TRANSCRIPT OF PROCEEDINGS

NATIONAL COMMISSION ON

ACQUIRED IMMUNE DEFICIENCY SYDROME

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Pages Pages 1 thru 182

Washington, D. C.
May 8, 1990

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NATIONAL COMMISSION ON AIDS

MEETING

Tuesday, May 8, 1990

Pan American Health
Organization Building
525 23rd Street, N.W.
Meeting Room B
Washington, D.C.

The meeting in the above-entitled matter, commenced, pursuant to notice, at 8:20 a.m., before:

JUNE OSBORN, M.D., Chairman

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P R O C E E D I N G S

CHAIRMAN OSBORN: Let's get started this morning. I apologize to our witnesses for the tardiness of the commission this morning. I don't know what they were doing last night. I was behaving myself. But we are very pleased that you took the trouble to join us, and I think perhaps in the interest of your schedules we should get started, and you'll excuse us if others come in as we go. This morning's theme for the first couple of hours is Scientific and Care Community, and in our first panel are some very important participants in the care community.

And I would like to invite you to proceed. I think, Don, were you going to speak first.

DR. ABRAMS: Yes.

CHAIRMAN OSBORN: Dr. Donald Abrams will lead off, and if you can tell everybody who you are as you start because there are people in the audience who will not necessarily have your full title in front of them.

DR. ABRAMS: Thank you. I'm Donald Abrams, Assistant Director of AIDS Activities at San Francisco General Hospital, Associate Professor of Clinical Medicine at the University of California, San Francisco, and Chairman of

the Community Consortium, a community-based group in San Francisco conducting clinical trials that I am here to describe today. And I thank you for the opportunity to appear before you.

What I'd like to do is briefly trace the history of the Community Consortium in San Francisco and discuss some of the issues that we are facing in attempting to do community-based clinical trials. The Community Consortium was established in March 1985 in an effort to increase communications between investigators in the AIDS program at San Francisco General Hospital and the increasing number of private practitioners in the community caring for patients with clinical manifestations of HIV infection. One of our initial objectives was to keep community providers apprised of experimental treatment protocols that were being conducted in the AIDS program to facilitate patient referral to these studies.

It soon became apparent, however, that the community physicians desired to participate more actively in AIDS treatment trials. They had access to an ever enlarging patient population in their practices, and they were eager to contribute to the overall AIDS knowledge-base by participating

in clinical trials. To this end, the Consortium embarked upon our first community-based clinical trial in early 1986. At that time, there was no standard of practice for preventing repeat episodes of Pneumocystis pneumonia in patients who had suffered an initial bout. Some physicians used no further treatment. Others maintained patients on lower doses of agents that had treated the acute infection.

Consortium physicians sat down monthly for six months to reach consensus on a protocol to compare four different possibilities that were already being widely employed in the community but in the absence of data collection. Physician investigators had chosen a common problem and created a study that was feasible to conduct within their own offices or clinics that would hopefully answer a significant question of major importance to a large number of people with HIV infection. As well, physicians and patients could retain the very important primary relationship that had already been established, thus combining aspects of clinical care with clinical research. Rather than having patients referred to a remote tertiary care site to participate in this trial, the consortium study would expand participation in clinical trials to increased number of physicians as well

as patients.

This first Pneumocystis prophylaxis trial was launched in July of 1986. Shortly thereafter, AZT became available for the same population with restrictions on allowable concomitant medications. Eligible patients opted to wait for the potentially life-saving antiviral agent, and our first attempt at conducting a community-based clinical trial came to a rapid halt. In April of 1987 after much discussion with those then in command at the AIDS program of the NIAID, an application was submitted by the Community Consortium to become an AIDS clinical study group. Our proposal requested financial support for infrastructure based on itinerant research nursing staff that would assist community physicians in enrolling and monitoring patients on to community-based clinical trials.

As the second part of our application in 1987, the consortium submitted a new protocol to evaluate the efficacy of three different doses of aerosolized pentamidine for prevention of Pneumocystis pneumonia. With the increasing availability of AZT and a desire to minimize other systemic therapies that might interact and with increasing anecdotal reports of the efficacy of the inhaled drug, aerosolized

pentamidine therapy was rapidly becoming the community standard in San Francisco for PCP prophylaxis, again in the absence of any efficacy data.

Consortium physicians seized the opportunity to design a three-arm trial which we and our patients were eager to commence. Funding of our application would have provided data as well as expanded access of this promising investigational agent to patients who are otherwise unable to afford the expensive, unproven, and hence not reimbursable treatment.

In hopes that our NIAID application might be favorably reviewed, the consortium launched the aerosolized pentamidine prophylaxis trial in July of 1987. Within eight weeks, 69 physicians had enrolled 444 patients on to the trial. Patients were receiving care at 12 respiratory care centers in four San Francisco Bay Area counties. The necessary staff to assure that the trial was conducted per protocol and to collect and analyze the data were not yet on board, but had been requested in the proposal. When our application received a low priority score for being too novel and too community-based, we were truly left stranded.

Emergency funding from the University-Wide Task Force on AIDS of the University of California San Francisco

allowed us to hire a project manager to begin to salvage the study. Pharmaceutical support ultimately followed once it became clear that our federal application would not be funded. The NIAID appreciated, however, that there may be some potential in the community-based clinical trials program. Although somewhat biased by what were felt to be unremarkable performances by community-based study groups in Europe and in our own country's community oncology programs, AIDS program staff awarded the consortium a one-time stipend that allowed for the hiring of our project manager. An additional presidential award from the American Foundation for AIDS Research allowed us to bring our nurse clinical trials coordinator on board.

By now, the aerosolized pentamidine study was already bearing fruit, and we were ready to launch the next phase of the consortium's community-based clinical trials program. This time, however, we were going to be asking for increased commitment and input from our collaborating clinical investigators. Realizing the physicians in private practice have little extra time and less patience for yet another form to complete, consortium staff worked for four months to develop a generic case report form that would be

used for all consortium trials and that providers could also employ as their own clinic chart note.

With these forms, our next trials were launched in November 1988. These studies were also proposed by consortium primary care providers and refined by our scientific advisory committee. The community advisory forum is a panel composed of people with AIDS and their advocates and representatives of a number of AIDS service organizations in the Bay Area. I understand John Caldwell was here yesterday and addressed this group. He is a member of our forum. This group meets monthly and is encouraged to suggest trials that they would like to see performed by the consortium. In addition, they review all planned protocols and have input into design in hopes of making our studies more attractive to potential participants.

To date our studies have sought to answer clinically pertinent questions using readily available agents in Phase II/III trials with gross clinical end-points requiring no more than standard of care laboratory monitoring. Current studies are evaluating the efficacy of clofazimine in preventing Mycobacterium avium-intracellulare infection, Vitamin B-12 in preventing AZT-induced anemia, and Megace for

treating the HIV related wasting syndrome.

In addition to these three interventional trials, three observational data bases have been established. The Zidovudine database was created to collect our standardized set, data set, on any patient begun on any dose of Zidovudine for any indication. Although there is no real intervention here other than standard of practice care, clinicians unfamiliar with standardized data collection and the monitoring conventions of clinical trials can easily participate in this labor unintensive project employing our user friendly set of case report forms.

Aware that a significant number of patients in the community were employing alternative therapies for treatment of their HIV infection, often making claims of efficacy in the absence of data, the consortium created an HIV-alternative treatment database. Patients could inform their physician of the regimen that they were using and ask to be followed using our standardized data collection forms. The recently initiated ddi database attempts to collect a local set of information on patients taking this anti-retroviral under the expanded access program.

To date, a total of 40 physicians in 25 sites

including one in Los Angeles are currently participating in our clinical trials program. In addition to the initial patients on the PCP prophylaxis study, another 500 participants are now enrolled in these six community-based protocols.

1989 was a good year for the community-based clinical trials movement. Both AmFAR and the NIAID saw the potential for expanding access to trials and increasing the rapidity with which questions could be answered in the community setting. The Community Consortium received a grant from AmFAR and a contract from the Community Program for Clinical Research on AIDS which has allowed us to further expand our research nursing and support staffs. Although our budget may rank among the largest of the established community based programs, it is still inadequate to support the work that needs to be done.

Participating community providers are too often relying upon volunteerism, their own and their staffs, to complete the paperwork and procedures necessary to maintain their patients on trials. A method of reimbursing physicians either financially or with office base support staff could provide increased incentive for physician participation in

the community-based clinical trials program.

Unlike ACTG trials where patients have their visits and laboratory paid for while participating, our patients on protocol receive no such benefit except for free drug when interventions are being evaluated. For some, entering into a community-based clinical trial may be their first entry into the health care delivery system. Often as the demographics of our Bay Area population shifts we find that those accessing the trials cannot, in fact, afford to access the accompanying care. Equalization of access to community-based clinical trials is bringing many of us face to face with the reality of the inequity of health care distribution in this country.

Certainly community-based clinical trials will not correct all of the social ills of an America facing the HIV epidemic in the last decade of this century. What these programs can do, however, is enlist the support of the legions of primary care providers out there, the AIDSologists, providing compassionate and state of the art care to their patients. Expanded access to trials benefits not only the patients but also their providers, who may obtain an antidote to AIDS-related burnout from the very active contributing to group studies with the attendant change of routine and sense

of belonging and cooperation that is thus fostered.

We are delighted with the progress that the community-based movement has made from the days not too long ago when we were considered too novel. We are also well aware of and grateful for the significant role that Admiral Watkins' Commission had in bringing the concept into wider view. We urge you to continue to support, both in spirit and with recommendations for increased funding, a movement that may very well foreshadow the manner in which medical care and research is conducted in the next century. Thank you for your attention.

CHAIRMAN OSBORN: Thank you very much. Why don't we hear from each of you and then we'll get a chance and hear some of the comments. Appreciate it very much.

DR. THOMPSON: I am Melanie Thompson, a physician in the private practice of internal medicine in Atlanta, Georgia. I am President of the AIDS Research Consortium of Atlanta which is non-profit, tax-exempt community-based research group. It has been a privilege to be a participant in the community-based AIDS research movement, which has exploded throughout the country in the last two years. Like most movements, it reflects an idea whose time has come, not

subtly or silently, but with a striking momentum and enthusiasm. It is a groundswell from the grassroots led by patients and their medical care providers.

It has filled a void and proven its merit, and may forever change the face of medical research. Community-based research means conducting research in the context of primary care. AIDS is a primary care disease. The vast majority of HIV-infected patients are cared for by private practitioners in public clinics rather than by academic institutions. In fact, before community-based research, only a small fraction of HIV infected individuals were able to gain access to clinical research opportunities. Clinical trials conducted in the primary care setting have access to large numbers of patients and are likely to fill quickly and finish as rapidly as possible.

Patients see research as an opportunity to receive promising new treatments before they become widely available. They are also eager to contribute to the body of knowledge about this disease which threatens their very lives. Community-based clinical trials promise to deliver research of unsurpassed quality because of the unique resources available in the primary care environment. These trials take

advantage of the doctor-patient relationship and the ability of primary practitioners to follow patients closely over time.

In this setting, fewer patients are lost to follow-up and documentation of clinical data is better. Community-based clinical research is ideally suited to multi-center trials requiring large numbers of patients in order to answer the pressing questions of the day whether they concern epidemiology, prophylaxis or treatment. The community-based research movement is also ideally suited to address the needs of groups which consistently have been under-represented in research studies, particularly racial and ethnic minorities, women and IV drug users.

Traditional research institutions may be inhospitable to these populations, and creativity must be used to address issues such as transportation, child care, and substance abuse. Access to research then opens the much larger question of access to care because community-based research is inextricably interwoven with the delivery of medical care. At present, there are over 40 community-based clinical trial centers in various stages of development. These centers are not a homogeneous group of look-alike institutions. An organization which is truly community-based

will reflect the demographics and needs of its community. Diversity is the greatest strength of the community-based research movement, and constantly challenges the flexibility of our old methods and assumptions.

Our approach must be broad enough to meet the needs of persons in San Francisco and in Harlem, in Santa Fe and the Bronx, in Dallas and Atlanta. In Atlanta, ongoing clinical research exists through the AIDS Research Consortium of Atlanta, or ARCA, because there is no interest in AIDS clinical research by our local university, and our nearest ACTG is 400 miles away. ARCA began two years ago as a group of 15 physicians who wanted to formally organize and begin clinical trials.

With volunteer support only, we formed a board of directors, a scientific advisory committee, and an institutional review board and became a non-profit, tax-exempt corporation. We have since attracted six major industry sponsored drug studies and a large epidemiology study with CDC, which has become the basis of our observational database. Our active drug studies are all fully enrolled. And our database has enrolled over 1700 patients in just three months. Our members now include 45 private practitioners as

well as the Grady Memorial Hospital Infectious Disease Clinic and the Veterans Administration Infectious Disease Clinic.

We are funded through NIAID as a Community Program for Clinical Research on AIDS site as well as through industry sponsored studies and grants from private foundations such as the American Foundation for AIDS Research, AmFAR. We have broad-base support in our community among care providers, patient advocates and business leaders. Because our care providers are overworked already, our mission is to provide total administrative and clinical support so that patients can enter clinical trials and maintain their relationship with their physician. To that end, the consortium employs nurses who take study drug to the physician's office, see the patient with the physician, collect data, draw blood and return to our central office to complete case report forms.

Our enrollment in studies has been excellent, and our data collection is equal to or better than traditional academic sites. We have learned from older community research groups and we have shared our experience with newer groups. In fact, the spirit of cooperation among distinctly different community-based centers has been inspirational during the past year. Working by fax machines and conference

calls, a cohesive network has developed, and with egos put aside information has been shared, technology transferred and the work begun. Working groups have formed to address research issues, create common data collection forms, organize a national HIV observational database, determine compatible computer hardware and software for communications among all groups, develop strategies for education and training and address issues of minority recruitment and lobbying.

Unfortunately, only 18 of the 40 centers were able to share in the limited funding of the NIAID Community Programs for Clinical Research on AIDS. It is crucial that the CPCRA be supported and expanded to include the rest of these groups for the future of AIDS research surely must focus on the wealth of clinical resources available in our communities. Thank you.

DR. PEREZ: George Perez. I'm the director of the Inpatient AIDS unit at Saint Michael's Medical Center in Newark, also the Director of the Virology Lab there and the Medical Director of the North Jersey Community Research Initiative. Our history is a little bit shorter in the Newark area than is those of the San Francisco and Atlanta

groups, not in terms of HIV disease certainly but in terms of our organization into a community-based research activity. AIDS really came on the scene for us soon after the reports had come out from the west coast and San Francisco and in New York. Our community has been involved in different hospital settings since early 1982.

Initially when we established our clinical settings in Newark at our own hospital in Saint Michael's, this began as a half-day clinic in one afternoon to have some training for our infectious disease fellows in outpatient management. At the present time, that is now four of the five days that that clinic has expanded to, and we went from originally having a patient population of about 50 charts in 1982 to now over 1800 active charts in that one medical center. Because of the demands put on the physicians in our community in the care of AIDS primarily among the infectious disease sub-specialists and the lack of that light at the end of the tunnel that many of our practitioners saw, the idea of the North Jersey Community Research Initiative came from a community as well as physician intent to relieve some of those pressures.

The feeling being that cooperation would be

excellent in terms of exchanging data and providing new insights and new ways to do research. The organization was formed about a year and a half ago. My involvement has been for about the last nine months as the medical director. I can say that in that short period of time our accomplishments have been many. We've been able to enroll 40 participating physicians. We were able to get funding from the New Jersey State Department of Health as well as the American Foundation for AIDS Research. And most recently, named also as a NIAID Community Based Clinical Trial Group.

It is with the help of these funds that we've been able to start some of our own trials, which have included an observational database which for the busy clinician in the Newark area is no small feat. It is only by the provision of a clinical research assistant to go to these sites and help fill out the case report forms, in fact, that any data can be gathered at all. The physician who many times has 40 patients to see during those clinic times, which may range from four to five hours, even though the form may be simple and require only a three minute or four minute time interval, for him it's a lifetime. And that information has to be done by someone else.

That simple funding for that CRA has allowed us to enroll almost 300 patients now in our observational database where in the past we had zero. The next trial that we embarked on was one on the attempt of the use TMP/SMX as a prophylactic agent for the prevention of Pneumocystis pneumonia. We were very pleased with the results that had come from the San Francisco group in terms of the use of aerosolized pentamidine and we offered it as an option to many of our patients. However, access to medical care, which Dr. Abrams mentioned earlier, is a real problem for us in the Newark area.

The majority, in fact, of our clinic patients, 75 percent, have no insurance or way of paying for their care when they're initially enrolled in our clinic setting. Aerosolized pentamidine because of the cost involved of the equipment as well as the medication became a treatment that was really out of range for most of our patients. The use of a much less expensive agent was one that was interesting to us. Earlier trials had been done. Our attempt was to find a dose which perhaps would not have as much toxicity and yet would be easily taken by most of our patients. That was our next trial that we set up, and it has enrolled at this point

over 60 patients in less than two months.

We're very pleased with that type of enrollment from our physicians who in the past have never participated in any type of clinical trial formation. The alternative (p. 12) database was also established in the Newark area, again based a lot on what the information that the San Francisco group had been able to give to us, and we owe them certainly a debt of gratitude for being one of the first in terms of community-based research organizations. However, this again showed us the variability and diversity in community-based groups. In the Newark area, there really was very little in terms of alternative treatments that were available. In fact, the standard of care was very low and access to that standard of care was, in fact, very low.

When we examined our mortality data and our morbidity data in our Newark area, we were always surprised and not really shocked, I should say, by the fact that our mortality was always much higher than in other groups that were reporting, primarily because our patients, in fact, were not coming in for medical care until they were much sicker or much farther along in their illness. The majority of our patients are, in fact, intravenous drug users. In the state

of New Jersey over 50 percent of the patients with AIDS are intravenous drug users. In our clinic population, about 70 percent are intravenous drug users.

The majority of our patients are minority patients. The black population makes up about 50 percent of our population at the Saint Michael's clinic area, about 40 percent for our total North Jersey CRI group. The hispanic population, primarily the Puerto Rican population, makes up about 20 percent of our clinic population in Saint Michael's and about ten percent of our North Jersey CRI population. The recruitment of physicians that can deal with these cultural and minority groups has been very important to our group. We have attempted certainly to enroll hispanic physicians as well as black physicians as primary treaters as well as enrollers in clinical trials.

Our feeling being that it is that rapport between physician and patient, in fact, that allows you to have the greatest success when you do a clinical trial. The lack of access for most of our patients into any ACTGs, and again the 400 miles that Melanie mentioned is not one of distance for our patients but rather one of availability. New York City, which can be as close as ten miles away for some of our

Bergen County participants might as well be 450 or a thousand miles away because of the inavailability of transportation to those sites or the fact that they just don't want to go to a new physician or be associated with an experimental project.

However, their own physician, doing clinical research, is something which appeals highly to our group. They have been very open to the fact that their own physician provide them care and in our opinion in the North Jersey CRI that experimental care is really part of regular care when you're talking HIV disease. When you limit the availability of any of these patients to some of the experimental drugs that are being worked on, you are limiting their own care in terms of the treatment of their illness. We are very proud of the fact that we've expanded access to a lot of patients to simple drugs such as Zidovudine or AZT and now even expanded access and parallel tract with the use of ddi for those of patients that were unable to tolerate AZT earlier.

It is the small successes, I think, which keep us going. Now with the NIAID funding that has come to our group, the points that Melanie made before -- Dr. Thompson -- are very, very apropos. I think the cooperation among all the groups to come up with trials that will yield important

information done from a community-basis is a real possibility, and I'm happy to say I'm very optimistic about the success we're going to have with those trials. The first two trials that we're going to undertake, one will be a large scale study looking at the prophylaxis for Toxoplasmosis. This is a particular trial that could certainly not be done by any one academic center because of the incidence of the disease and because of the variability of the illness progression.

But it is something which can be done in the community-based network, again providing for perhaps minimal intervention in terms of the community-based physician, just the routine standard follow-up care, but providing very important information, not only on the potential prophylaxis for this disease, but on the real incidence and dangers of this illness.

The second trial is one that is very exciting as well to our group. And that is the possibility of looking at the use of two investigation, at this point, nucleus site analogs, both ddi and ddc, for those patients that are unable to tolerate AZT or Zidovudine, again, giving you the basis for perhaps gaining information on two investigation agents where many of those patients perhaps would have had parallel

tract or in our situation not have access to any drug at all. Again, because of the paperwork that is involved in filling out report forms, no matter how simple they may appear when they're initially constructed by the drug company or by the investigators, for the clinician it is a nightmarish situation to have to complete those forms.

With our CRAs, again, going to those sites, helping to complete those forms, our physicians are no longer shrinking away when we come to their door with a new trial, but are anxiously awaiting to see what we have to offer because of the exciting possibilities of some positive research that can be done with the use of their patients and with the use of the minimal amount of their time. It is this enthusiasm which has kept our group growing, and it is enthusiasm which has to be fostered, I think, on the national level. The AmFAR funding has helped in the past. The NIAID funding has certainly helped, but there is many more groups that want to be involved. There are many more trials which need to be done. It is by recommendations from a commission such as this and by the continued support from other agencies that we hope to complete many of those tasks and hope to have many successes on the records of the community-based trial

groups. Thank you.

DR. FRIEDLAND: My name is Dr. Gerald Friedland. I don't really speak as a representative of a particular program but rather, I think, as an individual physician involved pretty much from the outset of the HIV and AIDS epidemic in clinical care epidemiology, and more recently some experience with clinical trials. I have to say somewhat enviously not in the community-based clinical trial world, which sounds exciting and really what we've needed for a long time. My views are somewhat generic and personal then and not really programmatic.

I think what I'd like to say is that clinical trials, be they tertiary care, academic based or community-based, really have to be seen in the context of HIV disease itself, which as we all know is a chronic viral infection which is progressive and has extraordinary biologic clinical, social and I would say now demographic complexity as well. In the clinical trials process, however we construct it, is constructed in the context of this disease itself. It seems that although I don't want to in any way be discouraging, the inexorable slow clinical progression of HIV disease makes it important for us to think not just in terms of short-term

successes but really long-term chronic, complex and not necessarily curative therapies which prolong life and health, but which are in, I think, by their very nature the hardest to develop tests, evaluate and make available to those in need.

Therefore, we're really talking about a prolonged complex, long-term, clinical trial process, and the expectation of quick fixes, of immediate results, of striking and dazzling successes, although they occur on occasion is really not, I think, appropriate to the disease at hand. Clinical trials are often criticized and demeaned. If they are faulty and flawed or inadequate to the problem, I think this is deserved, but also I believe that they're often criticized regardless of where they're constructed and carried out. Again, in the context of this disease and other chronic diseases, because they don't often produce quick results, and again, I just want to emphasize that as many times as I can, that there is a great danger in the construction of clinical trials now for this disease that we will become discouraged quickly because the answers are not forthcoming in the short-term but rather in the long-term.

The work itself, as was mentioned by previous

testifiers, is often mundane, tedious and restrictive, and although there may be initial enthusiasm in the construction of clinical trials, the actual carrying out of the work is repetitive and tiresome and mundane and can result in frustration and in addition the results often, even in the best constructed clinical trials, are sometimes ambiguous and incomplete requiring repetition, reanalysis, reinterpretation, embellishment, et cetera.

So the vision of penicillin curing Pneumococcal pneumonia dramatic and immediately understandable with a single case, I think, is not the situation that we're dealing with clinically, and one that makes the public and certainly our patient community and also the provider community frustrated and demoralized. I think ways of speeding up the clinical trials process have really been discussed at this table. The first and obvious one is to increase the number of enrollees dramatically. And it seems like the most creative way of doing that is what we've heard this morning, and that is opening up the clinical trials process away from the tertiary care institutions and into community-based trials where large numbers of interested physicians, providers and patients are available, that is broadening the effort.

The second thing, I think, is simplifying studies. My own personal experience with clinical trials is that they're often overly complicated, constructed in part to protect patients and therefore requiring a tremendous amount of data collection for safety monitoring, often at the insistence of the pharmaceutical company that's sponsoring the drug. But this impedes the progress of clinical trials in that data, huge amounts of data is collected which oftentimes is never used, is often irrelevant to the study conduct itself, and takes away from the central aim of the study.

So increasing enrollees and simplifying studies, both of which, I think, are unique features of community-based clinical trials, are very, very important. I think I want to say a word about clinical trials in the context of the health care system because clinical trials, as you've heard, and I think as we know, but it can't be overly emphasized, clinical trials cannot exist and be productive in a health care vacuum. They really must exist in the context of the existing health care system. Although they may offer clinical care where no care exists, they really can't replace or substitute for a clinical care system. Nowhere is this

more obvious than in the inner cities despite the creative solution in northern New Jersey. This is not true in most inner cities where the epidemic is mounting its greatest force.

Without clinical providers to identify HIV infected individuals, to assess their clinical status and to refer them or even perform clinical trials existing in the health care system, there are no clinical trials. The converse is true. It's an empty victory if there are fruits of clinical trials which improve health status of individuals who are infected with HIV or other diseases, but there is really no health care system available to make those fruits available to those in need.

An example, I think, a recent one, is the results of the ACTG 019 protocol, which indicate that early administration of zidovudine to individuals who are asymptomatic can result in a decrease in progression of disease, but for most people who are HIV infected and asymptomatic that neither the knowledge of that status or the system to provide the results of that clinical trial is in place. I think it's important to note that clinical trials in whatever system they're performed are exceedingly labor intensive, and this,

in fact, may represent one of the most important rate limiting steps. Staff to carry out the trials, physicians, nurses, particularly physicians' assistants, although available in the community-based clinical trials programs that we've heard described are not readily available in most situations.

This is particularly true in New York. I'm sure it's true in other areas of the country as well. But the ability to expand the clinical trial system and to enroll more patients in clinical trials is heavily going to be dependent upon the availability of people to actually carry out the clinical trials and as a mundane, not highly rewarded clinical activity, I have great concerns for the limits to our ability to expand these trials.

I think I'd like to say that in conclusion I want to emphasize again that the long-term nature of this disease, it's chronic, progressive nature, requires both short-term innovation, as we've heard in terms of developing systems for clinical trials, but also the appreciation that there is no quick fix, and our commitment to providing clinical trials and clinical research must not only be a substantial one, but also a continuing and long-term one, and as relentless as the

disease itself. Thank you.

CHAIRMAN OSBORN: Let me thank all of you on behalf of the commission. I have to confess there are days when as one of the minority of physicians on this commission, I feel a little embarrassed about being one. Today I'm rather proud to be in the company of such physicians, and so we appreciate your input very much. I'd be glad if the commissioners have questions.

DR. J. ALLEN: Again, I want to reiterate what June said. Tremendous testimony, and I think very exciting foretaste of what I hope we'll see a lot more in the next several years. I've got several questions. Let me just start off with two, and then if there's time I'll come back. Dr. Friedland, you talked about simplifying the trials, and the fact that you felt that some of the excess data collection was for the protection of the patients or perhaps on the company's, on the manufacturer's side for the protection of the company to make sure that they've got everything.

How much of this excess data collection, at least in the past, has been because of the inability of the company to know exactly what the FDA is going to require and therefore we want to make sure that we've got everything that we

possibly can the first time around because we can't go back and get it later, and we just don't know what we'll really need in order to get approval of our new drug? And perhaps with the somewhat more open relationship that has been developed recently between the FDA and the manufacturers in the design of clinical trials and so on, there really as an opportunity here to simplify at the beginning?

DR. FRIEDLAND: I can't answer that with fact or with expertise, but I believe that you're right in that question that from the drug companies' point of view the most important thing is to get the drug licensed and to create an application to the FDA which is air-tight and all the holes are filled on all the data that they expect the FDA will want to have in order for the drug to be approved to be collected. So that that aspect of the drug approval in clinical trials system, I think, is at least in part reflective of what may be an overly protective position on the part of the FDA.

I'm not the best person to make that statement. I understand, though, that there is increasing flexibility in the process, as you say, because of increasing dialogue. In this situation, there is a certain urgency obviously in the AIDS epidemic which we all experience that makes business as

usual in terms of drug licensing something that has to be reexamined as well, and I think that's one of the issues that may speed up development of drugs and available therapy. It comes down in a practical way to the actual execution of clinical trials where it is a rate limiter.

DR. J. ALLEN: The second question is directed to Drs. Perez, Thompson and Abrams, and I'll let you divide it the way that you want. I think all of you clearly emphasized the time difficulties that physicians in practice have in terms of getting involved even with the simplest of the data collection forms and the additional time, perhaps, just to do a little bit more examination, to draw specimens, or obtain specimens for a few additional laboratory tests, and the role of the clinical trial's associate or whatever the name of the person would be. Are you all using different models in terms of perhaps some of you having the clinical associate in the office of the physician fulltime?

Dr. Thompson, you indicated that in your instance, the person went from the central facility out to the areas. Are we looking at different ways of doing this, and is this the most efficient way to collect this kind of information?

DR. THOMPSON: Maybe I'll start with that. No,

it's not the most efficient way is the first answer, and yes, we are looking at different models. I think that actually the three of us may have some similarities in the way that we do things. Looking at the 40 community-based research groups that I'm in touch with, I feel that, again, it depends on the needs of the communities. The way studies are conducted in Harlem at Harlem Hospital will be very different than the way they're conducted in private practitioners' offices.

In Atlanta, we have a large number of private practitioners participating in our studies, and we also have two large clinics. In the clinic setting, for example, at Grady Hospital, we pay for a research nurse to be in the Grady clinic. We bought them a computer, and what we are trying to do then is to staff Grady to make it possible for those patients to participate in clinical trials. Again, the physicians just can't do it. And our research nurses provide the quality control and also provide the legwork. In terms of using nurses who are hired by the consortium and then travel to different sites, I think it also depends on the intensity of the study that you're doing.

We're doing six large pharmaceutically based trials, and as Jerry mentioned, they require an incredible

amount of data collection, you know. An adverse event is a headache and it started on the 14th and ended on the 15th, and that has to be clearly documented. And it's never documented unless you have a research nurse there to ask those questions. So expanding pharmaceutically based trials out into the community, I think, requires slightly different methodology than expanding, for example, the Toxoplasma prophylaxis study, or a large low tech study, in which I think the physicians are able to take a little more of the load.

But we are always going to need support in the physicians' offices. It may be as simple as being able to staff some of the offices with help, which is always there. Our method works. It's not the most efficient, but we do have good control over the data and at a time when we're trying to prove ourselves as a viable research mechanism, that's very important. So, Donald.

DR. ABRAMS: The consortium consists of 175 physicians. Only 40 are currently participating in our clinical trials' program. Some of those physicians are not practicing. Some are psychiatrists and some people who attend our two monthly meetings come just for education and

were not interested in doing community-based clinical trials. We surveyed the entire group of our membership to ascertain why people who are not participating who could aren't in the clinical trials program. And part of the survey was modeled after a survey done of community oncologists and difficulties they have in putting patients on community oncology clinical trials.

Some of the reasons that came out of such a study were difficulties discussing informed consent, difficulties in altering the doctor/patient relationship that you have when you become a subject, an investigator, et cetera, and these ideational type difficulties in doing community-based clinical trial. And interestingly, from our consortium physicians, none of them rated these problems, informed consent, changing relationships; difficulty and fearing you're putting somebody on the wrong arm of a study, as issues that prevented them from participating in trials.

The number one issue was time, and the number two issue was fear of paperwork. So it really is a problem. We currently are using nurses as our buffer between the provider and the research. And we don't know which is the best way to use our nurses. We have only three in addition to our nurse

trials coordinator. And we're attempting to experiment with different possibilities. For example, as Melanie stated, in one institution we provide partial salary for a nurse that's based in that clinic.

In others, we have our nurses are assigned to different providers and collect data from them, and in another situation we have a nurse assigned to a particular study, and she collects all the data on that particular study. So we're trying to see which one of these is the best way. But I think at this time it's not entirely clear. In answer to your first question on the amount of data that's needed, I think we do have some experience of that with the Pneumocystis prophylaxis pentamidine trial where because we didn't get the up-front funding that we were hoping for, we had a very streamlined protocol.

In fact, in our study, no data was collected directly from participating physicians. The only data from the San Francisco arm of the PCP prophylaxis study came from respiratory care centers where the respiratory care providers filled out information on the treatment that they gave and the patients filled out adverse reactions and how are they doing. And ultimately we had to go back and do chart reviews

to see when people developed Pneumocystis, which was the clinical end-point. So we had no information on CB-4 counts, and in fact, no toxicity data of the treatment.

Fortunately, our brother or sister institution in New York, the Community Research Initiative, was collecting data on toxicity, chest X-rays, pulmonary function tests, that we were not collecting as part of our study. So the combination of the data from the two studies, our data on the efficacy and theirs on the toxicity, is what ultimately was put together in a rather creative manner by the FDA to lead to approval and licensing.

DR. J. ALLEN: Thank you.

DR. PEREZ: I think Dr. Abrams pretty much showed our view in terms of our results of the survey we conducted with our physicians as well, and fear of paperwork was the number one thing. I mean the physicians felt they had enough paperwork to do already on site. They didn't want anymore forms to fill out and certainly did not want forms that duplicated what they felt they were already doing in their clinic. Coming up with one generic form that fit everyone in the multiple settings of hospital clinics as well as private practice was a problem. Therefore, the CRA, or the clinical

research assistant, was very important in terms of getting that individual out. The way we've done it in our site really have a clinical research assistant assigned a number of sites, usually three sites per clinical research assistant. So they set up a rapport with the physician at that site as an expected day and time to be there, which may be at the same as the clinic's time. So that he will see the patient together with the physician or fill out the chart at that time, or a time when there was no clinic at all scheduled, and the free time is there for the physician to have the list of patients given to the CRA and he fills in all the data for that particular physician.

It's this advantage that we offer, I think, which has most of our physicians interested in joining. As soon as you go to them and tell them we have paperwork, they sort of sit back in their chair and say, all right, I've got a lot of paperwork to do already. If you say you can provide some help in doing the paperwork, the ears perk up. And then what happens is as soon as we get any data at all, we've tried to have a rapid turn-around time in getting that data back to the physicians. So that the feeling is not there that they're really contributing that into a black hole.

I think what happens a lot of times is when people fill out paperwork, and they don't get anything back. Their feeling is this is not going anywhere that's beneficial. We've tried to provide data not only on what's going on in North Jersey CRI for the entire group but a sub-form of that, giving them their particular data on their patients back, which for many of them is the first time they actually get a chance to see it in an organized way when it goes back to them.

So those two factors, I think, have probably been our greatest allies in terms of getting physicians involved and keeping them involved with a minimal amount of work and yet getting some positive feedback on either the observational database or the prophylaxis studies.

DR. J. ALLEN: Thank you.

CHAIRMAN OSBORN: David Rogers.

COMMISSIONER ROGERS: Let me add my congratulations, very refreshing, and gives me hope about physicians. I must confess here, your community-based trial sounds so much more refreshing that some that Jerry and I have been involved with. Possibly one of the things that Dr. Friedland voiced concern about was the critical lack of personnel, and I think

that's been a big problem in many of the ACTG studies. Is it as much a problem for you? You've mentioned nurses. You've mentioned working with some other kinds of people. Are you able to get enthusiastic health professionals or others to work with you? Are personnel other than physicians a critical block point or not? In New York, for example, a lot of things haven't opened because we can't get the health professionals but that may be the genius of how we design academic programs.

DR. ABRAMS: I think in San Francisco we've been very fortunate in that a lot of nurses, particularly nurses who have been ward nurses or clinic nurses dealing with patients with HIV infection, ultimately tend to get a little fried around the edges and feel that they'd rather do something less clinically oriented and more contributing to the research movement. So we have opportunities both in the AIDS program in San Francisco generally for research nursing and, in fact, the position in the consortium appear to be coming even more appealing because there is some freedom of this wandering itinerant as opposed to staying in one place all day with your case report forms, and the nurses get out and interact with physicians in private practices and see

different alternatives.

So, in fact, since our system is based heavily on the nursing staff, we have been fortunate. But I think there is a critical shortage of nurses in the country, and we certainly do experience that in San Francisco, but we find that as our nurses turn over from providing direct patient care, they're happy to come into our community-based clinical research setting. We also hired on the CPCR a contract recently, a community outreach worker, and we had many applications of very high quality for that position, which is basically earmarked to increase representation from under-represented communities into our clinical trials. So again in those instances, we've been lucky to attract very high quality exciting, interesting, and refreshing people into our program.

DR. THOMPSON: I would agree with Donald. There is a nursing shortage. In Atlanta, we don't have a pool of research nurses to draw from. There are not nurses with a lot of research training. There are, however, oncology nurses who are accustomed to doing protocols and collecting data and that sort of thing. We have found that we do better when we look for nurses, first of all, who have experience

with HIV patients, who are bright, who express a strong desire to do this kind of work, and then we train them. And that means that we have to have our own training program.

And, you know, research is not that hard. As Jerry said, it is really tedious. It is really frustrating, and you have to deal with a lot of doctors. And that is really tough because doctors like to do things in their own ways, and it's always the right way, and the nurses never know more than the doctors, and it is always for the nurses a frustrating experience at some point. I think there are many, many rewards as well. So they do feel that they are contributing in an important way.

We have found that a support group for our staff is very important, and we have a psychiatrist who has offered to conduct a group for us, and this has been going on for several months now once a week, and the nurses can vent their frustrations and share the sadness that they feel as they watch their patients go through this disease, and also deal with the positive aspects. So I think having support for the staff is very important. I think making use of a multidisciplinary approach is very important.

For example, as Donald mentioned, the community

outreach coordinator. Our nurses spend a lot of time trying to deal with the social aspects of patient care. One of our nurses went out and bought a pair of eyeglasses for a patient because she found that he couldn't read the informed consent, and he couldn't do the psychological testing because he just couldn't see the forms. You know our nurses have bought tokens for the bus, and we've tried to provide transportation needs as necessary. But I think that is not primarily a nursing task.

The other way we have stretched our nursing time is to hire a data manager, so we have a person who does some of the mundane stuff, just transcribing vital signs, transcribing all those labs, transcribing adverse events into the case report forms themselves, and that sort of stretches time. But I think it is very important to get the non-physician personnel involved, and to use people as creatively as possible. We also use a system of data abstractors which is primarily for our observational database, and as George mentioned, observational databases require a bit of selling. So we use data abstractors to cut down on the work that the physicians have to do. And they really don't have to do anything at all to involve patients in our observational

database, and they like that the best.

COMMISSIONER ROGERS: Dr. Perez.

DR. PEREZ: I can tell you from the Newark experience, our problem has been that we don't have any people that are really skilled in doing clinical research. There there hasn't been much clinical research that's been done in the past. We had a wish list when we initially started of the type of personnel we would like to have recruited for our organization, but when we had no applications and we had no one show up after our ads were out, we realized that the population probably wasn't there.

What we decided on doing really was looking for enthusiastic, bright individuals who were either becoming tired of doing clinical work or were anxious to start on something new, and that was the group we went to without any experience in clinical research. Our feeling was that the enthusiasm that was there combined with the training program would probably overcome that initial deficit that they had. And I think the point we have to keep in mind as community-based groups, which we've gone over and over again, is that we can try and make things simpler. So that that research experience which we don't necessarily have doesn't have to be

a block in the way our programs work.

If we can, in fact, modify research to make it easier at the community level and take it from that route rather than training our personnel so that they become so highly skilled you're not going to be able to do those trials anyway in terms of most of our patient populations. So that's a wasted expense and extravaganza you go through. Rather make the research simpler, modify that enthusiasm and interest you have to get those people some minimal training. And we've done very well because that enthusiasm goes a long way, sometimes a lot more than the experience does.

COMMISSIONER ROGERS: Thank you. It sounds so eminently sensible. Harlan and then Eunice and then Don Des Jarlais.

COMMISSIONER DALTON: Unlike all the speakers to date, I am not a doctor. June lamented being a minority on the commission, but I think one of every three commissioners is a physician, and that's probably gracious plenty. Indeed, I was accused at one of our working group sessions of doctor-bashing. This panel is tough for me, but you're sort of defaming me a little bit. I hate seeing my admiration for doctors grow, but thank you.

(Laughter.)

COMMISSIONER DALTON: I'll be okay. Larry says I'll get over it. My question is for Dr. Thompson. The penultimate, which is to say the next to the last sentence of your testimony, is really rather laconic, but I think there is something behind it which I'd like to explore. You say unfortunately only 18 of these 40 centers, community-based centers, research centers, were able to share the limited funding of the NIAID Community Programs for Clinical Research on AIDS.

I guess I wanted to ask you did more than 18 of these centers apply for funding? Is this a comment about the limited amount of funding available from the federal government or the difficulty in community research groups of getting funding applications together? What's going on here?

DR. THOMPSON: I think a number of things were going on. Yes, there were many more applications, and I think there were some very exciting applications that didn't get funded. There was a very limited amount of money, and I think that's the first point. The few million dollars which were available to this group, 6 million in the first year, 6 million in the second year, are just woefully inadequate so

the number of funded programs had to be limited.

In my mind, there was a limitation at the point that the request for proposal came out of NIAID and hit the desk of the physician. I mean I sat in my office and I got this big thick package that came to my desk, and it was 193 pages long, which was longer than George Bush's budget at that time, and I was very impressed by that, and I looked at it, and I said I've got to form a committee. You know I need a committee to read this document because it was so full of information that I had absolutely no expertise in understanding.

So I felt that we were lucky. We had people who had dealt with government contracts before, and we got a little ad hoc committee together to read the document and to help us prepare a contract. I hear from many, many other groups that they, first of all, looked at the document, thought it was a great idea, and filed it away, and thought maybe next year or the year after we would be able to address it.

It cost us probably $3,000 to apply for our funding. To xerox 35 copies of a 200, 300 page application costs a lot of money, and that costs us money. And the time

our staff diverted from the work at hand in order to do the work of the application process, it was sad actually. We really slowed down a couple of clinical trials that we wanted to start because all of her personnel was busy in one aspect or another of applying. So I think the application process has to be simpler. You know you just can't ask people who are overburdened with the work they're doing to address all the intricacies of such a proposal.

And actually there were probably about ten pages in it that you really had to read to understand what was going on. So you know, I think that. And I think really the financial issue is the bottom line because there were many, many groups ready to do clinical trials who applied who just couldn't get funded.

COMMISSIONER DALTON: Dr. Abrams.

DR. ABRAMS: I would just like to restress the bottom line there that $6 million was the total allotment in the first year of this program. 18 groups shared $6 million, and so you can do your calculations and figure out what the average award was. And when one compares that to the annual budget of the ACTG, which I don't have on the top of my head, but many of you probably know already, it's really quite

shameful.

COMMISSIONER DALTON: That number is very helpful because yesterday we heard from Dr. Fauci that he, too, at least in theory holds out great hope for community-based research, expanding the number of enrollees, thus speeding up approval of drugs, and thus reaching different populations. And yet we didn't have time to get information about the amount of money being devoted to this effort. And $6 million in year one obviously seems woefully inadequate. What is the funding for fiscal '91? Do either of you know?

DR. THOMPSON: We could call on the consultants.

COMMISSIONER DALTON: For community-based clinical research?

DR. THOMPSON: My understanding is we had $6 million for the first year; $6 million for the second year; and then beyond that, we didn't know whether we would be able to continue at all, or whether we would stay at that level or whether -- I think we're asking for quite a bit more, you know, at least 25 million, I think, is what people are looking at. But as to what we'll get, I really don't know. There are some other experts here you could call on.

COMMISSIONER ROGERS: Eunice.

COMMISSIONER DIAZ: Would it be possible to get that figure from Dr. Datin who is in the audience now?

COMMISSIONER ROGERS: And Dr. Hamburg may have that.

CHAIRMAN OSBORN: Dr. Datin is in the audience.

DR. DATIN: The amount in fiscal '89, which was the first year, was 6 million. The second year was an additional 6 million for fiscal '90, making the total budget 12 in fiscal '90. And fiscal '91 figures, I don't think are final yet. But we are going to add a significant amount, probably another six to eight million.

COMMISSIONER ROGERS: Does that mean 18 million?

MR. DATIN: Yes.

COMMISSIONER ROGERS: Thank you. Yes, Eunice.

COMMISSIONER DIAZ: I have two very brief questions for Dr. Perez. Number one, a number of places around the country have reported a lot of difficulty in the recruitment of minority physicians which seems to be a really key point in bringing a greater accrual of minority patients into clinical trials. And I know you have talked a little bit about streamlining the paperwork, sending the CRAs, but if you could just give us as a commission some pointers of what

other kinds of inducements, encouragements and strategies you've used in recruiting additional minority physicians, which I think are really the key to bringing in more minority patients?

And then the one thing that you touched on, which I wish you would describe a little more, is being that your patient population is heavily minority and IVDU, Latinos and blacks, I want to know what you're doing for the family unit as such? What approach have you used in bringing other family members that may be at risk for HIV or already infected into the care system that you provide?

DR. PEREZ: Both questions are hard. The first question in terms of recruiting of minority physicians, I can tell you it's very difficult, and it was certainly back in '82 and '83, becoming just slightly easier now, to get physicians involved in the treatment of AIDS patients at all, be they minority or non-minority physicians. I think the premise behind our entire organization is that you tend to do better research, and you tend to have better recruitment when you have that physician-patient bond that has developed.

That's been the reason we've gone the route we have in terms of starting our group, and that works well. The

problem that we run into then is that the majority of our minority patients are seen in clinic type settings where they do not have a private physician who they bond to. In our own situation at Saint Michael's where 20 percent of our patients are hispanic, for example, we have five clinic physicians. Only two of us speak Spanish.

So that means that those 20 percent of our patients are really seen by two physicians who they feel comfortable with in talking to, and certainly in terms of explaining a protocol, you're not going to rely on someone who doesn't even speak the language to get that protocol across, and having a translator is not the same as being the physician who really understands what the protocol is about.

And I am very successful in recruiting minority patients, especially hispanics for that reason, because if [speaker speaks in Spanish] -- if he says it's okay, then it's very good with me, and I'll go do it because they trust you as the physician. You are their primary care giver. And there is no substitute for that in terms of doing clinical research. Where we can attract more minority physicians from to build up our pool is a question I wish somebody would answer for me because that's really difficult. First, there

is not many minority physicians that are staying in our area to treat patients. Many of them once they get their degree have other areas they want to go to or other areas they want to be involved with.

And getting a lot of physicians interested in AIDS research is, again, a difficult thing to do. So for both those reasons, we don't have many physicians that stay in Newark. We don't have many minority physicians to start out with. We've had a hard time. We've attempted to get one physician at each of our sites that's Spanish-speaking, and that we've had some success with. That person is there usually only for a very small period of the time that we're enrolling patients. So we need help there as well although we've come, I think, a little bit of the way. We still need a lot of help.

In terms of the other question about the family unit, our clinical sites really are also counseling and testing sites in the state of New Jersey. That is individuals come to be tested anonymously, confidentially. They are found that they are positive and then they're given referral sources where they can go to have follow-up done. And most of the time it's at the same hospital where they were tested

since the clinic site is also there. Once that individual is identified through a team approach involving social workers as well as the physicians, we attempt to identify anyone else in the family who we feel is at risk.

Many times that involves having the female partner be the first one who comes in to be tested, finding they're positive, getting the male partner that way, and then finally bringing the children in to be tested. The other route we've also had now more recently is because of expanded testing for neonates, finding that the baby, in fact, is the first one to test positive out of the family, having the parents then come in to be tested. What we've tried to do to accommodate those patients is set up a family clinic day actually so that one day at each of our sites has been established as a family clinic day where the entire group can come in to receive care at the same time.

In Newark, we're fortunate in that we do have an ACTG, pediatric ACTG at UMDNJ at Newark, and for that care the child is then referred to that unit, but for their normal clinical follow-up, they're seen as a family unit with the female and male partner as well. That's helped us in terms of getting better compliance in terms of follow-up visits

because it's tough for the mother to go two days during the week, once to have her child seen in another clinic, and another time to have herself seen, and then sometimes come with the husband who may be sicker, bring him into the clinic and to have someone to babysit for the daughter or the other child at home.

So setting up that family clinic has helped. We have a pediatrician who works that clinic along with a female doctor as well as a male doctor. And many times even if three different physicians see the three different members of the clinic, at least they're seen at the same time and they're expeditiously moved through. It's a problem. It's one that in New Jersey we're going to face more of because of the high incidence of the intravenous drug user as a primary risk factor for having HIV disease and then having the entire family involved.

DR. FRIEDLAND: I'd like to make a comment about a specific issue which hasn't been addressed although I know it's part of our all of our lives and probably our clinical trails as well, and that is IV drug users themselves, since they represent an increasing proportion of people with HIV infection, and in some geographic areas like New York and the

New York Metropolitan Area actually represent the majority and have traditionally been individuals who were not connected to the health care system, and parenthetically likely not connected to the clinical trial system.

I wonder what the experience is -- I guess I'm not supposed to ask a question. Can I ask?

CHAIRMAN OSBORN: You get senior statesmen status so you can ask. Yes.

DR. FRIEDLAND: And I also I want to make a point which hasn't been made that another place to do clinical trials, which we haven't mentioned but which is a very important one to consider, is within drug programs themselves. And because even that distance from New York to New Jersey, which may seem like 450 miles, in our own drug program in the Bronx, the journey across the street into the tertiary care health center of two blocks really has that same perceived distance. I wonder what you all have been able to do with drug users.

DR. ABRAMS: Well, of course, our experience in San Francisco is very different because we are just seeing the beginning of the epidemic of AIDS and HIV infection in that population. But despite that, the incidence or prevalence of

infection in our IV using community is 20 percent, which is much different than yours. Representation of people who are injection drug users in our consortium clinical trials is twice their percentage of people with AIDS in our San Francisco statistics, but again, it's a very small number.

We have just launched consortium trials in the methadone maintenance program at San Francisco General Hospital, which is where we're based, and we're also working with some of the other clinics. Again, what we're finding here is the same problem that I mentioned and that has been echoed, is that these people as they access clinical trials are actually first coming into a medical care or care for their HIV infection system, and the question is can they subsequently access the rest of the care after the trial is completed, and this is a difficult issue that needs to be dealt with and creative thinking needs to occur.

CHAIRMAN OSBORN: I think Don Des Jarlais and then Don Goldman, and then I think we're probably going to want to move on pretty quickly to the next panel.

COMMISSIONER DES JARLAIS: A question for Dr. Thompson. You mentioned that the VA in Newark was part of your system. How is that working out? Do you feel that that

should be replicated in other cities where there is very often a VA with a drug abuse unit that might be brought into these community-based trials?

DR. THOMPSON: You said Thompson and you said Newark. You mean Atlanta or did you want to Dr. Perez?

DR. PEREZ: We don't have the VA in our system.

DR. THOMPSON: Okay. Well, I'll take that question.

DR. PEREZ: The VA is in East Orange in our center, and we have participating physicians who are at the VA who comply with our North Jersey CRI, but it has been difficult at this point to get patients from the Veterans Administration Hospital to be part of our clinical trials. The physicians appear to be willing, but there is a lot more paperwork that many times has to go on in the Veteran Administration hospital in terms of approval of protocols, in terms of having paperwork done in a correct way. So our enrollment and our participation from the VA in our East Orange has been rather limited.

I think actually Melanie may be better able to answer that question because she has done a good job in getting the VA in Atlanta involved. We have not been able to duplicate that effort in our northern New Jersey sites.

DR. THOMPSON: Our involvement from the VA in Atlanta has been based around Dr. Dave Rimlin who is in charge of the Infectious Disease Clinic there and basically runs the clinic all by himself. He sees about 300 patients. He has been able to get some fellows and some folks from CDC to come over and staff the clinic a little bit, but he basically runs it. He has kept wonderful records on his patients, and again as in a situation with Grady Hospital, we have tried to provide administrative and clinical support so that those patients can enter clinical trials. And that includes nursing support, someone on site, to help with that, and we're in the process of providing him with a computer so that we can all be on the same network.

I think we really have to provide all the support that is needed for a clinic to be able to participate. That clinic is not specifically linked with any drug treatment clinic, but I think that the idea is analogous, that in order to take a drug treatment clinic in which the staff is already overburdened, you just have to figure out some creative way of supplying the person to do the paperwork and to do that sort of tedium which doesn't directly contribute to the patient's care at the time.

DR. ABRAMS: I'd just like to say that we've had tremendous bureaucratic obstacles because of the VA system in enrolling patients from the VA, and I think it's very unfortunate, and perhaps something can change.

CHAIRMAN OSBORN: Don Goldman says he'll pass. Jim Allen has a quickie, and then we should move on.

DR. J. ALLEN: Not a question, more of a comment. Jerry, you've made a comment that you felt that many of the drug users typically were disconnected from the medical care system. Perhaps the converse is also true that the medical care system is disconnected from them, and that one of the things we need to do as we try to link primary medical care and drug use treatment services, which is one of the things that we are moving slowly towards doing in the Public Health Service with joint funding coming from ADAMHA and HRSA for this kind of program, that we need to look at tying it in with the community clinical trials, and I know that Dr. Deton's program has talked about doing this, and that they've talked with HRSA about this and ADAMHA about this type of thing.

And it seems to me that that may, providing that kind of service and opportunity for participation to drug

users may be a very nice incentive for them to continue with the treatment program as well as with their medical care services.

DR. FRIEDLAND: I agree. I think it has to be done on site in the drug treatment center.

DR. THOMPSON: I would like to make one comment to change the subject slightly, but I do want to thank the commission for coming to rural Georgia and I think that you all may not realize the impact that you have, but when we realize that you do have a great impact and even to say the "A" word in rural Georgia is, I think, brave, and I think that you all have made it possible for other people to talk about the issue, and we thank you very much for that.

And I also would like to point out that when we talk about even the pyramid of community-based groups, 18 funded by NIAID, 40 in the community-based network, that is the tip of the iceberg, because in rural Georgia you did not see any community-based research, neither did you see any academically based research on AIDS, and indeed this rural network is totally left out. We have been approached by Albany, by Augusta, by Columbus, centers who have hospitals, who see patients with HIV, who want access to the drugs that

in Atlanta we are able to provide through clinical trials.

And it is very upsetting to me to have to say I'm sorry, you know, Augusta can't be part of the AIDS Research Consortium of Atlanta because we don't have the staff to send to Augusta to do the research, to provide the kind of care, to provide the quality assurance. I mean again we're trying to prove ourselves. We have to get accurate data in order to continue to exist. But I think we do need to address the fact that there are local communities out there that probably will never have a large research consortium like the one in Newark or in San Francisco or Atlanta, but there are community-based health centers. And we absolutely must address training and education and ways to make those people part of the clinical research network as part and parcel of expanding their access to primary care.

CHAIRMAN OSBORN: Thank you again for a very inspiring as well as enlightening testimony. Appreciate your taking the trouble to come. Our next panel includes Cecelia Hutto, Janet Mitchell, Amy Simon-Kramer, Mathilde Krim and Ron Sable, and let's take a minute while people get a chance to relocate.

Thank you all for joining us, and Dr. Hutto, would

you like to start? And tell everybody who you are as you go since I'm not sure everyone has that information.

DR. HUTTO: Okay. Good morning. My name is Cecelia Hutto, and I am a pediatrician and an assistant professor in the Division of Infectious Diseases in Immunology at the University of Miami School of Medicine in Miami, Florida. During the past five years, I have been participating in the diagnosis, care and treatment of children with HIV infections at Jackson Memorial Hospital in Miami, Florida. My colleagues and I in addition have conducted several research efforts which have involved these children and their families.

I've been asked to speak to you this morning about research issues related to pediatric AIDS and HIV research. More than 2,000 cases of AIDS in children younger than 13 years of age have been reported to the Centers for Disease Control. However, the true impact of HIV infection on children is much greater. HIV infection is one of the ten leading causes of death in children one to four years of age in this country. Data from the March of Dimes suggests that the number of children of perinatal HIV infections is increasing at a faster rate than any other congenital

infection. Almost all new infections in children younger than 13 years of age are acquired perinatally.

The rate of HIV infections among women is increasing faster than for many other population groups. Because pediatric infection so closely parallel infections in women, it is anticipated that the number of infected children will continue to increase. Our understanding of HIV infections in children and pediatric AIDS has increased rapidly during the past few years largely because of studies funded with research support. These studies have allowed us to determine the routes of infection for children and provided estimates of the risk of transmission. Natural history studies of infected children have demonstrated the clinical and immunologic manifestations of HIV including the variability of the disease spectrum associated with HIV in children.

Data from these studies have provided a framework upon which the anti-retroviral drug trials have been conducted in children. These trials also funded by research led to the licensing of the first anti-retroviral drug for children just last week. Despite the progress which has been made in understanding this infection, there are still many questions to be answered and continued funding for pediatric research

is critical. I would like to suggest areas where more information and efforts are needed and indicate problems and issues related to research in pediatric AIDS and pediatric HIV infection and AIDS in the time remaining.

Continued studies investigating more effective therapeutic concoctions for children are needed. And expanded access to these drug trials should be made available to as many children as possible. For children already infected better assays for diagnosis of opportunistic infections and new approaches to therapy are also needed. Well designed studies and populations of infected children could provide better information about the pathogenesis of pediatric infections, factors that are associated with the variation in the clinical spectrum of HIV-associated disease in children, and prognostic factors for disease progression in children.

HIV infections among adolescents have received very little attention until recently. Studies are needed to provide better data about the magnitude of the infection among adolescents, and we need better information about risk behaviors which may place this age group at greater risk for infection. Adolescents need access to drug trials. Strate-

gies for providing psycho-social support to infected adolescents should also be developed. Another group of children for whom research efforts have not been available are foster children.

Because of legal constraints which are designed to protect these children, we are unable to include infected children who are in foster homes in any research protocols including drug trials. This has prevented many eligible children who might benefit from drugs provided through these trials access to these drugs or access to any other benefits that are derived from research programs. Research efforts in children should focus not only on providing better understanding of infection and better therapy, but also in prevention of infections through interruption of perinatal transmission.

I come from a hospital where recent seroprevalence study among the obstetrical population indicated that as many as 300 seropositive women may deliver every year. According to current estimates, one-third of their infants will be infected. Clearly, approaches are needed to prevent these infections in infants. These approaches should include clinical and basic studies to investigate the timing and mechanism of transmission, and factors associated with

transmission risk.

Prevention of perinatal transmission will also require better methods of identifying infected women. A final issue related to research in this area is the inability to separate clinical research and care in HIV-infected children. This is an issue that has just been discussed fairly extensively among adults, too, in the past hour. A sick child presenting for a research appointment is cared for by the research team. In this context, care and research cannot be separated, and it's difficult for the family to perceive the difference. Research is, therefore, much more labor intensive and requires the utilization of many health professionals including nurses, physicians, social workers, and other health care providers.

Finally, pediatric HIV infections are a family disease. Not just the child but mother and often other family members are infected. The majority of families with infected children are from low income groups, and have difficulties meeting their basic needs without the burdens that he diagnosis of HIV infection in two or more family members brings to their family.

Assisting families with meeting their needs through

social workers and other support services has been critical to maintaining research programs in pediatric HIV infections. Resources to provide for the personnel and other support required for these studies have to be factored in any clinical research effort involving pediatric AIDS and HIV infections. Thank you for your attention.

CHAIRMAN OSBORN: Thank you very much.

DR. MITCHELL: My name is Janet Mitchell. I am Chief of Perinatology, that's high risk obstetrics, in the Department of OB-GYN at Harlem Hospital. In my biography, I left out the fact that I am also an assistant professor at Columbia University because that is only a paper association, and Columbia has little to nothing to do with what occurs at Harlem Hospital. I was asked to speak to you about the needs and issues of women.

First, I would like to thank the commission, the members of the commission, for allowing me to testify. Women are most often overlooked in this epidemic. They are grouped either with adults, but in this epidemic that most often means men, or they are included in issues related to children. The tendency, however, is not to allocate the necessary time, money or importance to issues involving women, simply because

they are women. The consequences of this oversight has resulted in an alarming increase in rates of infection in the heterosexual population, read women, and in perinatally acquired infection.

Couple this with the reality that the women who are infected are at highest risk of infection are overwhelmingly women of color, African-American and Latino, and are women of poverty, creates an environment of indifference and neglect. While the behaviors that put women at risk are generically the same, the motivations behind these behaviors are oftentimes different from the identical behavior seen in the male population. Instances such as advocating for safer sex practices in cultures where women have no power have proven unsuccessful.

Differing patterns in the use of drug treatments require designing programs to meet the specific needs of women. When we talk about the manifestations of the disease, again, there may be generically very little differences between men and women, but for other diseases we know that responses to treatment may be modified by the physiological differences that exist in women. Sadly, because there are few in charge who are interested in quote "women's issues,"

many questions still remain unanswered. Resear
women need to include a variety of issues on many levels that go beyond the traditional scope of medicine.

Firstly, there are psycho-social issues to be considered. If education and information are to be effective, then research into the factors that motivate women, especially those who are of color and impoverished, must be a priority. We have only to look at our inadequacy in educating the second group of women about the benefits of early and consistent prenatal care or the benefits of delaying child-bearing until after the adolescent years, to know we have a long history of failure.

Secondly, understanding the complexities of the behaviors that place women at risk must be of the highest priority. The relationships between culture, ethnicity and gender must be explored. There will be no magic bullet. Approaches to modifying behaviors will be varied and must be targeted toward specific groups. Drug treatment programs intended for opiate users may not work for cocaine users, and especially those who use crack.

Thirdly, research into the treatment of the disease and its complications must include women at all stages. The

historical precedent for excluding women of childbearing age from treatment trials can no longer be allowed. On the other hand, including women, especially pregnant women, only for the sake of improving the outcome of the child, is also intolerable. Women have a right to be included simply because they are infected and are dying. No other reason is needed. Despite all that I have said, the major barrier to prioritizing the needs of women who are HIV infected is who the women are.

No matter how we try to dress them up, the reality is that the majority of HIV infected women belong to our forgotten population. They reside in decaying or in urban areas or rural reservations. The color of their skin is not white, and they contribute little to our tax base. In the last years of fiscal belt-tightening, they have been dropped from our list of priorities. The health care system that cares for them and their families has been allowed to crumble, yet asked to meet their needs in the face of this epidemic.

Research into purely women's issues has never been a priority except in terms of infant outcome, i.e., infant mortality. Research into issues that affect minorities have never been a priority. We all remember the Heckler report.

Research into issues that primarily affect the poor had its hay-day in the 1960's. Put the three together and you begin to understand why in 1990 we are still asking the questions about what should be the research agenda for women who are HIV infected. Although the NIH's Community-Based Programs will hopefully address some of these needs in terms of treatment, it cannot be expected to provide the amount of fiscal support the public institutions need to survive.

For instance, Harlem Hospital has one of these grants, but we still cannot recruit the doctors, nurses and other ancillary staff needed for the care of our patients. I run a prenatal program for chemically dependent pregnant women. In 1988 the program enrolled 124 new patients. In 1989 we enrolled 204. 80 percent of the women list crack and/or cocaine as their drug of choice. Preliminary data from another study on our obstetrical service says that approximately 14 percent of our pregnant cocaine crack users may be HIV infected. Yet the Harlem area has few drug treatment programs for pregnant crack users. I work in a community that not only has one of the highest rates of HIV infection in this nation, but also has some of the highest rates of infant mortality, drug abuse and adolescent pregnan-

cies, all markers of behaviors that put persons, especially women, at risk for HIV.

If we cannot commit adequate resources to fund research on the motivations behind these behaviors, motivations that may include low self-esteem, high unemployment, and extreme poverty, if we cannot commit to modifying these behaviors that may include issues that are traditionally non-medical, like better housing, we in the high risk, decaying urban areas of this nation will be left with providing care, expensive care for a disease that is technically preventable.

CHAIRMAN OSBORN: Thank you very much.

MS. SIMON-KRAMER: Hi. My name is Amy Simon-Kramer. I am currently director of clinical research at the National Hemophilia Foundation, and effective June 1, I will be assuming the position of Deputy Executive Director. I'm here to talk to you about some of the issues that are relevant to the hemophilia community, but I think you'll find that these issues are relevant beyond the hemophilia community, as we really represent a microcosm of the country as a whole. For hemophilia patients who are Factor 8 dependent, state of the art technology has rendered the concentrates that they use to treat their bleeds virtually safe from HIV.

Unfortunately, that same is not true for patients who are Factor 9 dependent as the state of the art technology for Factor 9 is not FDA approved at this time. Technology notwithstanding, though, access to these products is very limiting for many hemophilia patients because the products are so expensive and it's probably the greatest AIDS preventative, but people can't all afford it. When we looked at clinical trial participation for hemophilia patients, it was pretty clear that there were many barriers to study participation. Things like transaminase levels that were two or three times the upper limit of normal excluded the bulk of hemophilia patients. Pediatric trials -- no offense -- that required perinatal transmission excluded hemophilia pediatric patients.

The hemophilia community is not limited to New York and California. For patients in the middle of the country, access to trials was a tremendous problem. The other thing that is unique to the hemophilia community, though, is that there was a reluctance by many of the AIDS clinical trial unit physicians to treat hemophilia patients. Comprehensive hemophilia treatment centers where the bulk of the hemophilia patients receive their care were underfunded to allow them to

also do trials. And finally the hemophilia community represents about 80 percent of the identified HIV infected adolescent population, and unfortunately, these trials fail to meet the special needs of the adolescent community.

When we were looking at how to address the problems that we identified, we realized that we had something very unique, and that was a network of comprehensive hemophilia treatment centers -- there are about 200 around the country -- that are funded by OMCH and about 50 percent of the hemophilia community receives their care within this comprehensive care setting. Comprehensive care provides, as the title would indicate, comprehensive services, medical services for hematologic and orthopedic related problems, and something that the comprehensive care centers offer that some of the other systems don't, that is psycho-social support as well as outreach activities to the unserved/underserved, culturally diverse and sexual partners of persons with hemophilia.

And what we came to realize quickly was that the comprehensive care setting was a perfect foundation on which to implement an effective mechanism for conducting clinical trials. We, therefore, developed what we call the ACTU

Without Walls Network. Essentially what this is is under the administration and coordination of the National Hemophilia Foundation, there were ten what we call regional coordinating centers, one in each of the ten Health and Human Services regions, who is responsible for coordinating the activities on a local level. Participating hemophilia treatment centers within those regions are coordinated by the regional centers.

We also did one trial through the system, an AZT placebo controlled trial, and learned some very important things from that trial. That within the comprehensive care setting, quality data could be collected. We had an error rate of less than one percent. It was a real tribute to the nurses at the regional centers who visually edited every data form that was collected for that study. That in an environment where patients are comfortable and familiar and where supportive services are available, there is likely to be compliance. We had no one who was lost to follow up in that study.

That access to trials for persons in the middle of the country is as important as it is for persons who live on the coasts. Some of our highest accrual were in centers in the middle of the country. And that there is a possible cost

savings when patients don't have to travel tremendous geographic distance to get access to experimental drugs. With that said, the National Hemophilia Foundation would like to make the following recommendations. One is to recognize and provide adequate funding for comprehensive care as a prerequisite and complement to effective implementation of trials including adequate staff to ensure quality care delivery.

Two is to remove artificial barriers to clinical trial participation such as route of transmission, liver function, and geographic limitations. To streamline protocol development for HIV infected, asymptomatic individuals. To encourage expeditious FDA review and approval of Factor 9 and recombinant products to prevent further viral infection, and to replicate the ACT Without Walls concept in other populations to involve smaller hospitals and local physicians under protocol direction, to follow patients and collect data, and to utilize chapters. We have about 48 chapters. It's probably the equivalent of community-based organizations and consumers as pure educators in the clinical trial process.

We did use chapters in that way for the AZT study we did, and it proved to be very effective, and finally, even

though there have been improvements, there remains a need to increase attention to children and research. Thank you.

COMMISSIONER ROGERS: Thank you very much, Dr. Simon-Kramer. I think we'll now hear from Dr. Mathilde Krim. Or excuse me. Is that the order in which you wish to proceed.

DR. KRIM: It's fine with me.

COMMISSIONER ROGERS: The lady comes first.

DR. KRIM: Mr. Chairman and distinguished members of the commission, my name is Mathilde Krim. I'm a biologist, Ph.D. I'm a founding co-chair of the American Foundation for AIDS Research and adjunct professor in Public Health at Columbia University. I am grateful to be able to be here in response to your invitation to present the views of the American Foundation for AIDS research. I must, however, state at the outset that because the invitation was received late, only a few days, it did not allow us sufficient time to have it formally approved by our scientific policy committee of the foundation, and my statement is for the time being a personal statement.

Also because AmFAR cochairs the Committee on Research of the National Organizations Responding to AIDS, or NORA, it was our hope that my statement could, as indicted in

your agenda, reflect the consensus of opinion among all those organizations. Again, lack of time precluded our arriving by today at the precise language. So my statement is not delivered in the name of NORA although we hope to be able to submit in writing very shortly a true consensus statement.

Having said this, I should also state that AmFAR's and NORA's official positions will not be very different from the opinions I'm about to express here. Since the matters we addressed today were often discussed within AmFar and also we had extensive discussions already with NORA as well.

First of all, I believe that the relative overall importance of AIDS research must be gauged in the light of the health problem it addresses, and this problem, I hardly need to tell you, is an entirely new one for mankind and a very grave one not only because of the ravages that we know the epidemic of HIV infection has caused, but because there is every reason to believe that this particular epidemic will not, unlike others, be self-limiting. Only human medical interventions can stop it. Such an assertion is based on two sets of facts.

Number one, HIV infection destroys the human natural immune defense system which precludes the acquisition

by humans of long-term immune resistance to the virus. Two, because of the modes of transmission of HIV and the very long incubation period for AIDS, HIV can spread silently among people engaging in behaviors, sexual activity or the use of contaminated hypodermic needles, on which educational exhortations have, by themselves, only a limited effect. WE have already ample evidence of how difficult it is to control these behaviors through educational and public policy interventions, particularly among the very young and the poor and less educated adults.

Therefore, there is every reason to believe that although the rate at which HIV will spread in the future remains unclear, it will nevertheless continue to spread indefinitely. The epidemic is, of course, also a grave problem because HIV's long-term effects n both the immune and the nervous system are incompatible with survival. To date, our research efforts have not been able to modify the course of HIV infection sufficiently to change its fatal outcome.

The World Health Organization has estimated that the global AIDS crisis will be tenfold worse in the decade of the '90's than it was in the '80's. Unless research efforts are extraordinarily and rapidly productive, such a prediction

is likely to be valid for the United States as well. We know that during the coming decade, this nation is likely to face a total of one million cases or more of AIDS and consequently half a million or more fatalities due to AIDS.

It is with these facts and figures in mind that I make my recommendations to you. I believe that this country has the resources, scientific, technical and economic, to find fundamental answers to HIV/AIDS within the coming decade in the form of antiviral and other therapies as well as vaccine. Recent scientific evidence strongly suggests that it will eventually be possible to suppress HIV multiplication in the human body so as to slow disease progression and perhaps even prevent AIDS altogether. It will also be possible, I believe, to develop a vaccine.

However, I am convinced that such solutions can only emerge from a broad-based and intensive biomedical research effort, one that is conducted within the context of a highly supportive society and that uses the most sophisticated biomolecular knowledge, technology and clinical trial designs, all in a highly rational and coordinate fashion.

Polls have shown that the majority of the American public wants AIDS research to be given high priority, even if

this can only be achieved at the cost of higher taxation. The goal of your hearings is to determine whether the economic and organizational means that have so far been put at the service of AIDS research by our government appear sufficient to achieve what the public, the biomedical research community, and of course, people with HIV infection all want as soon as possible.

My comments and recommendations can be summarized as follows. In regard to funding levels, number one, all basic biomedical research is interrelated and interdependent. Increases in AIDS research funding must never be achieved at the expense of other basic biomedical research. All biomedical research should receive a higher level of support in this country, one that is commensurate with the $600 billion a year health industry research fuels.

Two, among the proposals received by the NIH and approved for funding by peer review, only ten to 15 percent are actually funded as extramural biomedical research grants. At least 50 percent of them should b funded across the board, as was the case in the 1970's, and 100 percent of those peer reviewed and approved projects directly relevant to AIDS today.

Number three, the NIAID's AIDS Clinical Trial Group, or ACTG, is currently overwhelmed by the number of clinical studies it should be doing. Clinical research on promising experimental drugs should nevertheless be rapidly expanded and accelerated. This could be done if the NIAID supported program on Community-based Clinical Research, CPCRA, received increased funding for expansion and consolidation. I urge its funding at the level of $25 million in 1991.

And by the way, earlier when we heard about this funding in preceding years, it was mentioned that funding took place over a period of two years, but actually it was given out one time in October '89, and it was $9 million paid out. Three million of the total of 12 million was probably used by the NIH itself for in-house activities.

AIDS research program. Basic biomedical research on AIDS would be accelerated and made more cost effective if with presidential leadership and backing coordination of efforts, exchanges of reagents, and shared use of equipment and expertise were facilitated between academic, industrial and NIH scientists. I urge, therefore, that the research facilitating and coordinating entity be formed that enjoys prestige and authority conferred by the President himself but

that is independent of government.

Capabilities in the evaluation of experimental drugs in humans have not kept pace with the rate at which promising new compounds have been identified at the bench. Such capabilities must be increased and used more rationally. I urge that the ACTG concentrate its efforts on Phase I and II technology-intensive studies of a larger variety of drugs than it has studied in the past and that the capacity of all community-based clinical research centers to conduct Phase II and III trials be rapidly upgraded so that both systems are used optimally as soon as possible.

In the past, research on the diagnosis, prevention and treatment of opportunistic diseases has received scant attention and support from the NIH. I urge that the recently instituted NIAID program on such diseases receive optimal funding and that it address intensively both the drug discovery and the clinical evaluation aspects of such research.

No comprehensive database has been established that contains systematically compiled information on HIV infection and its complications. Although the opportunity to collect information on the natural course of this disease has, by now,

been missed, such a database established now could still be invaluable to the detection of changes in epidemiology, pathology and symptomatology of HIV disease. It will help with the selection of research priorities and the quantitative and qualitative assessment of the use of various prophylactic and therapeutic approaches as well as their impact. I urge, therefore, the establishment and support of a National HIV/AIDS computerized database.

And by the way, I heard yesterday that this exists for rare disorders, for example. It's amazing that it was never done for HIV disease. Large segment of the HIV infected population are under-represented in ongoing clinical trials. I urge the funding and implementation of outreach programs so that all groups of all HIV infected people can be enrolled in clinical trials and can be offered equal opportunity in the work of both the ACTG and the community-based system.

Traditionally, clinical trials have not been carried out in children. This has long deprived infants with proven HIV infection of life-prolonging experimental treatments, as we just heard. I urge that clinical trials of promising experimental drugs be conducted in all children,

even less than 15 months old, who have confirmed HIV infection, and that this be done as soon as the drug has been demonstrated to be safe and to show promising activity in HIV infected adults.

Currently, some 9,000 people with HIV/AIDS are enrolled in clinical trial while an estimated 400,000 to 600,000 HIV infected individuals in the United States have either AIDS or prodromal symptoms of AIDS and could qualify for enrollment in trials.

I urge, on behalf of the many individuals who cannot be enrolled in trials, but could benefit from treatment with experimental drugs, that the parallel track distribution system for selected experimental drugs be speedily approved by federal authorities and be implemented as soon as possible.

Over recent years, the design of clinical trials has strived to achieve homogeneity in study populations in order to reduce and control all variables other than the experimental drug itself. And two, it has been designed to use the smallest number of study subjects necessary to obtain statistically significant results. For a number of reasons, this is not a model that is always the most appropriate for clinical research on HIV/AIDS. I urge that trials with less

rigid entry criteria and be designed to enroll large numbers of study subjects be used in the community-based clinical research setting so as to allow more patients to be involved and to rapidly obtain results that following stratification and analysis are relevant to the total patient population.

Widespread dissatisfaction in the AIDS community with the priorities and pace of past clinical research conducted by the ACTG has led to mistrust between investigators and patients, slow enrollment and low patient retention in trials as well as widespread non-compliance with protocol requirements. I urge for the sake of reestablishing a relationship of mutual trust between investigators of ACTGs and study participants that each ACTU, each unit, establish a community advisory panel for the purpose of regular dissemination of information to and consultation with the community in the conviction that this will improve the quality of research data.

All agencies sponsoring clinical trials in HIV/AIDS have in the past been very slow in publishing results to the public. I urge that such agencies be more accountable to an anxious public, and that they actively and expeditiously release specific data concerning the results of their

clinical trials. There currently exists a perception of conflict of interest among investigators who play an advisory role with the NIH in setting national AIDS research priorities. I urge Secretary Sullivan to mandate the full disclosure of all consulting relationships these investigators maintain with pharmaceutical companies.

The salaries of scientists and administrators working for the NIH and the PHS, in general, are not competitive anymore. I urge Congress to rectify the situation to ensure that our national biomedical research and health agencies can continue to attract the best and the brightest. These are my major recommendations regarding strictly speaking our research efforts in HIV/AIDS. Other recommendations could be made, in particular, concerning the provision by all institutions conducting clinical trials of primary medical care. This would be highly desirable given the present lack of access for so many people with HIV/AIDS to appropriate medical attention.

It would immediately and greatly increase the flow of patients available for enrollment in clinical trials. However, such a recommendation touches on two different large issues, namely that of that right to medical care in this

country and that of our system of payment for medical care and the failures of the system. I hope that these two subjects will soon be considered by your commission at subsequent hearings. Thank you.

CHAIRMAN OSBORN: Thank you very much, Dr. Krim. Dr. Sable.

DR. SABLE: Thank you, Dr. Osborn and commission members. It's a real pleasure to be here today. My name is Ron Sable. I'm a general internist and I work at Cook County Hospital in Chicago, and I've taken care of people with AIDS just about every working day since 1983. I'm not sure exactly what I'm representing here today, but I think it's the vast part of the United States between New Jersey and California, and while I can't pretend to represent all of what's going on out there, I certainly can give you something of my perspective as a primary care physician at the largest hospital in the city of Chicago and the only public hospital.

As I said, I've been doing AIDS for a very long time, much longer than I care to think about, and Dr. Renslow Sherer and I founded the AIDS program at Cook County Hospital in 1983, which started as a single general medicine clinic that we shared, and has grown today to be seven full clinic

sessions a week, an inpatient service, a consultation service, and all of the array of psycho-social and support services that are common to developed programs dealing with HIV infection. We have in the last year added a program for women and children which is very much a family centered program underwritten by a grant from the Robert Wood Johnson Foundation, not from the county of Cook, I'm sorry to say.

But that has in just a year enrolled 240 women and children, far, far greater than the number that we expected to be enrolled at that point. Cook County Hospital again represents the care provider for approximately 20 percent of the people with AIDS and HIV infection in the city of Chicago, has again a clinic base of 1400 patients, approximately 85 percent of which are black or African-American or hispanic. 90 percent are men, and I mentioned the women and children's project that we have. In preparing for my remarks today, I talked to a number of the physicians that I work with in the city as well as patient activists, if you will, about what I perceived one of the things that we wanted to talk about, which was barriers to access to the kind of clinical research trials that we all want to promote.

And I think, first, from the perspective of the

provider, and this has been alluded to, that those of us who have been doing AIDS for a long time who have problems, but there is an enormous reservoir of provider ignorance out there about AIDS and HIV infection and a reluctance to deal with it still as a primary problem for every internist, pediatrician, general surgeon, whatever. I think that is a barrier to overcome. Now that is not something that exists for those of us in large institutions or with large clinics who have been taking care of people with AIDS and HIV infection, but it is still a major problem in getting our reach to the pool of people who need care out there and who need information.

Cook County Hospital is right across the street literally from an ACTU at Rush Presbyterian and Saint Luke's, but as others have alluded, that distance can be as great as miles in terms of the distance that it means for a patient to travel from my institution to theirs. I often feel like that I only hear from these ACTUs, too, about what's available when they're really having difficulty filling their protocols. And that the information is not there on a regular basis. I get as much as my information from the AmFAR directory that is published and from local patient generated treatment

newsletters, and I guess if those are the sources of information, then they should be supported more heavily by the government because I think that is the experience of many community-based providers that that is a most important source of our information.

I think there are important things to consider from the perspective of the patient, and one of them, again, is an information base. I saw three patients yesterday in clinic who had just recently been tested, and their understanding about just HIV infection and the implications for their lives was next to nothing. It was the amount of information that they had been rendered at the counseling session that followed their test. So you're talking about -- and if you're talking about convincing people to be a part of a clinical trial, you're talking about a level of information that is way beyond that.

So I think that this is something to consider with relationship to a number of people who are still being identified these days and will continue to be in the counseling and testing centers. Again, in addition to the level of information that's needed about basic HIV infection itself, a level of information about what clinical trials are and where

they are for patients, it's ironic, I think, that in this last week literally a brochure published from Health and Human Services that is directed at patients to introduce them to the idea of clinical trials arrived in our office.

I mean this ironic. I walked across the hall to an administrator who had a pile of these on his desk, and I said where did you get this, you know. He said, well, it just came this week. I said is there a Spanish version? He said, yes, but you have to order it. So we're ordering it. But again the amount of information that is out there for patients, I think, is extremely limited about what's available. I want to talk a little bit about what I think is an important criterion for getting people involved, and that is the level of trust that needs to exist between the provider and the patient. I think this leads us to things that have been spoken of at length earlier that I would echo that you've got to do trials in the places where people are taken care of, and you've got figure out how to support the work in those institutions.

It's hard enough for the kinds of barriers that I've described for people to overcome for you to expect them to go to an institution that seems very remote to them to be

seen by people that they are not familiar with and so that the support, the kind of trust that's developed between a provider and a patient is an important component of your being able to successfully enroll people in a trial. I want to say one thing about language. It's extraordinarily important if you expect to enroll Spanish-speaking patients to have providers and information from them. One physician that I spoke with who's a part of our consortium, and I'll talk a little bit about, said that the only patient, Spanish-speaking patient that he sent to the local ACTU, came back immediately. The details of the difficulty in interaction were not described but this patient never went back.

And you know I think that has been very much a different sort of experience than we've had at Cook County Hospital where our education prevention staff is almost completely bilingual and is able to, again, generate a kind of relationship with a patient that is absolutely the bottom line for drawing them into this kind of a setting. Again, I think that Chicago is at a different place than some of the panelists that you heard before in terms of the development of a community-based initiative. We do have a consortium of about 12 physicians that together it includes a number of us

at Cook County Hospital and a number of community-based providers, but that together represents a reach to approximately 40 percent of the HIV impacted community in the city of Chicago, and is as broadly representative of the racial, at risk, and demographic make-up of that population as any other group.

Now that has just been put together in the last year as a result of the initiative of the NIH initiative, but there is no reason that it couldn't have been there before had there been an impulse to do that. We have a lot of optimism about the promise of that, but again I think we're just at the very beginning stages. I guess it leads me to say that in terms of wanting to provide clinical based research or to expand the reach of the patients that we enroll in trials, that we have for a long time ignored Sutton's law, Willy Sutton, who was the bank robber, who said why do you rob banks; that's where the money is. In many, many communities in this city where the patients are is in community settings, not the ACTU centers, and we are eager to participate in these studies if the resources are put into them, and very capable and interested in doing that.

Thank you very much.

CHAIRMAN OSBORN: Let me thank all of you for very helpful testimony, and I'd like to see if there are questions from the commissioners. We got started a little bit late this morning, and I think we want to take full advantage of your having joined us. Are there questions? Belinda.

COMMISSIONER MASON: I want to thank all you women for coming and sharing your compelling kinds of stories and the hard work you're doing. I wish you were my doctor, Dr. Mitchell. You can make a house call in Kentucky or something?

DR. MITCHELL: Believe it or not, I'm from Kentucky.

COMMISSIONER MASON: All right. Do I need to say anything else? But my question is actually -- and I was interested to hear about Chicago as well, because, you know, I'm kind of in the middle of the country, too -- my question is for Dr. Krim, and it's the thing that I probably should have asked Dr. Fauci yesterday but nobody helped me out. I had to ask all the questions, and so I couldn't think of all of them. In the last paragraph of your testimony you alluded to the conflict of interest or the possible conflict of interest between investigators, I mean that arises when investigators for the NIH end up in consulting and intimate relationships with pharmaceuticals.

I'd like to hear your feeling about whether or not that perception, you know, what it's grounded on, and maybe some specific examples of that.

DR. KRIM: The perception is grounded on facts, not with regard to any acts of dishonesty and so on, but the facts regarding the existence of consultantships that are provided by pharmaceutical companies to investigators in academia, and this is a system that exists all across the country. It's very widely used. In fact, I was myself a consultant to a pharmaceutical company for a number of years. And you are supposed in exchange for payment, which can be, you know, starting with a couple thousand dollars a year to five digit figures, quite considerable, you are expected to inform the company, provide information, keep an eye open for opportunities that the company could pursue, et cetera, et cetera.

So you have a working relationship and a certain allegiance builds on the part of the investigator for the company that supports him, that helps him financially, and these kind of arrangements are very often very valuable to investigators because as you probably know scientists are very poorly paid in academia so this is one way of making a

little more money. Now the pool of experts in AIDS research started off by being extremely small so that the same little group of people was appointed to different committees by the NIH, not only peer review committees that look over grants, but also advisory committees to different institutes, particularly the NIAID that directs research on AIDS.

And some of the scientists have come and continue to have their arrangements with pharmaceutical companies. There is an understanding in academia that one doesn't ask questions about these kinds of arrangements. When I was at Sloan-Kettering nobody ever asked me to disclose my arrangements, and I could not make people working for me disclose their arrangements to me, which angered me very much. And in fact, I know that certain things happened that should not have happened because of this kind of arrangement.

Now in the patient community, because of the level of anxiety that is there, you know. People look at everything that could be done differently or better, and one of the things that came up recently is the consulting arrangements of some of our scientists who advise the NIAID, in particular, have with pharmaceutical companies who are developing drugs for AIDS treatment, and how does that impact on decisions

regarding priorities and selections of drugs and so forth made by NIAID.

And I think this kind of cloud -- I don't believe necessarily that anything dishonest has happened -- but the cloud should be removed and scientists who have an important advisory role should be asked to disclose their personal arrangements with pharmaceutical companies.

CHAIRMAN OSBORN: I think it might be important to make the distinction between the advisory committees, since you mentioned that in the same context, as one of those people who now is called a senior scientist, to my horror, and has served interminably on advisory committees, we are asked to disclose our contributions to anything and our receipts from anything and to exempt ourselves from anything that has to do with any kind of industry. So I think it may be important to make sure that distinction is well-known.

DR. KRIM: You mean you as commissioners or in general?

CHAIRMAN OSBORN: I'm talking about advisory roles to NIH, FDA, CDC, the context in which you were just speaking. As somebody who has for a long time played that role, I have had to figure out every year whether anything new had

twitched in my financial environment and to sign my life away that it has not or that it change in this or that quite small way. So you're talking about a different level, I recognize, and I'm not contesting what you're saying. But I think in the interest of clarity, it's important to say that at the advisory level for the U.S. Public Health Service agencies, the extent of disclosure is nothing short of embarrassing. I'm always embarrassed because I don't know how to make money.

DR. KRIM: Yes, I'm talking about this advisory level.

COMMISSIONER DIAZ: I wanted to ask Dr. Mitchell about the need that you briefly described -- I asked the previous panel -- of bringing the family into care. I know that your focus is primarily women in the perinatal setting, but a lot of these women have significant others and spouses and families that may also be at risk. And I just wanted to hear. I've heard you before, but could you share some of your perceptions as to the need to do that, particularly in working with black and Latino families?

DR. MITCHELL: Yes, I alluded to it in the testimony, but I think that it's extremely important to under-

stand, as I said, the cultures from which the women come, and it is obvious, it has been obvious even before HIV, that if you deal with only the woman around issues of sexuality and pregnancy and what not, that's why we've failed. I mean I like to use the whole issue of adolescent pregnancy as how we have considered pregnancy as something that happened to women, and it was only in the last few years that they began to give recognition that there were men impregnating women, and so you had programs targeted toward adolescent males.

But I mean they were always there. But we have consistently around family planning and pregnancy, unless you are middle class, and then you make sure your spouse is with you and goes to all your prenatal appointments, and he better be there for the birth, but what we have consistently left out the other members of the family when we deal with women as if they are doing this all on their own. And that's why we've had such poor results with what we've been doing.

So the program that we -- one of the things I'd like to say in support of Dr. Sable is that, one, our research grew out of being primary care providers for the community. I mean Harlem Hospital is a large municipal hospital, but it provides care for a community that is fairly

stable. And I don't know if any of you saw the front page article in The New York Times this past Sunday, but when you start to talk about HIV, you can't ask this community to make it a priority when there are other problems in their community, and so we don't look at HIV as something different and strange and what not. It's just one more health problem that has impacted this community that has always been impacted by health problems.

So we grew out of a need to continue to provide the kind of care that people talk about, that city hospitals because of the underfunding have not been able to provide, and so we got into the research arena because we had to find ways to support the program. I mean I know that Dr. Allen and what not have heard me say many times because my concern is chemically dependent women, if I have to write a little AIDS in it to get money, I'll write a little AIDS in it. But that's not what my concern is. It's trying to provide the kinds of services that these populations need, and if it means then we turn into researchers to get the services that are needed, then that's what we've done.

So that we've always had a family centered approach. We've always said that you've got to get the male in. We

have a hooker in pregnancy that doesn't even want to hear the baby's heartbeat. But we also deal with all of the significant others in the family. Oftentimes when the pediatrician talks about foster care, well, I think you need to not just talk about having foster care kids being available for treatment trials. We need to look at why we have so many of our kids in foster care.

And that's what the real issue is. I mean we've got to stop looking at these little minute tops of the pyramids and begin to look at the real issues of why there's so many kids in foster care. And then if you could address that issue, then you wouldn't have to deal with the issue of getting drugs to kids in foster care. So we have to become broader in what we're looking at. We're looking at a societal problem. We're looking at a poverty problem. We're looking at economics. And AIDS is just another tip of the iceberg. I mean yesterday I got a call because we are in the midst of an epidemic of congenital syphilis, and the CDC and the city health department called me up at Harlem because Harlem Hospital ranks among the top of congenital syphilis. Now a lot of that is HIV related and a lot of that is drug related, but I mean I can't say that all of my attention is

on AIDS because it's not.

The chemical dependency problem is what is the basic reason for my women who are HIV infected, either their own or their partner's. So you've got to involve the whole family. You've got to be a primary care provider of care for the whole family and not just health care, but all care.

CHAIRMAN OSBORN: Harlan Dalton, Don Des Jarlais, Charles Konigsberg, Don Goldman. Then we'd probably better break.

COMMISSIONER DALTON: I'd like to apologize to the first three speakers for being out of the room unavoidably but regretfully during your testimony, particularly I guess I'd like to apologize to Dr. Mitchell, because I think that issues relating to women and HIV and women and drug use easily get short shrift.

I'm also a little tired this morning. I know that you can issue a wake-up call in a minute, and I would have liked to have been bored by your testimony. So I want to direct my question to one of the people I did hear, Dr. Krim, in particular your sixth recommendation. You observed that in the past research on opportunistic diseases has received scant attention and you suggest full funding for recent NIAID

initiatives in that regard. Yesterday in our testimony from the NIAID, I at least was left with the impression that opportunistic infections research has, in fact, been a major target of funding and effort, and we were shown a couple of slides to that effect, one of which was that I think of the new protocols, newly approved protocols for the coming year, 12 of them are devoted to opportunistic infections and five to antivirals, or something of this sort. I wonder if you could put some content on your characterization of past efforts as being scant with respect to OIs, opportunistic infections, give a sense of why that is, and tell us what, if anything, has changed that can give us some hope that in the future more research dollars and other resources will be devoted to that?

DR. KRIM: First of all, we have to remember that HIV infection is one disease and opportunistic diseases are many. And very little is known about most of them until AIDS because they were very rare. Even methods of diagnosis are still over invasive methods, painful, difficult, costly. And very few could be treated, or can be treated effectively as of today, and they're still the cause, the immediate cause of death of most people with HIV infection. So they are

diseases that are uppermost in the mind of patients or people at risk of them, of these diseases. Although in the mind of researchers with limited resources, it was probably more attractive to go for a solution to the fundamental problem which is HIV infection.

And I think this is the origin of this apparent neglect, you know. My reason to say that there was a disproportionate inattention to opportunistic infections is that last year I requested from NIAID a list of all the grants they'd given out in the area of HIV and AIDS research, and to my surprise there were only seven grants out to opportunistic diseases. And when you think of the number of these diseases and how little we know about them in the areas of diagnosis and treatment and prevention, seven grants was very, very little. And this is basis of my conclusion.

COMMISSIONER DALTON: What has changed to make us think, what --

DR. KRIM: What has changed is that there have been loud complaints on the part of the AIDS community, and, you know, a sense of the importance the community gives to these diseases has permeated and reached NIAID, and there is a response now to it.

CHAIRMAN OSBORN: Don.

COMMISSIONER DES JARLAIS: This question, I think, is sort of to the panel as a whole. While we are addressing a lot of biomedical research issues today, we are also interested in behavioral science prevention issues, and I know, Mathilde, you work in a foundation that addresses a lot of behavioral science issues, and the rest of you are basically working with people where our prevention efforts have not been successful. And so I'd like to throw out a general question of where you see the federal government effort succeeding or not succeeding in prevention based research?

DR. MITCHELL: Well, you could see that the first two of my three recommendations were psychosocial issues. I think that we have to be very careful to understand that in certain regions and in certain areas the epidemiology of this disease has changed. And that we're now dealing with populations where we don't know a lot about what motivates them and why they undertake certain behaviors. And therefore, when you decide to educate or to help them change their behavior, you're working from isolation. And I think that that is why we have failed.

That's, again, why I went back to the adolescent pregnancy, and I drew the things in my testimony about self-esteem because we know that adolescents who have high self-esteem and intact support systems are less likely to get pregnant or likely to terminate a pregnancy and to continue school. So those are the things that we have to look at, what motivates people to change behavior? If you live in a very impoverished neighborhood where your only way out is the use of drugs, then I can tell you don't use drugs and clean your works all I want to, but I've not really addressed the issues that caused you to use them. And, you know, it's the same thing when we talk about the use of condoms in certain cultures, and we address them to women and we don't understand that they're not in control in the bedroom.

Those are the kinds of issues that really do need basic research, and that's why while I understand as a physician the need to be able to adequately treat people, as someone who has always provided care to these communities, I am more concerned with changing the health behaviors of those communities, and that's where we have fallen very short, and you know that from the work that you've done.

DR. SABLE: Yes, I'd say that just as in every

other area of medicine or of health, prevention strategies always get short shrift, you know, whether you're talking about resources for those prevention strategies or researching the things that work, and I think that with HIV infection, even when we've found things that do work, helping people change sexual behaviors, whatever, that if the material that's sexually explicit that does that draws tremendous political fire, you know. And so there are problems even when you figure out what it is that works, getting the resources there to implement that.

MS. SIMON-KRAMER: For the hemophilia community it's a little bit different. But, as I mentioned in my statement for us to pay for state of the art technology that keeps factors safe is a big issue. For us, though, also a secondary epidemic in the sexual partners of hemophiliacs has been a big area of concern. There have been about 55 sexual partners that have developed AIDS. The number that are HIV infected remains somewhat vague, but probably higher than we'd like to see. So we actually have a whole national agenda through some funding from the Office of Maternal and Child Health that's strictly devoted to the outreach to sexual partners of hemophiliacs.

I think, though, that we've also done some workshops, things that addressed behavior change and behavior relapse, but I don't know how you guys feel about this, but a big problem that we've identified is that the people who are supposed to be doing risk reduction education are not necessarily trained to do risk reduction education, and you can use a cucumber and you can use a condom, but if you're not comfortable with it, and you've never been really taught to do it, then I'm not sure how effective those can be without training for the trainers which is something we're trying to deal with but have not yet fully been able to realize.

CHAIRMAN OSBORN: I'm going to suggest that Dr. Konigsberg and Mr. Goldman make their questions as brief as they can. Otherwise we're going to lose some coffee options that I, at least, need badly at this point.

COMMISSIONER KONIGSBERG: Yes, I will make it brief. A question for Dr. Hutto. I'm a little bit familiar with the problems with pediatric HIV and AIDS in south Florida. Could you elaborate a little bit on the difficulties you've had with the clinical trials and other care issues with the foster children and maybe a bit about some of the

bureaucratic barriers that may exist with perhaps the Department of HRS?

DR. HUTTO: I can tell you a little bit about the bureaucratic, but I haven't been directly involved in dealing with those personally. I think it begins, the problem with foster children actually begins with identifying infants who are born to HIV infected mothers, identifying which one of them are actually infected so that they can even be provided adequate care, and even determine whether or not they're even eligible for clinical trials, even if we could put them in trials. Because of legal constraints in the state of Florida, we are unable to test children known to be at risk who are placed in foster care at birth or shortly after birth. Without a court order, we have in the last year, year and a half, been able to start obtaining court orders for testing, but it takes several weeks to months before we're able to obtain those court orders. Many of those children are infected and develop systems and even die before they're ever diagnosed.

And frequently, because of that delay in diagnosis, we diagnose them with they present with their first opportunistic infection and die because of the legal constraints.

So it begins with actually testing and identifying infected infants. For older children who are known to be infected and who are in foster homes primarily because their mothers have died before the children, or because their mothers are unable to take care of them for other reasons, but it's generally because of the death of the mother, they are ineligible for any type of research studies.

COMMISSIONER KONIGSBERG: I'd like to point out that in the Florida system, the state age program and the foster care program are in the same overall agency.

COMMISSIONER GOLDMAN: I'd like to ask a question of Amy Simon-Kramer. In the last panel we had I noted that Dr. Thompson from Atlanta indicated that it would be impossible to include a program in Albany, Georgia in their Atlanta program because they simply didn't have the money to fund data collectors and coordinators going back and forth between Atlanta and Augusta. Yet you have been able through the foundation to maintain a national network without requiring everybody to go traveling everywhere, and I was wondering if you could explain how you've done that so that it might be useful for others who might as a way of breaking that barrier?

MS. SIMON-KRAMER: We did two things. One is comprehensive hemophilia treatment centers. As I indicated, there are about 200 around the country. They're very -- they're spread out so that for patients, they could go to the center that's nearest them. However, the nearest center in the middle of the country can still be hundreds of miles away. We used what we call this local physician, local M.D. system, where for in between visits we required the patient to go to the main treatment center under the auspices of the principal investigator at that center monthly or every other month and to see a local physician who consulted with the treatment center physician every time a visit took place.

And we established systems for communicating how the data would be collected, lab values, that kind of thing, and in the event of a toxicity or a worsening in the patient's clinical condition, the patient was still required to travel to the center. But for a patient who was doing basically well on the study regimen, he wasn't required to travel hundreds of miles every month. As long as there was good communication between the local physician and the treatment center physician, it really did not represent a problem at all.

And the nurses on occasion from the regional centers went to visit the local M.D.'s to train their nurses to make sure that they were doing good assessments and filling our forms properly.

CHAIRMAN OSBORN: Thank you very much. We appreciate the testimony each of you has given in helping us to keep chipping away at an extremely difficult problem, and we admire your work. I think I can say that on behalf of the commissioners. Dr. Krim, your individual opinion is most welcome, and the official can come later. We are most interested in your analysis.

DR. KRIM: Thank you.

CHAIRMAN OSBORN: And Dr. Sable, thank you for helping to represent the center of the country. Some of the rest of us work at that, too, but we very much appreciate having you with us. Thank you all. And I suggest that we should break until about ten after 11 then and then reconvene.

MS. BYRNES: And if I could make one housekeeping announcement, please keep the cups outside this room. PAHO is fairly insistent on not carrying paper cups with coffee back into the carpeted, well-decorated room.

(Whereupon, a short recess was taken.)

CHAIRMAN OSBORN: Let me thank Drs. Watters and Vaughn and Ms. McInturff, for your patience with us. We are at the end of a very intense couple of days of hearings, and so we needed the break. But we're very pleased that you could make it to join us. I hope, as you start speaking, you will just say who you are for purposes of the record and also for people who may not have the program directly in front of them, and we'd like to hear from each of you, and then we'll have a chance for the commissioners to ask questions. Welcome.

DR. WATTERS: I'm John Watters. Can you hear me? Is this thing working? I'm John Watters, and I'm an Assistant Adjunct Professor at the University of California, San Francisco, in the Department of Epidemiology and Bio-Statistics, and on the faculty of the Institute for Health Policy Studies in the School of Medicine at UCSF. And I have been with my colleagues conducting studies of HIV infection and behavior change in IV drug users since 1985. And I'm going to talk a bit about the data that we've collected since 1985 and somewhat about the prevention efforts that have grown out of this.

I guess I'll just go ahead and start with the data.

This represents five cross-sections, six cross-sections of data that we've collected since 1985. The first one in 1986 we collected a baseline from 400 IV drug users. We removed all the males with a history of same sex intercourse to approximate a heterosexual population. This slide represents the ethnic distribution. As you can see from the total column, which is at the extreme right, it's approximately 40 percent white, 40 percent black, 20 percent hispanic, and a smattering of others.

The population is about one-third female and about split evenly half and half between those who were enrolled in treatment programs at point of interview and those who were not in treatment. It's interesting also to note that about 40 percent of the population had no treatment experience whatsoever. Now between the first observation point in early 1986 and the second observation point in early 1987, an intervention program was started in San Francisco which fielded people that were called community health outreach workers and who dispensed condoms and one ounce vials of bleach to IV drug users in inner city settings.

This program has been expanded over the years. There are now several programs in San Francisco which provide

these services. Condoms and bleach are readily available in STD clinics in San Francisco. Some drug treatment programs also dispense them. And based on some of the early work that we did hear and some others did in other parts of the country, the National Institute on Drug Abuse which funded this study implemented a large-scale national project, the National AIDS Demonstration Research Project, which set up a system of community-health outreach in over 50 sites around the country together with standardized data collection methods to determine what was going on with respect to behavior change and in most locations HIV seroprevalence.

As you can see from slide, there were statistically significant changes between 1986 and 1987 and additional changes after that period. However, I'd like to point out that the mean score for each one of these cross-sections, if you'll look the peaks are about 25 percent. So if you think of this next set of slides you'll see, each cross-section has a mean score. You might think of it in the same way as you would think of an SAT mean score for a school system. The 1988, late '88 cross-section, had a mean score of 25 percent of the time condoms used during intercourse.

Now where that's a surprisingly large increase from

almost none of the time in 1986, you have to ask yourself the question of how important this is epidemiologically with respect to lowering transmission of HIV, progress nonetheless. This is an index of the number of needle sharing partners in heterosexual IV drug users over the same period. It roughly corresponds to the size of a sharing circle for an IV drug user, and you can see within these 95 percent confidence intervals that there has been a substantial reduction in the size of needle sharing also over the same period.

This is the self-reported percentage times used safe needle hygiene, and safe needle hygiene for us includes not sharing or cleaning needles with hydrogen peroxide, bleach or alcohol or boiling in water which, of course, no one does because it takes too much time. And again, we have an initial change in behavior, a very steep curve between 1986 and 1987 and what may be some continued increase after that point to a fairly high level such that the 1989 mean score was close to 80 percent, which would suggest that most of the IV drug users in San Francisco are using safe, what we would define as safe needle hygiene most of the time. That is to say they're not sharing needles or they're disinfecting them with a method that we would consider safe.

This is use of bleach only, and this is only for IV drug users who share needles. 1986 that was about 92 percent of the IV drug users. By the first half of 1989, that was 60 percent of IV drug users. So there has been a very large increase in the number of IV drug users who report to us that they no longer share needles, but for those who do continue to share needles, you see a very dramatic increase over time in the self-reported use of bleach to disinfect syringes when sharing.

And this is HIV. There is a significant increase between 1986 and the first part of 1987. For heterosexuals it goes from about six percent to about 13 percent, and we have some sampling artifacts here. But essentially what we don't have is the kind of increase that we have seen in so many other North American, European and Asian cities where there are substantial reservoirs of HIV infection in one risk population coinciding with or coexisting with an IV drug using population. And certainly in San Francisco, with 50 percent plus infection rates in the gay bisexual communities, and some considerable overlap between that community and the IV drug using communities, the absence of a rapid rate of increase in seroprevalence is certainly encouraging.

Clearly the data are not conclusive with respect to cause and effect here. There is some corroborating evidence. Fran Taylor's study of incident cases of hepatitis B at San Francisco General Hospital shows a significant decline between 1987 and 1988 in patients with IV drug use risk. But the data certainly are suggestive and promising. Now one of the things that is useful about studies of this type where IV drug users are recruited from non-institutional settings and non-treatment settings is that we find differences in these populations.

Now, this slide raises more questions than it answers, but basically what we have here are black and white IV drug users sorted into three categories: those who had no drug treatment; those who had at least one day but less than 12 months of drug treatment total in the previous five years; and those who had a total of 12 months treatment in the past five years. And the percentages across the bottom show you what percent of that 1300 people that is. Most of them, only 13 percent had at least a year of treatment. Again, most of the IV drug users are not in treatment. NIDA estimates that only 15 percent of the IV drug users are in treatment at any point on any day.

And our study as well as the National Demonstration Projects coincide in their finding that 40 percent of these individuals have never had any treatment. You can see that they're rather striking differences between HIV infection for the group who had little treatment. That is to say whites had a seroprevalence rate of nine percent where blacks had 22 percent. This may suggest something about the quality of treatment that blacks receive. This is one of the sort of serendipitous findings that can be obtained from this type of research.

So I suppose, in conclusion, there are two points I'd like to make. One is that the community outreach program, which places in the hands of risk populations the materials that they need to protect themselves certainly has a profound impact on knowledge and verbal behavior. And the serologic data from the HBV study and HIV study suggests that this may be a factor that is associated with flattened seroprevalence and lower sero-incidence in these populations.

The other point I'd like to make is that in the National AIDS Demonstration Research Project, there was established a wonderful mechanism for the collection of systematic standardized epidemiologic and risk behavior data

on a national scale. Now that program was formerly funded at about a $55 million annual level by NIDA. That amount is now, I believe, $9 million for this upcoming year and will be devoid of its prevention associated efforts.

That means that the data collection scale will be shrunk enormously, and the prevention element will be almost completely foregone. And I would say it would be most unfortunate, indeed, to lose both of these mechanisms. Thank you.

CHAIRMAN OSBORN: Some war. Thank you.

MS. McINTURFF: Good morning. I'm Patricia McInturff, and I am the Director of Regional Services for the Seattle-King County Department of Public Health. And I'm here this morning represents a service demonstration project. The first case of AIDS was diagnosed in Seattle-King County in 1982. As of today we had approximately 1300 cases of AIDS diagnosed in Seattle-King County. Seattle is often described as a second-wave city in terms of the AIDS epidemic. That is we follow the New York and San Francisco's by approximately three to five years. That's given us the opportunity to learn from other cities and to plan our programs before resources were overwhelmed.

As I say to the people that I report to, the city and the county, nothing new ever happened in Seattle, Washington that hasn't happened somewhere else. The positive working relationship between the health department that I represent, the University of Washington, and the at risk community has given us a tremendous advantage and allowed us to implement programs probably quicker and more effectively than many other cities. I used to say that our greatest success was getting the chicken soup brigade, which does exactly what you think it does, and Swedish Hospital, a large, private hospital, to agree on what our services would look like in our count,y my greatest success.

I changed that now. For the last year, the Seattle-King County Department of Public Health and Act-Up have jointly run a needle exchange program in downtown Seattle. I think that is pretty unique across the country for that kind of cooperation. We built our system of care on a systems approach, and I think in the packet that I sent you I showed what our continuum of care looks like, all the services that we thought someone needed from diagnosis to death. And we adopted principles and guidelines as we sat that up, and there are four key ones that I will just mention.

They are a lead agency approach. We appointed lead agencies both in government and in the community, the health department, the Northwest AIDS Foundation, People of Color Against AIDS Coalition. We agreed on a case management system where everyone would have the opportunity that had a case manager, who had Class IV disabling AIDS. We believed and set up systems where we promoted diversity of options so that people would have different sets of options in terms of housing, medical care. And the fourth key concept was that we would support and enhance our very strong volunteer system.

Evidence of success based on outcome data are really two studies that I like to quote. The first is by Dr. Lafferty from the State, and one of my staff, that shows that the mean length of stay in hospitals from 1984 to 1987 was reduced from 18 days to 11 days. The cost per hospitalization in the same period was reduced from $13,000 to $6,000. And the mean overall inpatient costs were reduced in the same period from $33,000 to $20,000. That's about a cut in half in terms of costs. Now we haven't published yet the '88 and '89 data, but the trends have continued down.

Another set of data done by one of my staff shows that place of death has changed significantly in our com-

munity. Home deaths have risen from 1984 to 1988 from 11 percent to 29 percent. And hospital deaths have decreased from 89 percent to 57 percent. We think those are indicators of less expensive and more humane systems of care. The health department today in the 1990 calendar budget has about $9.2 million for AIDS. However, in the next year we will lose in our community four major grants, two demonstration projects that pay for continuum of care services. Those are HRSA, the Health Services Resources Administration, and Robert Wood Johnson Foundation.

We will lose two prevention and education grants, one from NIDA, the National Institute of Drug Abuse, that targets IV drug users and their sexual partners, and another from Robert Wood Johnson that targets high risk adolescents and Native American youth. Those are nice numbers, and I can quote you all the statistics you want, but I would like to do as a representative of the service demonstration projects is tell you what that means in terms of real loss of services. This list is not total. It is not all inclusive. It is some examples of what's going to happen in our community. We will lose the ability to do 400 assessments and placement of PWAs in low-income housing. That's a 60 to 70 percent decrease in

our program, and we have a very good housing program.

In terms of meals, we will lose the ability to provide 30,000 meals by volunteers and contract. That's a 75 percent decrease in our meals service in Seattle-King County. Our case management system that is the glue that holds our system together will be reduced by one-third. The loss of HRSA and RWJ demonstration projects will result in a loss of approximately 2500 primary care visits. They will translate into a loss of attendant care for approximately 45 PWAs that will not be able to live independently. And it will devastate our volunteer system and our volunteer coordination system. We have about 13,000 volunteer prepared meals. We have about 450 hours per week of homemaker chore service and about 70 trips per week that will be lost as a result of these demonstration projects.

In terms of prevention and education, we will lose approximately a million dollars next year. Services targeted, prevention projects targeted at gay and bisexual men, IV drug users and their partners, high risk adolescents, and Native American youth. While I'm here as a representative of Seattle-King County, I spent yesterday in Baltimore with representatives of the HRSA projects at our annual meeting,

and I can say in all seriousness that what's happening in Seattle is happening all across the country. There are 17 high incident cities that are up for HRSA funding in your FY '90. All of those projects, those 17, are experiencing the same kind of devastating cuts in our systems of care.

In my other job with the health department, besides running a division, I am the liaison with Harbor View Medical Center, which is our county-owned and university-run hospital, and I can tell you that the impact of these kinds of community-based demonstration projects translate into two things: more expensive care and less humane care. Thank you.

CHAIRMAN OSBORN: Thank you very much. That is a most impressive presentation.

DR. VAUGHN: Okay. My name is Dr. Anita Vaughn, and I'm Medical Director of Newark Community Health Centers, and I have to apologize since I am a practicing provider not being able to send you ahead of time my testimony, but I'll be forwarding it to you. Unfortunately, we have had quite a few of our patients who have died within the last three or four days. So patient care comes first to me. I just want to demonstrate, talk to you for a minute about how Newark Community Health Centers became active in treating HIV

positive patients and their families.

I became involved because you just look at see what your patients are affected with and how that affects the family. And this started in 1984 actually. Our health centers, and we have three located throughout the city of Newark, are located in the most drug-infested, poverty stricken communities in the city. Our patients are primarily blacks and hispanic. The majority of the patients have incomes below the poverty level, and even these patients oftentimes do not benefit from welfare, health insurance, or other social programs. As you may guess, over 62 percent of our patients who are HIV positive acquired their disease either from intravenous drug abuse or heterosexual contact of intravenous drug abusers.

We provided services, comprehensive, primary medical care and also following the patients in the in-patient setting during this whole period of time. The patients that we saw at the health center were often at the expense of providing services to other patients because we received no funding up until April of 1989. At that time we were the recipients of a HRSA, Robert Johnson grants, where HRSA demonstration grants that enabled us to begin case

management. We were able to employ a case manager, an MSW, and a "health educator/outreach worker." Also, too, in September of 1989, we were one of three health centers in the nation to receive jointly sponsored CDC and HRSA HIV demonstration grant.

With this funding, we've been able to expand our case management to include an RN case manager, two other social worker case managers, two on-site certified drug treatment counselors, and this has been extremely important, again, since over 60 percent of our patients are substance abusers. The counselors were initially responsible for providing counseling on-site and then for enrolling patients and also following them in the drug treatment program that is a few blocks from our health center.

In addition to that, we have nutritionist, we have transportation because oftentimes even though the distance may not be that far for those of who have cars, those people who don't have money for transportation, it can be like going over a mountain in order to obtain care. We also have a psychotherapist who does on-site counseling, and the health educator, the case managers, and the psychotherapist provide on-site support groups for our varied patient population. I

have to say that the case managers have been tremendous in helping me to be more effective, and the other physicians and nurses, to enroll people both in their primary care, to get people to come back for their follow-up visits, to get people to come in the hospital even though they don't want to a lot of times, and then also to participate in clinical trials.

Finally, in October we were able to receive funding through the National Institutes of Allergy and Infectious Diseases to conduct clinical trials for HIV. Oftentimes even though the university in only half way across the city, accessibility was a problem for our patients, again, because they are not the most, thought to be not the most cooperative patients. They were not often sought unless they had a special project for the week, it seemed like. Through the case management, we have been able to push other agencies now to help in the fight for HIV patients. We, through the demonstration project, some of the goals are to, one, document that risk reduction behavior activities somehow will translate over a period of time to decreased numbers of patients who are HIV positive and also, too, in a small segment that through these interventions that we will have less whose sera convert for the patients that we've been

following for the last four or five years.

Another goal of this project is to be able to document a feasible compendium of care that integrates both private and local and federal funding sources to provide the comprehensive care. We are integrating through our various programs the drug treatment programs, the hospitals, the local and state and federal government programs. At Newark Community Health Center, our program for HIV patients is integrated. We don't have an AIDS day. And Newark still continues to be a very reactionary city. We still don't have intermediate nursing facility for the patients even at this day and time when we have over 2,000 patients that have been HIV positive.

Problems for us: once the case management funding ends, we're through the HRSA again, the funding will be up this year, what's going to happen? I'll be less effective again, continuity of care will suffer, and ultimately I think it's going to bring the demise of our treatment efforts. As far as representing community health centers, a lot of community health centers are located in rural areas, migrant farm areas, and funding also has to be served for these areas that are seeing increasing numbers of HIV positive patients

in their funding.

Also, two, community health centers have to have greater accessibility to reliable training. Those of us who have been treating HIV patients are often overwhelmed and also been dumped on by other facilities. We need to have increased funding and educational sources so that we can get greater people to get involved in everything because certainly the number of patients that are out there in our families are just increasing. In Newark, our percentage of heterosexual spread is 28 percent. Our numbers of patients who are HIV infected are 50 percent are female, and 50 percent are males in our service area. So we need help.

CHAIRMAN OSBORN: Thank you very much. Thank you, Dr. Vaughn, for your priorities, which we approve of very strongly, and we appreciate your verbal testimony because it is most helpful to us. And Dr. Watters and Ms. McInturff. I'd like to ask the commissioners who have questions. Charlie Konigsberg.

COMMISSIONER KONIGSBERG: I guess I have great sympathy for the concern over the loss of the demonstration projects. If I were still the Director of Public Health in Broward County, Florida, it might well be me sitting up there

bemoaning what I know they are also about to lose. I'm sure Jasmine Shirley down there is facing the same crisis, but having left there a year and a half ago, I've also had an opportunity to reflect a little bit about raising expectations in communities, setting up, I won't say an ideal system, but semi-ideal systems, and sometimes even idealistic systems, systems that perhaps exceed what other care systems, in fact, look like in a community with now facing the prospect of what will be disastrous cutbacks and much lower expectations, which I guess is sort of my way of seeing the urgency in the care act. And I guess my concern is what efforts are being made in communities to really deal with the state and local funding aspects and really kind of address that issue?

I guess the other question to Ms. McInturff, as well, is the role of the health department in the leadership, why you think that was appropriate, and how you went about trying to get cooperation from all parties? So if we could just get some conversation going on that, I think, that might be helpful. I realize I made more of a statement than I asked a question.

MS. McINTURFF: Would you like me to -- to state and local. The demonstration grants have been going for four

years, and as you know, people are living twice as long, and the cases are still doubling. The way we've been able to maintain our systems the last four years on a status quo budget is if you look nationally it's been the states have really chipped in, and our state, we in the last two years, we now have $6.6 million statewide, and two years ago we had zero. So the way we've been able to maintain with RWJ and HRS is the states have really chipped in.

What I've been doing the last three months, I will tell you, is the presentation I gave here today. The reason I could get it together so quickly is I've been sitting before the city council members, the county council members, the mayor and the county executives and saying you've only chipped in about three percent each. We've been very, very successful in this city in outside funds. You've been off the hook. Those days are over. And I can tell you that I was a lot more popular when I came to them and said aren't we lucky, we got another grant. They're not very happy to see me these days because when I got it they said to me, Patricia, are you going to be back here in four years, and are you going to ask for those funds, and I smiled, hoping that I would never have to find this day, put on my power suit, and

said absolutely not, knowing that I really had no choice but to answer the question that way.

Believe me there was great discomfort when we applied for these grants, and I'm going back to them saying this is the reality. So I think that we're all clearly looking to the Kennedy-Waxman bill. We're looking to our state legislatures. We're already starting to gear up for the session that starts in January, and we're looking at city and county. I think it's going to be a joint responsibility. There is not one answer to this. And your next question was why did the health department take the leadership? It just seemed it was a public health problem, and it was the appropriate thing to do.

Also, in our community, when you have the at-risk community and the university, somehow we're the people that can bring everybody around the table. We're a little more comfortable than those two sides, and it just seems like an appropriate role for us as a health department.

CHAIRMAN OSBORN: Jim Allen. Then Scott Allen.

DR. J. ALLEN: I want to follow up on that question and your response, in part I guess because I'm sitting here in the Health and Human Services seat, and am wrestling with

trying to put together budgets to deal with these things. I work with the agencies that met with the Robert Wood Johnson obviously, but certainly with HRSA. And it's their programs that are being faced out or being redirected in other efforts, and I guess that is part of the problem with the term "demonstration project."

It was supposed to demonstrate something, and it did, and it was successful, and then people say all right, what are you going to do for an encore, not just an encore, but I think the real issue is one of continuing service. And you clearly demonstrated the impact of the loss of the monies from the federal demonstration programs as well as the foundation grants. In just running through your list, housing, meals, case management, primary care, attendant care, and the volunteer network. And let me take the devil's advocate position which I'm not comfortable doing, and say, well, none of those are really AIDS specific problems.

They are all made worse by AIDS but none of them were caused by the AIDS epidemic. We're really talking about something that is much broader. You've already partially answered it by indicating the need for joint or shared responsibility in terms of addressing it. I guess looking at

it from the state level, where in the federal government do you see the primary responsibility? Is it through a separate bill of the type that Kennedy-Hatch care bill? Is it through, and again, that's short-term. And maybe we're talking about long-term needs and the need to establish permanent programs. How should this be done, where, and how do we get it out of the AIDS money but more into the dealing with the broader social issues that are there? It's kind of a badly phrased question, but it's a lot things, a lot of concerns rolled in there?

MS. McINTURFF: Well, I think that AIDS has just brought to life the problems we've all had for a number of years. There is nothing unique about AIDS. But it is hitting a younger population, and our housing situations are not set up for this population. It is bringing to light and making certain problems that were ongoing absolutely exploding in our faces, and I think you know as well as I do, if we don't solve them we will all wind up with our public hospitals -- I sit on the finance committee for one of those so I know what its impact is.

In terms of what we need, we need ongoing funding. There are clearly things to be demonstrated, but I think

we've demonstrated that these work. Some of us do not need to be any panics every two years going back to our state legislature, throwing ourselves on the floor, begging for dollars. That's not, this is not a problem that is going to go away next year or next year or the year after that. And it seems to me we need an ongoing stream of money.

I go back to the old TB Milledge days. There is something where we can follow the number of cases so that we can plan because planning is the key to this. So that we're not, we're anticipating, we're not always reacting, and I would leave it to those of you in Washington to figure out how best that happens at your level. I can certainly work it out on my local and state level, but clearly we need an ongoing stream of dollars that doesn't even every four years and we have to prove something.

DR. VAUGHN: Well, the problem, I just wanted to address the problem. In Newark right now, we're -- really in the state of New Jersey -- they're facing tremendous financial deficit, and all departments run by the state have been asked to cut their budgets, and of course, HIV, you know, the AIDS program is another area that is going to be cut. What do you do when, you know, the state has a deficit and the need is

ever increasing? That's a big problem that we're facing right now. And the budget for HIV care is slated for over a million dollars.

MS. McINTURFF: The other thing we get hit with is I think you're saying is why should we do AIDS specific funding, and I respond to that often. And I think we've done disease specific funding in the past. To pretend we haven't done it in naive. We certainly did it with tuberculosis. I also run the TB program, and we did have a Milledge in our state. We've done it with kidney dialysis. We've done it with AIDS. I don't think it's anything terribly unique. And I get asked that why is AIDS special? Well, it is. That's just the bottom line.

COMMISSIONER S. ALLEN: Jim, I don't think it's unprecedented for HRSA to move demonstration grants into the permanent budget; is it? Just a question.

DR. J. ALLEN: No, it certainly has been done, and as a matter of fact, in some of them there has been a very subtle shift where without any change in a program whatsoever we simply dropped the title "demonstration projects" and made it service grants. The problem is one where the need outstrips the willingness of the powers that be to provide

the funding that's necessary.

COMMISSIONER S. ALLEN: And apparently that is a definite problem at this point, but I think we need to look at that option. Definitely the Human and Social Issues Working Group is definitely sensitive to the continuum of care and the lack of, especially in the light of the way the epidemic is going in the media blitz perhaps of early intervention and the illusion thereof possibly that's there. And not only just medical early intervention but also the social issues, and just a statement that we are planning, we announced yesterday that we're going to be coming to Seattle at the end of July. We're going to go to Dallas and to Seattle to look at the models and also to bring in folks from the geographic surrounding areas, and the question that I have, though, out of Seattle or any of you, is that you've talked about the federal government and state and local. What about private foundations? How have they been involved in all of this? What is the mechanism that you have developed to solicit funds and what has been the response?

DR. WATTERS: Well, there have been several foundations that have had interest. AmFAR has been as generous as they can be in funding some of our research

that's relevant to documenting the effectiveness of various outreach or prevention mechanisms. But I don't think looking to the private sector is the answer. The enormity of the need is to great, and if the federal government does not play a decisive role and looks to the state and municipalities to pick up the tab, nothing will happen.

We've already seen the problem bog down in local politics in New York and Los Angeles with respect to IV drug use. It's 1990 now. We've been talking about this stuff since '82, '83. And we can thank some of our friends that are here today for correcting some of the thinking in the Congress this past go-round for the current HHS appropriations. But again, we're getting rather late in the epidemic to be having these kinds of discussions, and I sort of feel as if we are in a football game with three teams on the field and the ball at the 50 yard line, and it's been fumbled, and everybody is standing around trying to figure out whether or not they should touch it.

DR. VAUGHN: We're also a member of the North Jersey CRI, and participate in some clinical trials from AmFAR. And there has been some foundation money for prevention activities, but a lot of times patients were saying

prevention is needed, but we need treatment. And up until we got the last CDC HRSA funding, there was no funding that I knew of for treatment. I think that what ever effective programs that we're going to be able to develop is going to have to be combined effort with the private, combined effort with the federal and state and local. And I don't think that, you know, people saying that you have to just go to private sources is going to be adequate.

MS. McINTURFF: We have found that primarily private foundations give to non-profit agencies. They don't give to government. And they've been very, very generous to the Northwest AIDS Foundation, one of our lead agencies. We're also building a 35 bed long-term care facility with a price tag of about $6 million. I'm on the board of that, and we've raised about 4.5 million to date. And if you look at who's giving, it's quite impressive. It is Boeing. It is SAFECO. It is PATCAR. We've had tremendous success from the corporate community for those kinds of projects, but as I said, I don't think they give to government. They need to give to non-profits.

COMMISSIONER ROGERS: I'm sorry that members of the executive branch and agencies and Congress weren't here to

hear you three eloquent people. My fellow commissioners have heard me say this before, but why in this country we continue to feel that there is some magic revenue ceiling when we've got people hurting in the ways that you've mentioned continues to mystify me. I went back to my briefcase because in a little piece in the Times yesterday another president in this country said the following. This country is rich enough to do anything it has the guts to do and the vision to do and the will to do. And I think if more people heard what you were saying, perhaps we'd stop this nonsense about we can't afford it and go ahead and fund the research and the people programs that are absolutely vital.

I agree AIDS is not that different, but it certainly has put the spotlight on some things we're doing dreadfully for fellow Americans, and we're privileged to see all three of you working so hard in this area.

COMMISSIONER GOLDMAN: Any of you can pick this up, but I'd like to ask you what your experience discloses the impact of the demonstration monies and the ability to increase the level of care, and how, if at all, it has complemented and strengthened your prevention efforts in the community and what the consequences on your prevention

efforts are going to be if the HRSA demonstration monies are not renewed?

DR. VAUGHN: Okay. One thing I think that has helped and which will be damaged that in the collaboration with the local community, as far as the whole gamut of HIV services, we've been able to kind of specialize where we've collaborated with the drug treatment program, we've collaborated with Planned Parenthood who's got large funding for prevention efforts, and we've been able to collaborate with other agencies. What the loss of the funding as far as the prevention activities then I think that we'll be less effective as far as outreaching and also getting to patients who still are not getting care now.

We would like to develop a program, but we don't have the funding yet, a collaboration with the drug treatment program, to develop a program for women with AIDS and their children on site at a drug treatment program. With decreased funding and everything from the federal government and then also, too, like I said before, decrease as far as the state, then I don't think that's going to be possible unless we volunteer. In order to expand into those fringes that are not being touched now, the teenagers who are addicted to

crack and everything, without having outreach and other fundings from CDC that go on prevention, then we can't get them in to get treatment, which, you know, those of us who have received HRSA fundings and everything will be less effective, and therefore increasing the number of young people who are affected.

MS. McINTURFF: As an old public health person, prevention and education rank at the top of my list. And I think we're going to see two very significant impacts. Number one, it's very difficult for people to talk about lifestyle changes when they don't have a place to live, and they don't have any food, and they don't have primary health care.

I think losses of continuum of care services will directly impact our ability to do counseling and testing and prevention and behavior changes which all of us who wear our seat belts everyday know are not easy changes in our lives. The other is I think it's always -- when we start to split the pie, and we have sick people, I think the easy thing that happens for those of you who deal in the political arena is the funds will go towards services, and prevention will get short-changed. So I think as funds are cut, both of those

things will happen.

It will be far more difficult to reach the people, to bring them in for counseling, testing, and the other is when we start dividing up our discretionary funds, it will be very difficult to say no to primary care and food and put money into prevention pots.

DR. WATTERS: I'd just like to add to that, if I might. And I don't think it's necessarily just an issue for HRSA and what will happen with elimination or diminution of HRSA funds. It's the absence of a coherent funded strategy for dealing with HIV in this country. This morning we heard a lot from clinical providers as to what the consequences of that have been on the east coast. And we have the rest of the country now. From the data that are available, from 1987, which was the last time there was a panel study, attempt to organize on a national scale these seroprevalence studies, the Han article in JAMA last year, which is data circa 1987, we know that populations of IV drug users are becoming infected all over the country at different rates in different places.

And unless we're willing to accept that responsibility now and deal with those prevention issues today,

those people will be cases later. And if we're worried about where the money for little bleach bottles is going to come from and paraprofessionals to go out and distribute them, where is the money going to come for the sick people when these people become infected and down the road and when they start to become symptomatic. Who is going to pay for the equipment and medication for aerosolized pentamidine. Where is that money? Well it's not going to be there. We'll just have a worse situation on our hands.

COMMISSIONER KESSLER: Thank you all for your vision as well as your compassion. And I think I know the answer to this, but I think it would be helpful for the record if either or all of you could address the issue of morale as well as recruitment and retention of staff, volunteers, and clients that, I suspect, is a problem now that there's a threat to your funding, either being level-funded or cut or eliminated in terms of certain programs and so on. What's the impact there, and how are you addressing that, if at all?

MS. McINTURFF: Well, I think there is a great deal of denial because no one can really believe that everyone spent all of these years building up these systems that work,

and as the numbers increase and people live twice as long, that anybody with a fair right-thinking mind is really going to stop us. I think there is a tremendous amount of denial. The HRSA meeting I was at yesterday could have been a funeral it was so depressing. But it is true there are millions of volunteers, millions of staff, working for not a lot of money. And when you lay them off and you stop the systems, I'm not sure they'll ever come back into the system.

So I see the systems that work falling apart, and our collaboration and our cooperation and what's worked so well for us being very difficult to go back in and say, you know, if funding comes a year later again, let's get around the table and build this back again. I'm not sure the same people will sit around the table with me.

COMMISSIONER MASON: Thank you all for coming. My question is for Ms. McInturff. As you so aptly noted, oftentimes, at least, in the media and I think in reality, public health and advocacy groups like Act-Up are in an adversarial relationship. So I'm real curious to hear from you how you managed to form this partnership around, of all things, a needle exchange program, and what kind of political climate you have in Seattle that allows you to get away with

such an endeavor? And whether or not we can like clone some of those politicians?

MS. McINTURFF: Well, we always say a couple things about Seattle. One is it looks like a big city, and there are really just 200 of us there, and so we've all known for each other for a very long time often. The other is that I think Vince Marr, who is from Brown University, came out to evaluate Seattle, and he said he knew how Seattle would approach any problem because the way it's approached problems in the past, and he sort of said Minneapolis and Seattle are the same. And what somebody speculated was that it's a Norwegian influence. I have no idea if that's true. But it is sort of a culture in our city that you work together.

It's expected that you work together. It is not expected that the at-risk community and the health department are enemies. It is expected that you will sit around the table and work out a problem. And I don't think any of us would have our jobs very long if we didn't approach it that way. I will tell you a simpler answer is that Act-Up started needle exchange when we wanted to and we couldn't. Our politicians were not ready to give us the go-ahead.

Act-Up started it, helped us by pushing it into the

limelight and then the people we work for said, my goodness, the health department better do that. So it was really very useful that they called attention to it and got it going. And those kinds of partnerships where they can do things that I can't because I'm government have worked extremely well. We don't agree on everything. I will certainly not go that far, and we certainly have our critics, but I think we've all kept our eye on the prize.

What we're out here is serving people, preventing cases of AIDS and serving people with AIDS, and that goal has been kept out ahead of our own personal turf with a lot of backroom yelling at each other that we don't do in public.

DR. J. ALLEN: Question for John Watters. Was your program was funded primarily or in total through the National Institute on Drug Abuse; is that correct?

DR. WATTERS: Well, I don't know what you mean by my program.

DR. J. ALLEN: Okay. Your service demonstration project.

DR. WATTERS: Initially that was funded by an RO1 for one year, and then that was picked up by an additional RO1 from NIDA for three years, and then the demonstration

projects kicked in simultaneous to that second RO1. That funded the bulk of the program. That lifted the level of effort from seven outreach workers to about 23 outreach workers.

DR. J. ALLEN: Okay. When you say it was funded by an RO1, was it funded primarily as an investigation, that is a study right from the beginning or was it --

DR. WATTERS: Yes.

DR. J. ALLEN: It was not funded primarily as a service --

DR. WATTERS: Correct.

DR. J. ALLEN: -- project? Okay.

DR. WATTERS: It couldn't have been by NIDA. And right now the NIDA demonstration funding will expire in August, and that will be the end of about two-thirds of those positions. The remainder, most of the rest of those are funded through a service mechanism through CDC.

DR. J. ALLEN: And is there adequate support for that through the CDC programs?

DR. WATTERS: No, it picks up only a small portion of the program, maybe about 25 percent of its operating costs. So the service component will shrink commensurate,

and the funding mechanism is not at all secure. So the funding, that mechanism is through December, and it's unclear what will happen in the next calendar cycle for CDC.

DR. J. ALLEN: Are you having good success in your program in terms of bringing people who have not before been into treatment into treatment?

DR. WATTERS: There is some success there. For the most part, people that we identify as HIV positive who have not been in treatment are suddenly interested in drug treatment. There has been increased interest in drug treatment because of AIDS awareness. At least in the self-report data, over the time frame that I've shown you, there is a significant change in the orientation to willingness to accept treatment if offered the next day. But in San Francisco, as in most U.S. cities, there are waiting lists to enter publicly funded drug treatment programs although priority in San Francisco is given to HIV sero-positive individuals.

DR. J. ALLEN: To run a citywide program in San Francisco, can you just back up and tell me about how many injecting drug abuses, drug users you have?

DR. WATTERS: It's a city of about 740,000 people,

and depending on whose crystal ball you stare into, you get ten to 16,000 IV drug users.

DR. J. ALLEN: Okay. And to run a citywide outreach and education program to bring them into treatment, not to fund the treatment itself, but just the education and outreach programs, what would you estimate that would cost annually?

DR. WATTERS: Well, I don't think, if you'll allow me to invert your question?

DR. J. ALLEN: All right.

DR. WATTERS: I don't think that's an appropriate goal. Most IV drug -- well, let me not say most, but a substantial minority at this point in time according to our data are still not interested. It was the majority in 1986, about 60 percent said they would not accept treatment the next day. By early '89 that was 40 percent said they would not accept treatment. So there has been a shift in orientation, but for that very large population of IV drug users who are not oriented to present for treatment, it would be a waste of time if that were the objective of your intervention.

On the other hand, as our data suggests, you can have substantial impact on at least certain domains of risk

behavior in a relatively brief period of time. I'm not sure I answered your question.

DR. J. ALLEN: You did in part in terms of focusing on the services that you believed were needed. You didn't --

DR. WATTERS: Well, that's not to say that drug treatment isn't needed. It's very important. It would be part of a comprehensive approach, and outreach program does, in fact, refer many people to drug treatment who are interested. I would say -- you're asking the question what's the level of effort in order to operate this program, and that --

DR. J. ALLEN: Well, I guess to get most directly at what I'm asking. There has been a large increase in the amounts of money available through the ADAMHA treatment programs, through the block grants primarily. There has been no specific money targeted for the outreach prevention, HIV prevention/education side of it, which I think there has been, you know, through your study and others, there have been a lot of obvious information that it's very effective and very useful. I'm simply trying to isolate that as a component were it be funded separately or were we to try to develop separate monies. What for example in a city the size of San Francisco might you need in order to operate that on

annual basis.

DR. WATTERS: Well, that's a difficult question to answer because it's a component of a program with many objectives.

DR. J. ALLEN: Yes, sure.

DR. WATTERS: But I would be making numbers up.

DR. J. ALLEN: Okay. Well, let me turn it around and ask it a different way. If California receives block grant monies for this, are they amenable to providing this kind of outreach service also and education?

COMMISSIONER ROGERS: John, why don't you just make up a good big figure for him.

DR. WATTERS: $300,000. $300,000 to refer people to waiting lists.

COMMISSIONER DES JARLAIS: This follows up a little bit on Jim's question. But you clearly have shown large changes in HIV risk behavior around cleaning needles with bleach and increased condom use. Are you seeing new questions develop around potential transmission? I know in New York we are seeing increased crack use among our IV drug users and a greater potential for heterosexual transmission; that the epidemic in New York certainly among IV drug users is

changing over time, and I would like to know what you are seeing in San Francisco around potential sort of changes in HIV transmission behavior in addition to the positive ones of increased bleach use and increased condom use?

DR. WATTERS: Like so many things we see in San Francisco, the first have been seen in New York. Play, for example.

(Laughter.)

DR. WATTERS: But we're seeing a similar trend. Crack use, of course, has become epidemic. When we began in 1985 there was no crack use in San Francisco. Now it's a very important part of the staple diet of many IV drug users. Many IV drug users who formally injected cocaine or used cocaine in combination with heroin are now smoking rock cocaine. In one drug treatment clinic where we used to recruit research subjects, it became very, very difficult to find IV drug users because they had been displaced to a very great degree by crack cocaine smokers.

So we are seeing that, and again I want to stress that although we see self-reported change and improvements, and they are statistically significant with respect to condom use, it's still at a relatively low level, and if you take

the data at face value and assume that the self-report are correct and accurate, valid reflections of what's going on, then you have plenty of room for sexual transmission because of the relatively low rate of adoption of condoms in this population, and sero-conversion as a result of shared needles may have come very close to a standstill but probably not along the sexual line. And only because we have a relatively low reservoir of infection in the heterosexual population have we not seen, in my view, in my opinion, have we not seen that take off as a result of sexual transmission. So we are seeing both, and I think that Andrew Moss' data suggests the same basic pattern.

DR. VAUGHN: I know in Newark which is right across the bridge, we've seen IV drug abuse continuing in the older IV drug abusers. They may smoke crack occasionally, but they go back to the old habits. But the crack epidemic is a much greater problem in the younger patients, the teenagers and younger, and then we've also seen especially in older teenagers and the patients up to 20's and early 30's, a tremendous increase in secondary syphilis. Just this year, I've admitted already 12 patients to the hospital to treat for secondary syphilis and concomitant HIV disease.

So the heterosexual spread and the concomitant other STDs and everything are a tremendous problem, especially in the younger patients that we have.

CHAIRMAN OSBORN: Other questions from the commissioners? If not, let me thank you, especially, as several of the commissioners have stated, your testimony was particularly helpful in inspiring us as well as instructing us. And I hope we can make, we're going to try hard to make a difference insofar as at least the care bill is concerned, and you may be interested to know that those commissioners who can are going to go down and try and talk to the Senate leadership this afternoon. And I plan to try and quote some of what you've said directly. So let's hope that we can keep it moving.

Thank you. Let me suggest to the commissioners that we can leave our things here. We'll have a reasonably quick lunch and come back and try and finish our business by quarter of two in order to go down to the Capitol.

(Whereupon, at 12:30, the meeting recessed, to reconvene at 1:20 p.m., this same day.)

A F T E R N O O N S E S S I O N

CHAIRMAN OSBORN: Let me try and get us a bit organized for a few minutes. I think we're set so that at quarter of two we will catch taxis down to the Capitol. David and Belinda have another engagement for the moment and will probably intersect with us at 2:45 when we go to Senator Mitchell's office. But we will start at Senator Dole's office and Carlton is going to meet us down there and take us through the mazes of the Capitol to get there.

I told some but not all of you, it is my understanding that not only with Sheila meet with us, but Senator Dole will, too.

COMMISSIONER KONIGSBERG: I'm glad I've got my sunflower on.

CHAIRMAN OSBORN: Yes, I am too. I need to race back and get my oval office pin, but I don't have time.

COMMISSIONER KONIGSBERG: This is a well spent $3.50. Can I bill it now or --

(Laughter.)

CHAIRMAN OSBORN: And it is our tentative information that Senator Mitchell as well as his chief staff person will meet with us at 2:45. So we should be in a position to

convey our sense of urgency to both of the Senate leaders and Senator Kennedy will not -- and Kennedy and Hatch will not be there, but are very, very enthused that we are doing this. And Senator Kennedy is going to be calling in at 3:30 to his office to know how it went.

So I think that altogether we may be in a position to help break the logjam. It sounds like there is at least some possibility of it from talking to the Senate staff on the phone just now. I thought -- I don't remember that we have specific other agenda items, but I thought that what we should perhaps do is take a few minutes among ourselves to sort of debrief about the things that we found to be the most, either the most disturbing, or the most amenable to recommendations, as the beginnings of some material for another report in the context of things that aren't working as well as they might or aren't working at all, in the context of the biomedical and behavioral research thing, not that we need to write any report or even get language, but more the things that struck the different ones of us while listening in the last two days.

I, for instance, think that we should not leave it uncommented that there is actually a five month gap in the

ACTG activity because of a switch in computers in the middle of a hot epidemic. I mean it's that kind of thing that I think needs to be an example of what I think of as sort of business as usual approach to a major developing health care dynamic. Don looks like he doesn't think that's a good way of putting it.

COMMISSIONER DES JARLAIS: Well, having been in a crisis mode for eight, nine years around AIDS now personally, that's not that unusual that you get a glitch like that, and --

CHAIRMAN OSBORN: The only trouble is that is 382 million out of the total 800 million invested in AIDS research right now is on hold for five months. And in the meantime we're hearing about how the community research initiatives couldn't be funded here and there and so forth at one-tenth or less that level. It's more as an example of a disproportion in the system, sort of the big stuff keeps moving with its own momentum, and new and small things can't -- you know, I don't mean it be a free-standing thing. But it's more -- I was hoping that facts like that that snagged other people's attention.

If we collect them, I think we can weave them into

a sense of how we have to start doing business other than as usual and get out of the crisis mode, and lapsing back and forth.

COMMISSIONER DES JARLAIS: Okay. But I think the ACTUs have not been business as usual. They've had glitches. They've had major problems and such, but they really have not been business as usual for drug development. They've been a radical change in the way NIH and FDA have gone about approving drugs, and I think those agencies could really be complimented on that because for no other disease have they attempted to set up a rapid drug development program. As slow as it's been, it's still been rapid compared to everything else, and I think Fauci's point that it's NIH directed rather than drug company directed is also important. So I don't feel right about criticizing them on their computer glitch.

CHAIRMAN OSBORN: Okay. Please, maybe that was a bad way to start. I was trying to collect all the positives and negatives, and hope that in the longer haul, we'd be able to weave them into an appropriately constructive context. I think everything you just said would be the background that I would want to emphasize. But rather what I'm concerned about

is that we sat and listened to things that aren't right, and it's easy enough to walk away and let that over-arching sense that things are going better dilute our attention or leave us forgetting that there were some things --

I was just thinking right now we could perhaps make sure that we had, while our memories were quite fresh, that things that troubled us particularly could be brought out so that they could be part of a balanced report later. Because at least the way I'm inclined to think about things, I tend to end up being both optimistic and somewhat trying to stay in the constructive mode, and forget these things that troubled me at the time. I don't know. Maybe that's not a good way to go.

COMMISSIONER DES JARLAIS: Well, I think part of the reason ACTUs are having problems is that they are new, and that you certainly wouldn't -- given two years, three years of hindsight now, you wouldn't do it the same way. But part of the reasons they have gotten bogged down, that they haven't enrolled the right number of subjects, they haven't enrolled the right categories of subjects, is because they really didn't know what they were doing when they started out, and they were under a non-business as usual method,

which is not to forgive their sometimes rather large mistakes.

COMMISSIONER S. ALLEN: Well, I agree with you, Don, but I think we ought to speak along the lines of what June is saying about some major modifications and say this is a good system that's beginning, but now let's stop, evaluate, and encourage major modifications in the way things are done. And especially what concerns me the lack of infectious, opportunistic infections, the way that that is the lack of emphasis in that area through the ACTUs. And so I think we should make recommendations saying we are pleased that they are broadening that, but that is not enough.

And a concern that I have of the evaluation process and the accountability, I think we need to really say, okay, let's stop midstream and talk about accountability of what has been done so we can make it better. But not to bash the whole system. And then along the lines of the CRIs, I think we need to say that's not enough funding. That is not enough, and it's not broad enough. And that's really something that we could really concentrate on. That's my feeling.

COMMISSIONER GOLDMAN: Along the same lines, I think one of the conclusions that I think that the hearings

and the testimony that we had over the past two days, I think, demonstrates and today, in particular, but I think even what we heard yesterday as well, is the synergistic effect of care and clinical trials, and the potential disruptive effects when those two are attempted to be divorced from each other and that neither of them become more effective. And yet I think the right word is, in fact, synergistic effect of care and trials together, and I think we can make some statement to that effect in some way that would, in fact, suggest that care and trials go together, and that both of them complement each other, and that there is that synergistic effect.

And that in terms of future organization and development and funding, that just as Tony Fauci indicated, when they begin to look at the next cycle of funding for ACTGs, one of the factors that I think correctly they're going to be looking at is the enrollments of minorities and other sub-populations. I think one of the other things that also ought to be looking at in terms of quantifying what kind of funding various ACTGs get is the extent to which the care and research have, in fact, been put together in a synergistic fashion to complement each other.

And I think the second area is that I think that while they have given lip service to removal of what I call artificial barriers to entry of one kind, and we heard from differing communities as to the differing kinds of artificial barriers, I think essentially the point that Dr. Krim made in one of her recommendations in that the idea that perhaps, at least in this arena, the idea of trying to maintain the purity and homogeneity of the protocols and studies in terms of doing them with a small number of homogeneous groups, maybe that's appropriate in some circumstances. But it ought to be a focus of that nature which directs, which necessarily directs, 90 percent of a funding of trials. And I think if we, those two areas, it seems to me, encompass the concerns, in part, that some of us have felt, and that's what I came away with.

CHAIRMAN OSBORN: The other thing I think is perfectly obvious is that the sudden discontinuity of demonstration projects when they have demonstrated themselves to be effective is a grossly disruptive thing. And I think when we make our next report, that probably is going to have to be an item in it because I think that is about to happen, and the discontinuity in staffing. It's one thing to

discontinue a failed demonstration project. It's another to let one build to a high level and then suddenly decide that it should be thrown to unknown funding source without specification, without advance planning. And clearly, again, that's a kind of thing that has no business in an escalating, even a steady state, it would be disruptive. In an escalating situation, it has disastrous potential, and I think that may turn out to be a big dynamic.

COMMISSIONER KONIGSBERG: Yes. I obviously strongly agree. There's a couple of things I might just kind of throw in that conversation. I suppose a case could be made for at least gently trying to remind the Robert Wood Johnson Foundation of the same issue. That's a little more delicate because I mean I really don't think foundations are in the business for ongoing funding of health care. But I know that issue has come up before.

And the other is the demonstration projects are fine, but I think it's been alluded to before that this is somehow has got to be folded into ongoing financing for care. But there is no doubt that the demonstration projects have got to be extended or there's just going to be some communities in a real mess.

DR. J. ALLEN: I think it's important to realize that the term "demonstration project" is a very broad wastebasket kind of a descriptive term. And there are several different aspects to it. The HRSA demonstration projects that Patricia McInturff was referring to, in fact, we really are trying to get rid of the term "demonstration project" and move them more into service grants. And I'm not sure -- I'm going to have to talk with some of the HRSA people and find out exactly what happened in this one instance. Apparently, they are coming up money that's considerably shorter than less than what they had anticipated. It's not really, it wasn't a plan -- if I understand it correctly, it wasn't planned.

CHAIRMAN OSBORN: Yes, but I think that happened across the board, Jim, because I was at the Robert Wood Johnson Foundation summary meeting just a couple weeks ago, and those tend to be the HRSA cities.

DR. J. ALLEN: Yes.

CHAIRMAN OSBORN: And I think it was true everywhere.

DR. J. ALLEN: But what I'm saying is I don't think it was an intentional. It wasn't a plan we're going to stop

all the money at this kind of a thing. I've got to go back and get some additional information. And that's a very different situation than what happened with the NIDA demonstration grants where they did do what you just alluded to. They said we've got the three years of money out there. It's being phased out, and there was not intent or plan to continue it, and we are taking steps at the present time. I think it would be fine for the commission to address it.

My feeling is that just looking at it very quickly that the very least demonstrations have got to go on for about a five year period of time. I think it takes one year to get things up and running, at least one year to collect data, and the third year really is the period during which you're analyzing it and making some decisions.

And I think you've got to build in at least a one year, if not two year, phase out. And the NIDA demonstration grants, probably NIDA is not the appropriate continuing source, but then the question becomes what is the appropriate continuing source? Don's raised the point, however, of the need for continuing collection of information, which I think Watters did also. And that's a separate issue. We're going to need to look at that as opposed to the need for continuing

services in their own right.

CHAIRMAN OSBORN: Scott, did you have something to add?

COMMISSIONER S. ALLEN: Yes, I sure did. Out of the 21 present demonstration projects, 17 will be continued, which is very concerning, which is, I think. There will be some continuation process, I believe, of 17. But out of 21. And it is depletion of funds. It's not what was hoped for. I think that's the case. Do you know if that's true or not?

DR. J. ALLEN: You're talking about the HRSA?

COMMISSIONER S. ALLEN: Yes.

DR. J. ALLEN: I'm going to have to go back and check.

COMMISSIONER S. ALLEN: Okay. I think that's the case, but also it's far more complicated than that in that we're talking about any money coming down coming through block grants, and that kind of situation is very concerning is well. So we've got, there are several different issues along that line.

DR. J. ALLEN: Yes, and the problem is that you get involved with a lot of politics in that.

COMMISSIONER S. ALLEN: It's a political world.

DR. J. ALLEN: Yes.

COMMISSIONER DES JARLAIS: I think before we issue a report we're going to need to do some real careful thinking and writing as to the role of research in the AIDS epidemic. That because it hits certain groups first, there were basically two ways you could do things. You could do it private organized gay men's health crisis way of doing it, or you could do it at the federal level through research, and that that was really at the federal level the only way you were going to do it is if it was somehow a research project both at CDC, ADAMHA, and NIH.

That was really, I think, lucky in the sense that there was an awful lot more creativity coming out of the research studies than you would have gotten if you had gone to HRSA first to set up AIDS services. We are now reaching at a much later point in the epidemic. I don't want to call it a mature epidemic, but we're reaching a later point where we need to split off some of the services from research, but we still need to continue doing research. The epidemic is changing. It certainly hasn't gone away, and we need to keep the creativity that came out a lot of those research projects going. But we have to realize that we used the broad term

research and demonstration and such to get services out to people and that we can't simply just remove those services simply because they were funded under research.

COMMISSIONER KONIGSBERG: Let me see if I can continue to work on this just a little bit. I think one buzzword with the so-called "demonstration projects" is perhaps "transition." I think that what I would like to see happen is that these projects transition into something ongoing, perhaps funded by something like the Care Act that would incorporate and does, I guess, to some extent, what was found, what amounts to a type of health services research.

And I know that that's being evaluated by Brown University and some others. I have a little bit of a long-standing concern that we not create more -- I may make somebody made with this, but I'll go ahead and jump in -- that we not create more community health center type scenarios, how that's gone over the last 21 years, 22 years, whatever it's been. And I'm a little bit concerned that that could be the case. I would like not to see that happen with anything else because what this could do is wind up taking a life of its own. You'll have an organization of the national association for AIDS service delivery, whatever, and then it

gets out of context with the whole care delivery system.

And I think if there is anything that -- there's a number of things that Robert Wood Johnson Foundation and HRSA did right at the front-end as opposed to community health centers didn't do right at the front-end, which is build community-wide partnerships. And I know that didn't work perfectly in every area. It probably worked better in Seattle than some. I'd like to think that we did at least about 75 percent well in Fort Lauderdale, which for us exceeded anything else we did. And only now do you see in the last five or six years community health centers coming back into this and now saying, oh, we've got to build these bridges.

Now, again, not everybody is going to like those kind of comments, but I think we need to really make sure that these projects transition into something that is lasting, that will build upon the strengths that the innovation had, that will use some of the research that's been done on that, not the real hard science, but the health services research which, I guess, is a type of hard science, but not quite like -- yes, it's a hard to do science, but one that's not done enough.

I don't know if I'm making myself clear, but one thing, in spite of all this there is no doubt that just cutting them off is just flat wrong, inhumane, immoral, unethical, whatever you want to say, bad.

COMMISSIONER KESSLER: I wonder -- I'm not sure this will be helpful, but I have a thought about whether or not we at the commission or the commission in conjunction with another group, either the inter-governmental group at GW or NAN or somebody could do an audit on the downsizing and its effect in RWJ, HRSA, NIDA, whatever, and come up with some real numbers. I mean I think the doctor from Seattle was helpful to say, you know, you're losing 30,000 meals. What is it that the downsizing in terms of personnel, programs, services, and so on because I think that makes big volumes in this sort of the war on AIDS.

The first time, you know, you're conducting a war without supplying any extra tanks and extra artillery and militia. That may be very helpful to the public and to the editorial writers and so on if we can get that data because a lot of it is hidden, but I think it is real. And it has a real impact on individuals with AIDS, and it has a real impact on the human resource drive for the future. I'm very

concerned that we're going to send a signal out that this is not an industry, this is not a cause or not a concern you want to go near because it's very unstable. You could end up with a six month job.

And yet we know people have made careers out of this. It's not necessarily bad because they've devoted themselves 80 hours a week in their careers. But we might be sending a new signal that will make it even harder to get people involved in AIDS work in the future.

CHAIRMAN OSBORN: Jason has just given us the signal that our cabs are downstairs so we need -- if there are quick comments, we need to make them. But I think maybe one of the things to do is -- I don't think there is any sense, at least I have no sense that we want to do a report quickly. What I wanted to do was to get us at least started talking about what we had heard so that we can then go ahead and think our own thoughts and perhaps even write some summaries, but could collate. That kind of suggestion, I think, is exceptionally useful. I found that Seattle presentation very helpful as well. Don.

COMMISSIONER DES JARLAIS: One additional comment I want to point out that we're starting to see the pattern

repeat. That three years ago there was a massive move to get people into the NIDA demonstration and the HRSA demonstration. Today and yesterday we saw a lot of movement to let's get more women, children, adolescents, blacks, involved in clinical trials research. It's very easy to then say well, in three years there may be good reason to downsize clinical trial research. You know there could be a lot of good scientific reason for doing that. You will then have enrolled all these people. Their primary clinical trial will be coming. Their primary medical care will be coming out of research dollars, and then you may want to be downsizing that research dollars. What are you going to do with all those black women and children that you have enrolled in clinical trials if you have to downsize clinical trial research when clinical trials is giving them their primary health care?

So that we can see the pattern coming again. We're seeing it with HRSA and NIDA demonstration research. Clinical trials research also. That money is not going to expand indefinitely for the future either.

COMMISSIONER S. ALLEN: One quick statement is that I think we cannot forget the staff, the nurses, and the paperwork and that support system, and may need to incorporate

it in the personnel issues of research staff.

MS. BYRNES: Can I give you one quick announcement, too? I just got off the phone with John Ward from the CDC. He wanted me to share with all of you that next Wednesday and Thursday is the CDC Advisory Council meeting in Atlanta. They're specifically looking at prevention issues around drug use and the transmission of HIV. Anybody who is interested in that, that's as sketchy as it is for me right now. If you want to go, he's faxing me an agenda, but it might be very pertinent to some of the things we just heard over the last two days.

CHAIRMAN OSBORN: We're adjourned.

(Whereupon, at 1:45 p.m., the meeting adjourned.)