

## **Transcript of Proceedings**

GRIGINAL

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

Twenty-Fourth Meeting of the

NATIONAL ADVISORY COUNCIL ON REGIONAL MEDICAL PROGRAMS

Rockville, Maryland Tuesday, 3 August 1971

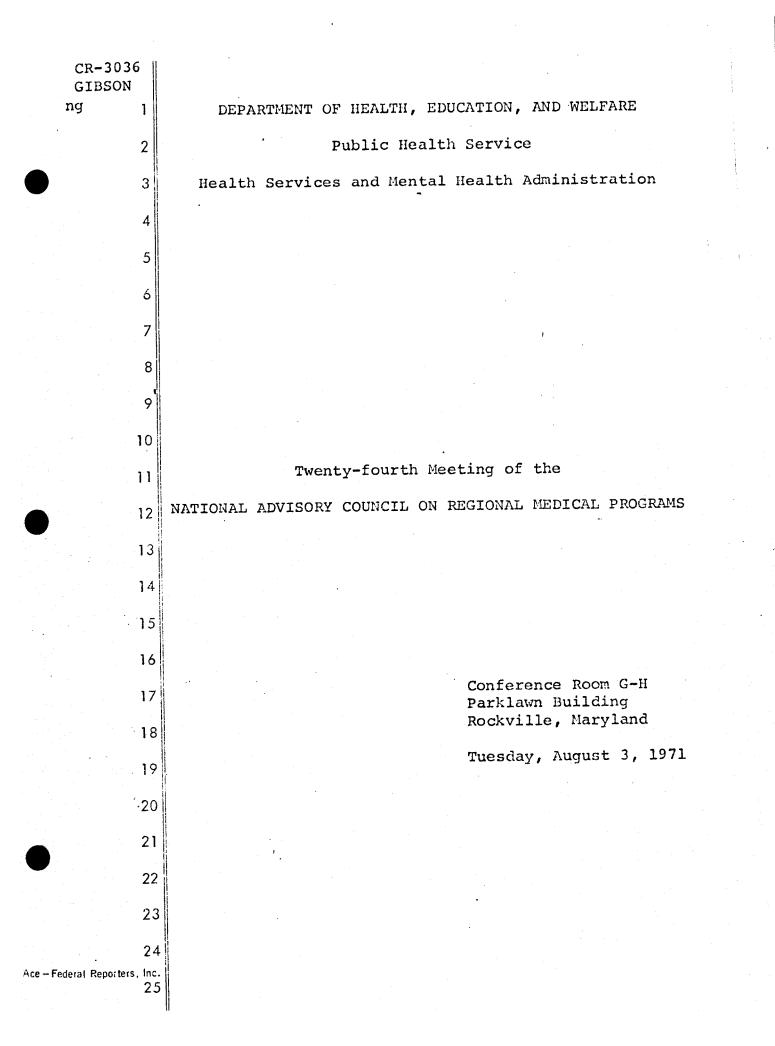
## ACE - FEDERAL REPORTERS, INC.

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## <u>PROCEEDINGS</u>

I believe we can begin the meeting DR. MARGULIES: 2 with just a couple of sort of technical announcements, one of 3 the most isgnificant of which is that these microphones have 4 been moved fairly close to the end of the table and we are 5 recording the meeting so that we can check back on what the 6 wise words were passed around the table. So please don't lean 7 back from the microphone but lean into it, and then we will Q have no difficulty getting things properly recorded. 9

Before we begin, I also must remind you that there is a confidentiality requirement and a conflict of interest statement which goes with participation in these Council meetings, and I think we are all aware of them so I won't bother you by reading them through.

We do have some people I would like to introduce 15 before the meeting begins so that you can all be fully 16 acquainted with one another. Some of these are new members of 17 the Council and some of them are new members of the staff. 18 There are six new Council members, not all of them able to be 19 present at the time of this meeting, and I will introduce those 20 who are present, but I'd like to mention first of all that 21 Mr. Ogden, who is a member from Spokane, Washington, was unable 22 to attend today, and Mrs. Mars, who comes from Virginia, was 23 also unable to attend because both of them couldn't make 24 arrangements as late as they were informed.

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Among the new members I'd like to introduce Dr. Tony 1 Komaroff, who is here on my right, who's had some experience 2 with regional medical programs which may or may not be helpful--3 we'll see; Dr. John Merrill, who is one of the people who, 4 among other gualifications, is an expert in the field of kidney 5 I'd like to point out that we now have two kidney diseases. 6 experts which relieves Mrs. Wyckoff considerably in her 7 responsibilities as a kidney expert. 8

Mr. Sewell Milliken, who among other things brings 9 us direct and full-time involvement in comprehensive health 10 planning where he's a director of the state agency, and will 11 be able to clarify for once and for all any kind of confusion 12 regarding regional medical programs and comprehensive health 13 planning, so it's up to you. And Dr. Watkins from New York, 14 who is also a new member, who is seated here directly on my 15 left. 16

I'd like to also introduce and ask them to stand as we go through some of the new staff members who have been added and who members of the Council would at least be able to recognize if only fleetingly this morning.

The first are the group of commissioned officers who
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And I'll just go through the list of new staff members 1 other than the commissioned officers, and ask them to rise as 2 The list if fairly long but they are also we go through them. 3 fairly important, so I'm eager to introduce them. Charles 4 Barnes in Grants Management -- not here. Richard Clanton in 5 That's an old title. We're not using Regional Development. 6 that any more. Mrs. Shirley Fairley, Smoking and Health; 7 Dr. John Farrell; Robert Handy, Office of the Director; Calvin 8 Jackson, Smoking and Health; Mrs. Glinter Johnson, Systems 9 Management; Dr. Alan Kaplan, Professional Division; Mrs. Nancy 10 McGuire; Roger Miller, Grants Management; Spero Moutsatsos, 11 Planning and Evaluation; Jeffrey Passer, who is not here today; 12 Roland Williams, Systems Management. 13

These are all people who will be added to our general responsibilities and potentialities and they will be available for you to know and for us to work with more effectively.

I'd like to call your attention now to the minutes 17 of the last meeting for any kinds of comments or questions 18 I'm sorry, let me stop the proceedings. I'm so used to the 19 fact that you're here all the time that I made a terrible error. 20 Ed had his back turned to me, but very ably representing the 21 Veterans Administration and most of the rest of the world, and 22 specifically representing Dr. Musser of the Veterans 23 Administration is Dr. Ed Friedlander, who is down there on the 24 right sporting a new mustache. Mr. Friedlander spent a number

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a number of years with the Regional Medical Programs in which he tried as well as he could to make them understand the better ways to do things and having succeeded, he left for the Veterans 3 Administration about six months ago --

> Almost ten months now. MR. FRIEDLANDER:

DR. MARGULIES: We're glad to have you here.

I would like to have you consider the minutes of the May 11 and 12, 1971 meeting. I understand there is one 8 omission, that there was a kidney proposal which by accident was not included in the report and that will be inserted, in case no one else noticed the error. If there are any other errors, omissions or alterations which you would like to introduce, they can be considered now. Otherwise, we will 13 assume that they are acceptable.

We will in the future be reporting not minutes of this 15 meeting, but a summary of them, to the coordinators immediately 16 after the Council meeting. Now, we were doing it quite rapidly 17 for a period of time. We then improved our process and slowed 18 it up by two months, so we will further improve that improved 19 process and we will expect to report the general highlights of 20 this meeting to the coordinators within a period of about 43 21 to 72 hours after the meeting is over.

22 Before we go on to any other discussion, I would like 23 to have you consider the future meeting dates which have been 24

listed here for you. Ace - Federal Reporters, Inc.

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Just a moment before we leave the minutes DR. ROTH: 1 of the last meeting, the Council took action and approved a 2 short I quess you would have to call it policy statement 3 which I think had as a purpose transmission to the Secretary 4 of HEW, and I have not seen this reproduced as part of the 5 minutes or in any other way part of the business of the Council 6 Do you recall the statement to which I refer? 7 DR. MARGULIES: Was it Council meeting before last? 8 Was this one that was prepared by Council and sent from Council 9 to the Secretary? 10 This was in addition to that. DR. ROTH: No. 11 Was it the missions statement? DR. MARGULIES: 12 It was left out of the minutes of the DR. CANNON: 13 previous meeting and the minutes of the last meeting made 14 mention of that and asked that it be included. 15 Let me say, at the last meeting I Yes. DR. ROTH: 16 was not present at the first session. I was only here for the 17 second day, so I was not around at the time of the approval 18 of the minutes and I don't know what happened except it was 19 omitted in the last minutes, and my understanding was that it 20 had bee noted and was to be reproduced or added in subsequent 21 minutes. 22 We'll check on that and make sure DR. MARGULIES: 23 that it's there. 24

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DR. ROTH: I move its inclusion in reports and minutes

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DR. MARGULIES: All right.

DR. CANNON: Second.

DR. MARGULIES: It's been moved and seconded that that report be included in the minutes of this meeting. All in favor say "Aye."

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("Ayes")

DR. MARGULIES: It will be done.

9 I'd like to have you consider now the schedule for
10 the future meeting dates. Some of them are to be reaffirmed
11 and some of them are to be considered for the future. Those
12 that had already been agreed to are November 9 and 10 for the
13 next meeting and February 8 and 9 for the subsequent meeting.
14 The others are May 9 and 10 of '72 and August 15 and 16 of '72.

We regularly cross-check these against any other major meetings which may present a conflict, and to the best of our knowledge, these are as clear as they can possibly be considering the busy schedule everybody has.

19 Well, if there are no objections, we will consider20 those the accepted meeting dates.

21I'd like to spend a little time with you now dis-22cussing some of the event which have taken place since the23last meeting which we had with the Council and try to bring24some of the newer Council members up to date on events whichAce-Federal Reporters, Inc.maybe cover a little longer period. I will omit the event which

impressed me the most, which was on May 18 when Iwas proceeding homeward and was struck down by an errant automobile which chose 2 to have entered the same particular part of the turf that I was 3 occupying at the time, and te-1 you that six days later we held Å a meeting with the Secretary which had been requested rather 5 urgently by the coordinators of the Regional Medical Programs 6 asking the Secretary to meet with them and a number of other 7 interested people to discuss Regional Medical Programs; how he 8 viewed their present status; how he viewed their future; and 9 that meeting was held on that date. 10

Dr. Russell Roth was there, not representing the 11 Council necessarily, but representing the interest which he 12 There were a number of has in medical care in this country. 13 other individuals and, by a series of happy events, they 14 represented the medical schools in the country; they represented 15 the coordinators; they represented the staff of the Secretary; 16 they represented the Kidney Foundation, and a number of other 17 people who are deeply concerned with health and with Regional 18 Medical Programs. 19

I think that it's fair to say that the meeting was a 20 remarkably successful one and in subsequent conversations I have 21 had with people who attended it and have had some sort of later 22 reason to consider it it seemed to be a kind of a turning point 23 in the understanding of RMP in the Office of the Secretary. 24

Ace - Federal Reporters, Inc. 25 I suppose there were about three kinds of interests

which were most impressive to me and I don't know whether they were the same as would impress other people or not. Perhaps Russ would like to comment on it as we go along. 3

One of them was that the assemblage of individuals there was able to address about all of the kinds of issues and all of the potentialities that RMP is associated with. There was the view of the medical school. There was the view of the Comprehensive Health Planning people. There was the view of the 8 practicing medical profession and so on; and it pretty well swung around over a short period of time everything we were 10 concerned with. And it seemed at that time that the Secretary and the staff of the Secretary found what they were being told 12 impressive and believable. 13

Secondly, I think that there is little question but 14 that the strong support we got at that time that I had not 15 fully anticipated came from the Secretary's staff itself. 16 People who were there who represented people directly in his 17 office, the comptroller's office and others were saying 18 extremely positive things about the Regional Medical Programs 1.9 at a time when we were starved to hear exactly those things, 20 and I think it was most convincing. 21

Finally, when Secretary Richardson was summarizing the kinds of new legislative programs which are anticipated and the general pattern of changes in health care delivery as viewed from the federal position, he talked about the

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unavoidable conclusion that if all of these various kinds of 1 programs are to be developed -- talking about national health 2 insurance; talking about some kind of regulation of the 3 insurance industry; talking about the development of area health 4 education centers; health maintenance organizations; the whole 5 panoply of federal initiatives -- he said that this obviously, 6 if it was to be rational, required some kind of regionalization 7 of resources. 8

He also recognized the argument which I think has .9 been our core argument defending RMP, that we do represent the 10 most effective way of dealing with the private health care 11 system; that the program which this Administration has laid out 12 is one that depends almost completely on the way in which that 13 private system is able to perceive what they are doing and be 14 responsive; and that RMP represented the best available 15 mechanism for carrying out those kinds of relationships. 16

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He summarized by saying that it was very possible that the Regional Medical Programs would be the key element in the kinds of changes which needed to be carried out. Those weren't his exact words but it was pivotal point or key element or something of that kind. And all of us came away with the feeling that there was a higher level of understanding than we had anticipated and from our point of view there was a sense 23 of optimism which we had not always been able to feel in the 24 past, although there has been enough of a tough history of Ace - Federal Reporters, Inc.

funding, etc., in this program so that I don't believe that any of us could go away with wild enthusiasm for what may happen until we see the positive results.

Russ, would you like to comment on that session? 4 DR. ROTH: Well, the only addition that I might make 5 is that one extraordinarily significant development, which may 6 have been accidental or may have been preplanned, was that the 7 Secretary had preconditioning in respect to RAP because in the 8 early days of Tri-State he was involved or had some connections 9 with the development of Tri-State and found them in general 10 unimpressive; and so his concept of RMP naturally was 11 inevitably colored by a rather adverse opinion of the way things 12 had been going in Tri-State in its pre-Leona Bumgardner days, 13 I guess that's about the best way to say it, and Bob Lawton (?) 14 who is known to many or most of you was there and able to give 15 him a very authoratative updating on the change of scene in 16 Tri-State RMP and to cite him chapter and verse about things 17 that were very familiar to him in the Boston area, and I think 18 this was very important in changing the preconditioning in the 19 Secretary's mind. I think that this was probably the single 20 most significant bit of testimony that was given at that 21 meeting. 22

Other than that, I would share all of Harold's views on the general nature of the meeting.

DR. MARGULIES: Thank you.

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Now, I think what will now happen depends on a number 1 of activities which are currently going on. At the meeting. 2 the Secretary spoke of the fact that he was requiring of his Ś staff some clearcut recommendations for him by July 1 on how 4 the federal health strategy would specifically be implemented; 5 what kind of functions would be carried out; where the assign-6 ments would properly be placed; and indeed, within a few days, 7 we were involved in that kind of conversation between, in our 8 particular case, Health Services and Mental Health Administration 9 and the Office of the Secretary. 10

It became clear during those kinds of discussions 11 that the role of RMP was constantly being deliberated and that 12 there were some clearcut and specific kinds of duties and 13 opportunities that we would have, that they very frequently 14 centered around the issue of measuring and attending to the 15 general issue of the quality of medical care, and that this was 16 constantly emerging as a bigger and bigger issue. In fact, as 17 discussions have proceeded, the question of the quality of 18 medical care as one measures it for the entire community at 19 service, regardless of the kind of health care system, has been 20 given more and more attention in the Administration and there 21 has been more and more recognition of the fact that the RMP is 22 the natural kind of device to deal with the quality issue, and 23 not only with the quality issue but with a good many others. 24

Ace – Federal Reporters, Inc. 25 Now, it will be interesting to see what in the

appropriations process and I need to bring you up to date on 1 where we stand with that and see what happens thereafter. It's 2 a difficult thing to evaluate the total effects of the current 3 appropriations interest because there is more than RMP involved. 4 There is, as I think anyone who is at all sensitive to 5 political affairs present -- as well as a certain amount of 6 political tug-of-war between Congress and the Executive and 7 possibly even between Republicans and Democrats -- I can't judge 8 that kind of thing -- nevertheless, the House appropriations 9 reported out a rather marked increase for the Regional Medical 10 Programs. 11

Well, let me back up a little bit to bring you up to date on what occurred. Late in the last fiscal year, there was a supplementary appropriation passed which did add \$10 million to the appropriations for RMP. This was finally considered within the last month of the fiscal year and was added to the \$34.5 million which had been placed in reserve. So we have for this fiscal year \$44.5 million in reserve.

19 If that had been undisturbed and if the recommendation 20 of the Administration had been preserved in House action, we 21 would have ended up with -- we'll just stick with the level of 22 grant -- we would have ended up with a level grant figure of 23 \$70 million. The House chose to add \$30 million to that figure 24 and this is what passed through the appropriations committee 25 and is the present state of understanding in the House. The

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Senate held their hearings very recently. They are being pushed to complete their appropriations hearings much earlier than 2 they have in the past so that the business of carrying out 3 programmatic efforts -- I hope that's one of the reasons -- can 4 be clarified a little instead of trying to plan for a fiscal 5 year that's already halfway through or beyond that. The Senate 6 added \$40 million I understand to the \$30 million which had 7 been passed by the House which now gets us up to a figure, if 8 it would be actually distributed to us, which is far and away 9 above what we had been considering and what has been available 10 to us in the past. 11

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It's going to be a very interesting question to see how this finally comes out in negotiations between the Congress HEW, the Office of Management and Budget, Health Services and 14 Mental Health Administration and the Regional Medical Program 15 I find it very difficult at this point to fix on any Service. 16 reasonable figure which we are going to finally come out with 17 because these are very large amounts and there are other events 18 in RMPS which are entering into the considerations, partly 19 because both of the appropriations acts in the health field 20 are going to provide funds well above what the Administration 21 This makes a difference not has requested across the board. 22 only for RMPS but for a good many other programs and creates 23 some budgetary problems which I'm sure are going to be the 24 subject of a lot of fighting and struggling and negotiation.

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One would think that out of all this, with a change 1 in attitude toward RMPS, with the very marked increase in 2 appropriations, with a large reserve which has been carried 3 over to this fiscal year, that we are going to end up with a 4 larger sum of money with which to run the program than we have 5 had during the past year. But the size of that is going to be 6 difficult for us to calculate and the best we can hope for is 7 a very rapid conclusion of deliberations so that we know where 8 we stand as early as possible in our plant. 9

One of the reasons why this is desperately important 10 is because we have to calculate even before the review process 11 has been completed what kind of distributional grant support 12 we should make in order to maintain the Regional Medical 13 Programs at their fullest possible function, making some kinds 14 of calculations now which will be meaningful next June. If we 15 fail to do that in an efficient manner, we'll find ourselves 16 in the middle or two-thirds through the year completely off 17 balance fiscally. 18

So we will have to stay very close to what is likely to happen and make some calculations on what we should do and act as quickly as possible when we know definitely how much money will be available.

Now, there may be some comments on this or perhaps some of you have something to add to it.

DR. ROTH: Harold, would you venture any opinion as to

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the contingencies that are implicit in the House \$30 million and the Senate's additional \$40 million in terms of grants of that money or allocations of that money to do things that RMP has not been doing? Do I make myself clear?

5 DR. MARGULIES: Yes. In the kinds of discussions 6 which we have been having with them, I think that there has 7 been a growing understanding, both in the Senate and the House, 8 that the directions of the RMPS which are represented by the 9 missions statement are those which are appropriate to our 10 activities.

I think there remains a strong interest in categorical 11 activities but in a much less splintered fashion than we have 12 seen in the past. There are specific kinds of activities which 13 have emerged in the discussions in the appropriations hearings 14 to which I think we'll have to pay some attention. Certainly 15 they are concerned with health manpower. Certainly they are 16 concerned with a stronger kidney program. This has emerged in 17 the discussions regularly I think. There has been expressed an 18 interest in better emergency care which is frequently centered 19 around the care of the acute coronary but which I understand 20 has to be based on a broader kind of consideration. 21

Now, in the Senate hearings, there is a kind of understanding that one does not propose the use of funds in any program for something that hasn't become law yet; so that such discrete programs as the are health education center were not a

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part of our discussion, but as Senator Magnuson said, "We'll talk about that when it exists. It doesn't exist." But I think the area health education center kind of concept has been clearly of interest to them.

We really didn't discuss in our own presentations 5 health maintenance organizations and I'm not sure that, at 6 least on the Hill, the relationship between RMP and HMOs has 7 been very greatly explored excepting for one aspect of it, and 8 that's the part of it which has to do with attention to the 9 kind of health services which are provided through an HMO and 10 special concern for the quality of care which may emerge from 11 any kind of an HMO type of an organization. 12

Herb, you were there for the Senate hearings. Would you like to add anything to that?

DR. PAHL: I think the only thing I would add is the Chairman was most gracious and lectured the Administrator on the need to spend the monies that Congress appropriates; also was interested in exploring some of the kinds of uses to which we have been putting our funds; and seemed most receptive to all the statements that Dr. Wilson made.

It was a relatively brief monologue by Chairman Magnuson, coming very late in the day, and it was a pleasure to hear following some of the prior conversation about some of the other activities in the health services.

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DR. MARGULIES: There is clearly some money which will

be used for construction, but regardless of what level of grant 1 support we get, the designation of a cancer treatment facility 2 in the northwest part of the United States remains firm and 3 there will be due attention paid to that. 4

There has been no other great discussion about the 5 use of RMP funds for construction, and whether that will come 6 up as a further issue or not I don't know.

Would I be correct in assuming that in DR. ROTH: 8 this preparation for classical eventualities of increased 9 money, that the Council might well take a hard look at doing 10 more with 910 proposals than we have? We've been holding most 11 of the 910 stuff back, but as I read the picture, 910-type of 12 RMP activity would have substantial appeal in supporting the 13 increased appropriations? 14

I think that's perfectly reasonable. DR. MARGULIES: 15 Our feeling has been that the Council would give first priority, 16 based upon prior discussions, that any increased funds we may 17 get to strengthening Regional Medical Programs which have been 18 hurt pretty badly by the restricted funds in the past, and I 19 think our first consideration would clearly be toward invest-20 ments where our strengths are in the RMPs and where they have 21 been hampered by reductions; but certainly the possibility of 22 the Section 910 funds being used is a high one for consideration 23

For those who are not familiar with that section of our legislation, it refers to an arrangement whereby there can

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be a combination of interests among Regional Medical Programs to support activities which cut across regional lines, so that we can use a different kind of mechanism for developing major activities, sometimes of national interest, sometimes involving several regions together, which may require a coalition of effort and level of cooperation which has not always been the essential part of the individual Regional Medical Program.

We've had a number of proposals of that kind, but with the restricted funding we have been unable to act on them, and I think the possibility, if we get significant funding increase, of developing that is a good one.

Probably the prime reason why we have not -- well, 12 there have been two reasons why we haven't used it in the past. 13 One is we really needed to put everything we had available into 14 the support of individual RMPs; and the second is the rather 15 strange phenomenon, which says that if you use a new section 16 like 910 everyone assume there's more money that goes with it, 17 and when it's all coming out of the same pot that creates great 18 confusion. That happens regularly. As soon as you say well, 19 we're going to put so much effort into some kind of activity 20 there's an assumption on the part of most people that somehow 21 we found more money, but that -- if that wasn't the case it 22 would be disturbing.

Any other comments on this?

(No Response)

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There are some other legislative activities which are going on in which we are very deeply concerned. They happen not to be in our legislation but they are of very prime interest to us, and that has to do with the area health education center concept.

You may recall this is an idea which was introduced formally in the Carnegie Commission Report and became very soon thereafter a part of the Administration's efforts to improve health care delivery.

Briefly speaking, it is a newly described but pre-10 viously existing community-based activity supported by grants 11 in all likelihood, which would combine the health delivery 12 mechanisms in the community with the health educational 13 activities; therefore, it includes, among other things, the 14 hospitals, nursing homes, out-patient facilities -- it would 15 include junior and community colleges which are training health 16 manpower, nursing programs in hospitals, etc., with a link with 17 the university health science center, designed in such a way 18 t hat the educational activities and the service responsibilities 19 are all part of one mechanism and are located, initially at 20 least, in areas where there is a need for better health services 21

These are usually described as either being in a rural area where health needs are great or in the inner-city where the problems are not so much those of geography as they are social and economic barriers to good health delivery.

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The area health education center was included in the 1 legislation under the new Health Manpower Act only in the House 2 bill, and there have been introduced in the House and in the 3 Senate two proposals for the area health education center. One 4 of them would place them in NIH in the Bureau of Health 5 Manpower, and that's the Administration bill which has passed 6 The other would have placed them in Title IX which the House. 7 is the Regional Medical Programs, and because there was 8 indecision between the Senate and the House about whether it 9 should go to NIH or the RMP route, the Senate bill did not 10 include area health education center when it went to conference 11 with the House. 12

This was done because they felt that the area health 13 education center, along with HMOs, could be dropped out of 14 consideration of health manpower and considered under separate 15 The last I heard they were in conference on that legislation. 16 issue, and unless we have a recent bulletin they haven't reached 17 a decision about whether AHEC would remain in as the House 18 proposed it, and be in NIH, or would be dropped out and be up 19 for consideration later, which is still not settled as to 20 whether it goes to NIH or to RMP. 21

In any case, the form that it was in in the House would require that any area health education center 'be developed 23 in cooperation with a Regional Medical Program wherever that 24 activity was located, and there has been from the very time that Ace - Federal Reporters, Inc. 25

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these considerations began a very close working relationship 1 between RMP and the Bureau of Health Manpower -- the Bureau of 2 Education -- well, I forget what they call it now, but it's that 3 crowd over there that deals with health manpower. We have been working very well together and we have a good understanding of 5 what we're going to do, and in any case, whether it comes to RMP or in NIH, there's going to be a way of working effectively 7 It will take a little while before we know how this together. 8 comes out. 9

In the meantime, the Veterans Administration has exhibited a high level of interest in area health education centers. Earlier in the year NIH mounted a number of site visits which we planned with them and they visited areas in which they could get some understanding of what might be involve in an AHEC and pretty well blanketed the country.

Within the last two or three weeks, the Veterans 16 Administration has carried out a number of site visits of its 17 These have been, for obvious reasons, differently own. 18 designed, but what the VA did, as I understand it -- and, Ed, 19 you may want to comment on this further -- is to identify 20 hospitals which are located in areas of need in the sense of 21 having inadequate medical services and where there was already 22 established a good working relationship with the Regional 23 Medical Programs. 24

Ace – Federal Reporters, Inc. 25 They then set up some site visits which included

people from NIH, from RMP, from the Veterans Administration, from HEW Regional Offices, to see what the potentialities were for establishing an area health education center which would include an investment and involvement on the part of the VA. In our discussions the VA made it quite clear that they felt an RMP relationship would be a very desirable one, if not essential in all cases.

8 Now, I think they have completed their rounds of 9 site visits. If not, they are very close to it, but they were 10 covering --

MR. FRIEDLANDER: Eight, and we finished the site visits this week in Fresno, California.

And the VA has decided very clearly DR. MARGULIES: 13 to make an investment in this direction and is going ahead with 14 So that one way or another, it's quite clear that this is it. 15 a rising interest; and as I move around the country and talk 16 with the coordinators, it's clear that the possibilities of an 17 AHEC are very attractive to them, interests them greatly, 18 and they recognize the possibility in RMP of doing with this kin 19 of device the kind of things which they're well fit to do. 20

Ed, would you like to comment further on the VA role in this?

MR. FRIEDLANDER: No, only the VA role, it should be remembered, was generated really out of the President's health message which called for a closer relationship between the

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Administrator of the Veterans Administration and the Secretary of the Department of Health, Education, and Welfare; and it seemed that the area health education centers were the ideal 3 kind of way to join the two together.

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It was Dr. Musser's feeling that rather than wait 5 until all the blocks were in place, it might be well for the 6 Veterans Administration, as you say, to move out in cooperation 7 with the Bureau of Health Manpower and with the Health Services 8 Administration, particularly with the RMPs, and look at some 9 places which were identified as having potential for such an 10 activity. 11

However, it's clearly understood that the Veterans 12 Administration and those people with whom we have talked to 13 date, both in the VA installations and with the NIH in the 14 Health Services Administration people, that only those things 15 which have a direct relationship to improved quality of care 16 and improved relationships to this end with the community can 17 be funded or will be funded through the Veterans Administration 18 providing some kind of a base which the area health education 19 center can pick up once the legislative authority has been 20 determined and authorization of funds has been made. 21

If you have any questions about it, I'll try and 22 answer them. 23

We will have later on in the day or DR. MARGULIES: 24 during this session a special report which you had requested on Ace-Federal Reporters, Inc.

the Watts-Willowbrook activity which represents many of the elements, if not all of them, in the area health education center, and I think this will give us a further opportunity to discuss what we might be able to do with this.

We did have a short, rather ad hoc meeting with half a dozen coordinators who were concerned with the AHEC and discovered or reaffirmed our knowledge I think that there is a great movement in this direction scattered all over the country and that many of the elements which are necessary to create that kind of center are present.

But there are some major uncertainties which as we 11 go along we're going to need some help on from the Council, 12 and among these is the very interesting issue of how one would 13 relate such a center with the university health science center; 14 what is the best kind of working arrangement which may be 15 involved; how does one influence the other; and I think as time 16 goes on I think this may be not only one of the more intriguing 17 subject, but one which may provide us a potential for change in 18 the medical education system which we have rarely had made 19 available to us. So I think we will be getting into this more 20 and more as we proceed. 21

Is there any other question about these issues at this time?

(No Response)

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I told you also last time that I would like to bring

you up to date -- and this gets back to some of our staff, efforts and then we'll pick up on some of these broader issues-I wanted to bring you up to date on what we were intending to do and were actually doing with our equal employment opportunity program, and at the time of the last meeting I gave you only a brief statement which indicated that we had initiated our programs.

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There has been a rising interest in equal employment 8 opportunity programs throughout all of government. We have 9 had the interest in RMP with or without that kind of government 10 interest. We decided a number of months ago, in response to 11 a request for an affirmative action plan, that we would aim 12 for certain goals in the employment of minority members and in 13 the employment of women, both of whom we were able to recognize 14 without difficulty were being given inadequate opportunities, 15 and in these kinds of circumstances we felt that we didn't 16 really have a program that was fully effective or which could 17 respect itself adequately. 18

We have agreed that by January of 1972 that we would 19 have a 6 percent net gain in minority employment; that 60 per-20 cent of the minorities gaining employment would enter into 21 professional service; that 50 percent of all vacancies at or 22 above the medium grade for RMPS would be filled by minorities; 23 that 40 percent of all vacancies and professional positions 24 would be filled by females, minority or non-minority. Then we Ace - Federal Reporters, Inc. 25

have some other goals for '73 and '74.

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· In order to reach those kinds of goals we have set up 2 a number of mechanisms which are I think working at the present 3 time quite well. We started out with a training conference 4 which was in March of 1971, a three-day training conference, 5 in which we had an opportunity for people to concentrate all of 6 their attention on the issues of employment and what they meant, 7 not only to RMPS but what they meant to the kind of social 8 environment we are striving for in this country. 9

This led us to adequate preparation for a career 10 development activity through the upper mobility program, so 11 that up to date, all employees in the grades of GS-1 through 12 GS-7 have been screened and counseled and identified regarding 13 any special employment problems they have; whether they feel 14 as though they are deadended in their activity or whether they 15 are underutilized; and we are going to continue with this kind 16 of screening activity for another group. 17

We have a council which is advisory to the Director 18 of RMPS dealing with EEO affairs. It meets at least every 19 other week and more recently it has been meeting weekly, and it 20 meets with me once a month and with a number of other people 21 on the staff, and provides a steady flow of advice and 22 information, and I can assure you it's not hesitant to point 23 out the deficiencies in the way in which we are making progress 24 toward our goals.

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Our progress has been good but not fully adequate. 1 Reorganization, which you will hear about later, has created 2 They've set up a monthly EEO newscertain kinds of problems. 3 letter. The deputy EEO officer or a representative is at all 4 of the staff meetings which we hold for the major professional 5 staff members here and is present at the executive officers' 6 staff meetings, those that deal primarily with personnel 7 matters, and there has been an EEO training conference by the 8 staff members as I indicated to you. 9

We are going to go beyond that and make sure that all personnel actions are fully screened even at the point of their initiation, as they are being reviewed before final action is taken, to make sure that there is adequate representation of interests and the protection of the opportunities for minorities and for women.

16 I think you will witness as you get reacquainted with 17 the staff this time that there have been some changes already 18 strikingly evident as a consequence of this activity, and as 19 time goes on I think we will be able to fill it out more fully.

Now, this also means that we have to pay increased
attention, as we have been, to the same kinds of problems as
they affect the Regional Medical Programs, and we are now
getting more explicit information than we have had before. It's
becoming increasingly clear to people in RMPs that these are
issues which cannot be separated from the other factors which

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1 determine the viability and the strength and general vigor of a 2 RMP, and that we will be reviewing these kinds of questions with 3 the same kind of scruplenessless that we have been reviewing 4 how the RAG functions and how the coordinator functions, because 5 they are, indeed, in separable.

50 you will be provided regularly an increasing amount 7 of information which you can clearly identify as you go through 8 the review process.

9 Is there any question about this? It's really a 10 matter more of just bringing you up to date, but I do want to 11 keep you informed.

Herb, I wonder if you'd like to comment on the orientation session which was held?

DR. PAHL: Yes. Yesterday afternoon, we held an orientation session for new Council members, and we were very pleased to have Mrs. Wyckoff and Dr. Schreiner and Dr. Ochsner also attend, in addition to Dr. Watkins, Dr. Merrill and Mr. Milliken.

The purpose of the orientation luncheon and afternoon session was to have in an informal setting opportunity to have staff present some of the larger purposes and broader organizational framework and some of the background and history of those kinds of matters that come before the Council.

Mr. Peterson dealt with mission, roles and organiza--Federal Reporters, Inc. 25 tional strucutre and activities of the actual Regional Medical

I dealt something with the organization of head-Programs. quarters and the responsibilities for legislative requirements 2 and roles of the Council, and something concerning our review 3 process and Mr. Baum participated in giving us an overall HEW-4 HSMHA framework. Dr. Margulies was able to attend from a down-5 town meeting and spent an hour in a very fruitful general dis-6 cussion with us and then Mrs. Dickens from our travel office was 7 able to provide specific information to the Council members. 8

9 On the part of staff we felt it was very helpful and 10 very constructive. We appreciate the Council members devoting 11 this additional time prior to the Council meeting, and depending 12 on perhaps some further consideration of this we might include 13

We seem to be very forgetful, Tom Roth also attended. He came a little bit late.

DR. MARGULIES: I'd like to now open for discussion an issue which may very well occupy the attention of RHP more than any other at the staff level, and may have more pervasive influence on future events, and that is the responsibility we have to set up methods for monitoring the quality of medical care.

I'd like to be as specific about that as possible and tell you what the considerations are which lie back of it. The health maintenance organization is going to be supported, as you all know, and is under active support at the present time.

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A number of contracts have already been let to establish HMOs through the HSNHA mechanism. There is an active interest in HMOs being exhibited by the Regional Medical Programs and some of them have been actively involved in at least investigating the feasibility of the HMO.

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We were assigned, but we were pleased to have the 6 assignment, two responsibilities for health maintenance 7 organizations which then extended beyond just the HMO and were 8 inclusive of general considerations involving quality of care; 9 and they were specifically to set up the kinds of guidelines 10 which would be necessary for monitoring the quality of care and 11 to describe for monitoring or for guideline purposes what's 12 meant by health maintenance. 13

Now, it began and remains at the present time for 14 immediate working purposes with the consideration of how one 15 monitors the quality of medical care in an HMO and has gone on 16 from there to the consideration of other kinds of quality 17 The reason it's gone on beyond that is because monitoring. 18 there is a growing awareness wherever we turn of the need for 19 a more satisfactory method of determining whether or not the 20 quality of care which is being provided and paid for, whether 21 with federal funds or non-federal funds, is indeed adequate. 22

I think there is little reason to doubt that there will be increasing demands for some kind of effective display of evidence that the quality of care is what it should be.

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Now, in order to set up the kinds of devices we're 1 talking about there are some important elements which have to 2 be bred into it, such as what kind of criteria you use; what kin 3 of data reporting system is it you're talking about; how do you 4 link together the hospital with the non-hospital medical 5 practice; what do you do about it when the quality of care is 6 less than it should be; and how do you determine the basic 7 question of what is quality; are you measuring it by the 8 individual patient care act or are you measuring it by what 9 happens to the entire community? 10

Well, I'd like just at this point to tell you the kind of process that we find it necessary to go through and some of the issues which are going to arise, and then throw it open for any discussion which you would like to have.

It's quite clear that in dealing with this kind of a 15 tough issue that we have to involve a number of people who have 16 something to contribute and also something to protect. There 17 are many elements in the Federal Government dealing with the 18 question of the quality of care. Certainly one of them is the 19 Social Security Administration which has been attempting to 20 measure quality of care by some kind of utilization review 21 process for a number of years. 22

The same thing is true of Medicaid. This operates more on a state-by-state basis, and yet there are some regulainc. tions which are becoming more generalized.

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The health maintenance organization will provide a device for some kind of display which will be required of quality of care which is being provided and particularly it refers to health care which is purchased by federal money, which is primarily Medicare and Medicaid.

So we are working with people in HSMHA, in NIH and in
the Social Security Administration to make sure that we're
talking about the same kinds of things; using the same kinds
of methods; or at least finding a point of agreement or disagreement before we proceed.

It's also true that around the country in Regional 11 Medical Programs and elsewhere there is intense interest in 12 this same subject and a number of activities which are being 13 carried out, and so we are setting up some meetings with RMP 14 coordinators and other individuals who are concerned with 15 measuring the quality of care or with finding a method for 16 monitoring it. We will be working regularly with them as well 17 as with people in organized medical groups who clearly would be 18 deeply concerned over this kind of an issue. 19

It doesn't require my explication to tell you that it is one which could be very sensitive and very volatile. It also is quite clear that there will have to be some kind of technique developed which will allow for an internal audit which would lead to some kind of external audit which will in all likelihood depend upon a peer review mechanism but which will

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require consistent and regular defense in a public fashion.

So we will be dealing with it and we will be calling on members of Council to contribute in their thinking and their special skills. But since we have only begun it and have outlined the ways in which we wish to proceed with it, I think this might be a good point to get your comments on how you think we should proceed and what sort of problems you see which lie ahead for us.

9 DR. MILLIKAN: Do you have that outline procedure available?

DR. MARGULIES: I would say yes, excepting that we tested it out yesterday and found it wanting with some of our colleagues, so that we have to retune it a little bit. But we will have to get back to it. It looked all right to us but then when they criticized it, I could see that the criticism was justified, so we have a little more work to do with it.

Naybe to narrow this a little bit for a moment, let me tell you about one other aspect of quality of care with which we are currently involved which is an old subject moving to a new level of interest, and perhaps you'd like to come back to this after you have given some thought to it because I can't believe that measuring the quality of care is something about which you have no judgment.

We are doing something on the Section 907 issue which 24 Ace-Federal Reporters, Inc. has been lying dormant for some time. Again, to bring up to

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date those of you who are not acquainted with it, Section 907 1 has been aprt of our legislation since the RMP was first 2 3 created, and it requires -- at that time the Surgeon General 4 and now it's the Secretary because the process has changed -requires him to publish annually a list of the hospitals which 5 contain the most advanced scientific techniques for dealing 6 with carcinogens, cancer, heart disease, and stroke, and to 7 this has been added in our legislation kidney disease and, of 8 course, related disease has been a part of it. 9

We have agreed to work toward the preparation of that 10 kind of a list. We will be holding a meeting with a number of 11 consultants on the 12th of August to get their further advice 12 It is agreed within HSMHA that this will be at the time on it. 13 of our original survey based upon those kinds of criteria which 14 we can establish which would identify hospitals which, in 15 essence, have all of the basic components necessary for doing 16 the most advanced kind of medical acts which have to deal with 17 these categorical diseases. 18

So that it will be not a list of all the institutions 19 where a part of it can be done, but rather a list of the 20 institutions which represent really superior and advanced 21 It will be a carefully selected list. It is performance. 22 likely that it will be designed around criteria which have been 23 derived from contracts which we have had with which you are 24 familiar to set up quidelines for cancer, for heart disease and 25

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for stroke, and will be derived from information which has 1 already been assembled in the kidney program to identify 2 institutions which would be appropriately included. 3

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It will also be set up in such a way that the hospitals which believe that they are a part of such a list 5 will have an opportunity to respond. So that it isn't going to be a compulsive kind of survey, but rather one which will be 7 based upon a voluntary response, and since the opportunity to 8 be listed as one of the institutions which is able to do what ġ most needs to be done in advanced medicine will be an attractive 10 one, I don't think we have any particular problems with that. 11

But it does mean that out of this effort will be 12 produced a list of hospitals which will be identified as having 13 those characteristics associated with special qualities, that 14 list to be given to the Secretary for him to publish as he sees 15 fit, and we have not in the past activated this section but we 16 are now doing so; and that is another aspect of looking at the 17 ways in which we look at the quality of medical care which is 18 an intriguing one. 19

Among other things, I think you ought to recognize 20 that it probably is the first real effort to identify quality by something other than minimal standards, excepting the ways 22 in which professionals do it, but we don't have the accreditatic 23 processes or review processes in general that do anything other 24 than establish minimum standards. These will identify some - Federal Reporters, Inc.

1 superior ones.

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2	DR. KOMAROFF: Is this section being activated at the
3	request of the Secretary or on our own initiative?
4	DR. MARGULIES: We were encouraged following an
5	inquiry from the Fountain Committee. It reminded us of it.
6	DR. HUNT: Does this entrance into this field involve
7	ourselves only with the programs authorized and monitored by
8	the Regional Medical Program area or is it on the whole aspect
9	of medical care?
10	DR. MARGULIES: It's a national survey, but the
11	legislation requires us to do it for heart disease, cancer,
12	stroke and kidney disease, but with all hospitals in the
13	country presumably eligible and recordable as covering these
14	elements.
15	It raises some interesting issues as we get into it,
16	because it also includes training, and when you say that there
17	is an extremely good kind of program you have to have some other
18	questions answered like are there ancillary services available
19	which make this really excelent or is it confined to one
20	individual leader and so on. It will have its hazards, but at
21	the same time, I think that with appropriate kinds of criteria
22	we can produce a list that has some substance to it.
	DR. KOMAROFF: Is this list being produced by the

DR. KOMAROFF: Is this list being produced by the RMP core staffs or by the staff here?

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DR. MARGULIES: The list we will probably produce

after the criteria have been established and the criteria will be established by some kind of contractual mechanism, and then it will be simply a matter of a questionnaire which will go out to hospitals and the questionnaire will be placed against the criteria. We will not involve ourselves in a site visit or something of that kind because we would get way beyond our depth if we did.

BR. HUNT: In other words, you're going to set up a system of regulations or of minimum requirements of physical equipment and people, and if that's there you're going to say that this is good medical care. It doesn't follow.

We've had some experience with it in the Pittsburgh 12 area for the past 20 years of reviewing good quality care, and 13 we've painfully come to the conclusion that unless you have 14 some monetary control -- and that may be very thin over the 15 practitioners of medicine -- there isn't much point in going 16 through with this because you reach a point of doing an exceller 17 review and the practice continues. Now, that monetary control, 18 as I say, can be very thin. It can be just a staff appointment 19 but I think the thought of the view on the part of practitioner: 20 of medicine that it's on-going has a good effect.

But I'm fairly convinced myself right now that unless there is some control over the people it's rather a fruitless effort. The threat of discontinuing an insurance mechanism or a staff appointment --

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DR. MARGULIES: But there's no intention at all in this 1 to do anything other than make it a list available primarily 2 There's no sense of accreditation of value to the profession. 3 or of regulation or of anything other than identification of 4 the fact that here's an institution which can provide, say, 5 in the field of cancer, all of the elements necessary for 6 dealing with major disease patterns, with the necessary labora-7 tory work, with the necessary training, with leadership, able 8 to utilize the latest kinds of techniques because of the depth 9 of the staff or the depth of interest which they have. 10

It would be just a list to be circulated for professionals and no sense of accreditation or approval or disapproval will be involved in it. It will be quite clearly a kind of value judgment which will be expressed against certain kinds of criteria.

And this is intended to influence who? DR. HUNT: 16 I think the primary purpose of it is DR. MARGULIES: 17 to try to make available, to physicians and to the public in 18 general, information about where this kind of medical care is . 19 available when it is not otherwise known. Whether it's a truly 20 worthwhile endeavor is one with which one could argue and we 21 have hesitated doing it. 22

But let me give you an example of the kind of thing which came up the other day. There was, as there is every year, a meeting of cancer specialists with leading science writers,

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and they were reporting on the current success in the management 1 of Hodgkins disease, and in the right kind of circumstances 2 some of the results are spectacular. I'm not closely familiar 3 with it but it's quite clear that this is a major kind of 4 activity which is going on in a limited number of places. The 5 science writers said, "Can you tell us where this is available, 6 because we are very hesitant to write about it if it then means 7 that the public is going to say 'well, that's marvelous, and 8 I've just had a diagnosis of Hodgkins disease. Where do I go?' 9 and the chances are neither the individual or the doctor knows." 10 It has that kind of an advantage. 11

It has the advantage also of identifying, if we're going to regionalize health services, where those kind of superior services exist and should, under the best of circumstances, provide a base for utilizing those kinds of specialized resources without duplicating them unnecessarily if it's handled right.

I think if you look at the kidney kind of a problem 18 it's closer to a representation of the advantages which might 19 exist in this kind of approach because if you know where there 20 are major resources and really superior resources and know where 21 they are not, you have the basis for some kind of planning, not 22 only in RMP but throughout the country which are presently not 23 Now, the kidney one is a little clearer because available. 24 it is so specialized, but I think this may also arise out of the

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other kind of approach. 1

We have hesitated to do this in the past because it 2 was envisaged as an extremely cumbersome and controversial kind 3 of thing to do, but the judgment now is if we limit it to those 4 institutions which are really superior we will probably be able 5 to perform a real service. Or, to put it another way, we don't 6 have much choice in the matter. 7

DR. MC PHEDRAN: If you say you're going to limit it 8 to the institutions that are really superior of those who 9 respond, for example, you're going to apply certain standards; 10 so I may be missing something, but I really don't see why it 11 isn't a form of, if not accreditation in the formal sense, 12 something quite similar to it. 13

DR. MARGULIES: Well, it will certainly be a form of recognition which might come out the same way. 15

DR. HUNT: You're going to confirm your original 16 impression. 17

I wonder if I might speak to the point DR. MERRILL: 18 I'm sure that these kidney people who you made a moment ago. 19 are here, I can think offhand of at least a dozen centers the 20 excellence of which there would be no question if that group 21 responded to the questionnaire. Then there would probably be 22 another 25 that would respond to the questionnaire that by 23 simply reading this and matching it against a set of criteria 24 would seem to be A-1, but there would certainly be hidden in

that group five or six who were not that excellent; and I think 1 that could be determined very easily by a few questions or even 2 perhaps a visit by someone qualified in this area. So I 3 wonder if you necessarily need to rule out that kind of 4 inspection system limited to those particular areas if some 5 question did exist. Otherwise, I can think of a number of 6 examples in which centers would respond to your questionnaire 7 giving you the impression of excellence who, indeed, would not 8 be providing the kind of services you'd like to certify. 9

We really haven't made any decision DR. MARGULIES: 10 on that so that these contributions are most worthwhile. 11 Well, I would like to comment on what DR. DE BAKEY: 12 I think it is one thing to establish criteria John just said. 13 of minimum standards and still a much different thing to 14 establish what you call superior standards. Now, there are 15 many criteria one can use to maintain minimum standards. 16 Hospital accreditation groups do this all the time and it's 17 Almost any clerk can review and decide whether very simple. 18 the hospital can be accredited. 19

But when you're talking about superior quality in almost any of these fields, then you're getting into some value judgments that I don't believe can be well determined by 22 I think here that you have got to means of a questionnaire. 23 in some way decide whether you're going to deal with the 24 simplest values or what you call the average quality of care or

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mean quality of existing care or are you going to deal with really superior. And if you're going to do that, then I don't 2 think any questionnaire will do that. It's just impossible 3 because you're dealing with value judgments. It's very easy 4 to meet certain requirements that you set down because there's 5 a limit to how you can set them down. It's very easy to meet 6 them and seem to be an adequate response. 7

I think there's a trap in this for DR. SCHREINER: 8 the Secretary and that is I think that it would be a very 9 dangerous intellectual exercise if this reflects lack of 10 sophistication and a kind of a superficial outlook on what 11 constitutes quality of medical care. 12

It's not too hard to do if you're dealing with two 13 things and it's like everything else -- when somebody talks 14 about ethics of experimental drugs, they always pick cancer 15 chemotherapy because it's nice and clearcut and you don't 16 really get into any problems that way. I can see where if 17 you're dealing with questions of big hardware or you're dealing 18 with questions of surgical capability of a procedure you 19 wouldn't probably get into too much trouble. But if you're 20 going to talk about handling kidney disease, for example, there 21 are places that have wonderful transplantation setups where the 22 availability of dialysis is quite poor. There are some places .23 that have marvelous dialysis facilities that don't have trans-24 plantation facilities. There are places that have both those

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1 things and can't do good diagnostic work. And the requirements 2 for treating a kid with renal tubular disease may be a good 3 biochemist but not without the availability of antilymphocyte 4 serum.

So if you equate -- in other words, he's got to take 5 some position it seems to me. It's one thing to give a list of 6 all places that do the cadaver transplants but it's another 7 thing to say this is a superior approach to kidney disease, 8 because you have capability A versus capability B. Then you're 9 making the kind of quality judgments that Dr. DeBakey has some 10 concerns about and I have some concerns about because it really 11 reflects then how somebody in the Public Health Service is 12 analyzing really the approach to kidney disease and what is 13 more important in a diagnosis, the electronmicroscopy or the 14 writing of a prescription for certain steroids. Now, these 15 are very, very difficult judgments. 16

I would only make a plea for this list DR. EVERIST: 17 to be a very small number because I can imagine the quietest 18 emotion many of the hospitals will have will be rage, and it 19 would seem to that we also have to recognize that even though 20 this is something we have to do, that its impact will be 21 considerable and we'll have to look at the growth potential of 22 these institutions that we identify because they are certainly 23 going to be crowded the day after this list is out. 24

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DR. MARGULIES: It depends on the train strike.

DR. MERRILL: Well, I simply wanted to add one intangible which I think both Dr. DeBakey and Dr. Schreiner 2 would agree with. That is, certainly one of the criteria of 3 a center of excellence in any kind of treatment is the knowledge Δ of when not to treat with some of these expensive machines and 5 techniques, and that may not be very easy to identify in a 6 questionnaire. 7

Well, it impressed me, switching for the DR. ROTH: 8 moment from kidney to cancer, that we went through an exercise-9 I don't know whether it should be called a fruitless exercise--10 with the American College of Surgeons in the area of cancer 11 They came up with a monotonous recital in specifications. 12 every field of human endeavor as far as pathology is concerned 13 on what it takes to be able to handle cancer adequately, and I 14 would assume that you would have to have parameters of this 15 kind in order to measure by. 16

When we took a good, hard look in this Council of 17 what came out with cancer, we decided that we had a -- well, 18 we disavowed it. And I don't see how you can do much better 19 when you have taken one of the major categorical areas and 20 heard the experts after they have convened and agreed upon what 21 it takes to have good well-rounded cancer therapy, to come out 22 with something like this and then decide how in the world you're 23 going to apply this or what use you can make of it across the 24 I think we've gone a fair share of the way in one country.

1 category, and to envision doing something like this in each 2 of the other categories and then the non-categorical areas 3 seems to me to be a further exercise in futility.

DR. MILLIKAN: For some of the people who haven't. 4 been here as many years as some of the rest of us, it should 5 be known that we have looked with dismay really at the day or 6 toward the day when 907 was going to be implements, and that 7 the letting of the three contracts have in a fashion occupied 8 our time up to this point hopefully in a manner in which we 9 would continue a kind of running discussion concerning 907 and 10 not get to this point. 11

I wonder if we could ask to have a little bit more 12 about the mandate which is being given to us at this point in 13 time, how extensive the pressures are. And I'm simply not 14 going to belabor the issue which others have talked to about 15 the difficulty involved in this entire type of procedure. This 16 is the reason I used the word dismay, because we have recognized 17 as staff has recognized and the profession has recognized and 18 the Council has recognized, this would be nothing but trouble 19 once we really got into a full response to the implications of 20 907. 21

Now, where are we really with this at this point? Now, where are we really with this at this point? Can we move this by simply listing a very, very few places that unquestionably qualify in each of these specified areas or Ace-Federal Reporters, Inc. 25 how much pressure is there on us, Harold?

I think it's a little hard to read, DR. MARGULIES: 1 but any direct inquiry from the Fountain Committee does draw 2 attention and justifiably so because they have investigative 3 zeal which can be quite troublesome. The fact is clear that 4 RMP has not been responsive to the specific language in 5 Section 907, so that if they want to say "You haven't done your 6 job," then they are quite right, and this can lead to a lot of 7 trouble. 8

What we have done is to indicate to them that we have 9 set up the guidelines and we have moved in this direction and, 10 therefore, have had to assure them that the next step would be 11 taken. I think that since we already have had some corres-12 pondence with them on this, to do anything less than produce 13 some result from it would be not disastrous, but highly 14 undesirable. So that I think we would have no difficult in 15 saying "This represents the list of institutions," just so we 16 get the job done, and if we set very high standards and produce 17 what is essentially an elite list. I think we could be more 18 comfortable with that than anything else, despite all the 19 hazards involved in it which I agree with. 20

DR. MC PHEDRAN: The question was asked a few minutes ago who would do this, whether RMPS or the different RMPs, and it may seem a trivial matter, but as I think about it, it seems more and more important that perhaps it is something that should be done by RMPS and not by local RMPs, because sure any of these

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fragile but valuable cooperative arrangements that have been established would just be shattered in any RMP by participation in making up such a list; whereas, if you do it, you will just-or the staff will just bear the brunt of the kind of criticism that you always have anyway and it doesn't seem to make -- still the service can go on.

7 DR. MARGULIES: I quite agree. I think it would be 8 shifting a questionable burden to them without any positive 9 results.

DR. HUNT: It would appear that some representation should be made to the proposers of this recommendation to the fact that this is a bundle of dynamite, because, in essence, you're not setting up peer review; you're setting up peon review, because if you're only going to review the superior ones the people who have to review them have to be lower than the peers. So what you have got, in a sense, is peon review.

DR. MARGULIES: Maybe that's what that "P" stands for. I thought it was peer but there may be something to that. DR. HUNT: Well, I didn't realize when I said it, but that's probably true, too.

DR. SLOANE: In earlier discussions that this Council has held on this subject when this was mentioned, even in the construction of the guidelines, it was agreed that a set of guidelines to be developed should be done by the medical profession for the medical profession, and this was the reason that

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we turned to national professional organizations to enter into 1 the guidelines discussion considering the possible establishment 2 of the list. It's our understanding that the Secretary and Ŝ. Dr. Wilson, if such a list has to be distributed, would like 4 to have the medical profession do it for the medical profession; 5 and, therefore, we have been in discussion with the Joint 6 Commission on Accreditation of Hospitals, the American Hospital 7 Association, the American Medical Association, the American 8 College of Surgeons and other national professional organizations 9 getting their impressions of the ways in which this might be 10 carried out, with the expectation that we would, under contract, 11 support and turn to one of those organizations and probably the 12 Joint Commission to undertake the construction of this list 13 for us. 14

I think this may get away from your fear of peon 15 Presumably, the Joint Commission, if it received such review. 16 a contract, would establish subcommittees of experts in the 17 four named fields. 18

Our discussion is just about 907; we're DR. CANNON: 19 not discussing quality across the board? 20

## DR. MARGULIES: Pardon?

The initial question I think you posed DR. CANNON: to the Council was how do we go about monitoring quality in all 23 health care programs and then you focused in very quickly on 24 907, so we are just discussing this 907? Ace - Federal Reporters, Inc.

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DR. MARGULIES: We are at the moment, but the question of how you measure the quality of care remains an open one, unless it's all settled.

DR. FRIEDLANDER: So you're just looking at the tip 5 of the iceberg.

DR. CANNON: Well, I think what Dr. Sloane has said 6 would be something that we could adopt by the Council. In 7 order to render valid judgments on quality of medical care 8 we must ask who is capable or who has the qualities to render 9 such valid judgment and, as she has stated, it must be the 10 professionals or those who have been rendering care. I doubt 11 that the recipients of care are qualified to give a valid 12 judgment as to the quality of the care they have received. 13

I believe that the American Medical Association and 14 other professional organizations have always maintained that 15 the establishment of quality should remain within the sphere 16 of the professionals and in education we've done this over a 17 period of years and, Harold, you have been in it for a long 18 time before you came here. The mechanism of establishing what 19 we consider quality training programs, quality medical schools, 20 are graded. Hany of us here have had delightful experiences 21 and some disappointments in this operation, but I would say the 22 Council first could state that any assessment of quality must 23 be done by those who have the expertise to determine what is 24 Ace-Federal Reporters, Inc. good medical care, and not by the Secretary or the Office of the 25

Secretary or the Bureau of Health Insurance or the Social
 Security Administration or any others who are concerned with
 maybe primarily costs or the economy of what the medical care
 Now, that's concerning the overall problem.

The second thing, concerning 907, I see a possible 5 way out of this dilemma by securing from many national 6 professional organizations a list of what they would consider 7 the top 10 or 15 or 20 institutions that can render the best 8 in medical care and whatever you feel you wish, and then have 9 this composite list that says "RMP presents this composite list 10 by the professional organizations" and then get us off the 11 hook. 12

DR. HUNT: Well, I think it's impossible to give a
good, honest, conscientious answer to an improper question.
That's what we're trying to do. You're going to have a
Republican list. You're going to have a Democratic list.
You're going to have --

DR. CANNON: Not if you stay within the professionals. 18 The concern I have is not so much that DR. DE BAKEY: 19 you can't compile a list, because after all, the Joint Commission 20 and various other organizations, the American College of 21 Surgeons and various other organizations, have established 22 certain standards in the various frameworks -- the hospital 23 accreditation, the training for residency approval, and a number 24 - Federal Reporters, Inc. of things. So it is possible to do this. 25

But, in general, they have attempted to maintain 1 standards that we have regarded as minimal requirements. That's 2 a lot different than being able to compile a list of what you Ś might call superior. Where does superior begin, for example, Δ in any list? Does it begin at the upper third or the upper 5 20 percent or what? How do you determine this? This is what 6 concerns me about this list, the superior list, and because 7 so much of it depends upon value judgment and in a sense upon 8 the evaluation by again a small list of people. You know, the 9 higher you get up on the pyramid, the smaller is the number of 10 people involved, and I'd be very much concerned about this. 11

Some of you may recall that John Knowles, some years ago, published an article about the 10 best hospitals in the country, and the following impact this had -- of course, MGH was number one, which is understandable. But I think what concerns me most about this is that you want to get the superior institutions. I'm not too sure that 907 says that at all.

I had the impression that what 907 says we have to do is publish a list of institutions where good quality care can be given.

DR. MARGULIES: Well, as you read it, you can make a variety of interpretations.

DR. DE BAKEY: That's right.

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DR. MARGULIES: There's no question it's open to wide Ace-Federal Reporters, Inc. 25

l that's pretty broad.

2	DR. DE BAKEY: That's right, and I think one thing we
3	should do is I think the approach that we have used of
4	contracting out, as Margaret Sloane has talked about, is a good
5	approach, and I think we can ask these organizations to give us
6	a list of institutions that meet the requirements we need to
7	meet in 907, and there I don't think we would get into any
8	difficulty. But when you start talking about the most superior
, 1 9	institutions in the country, then immediately you get into all
10	kinds of difficulties; assessing it in the first place, and
11	secondly, the impact it would have.

DR. MARGULIES: You really get off the problem simply by saying well, this won't be all of them, but it will be those that have recent advances, and you lower the threshold a little but it's still not minimum standards.

DR. DE BAKEY: That's right. This is what I'm saying. The only thing I'm worried about is the effort to try to establish what might be called the superior or best places in the country. As soon as you do that, you have bracketed a small group of institutions that leaves you open to criticism in how you did it.

DR. MARGULIES: Well, let me just raise one other issue, if I may, because we're going to have a chance -- I can't attest to the quality of the coffee break but we'll have something anyway. It hasn't been measured yet. The standards are

One of the questions that I raised in our discussions 1 and we really have to give the Secretary advice, if we are to 2 do this and we must, on what he does with the list. One of the 3 questions I raised which seemed not to have bothered people as much as it did me so I may have overread it, is whether this 5 is going to exaggerate some liability issues in the sense that 6 the patient has a bad result in a hospital which is not on the 7 list and says "How come you took care of me here when you're 8 not part of that special crowd?" And it just seems to me that Q this is an invitation to trouble but I got overruled on that 10 one also. 11

DR. HUNT: The thought just occurred to me, Harold, that if we're concerned about Congressional uproar over the fact that we didn't give them an answer on this, can you imagine the Congressional uproar that would come if DeBakey's clinic wasn't on the approved list this year?

DR. MARGULIES: We realize, of course, that that possibility doesn't exist.

DR. MERRILL: Am I summing things up correctly when I say that the reason we're discussing 907 now is because this is in response to a specific directive we have and this perhaps was emphasized by some interest by the Fountain Committee?

DR. MARGULIES: Right.

DR. MERRILL: And that we've got to do it one way or 24 ers, Inc. another and possibly we can think of a very good way to do it.

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But I also think, as someone else has mentioned, that this is, 1 indeed, the tip of the iceberg and if we are going to emphasize 2 what you have several times and is listed in much of the 3 literature here that what we really want is quality medical 4 care that gets out to the greatest number of people and places 5 where it is not available, we're really not as much concerned 6 about the most excellent centers in the world as perhaps we 7 are the application of techniques as provided by these centers 8 as they may be applied elsewhere. It seems here that we really 9 need control of quality. Is this going to be a subject of 10 discussion? 11

I think you're quite right, Yes. DR. MARGULIES: 12 because this is a powerful aberration away from our current 13 thinking as a carryover from where we were much earlier. NOW. 14 it may be meritorious but it may be a little disturbing about 15 the time we're talking in terms of community health needs and 16 the quality of care for everyone, really emphasizing the usual 17 things to the usual problems which we need to get to when we 18 come out with this kind of a list. So I've been a little 19 disturbed about it for that reason also. 20

DR. WATKINS: I hate to use inner-city language, but it seems like a discriminatory practice to set up a hierarchy in areas of care instead of to me trying to upgrade the inferior institutions so that they would provide more care for more people and with a strong peer review to do this work. So I don't think that people in the inner-city care too much about MGH, excuse the expression, but that six other institutions, perhaps Mt. Sinai, Harlem and others, get rated to be efficient for their services.

5 DR. MARGULIES: That's a fair statement. We really 6 have a dichotomy in our thinking here, there's no doubt about 7 it.

It seems to me that there's another 8 DR. KOMAROFF: danger, and that is at the same time our efforts are pointed 9 towards trying to avoid the duplication of specialized 10 facilities, that the list we create can't help but be viewed 11 as some kind of certification, and with 20 hospitals in 12 Manhattan able to do open heart surgery in the sense they have 13 a room available and a guy who comes in once a week, but only 14 four or five of them really doing that and doing it well, that 15 we may be certifying bad quality facilities and duplicative 16 facilities, even if we establish a minimal standards list that 17 isn't an elite list. 18

DR. MARGULIES: But, Tony, we may have a real advantage if only those five are listed, because certainly one criteria should be how much they're doing, and this will require some courage, but if it's done blandly it won't.

DR. ROTH: There's one possibility, just to throw this thought out, that rather than minimize the list to avoid Ace-Federal Reporters, Inc. 25 getting into trouble and sticking only with the admittedly

superior institutions, that you employ the services of the 1 experts in the several fields and compile a resource list for 2 If I, for example, am interested in the where one may turn. 3 applications of cryotherapy in neurology, to be able to turn 4 to a list and learn that cryotherapy in the treatment of solid 5 tumors is being done in such institutions and this is the place 6 to turn to, without designating that institution as necessarily 7 the all-around, all-American place for treatment of cancer. 8

I'm sure that these experimental approaches on which 2 we might appropriately focus are sufficiently scattered around 10 and sufficiently difficult to identify -- if you want to know 11 where they're doing a laser program on the treatment of skin 12 cancers, it's not in every major institutions that would be 13 designated as superior, but it would be mighty helpful for 14 somebody interested in this to have some kind of a compilation 15 of institutions in which constructive, well-oriented work is 16 going forth in these areas. 17

This is really what I was getting at. DR. SCHREINER: 18 You can get a fact sheet up which focuses on hardware and 19 surgical procedures. The place either has a million volt 20 cobalt machine or it doesn't; it's either working or it isn't; 21 and that's a factual statement and nobody can find fault with 22 The place has done human kidney transplants "x" number. it. 23 You could even line up those that did more than 50 or 25 or 24 These are facts and people can't argue with that Ace-Federal Reporters, Inc. so forth. 25

1 kind of situation. You can make a list of any number of 2 procedures or hardware or things you want. It's your use of 3 the term superior that bothers me.

The Council and the staff, in antici-DR. MILLIKAN: 4 pating some of these problems, gave a broad charge to the 5 contractees as we developed these three contracts for the 6 production of a set of guidelines, and it was this very thing 7 that's been discussed at length this morning that created the 8 breadth of that charge. And the charge really had to do with 9 an infinite series of levels of facility and personnel and 10 training, so that somewhere along in the guidelines one could 11 find descriptive material that might apply, for instance, 12 realistically to Sioux City, Iowa, as well, at another level, 13 to Boston. 14

I would wonder if the ultimate route in supply of the list might not be an extraordinarily broad series of listings that would literally include, under a variety of kinds of categories, hundreds of places.

The charge also included the idea that the optimum should be described for a variety of series of sized places, for instance, so that community efforts as people in a given locale attempted to upgrade their own facilities and personnel could look at an exemplary kind of model as being potentially achievable in their own size area; once again, getting to the idea that it's going to be impossible for ten places, for

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instance, in the U.S.A. to take care of a very significant 1 number of stroke patients. This, of course, is just literally 2 So you see the discussion point that I'm trying to impossible. 3 introduce here that the other way -- exactly the other end of 4 the spectrum, may be ultimately an easier way to go in the 5 development of the list; that is, literally having a good many 6 hundreds of places on the list rather than 10 or 15 for each of 7 the major categories because I think that is just fraught with 8 all kinds of difficulties. You get past the first four or the 9 first seven and which one do you leave off as just below that 10 That's the thing that people are worried about. level. 11

DR. MARGULIES: Well, we will have a group which is meeting to deliberate and which will keep you current on what's happening, and I'm sure they will have as many problems as the Council is already having right now trying to figure out how we go with this.

DR. DE BAKEY: May I just take one minute to say that 17 my comments were not intended to mean that I don't feel this 18 should be done. I am only concerned about how it's done and in 19 a sense the guidelines we use in determining of this list; for 20 example, superior list or list of acceptable standards; and 21 this is what concerns me. I think it's a desirable objective 22 and I think it, in a sense, is a desirable activity, but I 23 think, but I think it ought to be done extremely carefully and 24 deliberately, and I think the approach we're using with the 25

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contracts we've made is perhaps the best approach we can use at the moment. DR. MARGULIES: Okay. We will reassemble in about en e spes 15 minutes. (Recess) Ace-Federal Reporters, Inc. 

DR. MARGULIES: We will now reconvene the meeting 1 exactly on time as I had expected. 2

I'd like to introduce to you at this time Mr. Hall, 3 who is the Deputy Administrator of Health Services and Mental 4 Health Administration, who is representing the Administrator 5 of HSMHA at this particular Council meeting, and very pleasingly 6 so from my point of view because I think it's important that 7 you get acquainted and he has an opportunity to know you and 8 you to know him. 9

So we will give him the meeting for the next period 10 of time with the understanding that he will have some things 11 to say and offer you the opportunity to raise questions or 12 issues with him. 13

Thank you, Dr. Margulies. Harold and I MR. HALL: 14 are getting better acquainted by the day. We spent a good 15 fraction of yesterday before one of the panels that were 16 present on the Science Advisory Committee, and I will have a 17 few words to say about that session in my remarks. 18

In looking over the list of this group to see who I know, it turns out to be a rather short list and the two gentlemen whose names I'm going to mention may not even recall our encounters. I do recall that Dr. Roth and I were on the program up at Harrisburg this past spring for a statewide forum 23 on health care. He may or may not recall that session. 24

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DR. ROTH: I do.

MR. HALL: I heard your talk and I believe you heard 1 mine at that time. 2

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Dr. De Bakey I am rather sure won't recall our encounter when I visited him. I met him looking over his shoulder into an open chest, as a matter of fact. We were upstairs at the time he was in the middle of an operation and I was there visiting with some people from the General Electric 7 Company and the National Aeronautics and Space Administration, 8 and Paul Sanazaro's group at the time I was surveying the 9 facilities in the nation. 10

DR. DE BAKEY: I recall that very well.

We spoke with Dr. De Bakey on the intercom MR. HALL: 12 during the operation and he very graciously welcomed us during :13 that affair. 14

I think it's useful for me at least to know who I'm 15 hearing from when someone takes up 15 or 20 minutes of my time 16 for injecting words at me. I'm going to assume that you'd like 17 to know the same thing and so I'll bore you with just a few 18 minutes of my background before I read some remarks. 19

It's well to know from what bias one's words arise. 20 This helps you to evaluate them and to frame one's questions 21 about them. I'm a relatively new arrival on the health scene, 22 having joined Dr. Wilson as his Deputy Administrator and having 23 spent the preceding 27 years of my federal career service with 24 the United States Air Force and the National Aeronautics and Ace-Federal Reporters, Inc. 25

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Space Administration as an electronic engineer and public administrator. Now, the last eight years I was with the space agency was spent primarily in the basic research programs in the biomedical sciences working with Dr. Orr Reynolds and some others with whom I'm sure you're acquainted in that area. This is a new and refreshing challenge to me and I welcome it.

7 I do want to make a few remarks that I will read. I 8 ordinarily don't like to read talks but I did want to get a 9 few points over without inadvertently skipping them, so if you 10 will bear with me I will read the remarks and then I'll be 11 happy to respond to any response that you have.

This morning I want to speak with you as partners in the creation of a better health care system, giving you a picture of current developments that might bring substantial change in health care.

As trustees, in effect, of the Regional Medical Programs, you provide policy guidance for one of the most lively innovative endeavors of the federal health establishment. In the course of your work for RMP you need to know about surrounding activities that bear on your field of concern. I believe that the following fragments of news are significant to you.

Recently, the President's Science Advisor called for a new technological initiative in the United States, saying "that production of new knowledge and new science-based capability are essentials of national progress. Obviously,

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\$7 per hour American workers cannot compete with \$7 per week foreign workers except with the advantage of advanced technology. If we are to turn away from technological challenges in air transportation and space, we must find suitable alternatives or face not today's paradoxical pockets of poverty amid riches, but nationwide disastrous poverty."

7 Where can this nation direct the talents of additional thousands of creative people to derive the broadest public 8 I believe that the field of health care technology 9 benefits? is one that offers many rich potentials. What is technology? 10 Another word for it is capability. Technology is science-based 11 problem solving ability. It can be a device. It can be a 12 procedure. When we talk of health care technology, the 13 reference is not to the nucleus of medical science, but rather, 14 to contributions to health care know-how and facilities that 15 can be made from outside the traditional disciplines of medicine 16

In his day, Louis Pasteur, a chemist, was an outside technician making an unsolicited contribution. Health care professionals should welcome new tools and techniques because they offer the main hope for meeting speedily arising demands for health services while maintaining and even raising performance standards.

Fortunately, there is a growing interest in this potential in many quarters. My primary purpose in speaking with you today is to report that the field in which you have been

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laboring is getting new attention. In recent weeks, the 1 President's Science Advisory Committee has established a panel. 2 on health services research and development. Dr. Kerr White 3 of Johns Hopkins University, is the chairman of the new panel. 4 The group is beginning its work with an inventory of current 5 activities in health systems development, both in government ΄6 and in the private sector. 7

Another group under HEW guidance will perform a 8 similar survey but in more depth within government departments 9 10 alone.

The National Aeronautics and Space Council, headed 11 by Vice President Agnew, and served by former astronaut William 12 Anders as Executive Secretary, has begun a significant effort. 13 The Council has underway an inventory of the capabilities of 14 space enterprises that might be applicable to social welfare 15 problems, including health. 16

STill another special advisory group serving the 17 Executive Office of the President is working on the broad 18 problem of how to redirect aerospace and defense scientific 19 and technical capability for near-term public benefits. Typical 20 potentials are ecological monitoring from space and the use of 21 military communications equipment and helicopters to aid in 22 emergency medical services. 23

The President's Advisory Council on Management 24 Improvement, headed by retired General Bernard Schreiver(?) has Ace - Federal Reporters, Inc. 25

been devoting extraordinary attention to possibilities for the application of modern management and engineering know-how in the field of health care.

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As you know, medicine as an art tends to defy 4 systemization. However, medicine as a science becomes 5 increasingly susceptible to the methods that revolutionized 6 the production of consumer goods and brought the material 7 pleasures of the industrial age to the masses. My prediction 8 is, while there will be no sudden revolutionary changes, the 9 management engineers will make relentless progress in medicine 10 as they have in the formerly highly personal matter of 11 executive leadership. 12

Pending in Congress is a proposal to authorize 13 appropriations of \$25 million per year in support of development 14 of computer-based health care systems and subsystems. This 15 proposal has been enacted by the Senate and is being considered 16 in conference between Senate and House members. The House 17 previously enacted a health manpower bill without funds for 18 computer system development. The Administration opposes this 19 proposal, preferring to have health care technology funded as a 20 whole in its logical context rather than in an amendment to 21 manpower legislation. 22

23 Seven of 14 national health insurance proposals 24 pending in Congress have provisions for technological develop-<sup>Inc.</sup> 25 ment of health care systems. The provisions are reasonably

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direct in some cases and quite vague in others. Administration proposals for health care financing are limited to that single financial function. The Administration has made a policy decision to deal with various elements of its overall health care strategy in separate but clearly related pieces of legislation.

Next January, in San Francisco, the Health Services 7 and Mental Health Administration will sponsor a conference on 8 health care technology in the 1980s. This futuristic event 9 will have the purpose of identifying goals and potentials for 10 the employment in health care of capability from outside the 11 traditional disciplines of medicine. My personal belief is 12 that this conference could mark the beginning of a major effort 13 to infuse the medical establishment with new know-how and, 14 therefore, more power to perform up to the expanding desires 15 of the American people. 16

As you can see, we might find ourselves with more friends, more workers and more resources in the near future. Certainly the sounds from Congress are encouraging. I am encouraged by the number of leaders figuratively looking over my shoulder these days to see where there are opportunities to make progress.

23 My message to you today, therefore, is that your 24 planning for regional medical programs in a fast changing Ace-Federal Reporters, Inc. 25 environment, to me the signs look good. There is risk interests 1 that ought to propel our efforts even faster in the future.
2 Of course, like a brisk wind at sea, the gusts could swamp the
3 sailboat. I'm sure you will be as eager as I am to keep track
4 of the activities I have mentioned today and proposals and
5 legislation and actions that seem likely to develop in the
6 months ahead.

I can't help being reminded by my own remarks of the 7 parade of people that I have coming through my office -- and 8 this goes for Dr. Wilson and I'm sure Dr. Margulies and all 9 the other health administrators in this building -- hardly a 10 week goes by that I don't have anywhere from three to a half 11 dozen groups of self-styled experts in management systems and 12 health care technology to advise us on how to better run the 13 "system." Many of them I have to, in as kindly a way as I know 14 how, tell them that they are the sixth in the parade of this 15 type in a given week and we have more capability than some 500 16 people in our internal Booz-Allen and Hamilton group in 17 management consultants than they could possibly hope to develop, 18 and I'm sure some of you must react to some of the suggestions 19 I have brought forward here this morning in a similar way, of 20 being in the position of having more help than one could 21 possibly use under the circumstances from your professional 22 viewpoint. 23

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My urging to you would be that we take advantage of this newfound national interest in health services and 1

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intelligently turn it to the advantage of the health of the American people. It will proceed apace at any rate, and I think we should take advantage of the thrust and make the best 3 use of this newfound interest and the newfound resources which will accompany this interest. 5

DR. MARGULIES: Thank you. We are open for discussion 6 and comment. 7

DR. MILLIKAN: Would you care to make any comments on 8 your views as to the potential impact of technological initia-9 tives as a broad term on distribution of health services? 10

I'd like to make sure I understand the MR. HALL: 11 question before I start on the answer. 12

Just whether you have any ideas from DR. MILLIKAN: 13 your view on the facts from which the technological initiative 14 may make some impact on the distribution of health services. 15 Maybe you haven't gotten that far. 16

I presume that you're referring to the MR. HALL: 17 carrying of or distribution of health services to remote areas 18 There are a number -and the like. 19

They may be physically remote or they DR. MILLIKAN: 20 may be remote in terms of the availability of health services, 21 although geographically they may be right in the center of a 22 mass of people. 23

MR. HALL: I don't know that I have any panacea at 24 Ace - Federal Reporters, Inc. hand or even anygood example at hand. I'm aware of many 25

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1 attempts at demonstration of technological capabilities from 2 other fields on health care problems, most of which have gone 3 awry; my own guess is because they were misguided by competent 4 technologists totally uninformed in the field of health ser-5 vices.

6 The attitude that many technologists have is that 7 one can apply technology much in the same sense that one applies 8 butter to bread, rather indiscriminately and in broad, sweeping 9 strokes, and as you and I know, this has not proved to be 10 terribly effective in the health field or in other fields, for 11 that matter.

DR. MARGULIES: Could I speak on that for a minute? I always suspect when someone asks a question like Clark did that he has an answer in mind also.

DR. MILLIKAN: No.

MR. HALL: I might burden you with another of my biases, and I identify them that way because they are unproven. They have not been really given a chance in this new field. I tend to reconcile the so-called R&D activity in this field in the context of my past experience in defense based systems, and I hope you will forgive me for this. We all have to do this on the basis of our past experience.

There, we used the context called research, develop-23 ment, tests and evaluation, and my brief exposure to the health Ace-Federal Reporters, Inc. 25 field reveals a rich foundation in the research area, the "R" 

1	area, several billions of dollars worth of support annually
2	to basic biomedical research. I see increasing sums devoted
3	to testing of the kind that I just mentioned of projects that
4	are ill-conceived, maybe even inapplicable if they were given
5	a proper look by professionals in the field; and I further see
6	at the end of the spectrum, in the evaluation area, attempts
7	to evaluate activities about which we know very little in terms
8	of measurements. No end points have been established, therefore,
9	it becomes virtually impossible to identify whether one has
10	done something good, bad or indifferent during the process of
11	testing.
12	The letter I missed in the "RDTE" is development, and
13	in the health field I see a great void in medical engineering
14	development.
15	DR. DE BAKEY: Where do you see this several billion
16	dollar increase coming into this area?
17	MR. HALL: I'm sorry, sir?
18	DR. DE BAKEY: Maybe I misunderstood you. I thought
19	you said that you see the possibility of several billions of
20	dollars coming into this R&D area.
21	MR. HALL: I didn't mention a figure. If I did, it
22	was a psychological blunder. I reported that the increased
23	interest of these outside groups indicate to me the willingness
24	to invest heavily in new technological initiatives in our
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economy and that we, as health professionals and administrators,

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might very well wish to take advantage of this newfound interest 1 to direct them into the health care technology field. 2 My personal bias in this spectrum of research, 3 development, tests and evaluation is the developmental area is 4 the one in which I personally find the greatest shortcomings. 5 We in HSMHA do not have large, in-house resources in terms of ó facilities, or people for that matter, to carry out major new 7 activities in the medical engineering development area. 8 DR. DE BAKEY: Where is it going to be done, do you 9 think? Who is going to provide the leadership for it? Will it 10 be in HSMHA? 11 -- I'm not reporting I want to make sure MR. HALL: 12 on an actual program, as your questions would seem to imply, 13 Dr. De Bakey. I'm reporting on a tendency. 14 But you touched on something that I DR. DE BAKEY: 15 I agree that there's a void, think is extremely important. 16 but it's primarily due to the fact that there isn't money from 17 private sources for development. 18 MR. HALL: That's right, and if there is a proper 19 role --20 And there isn't at NIH, and you're not DR. DE BAKEY: 21 going to get anywhere without money. I mean, you can talk about 22 this all you want, and I hear a lot of rhetoric all the time, 23 but I don't find a specific program of appropriating money for 24 these purposes. This is really what I'm trying to get at. Ι Ace - Federal Reporters, Inc. 25

think what you're saying makes sense and I think it's important, but it's just a lot of language unless it's going to be backed up by some money and some leadership and a focus toward doing something about it.

5 This has gone on for ten years that I know of and there hasn't been really very much done about it. Now, in ó 7 HSMHA alone, there's an area in which there's tremendous potentialities for computer developments in health care 8 delivery systems which I think could revolutionize the medical 9 care programs of this country, but they haven't provided the 10 leadership to do it, I quess largely because they haven't got 11 the money, and they have been extremely cautious in what they 12 did. Personally, I think they're missing the boat completely. 13

MR. HALL: I'm trying to discuss this subject in terms of newsworthy new interests rather than new administration initiatives, and I appreciate the interest in it.

DR. DE BAKEY: I would disagree with you. I don't think it's very newsworthy because it's old hat. This has been going on for a long time. The only thing that's newsworthy about it as far as I'm concerned is your interest in seeing it **and** your background and knowledge about it. I would hope that you would be able to do something about it.

MR. HALL: I certainly share that hope, sir, and your
views as an individual or as a group would be welcome.

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DR. DE BAKEY: It's discouraging, really it is, and I

hate to be cynical about this, but it's very discouraging. Year after year goes by and this type of development has been with us -- the potentialities have been clear certainly for a decade and its application to medicine has been delayed longer than it has to anything else.

MR. HALL: From the viewpoint of the technologist --6 DR. DE BAKEY: Look at what happened the other day. It 7 you want to see something about fine technology, I think it's 8 absolutely astounding -- I say this all the time -- they can 9 send colored pictures from the moon and I have a heck of a time 10 getting colored pictures in the operating room right next door 11 because of the difference in the technology and, of course, 12 the people that run it, and something like \$5 billion. 13

MR. HALL: May I just respond to this a moment before we get into the next. My further bias on this subject is that the proper role for the Federal Government in this spectrum is precisely in the research and the developmental engineering end. We should not press federal activities further into the business of delivering health services in the communities --

DR. DE BAKEY: I agree with that.

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MR. HALL: -- but we should retain for the Federal Government the things we know how to do best, and this is to provide the heavy investment and resources at the basic research and developmental end which no community or hospital could ever alone carry out for itself.

DR. SCHREINER: Now are you going to begin that heavy investment? 2

MR. HALL: We have plenty of programs that could be 3 implemented in the light of adequate national interest and 4 I'd be happy to display my program for you. funding.

In your remarks you related to interest MR. MILLIKEN: 6 in the Administration to the wholeness of health, that you tend 7 to view some of these things as a wholeness. Would this have 8 some implications hopefully in terms of bringing many of the 9 peripheral and indirectly related health activities of the 10 Federal Government more --11

MR.HALL: By indirectly related, you mean mental 12 health? 13

> Yes, and many others. MR. MILLIKEN:

MR. HALL: Yes, it does. We got into quite a dis-15 cussion with Dr. White's group yesterday on this very subject 16 and I spoke somewhat in generalities about our response to the 17 Willard group recommendations and to other inputs that we had 18 about how to organize ourselves more effectively in the Health 19 Services Administration area. Let me pass on the same kind of 20 remarks here, if I may, if you think that would be appropriate. 21

I won't address the Willard group report itself since that is still not in a public category, except to indicate that it has been a very fine but a single input to the Administrator and the Secretary on how to organize the activities. As I'm

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DR. MARGULIES: NO.

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'MR. HALL: Upon the demise of the Environmental Services Administration, at which time the Environmental 3 Protection Administration was formed, some of the bureaus were left dangling, and HSMHA acquired two of them recently. One 5 is the Bureau of Community Environmental Management and the other previously called the Bureau of Occupational Safety and 7 Health, now the new National Institute of Occupational Safety 8 and Health. Those two bureaus have just recently joined HSMHA, 9 making the 12th and 13th program elements reporting directly to the Administrator.

Two others will join shortly as soon as we can get 12 the proper approvals from the Department. One is the Health 13 Maintenance Organization Service, which we have a nucleus 14 already formed. The other is the group formed to carry out the 15 Emergency Health Personnel Act of 1970. I never can remember 16 the new name for the service, Harold. 17

18 MR. HALL: And that's under the interim leadership of . 19 Dr. Mack Rimple. We're also proposing that as another program 00

DR. MARGULIES: National Health Service Corps.

themselves, in that through our decentralization concept we have pushed somewhere between a third and a half of our financial resources out to the regions where they are under the direct control of our regional health directors, not to mention a substantial fraction of our personnel resources.

So you add those ten people reporting to the 6 Administrator, two associate administrators, seven assistant 7 administrators, and God knows how many special assistants, 8 visiting scientists, special staff and so forth, that is an 9 administrative lineup with which one could not live for very 10 long. Dr. Wilson intentionally kept that reporting relationship 11 very broad during the early years because of the very sensitive 12 programmatic relationships and the personal reporting problems 13 involved. 14

The next consolidation will be in terms of limiting 15 that span of control somewhat and grouping of elements with 16 There will be like programs in the health services R&D area. 17 grouping reporting through a senior official of commissioner 18 level -- I'm not sure of these terms yet, but of that stature --19 and the so-called service programs. We're still in the business 20 of delivering a considerable amount of direct health services 21 through the Public Health Service hospitals, the 51 Indian 22 Health Service hospitals, 300 clinics and so forth. 23

24 Well, this is the kind of next step that's coming <sup>Inc.</sup> along. I'm sure when most of you see it you will contend that

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that is not yet the final solution in integrated program management or in the business of providing comprehensive approach to the delivery of health services, but this is an extremely sensitive and difficult managerial and technical problem and I think it's a logical next step but won't be the last.

7 I hope those general remarks are of some help.
7 DR. MERRILL: I'd like to go over some ground that
9 Dr. DeBakey mentioned to you again and ask you a question
10 prefaced by a couple of examples.

As you know, the National Institute for Arthritis 11 nd Metabolic Diseases did have a contract research program --12 still does -- which had to do with hardware and the development 13 of hardware by private concerns in the field of artificial 14 kidneys, heart, lung and so on. What they have done essentially 15 is to underwrite endeavors which were not thought initially 16 to be profitable enough to put things on the market but with 17 the help of the Federal Government they hopefully would be. 18 I think these things have developed some useful advances in 19 medical technology.

And I know also that there are a number of private concerns which are interested in multiphasic screening and the use of computers and so on which are seeking private investment capital, but that investment capital is not available because they do not believe that these things are ready yet. They are

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now willing to take the initial loss to develop these things.

Now, my specific question to you is does your organization have any plans for helping the private sector 3 in that way which is initial risk capital, if you will, for the production of technical devices, particularly in the area 5 of computers, multiphasic screening and so on? 6

MR. HALL: Yes, some small amount, some indirectly, 7 and there, of course, is still some division of responsibilities 8 within the health agencies. You, undoubtedly, are familiar with 9 the National Institute of General Medical Sciences, where some 10 of this responsibility still resides. 11

I don't know that any of our program objectives are 12 phrased exactly as you put it, in terms of risk capital, and 13 this, of course, is precisely what's going to be required to 14 turn the engines of the economy. But the things that we do 15 have are wrapped up in the kinds of incentives that we put 16 into both our contract and grant programs in the National 17 Center for Health Services R&D, some of the developmental 18 health testing activities in RMP; the HMO concept has some 19 incentives for groups to organize themselves in more efficient 20 ways. 21

But I think that you would contend that my response 22 is that there are low level and somewhat indirect programs at 23 HSMHA in that regard. I'm sure many of you know these figures 24 better than I, but to new people who are taking a first look at 25

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this field it's always staggering to look at a health industry which people variously talk about in terms of a \$60 to \$70 billion industry and look at the federal involvement in that which is about \$20-odd billion, and get down to the health services investment which is \$1.6 billion, approximately. Dr. Sanazaro's budget in HSMHA and Health Services R&D is in the neighborhood of \$60 million.

Now, in all honesty, one has to say that there are
significant R&D activities in HSMHA outside of the National
Center, so the real figure is probably in the order of \$100
to \$150 million in HSMHA annually.

But looked at in terms of what is directed toward providing contract or risk capital help for health care technology, the figure is \$7 million annually.

DR. MARGULIES: I don't know if there's anything prophetic about it, but the man who ran me down on my way home on May 18 was from the National Institute of General Medical Sciences. I think it's purely coincidental. I don't think he was aiming at me. I think he was blind at the moment but nevertheless I wondered about it since then.

21 DR. KOMAROFF: Mr. Hall, is there any thinking now 22 as to which agency or agencies within HSMHA would be responsible 23 for further push in technological research and development? In 24 other words, a lot of what HSMHA has done has been done through <sup>Inc.</sup> 25 RMP as well as through the National Center. Do you anticipate

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1 that joint responsibility continuing?

2 MR. HALL: The relationship between RMP and the 3 National Center specifically? 83

4 DR. KOMAROFF: RMP's role specifically in funding 5 technological research and development.

MR. HALL: Yes, I do envision that continuing. I. 6 think at your last meeting Dr. Wilson met with you and 7 reaffirmed his conviction that the RMP should remain a separate 8 program, but if I'm not mistaken, in the same breath, he **' 9** encouraged rather strongly developing more effective ties 10 between the Regional Medical Programs and the National Center 11 for Health Services R&D, and I know that Harold and Herb are 12 working at this very hard. I don't know how you picture RMP 13 in this RDT&E spectrum that I mentioned or whether you find 14 that a useful context at all, but I find what I know of RMP 15 residing primarily in the test-evaluation area with some 16 exceptions, of course. 17

18 It just does not provide the framework that I was 19 talking about for a critical mass of developmental engineering 20 and risk capital in the "D" area. It wasn't intended to.

DR. MARGULIES: I wonder if I could ask a question, getting back to the point that Mike DeBakey raised. Do you have the sense or are you implying in your discussion that despite the decade of promise and indecision in the use of technological skills in the health field, that there is a 1 different circumstance now, that the lack of attraction, or
2 the lack of support for a tremendous technological group which
3 was working in the space industry, etc., as this is declining
4 in the way in which it's exploiting our potentialities, there
5 is an increased --- a greatly increased potential for it to move
6 in the health field? This is associated with some differences
7 in social values which affect us.

DR. DE BAKEY: Yes, but here again, I think it's very 8 important to recognize the difference in the space activities, 9 there's a total budget on something -- well, it has always been 10 or almost always, except for the first or second year, over 11 \$4 billion, increasing that up to almost \$6 billion, most of 12 which was spent for R&D, most of which. Now, this meant that 13 you were contracting largely with industry. Therefore, it wasn't a matter of risk capital. They didn't take any risk. They 15 made a profit. So you could collect the best group of people 16 in the world to do the job. But you haven't got that kind of 17 money in medicine and I don't see it anyplace, and you can talk 18 19 all you want about what you want to do in this area and about the potential that exists, about the people who have been 20 working in space and no longer are going to be there; they're 21 not coming to work for health unless you can give them the money. 22 They're going to go to work wherever the money is. That's the 23 way people are. They've got to live. This is what you've got to 24 do, and until you can provide the money, all the high aspirations 25

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1 are going to go down the drain. This is what's nappened in the 2 past.

3 To make a comment further, I hate to seem sort of, 4 let me say, discouraged about this, but after a decade of 5 concern of all this one gets a little discouraged, and it's all based upon the lack of any sense of priorities. We have 6 7 got high priority on going to the moon and I'm all for that, don't misunderstand me. I was just as aspired and astounded 8 9 about what's taking place there as anyone. I think it's wonderful. But I can't help but feel that it's just as 10 important in the health area and the power for the technological 11 development can be just as astounding; and yet, in terms of the 12 total amount of research that's spent in this \$70 billion 13 industry in health, we spend less percentagewise for research 14 and development in health than we do in the electrical industry, 15 and in almost any area. It will average somewhere in the 16 neighborhood of 4 percent. Now, no viable industry will spend 17 18 less than 8 or 10 percent on research and development, but 19 health is obviously not a very viable industry.

20 MR. HALL: I would be pleased to respond to that in 21 this way. Here again, I'm not describing new Administration 22 programs. I'm describing my view of the Washington scene on 23 the periphery of the RMP program as you have viewed it here. 24 Ours is a technologically based economy, for better

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or for worse; it is that. That's what turns the engines of the

U.S. economy. You cannot shut down a war in Vietnam, deny an
SST program, taper off on the space program, without things
happening to that economic engine.

Now, my own personal bias, and it is a bias because
it's never had an adequate test, as you stated, is that advance
technology is ready and can bring about a revolution in the
health care industry in much the same fashion that the National
Defense Highway System in this country revolutionized the
distribution of consumer goods early in the 20th century, and
it did just that, and we're talking about distribution systems.

Now, that's my bias, and I guess my challenge -- well, 11 one further thing. I have found both supporters and critics 12 13 of this position of both technologists and health professionals. 14 I don't know if it's wright or not. I'm willing to test it, 15 and I guess my challenge to the medical profession and especially those who act as senior advisors to policy makers 16 in government on federal health programs is that you either 17 support the contention that this field, your field, is ripe for 1.8 exploitation in this manner or that that's a nonsense way in 19 which to spend the taxpayers' money, one of the two. 20

And if it's nonsense, if the field is not ripe for exploitation, then we certainly shouldn't pour our money down this drain. It is quite easy to pour away large sums of federal tax dollars in misdirected technological efforts. I have been engaged in some of them earlier in my federal career,

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1 and I'm old enough that I don't want to repeat those mistakes. 2 I don't have to repeat them to prove my position as a pro-3 fessional in this field.

My plea to you is, if it's a mistake, for heaven's 4 sake point out to us that it is so that we can use these 5 resources in more effective ways. But let's not close our minds 6 to the potential because the need for investment of these kinds 7 of resources is there for the sake of the economy. They will 8 be invested somewhere, and I want you to seriously question 9 your conscience about whether the health field should share in 10 11 these, I think, newly found resources.

DR. MARGULIES: Thank you very much. We appreciate it Thank you for your time. MR. HALL:

I'd like to draw your attention to 14 DR. MARGULIES: the agenda by telling you that I think that if we plan things 15 appropriately we can have at the end of the afternoon an 16 executive session to deal with some special issues which you 17 brought up -- most of which you brought up at the previous 18 Council meeting on which there's been some action in the mean-19 20 time.

What I'd like to do between now and the time of the 21 lunch break is to acquaint you with some of the internal changes 22 that's been going on in the RMPS which have a great deal to do 23 with how we're going to function with relationship to the RMPs. 24 25 These have been brewing for a long period of time and they

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represent organizational changes which also affect the way in which we carry out the whole operations with the Regional Medical Programs. For that purpose, I'd like to have Herb Pahl take over and explain to you what's been happening and answer any questions you may have.

DR. PAHL: Very briefly, I think we've reported to
you at earlier Council meetings that we have been undergoing a
reorganization, particularly on the operational side of the
program. This has been a major activity in recent weeks and
we are now at the point where we have announced to our staff
the overall parameters of the reorganization and are actively
implementing it this month.

I'd like to just give you the highlights if I might. 13 We have now a division of operations and development which has 14 as the acting director myself, and as acting deputy director 15 Mr. Robert Chambliss. The office dealing with the review of 16 grants is officially terms Office of Grants Review and is 17 under Mrs. Lorraine Kyttle, and there's a Grants Management 18 Branch under Mr. Gardell as before. This branch will have all 19 responsibilities for the fiscal side of the award process and of 20 21 the accountability for the funds.

The major reorganization has taken place, however, in terms of how we interact with the Regional Medical Programs and we have now four operational branches. these have been established on a geographical basis and we have what is

termed the Eastern Operations Branch under Mrs. Silsbee; the South Central Operations Branch under Mr. Lee Van Winkle; the Mid-Continent Operations Branch under Mr. Mike Posta; and the Western Operations Branch under Mr. Dick Russell.

Teams of professional and supporting staff have been identified for each of these branches, the size of the teams being somewhat different because of number s of local RMPs and regional offices which are associated with each of these branches.

10 In addition, we have identified a number of individual 11 in the other divisions and offices, such as Planning and Evaluation, the kidney disease programs, smoking and health, and 12 the division of professional and technical development, who 13 will serve as joint appointees with these operations branches. 14 So that there will be specific people who might serve as points 15 of contact for the operations branch to gain further information 16 or technical assistance as required in their interactions with 17 18 the regions.

19 This joint appointment activity is a two-way process, 20 in that by having a single team of individuals working with the 21 regions, we would hope to have much more information about what 22 is going on in the region, a broader view and perspective of the 23 activities both within the RMP and also in other related pro-24 grams such as CHP and research and development activities; and 4Ace-Federal Reporters, Inc. 25 to have some of this information brought back by the operational

branches from the regions into the professional and technical
division and the Office of Program Planning and Evaluation.

3 The division is composed primarily of the same individuals who have been with us, although there have been a few 4 people brought from the different offices into the operations 5 ó branches. We believe that the reorganization primarily will serve to improve communication back and forth between head-7 8 guarters and the regions, provide better information both through the management information system and on a personal 9 10 intelligence basis, and provide to the Office of the Director that kind of opportunity to obtain a more comprehensive pers-11 pective of what is going on in regions than we have had hereto-12 And I would hope that this would be reflected in the ways 13 for. in which we are able to bring information to both the review 14 committees and to you, the Council, and to take advice from the 15 Council back to the regions, and perhaps do this in a somewhat 16 more effective and efficient manner than heretofor. 17

The implementation of this reorganization is currently 18 Due to summer vacation schedules, etc., I suspect 19 going on. it will be early September before all of the branches are able 20 to get their teams together and interact appropriately. Just as 21 an aside, we have something of a space problem since, as Mr. Hall 22 indicated, more programs are being brought into HSMHA and so we 23 have to learn to house our present staff in somewhat reduced 24 space quarters than we had a short while back, and this is 25

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1 delaying somewhat the actual geographical establishment of the 2 operations branches.

Are there any questions on this particular divisional reorganization? Harold, would you like to tell a little about the professional and technical division?

DR. MARGULIES: Yes. I think that in the same way as this reorganization will influence the deliberations of the Council, so also will the professional and technical division which is going to take on a different kind of role than it has in the past.

It will be reorganized -- and I think it doesn't matter too much what the names of the branches are; it matters more for the purposes of today's discussion what kinds of things are going to be done in that division.

It's become obvious that some of the past practices 15 in the professional division have been largely a matter of 16 trying to do whatever seems to be necessary at the moment. It's 17 produced an interesting but rather scattered kind of activity 18 with the emergence from time to time of a practice which is best 19 known I guess as hobby-riding,, which has sometimes been all 20 right if it's been the right hobby, but if it's the wrong hobby 21 it's been of more interest to the individual than it has been to 22 RMP or RMPS. 23

What we will be doing instead will be on a very 24 -Federal Reporters, Inc. selective basis deciding what kinds of things really require

1 professional attention from the point of view of RMP and con-2 centrating our efforts on them so we can get a finished job 3 done.

To be specific about it, we will establish competence in areas which are critical to RMP development and maintain that 51 competence. We will turn out finished kinds of products in the 6 forms of status papers which will be kept current and which 71 will be made available to you. An example might be the present 81 state and the changing state of the art of medical record 9" 10 systems, which are an essential part of any kind of quality This is something which is perfectly appropriate to the review. 11' Regional Medical Programs. 12"

We will gradually move the kidney activities so that the state of knowledge of the end stage kidney treatment disease in which we're so much involved will be kept current. I think that has been done quite well in the past and we'll keep up that kind of activity as well.

If you look at the issue we just have gotten through talking about, the question of what kind of a role technical developments play in the improvement of health services, there are manifold possibilities for us, and probably those possibilities extend beyond our competence. So this serves to illustrate another way in which we'll function, by bringing up to the point of issue as clearly as we can what kinds of decisions have to Ace-Federal Reporters, Inc., be made with the advice of Council, bringing them to you in a

1 concrete form so that your deliberations are based on something 2 sound instead of simply on the assembled experiences which you 3 bring here and some fragments which we're able to provide.

But, in addition to that, we will have established and have already begun, and I think quite effectively, a working relationship with the National Center for Health Services R&D, so that if we're talking about a subject of technical interest or of new methodology in health services we're not dependent only upon our resources but on the resources of companion programs like R&D.

11 Beyond that, that program will have access to a wide variety of consultants who can assist us to have more massive 12 13 resources than we otherwise would have, not the least of which represent the RMPs themselves. I think only in the last two 14 years can one say fairly that the Regional Medical Programs in 15 enough instances have reached a level of experience so that they 16 can begin to say "We now know this because of what we have done 17 and we also know that these are the issues which we can't 18 resolve and on which we need more help." 19

I have been championing a kind of industrial model in the relationships between RMP and R&D, saying that really what we need from R&D are some specific answers to specific questions, and I think that through this kind of mechanism this Council can begin to help us to identify what we want brought to the attention of the people who are working in the R&D area,

1 if they are outside of RMPS, and say "Here is a problem and this 2 is something you ought to be working on and let's get together 3 and get it worked on," instead of hoping that their interest 4 which is going in one direction and ours which is going in 5 another, might at some point coincide.

Now, that requires being much more deliberate than we
have been in the past, and since that particular division, the
Division of Professional and Technical Development, is going to
have greater staff strength very quickly than it's had before,
I think we can get this kind of leadership.

11 Now, in turn, we will be asking the Council to do what it has already done to the operations division and the 12 professional division, and that is to be very definite about 13 what it sees we have not done, what needs to be done, what kind 14 of information you're lacking when you have to make some 15 decision, so that we have the promotion of interest which can 16 be derived from that kind of interplay. And we, in turn, will 17 have to talk with you about what we're capable of doing and 18 what is beyond our capacity, because it's quite clear that 19 whether it's all of RMPS or one division in it that we have to 20 decide between all the things which need to be done and select 21 those which we can do and stick with them. And when we rule 22 something out for our concern, we need to do it carefully and 23 with your involvement. 24

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I think this will get you in the interplay relationshi

with our functions as they affect the whole health care system through RMP in a manner which previously hasn't been available. We'll be asking you individually and collectively to provide us the kinds of inputs for that professional division and for the operations division which will make a significant difference in this reorganization plan.

So it really isn't simply a matter, as you can see, of having reorganized as agencies often reorganize. It is the expression of conceptual differences from the way in which we have functioned in the past which can be enhanced only by that kind of an organizational structure.

I think staff understands it well and I think most people feel intrigued and challenged by this kind of different direction from that which we have displayed in the past.

Now, there may be some questions or comments about this particular process.

DR. KOMAROFF: The four desks, then, will include teams of people who jointly pursue the problems of grants review and grants management after a grant has been awarded and liaison between the federal office and the regions. They will work as teams rather than separate divisions as they've been in the past. Is that right?

DR. MARGULIES: That's right. It means that whatever is done in the whole cycle in an RMP, no matter where you enter it, at the time that they prepare an application or at the time it's reported back to them or at the time that they are being generally looked at to see what happens, will be done by one unit of people rather than having someone start with one process, drop it, and somebody else pick up another process and so on. So that it will be a wholistic approach to the region which we are trying to do in our review process, and this will be done in a technical assistance manner.

I think that if there are no further questions about it, it's a rather logical point and I hate to burden you with all of these procedural issues but they're really the guts of what goes on in the program and when you get out in a site visit you suddenly discover that these things become quite critical to what you're doing.

This lead rather naturally, I think, to some general 14 comments on the review process itself. I think that you can see 15 that by the kind of planning which will go into the operations 16 division, that we can now anticipate and we do anticipate well 17 in advance when site visits will take place, who will be on the 18 site visits, what additional people will be brought in, who will 19 be reporting back into the review committee and into Council, 20 so that there is a way for everyone to plan his time and to plan 21 the input. 22

23 Now, this means that the review mechanism itself is 24 going to be sharpened greatly. The sources of information are Ace-Federal Reporters, Inc. 25 going to be more firmly identified. We will raise to a very hig

1 level of priority the finishing off of what we described to you 2 earlier in the management information system, and there will be 3 available to everyone a common base of information.

4 So that what we now have to consider is the manner in 5 which we are going to review programs, what sort of criteria we intend to apply, with the clearcut understanding that we 6 7 will be pursuing the policy which was established earlier on 8 with this Council and elsewhere, of making investments in the 9 form of grants awards according to relative program merit rather 10 than on some other kind of nondescript -- well, that's an 110 unfair statement -- some kind of generalized pattern. So we 12 are looking toward differentiation between programs on a kind of rank basis and I think we have developed a technique which 13 144 we have discussed with you partly in the past and which has 15 been tested further at the present time.

Herb, do you want to take over?

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DR. PAHL: All right. We'll try to not make this too Nr. PAHL: All right. We'll try to not make this too Nr. Peterson and I hope to present highlights of an activity which has taken a considerable amount of staff efforts since the last Council meeting relative to the development of a rating system, and I would like to call your attention to a few sheets which were handed out to you this morning, "RMPS Review Criteria and Rating System.

Just to place this in the proper framework, as we pointed out in this statement, there are actually several

factors which led to the need for the development of a rating system. Primarily, it can now be stated, I believe, that RMPS is a rather mature program. It certainly is a complex program, and important national activity. We are very cognizant of the fact that it receives close scrutiny by the Congress, by the public and certainly by others.

We are attempting to look at regions more and more in terms of the degree to which their own activities and priorities are somewhat consonant with our national priorities as they evolve and as they have been reflected in this mission statement which was given to the Council last time and which you endorsed.

We also have had in recent years some degree of dis-12 turbance relative to the fact that Council approvals, dollar-13 level, have been higher than what have been funds available to 14 the program, and this gap has made the administration of the 15 In this connection, I'd program somewhat difficult at times. 16 like to emphasize, as we pointed out on the bottom of the first 17 page of that statement, that it is most important that our 18 review committee and the Council continue to assess the merits 19 of regions and make recommendations on the basis of individual 20 merit of programs and leave to the Director and staff the 21 responsibility for implementing those judgments. 22

One tool to assist the Director in carrying out this 23 24 Ace-Federal Reporters, Inc. 25 Cone tool to assist the Director in carrying out this are use of a rating system which has now been developed and tested. At the last meeting of the Council, you

1 will recall there was some discussion concerning this, and since 2 that time a staff group has been formed and a rating system 3 developed which I'll present to you in just a moment.

This system was tested at the last meeting of the 4 review committee and it was applied to the 13 triennial 5 applications. We based this system primarily on an elaboration ő. 7 of the criteria which has been set forth in the mission statement, and which you will find in your black binder under 8 Section 9B. This was the mission statement that was given to 9 the Council last time and I don't think we have to look at it 10 in detail at the moment, but it does include those 17 broad, 11 general criteria. 12

The RMPS staff committee took these criteria and 13 somewhat reworked them, elaborated them, devised a weighting 14 system, and a scoring system, and made this available to the 15 review committee just before they met. The review committee 16 was asked to accept the system and try to apply it during the 17 course of their review of the triennial applications. They did 18 this and found it reasonably satisfactory with some suggested 19 modifications which Mr. Peterson will relate to you in a moment. 20

I woull like now, therefore, to go into what the rating system is, and we have provided to you under Section 8A in your black binder, the materials which we gave to the review committee and which also to some extent were used by site visitors at the time of visits to these regions currently under

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review.

First of all, I would like to ask you to look at the overall scoring sheet which is page 2 in that section and shows a grid with the regions identified across the top and the 17 criteria listed vertically under three major headings: "Performance, Process and Program Proposal."

In this system, performance was arbitrarily assigned 40 points; process, 35 points; and program proposal, 25 points; making a total of 100 points. The 17 criteria which were presented in the mission statement were classified under these three major categories and each of the 17 was then arbitrarily given by committee consensus a weight.

However, it was realized by our own group that these 13 criteria as phrased in the mission statement were so very broad 14 that it was quite possible for a group of people to have widely 15 16 varying interpretations as to just what would be included under any one criterion. Hence, much staff time was devoted to 17 1 18 developing subcriteria in the form of questions which are shown on the following three pages in that section, and break out for 19 you the kinds of questions for each criterion which were 20 developed for the purpose of helping to clarify what that 21 22 criterion includes and to give everyone on the review committee and yourselves at least a common denominator from which to start 23 The subelements themselves have not been weighted or 24

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25 graded in any fashion. These are merely to help direct the

1 thinking and point out important elements which go into each 2 major criterion. So only the major crteria have been weighted 3 and have been used by the reviewers in the scoring system.

I would like to just point out, for example, under Δ the first major area of performance, the first criterion is ٠Š goals, objectives and priorities; and I should like just as an 6 example to read to you what kinds of questions have been 7 developed to help clarify this general statement. For example, 8 "have these goals, objectives and priorities been developed and 9 explicitly stated? Are they understood and accepted by the 1Ö health providers in institutions of the region? Where appro-11 priate, were community and consumer groups also consulted in 12 their formulation? Have they generally been followed in the 131 funding of operational activities? Do they reflect short-term, 14 specific objectives and priorities as well as long-range goals?" 15 And finally, "Do they reflect regional needs and problems and 16 realistically take into account available resources?" 17

Now, it's not easy to answer categorically yes or no 18 or assign a number, but it does bring to attention the points 19 we feel site visitors, reviewers, staff should be considering. 20 On the next page, under process, I would like to point 21 out item four, assessment of needs and resources. The questions 22 there are: "Is there a systematic, continuing identification of 231 needs, problems and resources? Does this involve an assessment 24 an analysis based on data? Are identified needs and problems 25

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being translated into the regions evolving plans and priorities?"
And lastly, "Are they also reflected in the scope and nature
of its emerging core and operational activities?"

4 Then, as an example from the program proposal section, 5 I would like to read the ones under "Action Planned," which is ó criterion number one, and that is on page three of that set. Z Under "Action Planned," "Have priorities been established, and 8 most importantly, are they congruent with national goals and Do the activities proposed by the region relate to objectives? 10 its stated priorities, goals and objectives? Are the plan and 11 the proposed activities realistic in view of resources available 12 and region's past performance? Can the intended results be 13 quantified to any significant degree? Have methods for reporting 14 accomplishments and assessing results been proposed? Are 15 priorities periodically reviewed and updated?"

16 Those are the kinds of questions in those various
17 major categories which staff felt reviewers would be considering
18 and have been considering as they review applications and meet
19 with the regional representatives on site visits.

Now, in terms of scoring this, a rating system of 1 to
S was used with 5 representing an outstanding score; 4, good;
satisfactory; 2, fair; and 1, poor; and we asked each
reviewer to rate each of the 17 criteria on that 1 to 5 basis.
The reviewers had at their disposal on this score sheet the
weights assigned to the individual criteria so that they wouldn'

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be misled as to what the total effect would be in terms of the
2 1 to 5 score on any single item.

However, in addition to rating the individual 17
Criteria, we asked, under IV on this rating sheet, each reviewer
to give on a 1 to 5 basis an overall assessment, and then, as
Mr. Peterson will indicate, there was an analysis done as to how
the criteria related to the overall assessment.

We also indicated to the reviewers on this particular go-around, since it is a trial basis, that if they felt uncertain about a specific number, please put a circle around it so we would know the degree to which they were being force into a mold; and again, this was part of the analysis carried out subsequent to the review meeting.

Roman numeral V, we have requested each reviewer to just put a checkmark if the region requested a developmental component and if the reviewer felt that this was appropriate.

17 And, lastly, because it is very difficult, regardless 18 of the number of items that we try to quantify, to have individuals satisfied with feeling they have given all of the 19 information, we asked them under VI to check off as many items 20 as appropriate which best describe or release their sense of 21 frustration for the basis on which they evaluated the application 22 For example, the individual might have gone on a current site 23 visit or a previous site visit, only read the application, only 24 Ace - Federal Reporters, Inc. listened to committee discussion, or was a primary or secondary 25

reviewer; and by not limiting him to one checkmark, we would be able in some sense to match up his degree of uncertainty with his level of experience and knowledge.

The purpose of all of this, of course, was to try to bobtain as fair a test of this as possible, which had been pretested by staff and found satisfactory, and to permit analysis by our own staff looking toward modification of the system.

8 Now, I'd like to make just two comments and then turn 9 the discussion over to Mr. Peterson; and that is that the 10 reviewers felt that the 17 criteria were comprehensive and that 11 the subcriteria phrased in the form of questions were, in fact, 12 They were not useful in helping them to channel their thoughts. 13 meant to be exhaustive. They were not meant to limit the But they were found to be useful and I believe, in 14 thinking. general, in an executive session at the end of the meeting where 15 the 13 triennial applications had undergone this process, the 16 reviewers felt comfortable with the overall process that they 17 had engaged in. There was some degree of uncertainty, which 18 Mr. Peterson will relate, with respect to how to apply numbers 19 at this point in time against certain criteria because the ratir 20 system was designed in parallel with the review of these current 21 applications, so there had not been opportunity for the regions 22 or the site visitors or the staff to do the necessary groundwork 23 24 to provide the answers to all the criteria developed. So this 25 was tested under the most awkward and frustrating of conditions;

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and the fact, I believe, that the committee as a whole found this workable and satisfactory with suggested modifications leads us to believe that we have something which is appropriate to somehow representing in perhaps somewhat more common terms the judgments and discussions which have been going on all this time both at site visits and in review committee and in Council.

At this point, I think, Pete, I would like to ask you to briefly summarize the analysis that was carried out by our staff subsequent to the review committee engaging in this endeavor.

MR. PETERSON: Before I do that, let me just hang up one piece of paper which I will make reference to because as Herb indicated one of the things that did come up in the way of a major problem perhaps was the uncertainty about certain items, and I don't know how visible that really is.

Both the Office of Systems Management and the Office of Planning and Evaluation did take a look at in some detail the scoring that had been engaged in by the reviewers in connection with the 13 triennial review regions, and in discussing the results of those analyses, I think I'd like to group my remarks around two broad areas.

First, as it related to the ranking, or perhaps more 23' appropriately, the groupings of regions that resulted, I think 24'' from Herb's discussion, the manner in which the scoring was done, Ace-Federal Reporters, Inc. 25'' a 5 to 1 system, given weights that were then multiplied with the score given, the scores totaled by reviewer averaged out,
to come up with a composite or an average score for each region
that ran from a range potentially from 100 to 500.

From the scores that were obtained on the 13 regions, 4 they fell into three fairly general and natural groupings. 5 There were six that fell into a higher grouping, raning from a 6 287 score to a 327 score. I might note, because I think it is ·Z a reflection on the system, that these were the six regions 8 which, when the question was put separately in terms of 9 requested developmental components, the review committee voted 10 H favorably for the award of the developmental component to all 11 six of those regions. It did not for any of the others that had 12 requested developmental components. 13

There was a second grouping of regions that fell into There was a second grouping of regions that fell into a sort of middle range, ranging from roughly 215 to 234 -- three regions, as I said. And finally, there was a relatively long group of four regions ranging from 144 to 195, the score.

Now, we did try and look at -- others than myself, 18 because I'm not a statistician. We did try and look and cal-19 culate the extent to which there were differences among reviewer 20 looking at the same region to come up with standard deviations 21 and the like. Without getting technical about it, we did find 22 a somewhat higher deviation of those regions in the upper 23 grouping and a somewhat lower -- there seemed to be greater cer-24 Ace-Federal Reporters, Inc. The one that had the 25 tainty among those in the lowest grouping.

1 highest deviation I think is in a sense explainable. It was
2 California, because it really, I think from those of you who
3 have looked at California in the past with or without this kind
4 of scoring system, it really is a number of regions, and I
5 know Dr. Millikan, among others, is sorely aware of that.

6 On the other hand, the average variation among 7 reviewers was less than 7 percent, so I think those who can 8 interpret standard deviation and the like for me, that's a good 9 figure.

We also had an opportunity to further analyze the 10 scores in terms of the three broad groupings that Herb referred 11 to, performance, process, and program proposal; and again, while 12 there were some fluctuations within a group, there were no 13 fluctuation among groups so that a region that had an overall 14 score that placed it in the upper group might find itself, let's 15 say, in the third rank, that in one of those categories the 16 overall assessment was that it was second or fourth but that 17 they stayed within the groupings. 18

Now, we haven't been able to do that as yet in terms
of the 17 individual criteria. Similarly, as Herb indicated,
we had asked the review committee members, in addition to
scoring the regions using the individual criteria, to give their
overall assessment, and the groupings there bore a strong
relationship to the groupings in using theindividual criteria.
So that the same six regions, although not in necessarily the

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same order, using the overall assessment were in the high
 grouping, the same three in the middle and so on.

That sort of is a thumbnail analysis of how the groupings went.

Now, I think the one item that the committee, both 5 in the executive session and in our analysis of the results, 6 indicated they had some problems with was the uncertainty 7 factor. As Herb indicated, reviewers were asked if they felt 8 they were uncertain about an item they were to circle it, and we tried to analyze what it was and who was uncertain about 10 things, and that's where this little chart which I'm not sure 11 is as readable as it might be, and I haven't tried to include 12 all 17 criterion in it, but it does indicate, the blue line, 13 the percent of uncertainty, from a very low percent as far as 14 rating organizational viability and effectiveness up to such 15 as action plan, to a very high degree uncertainty as far as 16 three of the criteria in the program proposal were concerned, 17 questions relating to ambulatory care, continuity of care and 18 prevention.

The red line, which is drawn over on this side, we found that two reviewers accounted for nearly 50 percent of the uncertainty, and I would have to say that this is expressed uncertainty as they expressed it. And similarly, that these three items at the very top accounted for nearly 50 percent of the uncertainty as far as those items were concerned.

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I think the reasons for this are probably multiple 1 and certainly in our discussion with the review committee, the 2 item itself might be unclear; there might be information lacking 3 about it; and I think this is something I want to get back to as 4 far as continued support is concerned, evaluation and other 5 funding; or perhaps -- and this was noted in our analysis --6 that the things they tended to be more certain about seemed to 7 have been the things that we and the review committee tend to 8 talk most about or address most of their attention to. So that 9 when one talks about organizational viability or do they have 10 an action plan; that there was far less uncertainty in terms of 11 those criteria than in some of those relating to the program 12 proposal itself. 13

A couple of other observations regarding this uncertainty factor, as you might expect, there tended to be a little less uncertainty with one exception of the regions which had been site visited as opposed to those that had not. In that current cycle, I think seven or eight of the 13 had been site visited and four or five or six had not been site visited, but it wasn't terribly significant.

Similarly, there was a wide range of, again, expressed uncertainty by the individual reviewers ranging from zero to a high of 62 percent. Most of them, however, were in the neighborhood of 20 percent, items involving all the regions which they indicated or expressed some uncertainty.

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Similarly, again with hardly any surprise, the primary reviewers tended to be less uncertain than someone who was basing his judgment and indicating his score either on the basis of just the review committee's discussion or a reading of the application.

I think there's only one other thing, aside from 6 those two areas, that I would mention. I think we came to the 7 conclusion -- and I know some members of the review committee 8 9 in the executive session who were sort of quickly looking over their score sheets that second afternoon -- that in this 10 initial testing there had been damn tough scores. The highest 11 score given to any region was 327, 300 being sort of satisfactor 12 400 being good and 500 outstanding. Moreover, that the spread--13 and this probably is part of the uncertainty factor. I know 14 when I'm uncertain about things I tend to give a C or a 3 --15 and the spread was not that wide, so really we're talking about 16 17 a spread of 144 of the region that was thought to be the poorest or was given the lowest mark, and 327 at the other 18 end, which is only about 180 points. 19

We probably can anticipate and probably will have to make some provision in subsequent review cycles that the review committee, having looked at their scoring, seen they've been tough graders, may become a little more generous or lenient whatever word you want to use, and that we'll have to make comparisons either among groupings or to resort to some device

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such as a weighted means so the comparison from one review
 cycle to another could appropriately be made.

Herb indicated and I have alluded to the fact that we have made certain minor modifications in the criteria themselves, and also have taken a few followup actions based upon this initial use, the review committee's feedback to us in executive session and our analysis.

I'll just touch very quickly on what we have done 8 there. As far as the criteria are concerned, there were 9 several that we modified. The review committee felt that to 10 lump a lot of things under organizational viability and 11 effectiveness -- they didn't feel comfortable with that and 12 they, in effect, said "We'd rather take a look at that in terms 13 of its constituent parts or its major constituent parts so that 14 the revised criteria listing will include coordinator, core 15 staff, regional advisory group and the grantee organization. 16

Another one, where they had somewhat the same problem, Name was under management and evaluation, the management of the program and the evaluation of the activities. So we really separated it into its two component parts.

Similarly, at this end of the spectrum, relating to ambulatory care, prevention and continuity of care, we thought there might be some virtue in combining those into a single criterion relating to improvement of care. I don't think that, in an of itself, and we recognize this, will obviate the

uncertainty problem they have. But I do feel that perhaps
 coupling it with better staff analysis and input that it will
 at least narrow the problem and delimit it somewhat.

Finally, we have decided in order to give greater Ă visibility and to stress the importance, we had pulled out 5 as a separate criterion in the revised rating system, minority 6 There were a number of questions scattered throughout interests. the factors to be considered paper which you had which related 8 to this: was there minority representation on the regional advisory group with regard to employment of the staff on the 10 RMPs and other questions; and while it involved pulling the 11 pieces out from several places, we did decide -- staff did and 12 the Director concurred -- to pull out as a separate criterion 13 minority interests. 14

The only other thing that I think is worth mentioning 15 is, as I said, one of the concerns of the review committee was 16 its lack of adequate information about certain items, and we 17 had singled out and I put on the chart three of them here, 18 continued support -- that is, to the extent to which the region 19 was successfully phasing out or terminating RMP support after 20 the three or four year period and whether the activity was 21 indeed being continued, if that was appropriate. Since this 22 has been split apart, we're really only talking about the 23 evaluation part of it. Again, where activities have been 24 on-going for two, three and certainly where it's proposed to go

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on beyond three years of support, what kinds of data and evaluation findings are there relating more to the impact or the outcome of the activity as opposed to the simple progress reporting.

5 And finally, with respect to other funding, the 6 extent to which and the activities either being carried out by 7 the region in connection with its grant proposal to RMP or in 8 some of the other activities, the region is either looking for, 9 accepting, and how successful it has been in attracting other 10 funds.

So with respect to these items, what we have done --11 and this is an interim measure because we did have an August 1 12 deadline for applications for the October and November review 13 cycle -- we have gone to the regions who will be in for the 14 October-November cycle in two different fashions. Most of those 15 will be site visited and we have sent out the criteria to them, 16 but we've indicated some of these areas in which, based upon 17 its trial use by the review committee, they had some questions; 18 they were uncertain about information; and, no doubt, the site 19 visit would, among other places, be targeting in on those. 20

Some regions, a relative few -- I think four or five 21 at the most -- will not be site visited because their anniversary 23 review regions, and in those instances we did go out again with 24 something in the form of a request for some addenda material Ace-Federal Reporters, Inc. 25 whereby they could address themselves to these three rather

specific areas either by reference in their application or
 truly giving us some addenda material.

I think, Herb, in terms of the analysis and some of the very minor modifications and the kind of followup action we've taken since the review committee met and utilized the system, that would certainly be all I have to say.

Thank you. Let me just make one or two DR. PAHL: 7 further points. The system is still a trial system and so you 8 will not see priority scores on any of the blue summary sheets 9 which come to you from the committee. We will be handing out 10 to you in a moment these three groupings of the regions with 11 the ranges of priority scores. We're not asking you to take 12 action at this point following presentation on the rating 13 system. What we are requesting is that you keep these sheets 14 in front of you as we go through our own discussion later this 15 afternoon and tomorrow of applications, and then, following 16 that, you will have a better idea of whether you wish to concur 17 or not concur with the committee's overall rankings, and in that 18 way we'll have a better understanding of how you see the rating 19 system. So this is a matter of presenting to you the back-20 ground and what has been done so far. 21

The other thing I'd like to say is that -- and I'd 22 23 1 like to repeat this -- the rating system is one management tool 24 to provide assistance to the Office of the Director in imple-Federal Reporters, Inc. 25 menting the Council's decisions. It is not meant to be solely

mechanical and to dehumanize the system, but it does provide a
certain amount of information which I think the review committee
found helpful as they considered it.

4 The other point I would like to emphasize is that 5 although no time is perhaps good to introduce a new system, it 6 was developed at an awkward point in time in that for this particular set of applications the review committee literally 7 received the rating system, score sheet and instructions the 8 9 night before the committee met. So I would like for the public record to thank the review committee members for their patience 10 and acceptance of the trial and to say that even on that basis 11 they didn't find it overly frustrating and, of course, what this 12 does is charge the staff with developing and improving the 13 mechanics much more; and in doing that under our newly 14 reorganized system, we have made this information available now 15 to the coordinators so that those who have applications in for 16 August 1 will have the opportunity to provide additional 17 information. Those who are developing their applications for 18 November 1 deadline will be able to build appropriate information 191 into their applications by November and site visitors and staff 20 1 will have had an opportunity to study the criteria, the questions 211 and restructure site visit discussions and presentations on 221 both sides of the table. 23

24 So that by the time the October review committee Ace-Federal Reporters, Inc. 25 comes in we feel there will be a much better mode of displaying

information to the review committee and Council and for covering the points mentioned, and thus reducing uncertainty figures which were bound to come up in the initial trial.

4 With that, I would like to juse pass around to you a 5 sheet of paper which shows the three categories of the six top regions, the three middle regions, and the four regions in the 6 lower category which are presented to you in alphabetical 7 order with the range of scores. So this provides no embarrass-8 ment about having a specific priority known for a specific 9 region at this point in time, but does provide you the committee 10 overall results; and if you would be good enough to keep this 11 in front of you during the course of your discussions on the 12 applications before you at this time, I believe it would be 13 helpful; and then we can discuss again at the executive session 14 or otherwise tomorrow how your view of the applications matches 15 16 that of the review committees.

However, I believe it would be fair to say that we
entertain any comments, discussions, constructive criticism
you may have just on the basis of this presentation.

DR. DE BAKEY: I've only one questions to ask. In this uncertainty review criteria, you've got the percentages of these various criteria, but I don't think -- at least I missed --it's a portion of the total weights that were given that fell into the category of uncertainty.

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DR. MARGULIES: How much did this influence it?

MR. PETERSON: I think I understand your question,
Dr. DeBakey. That the three items about which there was the
greatest uncertainty by far, among them totaled six points.
The items on which there was the greatest certainty -- for
example, organizational viability and effectiveness -- had a
score of 12 points. Action plan -- and there were a number
interspersed along here -- had a weight of six points.

8 So, in one sense, these items of which there was the 9 greatest uncertainty about also were individually the lowest 10 weighted items. There were no items that had weights lower 11 than 2 and all three of those had weights of 2.

In some of the other instances, I think in singling 12 out what we needed to get more information about, we did look 13 at weights and also the ability to get information. 'The 141 coordinator, for example, in the new one will carry a signifi-15 cant weight, but that's not something you ask for addenda 16 material about; whereas these were areas where we felt one 17 could reasonably obtain the display as decent and objective 18 information that would be helpful to the review committee. 19

DR. MC PHEDRAN: I'd just like to speak about that a little bit. I really wonder whether that's so reassuring, because I wonder whether the same problem that makes us uncertain in evaluating them also makes us uncertain about how to weight them. The weighting, after all, was arbitrary. You didn't have any infallible ex cathedra source for doing that.

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ำ DR. PAHL: The weightings assigned, you're perfectly 2 correct, were subject to just committee discussion and consensus 3 I think it is a reasonable statement, however, that the 4 committee, after going through the process of these 13 applications, did not spend any time at all on discussing the weights 5 which had been assigned either to the major categories or to ó •7 the elements within those categories; and we were somewhat surprised because they did discuss understandings and perhaps 8 refining the categories a bit. So that, at least to this 9 extent, they felt comfortable with what had been given. 10

11 DR. MARGULIES: I think that as we apply this later on, you will have an opportunity to do your own thinking about 12 it; because this is, no matter how one alters it, the 13 formalization of some subjective observations and, as a conse-14 quence, the weighting and so forth is all subject to that kind 15 of question. But we do review by this kind of a process and 16 this is a way of describing it in a manner which is more easily 17 transferrable to some other arena. 18

I wonder if I might just make one MR. PETERSON: 19 I think the staff who were involved footnote to those remarks. 20 in this, as Herb indicated, there was a remarkable degree of 21 not unanimity, but very little spread of opinion if you talked 22 about the three broad categories of criteria. Performance, how 23 well had they done to date? Process, how good an organization 241 Ace-Federal Reporters, Inc. and region is that? And then their proposal. At least in terms 25

of giving relative weights for those three broad categories --1 and I think this reflects what staff has heard as it sat in on 2 meetings, that indeed, the review committee and the Council, 3 now that we have three, four or five years of experience with 4 regions, is really giving a good deal of weight to how well 5 they've done, how good a region it is, and that the proposal 6 is less of the overwhelming criterion judgment factor than it 7 was in the early days of the program when that was about all you 8 had to go on and the individual who may have been concerned or Ġ, individuals. 10

DR. ROTH: Which is the cart and which is the horse? Does the fact that this elaborate mathematical approach to the situation comes into fair agreement with the distillate of the non-mathematical evaluations of the individuals, does this agreement validate the mathematical system or does the mathematical system validate the way we've been doing it?

DR. MARGULIES: You pays your money and you takes your choice. My own feeling is that it, in essence, validates the way we've been doing it. I can't see any other explanation.

DR. DE BAKEY: Isn't that what came out?

DR. MARGULIES: Yes, which makes me quite happy because that was the argument I had in the first place.

23 I'd like to suggest, because it seems to me we have 24 exposed you excessively during the morning hours, that any further discussion be delayed until after lunch. I'd like to

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	suggest also at that time that you take a look at the items
2	under 9 which are information only, and what we'll do after
3	'lunch is very quickly ask you if you have any specific dis-
4	cussion. These are information items but they're important and
5	you may want to comment on them. We will move through the
6	afternoon activities as scheduled and we will also move toward
7	a fairly early executive session because there are some really
8	major issues which we have to discuss at that time.
9	If it's all right with the people who are here, we
10	will break now and plan to meet again at 1:30.
11	(Recess)
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## AFTERNOON SESSION

DR. MARGULIES: The meeting will please come to order. Dr. Pahl has an announcement first.

The announcement concerns only the DR. PAHL: 4 regional office representatives who are here today. Would they 5 please meet as a special emergency matter in Room 18A-30 6 This is a matter connected with tomorrow morning at 8:30 a.m. 7 the request from Mr. Hall, Deputy Administrator. It will 8 probably only require 15 to 20 minutes of your time and then 9 you're invited back to attend all of the Council meeting, but 10 that takes priority. 11

DR. MARGULIES: I should tell you that that has nothing to do with your jobs, reorganization or anything of that kind. It's a subject which needs to be treated with.

I'd like to just spend a short period of time on one major issue which the Council was deeply concerned with last time, and then we will get into the other request that you made which is to have a review of the activities at Watts-Willowbrook with which many of you have concern.

You discussed last time a fairly clearcut understanding of what kind of review responsibilities would be conducted under the triennial review trying to get a clearer picture of what came to Council, what actions would take place within the region once it had been approved under the triennial system, what would be the reaction of staff and so on.

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Now, under 8C, there is a short statement which is 1 short enough so that if you don't mind I'll read through it 2 with you to make sure that you have some agreement and we only 3 really need to read the first part of it. 4

Under the triennial review system, each Regional 5 Medical Program normally will be reviewed by the National 6 Advisory Council once each three years. The triennial review '7 serves to recognize the region as an accredited organization 'ğl and to set a general level of annual support for the three-year ø period. Thus, the Council's favorable recommendation constitute 10 a time limited approval for the RMP as an organization having 11 recognized capabilities, rather than being approved for a 12 specific set of activities. 13

In addition to recommending the general level of 14 support, Council actions on individual applications may include 15 advice to the applicant RMP or a specific condition for the 16 grant. Prior to review by the Council each triennial appli-17 cation will be reviewed by assigned RMPS staff and the site 18 visit team and the RMPS review committee. 19

Except as specified below, the Director of RMPS will 20 make continuation awards, including support for new activities 21 for second and third year support without further Council action 22 insofar as the proposed activities are consistent with rele-23 vant policies. The Council will be provided with a summary of 24 - Federal Reporters, Inc. such awards.

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Specifically, the Council's advice will be sought 1. (1) Supplementary funds are requested in addition to the 2 when: general support recommended for the year in question; (2) A new 3 or increased developmental component is requested; (3) The 4 Council, the Director RMPS or the region requests Council 5 review; (4) The applicant has failed in a material respect to 6 meet the requirements of the program or applicable laws, Z regulations or formally promulgated policies of the Department 8 of Health Services and Mental Health Administration for RMPS. 9

Now, this is about as defined as we can get in our discussions with you and as we said at the last meeting, there is
obviously an element of discretion on our part in deciding when
you need to be made aware of changes which are going on and when
they are staying well within the understanding of what was
presented and approved at the time that the Council acted on
that specific Regional Medical Program.

DR. MILLIKAN: In other words, a new and perhaps even massive project activity could be undertaken without review committee or Council, as long as it doesn't request supplementary funds?

DR. MARGULIES: That's right. There could be considerable latitude within what has already been approved. However, in talking with Regional Medical Programs about it, I have emphasized, and they fully understand, that they should keep us maximally informed so that we can decide when, for a

variety of reasons, it needs to come to Council; sometimes 1 because you'd simply like to know what's happening rather than 2 because you necessarily want to take some formal action on it. 3 Now, I think the first few times that we're doing this 4 that I will bring to your attention more than we normally would 5 so that you feel comfortable with what's happening and you get. ő 7 a clearer sense from one meeting to the next. If this is an acceptable concept, I would like to 8 · 9 have you take formal action on it so we can proceed on that 10 basis. I move approval of this. 11 DR. MILLIKAN: Second. 12 DR. ROTH: DR. MARGULIES: It's been moved and seconded. Is 13 14 there further discussion? 15 (No Response) DR. MARGULIES: All those in favor, say "Aye." 16 ("Ayes") 17 DR. MARGULIES: Thank you. 18 We've asked Dr. Al Haines to come here from Los 19 Angeles to present to us a capsule description of the 20 activities in which RMP has been interested, where we have 21 provided support along with a number of other people for a 22 number of reasons. This is Dr. Al Haines. I think most of 23 24 you do know him.

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We are interested because of the very special nature

of that program, because it involves us in the kind of activity 1 which is prominent and which is not too characteristic of a 2 good many other things we do; but also because it has many of 3 the elements of an area health education center which we've had 4 under active discussion; and I suppose one other reason --5 because it's the feeling of the Council, as I understand it, ó that from time to time we ought to take a deeper look at some of 7 the activities in which we're involved so that as a Council we à can share an analysis and understanding of them so we don't get too far away from the real core of what's happening in the 10 RMPs. 11

Now, what we will ask Dr. Haines to do is make the presentation as he has planned it and then stand by to expand on the basis of any further questions. So it's all yours.

DR. HAINES: Thank you.

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Let me say before I begin, that a couple of weeks ago 16 we were privileged to have a visit from Dr. Margulies and at 17 that time he mentioned he was planning to have this presentation 18 before the Council. I was bold enough to ask him whether the 19 Drew School could make the presentation and he warned me at that 20 time that he wanted to be sure that the presentation was 21 limited and that the Council would have a chance to go on with 22 the rest of its work. So I promised him that the presentation 23 would be limited to exactly the time which he stipulated and we 24 Ace-Federal Reporters, Inc. have been given half an hour and we will try to limit it to 25

half an hour. 1

	2	In order to do that, we have a programmed presentation
	3	for you and let me say that what we have done here is try to
	4	give you some idea of how we've been able to mobilize resources
	5	in order to develop this school; what we have done with the
	6	resources that we have gotten together to date and what we are
	7	looking forward to in the future.
	8	It is rather fortunate that this has been fixed for
	9	today because I've been told by the school historian that today
1	0	is exactly five years since the incorporation papers were
1	ίŤ	drawn up, so today is a rather historic day for us and we are
	12	very glad to share it with you.
1	13	(Film Presentation)
	14	(Applause)
1	15	DR. HAINES: I think there are ten minutes more which
1	16	I shall save for questions.
1	17	MRS. WYCKOFF: The earthquake didn't hurt the
1997 - 1997 - 1997 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 -	18	buildings, did it?
1	19	DR. HAINES: Not at all, fortunately.
	20	DR. MARGULIES: The safest thing to do with this
	21	program is to review it here rather than there, because they
	22	have more eloquent people scattered around that area than I've
	23	heard in any one spot in my life, and it's evidence of a real
	24	sense of inspiration which is all through that particular
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Dr. Haines is here to answer any question which you might like to raise about it. He has only referred in passing to the fact that it hasn't all been easy, and those of you who know some of the details of woirking there and not only the help they've got on request but much of the help they've gotten without requesting it, have some idea of how tough it's been. It's been a back-breaking kind of a thing and they've just steamed ahead.

9 DR. MILLIKAN: Al, how many out-patient facilities 10 scattered through Watts do you think it will take over a period 11 of five to ten years to really bring daily health matters to 12 the people?

DR. HAINES: Ideally, we ought to have a primary care facility that would serve anywhere from 15 to 20 thousand people. This would mean that enough to care for the population of 500,000 we ought to have 20 or 25 facilities.

DR. MILLIKAN: And that one that we are in has about 40,000 on the roster but their activities didn't amount to that much; that is, that many different people didn't necessarily come in during any year?

2) DR. HAINES: That's the Watts multipurpose center which 22 serves about 40,000.

23' MRS. WYCKOFF: That's the only one you have now? 24 DR. HAINES: Well, that serves an area of about 40,000 Ace-Federal Reporters, Inc. 25 but we have other centers.

Other OEO neighborhood centers there? 1 MRS. WYCKOFF: DR. HAINES: One OEO neighborhood center. The Health 2 Department has a number of clinics and traditionally the Health 3 Department clinics have been categorical clinics, you know, a 4 VD clinic or a well-baby clinic. However, they have a grant • 5 from Model Cities in the model neighborhoods, and some of the 6 Health Department clinics now offer, in addition to the 7 categorical clinics, comprehensive clinics in the evenings, 8 and there's more in this direction being developed. 9

DR.MERRILL: What percentage of the patients that are seen as out-patients are funded by third party carriers?

We are doing a study now to find out what DR. HAINES: 12 we may expect in this area. If you ask the private physicians--13 some of the private physicians in this area see as much as 14 75 percent of their patients who are on Medicaid. Now, this 15 does not tell us those who are not sick. And to get a better 16 view of what the situation is we would be trying to get this 171 from the community at large. 18

DR. MERRILL: What is your relationship with the private practitioner? Have you had any difficulty in getting them into the arena?

DR. HAINES: Well, this instituion was sponsored by the Drew Medical Society along with the universities and the community, so that the community physicians had a real input Ace-Federal Reporters, Inc. 25 into the development of this institution. As you saw in the 1 picture which showed the Board of Directors, the Chairman of 2 the Board of Directors, Dr. Williams, is a radiologist and a 3 member and physician from the Drew Medical Society; and we 4 have had some of the problems of "town and gown" that happens 5 everywhere else, but we've also had a very meaningful input 6 from the private sector.

DR. KOMAROFF: I know initially the County of Los
Angeles was going to provide the real substantial funding
support, gradually increasing over these last couple of years,
but that they've had unanticipated funding limitations recently.
How severely has their support for the hospital and
for the staff of the hospital been cut back?

The County of Los Angeles is a rather DR. HAINES: 13 unusual county when it comes to support of health matters. Ι 14 believe in this respect it's probably a little bit more 15 generous than some other counties have been. They have been 16 especially interested in the Martin Luther King Hospital 17 because of the circumstances which led to the development of 18 this hospital, and the county is committed to making this one 19 of the best hospitals in the county. 201

However, the county did fall on hard times during the course of the years as other organizations have and have had a fiscal crisis, and this has caused them to cut their contributions to the hospitals at a time when the need was great Ace-Federal Reporters, Inc. because with the Medi-Cal cuts it placed a heavier load on the

1 county hospitals than they had before and at the same time the 2 county was faced with a shortage of funds.

All of the hospitals, therefore, were cut, and the 3 King Hospital was not able to have the staff which it had '4 originally estimated. One of the most serious cuts was in the 5 Department of Community Medicine, because when it became 61 necessary to make cuts, the first thing the budget analysts 71 did was to cut out anything which did not exist in other 8 hospitals. And this hospital was supposed to have a Department of Community Medicine. No other hospital has a Department of 10 Community Medicine, so automatically this whole department was 1Ť wiped out. However, I'm rather pleased to say that the Depart-12 ment of Community Medicine was replaced, along with community 13 outreach programs which were planned for the department, and 14 I'm very pleased to say that that was done without any pressure 15 on my own part. That is, there were others who recognized the 16 value of community medicine in the hospital and had the budget 17 replaced. 18

So we expect that, although the fiscal situation has been very difficult, that this hospital and this program will continue to have a high priority with the county.

DR. KOMAROFF: Thank you.

22

DR. MARGULIES: You know, the effort to design a MEDEX program is the first of that kind which is being attempted Ace-Federal Reporters, Inc. 25 in an urban area and everyone has been highly interested in it. 1 I wonder if you would comment further on some of the problems
2 you alluded to.

3 DR. HAINES: Well, when we started the MEDEX program 4 we had our hopes that because the State of California had one 5 of what is supposed to be the best laws of the country encouragi 6 the training of physicians assistants, it would have been easy 7 to proceed with the program.

8 However, this law is supposed to be administered by
9 the Board of Medical Examiners, and so far, the Board of Medical
10 Examiners has not approved any programs in the state.

We have started off in the first phase of the program which really did not require special approval, hoping that by the time we finished that first phase the Board would have given its approval. The Board meets again later this month but it's unlikely that the Board will be ready to give approval to that program even though we have been urging them to give at least provisional approval of the program.

The problems they have had relate to such matters as 18 we are training primary care physicians' assistants and the 19 Board feels that the primary care physician assistant requires 20 a lot more training than the specialist assistant; and, there-21 We feel fore, the training should be fixed at a longer period. 22 that since we are taking men who have had some experience and 23 24 training before, we ought to take that experience and training Ace-Federal Reporters, Inc. 25 in the Armed Forces into consideration and build on that.

The Board is trying to insist that the physician assistant have as a prerequisite to enter into the program an A.A. Degree in Nursing, and we are saying that the physician assistant's functions are different from nursing functions, and requiring an A.A. Degree in Nursing doesn't address itself to the real problem.

In general, the Board I think is extremely cautious because it wents to ensure the best quality of care to the population, but we are equally concerned about this high quality of care, and the Board also I think is quite conscious of the fact that in the State of California there tends to be a lot more suits than in some other states and we are also extremely cautious about that.

We are still hoping that the Board will give us 14 approval. Just a few days ago we questioned the students and 15 asked them if we offered them several alternatives which one 16 would they take. That is, suppose the Board did not approve the 17 program by the end of this month, would they want to go into 18 other states; would they want to drop out of the program 19 completely; would they want to go into the government hospitals 20 and the VA hospitals which are more willing to take them; pr 27 would they want to stay with the program until the program is 22 approved? Most of the students said they want to stick with the 23 program because they feel this is something important and if they 24 can get the matter settled in the State of California for that 25

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1 group it would make it easier for subsequent groups. That's
2 the kind of enthusiasm we have on the part of the students.

DR. MC PHEDRAN: What kinds of difficulties -- I think you said there had been some, have you had with the community advisory groups? What are the types of problems that your own organization has had?

DR. HAINES: Well, the problem we have had has been a problem which is universal, and that is who does, indeed, represent the community? And if there's anyone who knows an answer to that question, I would love very much to hear it.

One of the problems we have had is when we attempted 11 to change from the district advisory committeee to the area 12 advisory group. To begin with, this area was a district of 13 Area 4 and Area 5, and the program was connected with the 14 district advisory committee. As the change was made from a 15 district to an area, there was also change of officers and so 16 on, and some of the persons who held the positions in the 17 district advisory committee were no longer in a prominant 18 position when the change was made, even though the 17 members 19 from the district advisory committee were incorporated into the 20 area advisory group. 21

This caused a little stormy period which I think is now over and we are moving along with the area advisory group. We have the peaks and troughs but we kind of ride with the Ace-Federal Reporters, Inc.

25 waves.

DR. MC PHEDRAN: So that really the problems had to do with organization and not with criticism of what the medical center was doing on substantive issues.

DR. HAINES: Well, of course, while there's the problem of organization, it does lead to criticism of everything, criticism of the program, criticism of the outsiders who come, physicians who were imported, and we have had our full share of criticism along all lines. That's part of the game.

Well, I think that my half an hour is up unless you want to go back to California time in which case we have three more hours.

DR. MARGULIES: Thank you very much, Al. I think that kind of concisive view of such an important activity is well worth the time and I'm sure that I speak for the Council in thanking you, Dr. Haines, for coming here and for that excellent presentation.

I told you before the lunch break that there are some information items which I thought you would be interested in taking a look at. In fact, I'd like to go a little beyond that on one of them which is listed under 9A, which is an item on computer assisted EKG analysis.

For some time this Council has been concerned with some sort of a status report on activities of this kind and since it bears a close relationship with this morning's dislnc. tcussion, I thought I'd ask Dr. Farrell and Dr. Gimbel to draw

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your attention more closely to this document. I might tell them, if they haven't heard it already, that at least a part of it has drawn the kind of criticism that they might have anticipated when they put it together.

Would you like to comment on it?

.5

DR. FARRELL: At the request at the last National
Advisory Council meeting, the clinical specialties branch was
asked to evaluate the RMP's role and involvement in computerized
electrocardiograms. Fortunately, Dr. Gimbel being in our
branch as a commissioned officer, is a cardiologist that was
very interested.

In 9A, we have his report. Particularly, just after
page 16 in that report, following page 16, is a summary of the
fiscal involvement over the last four years of the Regional
Medical Programs.

Dr. Gimbel then went to some lengths to review the whole field of computer assisted evaluation and came to the conclusions which are on page 22 which I will let him summarize.

20DR. GIMBEL: The five regions currently involved in21computerized EKG analysis have approached the problem22differently. In two regions, the EKG computer network has been23used for definitive diagnosis of electrocardiograms, at least24have developed this area. One region is using it to screen25coronary care unit arrythmia on a 24-hour basis; and one other

region is using it for screening purposes.

Presently, from a technological viewpoint, fully automated EKG analysis by computer has not been achieved. All current systems rely upon physician co-reading for the definitive diagnosis of electrocardiograms. Hence, the automatic electrocardiograms hasn't been arrived at yet and exactly when it will be arrived at is really uncertain.

8 On a slightly lower level, that is physician assistant
9 electrocardiographic diagnosis, progress has been made and
10 present computer systems do offer some benefits to physicians
11 in interpreting electrocardiograms. How important the benefits
12 are is open to considerable doubt, and this is an area that
13 you will have to evaluate.

At present, all systems dealing with definitive At present, all systems dealing with definitive diagnosis must be co-read by a cardiologist and interpreted, and though the computer speeds his reading time, it doesn't replace him, and that major benefit of the system hasn't been realized.

The other area where computers have been applied is the screening procedure and in this area they have been applied effectively but on a very small scale. The computer system is capable of separating normal electrocardiograms from abnormals very accurately and very reliably; at present, probably with a less than 1 percent false negative incidence. This varies with the computer systems. The incidence of false positives is

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1 considerably more, but in terms of a screening function this is
2 less important because the false positives can then be followed
3 up.

The question arising, though, is whether screening purposes fit the current goals of Regional Medical Programs, and how important they are, since a major facet of all the computer EKG projects have been their enormous expense, approximately \$3 or \$3.5 million in the current five projects that are being funded.

10 So it seems like this is an impractical area at 11 present to fund, though its potential remains great. Its 12 potential has been great for about ten years now and it still 13 hasn't been realized and I'll end it there and be open for 14 questions from the Council.

DR. KOMAROFF: It's been my impression that the major impediment is P-wave recognition and, therefore, arrythmia determination. Is that the stumbling block?

DR. GIMBEL: Well, there are several stumbling blocks.
The computer has been said to be very reliable in terms of
analyzing both contour and rythms and multiple programs have
been developed for analysis of both these areas. Contour has
had less problems than arrythmia, though some arrythmia programs
have been developed, notably by Leonporti at Mt. Sinai in New

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24 york.

Aside from difficulty in recognizing P-waves of small

1 size, the computer also has difficulty recognizing the onset and termination of QRS complexes and difficulties that the 2 human observer has in addition. The major benefit of the Ś computer in terms of accuracy is: (1) The computer never forgets its criteria and can remember multiple sets of criteria Ś so the chances of its missing a diagnosis by not analyzing it 6 from a different viewpoint, like the 18 different ways to 7 analyze left ventricular (?), is less likely; and (2) It 8 is much more reliable in terms of it sticks to the criteria ý II it's programmed to remember and doesn't change it because of 10 fatigue or arbitrarily. 11

But in terms of accuracy, both contour and rhythm 12 programs -- more with rhythm -- have shown a false negative 13 incidence now between 1 and 5 percent, and a false positive 14 incidence of between 10 and 15 and 20 percent, depending upon 15 how rigorous the programming is. How important the differences 16 are in terms of significant differences between the computer 17 and the cardiologist is again a question that has to be 18 answered. 19

In terms of screening, though, it can very reliably, with a less than 1 percent error, separate normal electrocardiograms from abnormal cardiograms or even questionable cardiograms and that's probably its most important function right now and something it can do most reliably. How important that function is, though, should be answered. DR. HUNT: Presuming that it is of value with that kind of correctness in the screening basis, have you established a per capita cost on a screening basis?

DR. GIMBEL: Cost in the ideal system that's been spoken about for the past three or four years has ranged from \$2 to \$4 per cardiogram. That cost, though, -- that's on a screening basis, and that would be a considerable savings, and the programs that do use it for screening purposes then refer the abnormal electrocardiograms to a private physician.

For definitive diagnosis you have to add on the charges of the cardiologist rereading the electrocardiograms. The most efficient operation has a slave population of readers, the residents and fellow staff, which keeps costs down, naturally, and that's been one of its major advantages.

But \$2 to \$4 has been projected as the cost, but this is achieved only when minimal input in terms of units of electrocardiograms are done yearly and computer time is used most efficiently. Current RMP projects haven't come close to that and subsequently, all their cardiograms cost considerably more and are not making money.

21 DR. MARGULIES: How much do we know about the use of 22 the electrocardiogram as a screening procedure, per se, regard-23 less of -- setting aside the question of accuracy?

24 DR. GIMBEL: It depends upon what you're looking for. Ace-Federal Reporters, Inc. 25 As a screening tool, I don't think -- and my knowledge is

1 limited in this area -- that enough is known about the incidence 2 of various abnormalities in large populations. Several studies 3 have been done during the last 10 or 15 years, analyzing 60 4 to 100 thousand electrocardiograms from variously defined 5 populations.

But certainly one attractive aspect of the computer 6 system would be opening up large areas of study in the area of 7 epidemiology because the interpretor function as carried out by 8 the computer only takes relatively a few minutes and the time . 9, for recording is about the same as with the standard machine. 10 A large volume of electrocardiograms could be accumulated and 11 because it can reliably separate abnormals from normals and 12 store that information, much information could be obtained. 13

How important that information is, both medically and more particularly from the RMP standpoint, is a question I can't answer.

DR. MARGULIES: Well, obviously, it would depend upon an associated, fairly complex system of examinations to determine what happens then, and that involves you in more manpower and more studies which is a question of just how much of a crop do you get out of that kind of an effort, and gets us back to some other major issues of a related kind which most people have had at least some experience with.

24 DR. HUNT: For your screening process, that's an rs, Inc. 25 expensive item.

If you're trying to pick up LVH 1 DR. GIMBEL: Yes. with a computerized EKG you much more cheaply can take a blood 2 pressure reading, and if you were diagnose symptomatic eschemic ÷3∦ 4 heart disease then a history of angina or appropriate history seems to be much less expensive way of getting it; and if you ·5# worry about asymptomatic abnormal EKGs, then the question arises 18 well, can we treat what we find anyhow; and does it justify .7 looking for it; and I think that's a very interesting area to • 8 I +9 get into.

DR. HUNT: Actually, the human being can screen these a little bit less expensive than that except he gets tired and the computer doesn't.

DR. GIMBEL: One approach has been to have technicians 13 premeasure, mount and even interpret electrocardiograms. Since 14 15 they haven't arrived at automatic electrocardiogram but a physician assisted one, surely a technician can provide the same 16 type of function, at least in terms of measuring and mounting, 17 that the computer can. How important the computerized diagnose 18 are is open to at least some doubt. Some systems utilize 19 clinical information and present definitive diagnosis and 20 relevant exclusions. Many others just present a list of 21 possible diagnoses and to the general practitioner this is not 22 very helpful. 23

24 This system presenting definitive diagnosis, though, Ace-Federal Reporters, Inc. 25 must be checked by a cardiologist, at least at this time, and 1 that makes it expensive.

Again, as a screening procedure, it's effective and '<sup>3</sup> it's reliable and it's important in this area.

4 DR. MARGULIES: I think from the Council's point of :5 view it's an extremely interesting subject to ponder, setting aside the technical issues which can be summarized by saying we 10 have a tool in which we have an invested considerable sum of :7 money, the usefulness of which is still open to doubt; and then <sup>,</sup> 8 the question is, is it appropriate for RMP to invest further 19 10 money in trying to determine whether this is a good tool or 11 anything like it a good tool, or is it more appropriate for 12 RMP to utilize this kind of a device -- this one or those like 18 it -- when its usefulness has been established and it can be 14 part of the system of health care.

15 I think we have tended clearly toward the latter. The last decision which was made regarding multiphasic screening 16 was essentially along those lines. It said that until we know 17 18 how useful this is, under what circumstances, what the costs are, what it does for patient care, what it does for regionali-19 zation, we should make no further investments; and our main 20 purpose for putting this in for information purposes was to 21 bring you up to date on about where the thinking is on this 22 23 particular activity also.

24 DR. KOMAROFF: One of the projects also gets back to Ace-Federal Reporters, Inc. 25 the question we were talking about this morning, involves the 1 contribution from the private sector, namely, Lockheed, at 2 least the proposal in California, San Francisco. What contri-3 bution are they making? What risks are they taking and how are 4 they supporting the federal money in that project.

5 DR. GIMBEL: Several private firms are engaged in 6 developing a computer system for EKG analysis and are marketing 7 it at present. The difficulties with that -- or at least one 18 difficulty -- is that they're out to make a profit and are not 19 necessarily concerned with providing a very high quality 10 product. The one at Mt. Sinai, in fact, is funded privately 11 through a company that designs computers.

12 This may be a very natural way to get a project like 13 this developed. Certainly, it's been an effective stimulus to 14 develop the Mt. Sinai project.

DR. DE BAKEY: There are other federal funds, though, that are being used to help develop and perhaps evaluate this type of project, so it's not just RMP money alone that's being used for this purpose.

19It seems to me that, certainly on the basis of our20experience in our center, that at the present time there is21some doubt about the efficacy of this kind of technological22development in all phases, whether it be in screening or in23diagnosis. But I don't think that it's possible at this point24in time to make a final, conclusive statement about it.Ace-Federal Reporters, Inc.I think from our standpoint, let's say at least from

1 our position, I would be inclined to say that there is a need 2 for the present to continue to evaluate this because there are 3 some new technological developments that certainly I know about 4 on the horizon, which could make a considerable difference, and 5 it could prove to be applicable on a broad scale. I think it 6 could change this from doubt to confidence and that would be a 7 considerable step forward.

I don't think we ought to at this point in time
 decide not to proceed with further assessments. We ought to
 support this a little longer.

DR. MARGULIES: Well, that would be consistent with Next we decided last time, that we should concentrate on the assessment of what we have already gotten started with but not initiate any further activities until we understood better what's happening.

Thank you very much.

17 This is really the basic purpose of bringing it to 18 your attention because it fits in with the other reports which 19 we have had.

Now, before we have the coffee break, there is just one other item of business which I'd like to bring to you, and then I think we'll be ready for that break, and following that, a meeting in executive session to deal with some of the issues which I discussed because I think that the time has come to

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16

25 deal with them.

I would like to have Mr. Ken Baum come up and bring you up to date on some of the regulatory processes which affect Regional Medical Programs. Part of this stems from the fact that we are a public agency and there is a need for public knowledge of our activities and certainly as we expand RMP into some areas that have to do with the issues of health care delivery in a broader way and a more identifiable way, the manne in which we do it and the degree of public disclosure which is involved becomes critical.

There also has been the problem of evolving policies over a period of years which need to be brought up to date so the people know where we are rather than where we were. I'd like to have Ken summarize some of the conditions under which we'll be functioning.

MR. BAUM: I'll try not to take too long and hold 16 up coffee break because I'm hungry, too.

I once made a speech after a dinner and somebody put a 18 ice cream sundae in from of me which kept melting and melting 19 and melting the longer I talked and I learned my lesson then.

I think I want to talk to you a little bit about what we're doing in terms of both trying to organize and codify our policy materials and to rewrite the RMPS regulations.

23 Essentially, this was an effort which I think can be 24 summed up in one phrase as being aimed at trying to bring the Ace-Federal Reporters, Inc. 25 rules of the game up to date so that everybody knows what they a I think perhaps it would be worthwhile to refresh your memory as to why the rules are out of date right now because there have been a lot of things that have taken place since the original RMPS regulations were written five years ago and the foriginal RMPS guidelines.

'6 First of all, the most recent changes in the law have resulted in new construction authority, new language referring 7 ľ to primary care, linkages between facilities, provision of services in underserved areas. We've added the kidney category. ġ There's been a complete revision of Section 910. Requirements 10 11 on Council membership and regional advisory group membership have been changed and there has been an additional requirement 12 added to the law requiring that before applications come before 13 1/1 us, indeed before they come before regional advisory groups, that they have to be submitted to the local "B" agency, Comprehensive 15 Health Planning, for review and comment. 16

There have been additional administrative changes, 17 some of which we talked about here this morning, the mission 18 statement, the new review criteria and rating system, the whole 19 system of triennial review. We've sent out standards for local 20 reviews of projects by the RMPs themselves. We have some 21 clarifying language again which is in your book trying to put 22 down more concretely what it means when you get in a develop-23 mental component. 24

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All of these things need to be codified and put down

1 someplace in a way that people can use them.

In addition to that, the guidelines with one A exception, really haven't been revised since the addition of the program. Much of our policy material has been put out in sort of looseleaf flyers which are in some ways difficult mechanically to index and so forth.

So, with all these things in mind, we have several efforts going in terms of revising policies and regulations, and let me start with regulations.

First of all, without asking the question, I think 10 11 I should explain, because most people including many of us 12 bureaucrats don't understand that regulations in effect have the 13 force of law. When we promulgate regulations and they're published in the Federal Register, they have the same effect as 14 1 15 if the Congress of the United States wrote them and the Presiden 16 signed the bill. The difference between a regulation and what 17 is in law is the fact that regulations are a lot easier to It takes some It doesn't take an act of Congress. 18 change. consultation with this Council and approval of higher authority. 19 There has been a development in line with the issuance 20 and promulgation of regulations that everybody here should be 21 aware of. On October 12, last year, Secretary Richardson 221 issued a directive which principally made these points: (1)231 That before rules and regulations are issued, notice of proposed 24 Ace - Federal Reporters, Inc. 25 rule making must be published in the Federal Register and

1 interested persons must be given an opportunity to participate 2 in the rule-making through submission of data, views and \_3 Again, for the purpose of filling in people who arguments. 4 don't know, the Federal Register is a thing that's published 5 daily in fine print by the Government Printing Office and is 6 the equivalent of a legal notice section in the local newspaper. So when something is published there it makes it official. Z So that's what we're talking about in terms of publication in the - 8 t :9 Federal Register.

10: Secondly, the Secretary said that the public benefit 11 from such participation should outweigh any administrative 12 inconvenience or delay which may result from the rule-making 13 procedure.

14 Three, that exceptions should be used sparingly only 15 in the cases of real emergency situations and where the changes <sup>16</sup> or proposed rules really are only minor technical points. What 17 this means in plain English is that when we publish something 18 as a new or revised regulation, we are required to publish in 19 the Federal Register what the changes are, a description in 20 plain English of what the changes are, and to allow the public 21 and all interested parties 30 days in which to make comment. 22 We are also required to make public what the comments are that 23 have been received when a request for that information is 24 received. After 30 days we are required to take the comments

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25 into account -- and I understand that HSMHA has some

administrative procedures for seeing that that is done -- and 2 to republish the regulation or rule in its final form.

The comments may result in changing things so drastically that another 30 days are required for comment, but J gather that hasn't happened yet.

At any rate, that is what the rule-making procedure 7 is. It sounds complicated but I don't think in actual practice 8 it will be.

9 The Secretary's memo is being enforced very 10 vigorously by the General Counsel's office in the Department 11 and I understand we had our wrists slapped for going around it 12 because we didn't know about it. It's being interpreted to 13 mean that major items that affect what you have to do to apply 14 for a grant, the way you're evaluated for getting the grant, 15 how much money you can get or how and what you can spend the 16 money for should be included in the regulations for the program.

17 Our discussions with the General Counsel's office 18 has boiled it down to this: You have got to tell people what 19 the rules of the game are and if you have any rules that some-20 body can't spend money for something or do something that 21 ordinarily they would expect to be able to do under the terms 22 of the legislation then you have to make that a regulation. You 23 can't just issue it as some sort of a policy that somebody 24 signs someplace and that's the way we do business. Ace-Federal Reporters. Inc.

25 So,

So, essentially where we stand on new regulations

1 is this: The current regulations have not been changed or 2 modified since the legislation was passed. In general, they are quite broad and general. They don't reflect some of our 3 new things like the mission statement, criteria and so forth. 4 We tried to do a patch-up job to bring them into line and add 5 language that would make them consonant with the latest amend-Ó ments, and when we took these down to consult with the General 7 Counsel's people about it, their attitude was this -- and I *1*8 think quite rightly -- that it made no sense to try to do a , **9**, 10 patch-work job on something that was written on the basis of old legislation five years ago; that we do have some of these 11 12 new documents, the amended statute, the missions statement, review process requirements and standards, review criteria, 13 developmental components statements and stuff about how we 14 15 work with CHP, the revised multiphasic screening policy, to 16 bring up something that came up recently, and we have turned these documents over to them and they have said that they would 17 prefer to write the first draft of new regulations taking into 18 account not onlythe new laws but these other documents that 12 represent how we are about to do business now. 20

21 Initially we were promised the draft by the first of That didn't materialize. We have been promised 22 this month. 23 the first draft in about three weeks from now. From our discussions, though, I can tell you that the fellow down in 24 General Counsel's office who is working on it is quite competent 25

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1 knows and understands the program, asks sensible questions, 2 and where he doesn't know he finds out. So it's not being done 3 by a lawyer some place in some isolated box without knowing 4 what's going on or trying to take into account how the program 5 operates or what it's trying to do.

A second thing that we are trying to do to straighten '۲ 7 up the whole process of bringing the rules up to date is to '8 codify in a manual or policy manual those items which don't have '9 to be written down or have the force of law, but which imple-10 ment the kinds of things that will be put into regulation. We started on this some months ago with a small committee con-TT sisting of myself, Mr. Nash, Mrs. Salazar, Lyman Van Noltrum and 12 a few others, and we made some initial progress. Then we got 13 to some problems because really a great deal of the material 17 that would have to go into that is, to use a phrase I don't 15 like, the nitty-gritty of what you can spend your bucks for; 16 what are the eliqible costs; what do you have to ask prior 17 approval for; that kind of thing. 18

Inasmuch as it's a grants management thing, we have had some considerable assistance from the grants management branch in preparing some of these other materials and it's principally been done by Roger Miller. Roger, stand up and take a bow. Nobody else but me has seen what has been done almost single-handedly by Roger, and he's really done an amazing job of pulling together all the boilerplate from the division of

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1 grants administration and policy at the department level, from 2 the HSMHA grants management office, from the equal economic 3 opportunity office -- we have a lot of material that has to go 4 in relating to EEO -- and trying to arrange it in a sensible 5 manner.

From what we have got so far, I should mention
indirect costs, too, because you have been interested in that.
I would say that we can probably have a first draft of that
that can start circulating to staff here at least internally
for comment in approximately four weeks. So essentially, that
is where we stand.

The General Counsel's office, on the basis of how we're running the program now and the most recent policy documents that have been developed, is going to rewrite a first complete redraft of the regulations. We on the speend level are trying to codify in some kind of an intelligible, organized, indexed form the policy manual to tell the grantees what they need to know to run their program on a day-to-day basis without calling Washington every five minutes to ask whether they can go to the toilet. Maybe that's not a proper analogy, but I understand in some offices, especially grants management, that practically is what happens.

23 DR. MERRILL: Now that the kidney is in it's very 24 important.

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MR. BAUM: That's about where we stand. Probably next

time we will have some pieces of paper that we can work on and react to.

<sup>3</sup> MRS. WYCKOFF: I was curious, you said something <sup>4</sup> about having to have a regulation for not utilizing a piece of <sup>5</sup> legislation that was on the books, and I wonder about 910 and <sup>6</sup> whether we needed a regulation to use or not to use it?

7 What we laid down -- and Don Young No. MR. BAUM: 8 is the man we deal with in General Counsel's office, and they're 9 **9** groping, too -- what he was talking about was if we have general 10 authority to fund certain types of projects, heart disease,  $\mathbf{n}$ cancer, stroke and so forth, and we issue a statement that 12 says, "All right. You can't do automated multiphasic health screening except to study the results of the few projects we 13 14 have now," that that would ordinarily be the kind of thing 15 that based on the law you would assume could be funded under 16 the program. But since we have taken an opposite view, that we 17 put them on notice that you can't do that by putting it in a 18 regulation. He wasn't talking about any legislative authority 19 that you don't utilize --

DR. MARGULIES: It's really an expression of judgment from time to time by the Council. For example, we have a variety of policies on what we support in the way of training, which includes some things and excludes others. That should be made generally known so that there's less confusion about it. Ace-Federal Reporters, Inc. We will bring you up to date at the time of the next

I meeting on revised policy manual.

I would like to say one thing before the coffee break. 2 You have been besieged in the last two or three Council meetings 3 with a great amount of material which has to do with the way 4 in which we run the affairs of RMPS and I have seen no 5 alternative to it because we have been going through a process 6 of rather profound change. I think we have just about reached 7 the point however where we can lean back from that kind of 8 thing in future Council meetings and concentrate much more on :9 professional issues which are associated with policy and 10 with professional judgment, and by professional I don't 11 mean technical; I mean those that have to do with health care 12 delivery, whether we represent the view of the provider or the 13 view of the community. 14

But up to the present time we have had to do this to keep you abreast of things, and I regret that it's been as ponderous as it has been, but if you look back over where we stand now compared with six or nine months ago, I think you will understand why all of this has had to occur. I appreciate the fact that you have borne with us and contributed so well and gone through these kinds of heavy kinds of machineries.

Now we will have a coffee break and give you a chance to stretch and talk with one another and after that we will be in executive session for the rest of the afternoon.

(Whereupon, the open session was adjourned at 2:45 p.m

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