the Interact packet that is sent out by ACT UP/NY (contact: Jean-Elizabeth Glass, 718.482.7741 or 718.260.3801) or the monthly ACT UP/NETWORK packet sent out by ACT UP/Dallas (214.528.4233)?

First of all, the newsletter would be put out more frequently than the Interact packet, aiming at two times a month. The consensus was that this newsletter would go out to individuals and groups, (many items within these Interact packets get misdirected or lost rather than reach the appropriate members of each chapter). The subject matter of the newsletter would be upcoming AIDS-related legislation, Congressional hearings (e.g., mandatory testing of health care workers), and national issues which impinge or reflect issues that are AIDS-related (e.g., the Oregon health rationing plan). This could be, but does not have to be, ACT UP related. One of the most valuable uses would be to track treatment issues in Congress.

Where would the information come from? Is there enough information of national import out there to fill a 2-page newsletter on a regular basis? The thoughts we came up with for how to fill the newsletter were: canvass the community, contact lobbyists, contact people we know ("friends") who may work in the power structure. We thought it might be fruitful to contact legislators, (especially those like Ted Weiss, with whom we have a relationship). What is upcoming on the legislative calendar? Who has contacts, resources and connections?

This is all very well, but how will it work? Originally there was a lot of interest in an offer to

tap into computer bulletin boards--especially the software at the Critical Path AIDS Project in Philadelphia. However, recognizing that many of the smaller chapters do not have access, machines, or the technical capability to deal with computers and modems, we decided to compromise. Therefore, information will be available on both computer bulletin boards and on paper, with a copy to go out through the Interact packet.

All information for this newsletter should be sent to Robert Warnock, ACT UP/DC, PO Box 9318, Washington, DC 20005, 202.328.AIDS. Remember to be brief; strictly limit yourself to 1 paragraph: who, what, when, where, why, how.

In addition, to see it go out on computer bulletin board as well, send it to Kiyoshi Kuromiya, Critical Path AIDS Project, 2062 Lombard Street, Philadelphia, PA 19146, 215.545.2212, 215.735.2762 (fax).

Strategy Working Session: Public Policy

Addressed several national issues, tactics and recommendations. Issues discussed: mandatory testing, the CDC and other Federal organizations. There is a need to duplicate the knowledge that has been developed on treatment issues and apply it to public policy.

There is also a need to work on issues such as immigration and public education on AIDS. It is important to work in home districts, not just in Washington, DC. Make the elected officials feel the pressure at home and in Washington. This may also be applied to state and local levels of government.

For more information:

Connie Norman, ACT UP/LA, PO Box 26601, Los Angeles, CA 90026, 213-669-7301

Strategy Session 2: The Drug Development and Approval Process

Facilitator: Aldyn McKean

1. FDA Drug Approval Process. The primary question discussed was how to make the process more effective and faster? There are a number of ways we explored the question. First, build coalitions with other disease groups who are interested in the same drug or similar drugs. Second, utilize direct intervention through contacts that have been developed at the FDA. At the same time, press for internal FDA reform. Other areas which will help the FDA drug approval process are a funding increase so that more drugs can be tested and a change in the laws concerning the drug approval process. Finally, the FDA drug approval process needs to include women in its trials, as current AIDS drugs affect women differently than men.
2. The Campbell Bill -- allows for compassionate drug use.
3. Orphan Drug Admentments of 1991 - S.2060 - revises the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Orphan Drug Act. Introduced by Senators Metzenbaum (D) and Kassebaum (R). A copy of this bill is attached.

Strategy Working Session: National Institutes of Health

This working session tried to answer the question: Can the ACTGs be salvaged? The answer is yes and no. There needs to be more work on this issue, and there needs to be more input from AIDS activists.

Another issue discussed was the desire to see a separate agency established, similar to the National Cancer Institute, which would deal exclusively with AIDS. This agency would be more pro-active to the need for more researchers addressing issues affecting people of color and women.

Clinical Trials 175 & 076 were also discussed. There was a consensus that these two trials need to be fought since they are not serving the needs of people with AIDS. It was concluded that the standards of research are not particularly high with regard to these two trials.

Also, NIH needs to examine the issue of alternative treatments. These treatments deserve the same type of testing that "normal" treatments are given.

The next two meetings of the AIDS Clinical Trials Group (ACTG) will be held in Washington, DC at the Omni Shoreham Hotel. The meeting dates are April 12-15, 1992 and November 3-6, 1992. The Ninth Meeting of the Community Program for Clinical Research on AIDS (CPCRA) is scheduled for March 22-24, 1992 in Washington, DC and the meeting of the AIDS Research Advisory Committee is on March 30-31 in Bethesda, MD.

NIAID - DAIDS

Division of Acquired Immunodeficiency Syndrome (AIDS)

Director Daniel F Hoth 248P CDB	496-0545
Dep Director Jack Killen 249P CDB	496-0545
Assoc Dir for Basic Research & Devel Pgm John McGowan 247P CDB	496-0638
Developmental Therapeutics Br Chf Margaret Johnston 245P CDB	496-8199
Pathogenesis Br Chf Gregory Milman 242P CDB	496-8378
Resources & Centers Br Chf (Vacant) 243P CDB	496-0755
Vaccine Research & Devel Br Chf Wayne Koff 234P CDB	496-8200
Assoc Dir for Clinical Research Pgm Daniel F Hoth (Actg) 200P CDB	496-8210
Community Clinical Rsrch Br Chf Lawrence Deyton 210P CDB	496-0701
Epidemiology Br Chf Sten Vermund 240P CDB	496-6177
Medical Br Chf Steven Schnittman 206P CDB	496-0700
Pediatric Medicine Br Chf James Balsley (Actg) 252P CDB	496-8210
Assoc Dir for Pgm Opers Thomas Voskuhl 250P CDB	496-0545
Biostatistics Rsrch Br Chf Susan Ellenberg 206W CDB	496-0694
Assoc Dir for Treatment Research Opers Pgm Daniel F Hoth (Actg) 248P CDB	496-0545
Operations & Data Mgmt Br Chf Dennis Dixon 203W CDB	496-8215
Clinical Research Mgmt Br Chf George Counts 207P CDB	496-8214
Pharmaceutical & Regulatory Affairs Br Chf Joseph Meschino 203P CDB	496-8213

Strategy Working Session:
Food & Drug Administration

Discussed the need to start a letter campaign that would pressure Kessler to establish a board which would work with the FDA on the drug approval process. This board would be similar to the ACTG.

The next meeting of the FDA Antiviral Advisory Committee is set for April 20-21, 1992.

Commissioner David A Kessler, M.D., 301.443.2410
Randy Wycoff, Director of AIDS Coordination, Office Of Science, 301.443.0104

Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

Strategy Session 3: Third Party Payment - The Health Insurance Industry and Government Entitlements

Summary by Karen Timor

Insurance is not regulated on a national basis. In contrast to the drug approval process, there is no central authority or central set of rules to petition for redress. Instead, it is regulated state by state, with practices and standards varying widely between states. We began by discussing the difficulty of finding out about insurance practices, so as to address which companies or practices particularly discriminate against PWAs. However, one of the techniques which has proved effective is to file individual complaints with each state's insurance commissioner. Another tactic is to utilize a letter zap in states where it is required that a complaint file be opened for each individual complaint received. Simply print up form letters, take them off to be signed by members of your community, and file them with the state insurance commissioners, who are suddenly deluged with new complaints about a specific practice or insurer.

Self-Insurance (ERISA) policies. What is self insurance? When a large company (usually with 50 or more employees) decides to "self-insure" rather than go to an insurance company and buy a policy to cover their employees, they are allowed by federal law to take the premium payments and bank them. They then use these funds to pay any claims that their employees make--hence, "self-insurance." These plans are sometimes called "ERISA Plans," because they grew out of a loophole in a piece of federal legislation called the Employee Retirement Income Security Act of 1974. The employer may process the claims themselves or hire a plan administrator. Many insurance companies, not being stupid, see that their former customers are self-insuring, and have subsequently set up separate business divisions that act as plan administrators, often using the same claims forms. Thus, an employee may fill out a Prudential claim form and mail it to Prudential for processing, not realizing that Prudential is only acting as the plan administrator for the employer.

Why is this important? Because ERISA is federal in scope; the Supreme Court has ruled that ERISA plans are exempt from any state regulations or state discrimination statutes. Employers can write ERISA policies any way they want to--thus many are excluding or severely limiting coverage for HIV-related illness. When you hear about a "cap" or "exclusion", most of the time you are hearing about provisions of an ERISA plan. For example, you may have heard about "lifetime caps" for all HIV-related coverage as low as $5,000, that is, after one has met his/her cap, the rest of his/her care related to HIV he /she pays out of pocket--with no reimbursement. ACT UP/NY is very interested in working with any of you (or other activists) out there to fight ERISA-based discrimination. It will take nationwide effort to curb these abuses. The insurance industry lobby is one of the nation's strongest.

Medicaid Reform. Medicaid is a government health care entitlement program, jointly funded by the Federal government and each state. When Medicaid was established, Congress spelled out certain services that every state must provide, and then a long list of "optional" services, that states may provide (1 from column A, 2 from column B...). This bizarre structure gives both the states and the feds an out as far as responsibility for Medicaid reform is concerned. This may also be turned to our advantage. Since states are somewhat autonomous, various ACT UPs target their respective state Medicaid offices, and share from one state to another what seems to work.

At the same time, ACT UP/NY, Lambda Legal Defense and Education Fund, and the AIDS Action Council (a Washington based lobby for AIDS service organizations) have been meeting with the Health Care Financing Administration (HCFA) to discuss federal reforms. HCFA is the office in charge of running both Medicaid and Medicare.

Mike Isbell, Lambda Legal Defense and Education Fund - 212.995.8585

AIDS Action Council - 202-293.2886

HCFA: Gail R. Wilensky, Administrator, H.H.H. Building, 200 Independence Avenue, SW, Room 14G, Washington, DC 20201, 202.245.6726
Kathleen Buto, Director, Bureau of Policy Development, East High Rise Building, 6325 Security Blvd., Baltimore, MD 21207, 301.966.5674

Oregon Health Rationing Plan One of the scarier developments in this area is Oregon's plan to trim their Medicaid costs. Remember, the federal government states that every person eligible for Medicaid coverage is guaranteed a basic minimum of health care [sic]. Oregon, attempting to cut its overall expenditures on Medicaid, has proposed a radical departure. They have made a list of all the conditions for which a person might need treatment. They then ranked the list in terms of cost - effectiveness of treatment and "social value" of treatment, with the emphasis on prevention. The idea was that, given a fixed amount of money, how could they get the most impact for the least amount of money? The question is, where did treatment of HIV disease fall on the list? There was a lot of support for "early intervention" and, having a good preventive value, it ranked at about 250 or so. However, those with AIDS (no more than five years life expectancy) fell to about 600 on the list, and people in this category would not be eligible for treatment, just "pain relief". What does that mean? Oregon said that they only had enough money to start at the top of the list, and pay down to about 450 on the list. This plan has a lot of support in Oregon, but it has to be approved by Gail Wilensky, the head of HCFA, which oversees all Medicaid programs. Other states are working on similar plans (Washington & Nevada).

For more information:

Insurance & Health Care Access Committee, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564.AIDS

Seh Welch, ACT UP/Santa Barbara, PO Box 4899, Santa Barbara, CA 93140

Strategy Session 4: The Pharmaceutical Companies

Summary by Garance Franke-Ruta

Knowledge is power. Every significant gain won by ACT UP has flowed from our unassailable command of the issues. There is a wealth of information about new AIDS treatments. Use it to your advantage. Drug knowledge should be available to all ACT UP members, not just to people who go to treatment issues meetings. Start a treatment library.

ACT UP's responsibility to the AIDS community includes being honest about new drugs. Sometimes, not much is known. We must always emphasize the bad effects along with the promise of new treatments. Otherwise, if the drug becomes widely available, people with HIV may injure themselves by taking the new drug on hype.

Call and write the sponsor and the FDA. The start of negotiations is figuring out who you are dealing with. Call the drug company contact listed in the AmFAR directory and find out who is in charge of developing this particular drug. Call the FDA and request the Consumer Safety Officer (CSO) for the drug. Ask both contacts for the latest information about the drug (safety, toxicity, efficacy, phase I, II, or III - if pre-clinical, what the animal studies show), trials underway (controlled or open-label? What is the control? is this a standard therapy? randomized?), and access outside of trials (compassionate use, Treatment IND, individual patient IND, parallel track). Don't take "no comment" for an answer. You have a right to know. ACT UP is watching. Then, write the sponsor a letter describing ACT UP's dissatisfaction with the slow pace of research and restrictions on access, or, thank them for their openness if everything is OK. Carbon copy the letter to the FDA (David Kessler, Carl Peck, David Feigal, the consumer affairs office, and the CSO). Ask for a meeting.

Make friends with researchers. If a drug company refuses to meet, call the FDA and government-sponsored researchers who work with the drug company and ask them to put in a good word for you. Drug companies live in fear of the FDA and will do just about anything to accommodate them. Sometimes researchers will speak up for us on their own. Without Richard Chaisson, it is unlikely that ACT UP/NY would have had its first meeting with Abbott Labs. Also, maintaining regular contacts with the researchers will give you access to preliminary data, and leverage when negotiating with the FDA.

The meeting. Before ACT UP designs an action, it is useful to have a meeting with the recalcitrant drug company. The threat of action is often enough to make companies try to resolve problems in meetings. If this does not work, it at least affords a site visit and logistics check. Sponsors who have never worked with us are shocked to find out how much we know, and how much contact we have with the federal research establishment. Often, it seems like we have more contact than they do. Emphasize that ACT UP can help them get their drug out faster. Then make veiled allusions to bringing 3,000 angry AIDS activists to their headquarters and staging a media extravaganza. (Or make threats in a non-threatening manner by casually mentioning, "Did you hear about the latest ACT UP action? 4,000 people demonstrated , and 100 were arrested. Even the NY Times had an editorial that supported us!") Personalize the issues. Ask them what they would want in your situation, knowing what they know about the drug. Often, this will be the first time they even tried to consider the issues from the perspective of the person affected, and are shocked by considering the possibility of their own death--however abstractly. Usually, they agree with you when the question is framed like this. Find out who they are talking to at the FDA and what their experience of that has been. Be clear about what you want from them.

Follow-up. Usually, it is a good idea to follow-up on the first meeting with a letter. If the outcome was good, tell them so. If it was unsatisfactory, say so or allude to other actions we might take. Copy the letter to the CEO and important stockholders. Sometimes drug companies are hostile and nervous the first time they meet activists, and only calm down and open up the next

time. Arrange another time to meet, or hold a teleconference. One of the activists at the meeting should write a report for the others to refer to.

The action. For the most part, pharmaceutical companies are much more worried about their public image than monolithic government bureaucracies. Make sure the action is well designed and that you have what you need for a successful action. Sometimes this includes handcuffs or electric power drills. Crucial to the success of an action is media coverage. Make sure that local media are informed (be that Japanese, small-town in NJ, NC, or Swiss); you want their closest neighbors and home-countries to know how inhumane they are. A good fact sheet and cogent demands are also crucial. Use pictures of key representatives on posters and signs. Do not hesitate to take direct action--even if it is extreme. ACT UP/Boston picketed Astra's CEO at night to make sure he was not sleeping when he should have been releasing foscarnet. If they dig in further, organize a boycott of their other products, and make sure the Wall Street Journal covers this. Zap stockholders' meetings. Zap company speakers at medical conferences.

Work with each other. Find out who else is working on an issue in other ACT UPs. Send a letter to all ACT UPs telling them of your efforts. Use ACT UP/Network. Sometimes one group can pick up where another leaves off. Coordinated actions at multiple regional offices can be very effective. Simultaneous actions at multiple sites with simultaneous pressure from multiple ACT UPs and other AIDS activists is our most effective tactic (i.e. Burroughs Wellcome and AZT pricing, Abbott and clarithromycin access, Hoffman LaRoche and ddC access, Burroughs Wellcome and 566c80 access). One ACT UP may succeed where another has failed.

Good cop/Bad cop. One advantage of working with multiple ACT-UPs is that we can play off each other. For example, one ACT UP can make a moderate demand, and get a foot in the door with a drug company, and then another can come along and say, "This is totally inadequate. We need more." This tactic was accidentally pioneered around ddC access when ACT UP/San Francisco induced Hoffman LaRoche to start the "limited access program," and then ACT UP/NY and others broadened the demand. It is a better idea, if using this strategy, to plan it in advance. If you are offered something, take it. You can always demand more later, but it is nearly impossible for drug companies to restrict access once they have begun to open it.

Peer humiliation. Make sure all of their colleagues know how inhumane they are. Organize a consensus statement signed by everyone from prestigious researchers to community-based organizations (CBOs). Get the word out in all the treatment newsletters and PWA publications. Consider negative advertising in a local newspaper or medical journal. Distribute fact sheets at major scientific conferences. Corner them in the hallway when FDA people are listening.

Compromise. Make sure that when you compromise, you are aware of who you are compromising. All too often, the compromise occurs around the testing of a drug in women, access for children, making sure doctors in public hospitals hear about a new access program, etc.

Once you've gotten what you want. Thank them for providing people with $30 million worth of free drug. Mention their good behavior publicly, and contrast it with that of an offending pharmaceutical firm with a competing product. Start talking to their marketing staff when the drug nears approval. Emphasize that profiteering will not be tolerated. Write to your local Medicaid offices and health departments. Make sure the medication is covered by third-party payors. Maintain the relationship--they will have a new drug soon.

Persistence. Never give up. Almost every instance where ACT UP has failed to get what it wanted from a drug company stemmed from our failure to keep the pressure on. Everything takes longer to happen then you would want. Sometimes a year elapses before anything changes. Sometimes the most vocal advocates for access to a particular medication have died by the time it becomes available. Activists get burned out, and leave or drop projects. Do not let important work fall by the wayside just because the person spearheading the effort needs to take time for him/herself, or moves on to an area where success seems more immediate. Keep at it. Eventually you will succeed.

For more information:

Garance Franke-Ruta, PWA Health Group, 31 West 26th Street, New York, NY 10001, 212.532.0280

Strategy Working Session: Inside Method for Working with Pharmaceutical Companies

Presented by David Peck

Note: The suggestions below assume that positive communication is the chosen approach; it does not replace CD.

1. Identify goals of interaction. For example, obtain wider access for a drug; expedite filing of a new drug application; review and comment on protocol and initiate a new drug.
2. Take initial steps to achieve goals. When making contact give great phone: Before cold calling, network for a name (having a referral is best) otherwise just calling and saying it's John Smith from ACT UP yields a call back from a relatively

senior representative. In a pinch, contact via marketing/PR department and pump for names--pretend to be a doctor; get names; flatter; use reflection.

Once you get through, communicate the threat in a non-threatening way; indicate strength in numbers; i.e. consensus statement via fax; follow up call; speak in the "we" form at first, i.e. "We've reviewed your protocol and have comments," then personalize as you feel more comfortable; "I'd like to suggest a working session to [state goals clearly]"; acknowledge common ground as early as possible; let them think they figured out what your goals are (give them an immediate goal, something relatively simple, then build on the success of the experience.) If possible, set up a meeting.

Or, meet at a conference, local event--where they live/but not threatening. West Conshohocken--"Lunch?" "Sure, I was going that way anyway; how about a tour?" Fax/send/communicate an agenda a week before (set goals).

3. Be a reality test to the people in the company. Send a video showing the reason for the need with real people. Personalize your experience; "I have a friend who got your drug, and it helped..." Send factual and emphatic letter to the key decision maker(s), and send copies to other names you've heard.

4. Learn views of key players--identify and exploit/use opponents. Project an interest in the views of people in the company. Project an interest in corporate culture/politics (if you can). Project an interest in support staff, i.e. secretaries, medical assistants, etc. What do they want from you? What are they afraid of? Identify those against your goals: Pay attention to the subtext. Personify areas of dispute in opponents--focus disagreements.

5. Discussion /allies: Establish long term working relationships. Community board idea.

Workshops (summaries for all workshops were not prepared)

1. Women's Treatment Issues: This workshop discussed the fact that women are not being included in the clinical trials in sufficient numbers that reflect the growing numbers of women who are HIV+. At this time women are limited in their access to drugs that will help them fight off the onset of AIDS. Also, women are subject to different OIs than men. These OIs do not fit the definition of AIDS and therefore they are not treated in a timely manner. There is the need to include more women in drug and treatment trials. This group also wants to see the establishment of a women's treatment network.

For more information:

Iris Long, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564.AIDS

2. People of Color: The conclusion was reached that there needs to be more coalition building among AIDS groups and people of color, and more researchers who are persons of color and sensitive to issues.

Also, there is the need to work on the issue that some drugs are not as effective on persons of color. (Note the VA study on this very issue.)

Also discussed was the possibility of an AIDS conference that would exclusively address those issues that are of concern to persons of color. This conference would lay the groundwork for networking and establish a working agenda that would meet the needs of people of color. One issue that is very important is the language barrier; there is the recognized need that many of the current documents on AIDS are unavailable to persons of color since not all have English as their principle language. In order to meet this need it was recommended that the documents be translated into the various languages and be culturally sensitive.

For more information:

Saundra Johnson, ACT UP/Chicago, 851 North Wood Street, Chicago, IL 60622, 312.829.6797

Moises Agosto, AIDS Treatment Data Network, 259 West 30th Street, New York, NY 10001, 212.643.0870

Elias Guerro, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564.AIDS

3. Standard of Care: As PWAs or HIV+ individuals we are the ones asking the questions. There is a need for doctors to be more willing to examine various OIs and be vigilant in their monitoring of patient conditions.

With regard to the insurance companies, we need to fight them and ensure that they do not cut the services that have been contracted. In many cases, insurance companies are using HIV/AIDS infection as a way of avoiding paying for medical care.

For more information:

Richard Richon, ACT UP/Boston, PO Box 483, Cambridge, MA 02142, 617.492.2887

4. CDC Working Group: It is recognized that the current AIDS definition is not sufficient and that it is not meeting the needs of various groups. It needs to be more inclusive of women's infections, and lower T-cell counts.

Also, this group addressed the issue of mandatory testing and the fact that it is a violation of privacy. This group is looking for candidates to sue the government over this issue.

For more information:

Tony Davis, CDC Working Group, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564-AIDS
Amy Meyers, R.N., ACT UP/Columbus, 1333 Ida Avenue, Columbus, OH 43212

5. Treatment Alternatives: These are defined

as non-pharmaceutical sponsored treatments. It is important to examine the treatment alternatives book published by ACT UP/NY. These alternative treatments need to be tested with clinical trials so as to protect all individuals.

For more information:

Jon Greenberg, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564.AIDS

6. Prisoners/Parolees: This needs to be included in the ACT UP agenda. Current estimates state that as many as 50% of prisoners are HIV+, and these individuals need a voice. One of the ways to assist them is to put pressure on elected officials at all levels.

For more information:

Steve Machon, Prison Issues Committee, ACT UP, 135 West 29th Street, New York, NY 10001, 212.564.AIDS

7. National Universal Health Care Teach-In: The two sessions covered many issues--the basis for the system, problems, the need for a national health service.

There are four principles on which a national health care system needs to be based: 1) All people need to be covered by a single system; 2) All health care concerns need to be addressed by the system, not just care, but also home care, preventive measures and education; 3) The system needs to be controlled by those who will be using it so as to ensure that the needs of those being cared for are being met; and 4) It should not be associated with any pre-existing health care program.

A national health care system is faced with a number of problems from the outset, and these should not be underestimated. The first is overhead; there is the need to be mindful of the cost of administering such a system. Second, and of equal importance, is the issue of financing such a plan. In an age of deficit reduction plans there is a reluctance on the part of legislators to institute such a plan. We need to remind them that with a national health care plan we can reduce the overall cost, and therefore the overhead.

Along with a national health care plan, a national Health Service needs to be established which would serve as the educational vehicle for training health care professionals. This could either work in conjunction with, or replace, the medical schools, and ensure that all have access to a health care career.

We also discussed the need, when lobbying for national health care, to appeal to a broad spectrum of legislators and concerns, instead of just focusing on AIDS. It is important to recall that all people are in need of health care. This tactic will help in ensuring the eventual passage of a health care plan for the nation.

For more information:

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OUT!, Washington, DC, 301.794.8829

ACT UP/Kansas City, 816.753.5930

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HIV/AIDS Specific Expenditures by Agency

Agency	FY 1992	FY 1993	$ change	% change	% real change*
FDA	72	75	3	4.2	+0.2
HRSA	322	349	27	8.4	+4.4
IHS	3	3	0	0	-4.0
CDC	460	505	25	5.2	+1.2
NIH	841	873	32	3.8	-0.2
ADAMHA	235	248	13	5.5	+1.5
AHCPR	10	10	0	0	-4.0
OASH	5	6	1	20.0	+15.0

* Percent change - cost of living increase of 4% = real change

HIV/AIDS Specific Expenditures by Activity

Activity	FY 1992	FY 1993	$ change	% change	% real change*
Basic Science Research	889	932	43	4.8	+0.8
Risk Assessment and Prevention	672	705	33	4.9	+0.9
Product Evaluation Research and Monitoring	72	75	3	4.2	+0.2
Clinical Health Services Research and Delivery	325	353	28	8.6	-4.6
HIV/AIDS Coordination	3**	4	1	33.0	+29.0
PHS Construction	7	0	-7	-100.00	-104.00

* Percent change - cost of living increase of 4% = real change
** NAPO was funded at $2 million in FY 1992, not sure where the additional $1 million listed here is in reference to .

President's Budget FY 1993

HEALTH

Committees that consider matters concerning health care programs and regulation of health care systems.

ALABAMA
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Chairman
Senate Health Cmte.
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State Capitol
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ALASKA
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Senate Health, Education & Social Services Cmte.
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Rep. Pat Carney
Rep. Georgianna Lincoln
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ARIZONA
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Senate Health, Welfare & Aging Cmte.
Senate Wing, State Capitol
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(602) 542-3171

Rep. Nancy Wessel
Chairman
House Health Cmte.
House Wing, State Capitol
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Rep. Ruth Eskesen
Chairman
House Human Resources & Aging Cmte.
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Rep. Walter M. Day
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COLORADO
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House Health, Environment, Welfare & Institutions Cmte.
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House Banking & Insurance Cmte.
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House Health & Rehabilitative Services Cmte.
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Rep. Elaine Bloom
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102D CONGRESS
1ST SESSION

S. 2060

To revise the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Orphan Drug Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 26 (legislative day, NOVEMBER 23), 1991

Mrs. KASSEBAUM (for herself and Mr. METZENBAUM) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To revise the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Orphan Drug Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Orphan Drug Amendments of 1991".

SEC. 2. DESIGNATIONS.

(a) IN GENERAL.—Section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)) is amended by adding before the period at the end the following: ", and on the basis of projections as to the number of persons who will be affected by the disease or condition 3 years from such date".

(b) EXCLUSIVITY.—Section 527(b) of such Act (21 U.S.C. 360cc(b)) is amended—

(1) by striking "or" at the end of paragraph (1);

(2) by striking the period at the end of paragraph (2) and inserting ";" and

(3) by adding at the end the following new paragraphs:

"(3) a drug has been designated under section 526 for a rare disease or condition described in section 526(a)(2)(A) and if after such designation such disease or condition does not meet such description: or

"(4) the Secretary has issued a termination notice under, and acted in accordance with, subsection (c).".

SEC. 3. TERMINATION OF ORPHAN DRUG STATUS FOR DRUGS OF SIGNIFICANT COMMERCIAL VALUE.

Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by adding at the end the following new subsection:

"(c)(1) If the Secretary determines that the cumulative net sales of a drug which is designated under section 526 are more than $150.000.000 during the 7-year period described in subsection (a), the Secretary shall commence the review of any other application under section 505, certification under section 507, or license under section 351 of the Public Health Service Act (42 U.S.C. 262), for such drug for such designation, if such review has not already commenced.

"(2) If the Secretary determines that the cumulative net sales of a drug which is designated under section 526 are more than $200,000,000 during the 7-year period described in subsection (a), the Secretary shall issue a termination notice to the holder of the approved application of such designated drug. The notice shall state that the Secretary is authorized, no earlier than 90 days after the date of the notice, to approve other applications under section 505, issue other certifications under section 507, or issue other licenses under section 351 of the Public Health Service Act, for such drug for any such designation, unless such holder makes the showing described in paragraph (3).

"(3) Not later than 30 days after the date of the termination notice, the holder described in paragraph (2) may submit evidence to the Secretary to demonstrate that—

"(A) the cumulative net sales of the drug are not more than $200.000.000; or

"(B) the exceptionally high costs of developing the drug in the United States exceeded $200.000,000.

"(4) Not later than 90 days after the date of the termination notice, the Secretary shall review any evidence submitted by the holder—

"(A) in accordance with paragraph (3)(A), and determine whether cumulative net sales of the drug are more than $200.000.000, or

"(B) in accordance with paragraph (3)(B), and determine whether the costs of developing the drug in the United States exceeded $200.000.000.

If the Secretary determines that the cumulative net sales of the drug are not more than $200.000.000, the Secretary shall, within such 90 days, vacate the notice until such time as such sales are more than $200.000.000. If the Secretary determines that the costs of developing the drug in the United States exceeded $200.000.000 the Secretary shall, within such 90 days, determine the amount of costs incurred in developing the drug in the United

States and vacate the notice until such time as the cumulative net sales are more than such amount.

"(5) In determining the cumulative net sales of a drug, or determining the costs of developing a drug for purposes of paragraph (4), the Secretary shall consider—

"(A) evidence submitted in accordance with paragraph (3)(A) or paragraph (3)(B);

"(B) data obtained through contracts with independent sources of comparative sales data;

"(C) data submitted by interested parties; or

"(D) other relevant data available to the Secretary."

"(6) Any person may submit to the Secretary a petition which contains evidence of the cumulative net sales of a drug and which requests the Secretary to determine whether a termination notice under paragraph (2) must be issued.

"(7) As used in this subsection, the term "cumulative net sales" of a drug means total sales of the drug in the United States minus discounts, allowances, and returns.".

SEC. 4. OFFICE FOR ORPHAN AND RARE DISEASES AND CONDITIONS.

Section 227 of the Public Health Service Act (42 U.S.C. 236) is amended—

(1) by striking subsection (a) and inserting the following new subsection:

"(a) There is established in the Department of Health and Human Services an Office for Orphan Diseases and Conditions. Such Office shall be established at a level within the Department with sufficient authority to assure full implementation of the functions and responsibilities established by this section.";

(2) by striking "Board" each place the term appears and inserting "Office";

(3) by striking "drugs and devices" in subsection (b) and inserting "Drugs, devices, and medical foods";

(4) by inserting "of chapter V" after "subchapter B" in subsection (c)(1)(A); and

(5) by adding at the end the following new subsection:

"(f)(1) There is established in the Office an advisory committee to advise the Office in carrying out the functions of the Office under this section.

"(2) The advisory committee shall be comprised of 11 members appointed by the Secretary, in consultation with the Office and the Commissioner of the Food and Drug Administration, from persons knowledgeable about rare diseases and conditions, including—

"(A) 5 representatives of organizations of persons with rare diseases or conditions;

"(B) 3 research scientists; and

"(C) 3 representatives of health-related companies.

"(3) The Secretary shall also appoint, as liaisons to the advisory committee, individuals from the Food and Drug Administration, the National Institutes of Health, and other appropriate Federal agencies.

"(4) Any vacancy occurring in the membership of the advisory committee shall be filled in the same manner as the original appointment for the position being vacated. The vacancy shall not affect the power of the remaining members to execute the duties of the advisory committee.

"(5) Members of the advisory committee, and liaisons to the advisory committee, shall not be compensated, but shall receive travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter 1 of chapter 57 of title 5, United States Code, for each day the member or liaison is engaged in the performance of duties away from the home or regular place of business of the member or liaison.

"(6) Notwithstanding section 1342 of title 31, United States Code, the advisory committee may accept the voluntary services provided by a member of the advisory committee, or a liaison to the advisory committee.".

SEC. 5. AUTHORIZATION FOR ORPHAN DRUG ACT.

Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking "$10,000,000" and all that follows and inserting "$20,000,000 for fiscal year 1992, $25,000,000 for fiscal year 1993, and $30,000,000 for fiscal year 1994.".

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THE NATIONAL COMMISSION ON AIDS

The Future of the HIV Epidemic: The Potential for Change

Remarks of Derek Hodel, Executive Director
People With AIDS Health Group
14 January 1992

Good Morning. My name is Derek Hodel and I'm the executive director of the People With AIDS Health Group. I want to dedicate my remarks today to my friend Jay Lipner, who recently died of AIDS after a long, courageous fight. Some of you probably knew Jay -- in the time I knew him, he taught me so much, about government, about AIDS, and about doing the right thing. Jay pushed hard for me to work more *inside the beltway*, and he would have been proud to see me here today. I only hope I live up to his expectations.

It is with great sadness that I appear before you today. Or, I should say that great sadness has prevailed over the great anger that very nearly prevented my appearance. As I struggled to conceive of the implications for the future of the AIDS epidemic, I was in turn discouraged, demoralized, and bitterly angry. This commission, the second of its kind, has conducted more hearings than I care to count, has visited care facilities, advocacy groups, prisons, research centers. You have talked to doctors, scientists, politicians, people with AIDS. In this time, while someone dies from AIDS every seven minutes, you have spent countless dollars and untold time preparing reports -- intelligent, forceful, landmark reports -- that have been virtually ignored by a callous, mean-spirited, white house that promulgates public health policies mired in politics. You already have the answers. You already know what you need to know. And so I ask myself: why bother?

Last November, on a day one sportscaster declared we would remember as vividly as we did the one that saw the assassination of JFK, the phones in my office began to ring. It was the media, seeking comment, and this gay white boy was forced to ask: *Who's Magic Johnson?*

Mr. Johnson, you must forgive me, because I don't know any basketball stars. I do, however, know hundreds of people with HIV, and among them are countless young black men, much like yourself, some successful, some not. Although they, too, are all HIV infected, to the best of my knowledge, the president has never called them.

Mr. Johnson, I watched as you became an AIDS hero, and were added to a very short list that includes mostly children, hemophiliacs, and people who think they got it from their dentist. It includes Ryan White and Kimberly Bergalis, whom I believe someone recently called a saint -- the so-called innocent victims of AIDS. It does not include most of the people I know.

Mr. Johnson, I ask with utmost humility that you take great care in your new role -- you are now one among many, exclusively innocent victims of AIDS, be they gay people, drug users, or those Ms. Bergalis saw fit to imply *had done something wrong*. To serve as our spokesperson, we ask you to embrace us all, to have the courage to speak with humanity for all those for whom you have been given a voice.

Mr. Johnson, as you changed the lives of Americans everywhere, you immeasurably changed my life, as well. After years of fighting this disease, I saw the nation suddenly awaken to the reality that is AIDS, the reality that I, as a gay man, live with every day. The reality that has killed over 130,000 Americans just like you and me. And yet, I saw that for most people, AIDS became a reality only because you upset the *us v. them* construction that had previously shielded them from fear -- and they were busily, desperately, putting it back in place. Still, the president of our United States blames those with AIDS for "refusing to change their behaviors", suggesting that AIDS is a price they must pay. *Magic* Johnson, hero, AIDS anomaly.

The great power you now wield to persuade, to convince, to inspire, is something I, in spite of dedicating my life to fighting this fight, will never know. I cried again for my brothers who desperately needed that power, years ago.

A long preface, perhaps, for the message I have to deliver. As I considered what issues to bring before the National Commission on AIDS, I struggled. Is it useful for you to hear, *again*, of 37 million Americans who have no health insurance? Of the federally encouraged, unchecked avarice of the pharmaceutical industry, among the most profitable businesses on the planet? Of the grievously misguided federal research apparatus? Of teenagers who have no information, let alone condoms, to help them avoid HIV infection, to whom we blindly suggest, *Just Say NO!* Of prisoners with AIDS left to die? Of drug users whom we blithely advise to stop shooting

drugs, but to whom we decline to offer drug treatment? -- who are counseled to use clean needles, denied access to same, then prosecuted if they should somehow turn some up on their own? Must we really hear, *again*, of rampant AIDS discrimination in housing, in employment, in public accommodation? Must we really?

Tragedy permeates the AIDS epidemic, and it does this commission's work. For this noble body, a smattering of great minds in its midst, is impotent. I demand to know: Does your responsibility extend no further than issuing reports? Can it be that your mandate, your moral imperative, permits you to identify the enemy, then abandon the fight? You, as commissioners, bear great responsibility, and must confront this truth: your reports, like AIDS itself, have been ruthlessly ignored by a callous, incalculably mercenary administration, for the sake of politics. Excuse me, two administrations.

My attitude has hardened, of late. I have no time for ignorance, ten years later. I have no patience for those who do not wish to know. I blame inaction not on benign neglect but on calculated, cold blooded malice. And I equate silence with death. I blame you for the death sentences implicit in your laissez-faire approach. It is immoral for you to have gathered such information, formulated such recommendations, without screaming bloody murder until you are heard. We are desperate for leadership. And thus, the only message you will have paid to have me deliver today: If this administration could only be convinced, be compelled, to implement the recommendations this commission *has already made*, we will have made greater progress than in the ten years spent.

Mr. Johnson, already you have given people with HIV great hope, by your will to live, by your will to beat this thing. Your taking control of your illness and your positive attitude show great courage. Sadly, they will not be enough to keep you alive.

Mr. Johnson, what ultimately propelled me to Washington was the opportunity to challenge you. I challenge you to do what this commission has been unable to do. I challenge you to call President Bush -- not to listen, because we already know what he has to say -- but to challenge him to provide the leadership necessary to stem the AIDS epidemic before it kills you, as I'm sorry to say, it probably will. I challenge you to educate President Bush, to challenge his simplistic, moralistic thinking that blames, rather than helps. I challenge you to confront President Bush, to push him to do more to support research into treatments for AIDS, for it is treatment, not compassion, that will keep people like you alive. Read the commission's reports, ask questions of those who have spent the better part of a decade fighting this fight. We'll take your call -- you help us to find a new voice.

My bet is the president takes your call, too. God knows, he won't take mine. And I would wager he won't take Dr. Osborne's, either. The choice is yours: you can demand that he provide leadership, or we can wait. We can do more fact finding, establish more task forces, issue more reports, pretend that we care.

Send the message, Magic: We are a thousand points of light, and we are being extinguished, one by one.

ACT UP/ DC
AIDS COALITION TO UNLEASH POWER
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Voice Mail 202.728.7530

ATAC 2

As a member of ACT UP DC I did not get to fully participate in the Conference due to various support tasks required to run such a conference. I did make a point of attending one session on Treatment and the various aspects of drug development which is my area of interest as and AIDS activist. The great thing about ATAC is a chance to share ideas with Activists from near and far who have a common interest in topics we often work on alone within our local groups. Our aim was to form a network of activists who would support a particular line of action. We formed our concepts in the breakout sessions after an introduction to the over all picture of new drug research and development. I joined a group which discussed the lack of input to FDA from PWA and the HIV community. We all felt it was time to go back to the FDA and ask for a place at the table to address PWA concerns on a number of issues. The foremost of these issues is the slow and bulky process of drug approval time and access to new agents when a PWA has run out of options. The various groups set up by the NIH to do research have community input but the FDA has none and we resolved to write and begin putting pressure on the FDA to set up a similar community advisory board system for each of the divisions in the FDA that concern people with HIV.

I think that ATAC gave us a unique opportunity to put our heads together and come up with a unified goal which we can work on together and individually knowing we have real support from around the nation. The issues that define AIDS activists targets are constantly moving and changing and communication is often hampered due to time and money within smaller activist groups. The chance to get together and pick out some of the big things we may have overlooked as individuals means we will be able to do something about these issues without devoting all of our limited resources to that issue. Getting a voice in the FDA is clearly very important to the future of People with AIDS and at ATAC we began working towards that end. In the 45 minutes we spent designing this project and planning our actions, alone you would have been fortunate to contact one person in one city. We had 15 activists from 10 different cities and are well on the way to getting the action off the ground in an unprecedented singular voice. This was a unique experience which helped to build trust and respect for the hard work every AIDS activist is doing around the country as well as adding to our portfolio of targets for the future.

Frederick Nunley
Treatment & Data committee
ACT UP DC

The Washington Post

METRO

SUNDAY, SEPTEMBER 29, 1991

Taking AIDS Battle to Capitol Hill

Suggestions Include Thank-You Notes, 'Terrorizing' Staff Members

By Karlyn Barker
Washington Post Staff Writer

AIDS activists from across the country got some expert advice yesterday on how to win friends and influence people in Congress. It takes time and patience, they were told, and it helps if you speak simply and send Capitol Hill staffers a thank-you note afterward.

But people with AIDS, many activists argued, are working against the clock and can't afford the legislative niceties associated with traditional lobbying. Instead, some suggested, maybe it's time for Senate office sit-ins or, perhaps, a campaign to "terrorize" House and Senate aides so lawmakers will have trouble getting staff.

Lobbying and more confrontational strategies were weighed during an often emotional gathering of about 200 people at an AIDS Treatment Activists Conference held here this weekend at the Omni-Shoreham Hotel. The conference, sponsored by the New York and District chapters of the AIDS Coalition to Unleash Power (ACT UP), attracted AIDS activists from about 40 cities who want to take on Congress and the White House in their push to combat AIDS and secure better health care for those who have it.

Tomorrow, AIDS activists plan a march to the White House and possibly some other actions to demand that President Bush appoint a national "AIDS czar." On Tuesday, they plan a march to the Capitol on behalf of a national health care program.

What fueled a tense debate over tactics, including some complaints that existing AIDS organizations aren't doing enough, was a depressing reality: More than 118,000 Americans have died from the disease.

"It's frustrating," said Mark Kostopoulos, 36, from ACT UP-Los Angeles. "We've worked for three years to help change the way AIDS is thought about, but all our successes haven't changed the fact that people continue to die."

Participants heard from invited speakers Tim Westmoreland, counsel for the health and environment subcommittee of the House Committee on Energy and Commerce; Susan Cohen, family planning lobbyist with the Alan Guttmacher Institute; and Steve Smith, executive director of the Human Rights Campaign Fund, a lobby for gay rights.

Their tips for how to work within the system, they said, did not preclude ACT UP from using other means to put the heat on unsympathetic lawmakers. However, none of the three was present at a later workshop where the idea for terrorizing congressional staffers was raised.

Much of the conference's anger was directed at Sen. Jesse A. Helms (R-N.C.) and Rep. William E. Dannemeyer (R-Calif.), who have sponsored measures opposed by gay-rights and AIDS groups. But the group seemed just as angry at what one activist called "our so-called liberal friends" who support such legislation.

"Why does the entire Senate allow itself to be held hostage to a person who is so clearly bigoted?" asked Maxine Wolfe, of ACT UP-New York.

Earlier, Smith tried to explain the political facts of life to conference participants. Most members of Congress, he said, "don't represent areas where they think AIDS is a major problem. I don't have a clue how to get William Natcher, of Bowling Green, Kentucky, to support AIDS legislation."

THE TRAVEL PARTNERSHIP
An Associate of Allegro Travel

9 January 1992

Dear Friends,

It has been my privilege for the past three years to provide travel planning services to Act Up New York, Act Up Los Angeles, and the ATAC Conferences.

My gay owned and operated travel agency, located in Houston, Texas, has successfully negotiated the lowest airfares for these groups to attend conferences in San Francisco, Florence, Italy, Washington D. C. and Florida.

This year we're working on the Republican National Convention in Houston, and the International Conference on AIDS in Amsterdam.

For the July conference in Amsterdam, we have negotiated very special rates from New York, Chicago, Los Angeles, Atlanta, and Houston.

To see Mr. Bush get re-nominated in Houston in August, and provide as much harassment as possible in my home city, we've been able to provide several options: group space from Los Angeles and New York, and deep discounts on individual fares from other cities.

It would be my privilege to talk to you, or your travel coordinator for these events, to ascertain if we could be of service to your members attending these important meetings.

When we're not working on such conferences, our primary focus is working with our gay brothers and sisters to provide fantastic vacation opportunities, such as expanding the conference trip to Amsterdam into a wonderful summer vacation in Europe.

The past two years we have witnessed an exciting and hopeful phenomenon: firstly, a burst of gay owned/operated tour and cruise operators, and hotel/guest houses, and equally important, incredible recognition by the travel industry at large of our substantial up-scale market profile. The travel industry now rates the gay market as one of the most profitable, and with the most long range potential of any market segment in the U. S.. Through the excellent work of IGTA (the International Gay Travel Association), we've received this long overdue recognition, and the travel industry is taking our community very seriously.

A charter member of this organization, we take our work very seriously too, and are rewarded each day by the pleasure and satisfaction we bring to our ever expanding client base.

Would you please give me a call, or pass this letter on to the person(s) responsible for travel planning?

Sincerely,

Sandra B. Wilkins
President

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The New Challenges of Controlling Tuberculosis Transmission

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By Gail S. Makulowich

Tuberculosis (TB)-infected patients, if also infected with HIV, are at high risk for developing active tuberculosis. Sometimes difficult to identify, these patients may pose a risk to other immunocompromised patients, healthy patients, and healthcare workers. Recent outbreaks of drug-resistant TB have heightened concern about TB nosocomial transmission. Yet diagnosing and treating this growing group of TB-infected patients is not an easy task.

AIDS-related conditions may cause these patients to cough, which can mask active tuberculosis. Moreover, HIV-infected patients may not react or may react atypically to tuberculin diagnostic tests, which can prolong the diagnosis and delay treatment. And they may be more likely to harbor drug-resistant strains of TB, which can make treatment fail, causing them to be infectious for a longer time. TB transmission is most likely to come from patients with unrecognized pulmonary or laryngeal TB, who are not undergoing effective anti-TB therapy and have not been placed in respiratory isolation.

In April 1989, the CDC Advisory Committee for Elimination of Tuberculosis (ACET) cautioned that, without appropriate control measures, the further spread of HIV infection among populations with a high prevalence of TB infection (for example, poor, inner-city Blacks and Hispanics) may result in dramatic increases in the disease. The ACET cited results of a study that matched reported TB cases with AIDS case registries in 43 states and 11 localities. It showed that 4 percent of AIDS cases appear on the TB registries; 10 percent of AIDS patients in Florida and 21 percent at University Hospital in New Jersey had a history of TB. The ACET also cites data showing that 29 percent of non-Asian adult TB patients in San Francisco were infected with HIV.

Ways to Prevent Transmission

Several tuberculosis outbreaks in healthcare settings were reported to the CDC during the past three years. The CDC outlined recommendations to prevent TB transmission in the December 7, 1990, *Morbidity and Mortality Weekly Report*, "Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, with Special Focus on HIV-Related Issues."

It recommended these actions to reduce TB transmission to persons in healthcare settings:

Promptly identify and treat patients with TB infection and active TB disease. Persons belonging to groups at risk for TB, including all persons with HIV infection or risk factors for HIV infection, should be given a Mantoux tuberculin skin test. Those with positive skin tests should be evaluated for preventive therapy with isoniazid, for example. However, HIV-infected patients are more likely to have a false negative result because of anergy, or inability to mount an immune response to the tuberculin antigen. In fact, this anergy, even among asymptomatic HIV-infected patients, is more common than initially suspected, prompting the CDC to recommend in April 1991 that an anergy test be given at the same time as the TB skin test. Moreover, the sputum smears of TB/HIV-infected patients are less likely to reveal acid-fast bacilli (AFBs). Diagnosis may be overlooked because of atypical clinical or radiographic presentation or simultaneous occurrence of other pulmonary infections, for example, *Pneumocystis carinii* pneumonia (PCP). Nevertheless, TB diagnosis should be considered for any patient with persistent cough or other symptoms compatible with TB such as weight loss, anorexia, or fever. Patients with suspected or confirmed TB should be reported to the appropriate health department to begin identification and evaluation of contacts.

When indicated, preventive or curative therapy should begin as soon as possible. Isolation precautions should be applied to patients who are suspected or confirmed to have active TB and who may be infectious. Procedure-specific precautions (for example, isolation room or booth with negative air flow, wearing a particulate respirator, etc.) should be followed for cough-inducing or aerosol-generating procedures such as sputum induction or administration of aerosolized pentamidine (AP).

Reduce microbial contamination of the air by providing adequate isolation areas and ventilation. This should be done with the assistance of experts in ventilation or industrial hygiene. Isolation rooms should have air flowing negative to the adjoining room or corridor and should be

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vented via air exhaust directly to the outside of the building. A similar local exhaust vent should be used for isolation booths used for AP or sputum induction procedures. In the ER, waiting rooms, and other general areas of hospitals where there may be a high risk of TB transmission, if air is recirculated, it may be advisable to use high-efficiency filtration such as HEPA filters and germicidal ultraviolet lamps. Although expensive, HEPA filters should be useful in removing infectious TB organisms before recirculating air. They are 99.97 percent effective in removing particles greater than 0.3 microns in diameter.

UV lamps are controversial because of the potentially serious adverse effects of short- and long-term exposure to germicidal UV rays. Some hospitals such as University Hospital in Newark, NJ, prefer not to use them. However, Lyndon B. Johnson Hospital in Houston, TX, uses well-shielded UV lights in the medical patient waiting room, in the outpatient clinic, and in the sputum-induction area to enhance the filtering effect of air conditioning. "The main concern about the safety of UV lights is that they are well maintained," says Judy Urteaga, R.N., C.I.C., infection control coordinator for the hospital. "They are turned off and cleaned each week and we change the bulbs every six months, because they lose their effectiveness over time."

Finally, in certain high-risk situations, healthcare workers should wear a disposable particulate respirator (PR) that filters out particles 1-5 microns in diameter and provides a tight face seal. PRs should be provided by the healthcare facility and be worn by persons in the same room with a patient whose signs and symptoms suggest a high potential for infectiousness and by those performing procedures likely to produce bursts of tuberculin droplet nuclei such as bronchoscopy, endotracheal suctioning, and administration of AP. Wearers should be adequately trained in the use of disposable PRs. The healthcare facility should implement a program for training, fit testing, care, maintenance, and medical monitoring consistent with the Department of Health and Human Services (DHHS) and National Institute of Occupational Safety and Health (NIOSH) guidelines.

Survey healthcare personnel and report TB transmission to investigate and control outbreaks. At the time of employment, all healthcare facility personnel should receive a Mantoux tuberculin skin test with five tuberculin units of purified protein derivative (PPD). Periodic retesting of PPD-negative healthcare workers should be conducted to identify persons whose skin tests convert to positive. Healthcare workers, who may be frequently exposed to patients with TB or who are involved with high-risk procedures such as bronchoscopy or sputum induction, should be retested at least every six months; others should be retested annually. Moreover, healthcare facility personnel and patients should be evaluated if they have been exposed to a potentially infectious tuberculosis patient for whom the CDC-recommended infection control procedures have not been taken.

Healthcare facility personnel with positive TB skin tests or with skin-test conversions should be clinically evaluated for active TB and appropriate therapy begun, if indicated. They should also be offered counseling and HIV-antibody testing, because HIV infection affects the management of TB. If a healthcare worker develops active tuberculosis, work restrictions may apply to prevent further TB transmission.

Are They Really New?

The CDC December 1990 document also details procedure-specific and setting-specific (ER, outpatient clinic, home, for example) precautions. The report essentially pulled together all previous CDC tuberculosis control recommendations for healthcare facilities into one document. Even so, several recommendations came as a surprise to some hospitals, which puzzled Jacquelyn Polder, B.S.N., M.P.H., nurse epidemiologist in the CDC Hospital Infections Program.

"I've been surprised at the reaction, the awe that these are all new recommendations, but they aren't," she says. She attributes this to the fact that some people have not been carefully following previously published recommendations, a fact borne out when the CDC investigated several major hospitals which experienced nosocomial TB transmission to healthcare workers and to patients.

The CDC investigated the first documented cases of nosocomial transmission of drug-resistant tuberculosis at Jackson Memorial Hospital in Miami, FL, in 1990. The Agency joined the hospital and local

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and state health agencies to investigate apparent skin-test conversions in eight healthcare workers on a specialized ward for HIV-infected patients from January through April 1990. Multidrug-resistant TB (MDR-TB) was defined as resistant to at least the standard drugs, isoniazid (INH) and rifampin. Case-control studies showed that those with MDR-TB were more likely to be HIV-infected and have had opportunistic infections, and were less likely to respond clinically to anti-TB therapy. MDR-TB tended to occur late in the course of AIDS, suggesting recent TB infection rather than reactivation of latent infection.

From January 1988 through July 1990, 10 of 28 (36 percent) HIV-ward healthcare workers had documented skin-test conversions, which coincided with the time case-patients with AFB-smear-positive sputum were hospitalized on that ward. Infection control policy on the HIV ward required that patients with any pulmonary symptoms and/or abnormal chest radiographs be routinely placed in TB isolation (AFB isolation) until a TB diagnosis was excluded or until they had been on anti-TB therapy for at least seven days. TB was not initially suspected for some patients who presented with nonpulmonary complaints. As a result, they were not placed in AFB isolation. Patients with TB who were on anti-TB drugs were not routinely placed in isolation on readmission, although some were later recognized to have AFB-smear-positive MDR-TB.

The Issue of Drug Resistance

The CDC cited the long time required for obtaining results of drug susceptibility testing as a factor leading to inadequate treatment of patients who had drug-resistant TB and to transmission of TB infection to healthcare workers. "It sometimes took from 2 to 6 months to determine if there was drug resistance," notes Ms. Hutton, B.S.N., M.P.H., epidemiologist in the CDC's Tuberculosis Division. She is a coauthor of the December guidelines and was on the CDC task force investigating the TB outbreak at Jackson Memorial. "It is dangerous to assume that TB medications are working after a certain number of days in the absence of clinical improvement," cautions Ms. Hutton. "The CDC recommends that a patient be clinically improved with reduction in cough and decreasing AFB in sequential sputum smears before isolation precautions are discontinued. And if drug resistance is suspected, AFB precautions should continue until the patient is improving and the sputum smear is free of bacilli on three consecutive days."

Other factors cited as contributing to the outbreak were: prolonged periods of infectiousness in patients; inadequate duration of and occasional lapses in AFB isolation (Doors on AFB isolation rooms were sometimes left open, those entering the rooms sometimes used masks improperly, and patients in isolation were sometimes allowed to leave their rooms if they wore masks, which they sometimes removed for short periods of time. Moreover, the airflow was sometimes positive out of the isolation rooms.); and delayed recognition of TB in some patients. Explains Ms. Hutton, "For any patient with TB, you can't assume that because they were sent home from the hospital on TB medication, they are well. If there is drug resistance, or medications are not taken as prescribed, a patient can appear to improve and then deteriorate, causing a problem when they come back to the clinic."

Patients with uncomplicated TB usually do not require hospitalization unless they have another medical problem. If diagnosed in the hospital, they usually can be released within a few days. However, for the HIV-infected patient, active TB may be one of several medical problems. And if the patient is not responding to TB medication and requires hospitalization for other problems, the opportunity for TB transmission in the hospital exists, according to Ms. Hutton.

"We had already started making changes even before the CDC came down to make their investigation," explains Joan Otten, coordinator of Jackson Memorial's tuberculosis control program. "We had been around TB a long time and were anticipating some problems...We cannot always identify TB patients when they come through our emergency room. But we follow CDC recommendations to put HIV-infected patients with suspicious symptoms in isolation and test right away for TB. As a result, we need more isolation rooms." Jackson Memorial has created entire respiratory isolation units for TB and TB/AIDS patients. They have contracted a consultant to install UV lights in certain waiting areas and the ER. Both air filtering systems go through HEPA filters and are exhausted outside. Ms. Otten estimates that more than 2[illegible] percent of Jackson Memorial's AIDS patients are infected with TB.

"You can't put everyone who comes into the E.R. in isolation."

The Houston Experience

AIDS patients make up 10 percent of those at Lyndon B. Johnson Hospital in Houston, TX. Lyndon Johnson replaces Jefferson Davis Hospital, Houston's original dedicated TB hospital. Houston has always had a high incidence of tuberculosis because of its growing population of Asians, many of whom had TB infection when they entered this country, and the many Hispanics who enter Texas from Latin American countries where TB is endemic. Now HIV-infected or AIDS patients are adding to the TB patient rolls. So for Judy Urteaga, who has worked with TB patients for 20 years at the dedicated hospital and Lyndon Johnson, the CDC recommendations were no surprise.

"Because we always had TB in our building there weren't as many changes for us [prompted by the CDC guidelines] as perhaps hospitals who haven't seen TB for years," asserts Ms. Urteaga, infection control coordinator at Lyndon Johnson. "We have made a couple of changes. We have always screened our high-risk employees every six months to see if they have been exposed and give them prophylaxis early on...We have worked to make employees aware that our HIV patients who are anergic, for example, those with ARC or advanced cases of AIDS, may have a negative TB skin test. You have to look at other clinical indicators for diagnosis in those patients. So we've increased suspicion of those patients with an underlying diagnosis. We isolate them from the time they walk in the door until they go home until we have a definite diagnosis. For HIV-positive patients coming in with any symptoms that might indicate TB, we isolate them, but we don't test them for TB if they are not symptomatic."

One study at Lyndon Johnson showed 5 percent resistance to isoniazid in a small group of TB patients at the hospital. Ms. Urteaga expects to find some multiply resistant strains in the still ongoing study, particularly in patients from Mexico, where antibiotics are easily obtained for self-treatment.

"Drug-resistant strains tend to perpetuate themselves," asserts CDC's Ms. Polder. "The problem is we don't know how to treat these strains. Drug-resistant TB could become a very serious problem in this country if we get a lot of TB that we don't have good drugs to treat."

Drug-resistant forms of TB are becoming a growing problem particularly in large urban areas like Miami, Houston, and Newark. Tuberculosis cases at University Hospital in Newark, NJ, have increased gradually for the past two to three years. Most of the hospital's TB cases come from the large homeless population around Newark, who are exposed to TB in the many shelters. The rest originates from University's AIDS patients, who are primarily heterosexual IVDUs, according to Debra Mayer-Quezada, M.D., C.I.C., hospital epidemiologist and director of infection control. She estimates that 15 percent of University's AIDS patients are TB-infected.

University Hospital had been practicing airborne precautions long before they received the December CDC guidelines. "If a person walks into the ER, for example, and they are coughing and can't control their cough, they go on respiratory precautions right away," says Dr. Mayer-Quezada.

Recognition in the Emergency Room

Not recognizing TB or considering it in the diagnosis is one of the biggest problems that occurs in a hospital setting, particularly with people who are likely to have other pulmonary problems, according to Ms. Polder. "So people come into the ER and hack and cough while they sit there for a few hours next to someone else. Whatever [the patient's] ultimate diagnosis, those evaluating them do not consider the diagnosis of TB. They consider possible pneumocystis. They might admit them to the hospital and never put them in isolation, because pneumocystis is not thought to be transmitted person-to-person. Since they don't consider treating them for TB, the patient stays in the hospital and exposes the people sharing their airspace.

"And then there's no way of later tracking people who were in the ER to see if they converted their skin test and should be put on medication. There is risk in areas where you have large groups of people who have symptoms that aren't adequately diagnosed at the time of admission and, as you know, you can't diagnose it on the spot. It's tough to deal with. You can't put everyone who comes into the ER in isolation. Most people, even if they have pulmonary symptoms, are not TB patients. There is a fine line regarding the decision to isolate someone

"The best way to protect patients and healthcare workers is to identify potentially infectious cases."

because you think they are very high risk for having TB." She warns healthcare workers, "There are risks. They need to be aware of what our recommendations are, and fastidiously follow them."

The Craze Over Particulate Respirators

Some hospitals have focused on particulate respirators as the key to controlling their risk, which has obscured more important preventive measures, according to Ms. Hutton. The CDC, as well as manufacturers of medical masks, have been flooded with calls about particulate respirators (PR).

"TB is an airborne disease of course, but masks have not been the main method of preventing TB transmission in hospitals ever and still are not," asserts Ms. Hutton. "The best way to protect patients and healthcare workers is to identify potentially infectious cases, get them on appropriate medications, and put them in AFB isolation. In circumstances when the medication needs time to take effect or when a person is not responding to therapy, it would be desirable for the healthcare worker to wear a disposable particulate respirator. The effectiveness of masks that have been used in hospitals for a long time has never been proven. And we're not sure they don't work. It's an unknown. In practical terms, the time the healthcare worker really needs a particulate respirator is if the ventilation is poor and the patient is very infectious and not responding to medication, or with a suspicious patient with a strong cough that would require suctioning, all things that would make the person more infectious."

Confusion about PRs, evidenced by the many anxious calls, has blown the role of masks in TB infection control way out of proportion, according to Ms. Hutton. "This is one of the least important methods for controlling TB transmission and yet we've gotten more calls on this than anything else."

The disposable PR recommended by the CDC for healthcare workers looks like a cone-shaped surgical mask. Certified by NIOSH to prevent inhalation of industrial dust and mist particles as small as 0.4 microns, it is manufactured by less than 10 U.S. companies. Theoretically, it should prevent inhalation of TB-sized particles, according to Chris Coffey, chief of the Air Purification Respirator Section, NIOSH Division of Safety Research. He says that aerosol physicists he's talked with agree that the respirator should function as intended regardless of whether an aerosol contains lead particles, silica particles, or water particles containing TB bacteria.

Mr. Coffey notes that since the Occupational Safety and Health Administration (OSHA) has not yet set exposure levels for bioaerosols such as tuberculosis bacteria, NIOSH has no plans to certify PRs specifically for bioaerosols. He reassures, however, that "PRs are designed to protect the wearer, whereas no one has tested surgical masks, which were designed to protect the patient from the wearer."

Although the PR recommendation is for healthcare workers, there may be some circumstances in which it might be advisable for a highly infectious TB patient to wear a PR, according to Ms. Hutton. For example, when such a patient is being transported in an elevator. "Ideally, you wouldn't take a highly infectious patient on an elevator, but if you must, it's advisable for him to wear a PR."

Additional Reading

"Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues." *MMWR* 39(RR17):Dec. 7, 1990.

"Purified protein derivative (PPD)-tuberculin anergy and HIV infection: Guidelines for anergy testing and management of anergic persons at risk of tuberculosis." *MMWR* 40(RR-5):Apr. 26, 1991.

"Nosocomial transmission of multidrug-resistant tuberculosis to health-care workers and HIV-infected patients in an urban hospital—Florida." *MMWR* 39(40):Oct. 12, 1990.

"Tuberculosis and human immunodeficiency virus infection: Recommendations of the advisory committee for the elimination of tuberculosis (ACET)." *MMWR* 38(14):Apr. 14, 1989.

Reprints of this article are available in bulk quantity. For information and prices, write to or call: Karen Ballen, *AIDS PATIENT CARE*, 1651 Third Avenue, New York, NY 10128, (212) 289-2300.