TRANSCRIPT OF PROCEEDINGS

NATIONAL COMMISSION ON

ACQUIRED IMMUNE DEFICIENCY SYDROME

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Pages 1 thru 157

Washington, D.C.
March 16, 1990

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Washington, D.C. 20002
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NATIONAL COMMISSION

ON

ACQUIRED IMMUNE DEFICIENCY SYNDROME

FRIDAY, MARCH 16, 1990

9:15 a.m.

Pan American Health Organization

Meeting Room B

525 23rd Street, N. W.

Washington, D. C.

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COMMISSIONERS PRESENT:

JUNE OSBORN, Chairman

DAVID ROGERS, Vice Chairman

DIANE AHRENS

SCOTT ALLEN

HARLON DALTON

EUNICE DIAZ

DONALD GOLDMAN

DON C. DES JARLAIS

LARRY KESSLER

CHARLES KONIGSBERG

BELINDA MASON

EDWARD D. MARTIN (Representing Richard Cheney)

IRWIN PERNICK (Representing Edward Derwinski)

JIM ALLEN (Representing Louis Sullivan)

STAFF PRESENT:

MAUREEN BYRNES, Executive Director

CARLTON LEE, Chief Liaison Officer

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C O N T E N T S

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P R O C E E D I N G S

[9:15 a.m.]

CHAIRMAN OSBORN: Let me call the Commission to order.

I understand that two or three of the Commissioners will be here shortly, but I think we probably ought to start, in the interest of time. And let me make a couple of inquiries while we're getting ourselves launched here. I've talked to some, but not all, of the members of the Commission, but I get the sense that we would all be less tense about our late afternoon schedules if we ended no later than 2:30, but possibly even by 2:00, depending on how we can get work to go.

I know that when I have a tight schedule, I start thinking about it rather than what I'm doing toward the end. I mean, if we loosen people's constraints a little bit, that may be helpful. So let's aim for 2:30, at the latest, and even sooner if we were all in agreement about some things. I don't think that's unrealistically, actually, because we've got things that we can do quite efficiently.

We'll get to the working group summary as a first item of business after I take a very brief period--I don't at all intend to take the time that's on the agenda there--to

bring you up to date on a few things that have been happening on the biomedical side of things, which I had said that I would do from time to time and which I thought would be of general interest. I will do it very briefly, but we can pursue anything that people are interested in.

As a general plan, then, we have three tasks, I think--maybe four, if you want to count it--that we definitely want to accomplish today. We want to finish the discussion from yesterday of the report that Chairman Ahrens and her group had put together and which has been discussed at quite good length.

We want to talk about the next working group report, which we inverted, and I think that we can get that discussion started. It may go very smoothly. If, however, we run into the kind of situation that we did yesterday where some redrafting would be of help, we may break into that discussion and have some redrafting done while we then turn to a major additional item, which is both dates for future meetings, sites for visits and discussion of that in the context of meetings, and agenda and work plan issues that we have begun to discuss.

I think those are very important goals to achieve

during this meeting, and we, as we mentioned yesterday, had purposely scheduled the work for today to be largely inclusive of those issues because it has been so packed in what we've done up until now that we haven't had a chance to think about those things as a group.

So those are my goals. I would hope by the end of the day that we would have proceeded to an appropriate point in all of those matters. Some of you have made inquiry about the financial circumstances, and so on. I think at lunch I'll ask Maureen to bring us up to date on that, too, I think in an informal way today because there will be some formal material available at a later date, but we will touch on that as well.

Okay. Does that sound reasonable to everybody as a general plan of work?

Belinda, I was saying that we will see if we can try and finish up by 2:30, at the latest, and possibly 2:00, in order to loosen up the deadlines that people are facing.

COMMISSIONER MASON: I'm sorry, June. I got caught in a crossfire. It was Don Goldman's fault.

CHAIRMAN OSBORN: It was Don Goldman's fault?

COMMISSIONER MASON: Yes. I'm really sorry. I

lost my watch this morning, and that's why I'm late. I'm so neurotic, I couldn't leave until I found it.

CHAIRMAN OSBORN: Did you find it?

COMMISSIONER MASON: Yes.

CHAIRMAN OSBORN: Good, good.

COMMISSIONER MASON: It made my day. It put a whole new light on the situation. It's going to be a good day after all. I found my watch.

[Laughter.]

CHAIRMAN OSBORN: Well, it's very pertinent because I was just saying that for people who were feeling some time pressure in travel, we might try and finish by 2:30, at the very latest, and even 2:00 if we were all well behaved--.

COMMISSIONER MASON: Okay.

CHAIRMAN OSBORN: --in order to take some of the pressure off people who have tight connections.

David.

VICE CHAIRMAN ROGERS: Could I add one other thing? June and I talked about it this morning, and I think with the general discussion we'll try and move in, also, to all of the suggestions that we discussed yesterday about issues you'd like to see, how you'd like to see priorities set, moving

toward the development of that work plan that we've agreed will be coming back.

CHAIRMAN OSBORN: Okay. Under what is billed as the Chairman's report, what I wanted to do was to--rather than billing it that way, you might want to say my individual report because one of the things that we talked about early on was trying to keep track of things both at the Institute of Medicine and in the U.S. Public Health Service; in particular, the FDA and NIH. There have been a series of interesting meetings that I thought you might like to know had happened, and then we can discuss the content to the extent you like.

First of all, so far as the Institute of Medicine is concerned, there are, I think, six different activities that they have going on in various stages of activity or completion dealing with AIDS, and one of those had been an oversight committee, an AIDS oversight committee that was a continuation of the Confronting AIDS group from 1986. There was a group that followed along and put in an updated report in 1988, both of which have served as a very valuable resource, I'm told from people all over the world, actually, but certainly in this country.

Dr. Ted Cooper had been chairing that, and they had continued the existence of the AIDS Oversight Committee until our Commission got established. This kind of a Commission was one of the major recommendations of the original report and it was reiterated in the '88 report.

I was somewhat startled. I guess we should all be pleased that when Maureen and I then met with them for what I thought was going to be an ongoing set of meetings to keep in touch between our Commission and IOM activity, they happily announced that they were now dissolving the AIDS Oversight Committee because we existed and they were very happy with us.

So the Institute of Medicine's AIDS Oversight Committee is no more. We have, in that rather formal way and in several informal ways, been tossed the ball, as huge as it is, in all of the kinds of areas that we've been focusing on, actually. I mean, it has all happened. It's just that we didn't know that's what was happening.

In the areas of health care, access to care, a lot of the social dynamics of the epidemic, the human issues--all these things that we have been talking about, we are now looked to by the Institute of Medicine for the leadership in that area. So it's good news; a little awesome news at the

same time. So, that is one set of meetings, and that dispenses with one committee.

IOM does have several other committees, and they have very persistently and devotedly asked for participation and we've been trying to do that. Maureen, sometimes Carlton, and I have tried to be at most of the stuff that has gone on, and they have been making some good progress that I wanted to tell you about.

Now, there's been a new committee formed at the--well, let me go in order here. The AIDS Program Advisory Committee to the National Institutes of Health had one of its meetings. Each year, they do kind of an updated overview of what they stand and what they're doing, and they did that again on December 11th and 12th at the NIH.

Out of that comes mostly a base-checking so far as they're concerned--where do they stand, and does everybody who is listening think that they have been covering bases pretty well; are there things that aren't being discussed in the research planning that's going on, and so forth.

That kind of activity is more for an internal cross-check for them, and I don't think had--at least the portion of that that I heard didn't have anything that you

wouldn't already know from either press coverage or journal coverage or our discussions. So, while it did happen, I don't think that was so newsworthy.

There were a couple of meetings dealing with the so-called parallel track that are of considerable interest, and those were the ones I thought you'd like to know the most about.

First of all, the FDA has created a new Anti-Viral Drug Advisory Committee, and that had a meeting a few weeks ago in which they reviewed the data. Some of you have heard the complaint that the data concerning early intervention therapy for people with early symptomatic disease and then for people with asymptomatic disease--that those data had not been published, and indeed still have not been published in readily accessible form.

But in an effort to try and bring that process along faster without journal publication dates in mind, there was a first meeting of that group, of the Anti-Viral Advisory Committee, back in January, I guess it was, in which those data were reviewed, along with the early indication that there was a very low level of carcinogenicity of AZT--I'll be happy to talk about those things--but then mostly the data

concerning the effect of using AZT either early in symptomatic disease or in asymptomatic disease.

In addition, at that meeting for the first time the earliest experience with didioxyinticine, DDI, was presented. And following right along from that there was a meeting at the beginning of this week, now put on by the Institute of Medicine Drug Vaccine Roundtable on AIDS that was created to try and make sure that was moving along.

Those data were re-presented with quite a bit more information and, of course, with the stimulus of last weekend's news stories, and I thought you might be interested in a summary of where that all stands from the vantage point of those two discussions now, both the FDA discussion and then this Monday-Tuesday meeting at the Institute of Medicine. I'll get back to that as the main thing I thought you'd like to hear in more detail.

In addition, there is a vaccine advisory group. The Institute of Medicine has one going; there's an FDA one. The Institute of Medicine had a very detailed meeting, a very intense, detailed scientific meeting about the status of AIDS vaccine research not too long ago, out of which came the general conclusion on the part of all there that while there

has been some progress with the simian model, that progress is very limited.

And instead of being back to the drawing board, we're on a new drawing board, but no further than that in terms of vaccine development. Again, if you're interested, I'll be glad to talk that through a little bit more. But I thought for sure you'd be interested in a brief summary of what was Monday and Tuesday, and let me just do that and then, please, I'd be happy to talk in more detail about some of the other things.

So far as Monday and Tuesday were concerned, the experience--well, first of all, the data with AZT which have been dealt with in the press have been well dealt with in the press. There is good evidence that you can extend the well-being of people with either early symptomatic or, even more so, asymptomatic HIV infection by the early deployment of AZT.

More interestingly in some ways, using doses that are about one-third of what had been the dose that was experimented with and prescribed as sort of the legitimate dose for treatment of very symptomatic people--that's about 15, 1,600 milligrams--going down to 500 milligrams a day, still spaced in fairly short segments, but nonetheless at a

much lower milligram-per-dose level and, of course, dollars-per-dose level, you could achieve not only the same effect, but markedly drop the toxicity.

It doesn't eliminate the toxicity, but it brings it down to a level where probably AZT is more tolerable to more people. It very substantially cuts into the severe hematologic toxicity which had many people who could otherwise tolerate the drug having to have repeated blood transfusions in order to tolerate it.

Of those roughly half who could tolerate the drug, about a quarter would end up having to be repeatedly transfused to overcome the toxicity for the bone marrow. That actually has also been helped and is en route to being helped by the development through biotechnology of a synthetic substance called erythropoietin, which is now on its way, is licensed for use in people with renal failure, and that process is moving along so that it can be available to overcome the bone marrow effects that both HIV, but also AZT have.

So, while that is less far along in terms of recommendations, it is happening, and so for a couple of reasons AZT is becoming more usable in terms of its toxicity

and ways in which it can be used.

COMMISSIONER ALLEN: I was wondering, was there any discussion about the potency level and the range of how long it remains potent?

CHAIRMAN OSBORN: There's been a lot of discussion about the wearing-off of the AZT effect. From my vantage point as a once-upon-a-time virologist, the most important part of that discussion is one of the development by the virus of resistance to the drug, and that is something that I think should concern us.

There are fragmentary bits of information right now, but what they say is that in people who have been on the standard kind of AZT for serious disease, in a couple of sets of studies if you take the virus from them late in treatment and when they are not doing so well on AZT anymore, all of the doses needed for those virus isolates to inhibit them will have increased greatly.

So, in essence, the amount of drug necessary to inhibit the virus is now much greater, which is a definition of resistance on the part of the virus itself. That has not yet been closely correlated with the observed clinical effect that if you have somebody on AZT for a couple of years, which

is between one and two years, they stop having beneficial effect from it to the extent that they had before or maybe altogether, which is what you're asking about, which has been referred to as clinical resistance.

The correlation is only a correlation, and whether that is occurring because the virus is resistant or because you've worn out something else is not yet established. So the phrases are a little bit too close in connecting them. It may turn out that that's the mechanism, but that hasn't been established so well.

A thing that worries me a lot, especially if DDI should turn out to be less optimistic than we think, is that even in people on asymptomatic or early symptomatic therapy, if they are in treatment for a long period of time and you start taking virus back from them, to some extent consistent with dose but not invariably, you'll start finding two or three out of ten people will now have virus that has increased its tolerance, if you like. It takes more AZT to inhibit it by a factor of three or five than it did before.

We're playing so close to the tolerable human levels in terms of the initial dose that these things are of some concern. The ongoing argument, therefore, is a very

important one, and that is there a finite interval during which you can use AZT so that if you moved it forward to the asymptomatic stage, you would have run out of its usefulness just about the time you needed it. That's a terribly important question, especially now that the recommendation is to start using it early.

The answer to that question isn't known, and that's where the action is, if you like, at the moment, and I am one of the people that worries a lot about it. Jim may want to make some comments, too, because since my background is in virology and anti-virals and, to some extent, viral immunology, I am very concerned about that.

Whether we are buying enough time in using it early to make up for losing it late, if that's what the tradeoff is, is a very important argument, and it has been going on in these fora, but it needs to go on some more. The data are accumulating to help answer that. We need to find out whether that clinical resistance and viral resistance are connected.

It sounds like they ought to be, but I should tell you that microbiologically there are a lot of examples in which--tuberculosis, for instance; tuberculosis will develop

resistance to the anti-tuberculosis drugs, but it also attenuates as it does so and becomes less of a disease-producer. There are examples of any kind of association and they just haven't been established right now. So those are very lively and important issues.

Let me tell you about DDI, and then I'd be eager to respond to more of those things as we go. With DDI, what was done was the beginning--and you've read about it in the context of parallel track. It was, in a certain sense, nothing new for FDA, except it's bigger and it's more systematized.

It has been true for a long time that FDA could have compassionate-use protocols for people to have access to drugs that were still experimental. Now, let me just say right off there's an enormous fiscal impact of doing that that we can get back to because that is more our business in the technical sense.

But, nevertheless, it's been possible for a long time for people to have access to drugs that had not yet been licensed. The parallel track mechanism was devised because partly people couldn't tolerate AZT or DDI and the experimental drugs or they couldn't get close to a medical center that

was running an experimental drug protocol and they had worn out their AZT.

There were a lot of things that made it hard for everybody who would like to have access and who couldn't take advantage of AZT to be able to get access to DDI. So Bristol Meyers sort of facilitated things--they are the makers of DDI--by volunteering to help establish a so-called parallel track protocol in which clinical trials are designed the way they always are, and then in parallel to that people who didn't qualify for these strictly-defined clinical trial sets--and they are strictly defined--could nevertheless have access to what--it turns out the easiest way to do it for them was to make it free--DDI in so-called parallel track protocols.

It requires that you have a physician who has decided you should do that. It requires that the physician keep some minimum safety data--a little bit of Tuesday was spent arguing about what kind of efficacy data, if any, you could get out of such circumstances--but some safety data to help augment the data coming from these more rigidly-defined clinical trials, and all of this to start at a stage considerably earlier than one usually starts using experimental

drugs in large groups of people, which meant that the people undertaking the parallel part of the track had to be well warned that they were taking more chances than usual.

Let me say a few things about the news items because it helps to summarize. People who went on to the parallel track by and large were very much sicker because some of the criteria for being in the clinical trials made that almost by definition. One of the reasons you couldn't go into the clinical trials is you were too sick for them. So if you still wanted DDI, then you could go into the parallel track mechanism. And so just starting with that, there was a very great discrepancy, really quite a great discrepancy, between the groups.

Another concern that was voiced and is still an open-ended issue, although it was not considered a serious one by the presenters on Monday and Tuesday, was could you get people into the clinical trial protocols if they had the parallel track option, since it is somewhat less onerous to be on the parallel track, with one important exception.

In either case, you need to have certain clinical tests--T-4 cells and that kind of stuff--at regular intervals, and if you were on parallel track, you had to pay for them

yourself. If you are on the research protocol, it's part of the research protocol.

There are some very worrisome inequities that seep into this system that we did discuss quite a bit on Monday and Tuesday, and it made a very interesting meeting. But for the moment, to finish off the medical side, DDI turns out to be unpleasantly toxic in two important ways that are still evolving.

One that has been evident for some time is that not immediately, but after some sustained use, people on DDI with fair frequency will develop a so-called peripheral neuropathy, which is to say that the neurologic function as it affects particularly arms and legs, and occasionally other things, may begin to be damaged.

Now, the mechanism of that isn't clear, but the association with DDI is. That's one of the hazards of that drug, just like bone marrow toxicity is one of the hazards of AZT. So, that's an unpleasant sort of a surprise and one that is going to limit its usefulness. It's not going to be penicillin.

The other thing that is just emerging is that pancreatitis is a much less common event that can occur

associated with DDI use, and that was part of the weekend's news stuff, was that in the clinical trials group there had been one case of pancreatitis and in the parallel track patients there had been six that had resulted in people who had died.

Now, the thing that wasn't so well reported in some of the reports--.

COMMISSIONER DALTON: June, what's the "n?"

CHAIRMAN OSBORN: That's what I was about to say. The thing that wasn't so well reported is that there are ten times as many people in the parallel track as there are in the clinical trials, and they are much sicker. It's perfectly possible that the pancreatitis effect is a combination drug effect. That hasn't been parsed out, and it may not be possible to tease it out of the much less well documented clinical trials group.

So there are a lot of issues there. At the start of things, with ten times as many people in one as in the other, and six-to-one is the pancreatitis thing, I think the most that one learns from that is that pancreatitis is another unwelcome event that can occur in the context of DDI usage, along with peripheral neuropathy.

That was absolutely the sense of the group, a very large group and very good group that discussed this Monday and Tuesday at the Institute of Medicine. It got a very full airing by virtue of the timing of that report. The thing that was much more distressing in terms of news coverage was this business of ten times as many deaths in the parallel track as in the treatment group. That is almost for sure a non-statistic in the sense that they are absolutely not comparable groups.

It was nevertheless well discussed Monday and Tuesday, and there was no sense that either of those news items should influence the thinking about parallel track. The one that might influence it in the longer haul was if it was so hard to accrue cases on the clinical case because everybody wanted the parallel track, that could jeopardize drug development in general. And that's a serious problem because drug development--acceleration of all kinds of drugs for all kinds of things--is not sort of poised on the success or failure of this DDI experiment.

COMMISSIONER ALLEN: June, I have a question about that.

CHAIRMAN OSBORN: Yes.

COMMISSIONER ALLEN: Is there a difference with the physician's energy as opposed to those in the clinical trials and those on parallel track? Is it more advantageous for a physician not to be a part of the research? Is that also an issue?

CHAIRMAN OSBORN: Up until now, I've been talking as if I were the person who knew all about this one when, in fact, the guy two doors down from me knows a lot about it and is coordinating the whole thing.

Jim, I wish you would not only answer that question, but if you could correct anything that I have mis-emphasized, in your view.

DR. ALLEN: I think you've given a very nice summary. Unfortunately, I got tied up with other things and wasn't able to attend nearly as much of the meeting as I had hoped.

I think the hope, Scott, with a wider availability type program is that many more physicians will get involved. The clinical trials are basically a very cumbersome, very rigidly controlled type procedure. For the most part, they are totally carried out by people in major medical centers in selected areas around the country.

To a lesser degree and as almost a new phenomenon associated with the AIDS epidemic, we are seeing the development of community-based clinical trials groups, a few that started on their own without government support. The National Institute of Allergy and Infectious Diseases is now supporting, I believe, 18 such community-based clinical trials groups around the country.

Some of them are about ready to start on their own protocols. In other words, they've got enough background and sophistication in conducting clinical trials that they're ready to move ahead directly. Another sub-group is going through a training phase before they will be ready to participate in the clinical trials.

So, right now, with the clinical trials, you're looking at a very--you know, you've got to be a patient in a geographically selected area and have access to that, be willing to put up with the vagaries of going through, you know, the major hospitals, one of the major hospitals in the country, and it's a very cumbersome process.

On the other hand, for the most part you ought to get premium, quality care. I say ought to; that certainly isn't always true. And, certainly, the cost is an advantage

to you, in that most of the costs associated with receiving the drugs, the physicians' costs, laboratory tests, and that sort of thing are going to be picked up as part of the clinical trials process.

With the parallel track concept, you don't get any of that. The drug under most circumstances will be provided free of charge by the company or by the sponsor, but any administrative costs--that is, going to the physician however many times a month you may need to, other clinical or laboratory type tests or monitoring that may need to be done in order to assure that you aren't getting toxic effects, or trying to pick them up early if they are occurring--probably are going to be your own. It may or may not be picked up by insurance, depending on what you've got, what type of coverage you've got, and so on. There are a lot of unanswered questions with that.

Does that answer your basic question?

COMMISSIONER ALLEN: What I'm asking--that's basically from the consumer's point of view of the advantages of the research track. What I'm wondering is are the physicians--are there enough incentives for physicians to be a part of the more formal research, or is it just easier to

cop out and say, look, let's just do it on our own time.

DR. ALLEN: Most physicians are not part of formal research trials now. It would take far too much of their time.

COMMISSIONER ALLEN: Okay.

DR. ALLEN: You've got to be in a major medical center, literally, full-time.

COMMISSIONER ALLEN: All right, but that's not going to be a reason why there might be diminishing roles within that.

DR. ALLEN: That's correct.

COMMISSIONER ALLEN: All right.

DR. ALLEN: The only other comment I'll make very quickly, June, is that with DDI it really is on a treatment IND basis, and we're trying to make the point that it's not really, truly parallel track because there are some differences between what we envision. The net effect is very similar, but it isn't quite that yet.

The other point I will just say in terms of the clinical trials--and I'm not an expert on this and I certainly don't want to be considered to be waving a banner, but I think we need to look very, very closely at the design of the

clinical trials.

The ones that have been done so far have--you know, they're probably models of what they should be in terms of complexity and the pristine nature of the patients coming in. You can't have had this, you can never have had that, you know. And one of the reasons that we've got a ten-to-one distribution of patients receiving DDI through the treatment IND as opposed to the clinical trials is that many of the patients who otherwise might have qualified for the clinical trials protocols were disqualified because their lab values were out of line here or didn't meet something there or they had already had aerosol pentamidine.

CHAIRMAN OSBORN: One of the things that would please you is if there was a change-oriented conclusion at the end of Tuesday afternoon's discussion, it was that point.

DR. ALLEN: Yes.

CHAIRMAN OSBORN: It was agreed on the part of the drug vaccine roundtable group, which, by the way, is quite broadly constituted with attorneys--it's intended, as a matter of fact, as a discussional rather than--attorneys such as Peter Hutt, for instance, who is the former general counsel of FDA; it has got people from FDA, from NIH, from

various research groups. Jim Igo is a member, from ACTUP, and Marty Delaney, although he wasn't there for this one, and Jay Lipner. I take it back. Jim Igo was part of the group, but Jay Lipner is the official representative from ACTUP on this. But it's a very good and freewheeling discussion group.

Their chief take-home lesson was that the clinical trial design was too restrictive for DDI, and to the extent there was a dynamic that could be readily identified as a problem, that was it.

DR. ALLEN: And the NIAID AIDS clinical trial group, ACTG, has established what they call their protocol diet committee that is intended to take these very complex, ponderous protocols and try to look very critically at does this need to be in there, does that, and to pare them down so that we really can make them as flexible and as available to the patients as possible.

CHAIRMAN OSBORN: Belinda.

COMMISSIONER MASON: I don't want to beat this to death. I know I always do. Jim, I'm encouraged about a lot of the stuff you said; it sounds good. I like to hear government people saying yes, well, maybe we screwed up about these trials because, you know, it has been the feeling in

our community for all these years that we were sacrificing people to science, you know; that we're going to have this really elegant, wonderful science that is built on the framework of the bodies of people that we love, you know. So, that's encouraging.

And I wanted to, you know, kind of say to Scott I don't know if this is exactly what you're asking, but one of the barriers--and this is probably too esoteric to pursue here, but, you know, I have to like spend my life apologizing for what I'm about to do.

But I think that it's probably really hard for primary care physicians in communities to access the DDI IND. I mean, for instance, my doctor--it just happens that she's a very sophisticated woman, you know. She's from St. Louis. I mean, she has dealt with these things before, but it's a voluminous amount of paperwork.

She's a very dedicated woman and she only does it because of being, you know, kind of sophisticated to these things already. But I think for the most part the very things that were designed to remove--you know, the IND program, as June said, was designed for people who live far away, who were too sick. But some of those people are still

going to be, just by virtue of where they live--their access to the kind of primary care that is available in the places where most of us live in this country is still not going to be, unless you've got a physician that's really wiling to--you know, so it's a big job of work and it takes a lot of dedication, I think, on the part of the doctor because they don't really--you know, except for getting a lot of extra money in their office for all those lab tests you have to pay for and stuff, I don't know otherwise that they really, you know--.

COMMISSIONER DIAZ: You can imagine the interest on this subject in California, and I have been asked repeatedly after the news article got out a week ago whether or not this Commission would be listening formally in testimony to anything from the other group, June. We know you serve on it and it is broadly constituted.

Mario Marich Soliz from Los Angeles serves on it and has been a spokesperson for the consumer community of Los Angeles, and Dr. Fauci came personally to L.A. when parallel tracks were being developed for a broad discussion with ACTUP, gay groups, AIDS groups.

But I just wondered what your feelings were on

this, or how we should answer to constituencies asking whether or not this Commission will support the work that is being done intergovernmentally or whether we will give an opportunity for a discussion, being that we are, in fact, by Congressional mandate, the body that will be advising direction for this country. I just really would appreciate knowing what to say as a Commission member about this.

VICE CHAIRMAN ROGERS: A suggestion, Madam Chairman. Eunice, it seems to me as we move on in the day one of the things this group ought to do, and said they were going to do yesterday, is to say here are the things we think the Commission should focus on. It would seem to me that would be an appropriate time to lay out our laundry list and then struggle about which are the most important. What are the things that are doable, what are the things that this Commission can be creditable on, what are the things we should leave to other groups. My suggestion would be that you bring that back at the time you go to that discussion.

COMMISSIONER DIAZ: The reason I'd just like for us to think about it, though--in contrast to some other issues, this one already has an organized and good constituency working on it, and you are a regular liaison with that group.

The report and feeling that I get is very positive in terms of what is being done on a widespread basis. Where there are other issues that are just kind of hanging, you know, this one is--.

CHAIRMAN OSBORN: To the extent that I was trying to do anything more than just touch bases, I wanted to give you a little sense of what was going on so that as we think about the agenda later in the day, you can decide as Commissioners.

I could make an argument 180 degrees that we shouldn't do it because there are a lot of people doing it. We should do a little more than we are now, but not get into it too deeply. You know, I could talk my way into any of those, and I think the Commission should think about it because it certainly is one of the things that would be on the list of agenda items that we want to prioritize, as we have decided.

Let's see; Diane next, then Irwin.

COMMISSIONER AHRENS: I would just wonder, Madam Chair, if you would just describe very briefly for us the composition of particularly the clinical trials in terms of sex, age, ethnicity, et cetera; just give us a sense of who

is on, who can take advantage of this or who is taking advantage of it.

CHAIRMAN OSBORN: Yes. That was extensively dealt with Monday and Tuesday. In fact, I really wish I had had everybody there Monday and Tuesday because some of these, I must confess, have not been quite so rich experiences, but this was, and there was some marvelous discussion about that issue.

Again, I'll get Jim Allen to help me with this if I misstate, but, in general, whereas the epidemic is really 50 percent minority, 50 percent white, non-Hispanic, the experimental activities are involving roughly 90 percent white, non-Hispanic, 10 percent minority.

Whereas the epidemic is thus far 11 percent women and the experimental group now is up to 9 percent women, that's a fairly recent increase and is a response to that kind of concern. There's been some effort to bring women into experimental protocols because of their notable absence.

However, that is a complicated issue because it is still true that epidemiologically the distribution of women involved in terms of large enough numbers to pull into formal clinical trials is very uneven, mostly East Coast, in terms

of substantial groups of women among whom there might be enough to want to participate in a group that was forming.

In addition, there are some very tough problems about treating pregnant women and women of child-bearing age. About, at the moment, 50 percent of the--I think that may be a little high, but 50 percent of the women are or have been caught up in illicit substance use as well, and that's another level of discussion.

In fact, the most heated discussion, I think, Monday and Tuesday was the failure to build into trials people who had a history of illicit substance use, with a very real possibility that that might be a different dynamic.

Jim, how am I doing on the numbers there?

DR. ALLEN: I think your rough numbers are very close and I don't have anything more precise.

COMMISSIONER AHRENS: What about children?

CHAIRMAN OSBORN: With children, it looks as if it will continue to be extremely difficult to work through the problems associated with the use of experimental drugs under the age of 12, and it's a little difficult even over the age of 12, a gray zone there where parental consent--there may not be parents to consent, but there are a lot of difficult

issues.

The AZT development for children is certainly moving its way along, but exactly the same things that slowed it down are now slowing DDI. There is no pediatric formulation, so that, in fact, it's not even possible for very small children to be treated with DDI at the moment, if one decided in all other ways that it was desirable.

There is no particular way to force the hand on that because the number of children that you could pull together is small. There is clearly now getting to be some knowledge of substantial risk, and there's expanding awareness that children may have a very sustained interval of well-being before they become ill.

So, that one is going to be tough at least to push through because you're not quite sure which agendas to choose to push. That's a tough one, and the same is true of treating pregnant women. That's a very tough one. It's not a straightforward thing where you'd want to get out on a barricade and say it ought to be done and it hasn't been done and we want to make sure it is. There are too many diverse threads to that.

What was clearly stated and beautifully stated--I

don't know how many of you have ever heard Dr. Mark Smith talk, but Mark was at his most. He was absolutely marvelous, and he had a very beautiful set of statements about the need to do two kinds of things; one, to involve people of color in experimental experiences so the data would surely pertain, but then an equal counterpart--and Dr. Larry Brown did likewise--an equal input about the very great sensitivity of people of color to the guinea pig business.

And so those themes were beautifully brought out in the discussion and, as I say, if I had known that it was going to be so good, we would have videotaped it and we could all sit and--that was sort of a surprise in the middle of what might have been a very dry meeting.

DR. ALLEN: June, let me just pick up and go back very briefly to the problems with the kids, which I think you addressed well. I don't think that those problems need to mean that we should back off and not push. We need to look at creative ways to take kids that are in foster care or who are border babies and find ways to get appropriate advocates with legal authority to sign consent for them to have experimental types of treatment.

I think I learned a lesson in the last five or six

months, however, in dealing indirectly through and with the FDA with some of the major companies. When we talk about people being stressed because they don't have enough time to do everything, you know, we often think of government agencies where there are ceilings in terms of hiring. We think of medical centers where there aren't enough staff and people to do it.

Surprisingly, it also applies to private industry when you're talking about qualified people to carry out a lot of these very complex things, to analyze mounds of data very quickly. June, you've worked with the FDA on their advisory committees. You've seen literally the carts full of data that are pushed in in support of applications.

I mean, what is required--the documentation is incredible, and when we ask a company to quickly move ahead on getting a treatment IND protocol for this one type of area or study or that one, then we ask them simultaneously to do something else for the children, to formulate, you know, their drug in a new suspension or new dosage levels, when everything still is not cranked up for the assembly line, but it's still being individually formulated so you've got the right dose and the right capsules and that sort of thing for all of

these different trials.

They run out of qualified people to do it, too, and we want to make certain that we don't compromise safety by a screw-up in people not analyzing data properly, in overlooking something, or in formulating materials badly. That's just the facts of life and it's one of the things that we have to be sensitive to and aware of. It doesn't mean we have to stop pushing, but there are some realities of life in this, too.

CHAIRMAN OSBORN: Irwin, then Don.

MR. PERNICK: June, why was the lead on the DDI weekend story the toxicity of DDI? Why was the stress on its toxicity? Was it purposefully put out that way? I mean, my wife came away from hearing that and said, boy, there's a new drug on the market and it's killing all these poor AIDS people. I said, what?

And I think she fairly represents the layman. I mean, I'm the layest of the laymen in our group, but, you know, at least I pay a little more attention and I have a little more knowledge than that. She represents the rest of the world, I think, on this issue. Was it purposefully put out that way, that kind of a slant or twist?

CHAIRMAN OSBORN: Nothing was put out. David wants to comment, too, but let me tell you what I know about it and then get him to add to it.

MR. PERNICK: Sure.

CHAIRMAN OSBORN: Nothing was put out. It is required in all of these situations that adverse reactions be reported. A reporter, whom I consider to be very responsible, picked up the phone, called Bristol Meyers, and said what are you getting, and got the pancreatitis data and reported that, in my opinion, modestly and responsibly with appropriate caveats.

Another reporter, whom I will quote other reporters as saying was wildly irresponsible in this, then picked up on the mortality data, and that's the story that then overwhelmed the pancreatitis story. It was entirely separate, and I have never seen working journalists so willing to say something bad about a fellow working journalist as on Monday and Tuesday. They were furious that that story took off and went that way.

So it was a two-event thing and the original story got drowned. The original story was a news item that got modest coverage, but suddenly toxicity got amplified because

the two went together.

David, do you want to comment?

VICE CHAIRMAN ROGERS: Yes. That's an accurate portrayal, and it's an all too human story, too. I guess the only thing I would add to what June said was this also was a reporter that had gotten fairly beat up by some of the ACTUP people, was feeling kind of punitive.

I had an opportunity to sit down the next day with the editorial staff of the New York Times and told them how destructive that had been, because patients were calling, people were terrified, saying I've got to get off this drug, I'm going to die. It was a totally irresponsible kind of piece, as I pointed out in some interviews.

MR. PERNICK: Of course, there hasn't been a third step.

VICE CHAIRMAN ROGERS: Well, we don't know who died.

MR. PERNICK: Yes.

VICE CHAIRMAN ROGERS: We don't know quite why. As has been indicated, they were ten-plus sick people, not three-plus sick. Maybe 600 would have died rather than 290 if they hadn't been on the drug. I mean, the evidence just isn't there, and I thought I was kind of troubled by Tom

Chalmers' statement that kind of fanned the flames there in terms of saying this was a disaster.

We have no idea, and my guess is that it's not that they were just dreadfully ill people, but that it was blown all out of proportion.

MR. PERNICK: If you even look at the figures that you mentioned, June, a ten-to-one ratio in terms of patients in the parallel track as opposed to the clinical trials, and only a six-to-one difference in deaths, my God.

CHAIRMAN OSBORN: You can't do that with those numbers.

MR. PERNICK: I realize you can't, you know.

CHAIRMAN OSBORN: Yes. Those numbers just simply don't mix. I think perhaps the take-home message and the one that the media will now have to join us in getting more sophisticated about is that when you have parallel track and an ongoing clinical trial, they are not comparable groups by definition and must not be compared.

They could come out in either direction distorted if you try comparing them. So, that was the fundamental flaw in that, is to look at experience on parallel track and try and line it up with people who, in this instance, had an

exceedingly tight control on their eligibility for the clinical trials. So to the extent that you could amplify a difference in experimental groups, this was done not systematically, but it was an automatic event.

Let's say. I've got Don DesJarlais, Harlon, Larry.

COMMISSIONER DES JARLAIS: Earlier in informal discussions, there's been some talk about forming a special subcommittee to look at scientific issues in the epidemic, current science, funding levels, potential future funding levels, social justice issues in the conduct of science.

In the hope of getting out of here by 4:00 this afternoon, I would like to suggest that we form such a subcommittee, hold hearings, if need be, draft reports, and such. I think it's much too important for us to ignore. There is not going to be any other national body that tries to get an overview of how science is going in the epidemic.

Certainly, in the initial Institute of Medicine reports and National Academy of Science reports that recommended a national commission, that was one of the major charges to the Commission, was to provide oversight to the scientific issues, and I think we really ought to form such a sub-group and have full reports covering the science of it

because I think it's really too important for us to ignore, but it's going to require too much work to do as a committee of the whole.

CHAIRMAN OSBORN: I think that's quite a helpful comment.

Harlon, then Larry.

COMMISSIONER DALTON: Actually, I had a technical question which my fellow Commissioner Mason answered for me. The other comment was just that--and you're not a camera, June, but I do have a real sense as of I was at the meeting, and I appreciate the report this morning.

CHAIRMAN OSBORN: Thank you.

Larry.

COMMISSIONER KESSLER: I wanted to support Don's proposal, but I also think that this whole incident is a perfect case study of the media's role, and sometimes their irresponsibility, in terms of covering this epidemic. And it brings us back, I think, to an earlier discussion we had six months ago about possibly doing something where we talk to the media or they talk to us, and vice versa.

I'm not sure how to structure it, whether it be a hearing or a special task force that gathers some data and

analyzes it, and that has been done on a certain level by some people. In fact, there's a new book out that just documents the first seven years of the epidemic.

But regardless of which clipping you're looking at--the New York Post, the Wall Street Journal, or the Times--they all basically make the same mistake and have it reinforced by not only Chalmers, but by Fauci. That kind of coverage really does create incredible anxiety for the clients that we care about, but also for those who are off in the wings trying to decide whether they want to be clients or get tested or access treatment. You know, they don't know who's on first. Somehow or other, this Commission has to call the media in and nail their butts to the wall.

CHAIRMAN OSBORN: I think that also is a very strong and appropriate suggestion, and I think that there was some discussion somewhat earlier. In fact, I think it is floating around on a list somewhere that a full Commission hearing in that instance might be--not necessarily for a full Commission, but in a committee of the whole--might be the way to do that because that's where we take very good advantage of the diversity of our expertise, and the different ways in which we receive the same kind of message becomes an enriching

thing.

So I not only think that's a terrific idea, but we may want to have that on the list of things that we prioritize for a whole Commission session or part of a whole Commission session.

David.

VICE CHAIRMAN ROGERS: I think, again, this is part of that agenda of not only what do we put on the list, but how do we do a number of things where the expertise lies not necessarily within this group. So I wanted to simply again highlight Don's suggestion. It seems to me one very effective mechanism would be to set up some task forces and some subcommittees that had Commission members, but had people of absolutely impeccable credentials that could feed back to this Commission.

I will simply indicate that, as many of you know, I chair the Governor's Advisory Council for the New York State Advisory Board. In finding we weren't getting listened to very well, I found a magnificently effective device--and no one ever turns me down--is to put together a subcommittee where I say, Harlon, help us with prison health to put together a blue ribbon group, or help us with Hispanics, or

help us with women and children.

I can put together ten people, all of them names that the governor knows, and so does the entire science community. They can come back in several months with a good, tough report. We can have control over those sorts of things. We can decide what we want to use. But I think that would add an enormous amount of muscle, and I know anyone we ask to help us would help us.

We can ask any distinguished scientist, or what have you, in this country to say help us on this thing and they will, and that would really extend our effectiveness, I think, enormously because we can't do it all with what we've got inside, and we don't need to. We're the ones that should be the final monitor of what moves out.

In our discussion of priorities, we may decide here's one we can't handle, but we could put up a group that really could bring us back in two months the information we need to deal with.

CHAIRMAN OSBORN: Identify yourself for the record, if you would.

MR. ALLEN: Bob Allen, Department of Veterans Affairs. June, I wanted to ask--at the NIH meeting when we

were there talking about AZT use, one of the very important things they were going to draft was information to clinicians about how to use what dose of AZT. There was supposed to be a draft report.

CHAIRMAN OSBORN: It's in my briefcase for review between here and California this afternoon.

MR. ALLEN: We've been asked Congressional questions.

CHAIRMAN OSBORN: The people who were participants have been sent the draft. It arrived just before I left for this meeting, and I think it's due Monday.

MR. ALLEN: Okay.

CHAIRMAN OSBORN: It's on its way. There is going to be a document that comes out that tries to regularize and help physicians in the context of these various recommendations. But I wasn't part of the discussion drafting, so I can't give you an overview of what it is because I haven't read it yet. It just came before I left the office.

MR. ALLEN: I would just like to put--even though, as we said before, the Department of Veterans Affairs is not a part of the Public Health Service, we would like to have our policies be consistent, and we can do that faster if we

get information as early as possible.

CHAIRMAN OSBORN: Yes. It doesn't technically exist yet until the drafters have a chance to see it.

MR. ALLEN: But we will be able to get one of the early copies so we can--.

CHAIRMAN OSBORN: Yes. I'm not the right one to ask, but I'm sure you can through the NIH convening group because I think it will be very widely disseminated as soon as it has achieved full review by the people who wrote it and the collective group.

What they did basically was to pull together--I didn't mention this as a separate meeting, but they had sort of an emergency weekend meeting the weekend before last, I guess it was, in which they got sort of a--they called it a state-of-the-art conference on AZT, and then had people who had done the clinical trials re-present the data. They had other people who were on the front lines discuss what was needed in terms of information.

They had different communities represented quite well, I thought, and they had a bunch of us called senior scientists who sat around and listened to that and helped with it. It's the product of that that I was referring to,

which will extremely quickly--I mean, I mention that only so you know the intensity of response that the unwieldy federal bureaucracy is really trying to mobilize to get that done in a way that's accessible and very usable to clinicians on the front lines as quickly as possible, still before the actual publication date of the data themselves. So it's whipping along in a remarkable fashion, and it's a contribution, really--a sad epidemic, but a major contribution of the epidemic to things overall, I think.

I feel uneasy because I think we've got so much work to do, and several very good suggestions have been made as to how to proceed with this line of discussion which is of intense importance and interest to everybody.

If it's all right with you, I would suggest--David had a suggestion about how to proceed with the working group summary report that we worked on yesterday which has been passed out to you. I don't know whether everybody has had a chance to glance. If there are specific places where you were concerned, you may want to take a couple of minutes to do so.

But, David, while people are paging, why don't you go ahead?

VICE CHAIRMAN ROGERS: Yes. Let me make a suggestion here because one thing that drives me up the wall is to watch a group try and edit a document. My feeling is we've got a very good document. It is imperfect, as are most such pieces of paper, but we are not trying to write the Declaration of Independence.

A distinguished subcommittee has worked valiantly on a report to put before this Commission. My suggestion, unless there's something that makes somebody have a convulsion, is that we accept with gratitude the elegant work of our subcommittee; that we recognize that over the next year this is going to serve as grist for our mill in terms of subsequent reports, and so on.

I do not feel it is imprinted in stone. Over the next six months, we may get smarter and we may wish to modify in one way or another a few of those recommendations, but we have gnawed at them enough so that I think they're close to what we want. And rather than go through what we did for the last hour-and-a-half yesterday, I think we should let Charlie and Diane and the group off the hook, thank them for their labors, accept the report, and go on about other business.

COMMISSIONER DALTON: I told Diane if I don't have

to call her distinguished, I can go along with what David has to say.

[Laughter.]

COMMISSIONER DALTON: But it would be useful just to know what the changes are since yesterday just so people don't have to page through it.

COMMISSIONER AHRENS: Madam Chair, let me just call your attention very quickly--.

VICE CHAIRMAN ROGERS: As long as that isn't driving a great big truck through that takes us another hour.

COMMISSIONER AHRENS: Yes. Page one, the middle of the page, we took out the sentence on silence; it's that second paragraph. Flip over to page four, and we added something there in terms of strategic planning for counties. On page five, under federal, the first sentence, we put the words "overall leadership" in.

Same page, page five, partnership, sort of the middle of that paragraph--I believe this was all added, and I think it was Don, I believe, that was concerned about this. Implicit in the concept of collaborative partnership, et cetera--the two sentences there were added.

Am I moving fast enough?

VICE CHAIRMAN ROGERS: Don't let anybody stop you.

[Laughter.]

VICE CHAIRMAN ROGERS: Ride over them like a truck.

COMMISSIONER AHRENS: Page eight is the critical one, in that the top two paragraphs are--.

VICE CHAIRMAN ROGERS: Don't even tell them that; just do it.

[Laughter.]

COMMISSIONER AHRENS: There is new wording at the top two paragraphs.

Madam Chair, I would move the acceptance of this document. Acceptance--is that the word we want?

CHAIRMAN OSBORN: That sounds like a very appropriate word because I think the point David was making besides that of driving a truck through was that that is what we're doing, is accepting a conscientious report from a group of people who have studied the issue. So I think that's a nice way to put it and one that we should look on as a way we go with small working groups.

COMMISSIONER KESSLER: I second her motion.

CHAIRMAN OSBORN: Thank you.

COMMISSIONER GOLDMAN: I just have a point of

inquiry. Do I understand it correctly that even though we've had a certain substantial role in making suggestions to the working group that by accepting this report, we are not necessarily adopting these recommendations as recommendations of the Commission as a whole, or are we, and are we publishing this and what do we intend to do with the document? That's why I said it's an inquiry.

CHAIRMAN OSBORN: Those are excellent points to bring out in this context. By accepting this report, we're doing just that. How we then proceed in terms of its amplification and use would be analogous to what we did earlier. In the document that we didn't yet circulate that was going to be a second mini-report, we had taken pieces of this, and that's something that we can discuss, and so forth.

But from this would grow either that sort of a communication or it could become a piece of what would be an interim report in August, somewhat intact, probably. I mean, I've been advocating that we may want to look at the interim report writing as something that is just that, rather than having the staff have to divert enormous amounts of time and basically put us on hold for a month. The legislative language is not much more compelling than that.

So it's conceivable that for the moment we can decide what we want to do with it, but it is a report of a small working group to the Commission. When the Commission accepts the report, I think it probably means that we don't find anything egregious in it, but it doesn't say what we do next or how we go from there.

Is everybody--.

MR. PERNICK: June, I think even that has gone too far, it seems to me. Gnawing in the back of my mind has been the question why are we involved in the report of the working group's report. It is their working group. They are presenting it to the Commission. We shouldn't be nit-picking their language.

You know, if they make errors, fine; we can discuss that when incorporating their language into the interim reports or into a final report. But this is their report and, to their credit, they've done a very good job. But we shouldn't be involved in telling them where the dots are.

COMMISSIONER MASON: Hear, hear, Irwin.

MR. PERNICK: And, of course, I'm speaking for a non-voting member, so I'm not sure--.

[Laughter.]

VICE CHAIRMAN ROGERS: You have my vote.

CHAIRMAN OSBORN: We will not listen to you, in that case.

Eunice, and then Don.

COMMISSIONER DIAZ: I just wanted to ask one question. I still think that the task force we're asking to be developed--were we intending with the new write-up and input from yesterday that it put forth a plan and it also be the implementors of that, because the two paragraphs are not saying the same thing? That is my only question. I have no quarrel with the whole report, except that.

You talk about the President designating this Cabinet-level task force to develop the plan. Right underneath, there is a need for all these government agencies to come together to implement. So, is it both, and if it is both--.

COMMISSIONER AHRENS: Madam Chair, in terms of accepting the report, that's just what it is. I think, Eunice, your concerns will come about, but if anything in this report is then picked up by our staff and put through as a recommendation in the interim report, then we have to hash this through.

But I think what we're doing today is simply receiving--maybe we should use the term "receiving"--receiving this report. We're not recommending it in any way to anybody and we're not putting our stamp of approval on it. All we're doing is accepting this report because it's the report of a working group. Then what is done with this document later will have to have a stamp of approval by this entire Commission, and that's what my understanding of the motion was.

CHAIRMAN OSBORN: Don Goldman.

COMMISSIONER GOLDMAN: Yes. I would just like to say two things. One is that whether or not we like it or not, I think all of us will have to be aware that even comments by one of us individually, much less a working group, do, in fact, in some way, whether it be by the media or otherwise, get attributed to the Commission by the press. Our merely saying that we're accepting it and not adopting it, and receiving it and we're not doing anything with it is not necessarily going to be accepted by all the rest of the world with which we deal.

I think we do have to be careful, and I think the kind of exercise that we went through was appropriate and therefore I don't think it was inappropriate to have gone

through. And I think it's important that even the working group, although this is a product of the working group--and don't forget, the working group submitted this draft originally with a request for input and comments from the rest of the members of the Commission. And it got that input and comment and respectfully tried to incorporate those comments with which it agreed within the context of the report, and I think that's an appropriate process and I don't regret it or the time spent one minute.

CHAIRMAN OSBORN: I must say I agree with that. That's why I said that we have to be sure there's nothing egregious in this kind of thing. That level of discussion is appropriate when a working group brings a report forward because if it clearly represents something that the Commission finds very uneasy to accept, then it needs to be worked through.

I think what David is commenting about, joking aside, is that when we recognize areas of that sort, we probably need to learn to have redrafting done out of the committee of the whole, and that was, I think, what the comment was about the discussion.

I think it is a little bit more than thank you, we

receive it. I think we do need to receive it with a general sense of comfort. The issue that Eunice raises is one, however, that probably, in its activation, we couldn't influence anyway.

As long as the direction is okay, Eunice, I'm not sure that I would get stalled on that any further than the careful reworking that it has now had. It is less directive by a long shot.

And, Jim, you may want to comment wearing your Public Health Service and pseudo-Cabinet hat, or whatever, since you're sitting in Secretary Sullivan's chair. But I think, in general, that unless you say otherwise, that concern was met that we perhaps had been too prescriptive in the way that was phrased. But that's one of those things that will evolve, and I'm not sure that we should get hung up on that now.

It has been suggested that the report be received by the Commission in the context that we just said. All those in favor, please say aye.

[A chorus of ayes.]

CHAIRMAN OSBORN: Opposed?

[No response.]

CHAIRMAN OSBORN: Abstaining?

[No response.]

CHAIRMAN OSBORN: Wonderful, okay. Now, I think the coffee is ready. We should take a break. We're going to have a brief legislative update when we get back, turn to the second working group's report, and get to the point where we can see if redrafting is needed. At the point at which it might be needed, we will then turn to discussing agendas, dates, and whatever, while the redrafting--.

COMMISSIONER GOLDMAN: Redrafting what?

CHAIRMAN OSBORN: Well, in that case, okay, it's a report, right.

[Recess.]

CHAIRMAN OSBORN: Let me propose that we get started again, and let's proceed in the following way. I will ask Carlton and Maureen to give us a legislative update, and they said that won't take very long, although I certainly would enjoy any comments and discussion that you have. I think we do have abundant time for our work today, and having worked well so far I think we can keep on going.

After they are done and after we have had a chance to discuss whatever we like there, we will proceed to Scott's

report for the other working group. He has proposed the following thing, which sounds like a good idea to me, that we have about a 45-minute discussion interval plan. The first 15 or so, Scott will present and summarize where the group stands, and that leaves half an hour for good discussion and the sense of what else needs doing with the report.

Obviously, at that point there will be some decisionmaking that we can revise. But if that all went well, we would have moved that along in such a way that we have both lunch and the afternoon to talk about a whole series of things, including dates, substance, locale of Commission activities, and a couple of very interesting suggestions this morning that have been made about the possibility for focusing some of the Commission's great interest in smaller working groups.

Again, I think that whole issue needs to be revisited because we've had such good products from several of those kinds of activities--the immigration activity that Don was--sort of his own working group, but that worked extremely well when it can be focused like that.

And I think that the federal-state-local working group just distinguished themselves with the quality of that

initiative, and has added greatly to our overall Commission capability by so doing. And I think that that will turn out to be true of the report that Scott is introducing.

So as we think about priorities and how to proceed, we need to keep that mechanism in mind because that can allow us to double or triple our time under certain circumstances. And it's as big as all outdoors, of course, so that's always a useful thing.

Anyway, I think we'll have time for all that, and let's get started now with the legislative update from Maureen and Carlton in whatever way you'd like to proceed.

MS. BYRNES: I'll just introduce Carlton. He's going to review the initiatives of the Commission, indicate where some of the current legislation is pending or planned and anticipated for this session of Congress, and then I'll review the Public Health Service, DOD, and Department of Veterans Affairs appropriations requests for FY '91.

MR. LEE: Okay. You should have just received a list of Commission initiatives which lists all the statements of support, statements on various bills, the resolution on immigration, et cetera. The only exception is the last item. I took off and put on your desk earlier the latest statement

we issued yesterday concerning whether or not the epidemic has peaked.

I will start with the first initiative we took, which was the endorsement of the Americans With Disabilities Act back in September, on the 6th of September. That bill, of course, is the bill that provides protections from discrimination for all people with disabilities, including people with AIDS and HIV, as well as those who are regarded as or perceived as having HIV or AIDS.

The Commission made clear at that time that such protections were not only necessary to enhance the quality of life for people with AIDS and HIV infection, but as the Presidential Commission on the HIV epidemic and the Institute of Medicine have reported, were the lynch pin, quote, "of our nation's efforts to control the HIV epidemic." That same month, the Senate went on to--in fact, the next day the Senate went on to overwhelmingly approve that legislation. I believe it was 76 to 8.

In the House of Representatives, the Americans With Disabilities Act has moved much slower than anticipated at that time. There were a number of controversies mostly centering around transportation issues. A number of members

were concerned about the costs involved in that area. HIV and AIDS have not been a real controversy in the House, for sure.

There was just this past week action by the Energy and Commerce Committee, which has jurisdiction over most transportation issues. There was a mark-up of this bill, finally, and it was approved, 40 to 3, in that committee. So we're very pleased with that news. That was the major stumbling block in the House. And I think maybe in the next week or so, Judiciary will mark the bill up. We anticipate no problems there, as well as in Public Works.

In the Energy and Commerce Committee mark-up, Congressman Dannemeyer offered several amendments relating to HIV, one being that people regarded as having AIDS or HIV should not be included in the bill, as well a provision excluding all currently contagious diseases from the bill. So any sexually-transmitted or contagious disease would have been excluded by the other Dannemeyer amendment. Those were defeated by a show of hands, so there was no recorded vote, although my understanding is, at most, he had five votes on any one of those amendments.

So, therefore, we could see this legislation on the

floor of the House of Representatives within, I would say, a month or so, which is great news for all of us and all people with AIDS and HIV.

The next item we did was, of course, a statement on the FY '90 appropriations bill. That was just a show of support for the increased funding, as well as a message that we would hope Congress would be deliberative in its policy-making around AIDS and HIV and shun amendments that were just on the floor of the Senate at the time that we anticipated might come.

The monies in that '90 appropriations included $30 million for AZT monies and about $20 million for home care. The monies were added by the Congress and were not included in the President's '91 request, and that was very unfortunate news. In fact, the HRSA budget was cut about 35 percent, which Maureen will probably refer to again.

The next item we did was we issued a statement supporting treatment on demand for drug users. Not much action has happened on that issue, as well know, and it's clear that that is going to continue to be a tough row to hoe, as we say back home in Texas.

The next thing we did was a statement on bleach and

HIV control research. Don was very active in this particular issue at the time. There were efforts by various members of Congress to not fund programs that were looking at the use of bleach and bleach distribution in controlling the HIV epidemic.

Through the efforts of many people, including Don and I believe several other Commissioners, we were able to fight that and, at the last minute, save those programs, and they are funded as of now. One important thing that happened during that time was Assistant Secretary Mason sent a letter over to the Appropriations Committee chairman indicating administration support for those programs. So, that was very instrumental in that victory, of course.

The next thing we did, of course, was a resolution on U.S. visa and immigration policy, which is one of the issues that has received most attention in terms of our initiatives. Again, that was in December. The press conference that we had was well attended by members of the media and representatives of national and international organizations.

I think it would be fair to say the Commission's statement regarding immigration was well received and of some

significance in focusing national attention on the need for immediate administrative steps to end this infringement on human rights and dignity of persons with HIV infection and AIDS.

Since that time, Dr. Osborn, Dr. Rogers, Don Goldman and several other Commissioners have been active in trying to secure satisfactory resolution to the problems of discrimination and the incoherent public health message that U.S. immigration policy presents.

In early January, members of a task force comprised of representatives from PHS, the Public Health Service, the Department of State, and the Department of Justice met and began discussions to ease restrictions. As a result of those discussions, steps have been taken to expedite visa applications and ensure confidentiality.

It is as of yet unclear exactly what the new regulations are. After the initial report of these changes to the press, a number of groups met with representatives of the administration to talk about these changes and trying to get further clarification of what the policy is. The success of these meetings is yet to be determined.

As recommended by the Commission, Assistant

Secretary Mason has called for, and did call for a comprehensive review of public health concerns regarding diseases designated as contagious or dangerous. Recently, the PHS announced that their recommendation is that HIV infection and all other contagious diseases, except active tuberculosis, be removed from that list.

While the PHS recommended the removal of HIV from the list, it has maintained that it does not have the power to remove HIV infection from that particular list because it was mandated by the Congress in '87 in a supplemental appropriations bill that the President add this to the list of dangerous contagious diseases.

There are some legislative initiatives underway, nothing introduced as of yet, to try to assert that the Public Health Service does have the authority, should have the authority, to make this determination.

June and David might want to comment on this. I know they've both very active. Don, if you have any comments, feel free to chime in on this one, or Jim.

COMMISSIONER GOLDMAN: I just want to say it's a continuing effort, it's a continuing battle, one that I'm confident that we'll ultimately succeed in. It's one that

we'll ultimately succeed in because there is--and I'm particularly appreciative of the efforts of the Public Health Service and Secretary Mason and Secretary Sullivan in terms of their efforts, and Jim as well, to work together on this issue.

It's a good demonstration of how, if a lot of people work together on an issue, effective changes can be had, and are potentially in the works. I think the problem will be solved, and hopefully certain aspects of it will be solved sooner. All of us are impatient, but I think there's a general agreement as to what's right, and when everybody gets together and agrees what's right and agrees to work together, it eventually gets done.

CHAIRMAN OSBORN: I think it might be worth commenting that in addition to the letter that I think you got in yesterday morning's packet, in the context of the upcoming March 29th speech, each time that has had any opportunity for input or discussion, we have tried to urge that were this issue resolved in anticipation of that, it would add greatly to the reception and credibility of that.

So as a last resort, we've urged that it be in that speech, but, in fact, rather than leaving it there, have

tried to suggest that since all of the hard background work did, in fact, get done through rather strenuous efforts on the part of the Health Service so that there isn't that lying out there as what should be on that list and everything, that's something that could be done that is basically dollar-free and would, in fact, send a strong message that would be received very warmly by people who have been concerned about attitudes.

MR. PERNICK: Where is the issue buried, then, at State or INS, assuming that it's past HHS?

DR. ALLEN: There are two sides of it. One is what might be done in terms of an administrative solution on a short-term basis until we can get the second component, the long-term solution, which is a legislative resolution. Right now, the Department of Health has, I think--the Department of HHS has gone on record as stating very clearly that from a public health point of view, there is no reason to restrict the travel of HIV-infected persons to the United States.

The Department of State is on record as believing that this should be resolved because HHS has said that it isn't really a health issue and they see no reason to, therefore, put forward restrictive measures if they're not

necessary.

The changes that need to be made have to be agreed to by Justice, and where we get the disagreement is in terms of how much flexibility there is in the interpretation and application of the law. And we're continuing to work on that, but have not gotten resolution from Justice that they've got the flexibility to make further administrative changes. We hope that they will change their position on that.

COMMISSIONER DES JARLAIS: It is not really a dollar-free issue. There are substantial dollars to be lost if the policy is not changed.

I understand there was a meeting in Frankfurt last Friday as to whether or not WHO would officially endorse boycotting of conferences in the United States. Does anybody have--Jim, do you know the results of that?

DR. ALLEN: The meeting was of the Advisory Board for the International AIDS Society. It really wasn't the WHO at all, although, obviously, WHO was following carefully what happened at that meeting. There were a number of representatives from the U.S. government; in particular, Dr. Ron St. John from my office, Dr. Alan Hinman from CDC, and Dr. Peter

West from the Department of State, who did attend as advisers in terms of giving the most current information and letting people know where the discussion was going.

After very intense discussion throughout the day, a lot of different positions that were fielded and options that might be taken, the decision was to put forward a strong statement that condemned the current position of the United States, that said that there was very strong support for the sixth international conference as a vehicle for sharing important scientific information, that people wanted to attend that conference, and that as long as there was visible progress made toward resolving the problem by the U.S. government, there would not be further withdrawal of support from that conference, but it's all pending.

The second part of it clearly was that if we have not resolved this issue, there will be no further support for international conferences in any country that has discriminatory practices in terms of HIV-infected travelers. What that translates to is that if we do not have a permanent solution in place--the dates are a little flexible, but I think you can read sometime in December 1990--i.e., if we don't have it by the end of this Congress, if we don't have

things in place by the end of this calendar year, there will not be a conference in Boston in 1992. It will be moved to some other country of the world-if indeed they continue to be held, you know, as a major international gathering.

COMMISSIONER GOLDMAN: If any member of the Commission would like, I have a copy of the resolution that was adopted in Frankfurt on March 9th.

CHAIRMAN OSBORN: Thanks very much.

MR. LEE: The next item was the letter to President Bush that was issued December 5th of last year. That was the first report in a form of a letter to the President. The report highlighted the testimony we heard at the November hearing on health care and financing. The Commission noted in that report about the growing complacency about the HIV epidemic; that the 1990s will be much worse than the 1980s. The link between drug use and HIV infection must be acknowledged, and there is no national plan for helping an already faltering health care system deal with the impact of the HIV epidemic.

Several weeks later, the Commission received a letter from Presidential adviser Bill Roper expressing appreciation for the letter, the report, and that was the

extent of our response from the administration. Sadly, the FY '91 administration budget recommended a 35-percent decrease, as I mentioned earlier, in the HRSA budget. So that was very disappointing, given our report. HRSA, of course, is the lead agency in developing models of HIV health care delivery.

The next item we--I don't know if David or June wanted to comment on that report, or respond to it.

[No response.]

MR. LEE: The next thing we did was, of course, the statement on the Care Act of 1990. That's the bill introduced by Senators Kennedy and Hatch and numerous other Senators which provides disaster relief to areas hardest hit by the epidemic, as well as monies to rural areas for the purpose of providing more effective and cost-efficient systems for the delivery of care, treatment, and early intervention. By now, you probably have several copies of that legislation. I think we've been saturated with that bill here at the Commission.

The bill authorizes $300 million for emergency relief to about 13 metropolitan statistical areas, many of which, I think, are represented around this table--those MSAs

with greater than 2,000 AIDS cases. According to the relative number of cases and per-capita incidence within the MSA, about 50 percent of those dollars would be distributed based on that. The other 50 percent would be awarded by the Secretary of HHS as supplemental grants to MSAs with greater than 2,000 cases of AIDS based on need, local investment, potential for immediate utilization, and the development of a comprehensive plan for the organization and delivery of HIV care, treatment, and support services.

The bill also authorizes $300 million for the development of comprehensive care programs. The funds would be distributed in block grants to the States based on the number of AIDS cases reported to the CDC by the State in the preceding 24 months as a percentage of all AIDS cases reported in the same period. All States receiving funds would be required to develop a comprehensive plan for HIV health and support services.

A hearing on this bill is scheduled for next week. The Labor Committee hopes to mark the bill up the week of April 4th, so this bill could very well be on the Senate floor within the next month or so.

With the exception of yesterday's item, which I

believe you have in front of you, regarding whether or not the epidemic has peaked, that sums up the Commission initiatives that we've done thus far.

In terms of legislation, I believe Mr. Waxman also talked yesterday about his Medicaid bill which has been introduced, H.R. 4080. You have a summary of the bill and a copy of the bill in your packets.

This bill basically has four components, the first being a prevention and early intervention proposal which would amend existing Medicaid eligibility rules to create a new category of patients that States may elect at their option to cover. The new group basically would have to meet three criteria. They must meet the current standards of poverty established by the State, they must be infected with HIV, and they must have serious immune deficiency for which medical intervention is needed to prevent further decline or AIDS-related illnesses.

I won't go into a lot of detail on this. I know Mr. Waxman did a very thorough job on this yesterday. Other issues, though--one major issue is the disproportionate share adjustment for Medicaid payment. This proposal would require States to pay a higher rate to hospitals that care for a

larger number of Medicaid AIDS patients.

This bill, I believe Mr. Waxman hopes to move fairly quickly in the next several months, and I don't know if Maureen has anything to add on that. I know you heard Mr. Waxman. I was out of the room, unfortunately.

Eunice has a question.

COMMISSIONER DIAZ: In regard to these two bills, the Kennedy care and the Waxman bill, could you just outline for me some of the very basic differences? If one is supported, does that exclude support of the other, or is it just two different ways of coming at financing?

MR. LEE: No. In fact, there's been a lot of progress. Senator Kennedy and Congressman Waxman have had discussions. There is agreement on a common direction to go, so that these bills will be conferenced in the end, and so we'll have a very nice, comprehensive AIDS bill in the end.

The Kennedy bill will be, through the committee process, expanded in terms of the early intervention piece, which Senator Kennedy certainly is very interested in having happen on the Senate side. Mr. Waxman, on the other hand, is also adding to his bill a disaster relief title. So there will be a number of common areas to the bills.

COMMISSIONER DIAZ: The Kennedy bill does not speak to assisting hospitals.

MR. LEE: Yes, it does.

COMMISSIONER DIAZ: It does?

MR. LEE: It does, yes, through the emergency relief, primarily, and, in fact, both titles.

MS. BYRNES: In a different way than the Kennedy bill does. And to some degree, Eunice, it has to do with committee jurisdiction.

COMMISSIONER DIAZ: Okay.

MS. BYRNES: If you're dealing with Medicaid reimbursement on the Senate side, those changes go through the Finance Committee. Labor and Human Resources doesn't have jurisdiction over the entitlement health spending. On the House side, the subcommittee that Mr. Waxman chairs has jurisdiction over both, discretionary impact aid types of legislation and assistance to hospitals, as well as enhanced Medicaid reimbursement either to an individual or a person.

I think in this case it has more to do with jurisdiction than any difference of opinion between the two members of how to respond in sort of parallel manners, both in terms of reimbursement as well as discretionary assistance

to heavily-impacted areas.

COMMISSIONER DIAZ: It has been very helpful, that explanation.

MR. LEE: Belinda had a question.

COMMISSIONER MASON: Carlton, I think you do a great job. I really appreciate the work you do.

MR. LEE: Thank you.

COMMISSIONER MASON: This is a lot of work, you know. I mean, look, it's like from September until now and we've sort of kind of jumped on most of the major things and kind of led some of the major things. I think Carlton has been carrying the water for us a lot. So, you know, a big--.

MR. LEE: You're too kind.

COMMISSIONER MASON: Yes. I'm also too stupid to think of what I want to say next.

MR. LEE: I don't think they can handle both our accents for very long.

COMMISSIONER MASON: That's it.

[Laughter.]

COMMISSIONER MASON: I guess this is sort of something that Don Goldman brought up yesterday. Is there some reason that we haven't particularly endorsed the Waxman

bill the way that we have the Care Act.

MR. LEE: Yes. Let me indicate that there is the early intervention piece that Waxman is working on. The Medicaid piece is separate; that is a separate bill. I did confuse things a little bit. The Waxman plan is to introduce probably in the next week another bill that is early intervention-focused only.

The Medicaid stuff, he separated because of various rules, reasons, et cetera, committee issues. But his plan is to introduce a bill in the next week or so which would authorize about $400 million for the next three years--each year, $400 million--for early intervention programs, and I think he may have touched on that yesterday as well. There is a summary of that planned bill in your packet, entitled AIDS Early Intervention Legislation, Grants and Entitlements.

CHAIRMAN OSBORN: David.

VICE CHAIRMAN ROGERS: And a quick answer, Belinda, might be that Mr. Waxman is just coming up to the plate, and Mr. Kennedy was at the plate when you were dealing with Elizabeth Taylor.

[Laughter.]

VICE CHAIRMAN ROGERS: I think we can decide how

we'd like to deal with this one. I would just recommend that you leave Belinda out of the testimony.

[Laughter.]

COMMISSIONER MASON: One more thing, and this is decent, I promise.

[Laughter.]

COMMISSIONER MASON: Carlton, can you give me some kind of realistic assessment about what's going to happen with both of these? I mean, how many friends do we have on this, and are people really going to--you know, is money going to be forthcoming? What are we looking at here in terms of the reality of having both of these things or parts of them adopted, and when is the time frame?

MR. LEE: As I mentioned, the Labor Committee plan is to try to have the bill out of committee in early April, so that there could be Senate action on a bill fairly soon. The Waxman plan, I think, is to move as expeditiously as possible as well.

I think in terms of the Care Act, the bipartisanship is very obvious between Kennedy and Hatch. You can't get much more bipartisan than that. Senator Hatfield, who is ranking Republican on Appropriations, is also on the bill.

There are a number of key Senators on both sides of the aisle supporting that bill. Waxman, I also think, has encouraging signs of support for his legislation from both sides of the aisle.

So I think--you know, jump in if you need to on this, but I feel confident that maybe by early summer we could have a bill that we could get through by the end of the session, which will probably be sometime in late September, early October. So I think we're all optimistic at this point.

CHAIRMAN OSBORN: Don Goldman.

COMMISSIONER GOLDMAN: Also, I think there's an important thing that I'd like to say, Belinda, and that is that I think it's important that except in rare circumstances that we not get involved and bogged down into the details of legislation, and that we not--and I think the statement that the Commission ended up making very carefully did not endorse the bill. It endorsed the process, the concepts, the ideas behind the bill.

I don't think that, except rarely, we want to get embroiled into literary language, debates over what clause belongs where and how it should work out. I know, in speaking to Roy Rowland, he feels strongly. As a matter of

fact, I asked him, why weren't you--you know, is there any reason why you weren't a cosponsor of some of the Waxman legislation, and he indicated that one of the things he wanted to do was as a member of the Commission--and he didn't think it would be appropriate for the Commission to get itself involved in endorsing specific pieces of legislation rather than dealing with principles.

He thought it would be more appropriate if he, as a member of the Commission, you know, stayed away from any specific endorsement of a specific piece of legislation at this time, and I think that says something that we ought to consider as we go along this process.

MR. LEE: Okay. I think that wraps up my piece, and I'll turn it over to Maureen to talk about appropriations.

MS. BYRNES: This is, in fact, a good place, I think, Belinda, to pick up in terms of what the prognosis for the legislation is, and then the next question always is, if you get the law, do you get the bucks? Sometimes yes, sometimes no; usually, not everything you want.

We will be moving, as always, at the same time with trying to get the Kennedy bill, the Waxman bill, other bills that may be pending--those move at the same time that the

appropriations committees and the budget committees are looking at how much available dollars there are to spend on overall health care spending and, in particular, for HIV and AIDS-related programs.

Those are things we need to monitor very, very carefully, and I promise you both Carlton and I will keep you very much abreast of that because things happen real quickly and when you're talking about legislation maybe getting passed by early summer and signed by the fall, appropriations bills determining how much money is actually going to be spent are getting marked up in early summer, sometimes eventually decided on in the fall. So you've got conceptual policy, good goal-setting, where we want to go in terms of the programs, moving at the same time that we're looking at spending money in the traditional way that we have through the existing NIH-CDC-ADAMHA-HRSA programs, and they take a very careful balancing act of trying to get the dollars into the most effective programs as opposed to simply getting the dollars in the first place.

A few things real quickly, and I don't want to belabor the obvious. We've handed out the budget justifications for the Public Health Service, talking about their

proposal for how much money there should be and how it should be spent in FY '91. I don't know if you have these in front of you, but we also have the VA and the DOD numbers.

By way of overview, I would just suggest that you may well, as you all have over the last couple of years, often see a lot of different numbers thrown around. If there's any confusion, we're here to clarify what, in fact, got tossed into the pot.

Usually, when you're talking about overall budget for FY '91, you'll see relatively large numbers presented because the federal government will promote an overall spending number through DOD, through VA, through HUD, perhaps, although as Congressman Green told us, very little specifically designated for AIDS-related beds, Public Health Service, and entitlement spending--how much Social Security money, how much Medicaid money is being spent. So it really is, when you look at an overall budget number, the kitchen sink; it has everything in it.

If you're looking at the investment in research, prevention, and the minimal dollars that the federal government provides for service delivery, you're looking at essentially the Public Health Service budget, which then

become the numbers that you mostly see reported in the newspapers.

Last year, the Congress appropriated approximately $1.6 billion in the Public Health Service. The President's budget for FY '91 for the Public Health Service is approximately $1.7 billion, a relatively small increase. One of the programs within the Public Health Service that is increased--there are other programs that are certainly proposed for elimination and drastic reductions--but albeit a relative increase when you look at what the need is, is for the area of HIV and AIDS.

In particular, you'll see the biggest change, if you will, from the FY '90 to the FY '91 year in the HRSA budget. It is a cut. It is not a slight, small increase. And I think, again, it's an area when you look at the budget that will help us as a Commission enter the debate that the Executive Branch is having with the Legislative Branch, and that is what is the federal government's role in service delivery.

The federal government will clearly indicate their responsibility in terms of reimbursement through the Health Care Financing Administration. But if it comes to the actual

delivery of programs, you see this with HRSA and ADAMHA, in particular. We've heard this discussed now at a number of our different hearings that we use demonstration projects to provide service delivery because there ain't no federal government service delivery program, or very little. Usually, it would come in a block grant format that goes to the States, who then, in turn, can determine the best use for their particular jurisdiction.

That's why I think--and this is sort of an editorial comment on my part, but I think that's why you see cuts in the HRSA program. It was not the administration, either the Reagan administration or the Bush administration, initiative to provide home health care services or to provide drug subsidy programs for AZT and other drugs, which I think is important. We now have aerosolized pentamidine and other drugs that can be reimbursed under that drug subsidy program.

It was not the administration or the Executive Branch that proposed planning grants to local communities that needed to think about what the impact of HIV and AIDS may be prior to a large case. It was the Congress that has, for the last couple of years, taken the initiative through legislation as well as through the budgetary process and the

appropriations process, to say we simply have to provide the services in even the minimal way that we do, in addition to recognizing our continual role in education, prevention, and investment in research.

It comes as no surprise to me that the funding for the drug subsidy program and the home health care program were not proposed in the administration's budget. I think it's also very interesting for us to take a careful look at the ADAMHA budget because it hasn't been one of the agencies getting the larger increases as well when you look at HIV and AIDS.

Again, to some degree, you'll see the bulk of the money going into basic research and some money going into service research through the opportunity of the demonstration programs. But I think HIV and AIDS and where the increases go in terms of research and prevention and education is a really good way to look at the debate, I think, that currently exists about what's the federal government's role in service delivery.

And I would hope that as we look at what the growing need is for people with HIV infection and AIDS, both people who are sero-positive as well as people with full-

blown AIDS, we'll talk about what the federal responsibility is in terms of funding and the actual delivery of those services.

We've given you the PHS justification that talks about where the dollars would go under the President's request. We've also provided you with a draft NORA document, the National Organizations Responding to AIDS. They propose about a $2.8 billion budget right now, a draft. I don't think it's been signed off by all of the members, but it's circulating. It's certainly something they would all want you to be very well aware of.

And the bulk of the additional dollars, if you look at the numbers in the packets that we gave you, go into prevention and education at the Centers for Disease Control and the service delivery programs at HRSA. They also would be very supportive of--I believe I would be speaking for them as part of the document--supportive of initiatives that would look at the expansion of Medicaid reimbursement for people who are currently not eligible with HIV infection.

Eunice?

COMMISSIONER DIAZ: Just one statement regarding HRSA and their role. Dr. Bob Harmon, the new Director for

HRSA, has just created a special body to advise him regarding HIV within the HRSA responsibility. And the chair of that body is Molly Coy and I'm a member of that task force, and it might be important.

Their initial discussion on the very first meetings was to at some time in the near future combine their efforts with ours in perhaps looking at the service aspect of HRSA. And Dr. Harmon seemed very open to this and it's something I think we should look into.

MS. BYRNES: One of the things that we try to do at a staff level, when we're aware of the meetings or are given notice of the meetings, is to attend in an observing capacity so that we're aware of what activities may be happening at HRSA. We don't necessarily actually participate because I think there may be a difference of opinion about exactly where the agencies should be going or what the roles of the different agencies are.

We've also at a staff level conducted staff study groups where we as a staff--we try once a week to invite representatives from agencies, organizations--NORA has come, the AMA has come, other organizations--to come and talk to us about what they're doing so that we're kept abreast of that.

Jason and Carlton and others have really done a nice job of getting an array of people to come, and it may well be a good idea for us to do something like that with the HRSA advisory committee, or at least attend the meetings that they're holding. That's a good suggestion.

CHAIRMAN OSBORN: As a wrap-up comment on this, I was very grateful to Belinda for initiating what I want to finish off here in her comments just a little bit ago about the amount of work that is encapsulated in this brief report. It doesn't even mention the staffing that has been done for the site visits, for the small working groups.

I think I mentioned very quickly yesterday that we didn't even have durable office space until about the beginning of November, and it is now only middle March. And I think that the accomplishments of the staff under Maureen's leadership are beyond my belief, quite frankly, in the smoothness that we have experienced, with very few major exceptions, in our function as a Commission, sometimes even pretending that we were running on something like office space, and so forth, when we really didn't even have the--we will all think wistfully of the day when we didn't have a fax machine, for instance.

But, nevertheless, I think you won't mind if I take the prerogative of thanking the staff at this particular time because that summary stands out as something that has to be something of a record-setting accomplishment for a small group of people who have been working against some tough start-up circumstances.

Given that they've worked that way in start-up circumstances, I think we have every reason to anticipate a very exciting potential for the Commission as we continue. And I think when we talk this afternoon about things that we want to do and the priorities, and so forth, we now have a sense of real security and pride that a staff and a foundation for our operations has been brilliantly laid.

So from my personal point of view, but I think on behalf of the Commission, all of whom are nodding as I say this, I want to say thank you.

[Applause.]

MR. LEE: I will send a copy of the Waxman bill as soon as it's introduced, the early intervention, testing and counseling bill, to all of you for your information.

CHAIRMAN OSBORN: Let's turn, then, if you're agreeable, to Scott's report and to some discussion of it

before we break for lunch.

COMMISSIONER ALLEN: Let me share with you some of the structure. I plan on, within the 45-minute structure, sharing with you a little brief history of how we got to this point of dealing with testing and all of its ramifications, describe a little bit about the Boston meeting, and open it up to Commissioners to give their impressions that were in attendance, and then to look at what the working group is going to have for future activities along the subject matter of testing and its ramifications. Hopefully, that will be half or less than half, and then the other portion of the time, we will be in full Commission discussion about what we are doing.

We decided, after getting together a laundry list of what we wanted to look at in the Human and Social Issues Working Group, that testing would be our first issue, and the potential uses of HIV testing and screening include helping to ensure the safety of donated blood, tissue and organs, the epidemiological surveillance part of the public health strategy, to identify contacts who may be infected; foster individual behavioral change as a component of infection control policies in hospitals and as an important adjunct to

patient care.

We decided to start out with patient care and early intervention. As you have heard quite a bit about, and we're going to look at legislatively, we're looking at early intervention as a major issue, and testing is a large component of that. So we decided to tackle that first.

We met in Boston, dealing with the early intervention, on February 15th and 16th, and it was basically to deal with early intervention and the psychosocial aspects of testing. Marc Roberts was our facilitator, Professor of Public Health at Harvard.

The morning sessions were testimony time, and then roundtable. I believe you probably have a list of who was in attendance on the roundtable, so I don't want to take up the time dealing with that. But let me just share with you some of what the testimony--the types of testimony we had.

It was an overview of testing issues by Dr. Paul Cleary, types and standards of tests by Dr. John Ward, State legislative trends by Dr. Kate Cauley, and the challenge of testing in different populations by Marie St. Cyr. Then we looked at the programs of the Public Health Service, the Centers for Disease Control and HRSA programs dealing with

the testing issue. Then the roundtable centered around the role of testing and early intervention.

The next day, we started out with the continuum of psychosocial needs, and a presentation by Dr. Marshall Forstein, and then a roundtable dealing with the psychosocial issues.

So I'd like to open it up to the Commissioners. The Commissioners that were in attendance were Larry Kessler, Eunice Diaz, Don Goldman, and Harlon Dalton. So I'll just open it up. Larry, do you have impressions? Do you want to just go around and share with the folks?

COMMISSIONER KESSLER: I think the number one impression is that we couldn't do it all in one session. We opened a very complex can of worms here. In spite of all our efforts to sort of keep it narrow, there is no way to keep it narrow and concise, at least as far as where we are right now.

The issue that comes up more and more, even when we talk about testing, like everything else we talk about, is money. Where does the money come from for early intervention? How is it administered? What is the access like for primary care, for monitoring, and so on?

But I don't think we also probably spent enough

time looking at the psychosocial issues. While we got into it, the more we got into that we realized fairly quickly that that, too, needed more time if we were going to put together a report that talked about the complexities. We really scraped the surface.

COMMISSIONER ALLEN: Do you want to share, Eunice?

COMMISSIONER DIAZ: I think the most insightful testimony for me to hear was that of Marshall Forstein from outpatient psychiatry at Cambridge Hospital. In my opinion, he articulated the short and long-term implications and psychological factors on getting people into testing that may not be so readily obvious when perhaps a large portion of our nation would be encouraged to do so without the proper checks and balances in the system to support that kind of action or behavior.

I frankly had never understood it as well as Dr. Forstein presented it, and I've heard a lot of presentations on the psychological and mental health support and counseling support needed by people that make a decision to be tested. But in looking at the whole testimony, I think that that particular presentation stands out in and of itself as something that really opened our eyes in terms of the kinds

of things that could happen to people that have not been counseled properly and the types of mass communication of a message in which a society has not yet set a response in place to be able to support the individual's decision to test or not to test.

So I would say, from all the things we heard, that one seriously made an impact on me in terms of the knowledge base that it came from.

COMMISSIONER GOLDMAN: Much of the--first of all, I want to suggest that despite the best efforts that I thought that the--I would seriously question reusing the format that we used a second time around. We had tried to work out a roundtable with the idea that we would get an open and frank discussion of views from the participants there, and I think most of the participants there were good, careful, effective advocates and, for the most part, gave the party line and were not open about any doubts that they might have about their own positions.

The kind of openness and frankness that really was necessary as part of that process really wasn't there, nor was--and no criticism of anyone, but largely because of some last-minute changes in terms of scheduling, there were some

disproportionate segments in terms of different points of view in different kinds of communities that were disproportionately represented, and particularly in terms of service delivery people.

Obviously, if you get a bunch of service delivery people, you're going to come up with a conclusion that there are not sufficient funds or resources available to provide the necessary services they provide. And I'm not saying that that's wrong; I'm just saying that that's what we were faced with. As a result, as I think Scott will discuss, we have decided or suggested that there be some other areas that we will be looking to focus on.

It was a very useful meeting. We did get some very effective--as Eunice pointed out, some very effective pieces of testimony from some of the participants there, very moving discussions. But it clearly was not complete, and I regret that unlike the well-organized group that Diane led--you were able to move it up, open it up, close it up and wrap it up in one session. I'm afraid that we're not as efficient as you were and we're going to have to keep on going.

COMMISSIONER DALTON: I suspect that Don's expectations may have been too high for any two-day meeting. I

didn't walk away feeling nearly so disappointed. I was disappointed that some folks didn't show up, and we need to find a way to hear from them, particularly public health officials.

I don't know if it's a mystery to people that we don't have a written report, just because we didn't feel we were at a point to present, or whatever word we're using--to have a report received, which is why we're proceeding in this fashion.

The draft report that Jeff did prepare, I think, did a terrific job at the beginning of talking about the nexus between testing and early intervention. The reason that we focused on testing is because, with the apparent advent of treatment methods that can be employed early in the game, there seems to be a push from lots of quarters, from the Gay Men's Health Crisis in New York, from parts of the federal government, to encourage people to be tested so that they can access early intervention. Our interest was, given that this issue was now being revisited--the issue of testing in this context--to take a look.

I did think that we got fairly uniform testimony, not about the precise way in which these issues ought to be

linked, but a pretty substantial consensus that early intervention is not available everywhere and to everyone, and that insofar as early intervention is not available to a particular community, whether that's defined in geographic terms or gender terms or race terms or risk factor terms--where it's not available, then some hard thought needed to be given to the question of encouraging people to be tested under the justification of early intervention.

This, then, tied in with the testimony on the second day about psychosocial issues and, in particular, the powerful testimony by Dr. Forstein, that asking people to be tested is not simply a matter of--that the activity of being tested for HIV is not simply a matter of drawing blood and having test results given to you, but that it brings up for people a host of concerns of a psychological nature that are really often very difficult to mediate and modulate and deal with. Therefore, testing is not exactly a free enterprise, a cost-free enterprise, on a kind of human level for people who are tested--wonderfully complex and textured testimony about that.

Larry said we scratched the surface. I think we got a lot of very rich testimony, but what it did for us is

it made us realize how much more there is out there; I mean, how truly complicated all these issues are. I think I at least walked away sort of proud of what we had accomplished, but a little bit chilled at what else there was to learn. So I think we're really in mid-process on this first of the issues that we have on our perhaps too ambitious agenda.

COMMISSIONER ALLEN: I would say some of my reaction to all of this was that, along with what Harlon's impressions are, it's a kind of a smoke and mirrors right now that early intervention is there. It's not there for the indigent. It's not there for those even with insurance because of the discrimination, because of the issues of workplace, as well as other factors. And insurance companies may not be paying for it, and then all of a sudden you access your insurance plan and it's gone; you lose it.

So we have a real problem when we're talking about early intervention. The funding is not there, and if we're going to be advocates we need to really examine--advocates for the justification of testing in early intervention--we need to examine what the system is. We can do smoke and mirrors with budgets and deficits, but not with human life, and that's a very cruel system.

And I think that what we came away with from that meeting is we still have more to do on early intervention as well, so let me share with you some of what we are looking at of the areas that we're going to examine. We will put this in outline form and a timetable, and then to examine where the balances are, and then move with that into where we need to get more testimony of what type of framework that will be in and keep you all updated on that.

Also, this is the time for your input on where you see we may be lacking in some areas, or we need to highlight, or what your reactions are with this list. This is the initial list of when we walked away from the meeting saying this is more. It does begin with more clarification of the early intervention.

The first is to what extent is early intervention available or unavailable--the Medicaid, the drug subsidy program, and so forth--to continue that process of looking at the availability.

The second is a summary of average cost of early intervention and data and other sources of materials, to put that together for you all; risk of loss of credibility of the public health system if it advocates testing using an early

intervention rationale where early intervention is not available or not accessible; then moral and ethical implications of advocating testing using an early intervention rationale where early intervention--this is one of Don's; hang with me here, folks--using early intervention rationale where early intervention is not available or not accessible. Is it moral or ethical to seek to create a demand for early intervention through widespread testing, knowing that such services are not available, hoping that the created demand will increase resources devoted to early intervention, which is something that really came up at the meeting.

Number five would be a continuum of care models. What are we actually talking about with early intervention? Are we talking about just medical intervention? Are we talking about the psychosocial needs, the entire gamut?

Let's see. Six would be the drug treatment, what kinds of drugs are on the horizon--again, it goes back to cost factors, and so forth, and availability; seven, the efficacy of counseling in the absence of HIV testing; eight, informed consent; nine, partner notification and name reporting; ten, monitoring and evaluating the amount of CDC funds spent on education versus testing; eleven, home test

kits; twelve, other aspects of testing such as blood bank standards, and so forth.

So those are some of the things that we're looking at, and we have not put together the outline and timetable, but that is our first project walking away from this. If you have any input on content, this is the time to just open it up, and we'll get back with you on the timetable.

VICE CHAIRMAN ROGERS: Scott, that's very elegant, and it also makes me realize, wow, you've got a tough, tough area. I'll ask one question of the group, and I'm going back to some suggestions that were made earlier. Is this an area where it would be helpful to have some other experts join you, or are you too far along?

COMMISSIONER ALLEN: Oh, no, no.

VICE CHAIRMAN ROGERS: Well, I mean there's a group process, and you obviously are already involved in it. Would the addition of three other people that could do some of the work--would that help? I mean, should we use this special subcommittee kind of device with you, or is it simply you just need to hear more testimony? It's such a tricky area.

COMMISSIONER ALLEN: I think it could be both. I think where we're really missing some of the expertise is,

unfortunately, Charlie couldn't be there in Boston, and I think we really need Charlie's input into some of these things.

CHAIRMAN OSBORN: A Kansas blizzard, as I recall.

COMMISSIONER ALLEN: Yes, right. When you talk about adding folks or getting expertise, there's one right there, and other public health folks. I think that we can expand along that line and to examine where we could bring in some folks. But what was very disappointing was that Charlie couldn't make it, because there are some public health issues in here.

CHAIRMAN OSBORN: Jim, and then Charlie.

DR. ALLEN: Just in the last 30 seconds, the issue I wanted to raise has surfaced very clearly. I think the information that all of you have presented today is very useful. It supplements the information that I got back from Ron St. John on my staff, who was there, and I think raises a lot of--I think the right word was the one, Larry, that you used, complex--the complexity, the intertwining of issues that just surrounds the one issue of counseling and testing.

But in the discussion that I've heard so far, except for the last 30 seconds, I'm concerned that there

wasn't much at all about the public health aspects. When the test was first licensed in 1985, from a public perspective, obviously, the primary use to which it was put was to make the blood supply safe. Then people very quickly began to realize also that, well, there are people are going to be interested in whether they're positive or not. Therefore, we've got to have what were then called anonymous counseling and testing centers, and so on.

Finally, it got around to the point that many of us realized very early that this was going to be an extraordinary--the antibody test was going to be an extraordinarily useful tool to detect very early, to identify people who were positive so that we could much better target the educational message. To those people who were clearly infected or positive, the message is modify behavior so that you don't transmit further. Also, the medical aspects that are now known as early intervention are becoming much clearer even though they aren't widely available.

The other side of it, however, is for people who are antibody-negative, and I realize that you can't just simply easily classify people positive or negative based on one test if they've had high-risk behaviors that may have

exposed them, you know, throughout that period of time. The point is that there are very clear educational messages that need to be gotten out.

You raised right at the very end the issue of partner notification, and so on, and we know that in areas where this has been done on a limited basis with selected populations that we're finding a population that is at extraordinarily high risk. Twenty to thirty percent of the sexual partners, in particular, who are subsequently, through the partner notification process, brought in and counseled and tested--20 to 30 percent are already antibody-positive. The others have continued to be at high risk, many of them not having realized that fact.

We have got to focus much more on the educational aspects of this, and I hope one of the areas of testimony will be the efficacy of counseling. I was impressed, again, with the statement that there is a lot of psychological down side to the counseling process. Too much, we have focused on sort of single-episode counseling. We need to look at what really needs to be done in order to make it effective.

And I think that there just hasn't been enough public discussion about all of these, and if we're going to

devise and put forward budgets to try to reflect what is needed, you know, I hope that you'll help us get a lot of the information that we need from a-public health perspective.

CHAIRMAN OSBORN: Charlie Konigsberg.

COMMISSIONER KONIGSBERG: Jim has brought up, I think, a number of very critical points about the HIV antibody tests, and I at various times have had to spend a lot of time, as I think a number of us have in public health, about the history of that test and then this rapid-fire introduction into the clinical and public health scene, which it really wasn't designed to do, and I think this has put a lot of pressure on us.

I think a number of good points, very important points, have been brought up by the group, Scott, and I think there are some things that need to be taken very seriously. And I, in the absence of a written report, took notes as fast as I could. I don't write very fast or very well.

Just a couple of thoughts on how to continue the process, and this afternoon, given the opportunity, when we get to the agenda-setting aspect that June has mentioned, I will bring up the prevention as a major agenda item.

I think that if the Commission agreed to do that,

what we need to do is come up with some sort of a--I'm not sure the word "coordination" conveys what I'm after--an interlocking process that makes sure that the ethical and moral issues are running in tandem with the public health issues, which isn't to say that there shouldn't be separate groups. I think there needs to be for a variety of reasons, but there needs to be a lot of overlap in some fashion, and I think that can be done.

Speaking as a practicing public health official, there is a constant balancing that goes on when we deal with many of our issues. And there's been a lot written by, for example, the Hastings group and others, and this is not say that all public health officials pay as much attention to that as they should. So I want to, you know, throw a caveat out there, and I think that's where the Commission can have an impact.

In order to do that, we have got to come up with one or more structures for bringing public health officials into the discussion, and that can be done in more than one way. In fact, I would urge that because--and I'll say this again this afternoon--when you get down to where the responsibility lies in the States and the localities, who usually

take their authority from the States, it lies with State health officials. It lies with State health departments, or whatever name these go by.

We've got to bring, also, the public health practice aspects into this, the real world. A lot of what I do in groups--and I assume the reason I was repeatedly asked back to CDC in spite of taking jabs at them occasionally--Jim Allen was at quite a few of those meetings--is to bring the real world in. Now that I'm at the State level, there is some question as to whether I'm still in the real world. But, nonetheless, I haven't been gone from it very long. So we've got to take this into account, and I think there are a lot of very serious issues.

I know that I got involved with some things in Fort Lauderdale with respect to testing that were done differently than anything else we do; for example, a passionate insistence on my part that we were doing to have special written and oral informed consent drafted by our staff attorney, no less--that's how seriously we took it--before we would institute expanded testing and counseling even in the STD clinic, much less some other settings. I was asked many times why. You don't do it for syphilis, you don't do it for a

whole variety of things. And I think you can probably guess why that had to be done.

I also think--and I don't know whether this is the appropriate setting--the one thing that's occasionally lacking, I think, with this Commission--we've got a tremendous balance--is the practicing clinical physician, the one that's actually seeing patients with HIV disease on a daily basis.

For some of us, it's a struggle to try to act like maybe we're actually able to discuss that, and that's different than the research angle. We need to start figuring out how to bring those in, and they won't necessarily come from big, major teaching centers in New York City or Boston. They may come from Wichita, Kansas, and I could make a good suggestion--St. Louis--excuse me. Well, Kansas City would be our equivalent; that's the big time.

So somewhere along the line if we can come up with some way to make sure that we've got this interlocking, I think it was difficult for me to be real comfortable with the absence of public health people up there. And in order for me to access those people, there's got to be lead time. They've got to know what they're getting into and what's expected of them.

COMMISSIONER ALLEN: Go ahead, Harlon.

COMMISSIONER DALTON: I've been waiting for a while, Scott.

A short response to Charlie. I, too, have really benefitted from hearing from doctors who are treating AIDS patients on a daily basis. In Los Angeles, all of us got the benefit of, for example, spending time with Dr. Wilbur Jordan, but there are any number of other doctors and I agree that we need to find ways to hear from them not only in this working group, but in lots of ways.

But, Jim Allen, you've actually, I think, been spared the various forms of my lecture about the bifurcation of public health concerns and other kinds of concerns. Charlie has not been spared, but it may not have taken as well as I had hoped.

I think this really matters. I think it's not just a matter of rhetoric to refer to public health concerns as somehow separate and apart from the kinds of things that the working group is dealing with. I think it's dangerous to refer to what Charlie did when he was a local public health officer each and every day of his life as involving at the real world, but looking at the kinds of concerns that we were

dealing with, like the psychosocial aspects of AIDS and like discrimination, as not involving the real world. I think that's both wrong and dangerous.

COMMISSIONER KONIGSBERG: That's not what I said or meant, by the way.

COMMISSIONER DALTON: But I think there's a great risk that when we talk about public health concerns as against ethical concerns or as against legal concerns, then we reinforce the notion which is certainly out there broad in the land that, on the one hand, we have people who care about the public health and on the other hand we have people who care about civil rights.

One of the forms that takes is that, for example, the organized gay community is viewed as people who care about civil rights or individual rights, but not about public health, and that is profoundly wrong. What group cares more about public health than a group that has been so deeply affected by this disease in terms of their own health as a group of people? So I think we need to watch our language and not reinforce that idea. That's one point I want to make.

Secondly, Jim, if what you're talking about is prevention, which is the word that Charlie used, or behavior

change, then maybe it's better to talk about that rather than, quote, "public health." I think early intervention is public health. I think being concerned about the psychosocial aspects of HIV is public health. I think being concerned about confidentiality is public health, and every good public health officer knows that, as Charlie has indicated.

The working group, as I said before, chose as the prism for this first cut at the problem of testing early intervention, and so in many ways that drove a lot of what we heard. We did not choose behavior change, which has for a long time been a justification for testing, as has been protection of the blood supply, as have been epidemiological concerns.

But we tried to focus on early intervention, the nexus between that and testing, and as a result we didn't get into as much of the other issues, as you suggested. Nevertheless, we got some quite useful testimony, not enough because we didn't focus on it, on behavior change and the nexus between testing and/or counseling and behavior change.

Marie St. Cyr--those of you who haven't had a chance to spend some time with this woman--I know some of you have--she's extraordinary. But one of the things that I

remember her saying--others said it, but I remember her unique way of saying it--was that for the group of people that she works with, largely women of color who have, among a raft of problems, HIV as a real or potential, when you think about testing as a way of sort of getting them to think about behavior change, it's actually only one of a group of forms of outreach and often not the most effective.

Sometimes education, not even necessarily about HIV, but about prenatal care, is the way to sort of get women sort of thinking about their health, and then in the context of working with them about that and other family issues or life issues, one can then begin talking about HIV.

Her point was that this idea of sort of testing as somehow an all-purpose hook for getting people--and I'm not saying that you're saying that, but I'm just talking about some of the testimony that we heard. Thinking of testing as a talisman for getting people to think about behavior change doesn't work everywhere for all people.

Now, as I say, this was almost a by-product of what we thought we were there for to talk about early intervention, but it suggests, again, some of the complexities in thinking about testing and prevention or testing and behavior change.

And it's a rich field and we need to hear from lots of people, and I think we know that. It's just that we didn't structure the session so that we could go very far in that direction.

DR. ALLEN: I think your comments are well taken, and let me just point out that in terms of focusing only on one component--i.e., early intervention--in a way, you are creating a bit of a dichotomy, too, because it then forces us to talk about the other side of it. And if you look at early intervention as an isolated event, then Don's comment that was read by Scott--i.e., you have to, you know, wonder if it's ethical to test when you don't have early intervention available everywhere--that's why you can't separate it in that way.

Let me just pick up very briefly in terms of what you said about looking at testing as the entry point. Absolutely, it should not be. It should be one component of a much broader focus of care that is being provided to a person where every health care provider considers in terms of the context of who the individual is, the person is, that is coming to him or her as a provider, is it appropriate, how do we introduce it, and so on.

That's why testing and counseling need to be part of the repertoire of every practicing physician in the United States and other health care providers, why it needs to be considered in terms of STG clinics, tuberculosis control clinics, drug abuse treatment centers, primary care centers throughout the country--prenatal clinics, women's health centers, and so on. It needs to be part of our routine medical care and not as separate, except for that small circumstance of people who, for whatever reason, don't want to use the regular medical care system and want a separate, free-standing counseling and testing center.

COMMISSIONER DALTON: Just a brief follow-up. I realize I'm poaching on you, Don. Some of the other testimony that we heard was really quite detailed and interesting testimony about the deficiencies in certain locations in the country of the kind of counseling that's provided in certain settings. That's something we need to think a lot more about; that is, we heard folks who have had experience with STD clinics talk about what it means when you have somebody who has got a job already--go down a whole list of things and tell them that there's HIV counseling on top of it and how it comes out in the real world. We need to think about those

kinds of very practical, grounded details as well when thinking about testing.

CHAIRMAN OSBORN: We have a nice line-up here: Don Goldman, Scott, Diane, Larry Kessler, in that order.

COMMISSIONER GOLDMAN: Thank you. In our statement on the fiscal year '90 appropriations on September 19th of 1990, this Commission said and pointed out that the most compelling incentive for individuals to step forward for HIV counseling and testing is the availability of effective treatment and appropriate medical care. That was in the context of seeking additional funding for appropriate care.

One of the things that I think that we found at the meeting that is most disturbing to me is that the way that the Public Health Service budget ends up being proposed for the new year is that the major increase, as Maureen reported, is in the area of information and education. The most extreme drop is in the area of providing care, and particularly the drug subsidy, which is the major effective treatment.

Of course, the other side is that the most important part of the new public relations campaign that the additional $60 million is going to be used for is to promote testing because all of a sudden there is care available. With the

same dollars, they simply took away the care.

The distortion of priorities and the unmanaged way in which that kind of system ends up working out raises both practical, moral and ethical implications that I think are some of the things that we ended up discussing and, from my way of thinking, are simply unacceptable, and even from the point of view of the public health system aren't acceptable because ultimately I think that a public health system can never succeed any further than it maintains its credibility and its believability within the communities that it's trying to deal with.

If the public health system attempts to promote a certain avenue of conduct on the basis of the availability of service, when that service is only a fiction, then its own credibility is lost, and that's the worse than any one particular battle because that's the entire war. I think we have to focus on those kinds of areas, and I think Harlon is right in that context. Public health concerns and care concerns for individuals are not separable. We're not talking about different interests versus each other. We're talking about the same thing together.

COMMISSIONER AHRENS: At the risk of introducing

some very simplistic concerns--I'm just fascinated by this discussion, but it seems to me that outcomes depend on inputs. And I guess what concerns me a bit about the discussion in terms of the meeting that you had in Boston was my assessment of this list, and when I look down it, most people are identified by where they come from. That doesn't necessarily mean that they view the world from their geography, but that would, I think, reflect their geography.

There are only three people outside of the northeast area that I can see on this list, other than those of you who were actually on the panel.

CHAIRMAN OSBORN: Diane, let me just interject. I've joked about the Kansas blizzard, but indeed there were people from Colorado who were--.

COMMISSIONER AHRENS: I understand that there were those invited, but I'm just looking at the list because I think what is heard is what perhaps is reflected, and that concerns me as you look at future meetings.

I think that Don has reflected the concern that the public health system is inadequate to address this issue because of the dollars involved and the numbers of people, and so forth. But when you look at the Northeast, it's

understandable that you would hear about the unavailability of services. The numbers are overwhelming.

But if you look across this country, most of the places the numbers are not overwhelming. The services, by and large, are available, and the testing is available and the counseling and treatment after the testing is available in the total sense. If you look at the pockets, absolutely right, but I think when we develop whatever we develop we have to look at the nation as a whole and not just the pockets. I guess that kind of is my concern.

I think that the public health issues absolutely should not be separated from the total context, but the sense here was that--and I can say this because in the area which I operate in, NACo, the county health officials are part of NACo and they have some very clear directions and impressions about what is being done and what ought to be done.

It's just terribly important that all of that become a part of the discussion that we hear, and I was just concerned about both the geography and perspective.

CHAIRMAN OSBORN: Larry gets his turn first.

COMMISSIONER KESSLER: A couple of things strike me. One is in partial response to Jim Allen and his vision

of the world in terms of physicians, and so on, and the whole testing thing. While we didn't get into this at our hearing, I think we need to at some point address the question of who is going to deal with the training of the physicians. Is it the responsibility of the feds, through some mechanism in the CDC or others, or the local medical societies or the AMA, or whatever?

There is definitely a gap, and as we promote testing what we're finding--and I can only speak for our hot line, but it's, I think, a good sampling because Massachusetts is a good mix of not only urban, suburban and rural, but you have the medical mecca at Boston versus Springfield, Worcester and then lots of smaller towns. But no matter where, the kinds of calls coming in our 800 number, which is Statewide, reflect that physician understanding of the tests in early intervention, psychosocial issues, and so on, is just dismal.

This is nine years into the epidemic where people are still telling spouses you don't have to worry, but just don't use the same shower, you know, or you've got HIV and you'll be dead in six months; on the flip side saying, you know, you're HIV-positive, but don't worry, it doesn't mean anything, you're a long way from AIDS, and no education about

safer sex, about sharing needles, what have you.

I think that's happening all across the country, and we need to address that as part of the down side of a testing drive. And then we also just this week heard from our Massachusetts Medical Society that there's absolutely no way you can mandate education; we won't stand for it, and we've had too much of this. It's the constant gripe of physicians now that they're overregulated.

The other thing that we talked about in some degree of detail at that hearing, but I think we need to go further, is we talked about the psychosocial impact on the individuals. I think it's time for somebody to start looking at the psychosocial impact on the community.

As larger numbers within given groups get tested, I think we're going to have a different kind of community psychosis around HIV than we've seen before where it was the tightly-guarded secret, an individual decision, an individual burden that was felt with a few people. But my sense is that we may find soon that the whole community may be impacted, and I don't know how that will work out.

It would be good to try to figure out where that's going. You know, will that result in more despair, more

disengagement from the system rather than engagement? Will it lead to a different kind of activity? I think on one level we can see a model of a community that has been impacted, and that's the gay community, but traditionally throughout this epidemic the gay community is only the model for the gay community, not for people of color communities or rural communities, what have you. That's going to shift, too, as more and more people get tested--mental health needs, and what have you.

And then in response to Diane, I think I know what Scott is going to raise, so I'll try not to take his thunder here. But on a certain level I agree with you, Diane, that depending on where you sit you have a different perspective, and it would be important for us to draw in those other perspectives. But I don't think they are particularly consistent when you're looking at the county level or the State level or the city level.

I mean, in a way, we sometimes preach to the choir and sometimes we only hear from choir members, and we've got to get out of our pews and out into the streets and the byways and talk to those folks who are not part of national associations, not part of federations, and not part of

associations that really are doing some of the education. Woefully inadequate as it is, they at least know how to spell AIDS, with capital letters, you know. But there are others out there who still think it's a bi-coastal problem and, after this week, that it's over.

CHAIRMAN OSBORN: Scott, you had waived your rights before.

COMMISSIONER ALLEN: Go for it, Charlie. I'll come back.

COMMISSIONER KONIGSBERG: We could get real formal and I could yield my time to the colleague from Texas, but let me try to clarify, I guess, kind of what I'm coming from. I'm not sure it's completely clear.

First of all, my remarks related to the laundry list, not one specific thing. I think that's important that we look at that, and I would not want to presume that the public health officials out there wouldn't be willing to engage in a serious dialogue about that. I've been involved in many discussions with ASTO groups before I was a State health official, with NACHO, also NACo, and other health officers, where these very same subjects come up. There are differences of approach and opinion; there's no question

about it.

What we sometimes run into--and I sent one of the most graphic examples of that to June and Maureen--is the misinformation that is put out, or misinterpretations. It's somewhat killing the messenger, but actually that's not exactly what it is. I've seen various things put out and statements made that make the leap of faith that expanding testing and counseling, in fact, is mandatory testing, which is something that is, I think, abhorrent to all of us and was certainly a dismal failure in Illinois with respect to marriage.

So I think the listening process goes both ways. I think the credibility issue goes both ways. You know, we are all under pressure from constituency groups that either did sort of elect us, in a way, in terms of nominating us, or we're not, or we feel that we relate to those, and that's as true for me as others. But I think that kind of dialogue can occur.

In response to you, Harlon, part of the real world--I made the comment about the balancing act. Sitting at a desk in the health department in Fort Lauderdale and hearing a report from Miami that two people committed suicide after

learning of their HIV test at the Dade County Public Health Unit--it does kind of get your attention and it does make an impact.

The other thing I would say, in a little bit of disagreement with Diane--I can't speak for Minnesota, but I can speak for Kansas and many other areas, I suspect. The care is not out there, and I think we need to be sure that when we set up the early intervention model as a public health model as well as a clinical model that we are careful about it. I think that's a message to the feds as well as to the States.

I can tell you right now I'm not about to go out in Kansas and start pushing this as public health policy, knowing the problems we've got out there. But what I am trying to do is prepare the private physicians, the hospitals, and the health departments for what I know is coming down the pike.

One way or another, there's going to be federal money. If Kansas doesn't want to put up a dime, if the care bill passes, I've got $900,000. We can actually do something with that, not enough, but it's a start. So, again, I think we ought not to knee-jerk on every end of this, and when I

see some of the things that are written, it just scares the willies out of me.

You know, I don't know what Steve Joseph said up in Montreal, okay. I don't know how he came across, but I am absolutely amazed at things that are not at all out of line with what is said around the country or that is carefully thought out that all of a sudden there's a firestorm. Let's find a way to make sure that within this Commission everybody gets heard, and I don't think that has quite happened yet with this list. And I understand that there is plenty of time, Scott, and I was really pleased to hear that the process isn't through.

CHAIRMAN OSBORN: You get the last word before lunch.

COMMISSIONER ALLEN: Don't get your expectations up, okay, guys?

Just a comment on the various things that were going around. First off, Diane, about some of your assessment of the people and the location, we were trying to have some cost containment on that process, and that was one of the factors. However, our evaluation of early intervention and whether it's there or not was not really based on locale as

much as on the CDC's testimony, on HRSA's testimony, and the governmental agencies that were there saying it's not in the budget, and the FDA saying a 500-count T-cell.

I wanted to clarify that because what we're basing it on is what is happening governmentally in the federal system, and that, wait a minute, here we are moving toward this momentum of early intervention. So I wanted to comment on that because that was the major factor. We heard it loud and clear.

I think that we saw in L.A.--and I'd try not to draw too much on past experiences, but the Legislative Task Force on AIDS in the State of Texas went to eight different sites and had public hearings all over the State of Texas, in rural Texas and in large cities, in places like Lubbock that are not that hard-hit, and everyone was crying out.

So in my own personal experience, I've seen it's not just New York, it's not just L.A., it's not just the Northeast; it's all over. The county systems are being inundated and the finances are just astronomical and the system is close to collapse.

So I wanted to add that, and that is also the reason--Charlie, I appreciate your seeing that we have not

finished, by any stretch of the imagination, early intervention. You notice we start out with saying, wait a minute, to what extent is early intervention available and not available, because we saw the deficiencies in that process. That's why we don't have something in writing for you because we are saying wait, this is a good start.

And we didn't get the public health folks we wanted. Some folks just didn't come. Some folks turned it down. I want that dialogue to take place. I, too, agree, Charlie, that we can't compartmentalize an approach to this. That is disastrous, and that has happened. We have isolated certain aspects of this and all of a sudden it gets out of balance.

We came at it with the approach of early intervention for the basic reason of saying people are dying. People have the chance of life, and we came at it from that saying this test is a part of that, but we need to find out how we can prevent the progression of this disease, and this is the forefront.

It seems to be our society is moving toward this early intervention method or modality, whatever I'm trying to say. We're moving in that direction, and we need to stop and

really closely examine this. So that's why I was disappointed. I would like for you to be a part of reevaluating this outline because you have some insights that we really--and choosing speakers, forums, because it would be absolutely instrumental.

CHAIRMAN OSBORN: Well, let me--.

COMMISSIONER KONIGSBERG: June, just a very quick response. The answer is yes, I'd like to do that, and then on the other side of it--not the other side; that's a bad phrase. If we, in fact, adopt two things, either a prevention agenda or an examination of the public health system, I think we need the same kind of overlap so that we're not working separately. That's what we need to avoid.

CHAIRMAN OSBORN: In closing up for our lunch interval, I would like to thank Scott and the group for having done an exceptionally succinct job with the most difficult set of issues, in many ways, that we need to grapple with. It's been a really helpful start.

I want to make a technical point so that there isn't any unease. I think there was room for unease in one part of the conversation. When Charlie is talking about public health, changing for a moment to the hat I think I

still have from people who pay me, that is a system. And when Charlie is talking about public health, in very many of his contexts he's talking about public health officers, State public health departments, not the public health--sometimes I say the health of the public in order to try and get away from the technical things.

So to the extent there was any sense of confusion there, I would like to be sure that we are all sensitive to two things. People are quite aware that there is a medical profession and a nursing profession. People are less aware that there is a public health profession, and I think a lot of what Charlie is talking about, and about the burden of some of the epidemic, and what Jim Allen was talking about, have to do with the public health structure and public health profession, with no value-laden stuff in there.

So as we discuss this, that's a sub-category of health professions, if you like, and I've been trying to push us--.

COMMISSIONER KONIGSBERG: And system.

CHAIRMAN OSBORN: Well, just as there's a medical profession and a system of medical care, there is a public health profession and a system of public health structure.

Nevertheless, the only thing that I didn't like in the discussion in terms of moving us forward was a sense that somebody might have misunderstood that. And since it's not widely acknowledged in the same sense that some of the other health structures are, I think that's important to keep track of.

I suggest we break now for lunch and reconvene in one hour.

[Whereupon, at 12:28 p.m., a luncheon recess was taken.]

AFTERNOON SESSION

[1:50 p.m.]

VICE CHAIRMAN ROGERS: June sends her apologies. She's still busy dealing with the press and Jonathan Mann's sudden and sorrowful departure from the scene, which is a tragedy for all of us.

I think we've accomplished more than I would have thought we could have at this session. Let me put three things before you, if I can get the attention of anybody.

[Laughter.]

VICE CHAIRMAN ROGERS: One is our meetings. Don has pointed out that this meeting on March 29th, which will star President Bush, Belinda Mason, and Lou Sullivan, as well as the CEOs of Time-Warner, in the person of Dick Monroe, Levi-Strauss, and a bunch of the business community--it's at the Willard, I believe, and I think members of this Commission are--.

COMMISSIONER GOLDMAN: Crystal Marriott.

VICE CHAIRMAN ROGERS: Excuse me--I'm thinking of the wrong meeting--at the Crystal Marriott. And I think members of this Commission are warmly invited. It is my fond hope that that will be an historic meeting, and all of you can

take some of the credit for it in terms of what we put in with our first mini-report. I think that had a significant impact.

Yes?

MS. BYRNES: It's my understanding that everyone got their own individual invitation and that you should be sending back very important information so that they can confirm your attendance. If that hasn't happened, please let me know because I know, in fact, you all are invited.

VICE CHAIRMAN ROGERS: Yes, and they will be fairly stiff about that by virtue of the fact that it's a meeting that the President will be talking at.

COMMISSIONER GOLDMAN: They need your Social Security number and date of birth to check into their computer.

VICE CHAIRMAN ROGERS: That's right.

Second, we have a planned rural site visit meeting in April, and then we have our next meeting planned on May 7th and 8th. The tentative plan, but give any input you wish to this, because of a number of things that are coalescing, was to look at the personnel issue, was to look at supply of personnel, the manpower issue.

Maureen, do you want to explain that any more? Well, I'll just ask if you've got any response to that. There are a series of requests from nursing, from others, so we thought that was an issue that we should deal with fairly swiftly.

COMMISSIONER DALTON: How far along is the planning for that meeting? In other words, if we were contemplating doing something different, does it require unsettling many settled expectations?

VICE CHAIRMAN ROGERS: No, I don't think so. If you would like, why don't I suggest--I would say if you have other things you feel are of critical importance, get back to staff swiftly with it.

COMMISSIONER DIAZ: You mean like other sites?

VICE CHAIRMAN ROGERS: No, not other sites, but other agenda items for May 7th and 8th.

COMMISSIONER DIAZ: Where is that meeting?

VICE CHAIRMAN ROGERS: That meeting is tentatively--.

MS. BYRNES: The plan is to have it here. Congress is very actively in session at that point in time, and to the availability of some of the members, as well as what the

Commission may or may not want to respond to, that was the plan. The timing of that--we tentatively thought we'd need to be in Washington, with a site visit in April somewhere else and a possible site visit in June somewhere outside of Washington, D.C.

VICE CHAIRMAN ROGERS: If there are other things you'd like to put on that agenda, get them back to Maureen as promptly as you can.

COMMISSIONER MASON: Dave, how are we determining the content of that? I mean, now primary care provider--the provider perspective?

MS. BYRNES: Broadly, yes; personnel, I guess.

COMMISSIONER MASON: Personnel.

VICE CHAIRMAN ROGERS: All manpower issues.

COMMISSIONER MASON: Okay. How was that decision made to take that up? Is there some kind of urgency related to that topic?

VICE CHAIRMAN ROGERS: Yes.

COMMISSIONER MASON: I just need some kind of, you know, input about that because, you know, I have my single horse that I ride to its exhaustion and, you know, there's an urgency there, too.

VICE CHAIRMAN ROGERS: There is indeed.

COMMISSIONER MASON: Research and treatment and drug development and clinical trials.

VICE CHAIRMAN ROGERS: Put it in.

COMMISSIONER MASON: But, you know, I'll be glad to hear some--I don't want to like--I mean, I don't want it to be like, you know, just sort of tacked on as an after-thought, and it needs to kind of grow thematically out of--so if there's some kind of rationale that I need to hear about why we're taking up the provider aspect next, especially because in some of the parts of the country that I visit there's not anything to provide, let alone the providers to do it with--I'm belaboring the point, so you might explain to me.

VICE CHAIRMAN ROGERS: No. That's perfectly appropriate.

Larry.

COMMISSIONER KESSLER: I think we can actually incorporate that if you look at human resources in the broadest sense of care providers, researchers.

VICE CHAIRMAN ROGERS: Well, I think part of Belinda's comment is her concern about availability of

medication.

COMMISSIONER KESSLER: That's different, okay. I thought you were talking about--.

VICE CHAIRMAN ROGERS: Is that right, Belinda? Am I reflecting your concerns properly?

COMMISSIONER MASON: Yes, but also, you know, the broad questions of science and research because, you know, there's a growing--just some of the things that Jim Allen said today about how trials are conducted and how it's really kind of costing people's lives, and we shouldn't just be kind of sitting, you know, around about it and saying, well, everybody is doing the best they can unless we satisfy ourselves to that, and I'm not satisfied to that. And I don't feel like I can answer to the people that I need to answer to about it until--see, for the PWA community, the issue of treatment and drug development is like the most compelling, the very most compelling.

COMMISSIONER DIAZ: Two of us have got to leave. Is it possible we can give a statement?

VICE CHAIRMAN ROGERS: Sure.

COMMISSIONER DIAZ: Some of us are concerned. We've had a longstanding invitation to site visit or commis-

sion part of a visit in Puerto Rico. I don't know that that has been set.

VICE CHAIRMAN ROGERS: It has not.

COMMISSIONER DIAZ: And I think that we ought to probably either get back to these people or in some way say this is not a priority for the Commission at this time, and give a justification, or it is a priority and we're not going to do it this way, or whatever we decide. But that's an invitation that's been there going on six months.

And the next one would be still the focus of a prison. Both Diane Ahrens and I felt it was somewhat hanging because we had thought of discussing the situation in prisons, but had not actually formalized it. I would say some of us, again, that have not had the opportunity to visit South Florida feel that is important. I would second her input to you before she had to leave.

VICE CHAIRMAN ROGERS: Thank you. Bye; safe journey.

Harlon?

COMMISSIONER DALTON: I want to say one brief thing about Puerto Rico, since Eunice just brought it up. I mean, I certainly like visiting nice places. No offense, to

Eunice; however, Puerto Rico would not be the place I would go if I wanted fun in the sun.

Maybe I was just too short in the other room, but the incidence of HIV in Puerto Rico rivals that in Central Africa. And as Karen pointed out, it being a territory, its relationship to our national health care system and to our legal system is really quite different than other places, and it is a place apart from any other place we are likely to go. It is still ostensibly a part of this country, and so we can sort of make light of it, but not to the point, I think, of being submissive.

But I really had my hand up because I wanted to build off of what Belinda said. I guess as I heard Don DesJarlais earlier before the lunch break, he had suggested that maybe the best way to deal with drug treatment issues, science issues, drug trial issues, drug research, drug development was perhaps through a working group. And I think, David, you suggested the inclusion in that working group of some experts who happen not to be sitting on the Commission.

I think that certainly is a good idea in terms of deepening our knowledge and working our way toward a set of

recommendations, if any. But I also think that it's important, quite apart from that, to as a full Commission hear from a range of people on these topics, both to inform ourselves--and by that I mean myself and some others, obviously. I mean, I learned a hell of a lot this morning. I was serious when I said that hearing June talk about those couple of meetings was a little bit like being there and very helpful to me.

But I also think that we as a Commission need to hear more, but we also need to signal that we are hearing. And it seems to me to devote some of our joint time as a Commission to these issues sends a very powerful message that these are important issues to us. And then it seems to me, after that, if we spin it off to a working group to do, wherever that working group's nose leads it--I mean, I would wholeheartedly endorse that. But I think it's not--I mean, I think there are reasons to do both of those.

VICE CHAIRMAN ROGERS: Charles, and then let me respond.

COMMISSIONER KONIGSBERG: Not on that topic. I wanted to comment on the site visits.

VICE CHAIRMAN ROGERS: Well, all right, let's hear

that, too, and then let me respond on that.

COMMISSIONER KONIGSBERG: Okay. Let me echo Eunice's comments about South Florida. There are two specific areas down there that I think are quite unique. There are probably three. We'll say Miami is, and I know that Miami is much visited. I also know that Belle Glade is much visited, but for those who have not visited Belle Glade, it will be just as interesting and disturbing as New York City.

Then there's Key West. Now, that may get back into fun in the sun again. There's a very unique situation down there in a community that doesn't seem to attract private and federal grants because it's a low-population area. And I just want to mention that, in addition to the fact that Florida is, in fact, one of the high-incidence States, which is kind of a political thing. But there are some unique situations.

I worked in Fort Lauderdale, and I'm not sitting here telling you there's anything unique to see there. But those other three communities, particularly Belle Glade and Key West, are critical.

VICE CHAIRMAN ROGERS: Let me make a suggestion.

We have two suggestions, and it seems to me staff could take a look at this. One, we do want to hit the personnel issue, and I won't go through all of the reasons for it. Belinda, I hear you in terms of where the concerns of the group we're most concerned with are. Let's have the staff explore that a bit in terms of whether that would be possible to do in this.

We've had two suggestions about areas for potential site visits. You might explore those, and then June and I and all of us can discuss that.

MR. PERNICK: David, Puerto Rico and Florida can be run together.

VICE CHAIRMAN ROGERS: Yes, I think they can, too.

MR. PERNICK: That's one of the conveniences.

VICE CHAIRMAN ROGERS: Yes.

MR. PERNICK: And Florida is important, and while Puerto Rico may be almost subsidiary, a sub-group of a sub-group can sort of hop over for a day or two.

VICE CHAIRMAN ROGERS: Fine. I agree with you.

Scott.

COMMISSIONER ALLEN: Just on the site visits, it would be helpful, since we've gone through this process of looking at what are priorities, if we could have some

specifics like we had in New York of the homeless, of why we're going there and how we can incorporate that into the larger picture, and some justification for that of where we can come out of that with a good report or something that may help alleviate some of the energies of going in different directions.

CHAIRMAN OSBORN: I feel a little funny about popping in, since I apologize for my absence through so much of this, but I'll add things, with your indulgence. In the context of Puerto Rico, one of the issues that had arisen was that something like 70 percent of people in prisons are sero-positive in some of the prison statistics.

I participated in the Puerto Rico think tank in August, and it becomes a little less startling when you start thinking about the almost completely free travel between New York and Puerto Rico and the drug problem that's burgeoning in Puerto Rico. So the combined effect has resulted in some extremely unusual but perhaps prototypic circumstances that are among the many reasons for concern there.

There is also a great--the issue of rural health, interestingly, comes up there, too, in the sense that there are basically two kinds of community-based health care kinds

of structure, a public health one and another one. I forget the right names, and Eunice is gone.

But there's a disassociation, so that some that should be involved are essentially totally uninvolved, and the access to care issue gets intensified far beyond what it otherwise might because of a very strong degree of non-coordination.

So there is, in fact, a great deal of room for concern about the circumstances in Puerto Rico, and there are things that feed into some of the other issues that are looking at in other contexts. My sense has been if we wanted to talk about prisons and jails, we should do more than one visit. Also, I think that has come up in the context of Alabama that that might be a way to look at it. So that's part of thinking that went into that line of suggestion, and I think that that kind of thing is worth knowing.

In terms, Belinda, of the concerns about health care providers, you, in fact, are one of the people who has sensitized me to the very great problem with the under-educated status of present health providers, and many people have educated me to the fact that nothing much, nothing appropriate is happening to increase either the quantity or

the quality of health care provision capability as these numbers double.

That, coupled with the expressed concern for input from the American Nurses Association, the American Dental Association, the American Medical Association, and the American Hospital Association, in terms of timeliness for an interim report and a first year's worth of work, to have not--several of those organizations were under the impression that we had appointment authority, so our first contact from them was why isn't there a nurse on the Commission.

I think if we listened to that kind of testimony, it would not be useful. But if we took that stimulus to phrase the questions of what are your problems with respect to health care provider training, attracting people into the health care workplace, there are a lot of answers there. I know that much. What are you doing to overcome those? What are you doing to train people specifically in universal precautions care in some instances, or compassionate response to the epidemic in other instances, or counseling in other instances?

I think if the questions are well framed, we could meet a certain amount of what you might call constituent

pressure in ways that would move an extremely crucial part of the agenda along. I would kind of turn around a little bit what you said and say if all those drugs are accessible and there's no one to deliver them and nobody who knows how to do so wisely, it won't do us any good to have the drugs.

So both of them have an urgency that makes me think that, you know, in a very important sense the urgency is in balance, and perhaps within one or two meetings it ought to be a matter of what can be set up when, since I share your sense of urgency.

The only thing I would say is that there are far more people talking about the issues that you raised, many of whom are conscientious, than there are the issues that I'm trying to activate about health care providers. I become frantic about the fact that in the medical school at my institution, for instance, still it is a matter of a very few hours mostly devoted to retroviruses as this epidemic just explodes.

People need compassionate care at a level of new sophistication at least about immunologic phenomena that they hadn't gotten trained for if they had been out of medical school since last June, even. You know, it isn't happening

as fast as it should, and I think that's an area of broad concern.

VICE CHAIRMAN ROGERS: Thank you.

Harlon?

COMMISSIONER DALTON: Actually, that was very helpful. I was wanting to respond to Belinda's question and that is really very helpful. June, I just wanted to say that when you first mentioned the organizations that were clamoring to speak--and, indeed, I heard from a nurse as recently as on the plane coming down, why wasn't a nurse appointed, and I hear it most nights at home.

But when I heard the names of the organizations, I got that sinking feeling that we were going to hear the party line. But as you talked, it sounded wonderful, and I think that ought to be a model from now on of us, when we invite people, sort of giving them, in a sense, a set of questions that we would like to have them answer, given their expertise, so that they don't just simply tell us--.

CHAIRMAN OSBORN: The party line.

COMMISSIONER DALTON: --the party line, but really help us get where we want to go. I was just so pleased to hear that, and I think it's not just for this group whenever

we hear from them, but from every group from now on.

CHAIRMAN OSBORN: With, of course, the caveat that having been provided the list of questions, the deadlines, and whatever, as you know as well as I, humans will sometimes be humans. So we won't guarantee the result, but it's important to try. I strongly agree.

VICE CHAIRMAN ROGERS: Go ahead.

COMMISSIONER KESSLER: I just have a suggestion on that level. I think it's sort of like getting references for an employee. You don't necessarily go to the first one that people tell you to go to. We know of people out in the industries--nurses, physicians, psychologists, whatever--who may belong to some of these associations and are recognized within the associations.

For instance, a Jeannie Martin, I think, would be invaluable to talk about the whole VNA level, but not necessarily speak for VNA of America, but can give us the perspective and the credibility without being biased or programmed by the board of directors of VNA. If we can find comparable levels in the nursing profession, psychologists, whatever, we may get just as much mileage and a more real picture, a more accurate picture.

VICE CHAIRMAN ROGERS: Jim, last comment, and then I'm going to wrap this up here.

DR. ALLEN: One other tactic that might be used in terms of trying to address the issue, particularly when you want action taken and it isn't the responsibility of the Commission to take action, is to perhaps empower a working group that includes not only a few Commissioners and staff, but also people from the AMA and others.

Particularly with the professional education component, to the extent that we can get each of the professional societies to buy into this and own it as their problem and begin to take action, we've succeeded in beginning to get the train moving.

VICE CHAIRMAN ROGERS: Harlon?

COMMISSIONER DALTON: David, I thought I heard you say to Jim--that's the point you made before, and I think his point was a little different. I think he wasn't simply talking about being able to augment our own expertise, but that insofar as we have the consumer pressure and insofar as we want these people themselves to carry the ball, involving them in working groups that won't necessarily produce a product for the Commission might serve those goals as well.

VICE CHAIRMAN ROGERS: I think we owe you, on the basis of what you did this noon, a listing of an array of areas you think are important to explore, filled out in ways that the staff feel appropriate so that you can make some judgments about it. For the next meeting, we will explore, Belinda, your area, as well as the whole health personnel manpower issues, for reasons that June has just explained.

As you know, the staff has been working on a paper which we would encourage you to input on. It is currently our plan to make use of that as a second mini-report, with any other suggestions you have with it, probably modifying it on the basis of what the President does on the 29th. So we've delayed the output of that. That ought to give people plenty of time to look it over and decide what they would like to add to it. I think our first one went very well. I think this one will, too.

I'll turn it over to June to let her close our meeting.

CHAIRMAN OSBORN: I get the feeling that maybe we missed a very important function while everybody was here, which was to extend the dates of the next meetings. We only go through July, and that's a little scary because I don't

know about your calendars, but mine is filling up fast.

I think given that we have only, I think, seven of the Commissioners here that it may not be a productive exercise to try and do that now, but that instead we should take very seriously a quick turnaround time on calendars so that the staff can work with them and look for Commission dates.

I would appreciate any comments you have about the general pulsing that we're doing, which is every two months this kind of a meeting, generally in Washington. The possibility of moving elsewhere is not out of the question, but certainly with some of the exigencies of, certainly, Roy and Secretary Sullivan, when he can be with us, and so on, it's a good idea to be here some of the time, but then alternating with that some site visits so that there is a pulsing of activity that the staff can cope with. We will try and look at that.

Is that general pattern of behavior that we've established reasonable so far as you're concerned in terms of the work plans that you've talked through, and so forth?

Site visits may not be able to be simultaneous with small working groups, so that it might not turn out to be

monthly site visits. But I think in terms of monthly tasks, if that seems to you like an appropriate pace, I think it may be just about all the staff can bear, and that would be an important question to have in mind.

So as we look for dates, you'd be looking for September or November, you know, like we did the first year, for a two-day hearing kind of a thing, and then the staff may look for dates when site visits are appropriate.

COMMISSIONER ALLEN: I have a question. With the annual report, will there be a need for, since that is part of the--one year is the interim report. Do you see any need for extra time or anything like that?

CHAIRMAN OSBORN: Well, let me ask your thoughts about that. My sense was in the language of the bill that there was at least some effort not to constrain us to a strictly report-writing mode. And in that intent, the language requiring an interim report at one year and a report at two may have been intentionally somewhat permissive.

I would myself be a bit concerned to have the staff suddenly turn around, take what we've been doing, stop the forward progress long enough to redo it all, and put it into some kind of a compendious format, as opposed to keeping on

going. But that certainly is something the Commissioners should comment on. And, Maureen, you may have a comment as well. We've talked only briefly about that.

MS. BYRNES: I think to some degree when we get back about other dates and outlining what the current dates are and where they will be and what the topic is for May, at least, in looking at the other issues we'll also indicate a timing for at least how to deal with an interim report.

I mean, I certainly would follow Dr. Osborn and all of your direction as to how to handle that. My feeling is that people will expect something from us, and my sense is that we have already done a lot and that we need to weave it together. And we'll do that as we identify what the other issues are, what we've done, how that fits in the plan, and in that way we'll almost be writing what we've done and where we we're going.

And, to me, that sounds like an interim report, but we'd need to approve that and promote that and at least have some sort of session that really indicates some summary nature, if you will, of what the Commission has done after one year and what our plans are for the coming year.

I think we can share some of that with you when we

get back to you on what some of the follow-up issues are, when the meeting dates are convenient for everyone, and target when that discussion about the interim report and structure would be, if that sounds acceptable to everyone.

CHAIRMAN OSBORN: Harlon?

COMMISSIONER DALTON: I agree. It seems to me the only reason to do an interim report is if we can get some mileage out of it. And the idea of having the interim report be essentially a compendium of our greatest hits, with kind of a nice sort of intro, is fine, but I would hope that we would be sort of too busy in some ways to sort of do anything different than that.

CHAIRMAN OSBORN: If there's no strong objection to that, I think that gives the staff at least a range of ideas as to how to proceed. It was important, I think, to be sure that you didn't feel that we should, in good conscience, try and do a very thorough reprise in this first-year interval.

I think that we are at a position to adjourn. Thank you very much.

Here is your moment.

MS. BYRNES: I haven't quite said it this way and I've been dying to say it. As the duly-designated government

official, I hereby adjourn this meeting.

[Whereupon, at 2:25 p.m., the meeting of the Commission was concluded.]